



**Prevention of infections  
associated with  
totally implanted  
venous catheters**

**Professional recommendations  
from a formalized expert consensus  
Promoted by: SF2H  
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# Table of contents

Preface	3
Contributions	4
List of main abbreviations	7
Context and methodology	
Justification for the study	8
Theme boundaries	8
Targets of the recommendations	9
Methodology	9
Questions raised	10
Summary of recommendations	11
<b>Introduction</b>	
Definitions	22
Physiopathology of TIVC related infections	23
Epidemiology of TIVC related infections	24
<b>PART 1</b>	
<b>Insertion and removal of the totally implanted vascular catheter</b>	
1-1 Purpose of the totally implantable catheter, as a function of the pathological context	28
1-2 Choice of the appropriate moment for insertion	30
1-3 Choice of device	32
1-4 Choice of insertion site	34
1-5 Skin preparation and conditions of insertion	38
1-6 Surgical antibioprophyllactic treatment	40
1-7 Insertion techniques	42
1-8 Removal at the end of treatment	44

## PART 2

### Use of the totally implantable vascular catheter

2-1	Choice of perfusion equipment and technical details	46
2-2	Initial use and needle insertion	50
2-3	Dressing	54
2-4	Preparation and management of administered medication	57
2-5	Manipulations and management of connections	61
2-6	Removal and and frequency of needle change	64
2-7	Periodic maintenance	67

## PART 3

### General policy aspects

3-1	Informing and educating the patient	70
3-2	Professional training and assessment of practice	72
3-3	Epidemiological surveillance	74

<b>References</b>	<b>76</b>
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### Appendices

Strategy used in the documentary and bibliographical search	85
Descriptive diagram of a totally implantable venous catheter with and without a valve	86
Proposed line arrangements	87
Reporting an accident or the risk of an accident (French AFSSAPS form)	91

# Preface

**T**otally implantable venous catheters (TIVC) are widely used medical devices, not only in hospitals, but also in ambulatory care, for the efficient delivery of long term intravenous treatment. Although they have been used since the 1980's, professional recommendations dealing with the prevention of infections associated with TIVC are scarce, and it was only in 2000, under the auspices of the French National Agency for Accreditation and Evaluation in Health (ANAES) (in a document entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance*), that French recommendations were published. Although the analysis of data found in the literature shows that these devices present a lower risk of infectious complications than other implantable venous catheters, these complications can be serious, leading for example to the delay of already initiated treatments such as chemotherapy, and in some cases to the removal of the implanted device. It is essential to publish recommendations for the prevention of this type of complication, all the more so since the literature dealing with this topic is quite disparate, because usage can vary considerably between hospitals, and because the management of such a device can be organized within a hospital or an outpatient care service, thus involving different health care professionals. It is important that a "preventive chain", passing from the hospital caring for the patient to the private nurse, but also involving the patient, be implemented to guarantee optimal care of these devices, and to ensure that the risk of

infection is minimized during their installation and use. For all of these reasons, the present study entitled "Prevention of infections associated with the use of totally implantable venous catheters" was conducted under the auspices of the French Society for Hospital Hygiene (SF2H). It united a considerable number of learned societies and organizations involved in this issue, which we wish to thank for their participation in the preparation of the present document, in particular since this topic necessarily calls for pluridisciplinary expertise. The methodology was rigorous, and involved the use of a formalized expert consensus, the method recommended by the French National Authority for Health (HAS).

Although the working group recommendations have been synthesized to make them easier to read, I would encourage all readers to read the entire document, in particular in view of the wealth of information provided in the rationale of each section.

On behalf of the SF2H, I would like to thank all of those who participated in this study – expert editors, coauthors, reading group members – and in particular the working group coordinators DANIÈLE LANDRIU and ANNE-MARIE ROGUES.

**Pr Philippe BERTHELOT**  
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- French Agency for the Sanitary Safety of Health Products (AFSSAPS)
- National federation of cancer fighting centers (FNCLCC-GPIC)
- National federation of homecare establishments (FNEHAD)
- French Society for Accompaniment and Palliative care (SFAP)
- French Society for Anesthesia – Critical Care (SFAR)
- French Cancer Society
- French Surgery Society (SFC)
- French cystic Fibrosis Society (SFM)
- French Nutrition Society (SFN)
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# LIST OF MAIN ABBREVIATIONS

AA	Antiplatelet agent
ABP	Alcohol-based product
ANAES	French National Agency for Health Accreditation and Evaluation
BBFE	Blood and body fluid exposure
AP-HP	Public assistance – Paris Hospitals
AVK	AntiVitamine K
CCAM	Common classification of medical acts
CCLIN	Regional Nosocomial Infection Control Coordinating Centre
CDC	Centers for Diseases Control and Prevention
CHSCT	Committee for hygiene, safety, and working conditions
CISCOH	Interdisciplinary conference on additional care in onco-hematology
CLIN	Committee for Nosocomial Infection Control (Consultative and follow-up body)
CRI	Catheter related infection
CTIN	Technical committee on nosocomial infections
CTINILS	Technical Committee for Nosocomial and Healthcare-Associated Infections
CVR	Central venous route
ESPEN	European Society for Clinical Nutrition and Metabolism
EPSU	European federation of public service unions
GERES	French working group on the risk of blood exposure
HAS	French National Authority for Health
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	Human immunodeficiency virus
HOSPEEM	European Hospital and Healthcare Employers Association
IDSA	Infectious Diseases Society of America
INR	International normalized ratio
IVD	Intravascular device
MA	Marketing authorization
MRSA	Methicillin resistant <i>Staphylococcus aureus</i>
PVPI	Povidone iodine or polyvinylpyrrolidone iodine
PICC	Peripherally inserted central catheter
RAISIN	French National program for early warning, investigation and surveillance of healthcare-associated infections
SFHH / SF2H	French society for hospital hygiene
SFTG	French society for the therapeutic training of general practitioners
SHEA	Society for Healthcare Epidemiology of America
SIP	Self-controlled infusion pump
TIVC	Totally implantable venous catheter
VD	Vascular device

# Context and Methodology

## Justification for the study

Following their appearance in the 1980's, the use of totally implantable venous catheters (TIVC) spread rapidly. TIVC have indeed become indispensable tools for the care of many patients, for whom the quality of life has undoubtedly been improved [1,2]. These devices are designed to permit frequent access to the intravenous system. They make it possible to directly access a large vein, providing efficient and rapid access for the delivery of iterative and long-term treatments. They can be used continuously or intermittently, and make it possible to preserve the patient's peripheral venous capital. The main indications for the use of TIVC are thus the administration of chemotherapy, parenteral nutrition, or a long-term parenteral anti-infectious treatment, and also the treatment of congenital or acquired blood diseases requiring frequent transfusions [3].

The insertion and use of TIVC can be accompanied by intermediate complications (of the malposition, pneumothorax, or even hemothorax type), or delayed complications ("pinch off" syndrome in which the catheter is squeezed between the first rib and the clavicle, catheter migration, extravasation, occlusion). Infectious complications are still the most frequent, and are the reason for most catheter removals [4-9].

In France, in 2000, the ANAES standard [3] for the evaluation of the quality of TIVC surveillance proposed good practice recommendations, which were later subdivided [10,11]. Internationally published recommendations specifically concerning the prevention of TIVC related infectious risks are rare [12-14]. The evaluations carried out in this field have reported heterogeneous practices [3,15-17]. The evolution of patient healthcare methods, in particular the development of homecare as well as the extension of TIVC into various pathological contexts, have led many

professionals to be involved in the handling of these devices. In order to respond to the variety of practices which could be misunderstood by patients, and detrimental in terms of the quality of care, the protocols developed on the basis of the experience of various professionals involved in the care and use of TIVCs have multiplied, with the sharing of regional procedures or procedures within various healthcare networks (examples: RIFHOP: the Ile de France pediatric hematology-oncology network, the Rhône-Alpes ONCOlogie network, the Central France regional hospital hygiene center, the ONCOLOR network in the Lorraine department ...).

The rapid evolution of medical and professional practices thus justifies the need to update current knowledge in this field, and to propose specific consensual recommendations for the prevention of infectious risks associated with TIVC.

## Theme boundaries

The present study is limited to the prevention of infections associated with TIVC used for venous access. Other implantations exist (intra-arterial, intraperitoneal, intrathecal), but are not dealt with in the context of these recommendations, since they are used infrequently and have been evaluated only in very rare scientific studies.

In addition, the following aspects will not be dealt with:

- medical indications (apart from a description of the advantages of TIVC as compared to other types of vascular access, in terms of their reduced risk of infection);
- the definition of TIVC associated infections;
- purely technical aspects having no known consequences with respect to infectious risks.

## Targets for the recommendations

**Targeted population:** patients fitted with a TIVC, children and adults.

**Targeted use:** hospital care and external care

These recommendations are intended for all professionals involved in the insertion, use, maintenance and surveillance of this device: surgeons, radiologists, anesthetists, other specialists (infectiologists, oncologists, hematologists, lung specialists, pediatricians, nephrologists, gastroenterologists, biologists ...) and general practitioners, homecare coordinating physicians, ... but also professional training institutes and authorities responsible for the fight against nosocomial infections in hospitals.

## Methodology

The method used in the elaboration of these recommendations is that of "Professional recommendations through a formalized consensus" as proposed by the HAS [18]. This choice resulted from the following points:

- bibliographies in the literature corresponding to only a small number of studies with high quality scientific evidence related to the field of prevention of infections associated with TIVC, in particular concerning their utilization;
- highly technical management, requiring pluridisciplinary expertise;
- the need for continuous management, of all the different users involved in the patient's healthcare, from the hospital wards to outpatient medicine.

The method used to prepare good practice recommendations through a formalized consensus involves the use of both recommendations and of a consensus. As a consensus method, its aim is to formalize the degree of agreement reached between the experts, by identifying and selecting, by means of an iterative rating with information feedback, the points of convergence on which the

recommendations are then based, and the points of divergence or indecision between experts. As a method for establishing good practice recommendations, its aim is to provide concise, unambiguous recommendations, which answer the issues raised.

This approach relied on three groups of professionals:

■ The steering group, thanks to its good knowledge of professional practice in this field, drafted the scientific rationale, after having proceeded with a critical analysis and summary of the available bibliographical data (assisted by project leaders for this task), as well as discussions relating to existing practices. It was organized in sub-groups, responsible for the drafting of different chapters. The documents were then proof-read during plenary meetings by all members of the group of expert editors. The steering group also drafted the proposals submitted to the rating group, and then prepared a summary of the retained proposals. This organization was conducted as a shared job, by two members of the SF2H: a doctor and a healthcare nursing executive.

■ The rating group, composed of professionals designated by each partner society, to which the steering committee added professionals who had participated in the preparation of protocols or scientific studies in the field of TIVC, whilst at the same time promoting regional representation from France and different professional categories, selected those proposals (n = 281) to be retained for the drafting of the initial version of the recommendations, taking the level of evidence and practical experience of its members into account. This rating system used a scale from 1 to 9 (1 = to be rejected ... 9 = to be retained). Following a preliminary rating, the summarized results (various scores given to each proposal, 10<sup>th</sup>, 25<sup>th</sup>, 50<sup>th</sup>, 75<sup>th</sup> and 90<sup>th</sup> percentiles), together

with their interpretation, were presented during a working meeting including all members of this group. This interpretation considered proposals that had received a nearly full consensus, with scores of 7,8 or 9 (or symmetrically a score of 1, 2 or 3) from at least 90% of the experts (n=146), to have a "strong agreement". For the remaining proposals, following debates during which all opinions were discussed in detail, the experts were invited to re-score the proposed recommendations during a second round; some proposal were reformulated (n=42) in order to improve their clarity. Following this second round, the nearly consensual (according to the same criteria) proposals were considered to have a "strong agreement"; those for which the median score was greater than 6 or less than 4 were considered to have a "simple agreement"; and all others were classed as "non consensual".

■ The reading group was asked to give its formalized opinions and advice concerning the content and style of the initial version of the recommendations, in particular on their applicability, acceptability and readability. This advice was of an advisory nature, and was made on an individual basis. It was analyzed by the steering group, with the view to its possible inclusion in the final version of the recommendations.

The scientific council of the SF2H read the prepared document in two phases, before submitting it to the co-author group (proposed recommendations and rationale), after having taken the comments of the reading group into account.

## Questions raised

In terms of the risk of infection, what are the advantages of this type of catheter, when compared to other types of central vascular line?

1. What measures can be taken to prevent the risk of infection at the time of (pre, peri and post-operative) insertion?  
Choice of device (with or without a valve / material), choice of implantation site, skin preparation, environmental conditions, insertion technique, antibiotic prophylaxis.
2. What measures can be taken to prevent the risk of infection during use?
  - a Selection of materials
  - b Needle insertion and initial use
  - c manipulation and changing of a line
  - d Preparation of perfusions and products
  - e Periodic maintenance: heparinization? Preventive antibiotic lock?
  - f Blood samples: indication limits, technique, equipment
  - g Needle changing (technique and frequency)
  - h Dressing: type, technique and change frequency
  - i Removal: when? Optimal duration of use, removal conditions
3. What general policy measures can be adopted? Follow-up and monitoring notebook, monitoring of infectious complications, training of professionals and education of patients/families.



# Summary of recommendations

## Insertion and removal of the totally implantable catheter

### USEFULNESS OF THE TOTALLY IMPLANTABLE CATHETER ACCORDING TO THE PATHOLOGICAL CONTEXT

**R1** In terms of infectious risk, the TIVC is the preferred long-term (greater than 3 months) form of central venous access (**simple** agreement).

**R2** In oncology, the TIVC is the long-term form of central venous access to be preferred. However, is not recommended in hematology in situations involving hematopoietic stem cell (hsc) grafts or acute leukemia induction (**strong** agreement).

**R3** The TIVC can be used for long-term (greater than 3 months) central venous access for:

- The care of patients with cystic fibrosis, to facilitate the repeated use of a treatment,
- Patients requiring discontinuous parenteral nutrition,
- Therapeutic care of solid tumors in pediatrics (**strong** agreement).

### CHOICE OF THE BEST OPPORTUNITY FOR CATHETER INSERTION

**R4** A TIVC may not be inserted until such time as the patient has been informed and has agreed to such a procedure (Regulatory).

**R5** Hemorrhagic complications must be anticipated in accordance with the recommendations made by the SFAR (French Society for Anesthesia – Critical Care), and the same rules must be applied to the

management of antiplatelet agents and anticoagulants as to any other surgical intervention (**strong** agreement). At the time of insertion, the platelet count must be greater than 50 000/mm<sup>3</sup> and the INR must be less than 1.5 (**simple** agreement).

**R6** With onco-hematology, the insertion of a TIVC must be considered and carried out as early as possible, outside any period of induced neutropenia (less than 500 neutrophil granulocytes / mm<sup>3</sup>) (**strong** agreement).

**R7** An ongoing infection must be placed under risk-benefit evaluation and may require insertion to be delayed, until such time as an effective treatment has been applied in the case of an active bacterial infection (**strong** agreement).

**R8** Following removal of an infected TIVC, it is preferable to observe a minimum delay of 48 hours of effective treatment, before inserting a new TIVC at a different anatomical site (**simple** agreement).

**R9** As a consequence of the risk of failure to heal, it is advisable not to use bevacizumab (Avastin®) for a period of 10 days following insertion (**strong** agreement).

### CHOICE OF DEVICE

**R10** The device must have a CE marking and correspond to the ISO 13485 standard (Regulatory), and the catheter may indifferently be made of polyurethane or silicone. The size of the implantable chamber is chosen as a function of the corpulence of the patient, and

the diameter of the catheter must be adapted to the catheterized vein. There is no formal proof of a reduced infectious risk with TIVCs fitted with a valve (**strong** agreement).

## CHOICE OF INSERTION SITE

**R11** Venous access in the superior vena cava system must be preferred, except in cases where the superior vena cava is compressed by a mediastinal tumor (**strong** agreement).

**R12** Under pre-operative conditions, whenever there is clinical suspicion of an obstruction, it is advisable to check the permeability of the selected vein (**strong** agreement). Insertion into the inferior vena cava system must be a second option only, since it increases the infectious and thrombotic risk (**strong** agreement).

**R13** In the case of breast cancer, although it is recommended to insert the TIVC on the side opposite to the tumor (**strong** agreement), there is no formal contraindication to the insertion of a TIVC on the ipsilateral side (**simple** agreement). In the case of a synchronous bilateral breast tumor, the decision to insert into the superior or inferior vena cava system shall take into account the size of the tumor, the size of its base, and the treatment plan. Asynchronous bilateral breast cancer is not an indication for TIVC insertion into the inferior vena cava (**strong** agreement).

**R14** The device shall not be inserted:

- in a zone which has been, or will soon be irradiated,
- in the vicinity of cutaneous metastases,
- close to chronic, uncontrolled skin lesions,
- close to an infected skin lesion (**strong** agreement).

**R15** The patient's condition (aphysema, dehydration, agitation, obesity, malnutrition) can influence the choice of venous route, thereby modifying the standard technique (**strong** agreement).

**R16** The choice of venous route shall take the operator's experience into account (**simple** agreement).

**R17** Following a confirmed infection of the implantation recess or skin tunnel, it is preferable, whenever possible, to use the contralateral side for reinsertion of a TIVC (**strong** agreement).

## SKIN PREPARATION AND CONDITIONS OF INSERTION

**R18** The insertion of a TIVC is a programmed surgical act, carried out by a trained or supervised operator. The use of a rigorous technique for TIVC insertion must be of the same standard as for any other surgical intervention. Whatever the technique used, the insertion of a TIVC must be carried out in a dust-controlled room, under surgically aseptic conditions. The use of a checklist during TIVC insertion is helpful, to ensure that infection prevention measures are observed (**strong** agreement).

**R19** Surgical site preparation prior to TIVC insertion must observe the recommendations applicable to any other surgical procedure. This involves the patient's personal hygiene (shower with shampoo, or full cleansing with an antiseptic foam solution), chemical or clipper hair removal at the insertion site (whenever necessary) and preparation of the surgical site using a hydro-alcoholic antiseptic, whilst observing the required antiseptic durations (detergent cleaning, rinsing, drying, antiseptic application) close to the incision (**strong** agreement).

**R20** In ambulatory surgery, the outpatient organization must allow the recommendations applicable to the preparation of the surgical site to be respected (**strong** agreement).

**R21** It is not recommended to systematically use nasal screening for *Staphylococcus aureus*, for the purposes of individualized decontamination, prior to TIVC insertion (**simple** agreement).

## SURGICAL ANTIBIOPROPHYLAXIS

**R22** It is recommended not to use surgical antibioprophyllaxis at the time of insertion, even in the case of a history of TIVC infection or known carriage of MRSA (methicillin resistant *Staphylococcus aureus*) (**strong** agreement), regardless of the immune status of the adult (**simple** agreement) or child (**strong** agreement) patient.

**R23** Following the removal of a catheter, for reasons of a suspected infection, the early re-insertion of a TIVC, if necessary, must be accompanied by an effective curative antibiotherapy (**strong** agreement).

## INSERTION TECHNIQUE

**R24** In terms of infectious complications, there is no difference between denudation and percutaneous techniques (**simple** agreement).

**R25** Whatever venous access is used, TIVC insertion can be facilitated by means of ultrasound guidance (**strong** agreement); in the case of a percutaneous jugular puncture, insertion should be carried out under ultrasound guidance (**simple** agreement).

**R26** The incision site must not be positioned opposite to the inserted device. A sterile dressing is used to cover the surgical site (**strong** agreement).

**R27** A chest x-ray must be taken after insertion, in order to verify that the distal end of the catheter is correctly positioned at the junction between the right atrium and the superior vena cava (**strong** agreement).

**R28** The first puncture of the TIVC is a medical act, which is performed intraoperatively during reflux verification, immediately after insertion (Regulatory).

**R29** With insertion following reflux verification, the Huber Needle is left in place by the operator only when it is intended to use the TIVC within a period of 24 hours (**strong** agreement).

## POST-TREATMENT REMOVAL

**R30** Removal of the TIVC is a programmed surgical act which must be carried out under the same conditions as insertion (surgically aseptic conditions in a dust-controlled room) (**strong** agreement).

**R31** Removal of the TIVC at the end of treatment cannot be planned without the consensual agreement of the various professionals taking care of the patient (**strong** agreement), and must be considered whenever the foreseeable duration of treatment interruption exceeds a period of six months (**simple** agreement).

**R32** The TIVC can be kept in place if sequential venous treatments are used (**strong** agreement), or in the absence of a peripheral venous network, when frequent blood samples are necessary (**simple** agreement).

# Utilization of the implantable venous catheter

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## CHOICE OF PERFUSION EQUIPMENT AND TECHNICAL ASPECTS

### GENERALITIES

**R33** It is strongly recommended that any incident related to the medical devices used for patient care be appropriately reported (regulatory).

**R34** It is strongly recommended to use safe equipment (regulatory) compatible with the GERES (French Working Group on the Risk of Blood Exposure) criteria, and to ensure the compatibility of all devices used to make up the line, in order to minimize any variations in flow rate, leakage and breakage (**strong** agreement).

### CHOICE OF NEEDLE

**R35** It is strongly recommended to use Huber needles (Regulatory), preferably with a 22 gauge diameter, even in the case of the perfusion of viscous medication (such as parenteral nutrition, labile blood products) (**strong** agreement). If it is found necessary to use a 19 gauge needle, it is preferable to remove the needle as soon as perfusion has been completed (**simple** agreement).

**R36** It is preferable to use a type 2 Huber needle, i.e. equipped with an extension in order to minimize manipulations of the needle hub (**strong** agreement), except for high flow-rate injections, for example in radiology where, in the absence of a compatible type 2 needle, a type 1 needle without an extension will be preferred (**simple** agreement). The length of the needle must be adapted to the depth at which the chamber is located, and the patient's corpulence (**strong** agreement).

## CHOICE OF LINE ACCESS MATERIALS

**R37** For any act carried out on the TIVC or the perfusion line, it is strongly recommended to use only syringes having a volume of at least 10 ml, in order to avoid over-pressure which could damage the TIVC (Regulatory).

**R38** It is desirable to use type 2 Huber needles with an integrated safety connector (**strong** agreement).

**R39** If a safety connector is used, for reasons of the infectious risk associated with some devices, a valve system with a pre-slit septum should be preferred to a system with a mechanical valve. It will then be necessary to implement monitoring of the incidence of TIVC associated bacteremia (**simple** agreement).

**R40** The use of a set facilitates patient care, in particular when it is carried out in the home (**strong** agreement).

**R41** All gauze used during TIVC manipulations must be sterile (**strong** agreement).

### TIVC FLUSHING

**R42** Efficient flushing involves the pulsed injection of 10 ml of 0.9% NaCl, through the use of successive impulses (**strong** agreement). The flushing efficiency is verified by the absence of any visible residues (**simple** agreement).

**R43** The use of 0.9% NaCl syringes facilitates the observance of good practice (**simple** agreement).

## INITIAL USE AND INSERTION OF A NEEDLE

### INITIAL USE

**R44** The first puncture of the TIVC is a medical act, which is carried out intraoperatively during reflux testing, immediately after insertion (Regulatory). It is preferable to avoid inserting a needle into an incompletely healed surgical site (**simple** agreement). The absence of local cutaneous signs (redness, pain, swelling, edema) is verified before inserting the needle (**strong** agreement).

### OPERATOR HYGIENE DURING NEEDLE INSERTION OUTSIDE THE OPERATING ROOM

**R45** The operator must wear clean professional garments; in the absence of professional garments, he/she must wear a disposable smock (**strong** agreement). The wearing of a sterile gown is required only when the patient is placed in protective isolation in a dust-controlled environment (**simple** agreement). The operator wears a surgical mask (**strong** agreement) and a medical cap (**simple** agreement). The operator uses a hydro-alcoholic handrub to disinfect his/her hands just before inserting the needle, and wears gloves just before carrying out the puncture (**strong** agreement).

### SKIN PREPARATION BEFORE NEEDLE INSERTION

**R46** Skin preparation is carried out before insertion of the needle. Whenever the needle is changed, the skin must be prepared just before re-puncturing the chamber. Adequate stripping of the patient must allow a large area to be disinfected. Skin preparation includes a deterative cleansing phase prior to skin disinfection, using a major alcohol-based antiseptic. A 0.05% water-based chlorhexidine solution must not be used. It is not recommended to apply a degreasing agent or any product which is irritating to the skin. If the use of a topical anesthetic is necessary, it is

preferable to use single dose packaging (**strong** agreement). Hair removal from the needle insertion site is not recommended (**simple** agreement), but if this is indispensable in order to ensure adequate fixation of the dressing, the use of clippers should be preferred (**strong** agreement).

### NEEDLE INSERTION TECHNIQUE

**R47** The patient is installed so as to optimize care ergonomics. He/she must wear a surgical type of mask; if the wearing of a mask is not tolerated, the patient should be asked to turn his/her head towards the side opposite to that of the TIVC (**strong** agreement). A sterile drape can be used during TIVC puncture (**simple** agreement); more specifically, this should be used in the case of insertion in the home environment (**strong** agreement). It must have an opening and be pre-cut in order to avoid any aseptic inadequacy at the end of the intervention (**simple** agreement).

**R48** It is strongly recommended to go completely and perpendicularly through the septum, until the needle touches the bottom of the chamber, without bending the tip (Regulatory). The skin is kept intact and the septum remains leakproof, by changing the puncture points in the chamber (**strong** agreement).

**R49** Correct operation of the device is verified by means of the following indicators: presence of venous reflux, absence of pain with or without injection, good perfusion flow rate (observed flow rate = expected flow rate), easy injection when using the syringe (**strong** agreement).

## DRESSING

### GENERAL CONSIDERATIONS

**R50** The dressing must never become wet (**strong** agreement). Whenever a needle is being used, it is not recommended to allow

showering, even in the absence of perfusion (**simple** agreement). If the patient takes a shower or is exposed to water, the dressing (whatever its type) must be protected through the use of waterproof material, and its leak-proof qualities must be verified beforehand and afterwards (**strong** agreement).

#### CHOICE AND INDICATIONS FOR THE DRESSING

**R51** During the immediate post-operative period, in case of exudation and bleeding at the surgical site or puncture point, the dressing should be of the sterile adhesive type with gauze. Once the surgical site has healed, it is preferable to use a sterile semi-permeable transparent dressing (according to the EN 13726-2 standard), as this allows the puncture site to be inspected (**strong** agreement).

**R52** The needle insertion site should be protected by a sterile and occlusive adhesive dressing. In all cases, in particular when a safety needle is in place, it is necessary to apply a sufficiently large dressing to ensure its water-tightness and that it is correctly held in place (**strong** agreement).

**R53** When removing the needle, a sterile adhesive dressing with dry gauze is applied to the puncture point for one hour. After the insertion site has healed, it is not necessary to apply a dressing on a non-infused TIVC when there is no needle in place (**strong** agreement).

