INSTRUCTIONS FOR USE

INFU-KT IMPLANTABLE ACCESS PORT KIT



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Target Audience
This leaflet (IFU) is intended for professionals who are trained or experienced in the field of device implantation and/or follow-up procedures.

User training
The following instructions for use are for informational purposes only. All healthcare professionals are responsible for their medical training and experience and must apply the following instructions in accordance with good clinical practice and according to the patient's state of health.

Information for users
Any serious incident in relation to the device should be notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
For any further incidents, please return the product concerned to the manufacturer and contact them directly by email quality@isomedfrance.fr.

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1. General description

MD Medical Device

The **INFU-KT** implantable access port is a subcutaneous device that allows repeated medical injections or infusions (continuous or not), as well as sampling. It can be used in internal medicine for parenteral nutrition in the hospital or in home hospitalization, in surgery for diseases requiring long-term central vascular access, or in oncology for long-term infusion of chemotherapeutic drugs.
The **INFU-KT** implantable access port is sold as a kit.
The wide range of the device allows the doctor a choice adapted to the patient's morphology related to their upcoming treatment.

The route of access is percutaneous or surgical.

ⓘ	Please refer to the BRO/COMPLETE[1] brochure to choose the best device for the patient in line with the treatment and the patient's morphology.

⚠	**Rx ONLY** This device can only be sold following a doctor's prescription.

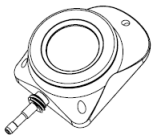
2. Composition of the kit

The **INFU-KT** implantable access port kit is single-use and comes in a sterile double package.

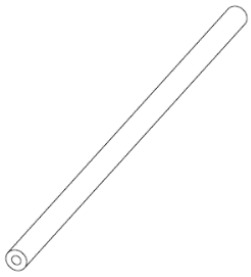
⚠	Do not sterilize again. Do not re-use.

2.1 Long-term devices

The long-term devices are:

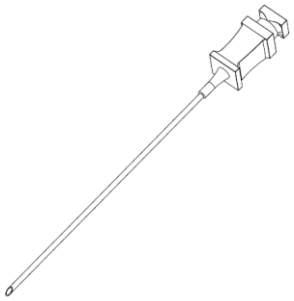
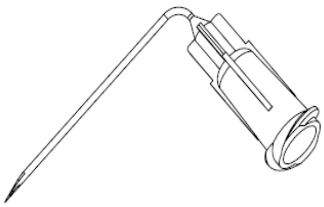
Implanted elements	Materials	References			
1 Implantable access port with a unique batch number marked with laser	Titanium[2] Silicone[3]	IVM		IVS	
		IVP		IVB	
		IVT			

[1] Available on https://www.isomedfrance.fr/
[2] 100% Titanium
[3] 100% Silicone

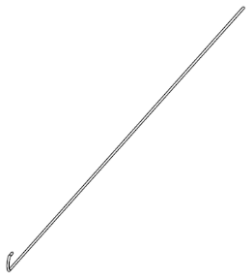
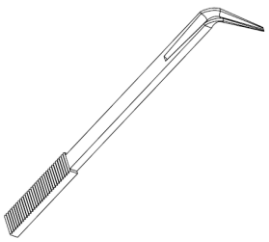
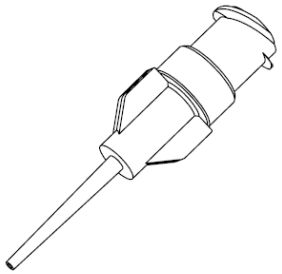
1 Silicone catheter adapted to the access port cannula	Silicone[4]	
1 Locking ring	Titanium[5]	

2.2 Temporary devices

The temporary devices are:

Non-Implanted Elements	Materials	References
1 Puncture Needle 18 gauge - L = 70 mm	Stainless steel	
1 Straight Huber Needle 22 gauge ; L = 25 mm	Stainless steel	
1 Curved Huber Needle (90°) 22 gauge ; L = 25 mm	tainless steel	

[4] 86% Silicone and 14% $BaSO_4$
[5] 100% Titanium

1 J-Guidewire L = 450 mm ⌀ = 0.035″	Stainless steel	
1 Tunneler L = 240 mm ⌀ = 3 mm	Stainless steel	
1 Peelable introducer or **1 PTFE peelable introducer (consisting of a dilator and a peelable sheath)** Size = 5, 7, 8, 9,10 French $L_{dilator}$ = 169 or 180 mm L_{sheath} = 135 or 142 mm	HDPE[6] and PTFE[7] HDPE and LDPE	
1 Vein lifter L = 47.6 mm L_{tip} = 9.2 mm	POM[8]	
1 Flush catheter L = 34.2 mm	PC[9]	

[6] high-density polyethylene
[7] polytetrafluoroethylene
[8] polyoxymethylene
[9] polycarbonate

3. Intended use and target population

3.1 Intended use

INFU-KT access port is intended to provide repeated access to the central vascular system for the delivery of medications, intravenous fluids, parenteral nutrition, and for collecting blood samples.

