INSTRUCTIONS FOR USE

GMI GABIPORT FULLY IMPLANTABLE CATHETER

REF 1500

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INTRODUCTION

The **GMI GABIPORT FULLY IMPLANTABLE CATHETER** is a fully implantable device providing prolonged and repetitive access to the vascular system.
The **GABIPORT** consists of Titanium chamber with a silicone septum for puncture using "Huber"-type needles. The catheter is made from implantable silicone and is available in neonatal, pediatric, and adult sizes.

Content:
1 Chamber / Implantable Port
1 Silicone Catheter
1 straight Huber needle
1 Hypodermic needle
1 J-shaped metallic guide wire with a protective cover
1 Tunneler
1 Peel-Away Introducer
1 10 mL syringe

The following table presents the product's dimensions and codes and identify the different calibers available.

Code 1500 – GMI GABIPORT FULLY IMPLANTABLE CATHETER						
Code	***Portal***	***Catheter Diameter (Fr) x Length (cm)***	***Flushing Volume (mL)***	***Catheter Flow (mL/min)***	***PORT Priming Volume (mL)***	***Catheter Priming Volume w/ 60 cm (mL)***
1500-10-04	1-Lactating / Pediatric	4 x 60	4.0	5.0	0.18	0.252
1500-10-05		5 x 60	4.0	7.0	0.18	0.276
1500-20-05	2- Pediatric / Adult	5 x 60	5.0	7.5	0.40	0.276
1500-20-07		7 x 60	7.0	20.0	0.40	7.5
1500-20-09		9 x 60	11.0	26	0.60	1.398
1500-30-07	3-Adult	7 x 60	7.0	22	0.60	7.5
1500-30-09		9 x 60	11.0	26	0.60	7.398

Flow Volume During Infusion

Needle size	18G	20G
Needle color	Pink	Yellow
Maximum Recommended Flow	5mL/s	5mL/s
Maximum Recommended Pressure Adjustment	300 psi	300 psi

PRODUCT DESIGN

PURPOSE / RECOMMENDED USE

The **GMI GABIPORT FULLY IMPLANTABLE CATHETER** is recommended for use in patients requiring repeated access to the vascular system. It is used for chemotherapy infusions, administering medications, fluids, parenteral nutrition solutions, and hemoderivatives, as well collecting blood samples.

The main recommended uses for fully implantable catheters include:

- Difficulty in peripheral venous access caused by veins that are not calibrous or increased adipose tissue.
- Long-term chemotherapy.
- Treatments carried out through frequent cycles and that involve the use of vesicant drugs that may cause phlebitis.

INSTRUCTIONS FOR USE:

Ensure that you have read the entire manual, including contradictions, precautions, and special care that is to be taken before initiating the procedure.

1. Select the location in which the catheter will be implanted. The interclavicle is a satisfactory location; however, the location may vary for each patient depending upon their specific characteristics. Select a location that offers an appropriate level of stability without causing the patient discomfort. Ensure that the location selected offers sufficient cutaneous tissue in order to minimize tissue erosion. Tissue with a thickness between 0.5 cm and 2 cm is appropriate;
2. Record all pertinent data related to the implantation, including the device's lot number;
3. Organize and prepare the sterile field and anesthetize the patient;
4. Carry out salinization of the catheter.

Important:

- Chambers must only be implanted by specialized medical professionals.
- Before implantation, fill the device with physiological or heparinized solution.
- Take all necessary precautions while implanting the device in order to avoid any type of alteration in the catheter's mechanical properties. Do not use the catheter if it has been damaged.
- The catheter and chamber must be implanted manually. It is therefore important to rigorously adhere to the connection technique described in the IMPLANTATION TECHNIQUES section in order to ensure that the catheter is not damaged and that a proper connection is obtained.

Implantation techniques

The physician responsible for implantation must determine the introduction method that is most appropriate for the patient, taking the risks and advantages of each method into consideration.

Any risk of gas embolism can be avoided by placing the patient in the *trendelenbourg* position (inclined with head lower than feet).