#### DRESSING REPLACEMENT TECHNIQUE

**R54** Disinfection of the hands using an ABP handrub should be performed before the manipulation of any dressing. Appropriate stripping of the patient allows provides access for skin preparation and safe manipulations (**strong** agreement).

**R55** When the dressing is replaced, the operator and the patient should wear the same garments as when inserting the needle (**strong** agreement).

**R56** The dressing replacement technique follows the same cutaneous preparation principles as when needle insertion. When a Huber needle is already in place, the various antisepsis steps should be performed using sterile gloves. Applying an antimicrobial ointment at the insertion site is not indicated. The dressing should be applied after complete spontaneous drying of the antiseptic (**strong** agreement).

#### FREQUENCY OF DRESSING REPLACEMENT

**R57** The first dressing replacement after a TIVC has been inserted should be performed within the first 48 hours (**simple** agreement).

**R58** Any soiled or loosened dressing should be replaced quickly (**strong** agreement).

**R59** If a sterile adhesive dressing with gauze is used, it should be replaced every 96 hours. If the transparent dressing is sterile and semipermeable, it can be left in place until needle replacement (i.e. for a maximum duration of 8 days) (**strong** agreement).

**R60** Dressing replacement does not systematically require needle replacement (**simple** agreement).

#### **PREPARATION AND MANAGEMENT OF ADMINISTERED MEDICATION**

##### GENERAL

**R61** It is highly recommended to carry out cytotoxic and radiopharmaceutical reconstitution in the pharmacy department within a controlled-atmosphere area (Regulatory).

**R62** The line should be installed in the simplest possible way under aseptic conditions, and the main line should not be replaced more often than every 96 hours. Active injection systems, which reduce the risk of blood reflux, should be preferred to gravity-fed infusion (**strong** agreement).

#### SELECTION OF MEDICATION

**R63** For parenteral drip-feeding, the use of ready-made mixtures is preferred: whether in a binary (glucose, amino acids) or ternary (glucose, amino acids, lipids) form, which reduces the manipulation and number of connections (**strong** agreement). Isotonic saline solutions should be preferred to glucose-based solutions for the purposes of continuous infusion through the main line (**simple** agreement).

#### PREPARATION TECHNIQUE

**R64** Disinfection of the hands using an alcohol-based handrub shall be performed before any infusion preparation. The preparation date and additives shall be noted on the bottle or bag (**strong** agreement), avoiding the use of markers or felt pens that could damage plastic bags (**simple** agreement). Single-dose additives should be used whenever possible (with the remaining liquid being discarded). Any turbid, broken or expired vial is unusable. Vial caps are disinfected using sterile gauze impregnated with an alcohol-based antiseptic (alcoholic povidone iodine or alcoholic chlorhexidine or 70% alcohol) (**strong** agreement).

**R65** The solutes prepared outside pharmacy departments should be used extemporaneously. (**strong** agreement).

#### SPECIFICITIES FOR BLOOD AND BLOOD DERIVATIVES

**R66** It is possible to transfer blood or blood components through the TIVC, provided thorough rinsing has been performed (see R42) after these products have been infused

(**strong** agreement). However, if another venous line is available, it should be preferred for infusion (**simple** agreement).

**R67** It is recommended to connect the blood and blood components to the proximal site (as close to the patient as possible) in order to facilitate rinsing of the infusion device. The transfusion bag tubing should be replaced for each new labile blood product. The administration duration of a bag is 4 hours or less (**strong** agreement).

#### SPECIFICITIES FOR LIPID EMULSIONS

**R68** It is recommended to connect lipid emulsions to the proximal site (as close as possible to the patient) in order to facilitate rinsing of the infusion device. The tubing shall be replaced at the same time as the bag (**strong** agreement).

**R69** In the case of pure lipids, the administration duration of a lipid emulsion is 12 hours or less. However, an administration duration of 24 hours is acceptable in the case of large volumes. In case of combined lipid emulsions (3 in 1 administration of amino acids and glucose), the administration duration is 24 hours or less (**strong** agreement).

#### MANAGEMENT OF INFUSION LINES OTHER THAN FOR BLOOD PRODUCTS AND LIPID EMULSIONS

**R70** The tubing of the secondary lines shall be replaced between two different products (**simple** agreement). Thorough rinsing (see R42) of the connections should be performed immediately after each tubing replacement when switching to a different product. When infusing the same product continuously, the tubing shall be replaced every 96 hours (**strong** agreement). In case of non-continuous infusion of the same product, the tubing is to be replaced immediately after each bag (**simple** agreement).

## MANIPULATIONS AND MANAGEMENT OF CONNECTIONS

### GENERAL MANIPULATION CONSIDERATIONS

**R71** All manipulations should be performed aseptically and after hand disinfection using an alcohol based product, and, as far as possible, should be limited in number and grouped together. For the manipulation of a connection in the venous line, sterile gauzes impregnated with an alcoholic antiseptic (alcoholic chlorhexidine, or alcoholic povidone iodine, or 70% alcohol) shall be used (**strong** agreement).

**R72** It is highly recommended to note the administration of a treatment and the difficulties encountered, on the patient's record and monitoring sheet (Regulatory).

### OPERATOR AND PATIENT'S GARMENT FOR MANIPULATIONS

**R73** For proximal manipulations, the operator shall wear clean professional garments; if clean professional garments are not available, a single-use gown should be worn in a hospital setting (**strong** agreement) and for community-based care (**simple** agreement).

**R74** For proximal manipulations, wherever these are performed, in addition to clean garments, the operator shall wear:

- a surgical type of mask (**strong** agreement),
- sterile gloves (**simple** agreement).

**R75** For proximal injection into the infusion line, a patient shall wear a surgical type of mask. If he/she cannot wear a mask, he/she will be asked to turn his/her head towards the side opposite to that of the TIVC (**simple** agreement).

### ADMINISTRATION OF SOLUTES

**R76** Before administering the solute: test the TIVC's permeability (no resistance to injection, observed flow rate as expected), check for extravasation (lack of pain or local edema). Check for venous reflux in the case of a malfunction or before administering a dangerous (blistering and necrotizing) product. It is mandatory for venous reflux verification to be followed by thorough rinsing (see R42) (**strong** agreement).

**R77** After the treatment has been administered, to avoid precipitation of incompatible products within the TIVC, thorough TIVC rinsing (see R42) shall be systematically performed, and the absence of conspicuous residues within the tubing and connections shall be verified. Whatever the solute used, in particular for lipid emulsions and blood products, the connections shall be rinsed immediately after disconnection following administration of the treatment (**strong** agreement).

### MANAGING LINE ACCESS POINTS

**R78** The replacement frequency of the associated distally positioned devices (stopcocks, ramps, valves or safety connectors) shall match that of the venous line. These items should not remain in place more than 96 hours (**strong** agreement).

**R79** The main line's injection sites should be remote from the bedding, using a long extension line and a ramp holder. Proximal connections and proximal injection sites shall be protected and kept at a distance from any source of contamination (**strong** agreement).

**R80** The injection site shall always be disinfected before use. If a stopcock is used for injection (without a safety connector), it shall be obstructed immediately after use by means of a sterile stopper. Each unused pathway shall be obstructed using a sterile device (**strong** agreement).

**R81** When a safety connector is used, efficient disinfection must be performed using an alcohol-based antiseptic before any injection. It is essential to rinse the internal lumen before use (**strong** agreement). If a safety connector is placed proximally, it shall be replaced every eight days, at the time of needle replacement (**simple** agreement).

#### BLOOD SAMPLING

**R82** It is possible to sample blood from the TIVC, provided that:

- a clear procedure is available for the technique,
- the asepsis and staff protection rules chosen for manipulating the proximal connection are observed,
- a single-use pump body is used for any sampling, including blood cultures,
- immediate thorough rinsing (see R42) is performed,
- no purge re-injection is performed (**strong** agreement).

#### **REMOVAL AND AND FREQUENCY OF NEEDLE CHANGE**

##### OPERATOR AND PATIENT'S GARMENTS WHEN REMOVING THE NEEDLE

**R83** The operator shall perform a handrub to disinfect his/her hands (**strong** agreement). He/she shall wear a surgical mask and non-sterile protective gloves to remove the needle (**simple** agreement).

**R84** The patient shall wear a surgical type of mask. If he/she does not tolerate the mask, he/she will be requested to turn his/her head towards the side opposite to that of the TIVC (**simple** agreement).

##### PROCEDURE WHEN REMOVING THE NEEDLE

**R85** Any person liable to remove a safety needle should be informed and trained for this procedure. When a safety needle is unavailable, a hand protection accessory should be used to remove the needle

(**strong** agreement).

**R86** The TIVC should be rinsed before needle removal, and the removal should be performed under positive pressure. Once the needle has been removed, a slight pressure is applied to the puncture point using an antiseptic-impregnated sterile gauze (**strong** agreement).

#### NEEDLE REPLACEMENT FREQUENCY

**R87** The needle cannot be kept for more than eight days (**strong** agreement). In case of daily non-continuous use of the TIVC, the needle can be left in place provided a risk-benefit analysis has been performed for the patient (**simple** agreement). In other situations, the needle shall be removed after use. The presence of local inflammatory signs requires needle removal (**strong** agreement).

#### **PERIODIC MAINTENANCE**

**R88** Routine use of a heparin lock or flush is not needed to prevent TIVC-associated infections. Routine use of an antibacterial (antibiotic, or the like) lock or flush is not useful to prevent TIVC-associated infections (**strong** agreement).

**R89** Use of a preventive antibacterial lock can be advised if the central venous capital is limited in a patient who has suffered from several TIVC-associated bacteremia or in patients with an increased risk of complications, in case of a catheter-associated bacteremia (for example, for those patients provided with a mechanical valve or an synthetic aortic graft). When an antibacterial lock is indicated, taurolidine or another molecule with proven efficacy in preventing catheter-associated infections should preferably be used (**simple** agreement). When a lock is indicated, the product used shall not be mixed with another one. If periodical maintenance indications are retained, a detailed written institutional procedure should be provided (**strong** agreement).

## GENERAL POLICY ASPECTS

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### INFORMING AND EDUCATING THE PATIENT

**R90** It is highly recommended that a surveillance notebook with all of the items provided in the circular letter No 96-6225 being given to the patient (Regulatory). The advantages of recording notes in the surveillance notebook shall be explained to the patient or his/her close relatives (**strong** agreement).

**R91** It is highly recommended to inform the patient about the infectious risk associated with the insertion as well as use of a TIVC as well as TVIC-associated incidents (Regulatory). The patient or close relatives shall be involved in the prevention of TIVC-associated infections and in the detection of TIVC-associated infections. They shall be informed about the conduct to be followed in the case of problems and shall be given phone numbers to call. The information provided to the patient or close relatives shall be evaluated and, if necessary, re-adjusted on a regular basis during his/her hospital stay (**strong** agreement).

### **PROFESSIONAL TRAINING AND PRACTICE ASSESSMENT**

**R92** Healthcare institutions in which patients fitted with a TIVC are treated shall designate a specialized team or referral persons skilled in the use of such devices. These persons may provide assistance to professionals seeking advice. Only staff members who have received specific training shall be allowed to install and use a TIVC. Any change in care modalities or hardware will require informing or training of all professionals in a given healthcare network (**strong** agreement).

**R93** Operators should use good practice procedures for the prevention of infectious risks, with procedures being written and updated as regards the installation, use and monitoring of the TIVC. Common procedures will be used among a given healthcare network (**strong** agreement).

**R94** Continuous clinical monitoring for local or general complications inherent to the installation or use of a TIVC is indispensable (**strong** agreement).

**R95** The knowledge and practice of professionals in charge of TIVC installation and of those in charge of TIVC use are assessed on a regular basis. All professionals who will have to care for a patient should be made aware of the importance of careful completion of the monitoring notebook. The traceability of interventions relies on the recording and sharing (between all hospital personnel involved in the patient's care) of the monitoring notebook (**simple** agreement).

### **EPIDEMIOLOGICAL MONITORING**

**R96** In hospitals, a program for the epidemiological monitoring of the TIVC-associated infectious risk is established by the authority responsible for nosocomial infection control and the hospital hygiene team in conjunction with the clinical departments involved. The definition of a TIVC-associated infection used for such monitoring was recommended nationally by the CTINILS in 2007. Infection rates are expressed as the number of infections for 1000 days of TIVC presence (**strong** agreement). They should be expressed as the number of infections per 1000 days of TIVC use. Within this framework, data collected in the surveillance notebook can be used to calculate the denominator. Epidemiological monitoring shall be performed when changing the healthcare procedures or the hardware used in a healthcare network (**simple** agreement).

**R97** Routine culturing of the TIVCs removed after treatment is not recommended (**strong** agreement). However, if a follow-up of colonization or infections is considered, systematic culturing of the removed TIVCs can be performed, subject to a standardized analysis technique (**simple** agreement).

**R98** The occurrence of a severe TIVC-associated infection (bacteremia, death, infection justifying removal) requires that this be reported to the operational hospital hygiene team (**strong** agreement) and that a root cause analysis be performed (**simple** agreement).



# Introduction

## Definitions

### 1- The totally implantable vascular catheter

The NFS 14-370-1 standard specifies that a totally implantable venous catheter is a sterile device placed directly underneath the skin. It is comprised of a subcutaneous injection container (the chamber), the upper portion of which is covered with a flexible membrane, and of a long catheter, which is inserted into a large vein. The chamber is most often composed of a base, a housing, and a silicone-based self-sealing membrane (septum). Injection is performed through the skin, with the needle then passing through the membrane (*see appended drawing*) [19].

Several designations may appear for this type of intravascular device: implantable chamber, implantable site catheter, implantable vascular access, implantable injection site, implantable site, infusion-related implantable chamber, implantable vascular access system, endovenous implantable system, however "totally implantable venous catheter", employed in the 94-370-1 standard, is the term which was retained by the French certification agency, ANAES, in 2000.

In 2000, ANAES defined the totally implantable venous catheter (TIVC) as an "*implantable system placed directly under the skin, allowing cutaneous access to the catheter. It may be used for infusion, transfusion, blood sampling as well as the administration of medication. It is mainly associated with long-term treatment (usually more than three months) requiring repeated access to the venous system, either*

*continuously or intermittently. The system is designed to remain in place for years after implantation. The device consists of a subcutaneous injection chamber and a central catheter*" [3].

### 2- TIVC-related infections

TIVC-related infectious complications can be loco-regional or disseminated and manifest themselves differently in the form of:

- a superficial infection of the surgical site;
- a superficial infection at the needle puncture point;
- an abscess of the subcutaneous pocket;
- cellulitis along the tunneled catheter path;
- bacteremia;
- infection of the catheter.

The aim of this document is not to discuss the TIVC-related infections, which vary according to the published research, with reports depending on the different situations, ranging from catheter or chamber colonization to local, superficial or deep infection of the **chamber**, with or without bacteremia [20].

In France, the definition retained in May 2007 by the Technical Committee on Nosocomial Infections, CTIN, is the same as that for central venous catheter-related infections, but for long-term catheters (tunneled catheters, implantable catheters) takes into account the fact that the catheter is not always removed, such that catheter-related infection diagnoses must be made with the catheter in place. The date of infection is the date on which a diagnosis was suspected, and not the date when the catheter was removed. "*In such a case, diagnosis techniques carried*

out with the catheter in place can be very useful, in particular for differential blood cultures and local sampling, when a protruding catheter is available. In addition, clinical signs which appear when a venous line is used (when connecting an infusion) are highly predictive of a catheter infection. The positivity time differential between central/peripheral blood cultures allows an infection to be diagnosed" [21].

## Physiopathology of TIVC-related infections

The onset of a TIVC-related infection involves different mechanisms, which in turn determine the strategies to be followed in order to prevent such infections. Firstly, it should be recalled that, as for other CVCs, interactions between thrombosis and infection are known, but not entirely elucidated. Microbiological studies have shown that the fibrinogen and fibronectin in the blood clot exert an attractive power on bacteria and increase their adhesion, in the case of staphylococci in particular, to the surface of catheters [22]. Clinical studies confirm this increase in infectious risk related to the presence of a blood clot within a catheter [23]. Conversely, it has also been shown that infection significantly increases the risk of catheter obstruction and thrombosis [24]. On TIVC removal, the presence of a blood clot within the chamber is very often associated with the presence of an infectious complication [25].

The formation of a biofilm on catheter surfaces occurs within the first twenty-four hours, in the form of a platelet deposition onto the catheter, thus promoting microorganism adhesion and accumulation. The production by polysaccharide substances of certain bacteria enhances adhesion (*slime*). The development of this biofilm explains the difficulties encountered in diagnosing, treating and preventing long-term catheter-related infections. These biofilms are single- or multi-microbial communities, which are difficult to eradicate as a result of the biofilm-plankton

forming cycle, responsible for problematic antibiotic penetration, a decrease in bacterial growth rate, a change in the expression of resistance genes, and metabolic heterogeneity [26].

The contamination mechanisms retained for TIVCs are similar to those described for other vascular catheters. Thus, it is common to distinguish between:

- Extraluminal contamination, which essentially causes infections associated with the insertion of a TIVC or a needle, with contamination of the insertion site from local skin flora or the exogenous flora introduced during treatment. These extraluminal infections, often accompanied by infections of the **chamber** and tunnelitis generally occur within a month of implantation, or more rarely, when needle-related contamination has occurred.

- Endoluminal contamination, when needles are used, when manipulating line connections, or more rarely through contamination of the infused solutes.

- Contamination of the intravascular portion of the catheter, or hematogenous contamination from a remote infectious site or during bacterial translocation.

The role of each of these contamination mechanisms is difficult to ascertain and has not really been studied. Migration of commensal skin microorganisms along the outer surface of the catheter is a less frequent mode of contamination with TIVCs than with CVCs. The predominant mode with TIVCs appears to be contamination of the catheter through an endoluminal route, even though contamination by cutaneous microorganisms at the time of puncture of the implantable site and blood-mediated infection from a remote site, or through bacterial translocation, are other possible modes of contamination [27]. In a prospective study of skin colonization occurring within three months of TIVC implantation in 41 patients, the authors concluded that there was

a relationship between the identified skin flora associated with the TIVCs and the microorganism responsible for a bacteremia, and considered that, during this follow-up period, contamination occurred through both extraluminal and endoluminal pathways [28].

Thus, contamination may occur at the time of surgical implantation of the catheter, when the chamber is punctured with a needle, or during manipulations of the connections and connectors [3]. Therefore, two major periods of infectious risk can be identified: an early risk period, within a month of implantation, and a more delayed risk, mostly of the endoluminal type, arising from the use of the TIVC.

## Epidemiology of TIVC-related infections

### 1- Incidence rate and risk factors

In a literature review, Maki *et al.* collated data from 14 studies and estimated the average incidence rate of TIVC-related bacteremia to be 0.10 for 1000 catheter-days [29]. In fact, according to these studies, the incidence of infections in adult TIVC carriers ranges from 0.026 to 0.86 for 1000 catheter-days, for all types of infection; from 0.016 to 0.24 for 1000 catheter-days for bacteremia, and is equal to 0.19 for 1000 catheter-days in the case of local infections. In children, the small number of existing studies reveals higher incidence rates, ranging from 0.11 to 1.94 for 1000 catheter-days, for all types of infection. It must be emphasized that the incidence of infection is not always expressed in catheter-days, that the type of infectious complication (superficial or deep local infection, with or without bacteremia) is not always specified, and that, although the most frequently described infectious complication is the onset of bacteremia, definitions often vary from one study to another. Finally, the type and mode of use are only rarely mentioned; in the multicenter study of Dal Molin *et al.*, in which the incidence of complications was very low,

half of the patients (that is, more than 10,000 catheter-days) did not receive any treatment through their TIVC, but received a monthly heparin flush (*Table 1*) [30].

The incidence rate of infectious complications depends, in particular, on the patient's condition: patients most at risk are immunocompromised patients with hematological malignancies [20,31]. The grafting of hematopoietic stem cells in severely immunocompromised patients is an independent infectious risk factor (OR=1.68, p=0.005) [32]. An increased risk of infection in patients with serious hematological conditions has been observed by many authors. The frequency of TIVC use, the number of openings in the venous line, the actual period of use and the depth and duration of episodes of neutropenia may be responsible for this increased risk in hematology. Finally, in such patients at risk of thrombopenia, due to the increased space between the septum and the skin surface, hematoma of the recess may lead to difficulties in identifying a suitable site and therefore to multiple punctures, which are sources of contamination, but also to needle dis-insertions, with a risk of extravasation. However, in the literature, the presence of a hematoma is not a specifically identified infectious risk factor [6,25,33-35].

Children are also a population with a greater risk of infection, especially in the case of children under 10 kg [36]. In a retrospective study of 175 children followed in oncology, LOH *et al.* reported an infection incidence rate of 0.44 per 1000 catheter-days; the average age and duration of implantation in the case of removal of the TIVC were 1.5 years and 111 days, as opposed to 10 years and 414 days in the case of maintenance [37]. Recently, a retrospective monocentric series of 209 children found an infection incidence rate equal to 0.15 per 1000 catheter-days, with a high risk of infection in children under the age of two [35].

As with other CVCs, parenteral nutrition is recognized by many authors as an infection risk factor [25,38,39]. In a historical cohort of 500 cancer patients, a body mass index greater than 28.75 was associated with a higher risk of TIVC-related infection [40]. In a cohort of 371 patients followed in oncology, of whom 80% were TIVC carriers, the multivariate analysis showed that the occurrence of infection was significantly associated with patients under the age of 10, the use of parenteral nutrition, and catheter implantation difficulties (OR = 25, 95% CI: 4.2 to 106) [41]. Other factors such as male gender were identified as an independent infectious risk factor [42].

Finally, patients infected with HIV are at greater risk of developing infectious complications than other TIVC patients. In a retrospective cohort of 123 patients followed for at least one year, the incidence rate of TIVC-related bacteremia was 0.96, as opposed to 1.50 per 1000 catheter-days in HIV patients (RR = 0.58, 95% CI, 0.27 to 1.26) [43]. A six-month prospective study assessing the impact of infections in two groups of patients: HIV-positive patients and patients followed for cancer, reported incidence densities of 3.78 and 0.30 per 1000 catheter-days, respectively;

this difference can probably be explained by the frequency of manipulations. In HIV-positive patients, risk factors independently associated with infectious complications were: the number of manipulations and the presence of neutropenia; in patients with cancer, the Karnovski index, and for both groups the presence of a recent bacterial infection [44].

Concerning the time of occurrence of infectious complications, the first months following implantation have the highest risk, due to intensive use of the device. In a former series of TIVCs used in onco-hematology, the average time between implantation and infection was 192 days [45]. In the study of Chang *et al.* carried out in oncology, nearly half of the infections occurred within 100 days following device implantation [46]. For other authors, the period of high infectious risk is limited mainly to the first 200 days of use, both in oncology patients and in children in hematology [32,34]. In a French historical cohort of 219 patients followed in onco-hematology, the cumulative probability of infection over five years was 37.2% [34]. Finally, it is important to note that infectious complications are still possible several weeks or months after the last use of the TIVC [34,40].

**Table I** – Incidence rate of infectious complications associated with totally implantable vascular catheters. Data from the literature, papers published after 2000.

First author [Ref.]	Publication year	Type of study	Number of monitored TIVCs	Patients	Total number of catheter days	Incidence of infectious complications for 1000 catheter days		
						All	Bacteremia	Local infections
Nosher [50]	2001	Prospective	22	Onco-pediatrics, parenteral nutrition	6579	0.45		
Chang [46]	2003	Retrospective	586	Oncology	209694	0.15		
Talfer [51]	2003	Retrospective	116		45963		0.22	0.02
Barbut [25]	2004	Retrospective	110	Oncology, parenteral nutrition, HIV	57018	0,43	0.24	
Biffi [52]	2004	Prospective	376	Oncology	178065	0,026	0.016	0.01
Munck [48]	2004	Retrospective	452	Cystic fibrosis	1205	0.3		
Wolosker [53]	2004	Prospective	519	Oncology	183467	0.23	0.46	0.23*
Wolosker [54]	2004	Prospective	20 (femoral route)	Oncology	4316	0.69		
Wagner [55]	2004	Retrospective	30	Sickle-cell anemia	12389	1.5		
Johansson [56]	2004	Randomized prospective	17	Onco-hematology	2874	2.78		
Adler [32]	2006	Prospective	246	Onco-hematology pediatrics	-		1.451	0.49
Charvat [57]	2006	Prospective	101	Oncology	-	0.048	0.024	0.024*
Conter [58]	2006	Retrospective	45	Onco-pediatrics	-		1.38	0.35
Ng [59]	2007	Retrospective	33	Oncology	5783	0.86		
Loh [37]	2007	Retrospective	80	Hemato-pediatrics	38203		0.37	
Royle [60]	2008	Retrospective	165	Cystic fibrosis	146072	0.16		
Samaras [6]	2008	Retrospective	201	Onco-pediatrics	47781	0.27	0.02	
Mancuso [61]	2008	Prospective	27	Hemophilia	39717	0.57		
Crisinel [34]	2009	Prospective	219	Oncology, parenteral nutrition, HIV	92773	0.37		
Hsieh [42]	2009	Retrospective	1348	Oncology	368373	0.108		
Teichgraber [62]	2009	Prospective	80	Oncology	-	0.15		
Nishinari [63]	2009	Prospective	350		74691			
Charles [64]	2009	Prospective	161	Oncology	32779			0.03*
Dal Molin [30]	2010	Prospective	1,076	Oncology	138868	0.07	0.03	0.04

\* Implantation site infection

The variable incidence of infectious complications associated with TIVCs reported in the literature can be explained by the methodology used in the study (duration and follow-up period; non-standardized definition retained: local skin or recess infection, the

presence (or not) of bacteremia; calculation of the incidence rate per day of use, or per day of device implantation), underlying pathology, and "patient" risk factors, but also insertion technique, type of equipment and conditions of use [2,31,44].

## 2- Microorganisms involved

A former prospective study found a predominance of Gram-positive cocci infections (65.5%) (coagulase-negative staphylococci, *Staphylococcus aureus*, *Streptococcus* spp. and *Enterococcus* spp.), followed by Gram-negative bacilli (21% for enterobacteria and *Pseudomonas aeruginosa*), and then Gram-positive bacilli (10%) and lastly, yeasts (3.5%) [45]. Similar proportions were also found in more recent retrospective studies [33,34]. However, the study by Chang *et al.* in oncology shows a trend towards a predominance of Gram-negative bacilli (40%), followed by skin flora staphylococci (37%) and then yeasts (23%). The high percentage of identified yeasts can be explained by the high number of patients receiving parenteral nutrition (22%). Indeed, the latter has emerged

as a risk factor for *Candida* spp. infections, for 71% of candidiasis, vs 8% of bacterial infections [46]. In neutropenic patients, a translocation originating from the gastrointestinal tract may explain the over-representation of Gram-negative bacilli and yeast [47]. These data are consistent with those of a study on cystic fibrosis patients of whom 14% were receiving parenteral nutrition, and in which 66% of the microorganisms responsible for TIVC-related infections were from the *Candida* genus [48].