3.2 Target population

INFU-KT access port can be used on patients with a minimum weight of 20 kg. The practitioner must know which access port size is suitable for the patient's morphology.

3.3 Indications

INFU-KT access port is indicated for patients requiring regular or continuous intravenous treatment, notably in oncology, parenteral nutrition or for recurrent blood sampling.

4. Performances and benefits

4.1 Clinical benefits

The **INFU-KT** access port protects the patient's venous capital and reduces the pain associated with direct vein injections, thanks to less invasive puncture. Installed under the skin, it also offers better protection against infection than external medical devices and allows normal physical activity without increased risk of infection.

4.2 Clinical and mechanical performance

The **INFU-KT** access port allows repeated and prolonged direct access to the intravenous central vascular system.

- The titanium material combines strength, lightness, biocompatibility and inertness to therapeutic products (Standard ISO 5832-3 for surgical implants).
- The silicone septum ensures no leakage for 1000 punctures per cm^2 according to ISO 10555-6 (and NF S94-370) with a 22G Huber needle, i.e. 1500 punctures for the IVT and IVB, 800 punctures for the IVP and IVS and 500 punctures for IVM.
- Catheters are made of silicone. Marking starts distally. Numerical marking every 5 cm, separated by lines every centimeter up to 30 cm.
- The connection between port and catheter is secured by a titanium locking ring, ensuring a minimum holding force of 5 Newton.
- The summary of safety and clinical performance characteristics (SSCP) is available on the ISOMed website: https://www.isomedfrance.fr/

5. Contraindications and adverse reactions

5.1 Contraindications

INFU-KT access port is contraindicated for implantation in the following cases:

- the patient has a known or suspected infection, bacteremia or sepsis,
- the patient's anatomy does not allow the insertion of the catheter into the site intended for implantation,
- the patient has already undergone radiotherapy in the chosen area,
- the patient has local tissues that prevent stabilization of the device and/or access to it,
- the patient is allergic or suspected of being allergic to the materials that make up the devices in the kit,
- the solutions administered are incompatible with any of the materials constituting the port or catheter,
- the patient has a history of episodes of venous thrombosis or surgery at the location intended for implantation,
- the patient has severe chronic obstructive pulmonary disease,
- the patient has hypercoagulopathy, unless it is decided to place the patient on coagulant therapy,
- any other situation judged by the physician that would be contraindicated for the implantation of an implantable port.

5.2 Potential complications (immediate and delayed)

Based on the literature and experience gained on the implantation of implantable ports, the following is a list of possible complications that have been observed:

Arrhythmia, tamponade, cardiac puncture	Development of a fibrin sheath	Catheter occlusion
Disconnection, rupture or fragmentation of the catheter	Hematoma	Pneumothorax
Air embolism	Hemothorax	Device rejection
Explantation	Infection/Sepsis	Bleeding
Erosion of the catheter or port through the skin	Brachial plexus injury	Thromboembolism/Thrombophlebitis
Extravasation	Nerve damage	Thrombosis
	Vascular lesions (laceration, perforation)	
	Port/Catheter migration	
	Necrosis	

These and other complications are well documented in the medical literature and should be carefully considered before the port is implanted.[10]

The placement and use of an implantable port should be performed by qualified practitioners who are familiar with the risks and procedures.

6. Warnings

6.1 Storage

We do not guarantee the functionality and sterility of **INFU-KT** access port if the storage instructions below are not followed:


Keep dry.


Keep away from sunlight.


Store and keep at temperatures between 5 and 30°C.

[10] Machat S. Eisenhuber E. Pfarl G. Stübler J, Koelblinger C. Zacherl J. Schima W. Complications of central venous port systems a pictorial review, 2019. Available on https://insightsimaging.springeropen.com/articles/10.1186/s13244-019-0770-2



Store and keep in an environment where humidity is between 30 and 65%.

6.2 Sterilization & use

The kit is sterilized with ethylene oxide.



Do not perform new sterilization of the items in the kit.



Do not re-use the items in the kit, they are for single-use only. Their re-use may create a risk of infection for the patient or user.



The kit is supplied in a sterile double package. It is sterile and pyrogen-free as long as the package is closed and intact. Examine the packaging carefully before opening the kit. This should only be opened and handled under strict aseptic conditions.



Check the expiry date before use and never implant a device after the expiry date.

Check for the presence of the kit items by referring to the label on the kit packaging. Inspect their condition before use to verify their integrity and absence of signs of damage.
This medical device should only be implanted or used by experienced personnel, in the technical and clinical aspects of implantable ports.



Do not use the product if the sterile packaging is damaged or unintentionally opened before use.

7. Precautions

7.1 General precautions

- The implantation, handling and explantation of the system should be reserved only for trained and qualified practitioners.
- Before using this device, the doctor must read these instructions for use entirely.
- Observe general precautions when implanting the port.
- Adhere to all indications and targeted population, contraindications and adverse reactions, warnings, precautions, and procedures as specified by the manufacturer to avoid injury to the patient and/or damage to the device.
- Ensure that the patient is aware of the benefits and risks associated with the placement of an implantable port. Consent is required.
- It is recommended not to proceed with injections of drug solutions within 8 days of the insertion of the port.