Introduction of catheter through vein dissection

1. Make an incision in order to expose the entrance to the vein and, once it has been isolated and stabilized, carry out the incision to the vein;
2. Insert the end portion of the catheter into the interior of the vein and advance the catheter along its length. Ensure that the "0" marker is inserted first. The use of a vein lifter instrument to facilitate the introduction of the catheter is recommended. The catheter's final location must be the junction between the superior vena cava and the right atrium. Verify whether the catheter has been positioned correctly using an appropriate technique;
3. Without cutting, use dissection to create a subcutaneous pocket in which the reservoir will be positioned;
4. Cut the catheter to the appropriate length at a 90º angle;
5. Remove all air from the reservoir using a 10 mL syringe filled with physiological solution and a Huber needle. Insert the needle into the silicone septum and inject the liquid;
6. Wash all of the system's components using an irrigation solution and subsequently connect the catheter to the reservoir.

Introducing catheter using the percutaneous method

1. Connect the puncture needle to the syringe and insert into the vein. Gently aspirate the syringe once it has been inserted. If the artery has been accessed, remove the needle and apply pressure manually for several minutes. If the pleural cavity has been accessed, remove the needle and check the patient for possible pneumothorax.
2. Remove the syringe, leaving the needle in the location in which the puncture was made. While opening the needle, use a finger to minimize blood loss and the risk of air being drawn into the needle.
3. Insert the guide wire after straightening the extremity.
4. Advance the guide wire as needed.
5. Remove the needle.
6. Make a small incision (approximately 1 cm deep) parallel to the clavicle, with the guide wire in the center of the incision.
7. Working carefully to ensure that the vein is not severed, move the vascular dilator and the sheath introducer forward simultaneously, leaving 2 cm of the introducer exposed.

8. Separate the introducer and delicately remove the vascular dilator and "J-shaped" guide wire, leaving the introducer at the site. Use a finger to cover the open introducer in order to prevent inadvertent aspiration.
9. Insert the catheter's extremity into the vascular access point and advance it along the vein. Ensure that the "0" marker is introduced first. The catheter's final position must be the junction between the superior vena cava and the right atrium. Verify that the catheter is correctly positioned using the appropriate technology.
10. Secure the two parts of the sheath introducer and pull them simultaneously.
11. Completely peel sheath introducer away from catheter. Ensure that the catheter has not exited the vein.
12. Create a subcutaneous space to accommodate the reservoir.
13. Cut the catheter to the appropriate length at a 90º angle;
14. Remove the air from the reservoir, injecting physiological solution using the 10 mL syringe and Huber needle. Insert the needle into the silicone septum and inject the fluid.
15. Wash all of the system's components using an irrigation solution.
16. Next, insert the catheter's locking system, connecting the catheter to the reservoir in a manner in which the conical extremity is covered, as shown in figure 01.

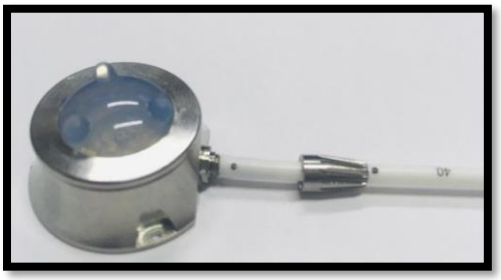


Figure 01 – Insertion

17. Thread the safety system to the reservoir as shown in Figure 02 by turning it until the end of the threading is reached in a manner in which the chamber is secure in order to ensure that no leaking occurs during infusion.