Thus, the microorganisms most frequently involved are those of the skin flora, mainly coagulase-negative staphylococci, *Staphylococcus aureus*, but also, depending on the patient's initial condition and use of TIVC, Gram-negative bacilli and yeasts of the *Candida* genus [49].



# Insertion and removal of the totally implanted vascular catheter

## 1-1 Purpose of the totally implantable catheter, as a function of the pathological context

### 1-1-1 Review of the literature

#### A – Existing recommendations

■ In its document drafted in 2000, entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance* the ANAES defines the indications and contra-indications for the implantation of a TIVC. These are:

- of therapeutic origin, for anti-cancer chemotherapy (the most common indication), parenteral nutrition, long-term antibiotherapy of patients who are immunosuppressed or suffer from cystic fibrosis, antiviral and antifungal treatment (AIDS patients), vasodilator and anti-platelet aggregation treatment for patients with primitive pulmonary arterial hypertension, the administration of medication for the treatment of congenital or acquired blood diseases requiring repeated transfusions, the treatment of pain when it has been found impossible to treat orally, and hemodialysis in certain cases.
- of humane origin, depending on the patient's clinical condition, venous capital, and the extent to which he/she is prepared to accept repeated puncturing of the skin.

The contra-indications to the implantation of a totally implantable venous catheter are: previously irradiated zones and ipsilateral breast cancer (relative contra-indications), cutaneous metastases, mediastinal tumors,

infected or burnt areas, major coagulation disorders, septicemia, and axillo-subclavian phlebitis antecedents [3].

■ In 2007, a summary of the existing recommendations for hematology recalled the usefulness of the TIVC, and recommended the use of tunneled catheters in situations requiring intensive access [12].

■ In 2009, the recommendations of the *European Society for Clinical Nutrition and Metabolism* indicated that for the purposes of domestic parenteral nutrition lasting more than three months, the choice between tunneled venous access and a TIVC should be made according to several factors: the patient's preference, the healthcare team's experience, and the frequency of use. Preference is given to the TIVC in the case of intermittent vascular access, and to tunneled catheters for continuous use (grade C) [13].

#### B – Analysis of the literature and rationale

On account of their underlying pathologies, patients fitted with a TIVC are especially exposed to infectious complications. The question to be answered is whether the choice of a TIVC contributes an advantage in terms of risk of infection, whatever the underlying pathological context, when compared with other intravenous access modalities, and in particular, for long-term treatments, normally defined as being longer than three months. Literature reviews dealing with more than 100 papers show that the frequency of infectious complications is always lower with a TIVC than with other types of venous catheter, whether they be used for a short or long duration, and

whether the frequency be expressed for 100 catheters, or for 100 catheter days [29, 65]. The first infection on a TIVC occurs later than on a CVC (88 days vs. 32.5 days) [66].

Several non-randomized trials have tried to compare the incidence of infectious complications observed with TIVCs, with the incidence observed with other types of long-term catheters, within the same population of patients. Although there is no adjustment for the number and type of use, and there is no indication of whether the complications were calculated for 1000 days of use or for 1000 days after implantation, the results are always in favor of the TIVC [33,45,59,66-68]. The value of 0.1 infection for 1000 catheter-days was found in one non-randomized prospective trial dealing with cancer patients with a TIVC for sequential use, and was compared with an infection incidence rate of 2.7 per 1000 catheter-days in cancer patients fitted with a tunneled CVC [45]. Finally, in the case of adults treated for a solid tumor, the rate of infection was 0.8 per 1000 catheter-days with TIVCs, as opposed to 2.54 with tunneled catheters [59]. More recent studies also emphasize this advantage in hematology, for cases of leukapheresis [36] or hemophilia [69,70].

In the case of bone marrow grafts in children, bacteremia occurs later and less frequently with a TIVC than with a tunneled CVC: 108.8 days vs. 52.3 days, and 1.45 bacteremia for 1000 catheter-days vs. 4.56 [32]. In a similar context, during the first 60 days following a bone marrow graft, *CONTER et al.* demonstrated the value of TIVCs, with 1.38 bacteremia per 1000 catheter-days as opposed to 2.69 with external CVCs [58].

However, for some authors the advantage in hematology, in terms of risk of infection, is counterbalanced by the risk of hemorrhagic complications (such as recess hematoma) following implantation. Indeed, in adult

leukemia patients, a randomized trial was stopped prematurely after five extensive hemorrhages observed as a consequence of the implantation of a TIVC [56].

In the field of parenteral nutrition, the incidence rate of infectious complications on TIVC is high, varying between  $\frac{1}{4}$  and 4 for 1000 catheter-days, and appears to be similar for TIVC and tunneled catheters [13,71,72].

In HIV seropositive patients, the French non-comparative prospective study carried out over six months and published by the Paris-North CCLIN found an identical infection incidence rate for TIVCs and tunneled catheters (3.81 vs. 3.39 for 1000 catheter-days) [44].

Thus, although the methodology of some studies may be questioned, in oncology and hematology there is concurring literature when it comes to the advantages of the TIVC, in terms of the risk of infection with respect to tunneled or non-tunneled CVCs. In other potential fields of application, as in the population of patients affected by cystic fibrosis, or for example in the case of repeated antibiotherapy treatments, there is no data comparing TIVCs with non-tunneled CVCs, despite the hindsight of many years of experience [73-75]. Finally, there is a lack of prospective data allowing the advantages of peripherally inserted central catheters (PICC) to be compared with TIVCs.

## 1-1-2 Recommendations

**R1** In terms of infectious risk, the TIVC is the preferred long-term (greater than 3 months) form of central venous access (**simple** agreement).

**R2** In oncology, the TIVC is the long-term form of central venous access to be preferred. However, is not recommended in hematology in situations involving hematopoietic stem cell (hsc) grafts or acute leukemia induction (**strong** agreement).

**R3** The TIVC can be used for long-term (greater than 3 months) central venous access for:

- the care of patients with cystic fibrosis, to facilitate the repeated use of a treatment,
- patients requiring discontinuous parenteral nutrition,
- therapeutic care of solid tumors in pediatrics (strong agreement).

## 1-2 Choice of the appropriate moment for insertion

### 1-2-1 Review of the literature

#### A – Existing recommendations

■ In 2000, in the reference document entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance*, the ANAES indicated that "no regulatory text, nor scientific data, imposes the systematic use of preoperative paraclinical examinations. The selective prescription of these examinations is based on data from the questionnaire, the clinical examination, the analysis of patient history, the type of anesthesia and the foreseen act. The key aim is to ensure the best possible safety of the patient who is to be operated on". In addition, infected or burnt areas, major coagulation disorders, septicemia, or a history of axillo-subclavian phlebitis are contra-indications for the implantation of a TIVC [3].

■ In 2001, the *Antiplatelet agent and perioperative period* expert conference of the French Society for Anesthesia - Critical Care (SFAR) indicated that, following a collegial discussion with the antiplatelet drug (antiaggregant) prescriber, the patient must be informed of the modalities and risks of modifying his/her treatment. It is recommended to use non-specific means to reduce perioperative bleeding, by choosing a surgical route allowing the best possible control of hemostasis, and through

early screening for an abnormal hemorrhagic syndrome requiring complementary surgical hemostasis. In a patient treated with an antiplatelet drug, although no level I or II evidence can be given, platelet transfusion is efficient in reducing or stopping postoperative bleeding. The taking of aspirin can be ceased for five days in the case of primary prevention, and should be maintained in all other cases, except when the patient has a high risk of thrombosis [76].

■ In 2002, the 2002-303 law of March 4<sup>th</sup>, relative to patients' rights and to the quality of the health system, indicates that the patient must be informed of his/her state of health or of the preventive actions which could be proposed, their usefulness, their possible urgency, their possible solutions, and the normally predictable, frequent or serious risks. This text is also relevant to healthcare consent: no medical act or treatment can be implemented without the free and informed consent of the patient, and this consent can be withdrawn at any time. When the patient is not in a condition allowing him/her to express his/her will, a designated trusted person or family member is consulted [77].

■ In 2008, the HAS drafted its clinical practice recommendations concerning the peri-operative management of AVK and heparin therapy. Some surgical operations or invasive acts leading to bleeding, which is occasional, of low intensity or easily controlled, can be carried out in patients treated for an AVK in the usual therapeutic range, i.e. the International Normalized Ratio (INR) between 2 and 3. However, in view of the need to puncture large vessels for the implantation of a TIVC, it is recommended to interrupt the AVK between three and five days before the act, and to replace them by heparin therapy [78].

## B – Analysis of the literature and rationale

Various studies have suggested that pediatric onco-hematology patients, for whom a TIVC had been placed during a period of post-induction aplasia, presented frequently with infectious complications. This was explained by the occurrence of a post-operative hematoma, and motivated the proposed implantation of a TIVC before commencing the chemotherapy [79,80]. It is normally accepted that the platelet count before implantation must be greater than 50000 and the INR less than 1.5, which in certain cases can be difficult to achieve [81]. In a retrospective study of 225 TIVCs, monitored for two years in pediatric onco-hematology and characterized by a 14.7% infection rate, a multivariate analysis showed that re-implantation was an independent risk factor for the occurrence of an early infection during the eight weeks following implantation ( $p=0.003$ ;  $OR=4.52$ ) and that thrombopenia at  $< 50000/mm^3$  was a factor associated only with the occurrence of a later infectious complication ( $p=0.005$ ;  $OR=4.24$ ) [82].

Concerning neutropenia, a retrospective study covering a three-year period, during which 39 patients with a malignant hemopathy and 14 patients with a solid tumor were monitored, revealed a higher rate of infectious complications which could be attributed to severe neutropenia [83]. An increase in risk of infection due to neutropenia had already been identified with tunneled catheters [84].

An uncontrolled septicemic or infectious episode is normally a temporary contraindication for the implantation of a TIVC, emphasizing that the presence of an active bacterial infection at the time of implantation must be considered in the light of a risk-benefit evaluation. SONOBE *et al.* described a TIVC infection, which occurred in a patient who had a pneumopathy at the time of implantation [85]. However, there is no study available of the

period of time to be observed between an infectious episode and the implantation of a TIVC. The infection history of CVCs can be a recurrence risk factor [86]. For TIVCs, in the case of withdrawal as a result of infection, no study has been found defining the ideal minimum delay to be observed before re-implantation, nor the authorized re-implantation site.

A history of phlebitis and partial or total thrombosis represents a contraindication for implantations recommending the use of a scanner or Doppler imagery to verify vessel permeability in the case of TIVC re-implantation or in patients with a mediastinal tumor [3,25].

Special mention should be made of bevacizumab (AVASTIN®), since a retrospective study carried out in 189 patients treated with bevacizumab, within 120 days following TIVC implantation, compared the mean delay between implantation and product perfusion in a group of 189 patients having presented with delayed healing (10.8 days) with the same mean delay in a group of 6 patients having no delay in healing (16.9 days) ( $p=0.01$ ). The authors concluded that the patients who received bevacizumab within ten days of TIVC implantation were, with statistical significance, at greater risk of non-healing of the operative wound [87]. More recently, in a small series of 57 oncology patients in whom a TIVC had been implanted during, or within the four weeks following, treatment with bevacizumab, no complications were observed [88].

On the other hand, on a series of 273 TIVC implanted in patients with metastatic breast cancer, 13 cases of wound dehiscence were observed. These delays in healing occurred when AVASTIN® had been administered within the 7 days following implantation of the device. This interval of not more than 7 days between TIVC implantation and the administration of AVASTIN® was observed for 150 TIVCs (13 wound dehiscences / 150 implantations = 8%) [89].

## 1-2-2 Recommendations

**R4** A TIVC may not be inserted until such time as the patient has been informed and has agreed to such a procedure (Regulatory).

**R5** Hemorrhagic complications must be anticipated in accordance with the recommendations made by the SFAR (French Society for Anesthesia – Critical Care), and the same rules must be applied to the management of antiplatelet agents and anticoagulants as to any other surgical intervention (**strong** agreement). At the time of insertion, the platelet count must be greater than 50 000/mm<sup>3</sup> and the INR must be less than 1.5 (**simple** agreement).

**R6** With onco-hematology, the insertion of a TIVC must be considered and carried out as early as possible, outside any period of induced neutropenia (less than 500 neutrophil granulocytes / mm<sup>3</sup>) (**strong** agreement).

**R7** An ongoing infection must be placed under risk-benefit evaluation and may require insertion to be delayed, until such time as an effective treatment has been applied in the case of an active bacterial infection (**strong** agreement).

**R8** Following removal of an infected TIVC, it is preferable to observe a minimum delay of 48 hours of effective treatment, before inserting a new TIVC at a different anatomical site (**simple** agreement).

**R9** As a consequence of the risk of failure to heal, it is advisable not to use bevacizumab (Avastin ®) for a period of 10 days following implantation (**strong** agreement).

## 1-3 Choice of device

### 1-3-1 Review of the literature

#### A – Existing regulations and recommendations

■ The law n° 94-43 of January 18<sup>th</sup>, 1994 relating to public health and social protection stipulates in article L5212-2 that the manufacturer and users of a device, as well as third parties aware of an incident or the risk of an incident arising from a device having led to, or which may lead to, the death or serious impairment of the health of a patient, a user or a third party, must without delay report this to the sanitary product safety agency (AFSSAPS).

The manufacturer of a device or his representative is required to inform the AFSSAPS of any withdrawal of this device from the market, for technical or medical reasons [90].

■ The NF S 94-370-1 standard of April 1994 determines the characteristics of implantable catheter chambers as well as the relevant test methods [19].

■ The NF EN ISO 13845 standard of February 2004 entitled *Medical devices – Quality Management Systems – Regulatory requirements* describes the requirements relative to the quality management system, wherein an organization must demonstrate its ability to regularly supply medical devices and services, compliant with customer requirements and the regulatory requirements applicable to medical devices and their associated services [91].

■ The recommendations of the SFAR and the CDC concerning the choice of short term CVCs normally recommend the use of devices made of Teflon, silicone or polyurethane, since these are less frequently associated with infectious complications than polyvinylchloride or polyethylene [92,93].

■ In 2001, the South-West CCLIN indicated in its Recommendations aimed at decreasing the infectious risk associated with implantable catheters, that there are two materials available: silicone and polyurethane. The authors argue in favor of polyurethane catheters: superior mechanical qualities, less frequent deformations, and smoother surfaces thus associated with a lower risk of thrombophlebitis [10].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* indicated that "*The constituent materials of the chamber are vary varied and include plastic, titanium, silicone, and polyurethane. The smallest diameter necessary for the foreseen therapeutic utilization shall be selected, in order to avoid the risk of thrombosis*" [14].

■ In 2010, in the chapter "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, recommendation R104 states that: "*Catheters made of polyurethane or fluoropolymers and stainless steel cannula devices are preferred [...] Antiseptic or antibiotic-impregnated catheters should not be used on a routine basis*" [94].

## **B – Analysis of the literature and rationale**

Contrary to the case of non-tunneled CVCs, no scientific study has been found, which was designed to compare the risk of infection associated with various TIVCs, as a function of their constituent materials. Silicone or polyurethane catheters are considered to be less thrombogenic [95]. Theoretically, there could be an advantage in preferring the use of a polyurethane catheter, since for an identical external diameter, the internal diameter of polyurethane catheters is greater, which theoretically reduces the risk of thrombosis. Furthermore, the ratio between the size of the catheter and the chosen vein can be a factor favoring thrombosis [96]. In a prospective

randomized trial comparing the implantation, via the subclavian route, of catheters of the same internal diameter made from silicone and polyurethane, there was no difference in terms of infectious complications. However, there was a difference in terms of breakage, to the advantage of silicone, even though silicone catheters have a significantly greater external diameter [97].

So-called "low profile" small-thickness TIVCs are preferred by some authors as a consequence of the reduced risk of extravasation. However their usefulness in terms of the prevention of infectious risk has not been studied [62]; furthermore, in certain positions they could be less stable. Suitable adaptation of the chamber size to the morphological characteristics of the patient and the chosen insertion site could prevent the occurrence of an infectious complication associated with the difficulties in using a TIVC of poorly adapted size.

The advantage of multi-lumen TIVCs, which are rarely used, has not been studied in terms of infectious risk.

Moreover, the presence of a valve would allow nursing time to be gained during blood sampling [98,99] and would be associated with a lower rate of thrombotic complications [42,63]. In fact, there are two types of TIVC fitted with a valve (*drawing in the appendix*):

- a model in which a valve is placed inside the chamber, next to the proximal part of the catheter [98,99],
- a model in which the catheter is equipped with a valve at its distal end (so-called GROSHONG® catheter).

Five studies have attempted to analyze the usefulness of these valve-equipped models, when compared to those without a valve, in terms of infectious complications. Randomized studies, shown in Table II, did not allow the theoretical superiority of catheters with a valve, with respect to those without a valve, to be shown in terms of a decrease in infectious risk

[98-100]. Nevertheless, in a recent retrospective study dealing with 1348 TIVC, the absence of a valve was identified as an independent infectious risk factor (when compared to a TIVC with a GROSHONG® type of valve) (OR=1.68; CI 95%: 1.43-1.98; p<0.001) [42]. Finally, in a retrospective analysis of complications which occurred over a period of 17 months for 350 GROSHONG® type TIVCs implanted in the superior vena cava, the authors concluded that these catheters could be used, as a result of their low complication rate (three early infections of the **recess** and 12 bacteremia) [63].

At present, there is no TIVC on the market, which is impregnated with an antimicrobial agent. Impregnated CVCs have been tested and evaluated, mainly for insertion periods of less than 30 days, which does not correspond to the use foreseen for TIVCs. In addition, the American recommendations are to make use of these devices only as a last resort, since their rate of infection remains high, despite the application of other recommended measures [101,102]. In the case of long term catheters used in chemotherapy or parenteral nutrition, a recent review of the literature concludes that there is no argument in favor of the effectiveness of these catheters [103]. The risk of selecting bacterial resistances in patients, who already have multiple risk factors for infection and/or multi-drug resistant bacteria colonization, could limit the theoretical advantages of these products.

### 1-3-2 Recommendations

**R10** The device must have a CE marking and correspond to the ISO 13485 standard (Regulatory), and the catheter may indifferently be made of polyurethane or silicone. The size of the implantable chamber is chosen as a function of the corpulence of the patient, and the diameter of the catheter must be adapted to the catheterized vein. There is no formal proof of a reduced infectious risk with TIVCs fitted with a valve (**strong** agreement).

## 1-4 Choice of insertion site

### 1-4-1 Review of the literature

#### A – Existing regulations and recommendations

■ In 2000, in its document entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance* the ANAES points out that the access for percutaneous technique are:

- the subclavian vein: in addition, it is recommended to puncture the subclavian vein outside the costoclavicular 'pliers';
- the internal jugular vein: this requires the patient's head to be in hyperextension with cervical rotation. This position may be poorly tolerated if the puncture point is situated high up in the neck. Preference should be given to a right-hand percutaneous approach of the jugular vein, for anatomical reasons. This is not less comfortable than the subclavian approach.
- the external jugular vein: this is not indicated as a common practice, as a result of the high risk of thrombosis;
- the basilic vein: there is little experience with this approach.

The exclusion criteria are irradiated areas, skin metastases, and areas of burnt skin [3].

■ In 2009, the *Queensland Health – Centre for Healthcare related infection surveillance and prevention* points out in its recommendations that the choice of implantation site must take into account anatomical criteria, the risk of infectious and mechanical complications, and any history of vascular catheterism. The selected anatomical area must ensure stability of the chamber, without compromising the patient's mobility, nor creating a pressure point or possible area of interaction with the patient's clothes. The skin thickness above the chamber must range between 0.5 and 2 cm. Venous access must be the same as for a tunneled catheter (subclavian, internal jugular, external jugular, basilic or brachial vein). The distal end

of the catheter must be positioned at the junction between the superior vena cava and the atrium [14].

■ In 2009, the *European Society for Clinical Nutrition and Metabolism* also emphasized in its recommendations that the choice of vein used for access depends on a number of factors, including not only the experience of the operator and the professionals responsible for the patient's care, but also the risk of complications, thus underlining the greater frequency of malplacement in the case of implantation on the left side, and the increased risk of infection in the case of the femoral implantation of a central catheter for parenteral nutrition [13].

■ In 2010, in the chapter "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, although it does not deal specifically with the context of TIVC, recommendation R106 recalls that "a catheter must not be inserted in the vicinity of weeping infectious skin lesions, or into a limb on which lymph node dissection or radiotherapy has been carried out, or on which a malignant tumor has been diagnosed, or with an arterial venous fistula, or next to a joint, or with an orthopedic prosthesis or into a paralyzed limb" [94].

**Table II** – Studies comparing the usefulness of TIVC with and without valves, in terms of the frequency of complications.

First author [Ref.]	Year of publication	Type of study	Number of monitored patients	Complications
BIFFI [100]	2001	Prospective randomized with control: no valve vs. GROSHONG®	302 cancer patients, 15 months follow-up	Delayed complications 10.7% vs. 17.1%, NS
CHANG [46]	2003	Retrospective and descriptive: no valve vs. GROSHONG®	572 cancer patients	Infections 5.4% vs. 5.8%, NS
CARLO [98]	2004	Prospective randomized with control: no valve vs. valve	73 cancer patients, follow-up at 80 days	Infections 2.8% vs. 2.7%, NS
LAMONT [99]	2003	Prospective randomized with control: no valve vs. valve	54 cancer patients, follow-up at 80 days	Infectious and thrombotic complications, NS

NS: Non significant

■ Finally, in 2011, in *Guidelines for the Prevention of Intravascular Catheter-Related Infections*, the *Centers for Disease Control and Prevention* (CDC) indicate that in the case of non tunneled central venous catheters used in adults, the subclavian vein should be preferred to the jugular or femoral vein, in order to minimize the risk of infection. There are no recommendations for tunneled CVCs (unresolved) [102].

## B – Analysis of the literature and rationale

The most frequently used insertion sites are the internal jugular, subclavian, and more rarely cephalic veins, the external jugular, brachial and femoral veins. A small number of studies have measured the frequency of infectious complications as a function of the venous access site and/or the chosen side of the body. In oncology, a non-randomized prospective monocentric study, comparing the complications arising in the case of subclavian (n=617) and internal jugular (n=614) access, concluded in favor of the internal jugular approach, although it did not find any

difference in the rate of infectious complications. For a mean duration of 363 days for subclavian, and 244 days for jugular implantation, the frequencies of infection were respectively 2% and 1.8%. However, in this study the incidence of thrombosis and catheter dysfunction was abnormally high in the "subclavian" group [104]. In an uncontrolled study in oncology, combining surgical and radiological implantations (359 external jugular, 179 subclavian and 15 internal jugular), the frequency of complications was higher for left subclavian implantations, and when the distal end was positioned in the upper third of the superior vena cava. However, this paper provides very little data related to the infectious complications [40]. With the subclavian approach, two authors reported a greater rate of complications for TIVC implanted on the left side of the patient. When the distal end of the catheter is at the junction between the right atrium and the superior vena cava, it is more difficult to position it on the left than on the right side, and these two studies show that the most significant factor for a risk of complication is incorrect positioning of the distal end of the catheter [40, 105]. It is thus possible that the "left side" risk is only one of several factors, including the main risk related to the position of the distal end of the catheter. In the case of a breast tumor, the radiotherapy ballistic data indicate a preference for implantation on the side opposite to that of the cancer [106]. However, a paper published in 2003 reported that in this context no greater number of lymphedemas were found when the vascular approach was ipsilateral to the lesion [107].

In a prospective series of radiological implantations in the right internal jugular vein of 28 TIVC, with a median follow-up of 208 days in pediatric oncology, 14% of TIVC became infected, with an incidence rate of 0.4 infections per 1000 catheter-days [108]. The retrospective analysis of complications, depending on whether the jugular access was at an upper (21 patients, with a mean follow-up of 284 days) or a lower (163 patients with a mean follow-up of 431 days) position on the

vein, did not reveal any difference in terms of infectious complications: respectively 2 and 11 infections, and concluded that the upper jugular access is a possible alternative in cases where difficulties are encountered with the classical access point [109].

Concerning the right external jugular access, WOLOSKEK *et al.* found an incidence rate of 0.23 infections per 1000 catheter days in a prospective study involving 500 oncology patients [53]. A non-randomized prospective study and a randomized trial conclude that percutaneous subclavian access has a low risk and a high rate of success, and that whenever this access is impossible, the external jugular vein can be a suitable alternative [110,111]. The systematic use of an ipsilateral external approach following two failures at puncturing the subclavian vein allowed the complication rates associated with multiple punctures to be reduced [110]. For some authors, the external jugular approach is the preferred method in pediatrics [112]. However, the authors do not always accurately address the issue of infectious or thrombotic complications. The thrombogenic risk with the external jugular route does not seem to be higher, although this form of access is unaesthetic for the patient [113-115].

The brachial or basilic veins have an advantage in terms of accessibility and discretion, but are accompanied by a higher rate of thrombosis when compared with a classical implantation (4.8% vs. 11.4%) [116-119]. The implantation of a chamber on the arm is an interesting alternative for ENT patients and is accompanied by a low rate of thrombosis, equal to 0.13, as opposed to 0.37 per 1000 catheter days in the case of pectoral implantation [120]. In patients with colorectal cancer, the incidence of infections was 0.2 and the rate of thrombosis was 0.3 per 1000 catheter days [121].

A small number of studies have analyzed the infectious risk associated with the insertion of a TIVC in the inferior vena cava system. In the literature, although the choice of the

femoral vein is generally associated with a higher rate of thrombosis and infection, there is certainly a selection bias towards patients who are frequently more seriously affected and have no other possible venous access. Just one randomized prospective study, comparing the femoral and subclavian approaches and finding a major risk of infectious complications (RR=3.04; 95% CI 0.63 to 14.82), was in favor of the subclavian approach [122].

A femoral implantation technique carried out in 86 patients having undergone a bilateral mastectomy has been described. The chamber is positioned at the level of the anterior iliac crest or the anterior abdominal wall. The authors concluded that it is possible to use the femoral access in this context, with three infections and three occlusions recorded at one-year follow-up [123]. In 20 patients with cancer, and having a TIVC implanted using the femoral approach because subclavian access was not possible, the incidence of complications was 0.69 infections and 0.23 thromboses per 1000 days of use, after a mean prospective follow-up of 215 days [54]. The positioning of the distal end at the level of the junction between the right atrium and the inferior vena cava limits the risk of thrombosis [124].

Other approaches (intercostal vein, in particular the epigastric vein, or basilic vein) have been described as an alternative approach when the classical approaches are not accessible [125,126].