The patient's consent is mandatory.

7.2 Precautions common to implantation procedures

- Reduce mechanical stress and accidental contact between sharp instruments and the fragile materials in the kit. Use atraumatic forceps with foam jaws.
- Do not suture the catheter to the port, the port cannula, or the local tissue around the port. Any damage or constriction of the catheter can compromise its performance.
- Avoid forceful handling of the catheter.
- During implantation, avoid bending the catheter at an acute angle; excessive angulation could compromise the permeability of the catheter lumen.
- Catheters should be positioned so that their marked end (distal end) is at the junction of the superior vena cava and the right atrium. Check the correct position of the catheter tip by fluoroscopy, ultrasound, or other appropriate technique.
- Do not use a catheter that shows signs of lesions or leaks.

8. Implantation

8.1 Before implantation

Inform the patient adequately and obtain their consent, to plan the surgical procedure. The doctor should use data obtained from preoperative assessments. These assessments can be performed using imaging techniques such as Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, and ultrasound. These examinations allow identification of possible contraindications, confirm the patient's suitability to undergo the operation and determine the best surgical strategy.

The choice of preoperative check-ups is up to the doctor who judges according to their experience, their needs and what is most appropriate for the patient.

8.1.1 Veins

INFU-KT access port should be placed in the venous circulation.
The recommended veins for implantation are the internal and external jugular veins and the subclavian vein.
Other possible routes of access are the axillary vein, the brachial vein, and the cephalic vein.
INFU-KT access port is not intended for use in arterial or intrathecal or epidural applications.

The final choice of vein is up to the practitioner who judges according to their experience, needs and what is most appropriate for the patient.

8.1.2 Vein entry site

The recommended vein entry site is at the neck or below the clavicle (for access to the internal jugular vein or subclavian vein, respectively).

Prevention of catheter pinching: Catheters placed in the subclavian vein should be inserted at the boundary of the middle and outer third of the clavicle, lateral to the entrance to the thorax. Insertion of the catheter medially into the subclavian vein should be avoided; such a method might damage the catheter. X-ray should be used to ensure that the catheter is correctly positioned and not compressed in the costoclavicular outlet.

Signs of catheter pinching:

- **Clinical:**
  - Issues with blood collection
  - Resistance to liquid infusion
  - Need to change the patient's position to allow for fluid infusion or blood draw.
- **Radiological:**
  - Grade 1 or 2 distortion on radiological examination of the chest
  - The degree of severity of the pinch should be assessed prior to explantation. Patients with any degree of distortion in the costoclavicular outlet should be closely monitored. The pinch grades that can be identified by appropriate radiological examinations are as follows:

Rank	Severity	Recommended Action
0	No distortion	No action
1	Distortion present without narrowing of the lumen.	An X-ray of the rib cage taken every one to three months to monitor the progression of the pinch to a grade 2 distortion. Note the position of the shoulder during chest cage X-rays as it can contribute to changes in distortion grades.

	2	Distortion present with narrowing of the lumen.	Consider catheter removal
	3	Cross-section or complete section of the catheter	Rapid catheter removal

8.1.3 Port implantation site

The implantation site of the port (or subcutaneous pouch) must:
- facilitate access to medical care and procedures,
- provide good stability to the port,
- reduce the risk of infection by keeping the subcutaneous pouch far away from the site of entry into the vein,
- avoid the creation of pressure points,
- allow the patient's mobility and not interfere with their clothing,
- consider the thickness of skin tissue above the port membrane as it may hinder access. Conversely, a too thin layer of skin tissue can lead to erosion of the port. A tissue thickness between 0.5 and 2 cm is considered adequate.

The recommended location for implantation is the subclavicular fossa in the chest area, although this may vary depending on the specifics of the patient. It is advisable to avoid certain areas, including:
- Armpits, elbows, and areas exposed to strenuous physical activity.
- Areas close to bones, such as the collarbone, to avoid the risk of injury or discomfort.
- Areas weakened by previous procedures, whether superficial or deep, due to an increased risk of complications.

The final choice of the implantation site is up to the practitioner who judges according to their experience and needs, what is most appropriate for the patient.

8.1.4 Implantation procedure

ISOMed claims two implementation procedures:
- **procedure 1**: percutaneous implantation,
- **procedure 2**: implantation in a bare vein.

The choice of the appropriate procedure is up to the practitioner who judges according to their experience and needs, what is most appropriate for the patient.

⚠ Choose an implantation procedure and follow it from start to finish. Do not change it during operation to facilitate safe and prolonged use of the **INFU-KT** access port.

8.1.5 Patient record

Complete the patient's implant record, documenting device-specific information in accordance with facility procedures and policies, including device reference and batch number.

8.2 Preparing for the operation

8.2.1 Patient

Place the patient in the Trendelenburg position with the head facing away from the venipuncture site to make puncture easier and prevent the risk of air embolism.

The choice of the type of anesthesia (local or general) is up to the practitioner who judges according to their experience and needs, what is most appropriate for the patient.