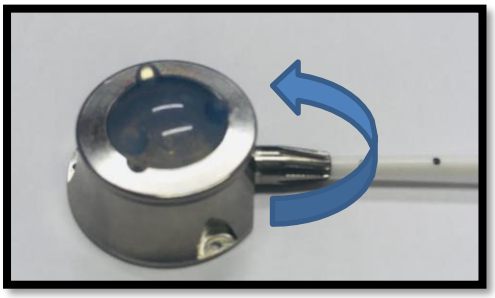


Figure 02 – Threading

18. Lightly pull on the catheter as shown in Figure 03 in order to ensure that it is properly connected.

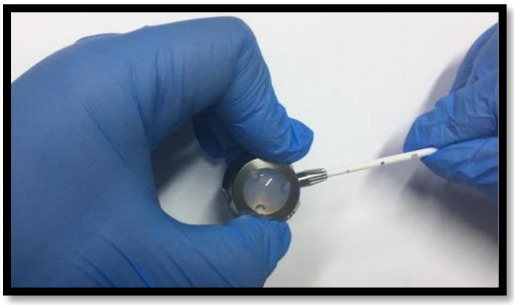


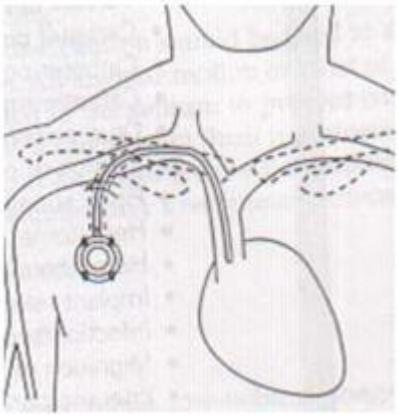
Figure 03 – Verifying proper connection.

19. Insert the chamber into the cavity and ensure that the catheter is not bent.

20. Proceed with salinization or heparinization of the device.

Tunneling catheter

1. Make a small incision at the venous access point.
2. Insert the end of the tunneler and move it forward in the direction of the area accommodating the reservoir, moving it carefully in order to avoid puncturing the skin;
3. Connect the catheter to the tunneler, making sure that catheter is secure;
4. Move the tunneler across the area designated to accommodate the reservoir. Carefully and firmly secure the catheter;
5. Cut the catheter to the appropriate length at a 90º angle;
6. Remove air using a 10 mL syringe filled with physiological solution and a Huber needle. Insert the needle into the silicone septum and inject the fluid;
7. Wash all of the system's components using an irrigation solution.



Internal view of the positioned catheter

Use and necessary precautions with Gabiport

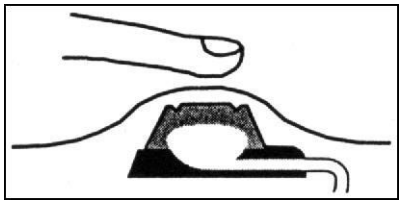
1. Carry out inspection and asepsis at the puncture site before use.
2. Identify the location of the chamber through palpation.
3. Introduce the needle in a position perpendicular to the skin and insert it up to the bottom of the chamber.
4. Verify the permeability of the device and that the needle is correctly positioned by injecting physiological solution, without applying excessive pressure or causing local diffusion.
5. If there are any concerns with regards to the integrity of the system, suspend any type of chemotherapy treatment and proceed with verification of the device using the contrast provided by an imaging exam.
6. Carry out the infusion of medicated solution using the puncture system.
7. When collecting a blood sample, do not use the first few mL of blood collected.
8. If administering multiple solutions is necessary, salinize the catheter after the infusion of each solution.
9. Immediately suspend infusions and take the necessary action at the first sign of extravasion.
10. Fill the device with physiological solution after each use.
11. Proceed with heparinization of the GABIPORT in accordance with institutional protocols.
12. Remove the needle, maintaining pressure in order to avoid any type of blood reflux in the interior of the catheter.

Gabiport Puncture Technique

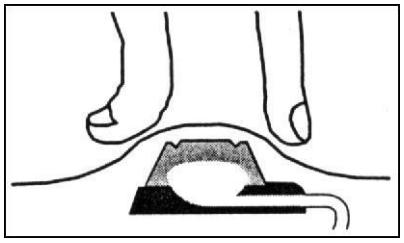
- Ensure that local instructions provided by each institution with regards to handling devices

and cannulae used in endovenous access are followed.

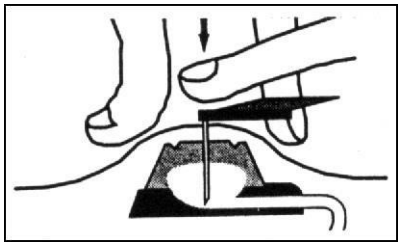
- Ensure that hands are clean before beginning procedure. Use sterile latex-free gloves.
- Clean the access location with the antiseptic recommended by the health institution.
- Repeat the operation several times.
- Prepare a 10 mL syringe (or with a volume greater than 10 mL) already connected to a Huber-type needle.



- Palpate the region in which the port is located (sterile technique)
- Locate the port beneath the skin.