### 1-4-2 Recommendations

**R11** Venous access in the superior vena cava system must be preferred, except in cases where the superior vena cava is compressed by a mediastinal tumor (**strong** agreement).

**R12** Under pre-operative conditions, whenever there is clinical suspicion of an obstruction, it is advisable to check the permeability of the selected vein (**strong** agreement). Insertion into the inferior vena cava system must be a second option only, since it increases the infectious and thrombotic risk (**strong** agreement).

**R13** In the case of breast cancer, although it is recommended to insert the TIVC on the side opposite to the tumor (**strong** agreement), there is no formal contraindication to the insertion of a TIVC on the ipsilateral side (**simple** agreement). In the case of a synchronous bilateral breast tumor, the decision to insert into the superior or inferior vena cava system shall take into account the size of the tumor, the size of its base, and the treatment plan. Asynchronous bilateral breast cancer is not an indication for TIVC insertion into the inferior vena cava (**strong** agreement).

**R14** The device shall not be inserted:

- in a zone which has been, or will soon be irradiated,
- in the vicinity of cutaneous metastases,
- close to chronic, uncontrolled skin lesions,
- close to an infected skin lesion (**strong** agreement).

**R15** The patient's condition (aphysema, dehydration, agitation, obesity, malnutrition) can influence the choice of venous route, thereby modifying the standard technique (**strong** agreement).

**R16** The choice of venous route shall take the operator's experience into account (**simple** agreement).

**R17** Following a confirmed infection of the implantation recess or skin tunnel, it is preferable, whenever possible, to use the contralateral side for reinsertion of a TIVC (**strong** agreement).

## 1-5 Skin preparation and conditions of insertion

### 1-5-1 Review of the literature

#### A – Existing regulations and recommendations

■ In 2000, in its document entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance*, the ANAES points out that *"the preparation of only one surgical dressing is to be preferred, to allow straightforward switching from one technique to another if the foreseen approach is found to be impossible to use"*. The document refers to Recommendation 82 of the CTIN, i.e. *"the installation of a central venous catheter is carried out by an operator trained in insertion, under conditions of surgical asepsis"*. This must be performed in the operating room or in a room specifically reserved for this purpose [3].

■ In 2004, in the *Pre-operative management of infectious risk* consensus conference, the SF2H pointed out that:

- Concerning hair removal, *"It is recommended to prefer not to remove hair, under the condition that the per- and post-operative requirements are not affected. If the local conditions justify hair removal, it is recommended to prefer shearing or chemical hair removal. It is strongly recommended not to use mechanical shaving the day before the intervention"*.
- Concerning personal hygiene and preoperative washing, *"It is strongly recommended to take a pre-operative shower using an antiseptic foam solution. It is recommended to remove jewelry, wedding rings, piercings, nail varnish, etc., before any intervention [...]". "Washing prior to the operation is carried out in the hospital ward or at the patients home under medical prescription, in the case of ambulatory surgery"*.

- Concerning local skin preparation, *"It is strongly recommended to apply detergent cleaning using an antiseptic foam solution, followed by broad disinfection of the surgical site. It is recommended to prefer an alcohol-based antiseptic"*.
- Concerning nasal screening for *Staphylococcus aureus* prior to a surgical intervention, *"It is not recommended to systematically proceed with screening to search for the carriage of methicillin sensitive Staphylococcus aureus, with the view to its pre-operative eradication, whatever the type of surgery"* [127].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* recommended installing TIVCs in premises in which aseptic conditions can be maintained (interventional radiology or operating room) and where the patient can be monitored (ECG, oximetry). Maximum barrier precautions must be taken: surgical garments for the operators and persons entering the operating area, surgical cap covering the patient's hair and the use of a large sterile drapes [14].

■ Also in 2009, the SF2H indicated in its recommendations concerning the *Prevention of cross-contamination*: *"R81 – It is highly recommended to use individualized decontamination in patients carrying MRSA with a high risk of infection (in particular for chronic dialysis patients, long duration central catheter wearers, and liver graft recipients)"* [128].

■ In 2010, In the chapter entitled "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, the following recommendations are given: *"The placement of a TIVC is to be carried out in the operating room (R109). Insertion is to be carried out by a trained operator wearing surgical garments (cap, surgical mask, sterile gown), with the help, in the case of TIVC, of an assistant wearing a clean gown, a head cap and a*

surgical facemask. Before placement, the operator carries out a surgical handrub and then puts on a pair of sterile gloves (R110). Skin preparation of the insertion site is performed in four steps: cleaning (antiseptic soap), rinsing (with sterile water), drying (with sterile pads) and antisepsis (with an alcohol-based antiseptic). Sterile drapes that are much larger than the catheterization area, are placed after the antiseptic has naturally dried (R111) [94].

■ In 2011, in their recommendations entitled *Guidelines for the Prevention of Intravascular Catheter-related Infections*, the CDC recommends the highest levels of precaution: sterile cap, mask, gown and gloves, as well as skin preparation using chlorhexidine with more than 0.5% alcohol (there is no comparison between alcoholic chlorhexidine and PVPI) (Cat. IB) [102].

## **B – Analysis of the literature and rationale**

The implantation of a TIVC is a surgical act (CCAM code: EBLA003) calling for classical preventive measures in this context. In a review of papers published until the year 2007, VESCIA *et al.* emphasize the importance of maximum aseptic precautions during insertion, making use of a sterile mask, cap, as well as gloves and large sterile drapes [20]. The results of the targeted audit, held by the HAS in France in 2006, have shown that 100% of TIVC implantations were carried out in a dedicated room, using surgical aseptic precautions [129].

In an observational study, the use of a simulator training program led to a statistically significant reduction in the risk of post-operative infectious complications, resulting from the installation of a TIVC in an intensive care unit (0.50 vs. 3.2 infections for 1000 catheter-days) [130]. Similarly, TIVC-related infections are less frequent when the implantation is carried out by trained professionals [2,131]. With the view to improving patients' safety before a surgical act

or the implantation of a CVC or other vascular device, the HAS proposed the implementation of check-lists, which make it possible to simplify good practice observance, and include elements of the procedures related to the control of infectious risk.

The eight-day, one month and three month monitoring of post-operative skin colonization in 41 patients showed that there is a correlation between skin flora, the occurrence of a catheter-related bacteremia, and the early appearance of infections. Colonization in the vicinity of the scar reaches a maximum within the first eight days following implantation [28]. Skin preparation of the insertion site, aimed at reducing the local skin flora, should thus observe the same rules as those recommended for any surgical act. Current data found in the literature does not allow a distinction to be made between the two major types of alcohol solution antiseptics available in France. Whatever the antiseptic retained, it should be used in accordance with the manufacturer's recommendations (AMM).

A patient who is a nasal carrier of *Staphylococcus aureus* is at a greater risk of developing a bacteremia than a non-carrier patient; a very small number of studies have thus concluded that nasal decolonization can be helpful in reducing the infectious risk of central venous catheters in hemodialysis [132,133]. In critical care, the impact of MRSA carrier decontamination on the rate of infection is less clear [134-136]. No study dealing with the usefulness of individual decontamination, through topical nasal treatment and antiseptic cleansing, has been carried out with the view to analyzing the decrease in TIVC-related infections.

## 1-5-2 Recommendations

**R18** The insertion of a TIVC is a programmed surgical act, carried out by a trained or supervised operator. The use of a rigorous technique for TIVC insertion must be of the same standard as for any other surgical intervention. Whatever the technique used, the insertion of a TIVC must be carried out in a dust-controlled room, under surgically aseptic conditions. The use of a check-list during TIVC insertion is helpful, to ensure that infection prevention measures are observed (**strong** agreement).

**R19** Surgical site preparation prior to TIVC insertion must observe the recommendations applicable to any other surgical procedure. This involves the patient's personal hygiene (shower with shampoo, or full cleansing with an antiseptic foam solution), chemical or clipper hair removal at the insertion site (whenever necessary) and preparation of the surgical site using a hydro-alcoholic antiseptic, whilst observing the required antiseptic durations (detergent cleaning, rinsing, drying, antiseptic application) close to the incision (**strong** agreement).

**R20** In ambulatory surgery, the outpatient organization must allow the recommendations applicable to the preparation of the surgical site to be respected (**strong** agreement).

**R21** It is not recommended to systematically use nasal screening for *Staphylococcus aureus*, for the purposes of individualized decontamination, prior to TIVC insertion (**simple** agreement).

## 1-6 Surgical antibioprophylactic treatment

### 1-6-1 Review of the literature

#### A – Existing regulations and recommendations

Unanimous recommendations have been expressed by learned societies and experts.

■ In France, the recommendations given in the 2010 publication *Surveillance and Prevention of healthcare-associated infections* state that the use of antibioprophylaxis during the implantation of a CVC or a TIVC is not recommended [94].

■ The same opinion is expressed by the CDC, the *British Committee for Standards in Haematology* [12,102], as well as the American societies for hospital hygiene (SHEA) and infectious diseases (IDSA). The latter strongly recommend (maximum evidence level, A1) not to use antibioprophylaxis during the insertion or use of central catheters [101].

■ In the United Kingdom, the recommendations in hematology allow for the possibility of using antibiotics, whenever there is a simultaneous procedure for the removal of a catheter for an infection, and the implantation of another central line, or if a patient requiring a central line presents with a contralateral thoracic skin infection. In both cases, these recommendations appear to be intended more for the curative antibiotherapy of an evolving infection, than for antibioprophylaxis [12].

■ In 2009, the *Queensland Health – Centre for Healthcare related infection surveillance and prevention* pointed out that the arguments in favor of prescribing parenteral antibioprophylaxis for the implantation of a TIVC, with the aim of preventing colonization or bacteremia, are limited and that there is no consensus in the literature. Thus, the need for antibioprophylaxis cannot be based simply on local factors such as a high incidence rate of infections [14].

#### B – Analysis of the literature and rationale

Surgical antibioprophylaxis involves the administration of an antibiotic, to ensure that it has a strong concentration at the surgical site at the time of incision. This is a short duration treatment, in general involving only one administration, strictly designed for the surgical act and directed towards an uninfected surgical

site. It is recalled that one of the elements weighed in the balance of the decision to implement a preventive treatment is the frequency of occurrence of the event in the absence of treatment. By analogy with the surgical context, the aim of antibioprophylaxis would be to reduce the risk of infection through the use of a fast antibiotic on the surgical site, at the time of insertion. However, since the infectious risk associated with TIVCs is lower than that of short duration or tunneled CVCs, the benefit to be expected from such an intervention can only be less than that achieved for the latter types of central line. This is relevant to both the risk-benefit ratio and the cost-efficiency ratio.

The literature dealing with the prescription of an antibioprophylaxis for the implantation of a TIVC is extremely rare, with the exception of a small number of observational studies [137]. Although several authors state that they have used an antibioprophylaxis, no study could be found evaluating the usefulness of an antibioprophylaxis at the time of TIVC insertion [100,138,139]. A recent monocentric randomized study including 432 patients, with a 30-day post-operative follow-up, found no difference in terms of the frequency of infectious complications in two groups (2.5% in the group with 1 g of cefazolin vs. 3% in the placebo group) [140]. A small number of studies have evaluated this concept during the implantation of other types of central line, and are evaluated in the COCHRANE review of 2005 [141]. The four papers analyzed in this review, as well as a trial which was not included, do not find any benefit in the use of antibioprophylaxis [142-142].

Concerning the more long term prescription of antibiotics, a retrospective review of the medical records of patients having received cefuroxime for thoracic surgery, either for classical surgical prophylaxis in three doses, or until removal of the catheter, did not find any difference in terms of the rate of colonization of the withdrawn catheters [147]. Two studies in neonatology have shown a reduction in the

frequency of catheter infections, with no change in mortality, through the addition of vancomycin in the parenteral nutrition. Moreover, the authors of these two studies thus recommend not to use vancomycin, because of the risk of resistance selection. These are old studies, which were not followed up and dealt with short duration catheters in a specific population [148,149].

The question of extrapolating these results to the implantation of pacemakers has not been completely resolved. Both procedures have in common that they require surgical implantation and central venous access. However, pacemakers are implanted for longer periods of time and are accompanied by the permanent implantation of electrodes, a procedure which is thus more similar to clean surgery with the implantation of prosthetic material. Theoretically, infectious complications of a TIVC are similar to those of a CVC, with a significant proportion of the infectious risk resulting from subsequent manipulations. Antibioprophylaxis during implantation could prevent early infections during implantation only, but not delayed infections, which are very often acquired intralumenally during manipulations. Thus, recent data concerning the usefulness of antibioprophylaxis for the implantation of a pacemaker cannot be extrapolated to the implantation of a TIVC.

There does not appear to be any reason to propose a different approach for immunosuppressed patients and/or MRSA carriers. In particular, since the greater risk of infection in immunosuppressed patients is most probably related to the frequency of venous access manipulations and to the extent of the patient's neutropenia, the impact of antibioprophylaxis during implantation would at best be rather limited. The carriage of a particular type of microorganism does not modify this choice. Indeed, it would in any case be responsible for only some of all possible TIVC infections, for which surgical antibioprophylaxis would have only a very limited interest.

A similar reasoning can be applied to the re-implantation of a TIVC following an obstruction. If the reason for removal is related to a mechanical problem, an antibioprophylaxis will not be helpful. If there is an infectious reason to remove the device, a curative antibiotherapy will already have been implemented. If a new TIVC must be implanted following the infection of a TIVC (or of a previous central venous catheter), several situations can arise. If the problem is one of a local catheter infection, with no associated bacteremia, the re-implantation of a TIVC at a distant site is not likely to represent a risk. If the blood cultures have not been returned, and the implantation of the TIVC must be performed rapidly, it is preferable for parenteral curative antibiotherapy to be administered before implantation. If it is a case of bacteremia on a TIVC, the risk in the case of early re-implantation is one of a bacterial graft onto the new TIVC. It is thus preferable for an active curative antibiotherapy to have been implemented at least 48 hours prior to TIVC re-insertion. This delay is necessary as a consequence of the sometimes slow bactericidal kinetics of some molecules on certain bacteria. In a retrospective study dealing with 225 TIVC in pediatric oncology, the multivariate analysis showed that re-implantation is a risk factor, independently of the occurrence of an early infection (OR=4.52; p=0.03) [82].

### 1-6-2 Recommendations

**R22** It is recommended not to use surgical antibioprophylaxis at the time of insertion, even in the case of a history of TIVC infection or known carriage of MRSA (methicillin resistant *Staphylococcus aureus*) (**strong** agreement), regardless of the immune status of the adult (**simple** agreement) or child (**strong** agreement) patient.

**R23** Following the removal of a catheter, for reasons of a suspected infection, the early re-insertion of a TIVC, if necessary, must be accompanied by an effective curative antibiotherapy (**strong** agreement).

## 1-7 Insertion techniques

### 1-7-1 Review of the literature

#### A – Existing regulations and recommendations

■ The decree n° 93-345 of March 15<sup>th</sup>, 1993 recommends that during the implantation of a TIVC, the operator should verify the presence of blood reflux and carry out the first injection [150].

■ The circular letter DH/EM 1 96-2517 of May 24<sup>th</sup>, 1996 relative to the safety of medical devices states: in the utilization of totally implantable catheters, breakage of the secondary catheter resulting from it being clamped inside the costoclavicular space can occur with polyurethane catheters as well as those made of silicone, and recommends puncturing the subclavian vein outside the costoclavicular 'pliers', through the use of a lateral approach. In addition, the operator must ensure that the chamber is correctly connected to the catheter [151].

■ In its document drafted in 2000, entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance* the ANAES points out that: "There are two implantation techniques: percutaneous puncture and surgical denudation. The former is the more frequently used, since it is straightforward to apply and can be performed under local anesthetic (subclavian vein, internal or external jugular veins, basilic vein). Denudation requires an incision. It is reserved either for cases in which the percutaneous approach has failed, or to gain access to a greater range of veins (internal or external jugular vein, cephalic vein at the level of the deltopectoral groove)". This benchmark also notes the specificities of TIVC implantation:

- The area of incision must not be opposite the chamber,
- The catheter's position must be verified using an x-ray intensifier during the intervention, before connection to the chamber,

- The operator verifies the blood reflux and flushes, to ensure that the site is permeable [3].

■ In 2009, the European Society for Clinical Nutrition and Metabolism recommended, whatever the type of central venous catheter, that insertion be carried out using ultrasound guidance, and did not recommend the use of surgical technique for reasons of cost, efficacy and risk of infection (Grade A) [13].

■ In 2009, the *Queensland Health - Centre for Healthcare infection surveillance and prevention* recommended that the cavity created for the chamber be as small as possible. The chamber is sutured to the fascia. The use of lidocaine with adrenaline can reduce subcutaneous bleeding [14].

## **B – Analysis of the literature and rationale**

There are two types of insertion technique, surgical access by denudation and percutaneous puncture, often carried out with x-ray imagery. A retrospective study dealing with 326 surgically implanted TIVCs, monitored for an average period of 348 days, concluded that this is a beneficial technique in terms of safety, cost and speed [152]. There are three observational series involving x-ray imagery insertion (one in a child using the internal jugular vein [108], another in an adult using the subclavian vein [153], and the last in an adult using the jugular vein [154]) with, respectively, 0.4, 0.04 and 0.15 infections per 1000 catheter-days. A comparison between 100 brachial TIVC inserted using x-ray imagery and 100 surgically inserted subclavian TIVCs shows that in the case of brachial access the success rate is greater, the esthetic results are better, and the cost is higher [119,124].

In the case of percutaneous puncture, several authors recommend using ultrasound guidance to locate the jugular vein or guide the puncture. This technique allows the number of failed attempts at puncturing the vein, which are considered to lead to thrombosis, to be

reduced, the mean implantation time to be reduced, and the rate of immediate complications to be lowered [155-157]. However, a retrospective analysis of 1070 TIVC, implanted percutaneously in the subclavian vein for the purposes of chemotherapy, identified post-operative complications in 8% of patients, of which 22 (2.1%) involved infections of the cavity and 9 (0.8%) involved thrombosis, and concluded that percutaneous insertion of the TIVC without ultrasound guidance does not increase the risk of complications [158]. Some authors recommend access by the supraclavian route [159] or lateral subclavian access using ultrasound guidance [160-162]. In a randomized three-armed study carried out in 403 patients affected by solid tumors and monitored for 15 months: percutaneous access to the internal jugular vein: one infection; surgical approach using the cephalic vein: one infection; subclavian vein using ultrasound guidance: three infections. The conclusions were that ultrasound guidance reduces the number of insertion failures but not the number of infections, which remains very low [162]. In a series of more than 3950 implantations of a central line by the same team, of which half were TIVCs, the introduction of ultrasound guidance was associated with an improvement in patient comfort and a significant reduction in insertion time [163]. Finally, a recent meta-analysis carried out using five publications and concerning the implantation of an internal jugular CVR in children showed the usefulness of ultrasound guidance for novice operators [164].

In order to evaluate the usefulness of implanting a subpectoral chamber rather than using subcutaneous access, in order to prevent skin necrosis, ROUZROKH *et al.* monitored post-operative complications in two successive groups of patients in whom the TIVC was placed in the internal jugular vein under general anesthetic. These authors concluded that skin complications occurred at a lower frequency when the chamber was implanted in a cavity under the pectoral fascia.

In terms of infectious complications, 13 infections and 2 hematomas were observed in the first group of 182 patients, as opposed to 8 infections in the second group of 342 patients [165].

### 1-7-2 Recommendations

**R24** In terms of infectious complications, there is no difference between denudation and percutaneous techniques (**simple** agreement).

**R25** Whatever venous access is used, TIVC insertion can be facilitated by means of ultrasound guidance (**strong** agreement); in the case of a percutaneous jugular puncture, insertion should be carried out under ultrasound guidance (**simple** agreement).

**R26** The incision site must not be positioned opposite to the inserted device. A sterile dressing is used to cover the surgical site (**strong** agreement).

**R27** A chest x-ray must be taken after insertion, in order to verify that the distal end of the catheter is correctly positioned at the junction between the right atrium and the superior vena cava (**strong** agreement).

**R28** The first puncture of the TIVC is a medical act, which is performed intraoperatively during reflux verification, immediately after insertion (Regulatory).

**R29** With insertion following reflux verification, the Huber Needle is left in place by the operator only when it is intended to use the TIVC within a period of 24 hours (**strong** agreement).

## 1-8 Removal at the end of treatment

The removal of a TIVC can take place in two different contexts: at the end of treatment, for which permanent central venous access is no longer justified, i.e. removal at the end of treatment, or in an urgent (or semi-urgent) situation in the case of a complication, an infection in particular. This section does not

deal with removal in the latter case, and does not define the steps to be taken in this context.

### 1-8-1 Review of the literature

#### A – Existing regulations and recommendations

■ In its document drafted in 2000, entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance*, the ANAES defines removal at the end of treatment in the following terms: "If the implanted catheter chamber must be implanted by a specialized team under conditions of surgical asepsis, the same requirement applies to the removal of this TIVC. The patient must be informed of the reasons for its removal" [3].

■ In 2007, the *British Committee for Standards in Haematology* pointed out that the TIVC must be withdrawn in an operating room or equivalent [12].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* emphasized in its recommendations that removal must be carried out under the same environmental conditions as the implantation and that a sterile dressing must then be placed on the site [14].

■ In 2010, in the chapter "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, it is pointed out in recommendation R99 that "[...] The IVD should be removed once it is no longer indispensable" [94].

#### B – Analysis of the literature and rationale

No maximum duration of TIVC use has been recommended to date. A recent French study showed that removal at the end of treatment represented one third of the indications for withdrawal, and that in 50% of cases an infectious complication was the reason for TIVC removal, even though

microbiological criteria for infection could be found in only 40% of cases [166]. In a less recent paper, only 15% to 20% of TIVCs withdrawn because of a suspected infection were really infected, and it was thus concluded that in the vast majority of cases TIVC removal was unnecessary and costly [167]. In order to avoid an abusive and *in fine* costly, and for the patient unpleasant intervention, the indication for TIVC withdrawal for reasons of infection must be based on the presence of clinical and biological infection criteria [21].

There are no studies in the literature allowing the ideal moment to be defined for TIVC removal at the end of treatment, and various practices are encountered with respect to this criterion. According to a national survey carried out in 1997 by the Interdisciplinary Conference on complementary healthcare in onco-hematology, 24% of surveyed doctors advocated systematic withdrawal of the device whenever the foreseeable length of treatment suspension exceeds six months [168]. In pediatric hematology, the difficulties encountered with removal and arising from adhesion of the catheter to the wall of the vein have justified the extended implantation of TIVCs for more than twenty months [169,170].

However, an infectious complication can occur independently of any utilization of the TIVC. In a historical French cohort involving 219 TIVCs, the mean period during which the TIVC was kept in place, after its period of use, was  $10 \pm 15$  months, with a total occurrence of three infections (representing 9% of the total number of infections diagnosed in the cohort), at least two weeks after the last utilization of the TIVC [34]. More broadly, during the follow-up of 550 oncology patients, with a mean

duration of 22.5 months, 16% of complications appeared after the end of chemotherapy, within a median delay of 182 days (with no further details on the nature of these complications) [40]. This shows that keeping the TIVC in place, when it has no further therapeutic use, does not remove the residual risk of complications.

## 1-8-2 Recommendations

**R30** Removal of the TIVC is a programmed surgical act which must be carried out under the same conditions as insertion (surgically aseptic conditions in a dust-controlled room) (**strong** agreement).

**R31** Removal of the TIVC at the end of treatment cannot be planned without the consensual agreement of the various professionals taking care of the patient (**strong** agreement), and must be considered whenever the foreseeable duration of treatment interruption exceeds a period of six months (**simple** agreement).

**R32** The TIVC can be kept in place if sequential venous treatments are used (**strong** agreement), or in the absence of a peripheral venous network, when frequent blood samples are necessary (**simple** agreement).



# Use of the totally implantable vascular catheter

## 2-1 Choice of perfusion equipment and technical details

### 2-1-1 Review of the literature

#### A – Existing regulations and recommendations

- Law n° 94-43 of January 18<sup>th</sup>, 1994 relating to public health and social protection, article L5212-2 of the public health code. Chapter II of book II relating to medical devices: *"The manufacturer and the users of a device or third parties who are aware of an incident or a risk possibly arising from a device having led to or which may lead to death or serious impairment of the health of a patient, a user or a third party, must without delay report this incident or risk to the administrative authority"* [90].
- The decree n° 94-352 of May 4<sup>th</sup>, 1994 relative to the protection of workers against the risks resulting from their exposure to biological agents holds the employer responsible for the safety of his/her personnel with respect to the biological risk. It is compulsory for the hospital director to evaluate the risks of biological exposure in order to implement the necessary preventive and protective measures [171].
- The circular letter DH/EM 1 96-2517 of May 24<sup>th</sup>, 1996, relative to the safety of medical devices, states that: *"Whatever its implantation site, an implanted catheter should never be cleared with a small diameter syringe: indeed, there is a risk of breakage and embolization of the catheter, whenever an attempt is made to unblock it using any sort of liquid under pressure"* [151].
- The circular letter DH/EM1 n°96-6225 of October 28<sup>th</sup>, 1996, relative to the safety of medical devices, determines the conditions under which needles and syringes are to be used: *"When there is a need for perfusion, heparinization or flushing, a small diameter needle tip with a tangential bevel (a 0.7 mm diameter, i.e. 22 gauge, Huber or other special needle intended for this use) must be used to puncture the septum of the implantable catheter's injection chamber ... the bevel-tip needle must puncture the septum without causing any significant damage to it. The use of small diameter needles preserves the septum's integrity and ensures that the device remains impermeable. Larger diameter needles (0.9 mm i.e. 20 gauge) must be used only for the administration of parenteral nutrition or blood products [...]"* [172].
- The circular letter N° DGS/DH/98/249 of April 20<sup>th</sup>, 1998 relative to the prevention of the transmission of infectious agents carried by the blood or biological liquids during hospital care, recalls the responsibility of the hospital director in terms of the protection of workers. It states that: *"In agreement with the CLIN, the occupational physician and the CHSCT, the hospital director must define a preventive strategy including the use of so-called safe medical equipment. These medical devices (sampling needles, catheters, containers, ...) allow the risk of BBFE to be reduced. They must be considered as additional preventive means, with respect to the general hygiene precautions"* [173].
- In 2000, in its reference document *Evaluation of the quality of totally implantable venous catheter use and surveillance*, ANAES makes it clear that *"In practice, the length of the needle is chosen according to the*

*thickness of the septum and the patient's build. The use of a curved needle equipped with an extension appears to be the post common practice; in accordance with the statutory provisions relating to materials vigilance, any incident or risk of an incident related to the equipment must be appropriately reported.*

*In addition, "In order to avoid complications such as an incorrectly inserted catheter, thrombosis of the system, or necrosis, precautions are to be taken before injecting any product, in particular when this a cytotoxic product:*

- *search for backflow of blood using aspiration,*
- *permeability test using the injection of saline,*
- *absence of extravasation*

*Whenever normal use is made of the TIVC (chemotherapy in particular), flushing with saline is just as efficient and more straightforward than with the conventionally used heparinized saline described in the recommendations. In the special case of parenteral nutrition, in accordance with the recommendations of some manufacturers, it would appear that flushing with diluted alcohol can prevent an occlusion" [3].*

■ In 2009, concerning the prevention of TIVC infections, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* recommended the use of sterile dressing kits including surgical drapes and sterile gloves when dressing the needle insertion site [14].