8.2.2 Operating room

Set up a sterile drape and ensure strict aseptic conditions before opening the blister.

8.2.3 Implantable device

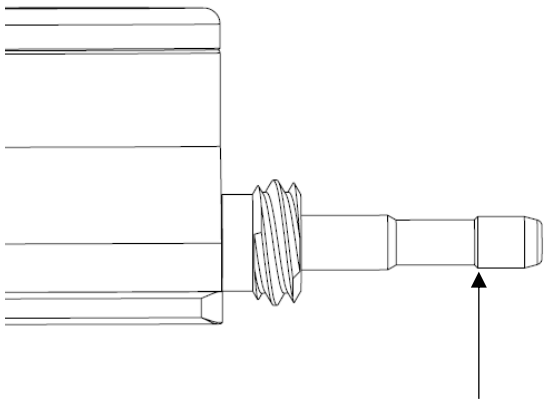
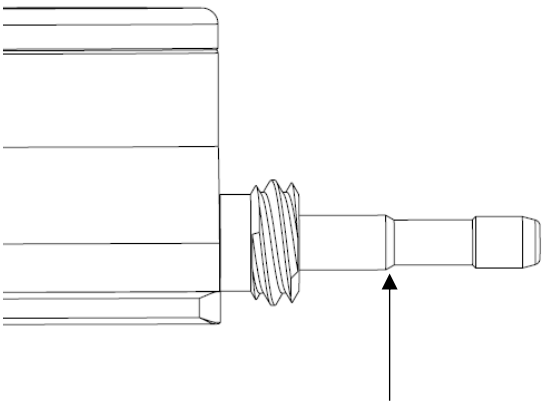
⚠	Check that the ring screws onto the port cannula when the catheter is inserted (see section 8.3.3) and apply a slight pull to check the hold of the port-ring-catheter assembly. When screwing in, ensure that the catheter does not come up on the thread.
⚠	Check that the port/catheter assembly is not obstructed. In case of obstruction, do not implant.
⚠	Do not use syringes with a volume of less than 10 ml. An infusion pressure greater than 172 kPa (25 psi) can damage blood vessels or viscera and is therefore not recommended.
⚠	Use only Huber ISOMed needles with the port.

Flushing the system prior to implantation can be done in two ways:

1) Checking the connection between the port and the catheter: connect the proximal end of the catheter to the port. Advance the catheter to the 2nd chamfer of the groove. Make sure the ring is screwable on the cannula. Unscrew.
   Rinsing the port: screw the Huber needle onto a syringe of at least 10 ml, filled with 0.9% sodium chloride. Puncture the septum perpendicularly with the Huber's needle and rinse the port. The port's cannula should be pointing upwards. The liquid should come out of the cannula without difficulty.
   Catheter flushing: screw the flush catheter onto a syringe of at least 10 ml, filled with 0.9% sodium chloride and insert it at the proximal end of the catheter. Rinse. The fluid should exit safely at the distal end of the catheter. Clamp with soft jaw forceps several centimeters from the proximal end of the catheter.

2) Flushing the system (port and catheter): connect the proximal end of the catheter to the port. Advance the catheter to the 2nd chamfer of the groove. Lock with the ring to check if there is a good screw. Screw the Huber needle onto a syringe filled with 0.9% sodium chloride of at least 10 ml. Puncture the septum perpendicularly with Huber's needle and flush the connected system. The fluid should exit safely at the distal end of the catheter. Clamp with soft jaw forceps several cm away from the proximal end of the catheter. Unscrew the port, ring, and clamped catheter.

Do not flush the catheter with a product other than those mentioned in these instructions for use.
If the catheter and ring have been connected and then disconnected, the catheter end should be cut to ensure reliable connection.

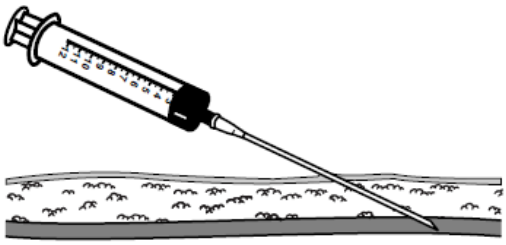
References: IVP1632 and IVT1632	**Other references**
 Advance catheter to 1st chamfer of groove	 Advance catheter to 2nd chamfer of groove

8.3 Port and catheter implantation

8.3.1 Procedure 1: Percutaneous implantation

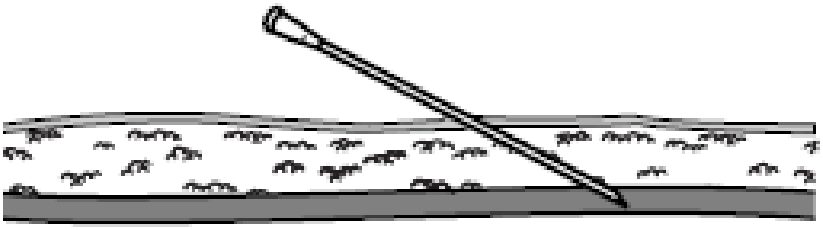
Step 1: Locate the vein selected previously in the “8.1.1 Veins” section.
Step 2: Perform vein puncture:

- make a small incision at the site of entry to the vein (or puncture site)
- screw the puncture needle onto a syringe, of at least 10 ml, filled with 0.9% sodium chloride,
- puncture the vein,
- check the position of the puncture needle by observing the blood flow.