Identify the ring surrounding the upper part of the port, keeping the reservoir between the thumb and pointer ringer.



Identify the center of the chamber through the septum's lobes and insert a Huber-type needle at a 90º angle until it reaches the bottom of the reservoir.
- Aspirate a small quantity of blood to verify whether the needle has been properly positioned.

- The appropriate technique to be used during the infusion of liquid into the interior of the implanted device is to slowly remove the puncture needle during the final 0.5 mL of infusion. This will help to prevent blood reflux and ensure that clots are not formed.
- Flush the device with 20 mL of physiological solution after each infusion. This procedure ensures that no interaction between incompatible fluids occurs and that clots are not formed.

Carrying out continuous infusion

1. Follow the previous instructions for percutaneous puncture with the Gabiport;
2. Connect the system for continuous infusion (sac containing medication or infusion pump);
3. Open the clamp and initiate infusion. Examine the puncture site for signs of extravasion. If signs of extravasion are identified, immediately interrupt infusion and take the necessary measures.
4. When infusion is complete, close the clamp on the extension line.
5. Flush the device with 20 mL of physiological solution. This procedure ensures that no interaction between incompatible fluids occurs and that clots are not formed.

NOTE: For additional security during infusion carried out using an infusion pump, fix all tube connections with adhesive tape.

Collecting blood samples

1. Follow the previous instructions for percutaneous puncture with the Gabiport;
2. Connect a syringe containing 10 mL or more physiological solution to an extension line. Close the clamp on the extension.
3. Aspirate at least 5 mL of blood through the catheter and discard;
4. Aspirate the desired quantity of blood using a 20 mL syringe;
5. Salinize the catheter with 20 mL of physiological solution. This procedure ensures that no interaction between incompatible fluids occurs and that blood clots are not formed;
6. Transfer blood samples to the appropriate tubes.

Clearing an obstruction in the catheter

The Gabiport may occasionally offer resistance to the passage of fluids which cannot be resolved through irrigation or attempts to aspirate the clot.

1. Follow the previous instructions for percutaneous puncture with the Gabiport;
2. Fill a syringe with the prescribed volume of fibrinolytic agent;
3. Inject the medication pushing and pulling on the syringe's plunger to promote mixing in the interior of the chamber. If a large resistance is noted, do not force the infusion of the entire volume of the fibrinolytic agent into the Gabiport;
4. Allow the Gabiport to sit at rest for at least 15 minutes while in contact with the medication. After this 15 minute period has passed, aspirate the solution and the clot. Repeat the operation if it has not been satisfactorily carried out;
5. Once the clot has been properly removed, flush the Gabiport with 20 mL of physiological solution.

RECOMMENDED USE AND MAINTENANCE

- A lack of maintenance may result in occlusion in the device.
- Only use Huber-type needles. The use of classic hypodermic needles is not recommended as they may affect the integrity of the septum.
- Do not reuse Huber-type needles since deformations in their tip may tear or damage the chamber's septum.
- Use Huber-type needles with large diameters (18 and 20H) for blood transfusion and parenteral feeding.
- Take the chamber depth, the anatomy of the patient, their age, weight, and height, among other characteristics, into consideration when selecting the needle length.
- Needles that are too short or too long may become displaced and subsequently create a risk of extravasion.
- Do not use the device if any signs of mechanical damage or leaks are present. Damage to the catheter may result in ruptures, fragmentation, potential embolism, and the need for surgical removal.
- Accessories and components with Luer-Lock connections must be used with this device.
- DO NOT ATTEMPT TO CLEAR THE CATHETER WHILE IT IS UNDER PRESSURE OR USE A SYRINGE WITH A VOLUME OF LESS THAN 10 mL in a manner that places excessive pressure on the device.
- Elevated pressure may damage the catheter or cause the chamber to become disconnected.
- The chamber must be properly connected to the chamber as shown in items 17, 18, and 19 of Implantation techniques – Introduction Using Percutaneous Method since inadequate connection may result in ruptures or the leaking of fluids at the connection.

RECOMMENDATIONS FOR REMOVING DEVICE

- Proceed with the removal of the catheter before the chamber. Do not pull using the chamber in cases in which the catheter has still not been removed. There is a risk of the device disconnecting or embolization of the catheter.