■ In 2007, the HAS drafted recommendations entitled *Hygiene and the prevention of infectious risk in medical and paramedical practices*. In their rationale concerning the "surveillance of totally implantable venous catheters" the authors indicate that: *there is a strong professional agreement on the need to flush with a saline solution before any injection or perfusion, between 2 solutes, and at the end of treatment, in order to avoid interactions between different medications" [174].*

■ In 2010, in the "Surveillance and Prevention of healthcare-associated infections" guide, recommendation R104 in the chapter entitled "*Infections associated with intravascular devices*" indicates "*Prefer safety devices when available and train carers in the use of such equipment [...] "* [94].

■ Also in 2010, in its *Guide on safety Equipment*, the GERES recommends that: "*In general, in the case of invasive acts, whenever they exist, medical devices should be preferred which:*

- *have an integrated safety system with irreversible activation;*
- *automatically provide safety, without user intervention, or allow single-handed triggering with the simplest possible procedure, call for gesture continuity and allow the earliest possible use of a safety mechanism following the gesture, ideally when the needle is still under the skin;*
- *otherwise, allow the user to single-handedly trigger a safety mechanism with the simplest possible procedure, and are equipped with an audible or visual safety locking indicator" [175].*

■ The Council directive 2010/32/UE of May 10<sup>th</sup>, 2010 enforcing the framework agreement between the HOSPEEM and the FSESP, related to the prevention of injuries by sharp objects in the hospital and health sector, was published on June 1<sup>st</sup>, 2010. One of the purposes of this directive is "*to prevent injuries caused to workers (including needlestick injuries) by any sharp objects intended for medical use" [176].*

■ In the 2009 - 2013 national Program for the prevention of nosocomial infections, it is stated:

*"Local action program: Improve the safety of procedures exposing persons to high blood exposure risks (training, sufficient supply of protective and safety equipment), during insertion and removal of needles on a TIVC, subcutaneous injections, insertion of intravenous catheters, ..." [177].*

■ In 2011, the document *Guidelines for the prevention of Intravascular Catheter-related Infections*, the CDC recommend the use of needleless connectors to access the venous line, in order to prevent blood exposure accidents (Cat. IC). Moreover, they also add that if such needleless connectors are used, a system with a pre-split septum should be preferred to a mechanical system as a result of the increased risk of infection associated with the latter (Cat. II). It is important to ensure that all of the system's devices are compatible, in order to minimize leakage and breakage (Cat. II) [102].

## **B – Analysis of the literature and rationale**

### **CHOICE OF NEEDLE**

Specific – so-called Huber – needles are used. These can be straight or curved, with a tangential bevel to avoid damaging the silicone membrane of the catheter. This beveled tip prevents "coring" of the TIVC septum. Correct choice of needle diameter (gauge) is important because it affects the flow rate of the perfusate and ensures integrity of the septum. This choice depends on the viscosity of the perfusate and the desired flow rate; however, prolonged insertion of a large caliber needle is normally avoided in order to minimize any damage to the septum membrane. In addition, a needle length which is poorly adapted to a patient's build can lead to complications:

- insufficient length: partial or total reduction of the flow rate and/or self-expulsion of the needle and septum, which can lead to extravasation or even necrosis,
- excessive length: a tipping effect which can expel the needle from the septum and lead to the risk of extravasation and/or incorrect attachment of the needle to the patient's skin [33].

There are two types of needle:

- type 1: simple needle, straight or curved, mainly for short, rapid injections,
- type 2: made of a right-angle curved needle

with an extension tube and a Luer Lock type of connector. It may or may not have a so-called needleless safety connector (some type 2 needles are compatible with high flow rate injections).

The manipulation of Huber needles is associated with a recognized BBFE risk. In the 2009 report of the national surveillance network (RAISIN), the incidence rate of needlestick BBFE through the use of a needle with a TIVC is 22.3 per 10<sup>5</sup> procured needles [178]. In a GERES survey into the circumstances of needlestick BBFE with safety equipment, the BBFE rate differs as a function of the generation of the safety equipment, thus providing an argument in favor of the use of devices ensuring (totally or semi-automatic) passive safety, rather than those requiring manual activation of the safety mechanism [179]. From the full set of safety devices studied by TOSINI *et al.*, safety Huber needles are associated with the highest incidence of needlestick injuries, with 16 BBFE for 10<sup>5</sup> safety devices. The authors emphasize that in 1990, in the absence of any safety mechanism for the needle, the observed rate of incidence was 410 BBFE for 10<sup>5</sup> procured needles [179, 180].

### **CHOICE OF LINE ACCESS MATERIALS**

Access is achieved through the use of two types of device:

- either a blocking plug, which requires opening of the central line in order to make a syringe injection or install a drip,
- or a needleless connector, also referred to as a safety connector or closed needleless system, or even bidirectional valve, which was initially designed to prevent the risk of BBFE, since it removed the need for the healthcare provider to use a needle. After having been used for approximately fifteen years in North America, these devices have been developed with different generations of materials, and although some studies have shown a reduction in the contamination of the catheter hub, the

bibliographic rationale presented in the recent recommendations of the CDC call for caution [27,102]. Indeed, several studies have reported an increase in bacteremia on TIVC, associated with the introduction of certain types of such devices with a mechanical valve. Several explanations have been proposed: internal technical configuration of the device making it more or less difficult to flush, lower disinfection efficiency resulting from the membrane design, lower disinfection observance of the membrane or septum before using the valve, insufficient replacement frequency, or utilization for blood sampling [102,181-183]. The various devices available on the market need to be evaluated.

Finally, the use of a syringe able to contain less than 5 ml generates a level of pressure in the chamber and connected catheter, which is not compatible with the strength claimed by the manufacturers (12 to 14 bars, depending on the model). To avoid any "forced" maneuver and preserve the integrity of the device, it is recommended to use syringes having a volume of at least 10 ml [184].

## CARE KITS

In the field of the care of patients suffering from cystic fibrosis, in its notice produced in June 2006, the product and service evaluation commission of the HAS recognizes the service provided by the use of an individual kit for domestic perfusions. This can simplify care, in particular in situations where it is difficult to ensure aseptic conditions.

## TIVC FLUSHING

The obstruction of TIVCs is an infectious complication risk factor and can arise from various mechanisms: thrombosis, precipitates resulting from the use of incompatible medications, lipid deposits. TIVC flushing, before and after use, allows this risk to be reduced. However, the following questions arise: which product, what volume, what flow rate?

There is no consensus on whether to use heparin or 0.9% NaCl. Many reasons are given for not using heparin: its limited useful life, hypocalcemia, induced thrombocytopenia, incompatibility with the perfusate [185-189]. Experimental studies have tried to determine the ideal volume of 0.9% NaCl for TIVC flushing.

After blood sampling, the density of red blood cells remaining in the TIVC progressively decreases, with an inflexion point in the curve at a cumulated flush volume equal to 7 ml. The results reveal the significant dilution effect produced by the first milliliters of flushing solution, and suggest recommending the association of a large flush volume (at least five times the device's internal volume) with a pressure effect, in order to minimize the risk of thrombosis of the implantable device [190].

Finally, another study tried to determine the most efficient method for maintaining the permeability of an intravascular catheter. The authors showed that "venous guard" flushing (500 ml pouch of 0.9% NaCl, at a flow rate of 0.35 ml/mn) was relatively inefficient during the first 12 hours (< 30%) and that the efficiency was not improved when the flushing was carried out with the help of a 10 ml continuous flow syringe with 10 successive 0.5 second pulses at a 150 ml/mn flow rate, thus corresponding to a total flow time of 5 seconds [191]. Some authors advocate a flushing technique involving rotation of the needle, in particular during the first flushing pulse, but without having demonstrated its efficiency. The results of a recent experimental study suggest that this practice is not useful, since it does not optimize the flushing process [192].

Finally, to limit the risk of contaminating injectable medication, prefilled 0.9% NaCl syringes are a useful alternative to the preparation of a "multidose" flushing solution in the hospital ward [185,193,194].

## 2-1-2 Recommendations

### Generalities

**R33** It is strongly recommended that any incident related to the medical devices used for patient care be appropriately reported (Regulatory).

**R34** It is strongly recommended to use safe equipment (regulatory) compatible with the GERES (French Working Group on the Risk of Blood Exposure) criteria, and to ensure the compatibility of all devices used to make up the line, in order to minimize any variations in flow rate, leakage and breakage (**strong** agreement).

**R34** It is strongly recommended to use Huber needles (Regulatory), preferably with a 22 gauge diameter, even in the case of the perfusion of viscous medication (such as parenteral nutrition, labile blood products) (**strong** agreement). If it is found necessary to use a 19 gauge needle, it is preferable to remove the needle as soon as perfusion has been completed (**simple** agreement).

**R36** It is preferable to use a type 2 Huber needle, i.e. equipped with an extension in order to minimize manipulations of the needle hub (**strong** agreement), except for high flow-rate injections, for example in radiology where, in the absence of a compatible type 2 needle, a type 1 needle without an extension will be preferred (**simple** agreement).

The length of the needle must be adapted to the depth at which the chamber is located, and the patient's corpulence (**strong** agreement).

### Choice of line access materials

**R37** For any act carried out on the TIVC or the perfusion line, it is strongly recommended to use only syringes having a volume of at least 10 ml, in order to avoid over-pressure which could damage the TIVC (Regulatory).

**R38** It is desirable to use type 2 Huber needles with an integrated safety connector (**strong** agreement).

**R39** If a safety connector is used, for reasons of the infectious risk associated with some devices, a valve system with a pre-slit septum should be preferred to a system with a mechanical valve. It will then be necessary to implement monitoring of the incidence of TIVC associated bacteremia (**simple** agreement).

**R40** The use of a set facilitates patient care, in particular when it is carried out in the home (**strong** agreement).

**R41** All gauze used during TIVC manipulations must be sterile (**strong** agreement).

### TIVC flushing

**R42** Efficient flushing involves the pulsed injection of 10 ml of 0.9% NaCl, through the use of successive impulses (**strong** agreement). The flushing efficiency is verified by the absence of any visible residues (**simple** agreement).

**R43** The use of 0.9% NaCl syringes facilitates the observance of good practice (**simple** agreement).

## 2-2 Initial use and needle insertion

### 2-2-1 Review of the literature

#### A Existing regulations and recommendations

■ In 2000, in its document *Evaluation of the quality of totally implantable venous catheter use and surveillance*, the ANAES indicates that during insertion of a TIVC, the operator verifies the presence of blood reflux, and proceeds with the first injection. No details are given of the delay authorized between insertion and initial use [3].

■ The decree n° 2004-802 of July 29<sup>th</sup>, 2004, article R-4311-7 indicates that, among his/her authorized professional acts, the nurse's specific role is: *"To monitor central venous catheters and implantable vascular access*

setups installed by a doctor, and carry out injections and perfusions into these catheters, to the exclusion of the former ..." [195].

■ The circular letter DH/EM 1 n° 96-6225 of October 28<sup>th</sup>, 1996, relative to the use of totally implantable venous catheters and needles adds that: *"In addition, brutal pressure of the needle on the bottom of the chamber can blunt the needle and thus degrade the septum when the needle is retracted [...] after injection or perfusion or an attempt at such, the same needles or syringes must never be reused"* [172].

■ The circular DGS/DH/DRT n°98-249 of April 1998, relative to the prevention of the transmission of infectious agents carried by the blood or biological fluids during healthcare in hospitals. General hygiene precautions or standard precautions must be applied to all patients whenever there is a risk of contact with, or projection of, blood, biological fluids, and also secretions or excretions, or a risk of any contact with injured skin or a mucous membrane.

The wearing of gloves is necessary *"if there is a risk of contact with blood or any other product of human origin, the patient's mucous membranes or injured skin, in particular whenever care is provided involving the risk of needlestick (hemoculture, insertion and removal of venous lines, implantable catheters, blood samples ...)"*. Healthcare protocols validated by the CLIN must cover the safety of the personnel [173].

■ In 2000, in the reference document entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance*, ANAES indicates that *"in the case of puncturing the implantable chamber [...] or changing the dressing, there is a greater risk of colonization of the intravenous device. It is necessary for the nurse and patient to wear a mask, and for the nurse to use sterile gloves and sterile gauze. The wearing of a gown and cap is not justified, except in the case of specific indications (aplasia, neutropenia). It is*

*recommended to respect aseptic technique during manipulations near to the implanted device and to check for the absence of any local inflammatory signs. It is proposed to use an anesthetic cream on patients for whom puncturing is painful. Double antiseptic cleaning of the skin is carried out with sterile gloves for the second application of antiseptic"* [3].

■ In 2001, in its Good Practice Guide *"Venous catheterism. Recommendations for the elaboration of protocols for the care of venous lines*, the Paris-north CCLIN recommends disinfection of the hands [...] before and after palpation of the insertion site and manipulation of the venous line, and to respect the conditions of access to the system by wearing a sterile mask and gloves. It is recommended to carry out cleansing and careful antiseptic cleaning of a large area with an antiseptic intended for unbroken skin [...]. The first antiseptic cleaning is carried out with bare hands, the second being carried out with the hands protected by sterile gloves [196].

■ Also in 2001, the South-West CCLIN recommended hand rubbing disinfection with an hydro-alcohol based product (HAP), [...] the wearing of gown and mask, as well as the use of sterile drapes on the insertion site. Skin preparation relies on different steps, in particular: cleansing with an antiseptic soap followed by rinsing with sterile water and drying with sterile gauze, then an initial antiseptics, with adequate drying time being observed before a second antiseptics, carried out with sterile gloves [10].

■ In 2005, in its document *Prevention of peripheral venous catheter-related infections*, inspired from the 2004 consensus conference on skin preparation for operated patients, the SF2H recommends preferring the use of clippers whenever hair removal is necessary (R15).

In the same guide, recommendation R27 stipulates that: *"It is recommended, when applying a topical anesthetic, to use single-*

dose or single-patient packaging (B3); in such a situation, during catheterization it is strongly recommended to carry out a detergic cleaning phase prior to antiseptics (A3)." [197].

■ In 2006, in its guide on the prevention of healthcare-related infections outside hospitals, the ministry recommends not only the use of hygienic hand washing or a hydro-alcoholic hand rub before any intervention on a chamber, the wearing of sterile gloves, a mask and a cap, but also a five-step disinfection of the skin [198].

■ In 2007, in its good practice guide for antiseptic practice in children, the SF2H advocates antiseptic cleaning of healthy skin in the case of acts associated with a high infectious risk, such as implantations, or interventions on catheters or implanted chambers [199].

■ In 2007, in its document entitled *Hygiene and the prevention of infectious risk in medical and paramedical practices*, the HAS recommends the first line use of either alcoholic chlorhexidine or alcoholic PVPI for the treatment of implantable chambers, and the wearing of cap and gown, in the case of aplastic or neutropenic patients [174].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* indicates in its recommendations that ideally, a TIVC should not be used for several days following its implantation, to allow sufficient time for the pain and edema to decline. However, should the TIVC need to be used immediately, the needle must be inserted in the operating room [14].

■ In 2010, in the chapter "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, dealing with the disinfection of the insertion sites for intravascular devices in general, recommendation R107 specifies: "*Degreasing agents, such as acetone or ether, should not be applied before IVD placement. If necessary,*

*remove hair with clippers, scissors, or depilatory cream (no shaving). If a topical anesthetic is required, favor single-dose presentations and apply the topical anesthetic before beginning skin preparation of the insertion site.* [94].

■ In 2011, in *Guidelines for the Prevention of Intravascular Catheter-related Infections* the CDC indicates that antiseptics should be allowed to dry, according to the manufacturer's recommendation, prior to catheter placement [102].

## **B – Analysis of the literature and rationale**

■ A retrospective study carried out in pediatric oncology compared the frequency of infections in 23 patients in whom immediate use was made of the TIVC, with the frequency observed in a group of 74 patients in whom the TIVC was used later. The incidence of infections was 22% in the first group and 14% in the second group, with no statistically significant difference [200]. More recently, in a descriptive study related to 180 patients in oncology, OZMEDIR *et al.* conclude that the administration of chemotherapy immediately after TIVC implantation does not increase the risk of complications; they observed 11 thromboses, 2 cases of sepsis and one cellulite [201]. A retrospective observational study of 815 TIVCs in patients followed in oncology revealed an association between the frequency of complications and the delay between implantation and the first use, with: 10.6% (17/160), 6.7% (13/193) and 2% (8/405), when the TIVC was used, respectively, within 0 to 3 days, 4 to 7 days, and after more than 7 days ( $p=0.001$ ) [9].

■ Catheter-related infections are facilitated by several mechanisms, including contamination at the time of needle insertion, which can be avoided through the strict application of aseptic procedures [27]. An infection associated with the insertion of a needle into the TIVC can be the result of a mechanism justifying the use of optimal skin preparation before insertion, as

well as the wearing of a mask by the patient, since the chamber implantation site is sometimes close to the nasopharyngeal area. One of the major alcoholic antiseptics is to be preferred before carrying out an invasive act on healthy skin: alcoholic chlorhexidine or alcoholic povidone-iodine, for the reasons of their spectrum of antimicrobial activity and efficacy [94]. However, at present, antiseptic alcoholic solutions are not all reimbursed by the French social security system or available for non-hospital practice. A combination of chlorhexidine gluconate, benzalkonium chloride and benzyl alcohol, the usefulness of which has been emphasized in studies dealing with TIVC in critical care, has a recognized microbial activity and could be an alternative for antiseptics prior to the insertion of a Huber needle, provided the various different durations for skin antiseptics (cleansing phase prior to antiseptics involving cleaning with a liquid soap, followed by rinsing and drying) are respected [202,203]. The rules governing the use of antiseptics are recalled in the advocacy from several professionals, calling for an improvement in the lifetime of TIVCs, and also emphasizing that the contact time needed to ensure antiseptic efficacy before inserting the needle often corresponds to that needed to put on sterile gloves [204].

■ The insertion of a Huber needle is one of the most sensitive care procedures for the patient with a TIVC, and frequently calls for the use of local anesthetics. No scientific studies have evaluated the consequences of such use on the infectious risk related to needle insertion, or on the efficacy of skin disinfection in this context. Since analgesic "patches" can contain fatty products, it is necessary to insist on the importance of the cleansing step before application of the antiseptic.

Finally, by varying the puncture point locations on the septum, possible adhesion of the skin to the chamber can be avoided (risk of skin tear or fistulization) and the impermeability of the septum is preserved [184].

## 2-2-2 Recommendations

### Initial use

**R44** The first puncture of the TIVC is a medical act, which is carried out intra-operatively during reflux testing, immediately after insertion (Regulatory). It is preferable to avoid inserting a needle into an incompletely healed surgical site (**simple** agreement). The absence of local cutaneous signs (redness, pain, swelling, edema) is verified before inserting the needle (**strong** agreement).

### Operator hygiene during needle insertion outside the operating room

**R45** The operator must wear clean professional garments; in the absence of professional garments, he/she must wear a disposable smock (**strong** agreement). The wearing of a sterile gown is required only when the patient is placed in protective isolation in a dust-controlled environment (**simple** agreement). The operator wears a surgical mask (**strong** agreement) and a medical cap (**simple** agreement). The operator uses a hydro-alcoholic handrub to disinfect his/her hands just before inserting the needle, and wears gloves just before carrying out the puncture (**strong** agreement).

### Skin preparation before needle insertion

**R46** Skin preparation is carried out before insertion of the needle. Whenever the needle is changed, the skin must be prepared just before re-puncturing the chamber. Adequate stripping of the patient must allow a large area to be disinfected. Skin preparation includes a detergent cleansing phase prior to skin disinfection, using a major alcohol-based antiseptic. A 0.05% water-based chlorhexidine solution must not be used. It is not recommended to apply a degreasing agent or any product which is irritating to the skin. If the use of a topical anesthetic is necessary, it is preferable to use single dose packaging

(**strong** agreement). Hair removal from the needle insertion site is not recommended (**simple** agreement), but if this is indispensable in order to ensure adequate fixation of the dressing, the use of clippers should be preferred (**strong** agreement).

## Needle insertion technique

**R47** The patient is installed so as to optimize care ergonomics. He/she must wear a surgical type of mask; if the wearing of a mask is not tolerated, the patient should be asked to turn his/her head towards the side opposite to that of the TIVC (**strong** agreement). A sterile drape can be used during TIVC puncture (**simple** agreement); more specifically, this should be used in the case of insertion in the home environment (**strong** agreement). It must have an opening and be pre-cut in order to avoid any aseptic inadequacy at the end of the intervention (**simple** agreement).

**R48** It is strongly recommended to go completely and perpendicularly through the septum, until the needle touches the bottom of the chamber, without bending the tip (Regulatory). The skin is kept intact and the septum remains leakproof, by changing the puncture points in the chamber (**strong** agreement).

**R49** Correct operation of the device is verified by means of the following indicators: presence of venous reflux, absence of pain with or without injection, good perfusion flow rate (observed flow rate = expected flow rate), easy injection when using the syringe (**strong** agreement).

## 2-3 Dressing

### 2-3-1 Review of the literature

#### A – Existing regulations and recommendations

■ In its reference document drafted in 2000, entitled *Evaluation of the quality of totally implantable venous catheter use and*

*surveillance*, the ANAES cites the CTIN recommendation n°86 “*a hermetically attached, sterile dressing is mandatory. Semi-permeable, transparent dressings allow daily inspections and palpations of the insertion point. The optimal interval for dressing replacement is not precisely defined: with a minimum of 48 hours is defined, which may be extended to 5 or even 7 days in the absence of soiling and loosening*”;

in addition, the RPC AP-HP states that “*for patients in oncology-hematology: dressing replacement every 7 days; for HIV infected patients: dressing replacement every 72 hours; following disconnection of the port, a clean dressing shall be applied for several hours. It is not useful for a dressing to be worn in situations other than those involving catheter connection* [3].

■ In 2006, the ministry’s *Guide for the prevention of healthcare-associated infections outside hospitals* recommends changing the dressing without delay in the case of soiling or loosening. The systematic or preventive application of an antimicrobial cream to the insertion site is not useful [198].

■ In a notice published in 2007, the HAS commission for the evaluation of products and services defines semi-permeable adhesive dressings as being indicated for: the protection of intravenous catheter sites. The minimum technical specifications for this type of dressing must comply with the EN 13726-2 standard, i.e. have properties allowing the passage of  $\geq 500$  g of water vapor per  $m^2$  in 24 hours [205].

■ In 2007, the *British Committee for Standards in Haematology* recommended that dressings be changed 24 hours after application, and then once a week, without indicating the type of dressing or the type of catheter used [12].

■ In 2009, the *European Society for Clinical Nutrition and Metabolism* proposed that the dressing be changed every 7 days, as soon as the insertion site has healed. It prefers the use of semi-permeable dressings for all types of catheter [13].

■ Also in 2009, concerning dressings used on TIVC, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* indicated that the treatment should be adapted to the type of closure used: if sutures are used, the incision shall be covered for 2 weeks, or until such time as they are removed (7 to 10 days); if an “external” suture or glue is used, the incision is dry on the day following insertion. In all cases, it is preferable to protect the incision for a period of one week. Sterile, transparent semi-permeable dressings are recommended to allow the insertion site to be monitored. A sterile adhesive gauze dressing can be used in the case of true contraindications and in the case of exsudation or bleeding at the insertion site. A sterile, adhesive, transparent semi-permeable dressing should be applied as soon as possible. The dressing as well as the semi-permeable dressing must not be wet or immersed. Until such time as the wound has healed, the dressing should be changed according to the manufacturer's recommendations, or every 7 days, whenever the dressing is soiled or loosened, or whenever there is an obvious inflammation or exsudation. If the dressing is made using gauze, it should be changed every 48 hours. If a gauze is used to stabilize the needle, but not to protect the puncture site, the dressing is not considered to be a gauze dressing and can be changed every 7 days [14].

■ In 2010, in the chapter entitled “Infections associated with intravascular devices” of the *Surveillance and prevention of healthcare-associated infections* guide, in R113 the SF2H recommends “Cover the IVD insertion site by using a transparent, semipermeable, sterile dressing made of polyurethane, to allow visual inspection of the IVD. Use sterile gauze with the sterile adhesive dressing in case of bleeding or exudation. Before exposure to water, temporarily protect the dressing with an impermeable material. Before manipulating the dressing, disinfect the hands (handrub). Proceed with dressing replacement only when it becomes loosened or soiled, or when

*inspection of the site is necessary, under the same conditions as during dressing application. Indicate the date of dressing replacement in the patient's file.”* [94].

■ In 2011, in *Guidelines for the Prevention of Intravascular Catheter- Related Infections*, the CDC recommend: “

- *Observing hand hygiene procedure, by washing with mild soap or an alcohol-based product (ABP). Practicing such hand hygiene before and after palpation of the insertion site, [...], or before catheter dressing replacement (Cat. IB).*
- *Disinfecting clean skin [...] with > 0.5% alcoholic chlorhexidine [...] and whenever dressings are changed. In the case of a chlorhexidine contraindication, an iodine derivative or 70% alcohol can be used (Cat. IA). No comparison has been made between alcoholic chlorhexidine preparations and alcoholic povidone-iodine for the disinfection of clean skin. This question remains unresolved.*
- *Not exposing the catheter to water. Showering is permitted if all precautions are taken to minimize the probability of introducing microorganisms into the catheter (example: during a shower, the catheter and tubing must be protected by an impermeable dressing) (Cat. IB).*
- *Changing transparent dressings used on totally implanted venous catheters or tunneled CVCs not more than once a week, except when the dressing is soiled or loose, until such time as the insertion site has healed (Cat. II).*
- *Visually examining the catheter insertion site whenever the dressing is changed or by palpation through the dressing, in order to detect any sensitivity, in accordance with the clinical situation of each patient. If the patients have any sensitivity at the insertion site, fever of no obvious origin, or any other local manifestations suggesting the presence of an infection, the dressing must be removed to allow close examination of the site (Cat. IB)”* [102].

## B – Analysis of the literature and rationale

There is no published study specifically devoted to the use of dressings with TIVC (choice, replacement frequency, ...), such that most protocols extrapolate recommendations which have already been established for other types of central venous catheter. In the case of TIVC, the aim of the dressing used after insertion is to protect the surgical site until it has healed; then, during use, to protect the needle puncture site.