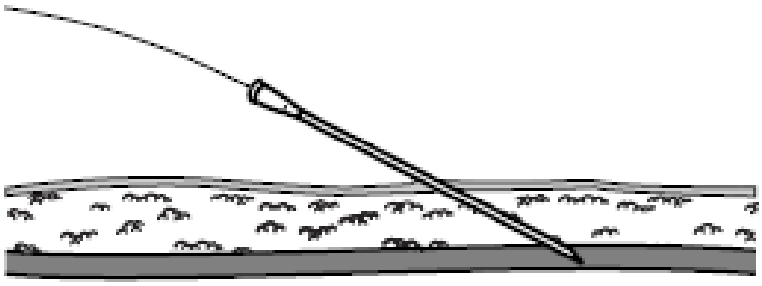


⚠ If the puncture needle enters the pleural space, remove the needle and check for pneumothorax.

Step 3: Detach the syringe, leaving the puncture needle in the vein. Place a finger on the hub of the puncture needle to minimize bleeding and the risk of air embolism.

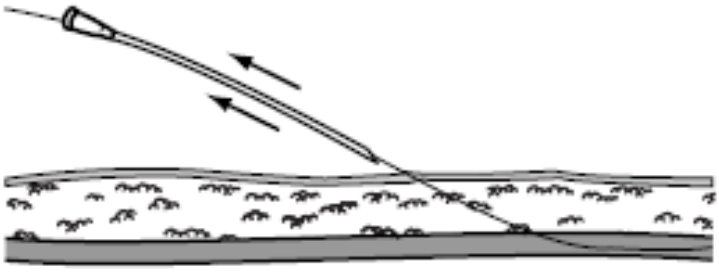


Step 4: Straighten the end of the J-guidewire with the straightener and insert it into the puncture needle.
Step 5: Remove the straightener from the J-guidewire. Then, move the guidewire into the superior vena cava and place it as far as necessary.



If the guidewire needs to be removed while the puncture needle is still inserted into the vein, the puncture needle should be removed first, before removing the guidewire.

Step 6: When the correct position of the guide is reached, gently remove the puncture needle.



Step 7: Using a rotating movement, insert the introducer (dilator + sheath) onto the guidewire. Introduce it into the vein, leaving at least 2 cm of peelable sheath exposed.

⚠	To avoid patient trauma or damaging the end of the sheath, do not move the sheath forward on the dilator. The two elements must be inserted as a single unit.

Step 8: Create a subcutaneous pouch to insert the port:

- make a 2 to 3 cm incision in the subclavian fossa,
- widen the space using a finger. This pouch should be wide enough to hold the port and, deep enough so that the port is not right below the skin incision. Check by inserting the port.

ⓘ	The distance between the collarbone and the subcutaneous pouch should be of at least 2 fingers.

Step 9: Create a subcutaneous tunnel from the site of entry of the vein to the subcutaneous pouch using a tunneler.

- insert the atraumatic end of the tunneler through the vein entry site. Push the tunneler in until it comes out of the subcutaneous pouch.

⚠	Avoid puncturing the skin or fascia with the tip of the tunneler.

⚠	Do not insert the barbel side of the tunneler into the blood vessel.

Step 10: Connect the proximal end of the catheter to the tunneler's barbel. The barbel must be completely covered by the tip of the catheter to ensure that the catheter is maintained during the procedure.

Step 11: Insert the catheter by pulling the tunneler through the tunnel formed towards the subcutaneous pouch.

Step 12: Disconnect the catheter from the tunneler. Cut off the end of the catheter that was previously attached to the barbels. Make sure to perform this last step. If not, it could lead to future rupture between the catheter and the port.

Step 13: Carefully remove the J-guidewire.

Step 14: Gently remove the dilator while keeping the peelable sheath in place. Keep your thumb on the exposed end of the sheath to prevent air embolism.

⚠	To avoid damaging the blood vessels, avoid leaving the introducer sheath inside the blood vessel without the internal support of a catheter or dilator.

Step 15: Make sure the proximal end of the catheter is still clamped. Insert the distal end of the catheter into the peelable sheath and advance it to the junction of the superior vein and the right atrium. Check the position of the catheter using fluoroscopy (for example).

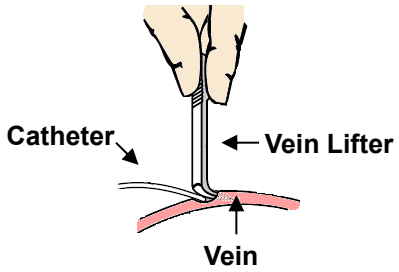
Step 16: Remove the sheath from the vein:

- peel the sheath using both handles outwards at the same time while pulling, step by step, the sheath upwards. The sheath must peel along the peelable limit,
- make sure that the catheter is not dislodged from the vein.