TRACEABILITY

3 self-adhesive labels and a card designated for the patient is provided in each package in order to allow the implanted Gabiport to be traced. A label must be placed on the patient's medical records, the patient card, and the fiscal document involved in payment for the device.

Information contained on label:

a) Product's commercial name;

b) Manufacturer;

c) Product model;

d) Product's nominal size;

e) Manufacturing lot.

Patient Card:

Frente

Verso

STORAGE AND TRANSPORT

Storage and transport must be carried out at room temperature and away from light and humidity. Under these conditions, the product may be used up to the expiration date printed on its packaging.

Notice: Sterilization of the product is not guaranteed if the packaging is open or damaged. The product must be disposed of after use in accordance with hospital standards.

CONTRAINDICATIONS

Contraindications exist for the implantation of the chamber in the following cases:

- Previous allergic reactions or sensitivity, whether determined to exist or suspected, to materials included in the device.
- Existence of a local or general infection such as bacteremia or septicemia.
- The substances used in treatments were incompatible with one of the materials making up the device.
- Presence of other venous devices at the same insertion site.
- Intraluminal centers such as pacemakers.
- Pre-existing hypercoagulopathy, except in circumstances in which the patient has received anticoagulant therapy.
- The structure of the patient's body does not accommodate the size of the implanted device.
- Presence of severe chronic obstructive pulmonary disorder.
- Previous irradiation at the location selected for insertion of device.
- Previous episodes of venous thrombosis or vascular surgery at the location selected for insertion of device.
- Factors with regards to local tissue that impede stabilization or proper access to the device.
- Venous access in the upper torso may be contraindicated due to anatomical characteristics such as burns in the upper torso, cervical thoracic trauma, plans for carrying out irradiation in the mediastinum, bilateral dissection of the neck, and incisions from median sternometry.

POSSIBLE COMPLICATIONS

The most frequent complications occurring during device implantation, in a non-exhaustive fashion, are:

- Gaseous embolism.
- Pneumothorax, hemothorax, hydrothorax.
- Hemorrhaging, hematoma.
- Traumatic brachial plexus injury.
- Heart arrhythmia, cardiac tamponade.
- Lesions in the thoracic duct.
- Arteriovenous fistula
- Occlusion and/or rupture of the catheter due to compression between the clavicle and first rib.
- Disconnection, rupture, and embolization of catheter.
- Occlusion in catheter or chamber.
- Venous thromboembolism / phlebitis, thrombosis.
- Extravasion.
- Cutaneous erosion.

- Local or general infection: bacteremia or septicemia.
- Implant migration.
- Inflammation, cutaneous necrosis in the implantation zone.
- Abdominal hernia, peritonitis, peritoneal leak (peritoneal sites).
- Reactions related to intolerance towards device.

WARNINGS AND PRECAUTIONS

The warnings and precautions described below must be adhered to in order to avoid incidents that may alter the device's function and to ensure patient safety:

- The silicone septum allows up to 1350 punctures (lactating patient), 1450 punctures (pediatric), 1450 punctures (adult/pediatric), and 2000 punctures (adult) using the unit's components. However, it is recommended that the device be replaced every 5 years, or in accordance with specific medical recommendations for each treatment.
- Do not use the device if the packaging is damaged, open, or the provided expiration date has passed.
- Keep away from light and humidity and store at room temperature. Under these conditions, the product may be used up to the expiration date printed on its packaging.
- Adhere to rigorous aseptic methods when implanting and using the device.
- This device (GABIPORT) does not interact with the electromagnetic fields generated by magnetic resonance imaging equipment.
- This product must not be resterilized or reused since doing so may damage the product and/or constitute a risk to the patient's health.
- Not recommended for infusion of large volumes of fluids nor for hemotransfusions due to its low caliber, which favors obstruction.

2 Reprocessing is prohibited.

STERILE EO Sterilized using ethylene oxide.

PACKAGING

The **GMI GABIPORT FULLY IMPLANTABLE CATHETER** comes in heat sealed packaging with blister, Tyvek, and surgery grade paper.

DISPOSAL

All materials used must be disposed of in locations that are appropriate for potentially contaminated materials after use.

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