A recent meta-analysis comparing “gauze” dressings with transparent semi-permeable dressings did not allow any conclusion to be drawn in favor of one or the other types of dressing, for the prevention of TIVC-associated infections. However, the semi-permeable dressing has the advantage for the patient of permitting less frequent replacements, as well as visual monitoring of the puncture point in the case of skin emergence CVC. In addition, in the case of TIVC, it can help to hold the needle in a stable position [206].

Sponges or dressings soaked with antiseptic, which until now were proposed in the context of high rates of infectious complications [13,92] have recently been analyzed in a French study, the results of which are highly favorable for their routine use in the prevention of CVC-associated infections in critical care [207]. However, to date no study has been made for the case of the TIVC, and there are no antiseptic impregnated dressings suitable for the configuration of a TIVC with an inserted needle.

The analysis of several protocols produced either by regional centers for the prevention of cancer, or by public hospitals with various services treating patients fitted with a TIVC (rehabilitation, day hospitals for chemotherapy, onco-hematology) has shown that most of these recommend the use of semi-permeable dressings once the surgical wound has healed. The dressing is then routinely replaced every seven or eight days.

## 2-3-2 Recommendations

### General considerations

**R50** The dressing must never become wet (**strong** agreement). Whenever a needle is being used, it is not recommended to allow showering, even in the absence of perfusion (**simple** agreement). If the patient takes a shower or is exposed to water, the dressing (whatever its type) must be protected through the use of waterproof material, and its leak-proof qualities must be verified beforehand and afterwards (**strong** agreement).

### Choice and indications for the dressing

**R51** During the immediate post-operative period, in case of exudation and bleeding at the surgical site or puncture point, the dressing should be of the sterile adhesive type with gauze. Once the surgical site has healed, it is preferable to use a sterile semi-permeable transparent dressing (according to the EN 13726-2 standard), as this allows the puncture site to be inspected (**strong** agreement).

**R52** The needle insertion site should be protected by a sterile and occlusive adhesive dressing. In all cases, in particular when a safety needle is in place, it is necessary to apply a sufficiently large dressing to ensure its water-tightness and that it is correctly held in place (**strong** agreement).

**R53** When removing the needle, a sterile adhesive dressing with dry gauze is applied to the puncture point for one hour. After the insertion site has healed, it is not necessary to apply a dressing on a non-infused TIVC when there is no needle in place (**strong** agreement).

### Dressing replacement technique

**R54** Disinfection of the hands using an ABP handrub should be performed before the manipulation of any dressing. Appropriate stripping of the patient allows provides access for skin preparation and safe manipulations (**strong** agreement).

**R55** When the dressing is replaced, the operator and the patient should wear the same garments as when inserting the needle (**strong** agreement).

**R56** The dressing replacement technique follows the same cutaneous preparation principles as when needle insertion. When a Huber needle is already in place, the various antisepsis steps should be performed using sterile gloves. Applying an antimicrobial ointment at the insertion site is not indicated. The dressing should be applied after complete spontaneous drying of the antiseptic (**strong** agreement).

### Frequency of dressing replacement

**R57** The first dressing replacement after a TIVC has been inserted should be performed within the first 48 hours (**simple** agreement).

**R58** Any soiled or loosened dressing should be replaced quickly (**strong** agreement).

**R59** If a sterile adhesive dressing with gauze is used, it should be replaced every 96 hours. If the transparent dressing is sterile and semipermeable, it can be left in place until needle replacement (i.e. for a maximum duration of 8 days) (**strong** agreement).

**R60** Dressing replacement does not systematically require needle replacement (**simple** agreement).

## 2-4 Preparation and management of administered medication

### 2-4-1 Review of the literature

#### A – Existing regulations and recommendations

■ The circular n° 377 of June 13<sup>th</sup>, 1967 relative to the use of infusion bottles, “no matter what their packaging mode” recommends:

“1- Disinfecting the outer surface of the rubber

*plug before use. This measure should be applied to all solutes, whatever their origin. After having removed the protective cap, dry the surface of the plug if necessary, rinse with alcohol, leave the alcohol for approximately one minute and remove the excess by tipping the bottle. Any truly effective disinfectant (for example alcoholic iodine) may be used.*

*2- Install the perfusion equipment. Air enters through a sterile cotton wool plug. Any other air admission device must be fitted with an analogous filtration system.*

*3- In cases where any medication is added to the solute, this should be injected into the bottle only when step 2 has been completed.*

*4- Any thus-prepared infusion must be used within one hour. In the case of vacuum packaged bottles, check before any operation that the seal is intact by verifying the presence of a vacuum in the bottle, using the following procedure: use the fist to tap on the bottom of the inverted bottle. If the vacuum has been preserved, a characteristic clicking sound can be heard. Eliminate any bottle which does not have this characteristic” [208].*

■ The circular letter DH-EM 1 n°96-5852 of October 18<sup>th</sup>, 1996, relative to the safe use of medical devices, recommends in the case of (unidirectional) anti-return valves for infusion lines:

*“[...] The function of the anti-return valve in an infusion line is to allow the infusion solute to flow in only one direction (from the solute storage device to the patient) and to prevent any retrograde reflux. It can be used on just one infusion line, but is normally indicated for the case of parallel infusions making use, for example, of a continuous gravity-fed infusion and a patient-controlled analgesia (PCA) infusion pump. In the latter case, the valve is placed upstream of the Y-tubing or the 3-line stopcock, on the gravity-fed infusion line, thus making it possible to prevent any reflux of morphine solute towards the gravity-fed infusion storage device ... “ [209].*

■ The circular letter DGS/DHOS/AFSSAPS n°03/582 of December 15<sup>th</sup>, 2003 indicates that:

*“In order to avoid the conservation of blood products in the ward or the hospital’s blood transfusion center, it is recommended to transfuse within the shortest possible time following delivery, without exceeding a delay of 6 hours ...”* [210].

■ The AFSSAPS good practice recommendations for preparation define guidelines for the preparation of sterile medication containing, in particular, dangerous or radiopharmaceutical substances ... the preparation is carried out in an internal pharmacy, in a controlled atmosphere zone [211].

■ In 1997, in its recommendations entitled *Prevention of infections associated with indwelling intravascular access devices*, the Canadian public health agency states that *“it is advisable to select the most simple possible configuration (minimal number of openings, connections, and access lines) with respect to the intended use of the catheter (BII)”* [212].

■ In 2000, in the reference document entitled *Evaluation of the quality of use and surveillance of totally implantable catheters*, the ANAES states that:

- *the maintenance of the venous line must be strictly aseptic, by respecting the notion of a closed system, whenever possible,*
- *preferably isotonic saline solutes, rather than glucose solutes, should be used for continuous infusion of the main line,*
- *in the case of blood deposits or reflux, the tubing must be changed immediately,*
- *the use of inserted antibacterial filters has not been shown to be efficient* [3].

■ In 2001, in its *Venous catheterism good practice guide – Recommendations for the elaboration of venous access protocols*, the Paris-North CCLIN recommends one absolute rule before use: systematically verify the permeability or the free flow rate in order to

ensure that the the needle is correctly positioned [196].

■ In 2001, in its *Recommendations for the reduction of infectious risk associated with TIVCs*, the South-West CCLIN recommends verifying the blood reflux and the permeability of the system before use, and systematic rinsing between successive administrations of medication and after each use with physiological serum [10].

■ In 2006, the Guide for the prevention of infections associated with healthcare dispensed outside health facilities states that *“all infusion tubing and auxiliary equipment (excluding extension tubing – first junction) should be changed every 72 to 96 hours. The infusion line shall be changed daily in the case of parenteral nutrition and after each infusion of blood, blood products or lipid emulsions”* [198].

■ In 2008, in its “Parenteral nutrition in the home” evaluation report, the HAS indicates that *“in this particular case, the administration of nutritious mixtures in the home must be carried out via a central venous line by means of a programmable infusion pump”* [213].

■ In 2010, in the chapter entitled “Infections associated with intravascular devices” in its *“Surveillance and prevention of healthcare-related infections”* guide, the authors recommend:

- *Preparing infused fluids whilst observing the rules of asepsis. Never use any solute with visible turbidity, leaks, cracks or material particles, or whose use-by date has expired. Prefer the use of disposable vials. Eliminate the unused contents of disposable vials. Handle multidose vials with strict asepsis precautions, and respect the storage conditions and durations. Clean the plugs of multidose vials with 70% alcohol before inserting any equipment into the vial. Use sterile equipment to puncture multidose vials. Eliminate any multidose vial whose sterility has been compromised (R115).*

- Complete the infusion of labile blood products within 4 hours after beginning its administration. Complete the infusion of lipid emulsions within 24 hours of beginning infusion. Replace used tubing after each administration of labile blood products and within 24 hours of the administration of lipid emulsions (R116).
- Respect the rules of asepsis whenever a heparin lock, continuous heparinization, a saline lock, or a valve is used” [94].

■ In 2011, in *Guidelines for the prevention of intravascular catheter-related infections* the CDC recommend:

- In patients who are not receiving labile blood products or lipid emulsions, replace the main infusion delivery line, including the secondary tubing and associated devices, no more frequently than every 96 hours, but at least every 7 days. Cat IA.
- Replace the tubing used for the flow of blood or blood derivatives or lipid emulsions (those combined with amino acids and glucose, delivered together or separately) within 24 hours of injection. Cat IB.
- Replace tubing used for the flow of Propofol every 6 to 12 hours following use, according to the manufacturer’s recommendations. Cat IA.”

There are no recommendations concerning the replacement frequency for tubing used for the intermittent delivery of products [102].

## B – Analysis of the literature and rationale

No specific study could be found dealing with the risk of infection associated with the preparation and administration of solutes with TIVC, such that for the purposes of consistency some recommendations related to short-term CVCs have been extended to TIVCs. Good practice in the preparation and administration of medication must therefore be applied, whatever the type of vascular access used.

All active injection systems which reduce the risk of blood reflux and obstruction of the catheter (electric syringes, volumetric pumps) are generally preferred to gravity-fed systems, since they are expected to be associated with a reduced risk of infection.

As a consequence of the risk of microbial proliferation, some products must be administered extemporaneously, i.e. immediately following their preparation. The tubing used for the infusion of some products must be changed following administration, and the duration of infusion of some products must be limited. It has been shown that there is no added value in changing a venous line more frequently than once every 96 hours [214].

Although no study has compared the consequences of the infusion device configuration on the risk of TIVC-associated infections, this configuration must be as simple as possible, in view of its intended use (minimal number of junctions and access lines), and the use of a short extension can allow manipulations of the needle tip to be reduced (see assembly proposals in the Appendix).

Finally, a *Burkholderia cepacia* septicemia epidemic was reported in premature babies who received lipid emulsion parenteral nutrition. The investigation of this case revealed that the elastomer plugs of the nutrition vials were not disinfected before being punctured. The microorganisms located between the plastic cap and the plug were thus introduced and administered [215].

### 2-4-2 Recommendations

#### General considerations

**R61** It is highly recommended to carry out cytotoxic and radiopharmaceutical reconstitution in the pharmacy department within a controlled-atmosphere area (Regulatory).

**R62** The line should be installed in the simplest possible way under aseptic conditions, and the main line should not be replaced more often than every 96 hours. Active injection systems, which reduce the risk of blood reflux, should be preferred to gravity-fed infusion (**strong** agreement).

### Selection of products

**R63** For parenteral drip-feeding, the use of ready-made mixtures is preferred: whether in a binary (glucose, amino acids) or ternary (glucose, amino acids, lipids) form, which reduces the manipulation and number of connections (**strong** agreement). Isotonic saline solutions should be preferred to glucose-based solutions for the purposes of continuous infusion through the main line (**simple** agreement).

### Preparation technique

**R64** Disinfection of the hands using an alcohol-based handrub shall be performed before any infusion preparation. The preparation date and additives shall be noted on the bottle or bag (**strong** agreement), avoiding the use of markers or felt pens that could damage plastic bags (**simple** agreement). Single-dose additives should be used whenever possible (with the remaining liquid being discarded). Any turbid, broken or expired vial is unusable. Vial caps are disinfected using sterile gauze impregnated with an alcohol-based antiseptic (alcoholic povidone iodine or alcoholic chlorhexidine or 70% alcohol) (**strong** agreement).

**R65** Solutes prepared outside pharmacy departments should be used extemporaneously (**strong** agreement).

### Special indications for blood and blood derivatives

**R66** It is possible to transfer blood or blood components through the TIVC, provided thorough rinsing has been performed (see

R42) after these products have been infused (**strong** agreement). However, if another venous line is available, it should be preferred for infusion (**simple** agreement).

**R67** It is recommended to connect the blood and blood components to the proximal site (as close to the patient as possible) in order to facilitate rinsing of the infusion device. The transfusion bag tubing should be replaced for each new labile blood product. The administration duration of a bag is 4 hours or less (**strong** agreement).

### Special indications for lipid emulsions

**R68** It is recommended to connect lipid emulsions to the proximal site (as close as possible to the patient) in order to facilitate rinsing of the infusion device. The tubing shall be replaced at the same time as the bag (**strong** agreement).

**R69** In the case of pure lipids, the administration duration of a lipid emulsion is 12 hours or less. However, an administration duration of 24 hours is acceptable in the case of large volumes. In case of combined lipid emulsions (3 in 1 administration of amino acids and glucose), the administration duration is 24 hours or less (**strong** agreement).

### Management of infusion lines other than for blood products and lipid emulsions

**R70** The tubing of the secondary lines shall be replaced between two different products (**simple** agreement). Thorough rinsing (see R42) of the connections should be performed immediately after each tubing replacement when switching to a different product. When infusing the same product continuously, the tubing shall be replaced every 96 hours (**strong** agreement). In case of non-continuous infusion of the same product, the tubing is to be replaced immediately after each bag (**simple** agreement).

## 2-5 Manipulations and management of connections

### 2-5-1 Review of the literature

#### A – Existing regulations and recommendations

■ The decree n° 2004-802 of July 29<sup>th</sup>, 2001 stipulates that: *“The nurse is responsible for the preparation, use and management of the healthcare file”* [195].

■ In 1997, in its guide entitled *Prevention of infections associated with indwelling intravascular access devices*, the Canadian Public Health Agency recommends that:

- *all staff members affected by exudative dermatitis or presenting with open lesions should wear gloves whenever handling catheters and connectors,*
- *the frequency with which the stopper is manipulated must be reduced to a minimum, in order to reduce the risk of contamination,*
- *any insertion site or open stopcock should be correctly closed after use,*
- *insertion sites and stoppers should be disinfected with 70% isopropanol or another suitable disinfectant. Cotton balls which have been used to clean the skin should not be used.* [212].

■ In 2000, in the reference document entitled *Evaluation of the quality of use and surveillance of totally implantable catheters*, the ANAES recommends that:

- *all manipulations be reduced as much as possible,*
- *connectors be disinfected before any injection. Permanent protection for connectors and tubing could be useful, especially when they remain in contact with the patient’s bed, although the efficiency of the various protective systems available is not fully demonstrated.*

Finally, the AP-HP’s recommendations for clinical practice are recalled. Manipulations of the insertion site are to be carried out whilst using sterile dressings soaked in antiseptic, and it is recommended to wear sterile gloves in the case of neutropenic patients. It is recommended to use a ramp protector, soaked (or not) every six hours in antiseptic, which is renewed at the same time as the ramp [3].

■ In 2001, in its *Venous catheterism good practice guide: Recommendations for the elaboration of venous access protocols*, the Paris-North CCLIN advises *“carrying out disinfection of the hands either by means of hygienic (antiseptic) washing, or an alcohol-based handrub, before and after palpation of the insertion site and manipulation of the venous line”* [196].

■ In 2005, in its document *Prevention of peripheral venous catheter-related infections*, the SF2H states:

*“R35 – It is recommended, before any manipulation of the catheter or any of the delivery system components, to disinfect the hands, either by means of hand disinfection with an antiseptic soap (or antiseptic washing), or by hand rubbing disinfection with an alcohol-based gel or solution [B2].*

*R36 – It is recommended to disinfect the tips and stopcocks before they are manipulated, with the help of a sterile gauze pad dipped in alcoholic chlorhexidine, alcoholic povidone-iodine, or 70% alcohol [B2].*

*R37 – It is recommended to install a new sterile stopper each time the access or the stopcock is opened [B3].*

*R38 – It is recommended to keep the stopcock ramps at a good distance from any source of contamination (for example bed linen, wounds, stoma) [B3].*

R39 – *It is possible to use needleless connectors as long as they are disinfected before the system is accessed in any way [C2]* [197].

■ In 2006, the *Guide for the prevention of healthcare-related infections outside hospitals* advocates:

- *Rigorously observing asepsis for all manipulations of the first connector or the insertion site: sterile gloves, sterile dressings, a sterile drape, antiseptic, mask for the operator and the patient (if the latter is not able turn his/her head in the direction opposite to the side being treated).*
- *Disinfecting the connectors before any injection; it is advised to protect these, if there is any possibility they could come into contact with the patient's bed (boxes or dressings regularly soaked in antiseptic).*
- *Disinfecting the connectors using dressings soaked in antiseptic, before any injection, and then closing them by means of a new sterile stopper.*
- *Limiting the number of times a venous line is opened by combining manipulations. Lines should not be left open when waiting for any manipulations*" [198].

■ In 2007, in its document entitled *Hygiene and the prevention of infectious risk in medical and paramedical practices*, the HAS recommends *the disinfection of injection ports and connectors using a sterile dressing soaked in an antiseptic, using either alcoholic chlorhexidine or alcoholic PVPI*" [174].

■ In 2007, the *British Committee for Standards in Haematology* specified *using injection sites (connectors, valves) to reduce the risk of infection for patients and blood exposure accidents for staff*" [12].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* stipulated *the use of alcohol-soaked dressings when accessing lines*" [14].

■ In 2010, in the chapter entitled "Infections associated with intravascular devices" of the *Surveillance and prevention of healthcare-related infections* guide, recommendation R114 indicates:

*"Reduce the number of manipulations as far as possible. Decontaminate the hands using an alcohol-based handrub before manipulating the IVD or components of the infusion device. Perform manipulations in an aseptic manner, whilst observing the closed system concept. Disinfect the tips and stopcocks before they are manipulated, using a sterile gauze pad dipped in an alcoholic antiseptic. The use of needleless connectors is possible as long as they are disinfected before use. Install a new sterile stopper whenever the access site or the stopcock is opened. Place a sterile stopper on any unused stopcock [94].*

■ In 2011, in *Guidelines for the Prevention of Intravascular Catheter-Related Infections*, the CDC recommends:

- *Change connectors at least as frequently as the tubing. Cat. II.*
- *In order to prevent the risk of infection, do not change stopcocks more frequently than every 72 hours, or than according to the supplier's recommendations. Cat II.*
- *Minimize the risk of contamination by cleaning the access with a suitable antiseptic and using sterile instruments. Cat IA.*
- *Clean the insertion site with 70% alcohol or iodine-based antiseptics before injection. Cat. IA.*
- *Place a plug on all stopcocks which are not in use. Cat. IB*" [102].

## B – Analysis of the literature and rationale

In the absence of any specific studies, and in an effort to ensure consistency, some recommendations intended for short duration CVCs have been extended to TIVCs.

The various junctions or connectors in the venous line, whatever their type or position, represent an entrance point which is potentially at risk of being contaminated through an endoluminal pathway; it is therefore important to organize treatment in such a way as to limit the number of openings of the infusion system. Their manipulation and management must be carried out under optimally aseptic conditions, and they must be kept well away from any source of contamination (bedding, wound, stoma, ...). In terms of the prevention of risk of infection, there is a demonstrated advantage to be had by using protective containers soaked in antiseptic [216]. The criteria for choosing a protective device and the way it is used, in order to reduce the risk of infection, have not been established.

Disinfectant hand rubbing with a hydro-alcoholic product, as well as the manipulation of junctions and connectors using a dressing soaked in an alcohol-based or 70° alcohol antiseptic, are essential preventive measures. The evaluation of the efficacy of disinfectant solutions, following experimental contamination of catheter hubs, was in favor of the use of an antiseptic in an alcoholic solution [217].

The choice of the type of gloves to be worn during distal manipulations (proximal manipulations being excluded) was analyzed in a 36-month before-and-after study in pediatric oncology, by comparing the incidence rate of bacteremia during a period when sterile gloves were worn with that during a period when no sterile gloves were worn. The observed incidence rate was 0.0075, then 0.0098, cases of bacteremia per day, with no statistically significant difference between the two periods (RR = 0.765 – NS) [218].

By extension of the use of cutaneous emergence CVCs, treatment protocols normally distinguish between proximal (first connector and needle) and distal manipulations, as a consequence of likely differences in the risk of infection. However, in the precise context of TIVCs, it is more difficult to justify this reasoning since the proximal device is completely renewed whenever the needle is changed. When blood samples are authorized with TIVCs, in the interest of the patient's comfort, this is done under strict, precisely defined conditions.

### 2-5-2 Recommendations

#### General manipulation considerations

**R71** All manipulations should be performed aseptically and after hand disinfection using an alcohol based product, and, as far as possible, should be limited in number and grouped together. For the manipulation of a connection in the venous line, sterile gauzes impregnated with an alcoholic antiseptic (alcoholic chlorhexidine, or alcoholic povidone iodine, or 70% alcohol) shall be used (**strong** agreement).

**R72** It is highly recommended to note the administration of a treatment and the difficulties encountered, on the patient's record and monitoring sheet (Regulatory).

#### Operator and patient's garment for manipulations

**R73** For proximal manipulations, the operator shall wear clean professional garments; if clean professional garments are not available, a single-use gown should be worn in a hospital setting (**strong** agreement) and for community-based care (**simple** agreement).

**R74** For proximal manipulations, wherever these are performed, in addition to clean garments, the operator shall wear:

- a surgical type of mask (**strong** agreement),
- sterile gloves (**simple** agreement).

**R75** For proximal injection into the infusion line, a patient shall wear a surgical type of mask. If he/she cannot wear a mask, he/she will be asked to turn his/her head towards the side opposite to that of the TIVC (**simple** agreement).

### Administration of solutes

**R76** Before administering the solute: test the TIVC's permeability (no resistance to injection, observed flow rate as expected), check for extravasation (lack of pain or local edema). Check for venous reflux in the case of a malfunction or before administering a dangerous (blistering and necrotizing) product. It is mandatory for venous reflux verification to be followed by thorough rinsing (see R42) (**strong** agreement).

**R77** After the treatment has been administered, to avoid precipitation of incompatible products within the TIVC, thorough TIVC rinsing (see R42) shall be systematically performed, and the absence of conspicuous residues within the tubing and connections shall be verified. Whatever the solute used, in particular for lipid emulsions and blood products, the connections shall be rinsed immediately after disconnection following administration of the treatment (**strong** agreement).

### Managing line access points

**R78** The replacement frequency of the associated distally positioned devices (stopcocks, ramps, valves or safety connectors) shall match that of the venous line. These items should not remain in place more than 96 hours (**strong** agreement).

**R79** The main line's injection sites should be remote from the bedding, using a long extension line and a ramp holder. Proximal connections and proximal injection sites shall be protected and kept at a distance from any source of contamination (**strong** agreement).

**R80** The injection site shall always be disinfected before use. If a stopcock is used for injection (without a safety connector), it shall be obstructed immediately after use by means of a sterile stopper. Each unused pathway shall be obstructed using a sterile device (**strong** agreement).

**R81** When a safety connector is used, efficient disinfection must be performed using an alcohol-based antiseptic before any injection. It is essential to rinse the internal lumen before use (**strong** agreement). If a safety connector is placed proximally, it shall be replaced every eight days, at the time of needle replacement (**simple** agreement).

### Blood sampling

**R82** It is possible to sample blood from the TIVC, provided that:

- a clear procedure is available for the technique,
- the asepsis and staff protection rules chosen for manipulating the proximal connection are observed,
- a single-use pump body is used for any sampling, including blood cultures,
- immediate thorough rinsing (see R42) is performed,
- no purge re-injection is performed (**strong** agreement).

## 2-6 Removal and and frequency of needle change

### 2-6-1 Review of the literature

#### A – Existing regulations and recommendations

■ The circular letter DGS/DH/DRT N° 98-249 of April 20<sup>th</sup>, 1998 recommends the wearing of gloves “*if there is a risk of contact with blood or any other product of human origin, the patient's mucous membranes or non-intact skin, in particular during care involving the risk of needlestick injury (hemoculture, insertion or removal of a venous line, implantable*

catheters, blood sampling, ...). In addition, this letter indicates that care procedures validated by the CLIN must include staff safety [173].

■ In 2000, in the reference document entitled *Evaluation of the quality of totally implantable venous catheter use and surveillance*, the ANAES indicates that the needle must be removed under positive pressure.

Moreover, the AP-HP recommendations for medical and nursing clinical practice are quoted, and advocate:

- *For patients in onco-hematology: removal of the needle after any single infusion, at the end of chemotherapy treatment, and systematically every 7 days in the case of continuous infusion;*
- *In the case of an HIV patient: removal when the line is closed, if single daily infusion has been used, and every 72 hours in the case of continuous infusion [3].*

■ In 2001, in its Good Practice Guide: *"Venous catheterism. Recommendations for the elaboration of protocols for the care of venous lines*, the Paris-north CCLIN indicates that: *"The removal of needles is a delicate operation for the personnel, as a consequence of the risk of a blood exposure accident resulting from the rebound effect when the needle is removed. Several protective systems can be found on the market [...]. It is important to use the same equipment within the same hospital structure, and for the personnel to be suitably trained (BIII)"* [196].

■ In 2006, the ministry's *Guide for the prevention of healthcare-associated infections outside hospitals* recommends the use of a sweeping gesture during removal, and the use of safety equipment in order to avoid the risk of needlestick injury resulting from the rebound effect at the instant when the needle is removed [198].

■ In 2009, the *European Society for Clinical Nutrition and Metabolism* proposed that Huber needles be left in place for not more than one week [13].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* indicated that *"the needle must be changed every seven days, and if necessary, depending on individual circumstances, the frequency of treatment, and the changing of venous lines. Blood reflux in the catheter must be reduced when the needle is removed; as a consequence of the rebound effect, non-sterile gloves and a safety device must be used"* [14].

■ In 2010, in its Guide on safety Equipment, the GERES recommends that the medical devices used for invasive acts be selected from models whose safety has been demonstrated. The GERES recommends the safety Huber needle, because when the needle is removed from the septum there is a high risk of needlesticking the contralateral hand holding the injection site, due to the needle rebound effect. Provided there is an alternative approach, the GERES recommends two-handed activation, through the use of an activation gesture requiring the secondary hand to be placed near to the sharp point, as well as the use of an external safety element. Furthermore, as a consequence of the needle rebound effect when it is removed from the TIVC, the GERES recommends to avoid the use of equipment allowing the needle to be secured during removal, and the use of accessories to protect the secondary hand.