ⓘ	It is recommended to ask a second person to hold the catheter in the vein entry site, while peeling off the sheath.

8.3.2 Procedure 2: Implantation in a bare vein

Step 1: Locate the vein selected previously in the section “8.1.1 Vein”.
Step 2: Expose the vein, by incision.
Step 3: Remove the clamp from the distal end of the catheter, flush the catheter, clamp the proximal end of the catheter.
Step 4: Isolate and stabilize the vein to prevent bleeding and air embolism, then make an incision.
Step 5: Insert the tapered end of the vein lifter into the incision and move it into the vein.
Step 6: While keeping the vein in position, slide the distal end of the catheter into the lower gutter and move it a few centimeters into the vein.



Step 6: Remove the vein lifter.
Step 7: Advance the catheter through the interior of the vein to the junction between the superior vena cava and the right atrium.
Step 8: Enlarge the incision to create a subcutaneous pocket to insert the port:

- widen the space by dilating with a finger. This pouch should be wide enough to hold the port and deep enough so that the port is not below the skin incision.

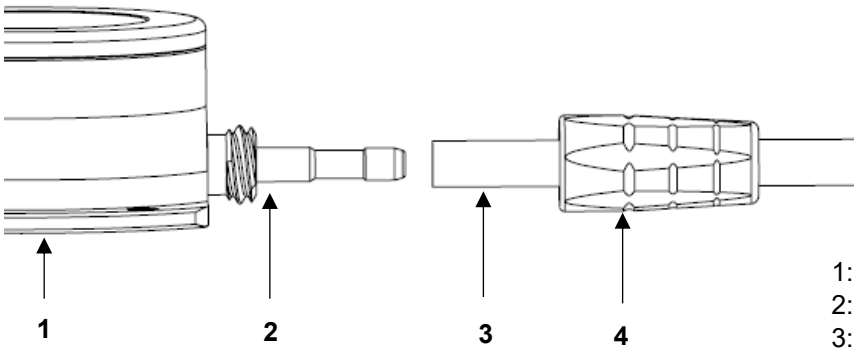
ⓘ	Be careful, the proximity between the site of entry of the vein and the site of implantation of the port creates a bigger risk of infection.

8.3.3 Attachment of the port and catheter

Step 1: Cut the catheter to the correct length, leaving enough slack to allow movement of the body and to allow connection with the port.

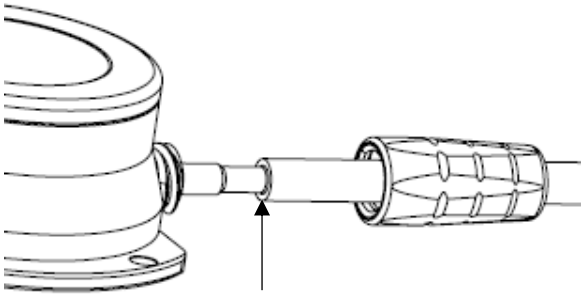
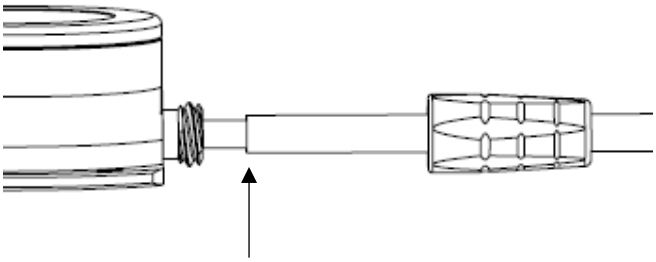
ⓘ	If the catheter is not inserted sufficiently, there is a risk that it will become detached, leading to extravasation. Inserting it too much will make it difficult or impossible to screw the ring on.

⚠	The catheter should be straight, with no signs of twisting. A slight pull on the catheter is enough to straighten it. Inserting the locking ring into a twisted catheter can damage the catheter. If the catheter has already been mounted on the cannula, the tip of the catheter should be cut to ensure reliable connection.

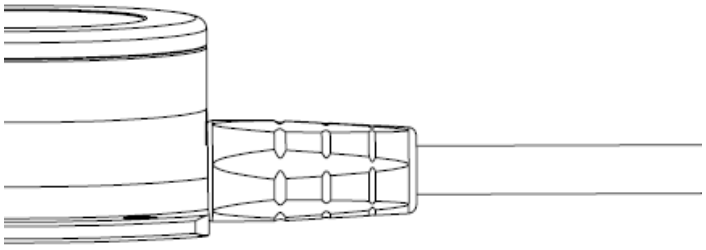


1: Port
2: Port cannula
3: Catheter
4: Ring

Step 2: Insert the proximal end of the catheter onto the port cannula. Advance the catheter to the 1st or 2nd chamfer of the port groove.