The safety criteria proposed for Huber safety needles are:

- *single-handed or bimanual safety procedure,*
- *irreversible locking with audible locking indication,*
- *visually verifiable safety system,*
- *small volume device, which is easy to use,*
- *simplest possible changes to the required gesture [175].*

■ In 2011, in *Guidelines for the prevention of catheter-related infections*, the CDC make no recommendation concerning the frequency with which totally implanted venous catheter

needles should be changed, nor concerning the period during which a needle may be kept in place (unresolved question) [102].

## **B – Analysis of the literature and rationale**

Needle removal is a delicate operation for the personnel, as a consequence of the risk of BBFE resulting from the rebound effect when the needle is removed, thus justifying the use of a protective system, of which several types can be found on the market [175,179]. In the opinion of some experts, since the removal of the Huber needle represents a BBFE risk, involving projection and needlestick injury, the nurse should wear a mask and non-sterile protective gloves. The patient must wear a mask or turn his/her head away from the treated area [219].

Technically speaking, removal of the needle produces a depression, which leads to blood reflux at the distal end of the catheter; this reflux can potentially lead to occlusion of the end of the catheter [184]. An experimental study has shown that the removal of the needle under positive pressure (with the needle being withdrawn whilst continuing to inject 0.9% sodium chloride) reduces blood reflux in the TIVC by 80% [220].

Concerning the frequency of needle changes, a retrospective study dealing with a cohort of 572 patients with a median follow-up at 242 days did not find a statistically significant difference in terms of infectious complications, if the needle was changed every three days or every seven days (5.2% vs 7.3%; NS) [46]. There is no other study designed to define the optimal rhythm for needle changes. Concerning the period of time during which the needle is kept in place, there are several possible cases: that of a patient whose TIVC is infused continuously and for whom the needle is kept in place throughout the full duration of the infusion, but also that of the patient whose TIVC is infused discontinuously during the day, and for whom maintaining the needle in place inside the non-

infused TIVC would probably pose a risk of infection. In practice, since this risk has not been evaluated, other elements such as the patient's comfort and the pain associated with needle insertion are often taken into account; for example a risk-benefit evaluation of daily needle changes for patients under discontinuous nutrition or receiving a daily infusion of antibiotics.

In general, the procedures advocate a needle change frequency corresponding to that of dressing changes, for cases involving continuous treatment. They tend to be imprecise when it comes to needle removal whenever the treatment is discontinuous. However, most procedures recommend that the needle not be left in place if there is no on-going treatment.

### **2-6-2 Recommendations**

#### **Operator and patient's garments when removing the needle**

**R83** The operator shall perform a handrub to disinfect his/her hands (**strong** agreement). He/she shall wear a surgical mask and non-sterile protective gloves to remove the needle (**simple** agreement).

**R84** The patient shall wear a surgical type of mask. If he/she does not tolerate the mask, he/she will be requested to turn his/her head towards the side opposite to that of the TIVC (**simple** agreement).

#### **Procedure when removing the needle**

**R85** Any person liable to remove a safety needle should be informed and trained for this procedure. When a safety needle is unavailable, a hand protection accessory should be used to remove the needle (**strong** agreement).

**R86** The TIVC should be rinsed before needle removal, and the removal should be performed under positive pressure. Once the

needle has been removed, a slight pressure is applied to the puncture point using an antiseptic-impregnated sterile gauze (**strong** agreement).

### Needle replacement frequency

**R87** The needle cannot be kept for more than eight days (**strong** agreement). In case of daily non-continuous use of the TIVC, the needle can be left in place provided a risk-benefit analysis has been performed for the patient (**simple** agreement). In other situations, the needle shall be removed after use. The presence of local inflammatory signs requires needle removal (**strong** agreement).

## 2-7 Periodic maintenance

In the literature dealing with TIVCs, two distinct notions are sometimes confused: that of “flushing”, which involves a single rinsing operation and can be immediately followed by catheter use, and that of a preventive lock, the principle of which is to instill into the catheter, as well as the chamber, a highly concentrated product which remains there for several hours or days. These flushing and locking techniques are used to obtain a high concentration of antimicrobial (antibiotics: vancomycin, gentamycin, minocycline, ... or other: taurolidine, citrate, ...) products, which are assumed to prevent the intraluminal fixation of microorganisms, or strong concentrations of anticoagulant products which are assumed to prevent the formation of thrombi (heparin, urokinase, ...).

Care must be taken however, since the concept of an antibiotic lock has also been applied to curative treatment, which can lead to confusion. Although the curative treatment of catheter infections is not included in the framework of the present recommendations, it is nevertheless important to note that those recommendations mentioning a curative lock state that it must be systematically associated with a curative systemic antibiotherapy [47].

## 2-7-1 Review of the literature

### A – Existing regulations and recommendations

■ In 2007, in its recommendations for the insertion and management of central venous lines in adults, the *British Committee for Standards in Haematology* recommends limiting the use of heparin, in order to avoid heparin-induced thrombocytopenia resulting from excessively frequent flushing. Heparin flushing can nevertheless be used when recommended by the manufacturer, in particular when this is done intermittently. The latter proposes flushing with 10 ml of 0.9% saline + possibly 5 ml of heparin, following each access to the venous line, or once a month. The flushing must be pulsatile and be carried out under positive pressure, using a syringe with a gauge greater than 10 ml to avoid excessive pressure, which would lead to catheter breakage. It should also be noted that TIVCs with valves do not require the use of heparin, and must be flushed with a saline solution [12].

■ In 2008, the SHEA/IDSA considered that preventive “antibiotic” locks should be strictly limited to the following two situations: patients having a limited venous capital and having repeatedly been affected by bacteremia on a central catheter, or patients with a foreign intravascular device (mechanical valve, aortic graft, ...) [101].

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* recommended not to use an antimicrobial lock, because of the risk of toxicity and the emergence of bacterial resistance [14].

■ In 2009, the *European Society for Clinical Nutrition and Metabolism* recommended regular maintenance, by means of a heparin lock (after flushing with a saline solution), of TIVC which have not been used for more than eight hours, whenever this is recommended by

the manufacturer. Catheters with valves must be flushed and locked only with a saline solution [13].

■ In 2011, in *Guidelines for the Prevention of Intravascular Catheter-Related Infections*, the CDC had a reserved opinion of the “antibiotic” lock. Indeed, in view of the risk of selecting resistant strains, or even of toxicity through extraluminal diffusion of the solution, the indications for a lock are restricted to specific circumstances: patients having a long term catheter and having multiple antecedents of catheter bacteremia, despite optimal observance of the highest level of hygiene precautions (Cat II).

Similarly, it is recommended not to make routine use of anticoagulant treatment to reduce the risk of infection in the general patient population (Cat II) [102].

## **B – Analysis of the literature and rationale**

Two studies carried out in pediatric oncology have dealt with the use of TIVCs. One randomized study included 64 patients who received (or did not receive) a vancomycin flush each time the TIVC was used. There was no difference in the number of bacteremia observed (2/30 vs 3/34) [221]. An open study of 14 patients was compared with an historical series, and investigated a minocycline-EDTA solution lock left in place and changed every week. No infection was observed after six months of follow-up, as compared to an incidence rate of 2.2 per 1000 catheter days in the historical cohort [222].

The use of an antimicrobial lock for the prevention of hemodialysis catheter infections produced several meta-analyses, of which three were published in 2008. The most complete of these included 16 studies and concluded on the efficiency of a preventive lock in reducing the incidence of bacteremia (RR = 0.44; 95% CI: 0.38-0.5) [223]. In the case of the other types of catheter, there is

less data available. A meta-analysis published in 2006 included seven studies dealing with locks or flushes using vancomycin [224]. Three of the studies used a lock, four used a flush, and only one dealt with adults. A reduced risk of bacteremia was also revealed (RR = 0.49; 95% CI: 0.26-0.95; p = 0.03) [221, 225-230]. A new non-antibiotic product appears to be promising since it has no risk of selecting resistant strains. Taurolidine, initially used for hemodialysis catheters, was recently evaluated in a before-and-after cohort study, over a period of four years in pediatric oncology. The bacteremia incidence rates decreased from 2.3 to 0.45 per 1000 catheter-days (p = 0.004) [231]. However, it is difficult to propose a reference protocol, because these studies covered a broad range of molecules (gentamycin, amikacin, minocycline, cefotaxim, cefazolin, vancomycin), concentrations (for example amikacin: 1.5 mg/ml diluted in 3 ml of saline solution; vancomycin: 2 mg/ml diluted in 3 ml of saline solution) and locking techniques (time left in place, replacement frequency, use or not of the catheter between interventions with the lock). The lock is re-aspirated before installation of the infusion, and is not flushed as a consequence of the toxic risk of certain molecules. Finally, in the case of multi-line TIVCs, each line must be instilled.

It is important to emphasize that in the case of the two national recommendations proposing the possibility of using preventive locks, the rationale is based on the occurrence of repetitive bacteremia, but not of non-bacteremial infections, and no specific antibiotic is recommended. In a patient affected by repeated bacteremia, it would be logical to try to deal with the pathogens identified at the time of the previous bacteremia. In the case of patients fitted with an intravascular device, the only solution which can be proposed is one based on the local ecology of the TIVC infections.

The choice of a heparin vs a saline flush remains controversial. Three meta-analyses of randomized controlled trials evaluated the role

of heparin in maintaining the permeability of peripheral or central venous catheters, and concluded that an intermittent heparin flush has no advantage over a flush using saline solution, except in certain specific cases such as the use of hemodialysis / apheresis catheters or infrequent venous access [232-234]. No randomized trial has determined the ideal heparin concentration, nor the frequency of catheter heparinization for catheters which remain unused for long periods of time. Nevertheless, the authors converge on heparin concentrations varying between 50 and 500 units per ml, and agree on weekly maintenance for small-caliber devices and every three to four weeks for large caliber devices [13]. A meta-analysis of randomized trials published in 2008 compared the efficiency of a lock or flush associating urokinase and heparin, with a lock or flush using heparin only, for the prevention of infectious complications associated with TIVC. It revealed a significantly lower risk in the case of urokinase associated with heparin (RR = 0.77; IC 95%: 0.60-0.98) [235]. Finally, an Italian multicenter study designed to assess the incidence of delayed complications in 1076 patients carrying a TIVC showed that the use of a monthly heparin flush can lead to complications; in effect, in the 561 patients for whom flushing was the only application for

which the TIVC was used, the rate of complications was 0.15 per 1000 catheter-days [30].

## 2-7-2 Recommendations

**R88** Routine use of a heparin lock or flush is not needed to prevent TIVC-associated infections. Routine use of an antibacterial (antibiotic, or the like) lock or flush is not useful to prevent TIVC-associated infections (**strong** agreement).

**R89** Use of a preventive antibacterial lock can be advised if the central venous capital is limited in a patient who has suffered from several TIVC-associated bacteremia or in patients with an increased risk of complications, in case of a catheter-associated bacteremia (for example, for those patients provided with a mechanical valve or an synthetic aortic graft). When an antibacterial lock is indicated, taurolidine or another molecule with proven efficacy in preventing catheter-associated infections should preferably be used (**simple** agreement). When a lock is indicated, the product used shall not be mixed with another one. If periodical maintenance indications are retained, a detailed written institutional procedure should be provided (**strong** agreement).



# GENERAL POLICY ASPECTS

## 3-1 Informing and educating the patient

### 3-1-1 Review of the literature

#### A – Existing regulations and recommendations

■ The law of March 4<sup>th</sup>, 2002 stipulates that “[...] all persons have the right to be informed about their health [...]” and that “[...] this information shall relate to the various investigations, treatments or preventive acts which are proposed, their usefulness, their consequences, the frequent or serious risks which they could normally be expected to involve, as well as the alternative solutions, and the foreseeable consequences should the patient refuse [...]” [77].

■ When this information is related to the risk of infection, more specific modalities are described in the circular letter DHOS\E2-DGS\SD5C n°21 of January 22<sup>nd</sup>, 2004 relative to the reporting of nosocomial infections and the informing of hospital patients. This obligation to inform the patient is recalled in the professional ethics codes [236].

■ Article L1111-2 of the public health code stipulates that: “*Written and oral information must be given to the patient prior to insertion. Exhaustive, clear and understandable, this information shall describe the benefits and risks, as well as the instructions for maintenance and the management of complications. The aim is to ensure the comfort and safety of the patient. This*

*information must be part of the patient information provisions. Articles R-5212-36 to 42 state: “The rules of traceability must be applied to the implanted material”.*

■ The circular letter DH/EM 1 n°96-6225 of October 28<sup>th</sup>, 1996 recommends that “*the surveillance notebook comprise the following elements: name of the patient, hospital where the device was inserted, model and lot number of the inserted device, key precautions to be adhered to during use of the inserted device, as well as the dates when infusions and injections were carried out. The notebook must be given to the patient, who must systematically show it to the medical teams who handle his/her catheter [...]*” [172].

■ In 2000, in the reference document entitled *Evaluation of the quality of use and surveillance of totally implantable catheters*, and more precisely in the paragraph entitled “Information and educative procedure”, the ANAES recommends verifying that the patient is aware that he/she is going to have a TIVC inserted. “*During the interview with the patient, it is recommended that he/she be shown the material and its localization by means of diagrams, that he/she be given an information leaflet, that it be proposed that he/she should meet other patients wearing a TIVC*”. This document also specifies that before leaving the hospital the patient must be informed about the need to monitor the insertion site during everyday life. “*At the end of the hospital stay, it is recommended to verify and evaluate the accuracy and understanding of the information given to the patient; update and correct as necessary*”.

*“When he/she returns home, it is possible that the patient may need to carry out certain acts on the TIVC himself/herself. This requires training, which implies the involvement of full hospital and outpatient services, and private nurses. It is thus recommended that the patient be taught:*

- *the manipulations he/she may be required to carry out: stopping an infusion, flushing (with or without heparin), removing the needle from the insertion site, dressing;*
- *how to detect the first signs of complications (inflammation, hematoma, infection);*
- *how to carry out a regular personal examination of the insertion area.*

*The retained evaluation criteria are thus as follows:*

- *The patient is informed (information medium) about:*
  - *incidents related to the TIVC as well as a basic understanding of surveillance;*
  - *the conduct required in the event of a problem, and the telephone numbers to be called.*
- *The information given to the patient is evaluated and, if necessary, adapted (and recorded in the patient’s file) before his/her discharge” [3].*

■ In 2004, in the consensus conference *Management of pre-operative infectious risk* the SF2H recommended that *“Patient information must indicate that any invasive act involves a risk of infection, and that all possible means will be used to prevent its occurrence, with the understanding that there is no such thing as zero risk. The clinician in charge of the surgical procedure delivers information to the patient allowing him/her to make a risk-benefit evaluation of the operation. The patient’s file must report the fact that information concerning the surgical, in particular infectious, risk has been provided” [127].*

■ In 2009, the *Queensland Health - Centre for Healthcare related infection surveillance and prevention* indicated its wish for patients to be

trained in dispensing the care they ultimately need to provide: TIVC access, dressing replacement, flushing. Whenever possible, the patient’s knowledge and ability to put this into practice are checked [14].

■ In 2010, in the chapter “Infections associated with intravascular devices” of the *Surveillance and Prevention of healthcare-associated infections* guide, recommendation R101 indicates that:

*“[...] The patient is informed of the risk of infection associated with IVDs and is thus included, together with his/her close relatives, in the prevention and detection of IVD-related infections through a suitable educative approach” [94].*

### 3-1-2 Recommendations

**R90** It is highly recommended that a surveillance notebook with all of the items provided in the circular letter No 96-6225 being given to the patient (Regulatory). The advantages of recording notes in the surveillance notebook shall be explained to the patient or his/her close relatives (**strong** agreement).

**R90** It is highly recommended to inform the patient about the infectious risk associated with the insertion as well as use of a TIVC as well as TVIC-associated incidents (Regulatory). The patient or close relatives shall be involved in the prevention of TIVC-associated infections and in the detection of TIVC-associated infections. They shall be informed about the conduct to be followed in the case of problems and shall be given phone numbers to call. The information provided to the patient or close relatives shall be evaluated and, if necessary, re-adjusted on a regular basis during his/her hospital stay (**strong** agreement).

## 3-2 Professional training and assessment of practice

### 3-2-1 Review of the literature

#### A – Existing regulations and recommendations

■ The circular letter DGS n° 381 of March 2<sup>nd</sup>, 1990 relative to the continuous professional training of nurses taking part in anti-cancer chemotherapy treatments, and more specifically making use of implantable vascular access devices installed by a doctor, provides in its appendix a continuous professional training guide and stipulates in particular that a certificate must be given to the personnel who have attended such training [237].

The order of April 13<sup>th</sup>, 2007 foresees that nurses be authorized to prescribe the accessories required in the use of a totally implanted venous catheter or a tunneled catheter: needles required for the totally implanted venous catheter; needle, transparent adhesive, extension tube, three-way stopcock; sterile, disposable accessories for heparinization: syringes or suitably adapted needles, extension tube, three-way stopcock, I.V. stand on casters [238].

■ The decree 2004-802 of July 29<sup>th</sup>, 2004 stipulates:

- Article R.4351-2, for medical electro-radiology manipulators: “[...] oral, rectal intravenous, sub-cutaneous and superficial vein injections, in implantable vascular access devices and central catheters [...]”.
- Article R.4311-5, for nurses: Surveillance corresponding to the nurse’s own responsibility: “31° Surveillance of scarring, injections and infusions mentioned in articles R.4311-7 and R. 4311-9”;
- Article R.4311-7, for nurses: Surveillance of central venous catheters and implantable vascular access devices installed by a doctor; 5° Injections and infusions, excluding the first of these, in catheters as

well as in central venous catheters and the following:

a) products other than those mentioned in the second paragraph of article R.4311-9;

b) products which do not contribute to the general or loco-regional anesthetic technique mentioned in article R.4311-12.”

- Article R.4311-7, for nurses: blood samples requiring a medical prescription: “35° Blood sampling by means of venous or capillary puncture or with the use of a venous catheter” [195].

■ The circular letter DGS/DH/DRT n°98-228 of April 9<sup>th</sup>, 1998 relative to standard precautions states: “These protocols must be known by the personnel and their application must be regularly evaluated” [173].

■ In 1997, in its recommendations entitled *Prevention of infections associated with indwelling intravascular access devices*, the Canadian public health agency states that the usefulness of specialized teams for the insertion and management of intravascular catheters has been documented. It recommends that: “Each hospital or organization should be organized such that the nurses and doctors, in particular those who are involved in emergency interventions, take part in regular training sessions and observe the policies and protocols concerning the use of intravascular catheters. The presence of a specialized team for the insertion and management of intravascular catheters simplifies the upkeep of a high degree of competence (AI). The patients should have access, whenever necessary, to trained professionals throughout the entire duration of the use of an intravascular device (AIII)” [212].

■ In 2000, in *Evaluation of the quality of use and surveillance of totally implantable catheters*, the ANAES refers to recommendation n° 82 of the CTIN, made in 1999, i.e. that: “[...] the insertion of a central venous catheter is carried out by an operator trained in insertion, under conditions of surgical

asepsis. [...] Regular clinical surveillance, in order to detect any local or general complication inherent to its insertion or use, is indispensable since it is vital that any anomaly, which could indicate the presence of an infection, be detected as early as possible” [3].

■ In 2010, in the chapter entitled "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, in recommendations R100, R101 and R102, the SF2H proposes the following:

*“ IVD insertion, management and surveillance techniques are described in datasheets or protocols and are updated following the publication of new recommendations. The insertion and surveillance of IVDs are carried out by authorized personnel. The traceability of the IVD insertion is ensured in the patient’s file: date of insertion, date of removal, type of catheter, insertion site, operator. Clinical surveillance of the IVD insertion site is carried out at least daily (search for local signs).*

*The healthcare personnel receives training in the use of IVDs, their insertion and maintenance procedures, and in the application of measures for the prevention of IVD-related infections [...].*

*The practice of professionals in charge of inserting and maintaining IVDs is evaluated on a regular basis. The evaluation of this practice is carried out using suitably adapted tools, including a checklist allowing the recommendations to be consulted and their observance to be evaluated. It is indispensable for errors in IVD practice to be identified and error rate feedback to be provided to the healthcare team” [94].*

■ In 2011, in *Guidelines for the Prevention of Intravascular Catheter-related Infections*, the CDC recommends:

- *Training the healthcare personnel in the indication, insertion, and maintenance of intravascular catheters, and implementing*

*appropriate measures for the prevention of catheter-related infections (Cat IA).*

- *Designating qualified personnel only, who have demonstrated their competence in the insertion and maintenance of peripheral and central venous catheters (Cat. IA).*
- *Regularly verifying the knowledge and observance of recommendations of all professionals who insert and use intravascular catheters (Cat. IA).*
- *Regularly monitoring the catheter insertion sites, by visual inspection or palpation through an intact dressing. If the patient presents with an induration at the insertion site, an otherwise unexplained fever, or other signs evoking a local or systemic infection related to the catheter, the dressing must be opened to allow closer examination of the site (Cat. IB)” [102].*

## **B – Analysis of the literature and rationale**

The difficulties encountered at the time of catheter installation are infectious risk factors [84]. In a cohort of 371 patients followed in oncology, of which 80% were fitted with a TIVC, multivariate analysis showed that the occurrence of an infection was significantly associated with patients below ten years of age, the catheter’s use for parenteral nutrition, and difficulties with catheter insertion (OR = 25; 95% CI: 4.2-106) [41].

The training of professionals and specialized teams in the use of central venous catheters are factors, which contribute towards a reduction in the risk of infection associated with central venous catheters, in particular in the field of parenteral nutrition [13]. A retrospective study of 221 patients in parenteral nutrition revealed a fall in the incidence rate of complications, from 6.8 to 3.2 per 1000 catheter-days, following the implementation of an intensive training program [38]. A recent publication asserts that training and infectious risk awareness during the insertion of central venous lines make it possible to achieve a significant reduction in

the number of complications, even in the case of poorly trained operators [130]. More generally, several studies have shown that a prevention program allows the avoidable proportion of infections associated with central intravenous devices to be reduced. Recent studies carried out in intensive care units are in favor of the implementation of combined measures, within the context of a global *bundle* strategy [239-242].

### 3-2-2 Recommendations

**R92** Healthcare institutions in which patients fitted with a TIVC are treated shall designate a specialized team or referral persons skilled in the use of such devices. These persons may provide assistance to professionals seeking advice. Only staff members who have received specific training shall be allowed to install and use a TIVC. Any change in care modalities or hardware will require informing or training of all professionals in a given healthcare network (**strong** agreement).

**R93** Operators should use good practice procedures for the prevention of infectious risks, with procedures being written and updated as regards the installation, use and monitoring of the TIVC. Common procedures will be used among a given healthcare network (**strong** agreement).

**R94** Continuous clinical monitoring for local or general complications inherent to the installation or use of a TIVC is indispensable (**strong** agreement).

**R95** The knowledge and practice of professionals in charge of TIVC installation and of those in charge of TIVC use are assessed on a regular basis. All professionals who will have to care for a patient should be made aware of the importance of careful completion of the monitoring notebook. The traceability of interventions relies on the recording and sharing (between all hospital personnel involved in the patient's care) of the monitoring notebook (**simple** agreement).

## 3-3 Epidemiological surveillance

### 3-3-1 Review of the literature

#### A – Existing regulations and recommendations

■ The decree 2001-671 of July 26<sup>th</sup>, 2001 relative to the reporting of nosocomial infections states that: *“Hospitals must anonymously report the occurrence of any nosocomial infection, in accordance with the criteria provided in article R.711-1-12”* [243].

■ In 2010, in the chapter "Infections associated with intravascular devices" of the *Surveillance and Prevention of healthcare-associated infections* guide, recommendation R103 states that ... *“Continuous surveillance of IVD associated infections (bacteremias) is established in high-risk units (critical care and intensive care units). The results are expressed as the number of IVD associated bacteremias per 1000 catheter-days.”* [94].

■ One of the objectives of the 2009-2013 National Program for the prevention of nosocomial infections is that 100% of hospitals should use tools assisting the observance of measures aimed at the prevention of infections, and methods for the analysis of the causes of serious infectious events [177].

#### B – Analysis of the literature and rationale

The published epidemiological data concerning TIVC-related infections is disparate, as a consequence of the heterogeneity of situations in which they are used, of the duration of surveillance and also the diagnostic criteria retained and means used to express the frequency of infections in terms of incidence rate (number of infections for 1000 catheter-days) or prevalence (number of infections per 100 TIVC) [244]. The frequency of TIVC use, the number of times the venous line is opened, and the effective

period of use, which must be collated in the surveillance notebook, are all significant elements for the interpretation of surveillance data.

### 3-3-2 Recommendations

**R96** In hospitals, a program for the epidemiological monitoring of the TIVC-associated infectious risk is established by the authority responsible for nosocomial infection control and the hospital hygiene team in conjunction with the clinical departments involved. The definition of a TIVC-associated infection used for such monitoring was recommended nationally by the CTINILS in 2007. Infection rates are expressed as the number of infections for 1000 days of TIVC presence (**strong** agreement). They should be expressed as the number of infections per 1000 days of TIVC use. Within this framework,

data collected in the surveillance notebook can be used to calculate the denominator. Epidemiological monitoring shall be performed when changing the healthcare procedures or the hardware used in a healthcare network (**simple** agreement).

**R97** Routine culturing of the TIVCs removed after treatment is not recommended (**strong** agreement). However, if a follow-up of colonization or infections is considered, systematic culturing of the removed TIVCs can be performed, subject to a standardized analysis technique (**simple** agreement).

**R98** The occurrence of a severe TIVC-associated infection (bacteremia, death, infection justifying removal) requires that this be reported to the operational hospital hygiene team (**strong** agreement) and that its causes be analyzed (**simple** agreement).



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# APPENDICES

**Strategy used in the documentary and bibliographical search**

**Descriptive diagram of a totally implantable venous catheter with and without a valve**

**Proposed line arrangements**

**Reporting an accident or the risk of an accident**

(French AFSSAPS form)

## Strategy applied to the documentary and bibliographical search

The documentary search was carried out by two project managers (Aurélié Bertaut and Pierre Cassier), and the bibliographic search strategy was defined by the pilot group. This included the interrogation of national and international databases (NosoBase, Medline, ScienceDirect, Cochrane) and the Internet sites of the main learned societies and institutes concerned by this subject. Only those publications written in French or English and including an abstract were searched. As far as possible, the search gave preference to papers published since the year 2000.

The following keywords were used:

“Port-a-cath” [MeSH], “Infusion pump” [MeSH], “Implantable” [MeSH], “Implantable port” [MeSH], “Infection” [MeSH], “Prevention” [MeSH], “Central venous catheter” [MeSH], “Indwelling” [MeSH], “Port-a-cath infection” [Text Word], “Port-pocket infection” [Text Word], “Jugular” [Text Word], “Subclavian” [Text Word], “Antibiotic lock” [Text Word].

The search strategy included cross-comparison of these keywords using the *AND* and *OR* operators.

A first selection was made based on the titles of the publications. The abstracts were read in order to refine the selection of papers dealing with TIVCs. Some bound publications found on Pub Med were consulted. Finally, consultation of the bibliographical references of the aforementioned papers allowed additional papers to be retained.

A summary table of all of these papers, indicating their date of publication, the main author's name, the type of document (recommendations, good practice guide, systematic review or scientific paper), as well as the key ideas conveyed by the paper, was compiled and distributed to the members of the pilot group in charge of drafting the various rationales and recommendations.

In addition, in order to identify discrepancies in their recommendations or practices, and in certain cases to assign them a rank, the group looked into the “local” protocols, which can be consulted using the internet and into the results of professional practice evaluations presented in various national conferences related to the use of TIVCs in healthcare.

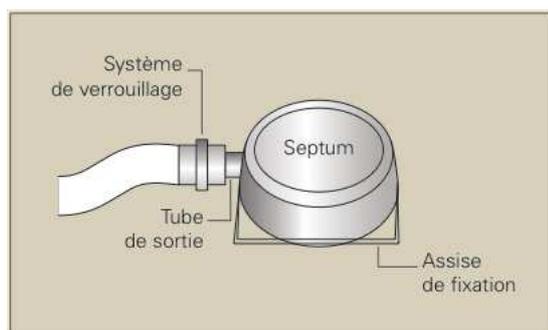
## Descriptive diagram of a totally implantable venous catheter with and without a valve

### A TIVC is comprised of

■ A subcutaneous injection container (the chamber), compatible with magnetic resonance imagery as a result of its passivity with respect to electromagnetic radiation, and fitted with a silicone-based membrane (septum) on its upper surface;

■ A catheter.

The chambers can be simple or dual, depending on the medical indications. The material from which they are made, together with their injection and infusion accessories, are governed by materials vigilance, which may lead to the withdrawal of certain products from the market.



#### Translation of terms used in the figure

*Système de verrouillage -> Locking system*

*Septum -> septum*

*Tube de sortie -> Output tube*

*Assise de fixation -> Attachment base*

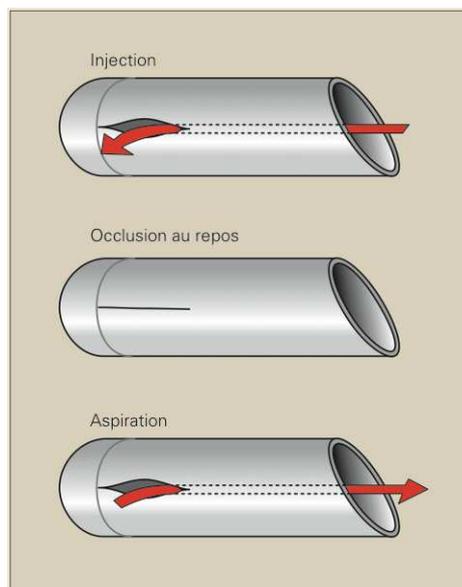
### Catheters

These are radio-opaque, are connected to the chamber, and are generally inserted into the vascular system via the jugular or subclavian access (via the femoral route when the latter two cannot be used), and can be attached to the implantable chamber at the time of manufacture, or be connected by means of a (locking ring) system which is installed at the time of insertion. The majority of catheters belong to the following two types:

■ The simple catheter (made of silicone or polyurethane) the distal end of which is open (conventional orifice);

■ The catheter fitted with a so-called GROSHONG® anti-reflux valve. This is made from a silicone elastomer, the end of which is not fully open to the circulatory flow. This distal end has an anti-reflux valve.

GROSHONG® catheter - valve operation



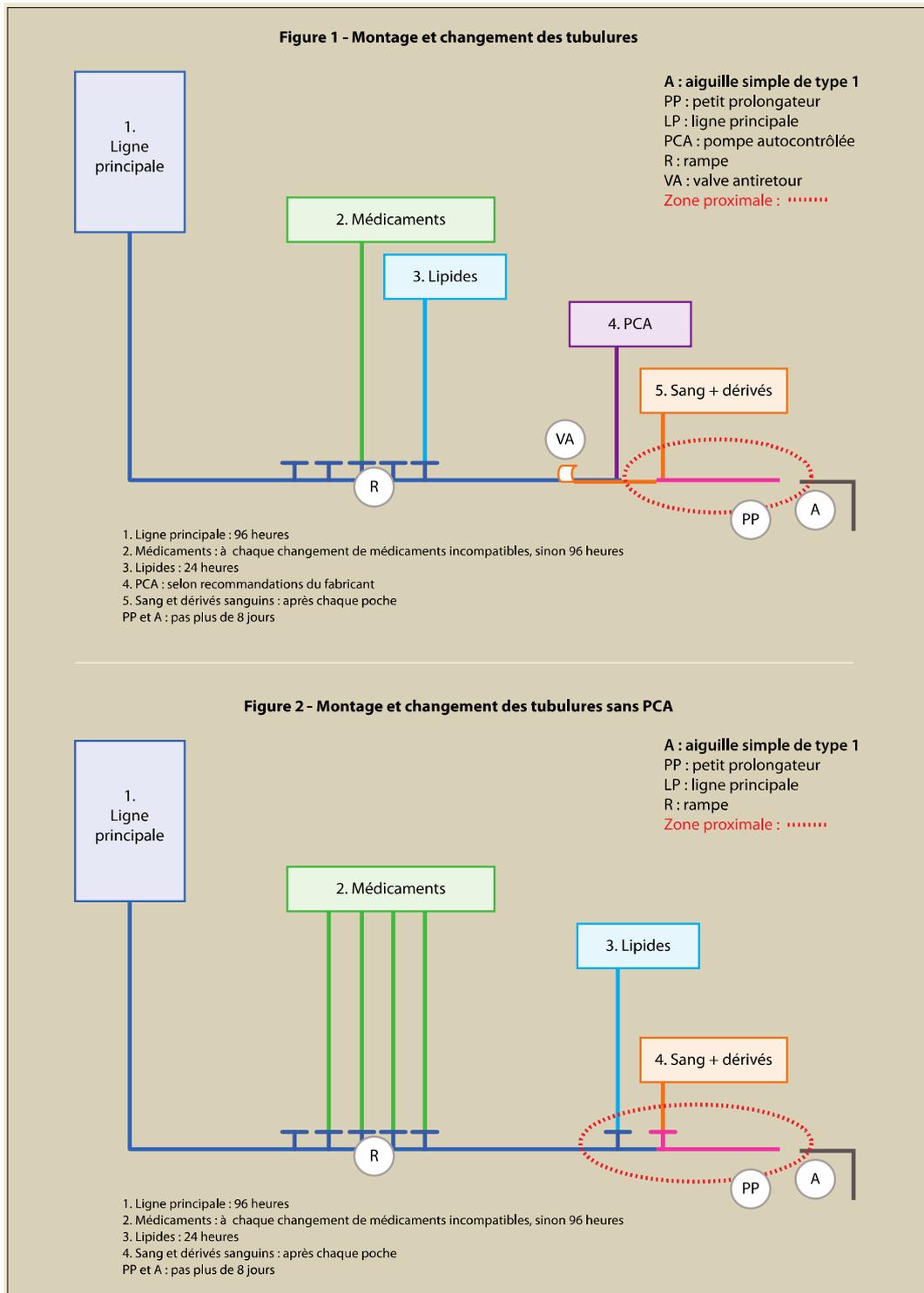
#### Translation of terms used in the figure

*Injection -> Injection*

*Occlusion au repos -> Occluded when at rest*

*Aspiration -> Aspiration*

# Proposed installation with and without Self-controlled infusion pump (SIP), with a type I needle



### Translation of terms used in Figure 1

**Montage et changement des tubulures -> Installation and replacement of tubing**

Ligne principale -> Main line

Médicaments -> Medication

Lipides -> Lipids

PCA -> SIP

Sang + dérivés -> Blood + derivatives

aiguille simple de type I -> Simple type I needle

petit prolongateur -> short extension

pompe autocontrôlée -> **Self-controlled infusion pump**

rampe -> ramp

valve antiretour -> anti-reflux valve

zone proximale -> proximal zone

1. Ligne principale : 96 heures -> 1. Main line: 96 hours

2. Médicaments : à chaque changement de médicaments incompatibles, sinon 96 heures -> 2. Medication: whenever incompatible medication is changed, otherwise 96 hours

3. Lipides : 24 heures -> 3. lipids: 24 hours

4. PCA : selon recommandations -> 4. PCA: according to recommendations

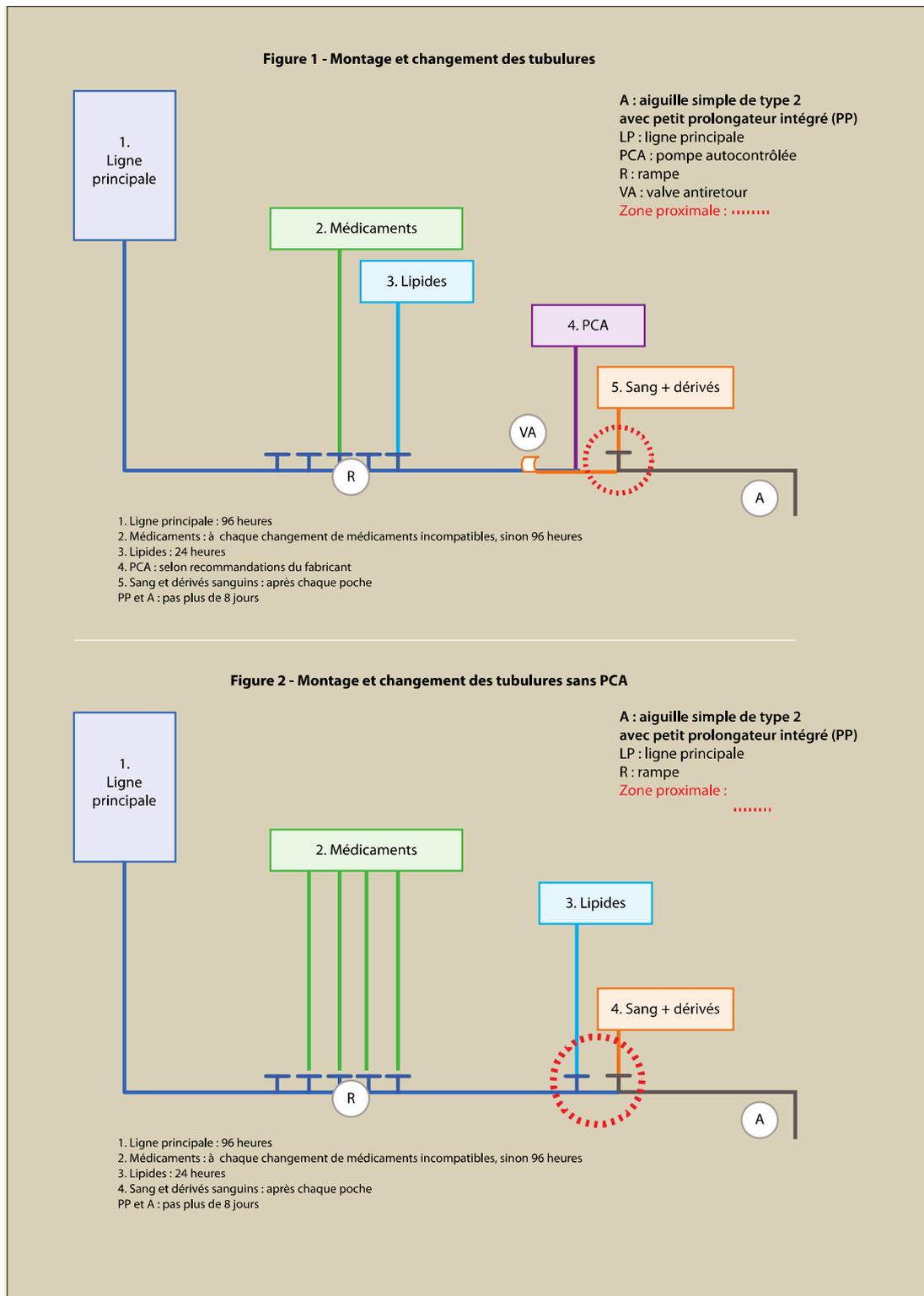
5. Sang et dérivés sanguins : après chaque poche -> 5. Blood and blood derivatives: after each change of bag

PP et A : pas plus de 8 jours -> PP and A: not more than 8 days

### Translation of the title of Figure 2

**Montage et changement des tubulures sans PCA -> Installation and replacement of tubing in the absence of SIP**

## Proposed installation with and without Self-controlled infusion pump (SIP), with a type 2 needle



### Translation of new terms not provided with the previous Figures

*Aiguille simple de type 2 avec petit prolongateur intégré (PP) -> Simple type 2 needle with short integrated extension (PP)*

*PCA : Pompe autocontrôlée -> **Self-controlled infusion pump***

*PCA : selon recommandations du fabricant -> SIP: according to the manufacturer's recommendations*

*Pas plus de 8 jours -> not longer than 8 days*

# Reporting an accident or the risk of an accident

(French AFSSAPS form)



**afssaps**  
Agence française de sécurité sanitaire  
des produits de santé

143147, bd Anatole France  
93285 Saint-Denis Cedex  
Fax : 01 55 87 27 02

**ENVOYER PAR FAX :**  
Si un accusé de réception ne vous est pas parvenu dans les 10 J, prière de confirmer le signalement par EMAIL POSTAL AFSSAPS A.S.



**SIGNALEMENT  
D'UN  
INCIDENT ou  
RISQUE D'INCIDENT**

Code de la Santé publique : articles L. 5212-2,  
R. 5212-14 à 19.



N°10246103

Code réservé à l'AFSSAPS

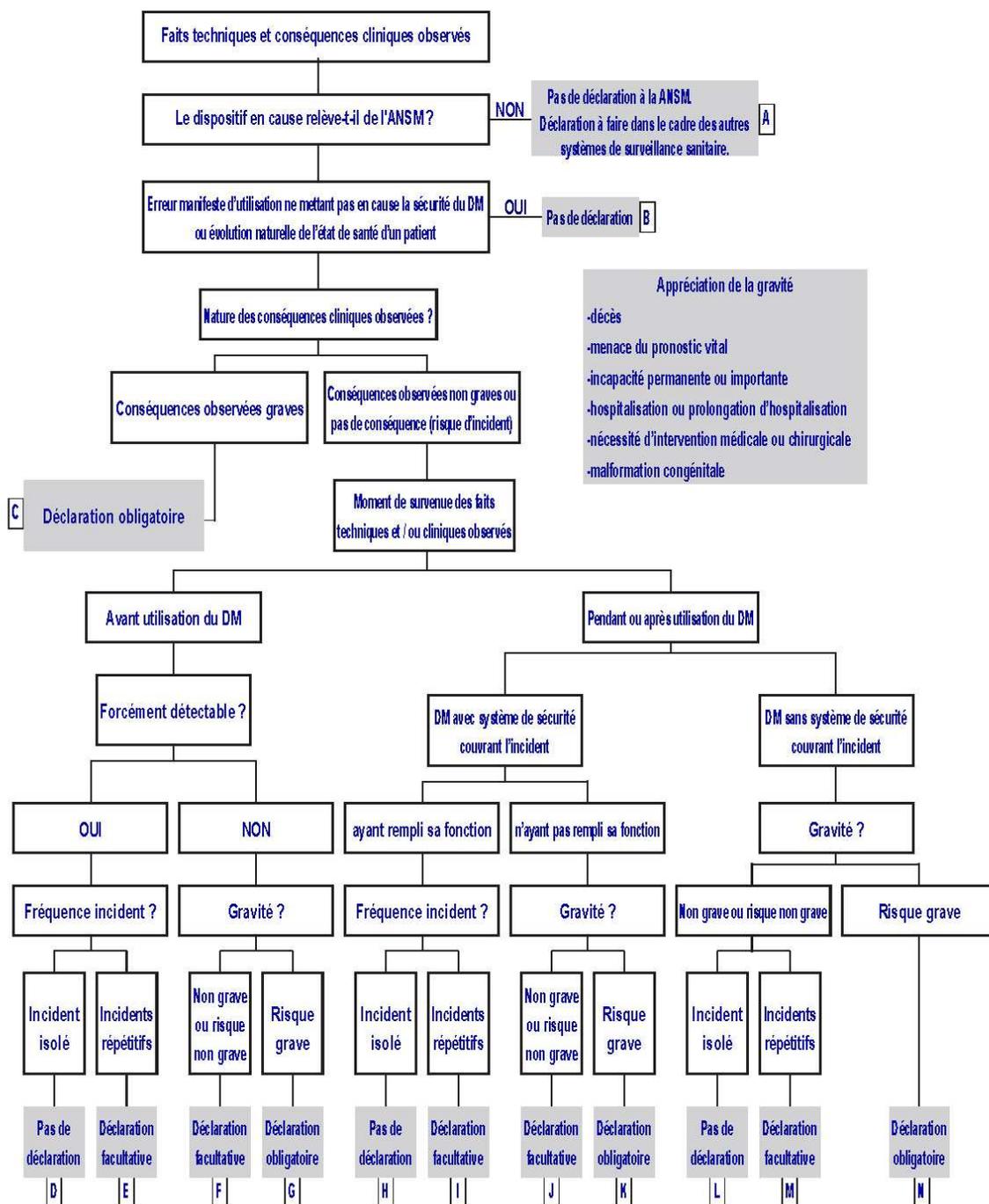
Numero  
Attributaire  
Droit-commission  
Date d'attribution  
Date d'envoi du signalement

<b>L'émetteur du signalement</b>		<b>Le dispositif médical impliqué (D M)</b>	
Nom, prénom		Dénomination commerciale du D M	
Qualité		Dénomination commerciale, modèle, type, référence	
Adresse professionnelle		N° de série ou de lot	Version logicielle
code postal / commune		Nom et adresse du fournisseur	
E-mail		code postal / commune	
Téléphone / Fax		Nom et adresse du fabricant	
<input type="checkbox"/> Etablissement de santé : N° FINESS <input type="checkbox"/> Association distributeur DM à domicile ?		<input type="checkbox"/> Fabricant / Fournisseur <input type="checkbox"/> Autre	
L'émetteur du signalement est-il le correspondant matérielogence ?		code postal / commune	
<input type="checkbox"/> Oui <input type="checkbox"/> Non			
<b>L'incident ou le risque d'incident</b>			
Date de survenue		Lieu de survenue	
Si nécessaire : nom, qualité, téléphone, fax de l'utilisateur à contacter			
Circstances de survenue / Description des faits		Conséquences cliniques constatées	
<p style="font-size: small;">Ce fait doit être décrit avec une description plus complète sur papier libre. Préparer avec le matériel de copie (papier, carnet, ...)</p> <p style="font-size: small;"><input type="checkbox"/> et reporter le tout de l'émetteur sur chaque page.</p>		Mesures conservatoires et actions entreprises	
Situation de signalement (de A à N) <input type="checkbox"/> voir recommander page 20		Le fabricant ou fournisseur est-il informé de l'incident ou risque d'incident ?	
		<input type="checkbox"/> Oui <input type="checkbox"/> Non	

La loi n° 78-17 du 6 janvier 1978 relative aux fichiers nominatifs garantit un droit d'accès et de rectification des données auprès de l'organisme distributeur de l'information (AFSSAPS).

**Imprimer tout**
**Valider**

# Aide au signalement des incidents



## Translation of the terms used in the AFSSAPS accident reporting form (p.1)

*Signalement d'un incident ou risque d'incident -> Reporting of an incident or the risk of an incident*

*L'émetteur du signalement -> Person making the report*

*Nom, prénom -> Family name, first name*

*Qualité -> Hierarchical status*

*Adresse professionnelle -> Professional address*

*Code postal -> Zip code*

*commune -> City or town*

*Etablissement de santé : N°FINESS -> Hospital : FINESS N°*

*Association distribuant DM à domicile -> Association which provided home delivery of the M D*

*L'émetteur du signalement est-il le correspondant matériovigilance ? -> Is the person making the report the MD vigilance correspondent?*

*L'incident ou le risque d'incident -> The incident or risk of an incident*

*Date de survenue -> Date of occurrence*

*Lieu de survenue -> Place of occurrence*

*Circonstances de survenue / Description des faits -> Circumstances of occurrence / Description of the facts*

*Situation de signalement -> Reporting situation*

*Conséquences cliniques constatées -> Observed clinical consequences*

*Mesures conservatoires et actions entreprises -> Conservative measures and actions taken*

*Le fabricant ou fournisseur est-il informé de l'incident ou risque d'accident ? -> Has the manufacturer or supplier been informed about the incident or risk of an incident?*

*Le dispositif médical impliqué (D M) -> Medical Device involved (M D)*

*Dénomination commune du D M -> Common name for the M D*

*Dénomination commerciale : modèle / type / référence -> Commercial name: model / type / reference*

*N°de série ou de lot -> Serial or lot N°*

*Version logicielle -> Software version*

*Nom et adresse du fournisseur -> Name and address of supplier*

*Nom et adresse du fabricant -> Name and address of manufacturer*

## Translation of the terms used in the AFSSAPS accident reporting form (p.2)

*Aide au signalement des incidents -> Incident reporting assistance*

*Fiches techniques et conséquences cliniques observées -> Datasheets and observed clinical consequences*

*Le dispositif en cause relève-t-il de l'AFSSAPS ? -> Is the suspected device covered by AFSSAPS rules?*

*Pas de déclaration à l'AFSSAPS. Déclaration à faire dans le cadre des autres systèmes de surveillance sanitaire.*

*-> No declaration made to the AFSSAPS. Declaration to be made in the context of other sanitary surveillance systems.*

*Erreur manifeste d'utilisation ne mettant pas en cause la sécurité du DM ou évolution naturelle de l'état de santé d'un patient*

*-> Obvious manipulation error, which does not raise concerns about the MD's safety, or natural change in the patient's health conditions*

*Pas de déclaration -> No declaration*

*Appréciation de la gravité*

- décès*
- menace du pronostic vital*
- incapacité permanente ou importante*
- hospitalisation ou prolongation d'hospitalisation*
- nécessité d'intervention médicale ou chirurgicale*
- malformation congénitale*
- > ...*

*Evaluation of the incident's gravity*

- death*
- life-threatening*
- permanent or significant disability*
- hospitalization or extended hospitalization*
- need for medical or surgical intervention*
- congenital malformation*

*Nature des conséquences cliniques observées ?-> Nature of the observed clinical consequences?*

*Conséquences observées graves -> Serious consequences observed*

*Conséquences observées non graves ou pas de conséquence (risque d'incident) -> Observed consequences not serious, or no consequences (risk of an incident)*

*Déclaration obligatoire -> Mandatory declaration*

*Moment de survenue des faits techniques et/ou cliniques observés -> Time of occurrence of the technical and/or clinical events*

*Avant utilisation du DM -> Before use of the MD*

*Pendant ou après utilisation du DM -> During or after use of the MD*

*Forcément détectable -> Certainly detectable*

*DM avec système de sécurité couvrant l'incident -> MD with a safety system in place during the incident*

*DM sans système de sécurité couvrant l'incident -> MD with no safety system in place during the incident*

*Ayant rempli sa fonction -> Functioned correctly*

*N'ayant pas rempli sa fonction -> Did not function correctly*

*Fréquence incident ? -> Frequency of incident?*

*Gravité ? -> Gravity?*

*Incident isolé -> Isolated incident*

*Incidents répétitifs -> Repetitive incidents*

*Non grave ou risque non grave -> Not serious or risk not serious*

*Pas de déclaration -> No declaration*

*Déclaration facultative -> Optional declaration*

*Déclaration obligatoire -> Mandatory declaration*

## Reporting an accident or the risk of an accident (French AFSSAPS form)



<p><b>HEAD OFFICE FOR THE EVALUATION OF MEDICAL DEVICES</b></p> <p><b>Vigilance Department</b></p> <p><b>Materials Vigilance Unit for Implants and Consumable Items</b></p>	<p>I.</p> <p>II. Zone reserved for use by the AFSSAPS</p> <p>File followed by: Anne-Elisabeth LIEOU Tel. +33 155.873.734 AFSSAPS reference: Email address: <a href="mailto:anne-elisabeth.lieou@afssaps.sante.fr">anne-elisabeth.lieou@afssaps.sante.fr</a></p>
	<p>III.</p> <p>IV. Zone to be completed by the hospital</p> <p>Questionnaire filled out by:</p> <p>Role: _____</p> <p>Date:     /     /</p>

### Questionnaire for “Accidents observed on totally implantable venous catheters (TIVC)”

Hospital: ..... Department: .....

Phone n° of person to be contacted: ..... Fax: .....

Installed by:            a surgeon                    an anesthetist                    a radiologist

Under:                    image intensifier            ultrasound                    Doppler

Approximate annual number of TIVC installed in this unit:

Date of TIVC installation   ...../...../.....

Name of the TIVC           Manufacturer: ..... Lot n°

Pre-connected model?    Yes                            No

The housing is made of:    Titanium                    Plastic                            Titanium & Plastic

KT material:                Pure                            Silicone                            Other

If “other”, give details: .....

Percutaneous access:    Yes                            No

If the response is ‘no’, indicate the mode of catheterization:

Access                    Internal jugular            Right                            Left

Subclavian                Right                            Left

Cephalic                  Right                            Left

Femoral                   Right                            Left

Other

Position of the distal end of the KT at the time of RX verification (installation)

Sup. V cava                Right auricle                Right ventricle

Inf. V cava                Other

- TIVC use  Intermittent  Continuous
- In a hospital sector  Yes  No
- In the patient's home  Yes  No
- Medication  Chemo  Parenteral nutrition  Antibiotherapy  
 Antiviral  Blood sampling  Other:.....
- Blood reflux  Possible  Impossible  Not checked
- Infusions  Straightforward  Difficult  Impossible
- Depending on the position of patient's arm  Yes  No

**Incident - Accident**

Date of accident ..... / ..... / .....

X-ray check done following accident:  Yes  No

At the time of connection to the site, before the accident, was there any blood reflux?

Yes  No  Not checked  Not known

Were there any occurrences of TIVC obstruction prior to the current accident?

Yes  No  Not known

**Type of accident observed**

Presence of pain during use of the TIVC?  Yes  No

Obstruction of the TIVC or the KT?  Yes  No  Not known

Aspect of the skin around the insertion site  Edema  Redness  Ulceration

**Clinical circumstances of the accident**

TIVC removal.  Yes  No

If 'Yes', item returned to manufacturer?  Yes  No

**Conclusions of the AFSSAPS expert**

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