References: IVP1632 and IVT 1632	**Other references**
	
Advance the catheter to the 1st chamfer of the groove	Advance the catheter to the 2nd chamfer of the groove

Step 3: Lock the connection by screwing the ring to the stop. Gently pull on the catheter to make sure that the assembly is done correctly.



Step 4: Screw the Huber needle onto a syringe, of at least 10 ml, filled with 0.9% sodium chloride. Puncture the septum perpendicularly with Huber's needle. Verify the integrity of the implanted system by observing a blood reflux and then inject the fluid.

⚠ Make sure the port/catheter assembly is not obstructed. In case of obstruction, do not implant.

Step 5: Place the port in the subcutaneous pouch, making sure that the port is not below the incision.

Step 6: Suture the port to the underlying fascia using a non-absorbable monofilament suture thread for each suture point. This anchoring technique reduces the risk of port migration and overturning. Leave enough slack in the catheter to allow for a slight displacement and check that it is not twisted.

Step 7: Close the surgical wound. Absorbable sutures may be used. Bandage the wound according to hospital practices.

⚠	Devices used during surgical procedures are likely to pose both infectious risks (due to contact with human fluids or tissue) and physical hazards (such as injuries caused by sharp or perforating instruments, particularly needles). Consequently, they must be handled and disposed of safely and in compliance with current legal guidelines governing the management of medical and hospital waste.

9. Use and maintenance

9.1 Initial visual and tactile diagnosis

Patient Preparation:

- consult the patient booklet, if existing,
- prepare the patient,
- disinfect your hands thoroughly,
- remove the bandage,

Check the condition of the patient and the injection site:

- proper wound healing,
- no symptoms (swelling, redness, warmth, irritation, other possible complications),
- assess the patient's pain and well-being.

Verify visually and by palpation the correct positioning of the port and catheter.

- no migration of the port nor catheter,
- No tilting of the port.

Explain the procedure to the patient. Warn them of the pricking sensation (the sensation of needle penetration decreases over time. It may be helpful to use a topical anesthetic).

⚠	If the brachial or cephalic vein is used, do not measure the patient's blood pressure on the corresponding arm in order to avoid the risk of occlusion or other damage to the catheter.

⚠	If there is any doubt about the condition of the port and surrounding tissues, it is imperative to carry out appropriate examinations to ensure the patient's health.

9.2 Asepsis of the area

- Disinfect your hands thoroughly.
- Put on sterile gloves.
- Thoroughly disinfect the area of the skin where the injection is to be made, with an antiseptic compress, starting at the port and continuing in a spiral move from the center to the periphery, over an area of 10-13 cm in diameter.
- Repeat the previous step with a new single-use antiseptic compress.

9.3 Use of the port

ⓘ	It is recommended not to inject drug solutions within 8 days of port implantation to let the wound heal and avoid the risk of infection.

ⓘ	It is recommended to change bandage and injection components every 24-48 hours.

9.3.1 General method of using a port

Precautions

- Always do a blood reflux test before using the port.
- Do not use syringes with a volume of less than 10 ml. An infusion pressure greater than 172 kPa (25 psi) can damage blood vessels or viscera and is therefore not recommended.

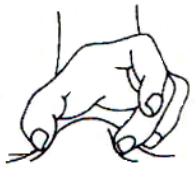
To reduce the risk of air embolism and infection, always:
- remove air bubbles from the system by flushing it and using clamps, plugs, or other methods when connecting with other devices,
- systematically rinse and overpressurize,
- ensure that the Huber needle always remains covered by a stopper when it is in place in the port, thus avoiding exposure to air.

Accessories and components used in combination with the system must have a standard Luer-Lock connection.

⚠	Only use ISOMed Huber needles with the port.

Use

- Locate the base of the port with your non-dominant hand.
- Locate the septum by palpation.
- Hold the port between the thumb, index and middle fingers of the non-dominant hand. Locate the center point between these three fingers.
- Insert the Huber needle perpendicularly to the septum of the port and gently move it through the skin and septum until it hits the bottom of the port. Do not handle the Huber's needle once it is inserted into the septum.
- Rinse the port with a saline solution. Clamp the connection line and disconnect the syringe.



ⓘ	If occlusion occurs, never attempt to clear the obstruction using high-pressure fluid, risking damaging the catheter or having it displaced. Contact the responsible physician and use a fibrinolytic agent if prescribed by the physician.

9.3.2 Blood reflux test

Always check for blood reflux before using the device.
Good blood flow is a sign of the integrity of the port and catheter (no signs of mechanical damage or leakage from the system).

ⓘ	Abnormal blood flow (too low or absent) can be a sign of a potential complication (occlusion, bending, rupture, catheter pinching, fibrin formation, thrombosis, or poor positioning). This reflux will need to be medically evaluated before using the device.

Rinse according to section 9.3.4.

9.3.3 Bolus or continuous sampling or injection

After checking for the presence of blood reflux and flushing the connected system, make sure you have all the equipment available to be able to inject or sample, non-exhaustive list:
- Huber's needle,
- Intravenous solution (if prescribed),
- 0.9% sodium chloride,
- syringe of at least 10 ml,
- pump and infusion stand (if prescribed),
- connection line with clamp (if prescribed),
- adhesive strips for securing connections (if required for continuous transfers).

⚠	In the case of continuous sampling or injection, secure the Huber needle with a clear bandage to prevent accidental removal.

⚠	The pumps used should be equipped with an automatic pressure limiting device, which stops the infusion as soon as the pressure exceeds 172 kPa (25 psi).

Deliver the fluid according to good medical practice,
Rinse the port according to section 9.3.4.
Clamp the connection line as soon as the transfer is complete.

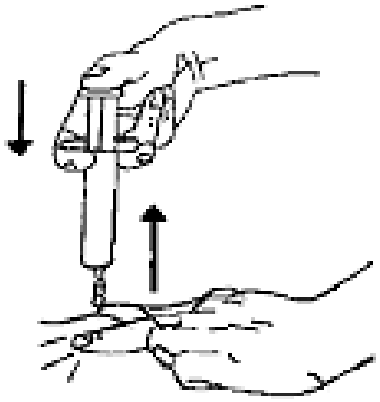
ⓘ	Look for signs of extravasation at the injection site; if any signs of extravasation, immediately discontinue the transfer and intervene appropriately.

ⓘ	Always rinse between the two intravenous solutions passing through the port during the same use (according to section 9.3.4).

9.3.4 Rinsing

Always rinse the port with a sodium chloride solution between two changes of intravenous solutions taken or infused, after each use (to close access to the port), and after a long period without use (at least once a month).

- Screw the Huber needle onto a syringe, of at least 20 ml, filled with 0.9% sodium chloride. Puncture the septum perpendicularly with the Huber's needle and rinse the port.
- Perform positive pressure to reduce the risk of blood backflow to the tip of the catheter and the creation of a clot in the catheter: remove the Huber needle slowly while injecting 0.5 ml of sodium chloride. Keep the port stabilized using two fingers when removing the needle.



9.3.5 MRI scan

MRI Scans Case

MR Compatible with MRI under defined conditions

Non-clinical tests have shown that **INFU-KT** ports are compatible with MRI examinations, under certain conditions. A patient with an **INFU-KT** series implantable port can undergo an MRI examination immediately after implantation, under the following conditions:

- Static magnetic field of 1.5 teslas or 3.0 teslas only.
- Maximum magnetic spatial gradient of 10,000 gauss/cm (extrapolated) or less.
- Average SAR (Specific Absorption Rate) reported, by the system, for the whole body of 2.0 W/kg for a 15-minute MRI (pulse sequence) in normal operating mode.

Risk 1: MRI-related heat generation:

In non-clinical tests, **INFU-KT** ports produced a temperature rise during a 15-minute MRI (pulse sequence) at 1.5 teslas / 64 MHz (Magnetom, Siemens Medical solutions, Malvern, PA. Software Numaris/4, version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3.0 teslas (3.0 teslas / 128.0 MHz, Excite, HDx, software 14XM5, General Electric Healthcare, Milwaukee, WI):

	1.5 teslas	3 teslas
Whole body averaged SAR, reported by the system	2.9 W/kg	2.9 W/kg
Whole body averaged SAR, measured by calorimetry	2.1 W/kg	2.7 W/kg

Maximum Temperature Change	1.7°C	2.2°C
Whole-body temperature, averaged SAR of 2 W/kg	1.2°C	1.5°C

Risk 2: Artifacts:

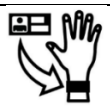
The quality of the MRI image may be affected if it is taken close to the **INFU-KT** ports. It may therefore be necessary to adjust the MRI settings to obtain a better image. The maximum size of artifacts observed on a 3-tesla gradient echo pulse sequence is stretched over approximately 15 mm relative to the implant size.

10. Discontinuation of use

- If the practitioner concludes that the use of the **INFU-KT** port is no longer required for treatment, they should consider removing it.
- The implantable port should be removed once treatment is complete.
- The duration of the system is determined by the duration of the treatment, which varies according to the treated disease, as well as by the functional performance of the device, particularly that of the catheter. Catheter damage is the most common wear-related problem.
- It is imperative to remove the system, if no longer useful.
- Removal of the port should begin with removal of the ring, followed by the catheter, before proceeding with the extraction of the port. It is crucial not to remove the port while the catheter is still attached, to avoid disconnecting the system.

ⓘ	After explantation, this system may be biohazardous; it must be handled and disposed of in an appropriate manner, in accordance with applicable laws and regulations relating to medical and hospital waste.

11. Symbols' guide

	Do not use if packaging is damaged and consult instructions for use		Medical Device
	Consult instructions for use or consult electronic instructions for use		Unique Device Identification
	Manufacturer		Keep away from sunlight
	Do not re-use		Do not re-sterilize
	Sterilized using ethylene oxide		Keep dry
	Catalog number		Temperature limit
	Date of manufacture		Compatible with MRI under defined conditions
	Use-by date		Batch code
	Humidity limitation		Sterile double barrier system
	Information website for patients		Patient identification
	Patient's name	Rx ONLY	On medical prescription only

CE
0197

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