INSTRUCTIONS FOR USE **REF 581**

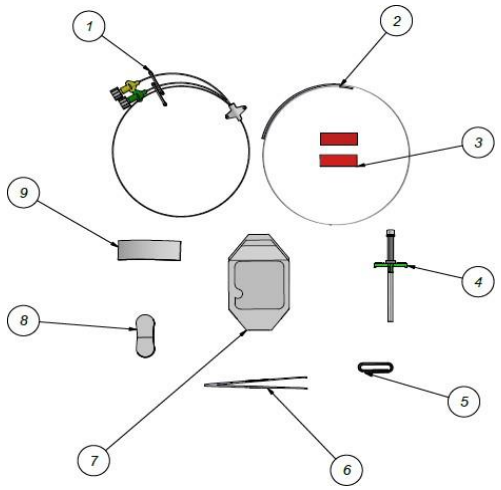
POLYURETHANE DOUBLE-LUMEN PERIPHERALLY INSERTED CENTRAL CATHETER – GMI

INTRODUCTION

Product dimensions and code:

CODE	NUMBER OF CHANNELS	FR	EXTERNAL DIAMETER (mm)	LENGTH (cm)	PRIME FOR LUMEN (mL)	TOTAL PRIME (mL)	MAX. FLOW (mL/s)	MAX. PRESSURE (PSI)	FLOW (mL/min)
581-02-30-2	02	2.0	0.65	30	0.16	0.32	2.0	220	0.7

PRODUCT DESIGN



1- Polyurethane Double Lumen PICC Catheter with Clamp, **2-** Perorated spool, **3-** Sheath label, **4-** Peel-Off Sheath Introducer, **5-** Tourniquet, **6–** Tweezer, **7-** Adhesive Film, **8-** Adhesive for fastening **9-** Measuring Tape.

PRODUCT DESCRIPTION AND COMPOSITION

The **POLYURETHANE DOUBLE-LUMEN PERIPHERALLY INSERTED CENTRAL CATHETER** is inserted through means of a peripheral puncture up to a central access point in patients requiring medium to long-term infusions.

- **Polyurethane Catheter** – markings for each cm, radiopaque, Luer-Lock connection at proximal end – this product is bio-based and hemocompatible, as well as offers increased duration of use. Manufactured from medical-grade polyurethane and barium sulphate; fixed connector with an adaptor for covered Luer-Locks at the proximal end of the silicone tube.
- **Peel-Off Sheath Introducer** – peel away sheath introducer with needle that is compatible with catheter. Its function is to introduce the catheter, providing peripheral vascular access. The needle is manufactured in stainless steel, with a polyethylene body;
- **Measuring Tape** – used to measure the catheter and act as a reference during cutting in accordance with previous measurements. Made from paperboard;
- **Tweezer** – used to introduce catheter through peel away sheath introducer. Made from 304 AISI steel;
- **100% silicone tourniquet** – provides venous distension, allowing the vein to be localized;
- **Plastic Sheath** – protects the catheter; perforated in order to facilitate its opening. Made from polyethylene;
- **Fastening adhesive** – protective Velcro tab for reinforcing fastening and providing protection against dirt; also acts as an internal anatomical design providing an appropriate and precise fit for the Huber;
- **Adhesive film** – protects the site at which the catheter is inserted while also allowing it to be viewed.

PURPOSE / RECOMMENDED USE

The Polyurethane Peripherally Inserted Central Catheter is recommended for short and long-term use in providing peripheral access to the central venous system for safe intravenous treatment, guaranteeing the preservation of the peripheral venous network, and reducing stress, pain, and discomfort due to multiple punctures. It is also recommended for use in collecting blood samples, infusions, or therapeutic use.

INSTRUCTIONS FOR USE

The instructions for use are only intended to be used as a guide and do not represent a recommended treatment for a specific patient. In order to use the device correctly, the respective medical professionals must be familiar with the specific techniques or surgical maneuvering necessary for inserting the peripherally inserted central catheter (PICC) and have received training in the positioning, maintenance, and use of the device.

Its use must adhere to protocols established by the institution and approved professional standards and guidelines. This procedure must only be carried out by trained professionals that are highly knowledgeable with regards to inherent risks while adhering to the following instructions:

PACKAGING

- Primary packaging: unit comes in thermally sealed packaging with a PVC/PET Polyethylene terephthalate blister and Tyvek paper which contains all of the items shown in the product design.
- Secondary packaging: Cardboard box containing 1 unit in primary packaging.

DISPOSAL

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

STERILIZED USING ETHYLENE OXIDE REPROCESSING IS PROHIBITED

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- Apply a protective dressing to the skin or another item allowing the catheter to be fastened;
- Salinize both of the catheter's channels before and after medication is administered.
- The improper positioning of the catheter may result in heart arrhythmia**.** Carry out procedure in strict adherence to aseptic standards; contamination of the catheter may result in phlebitis, infections, and sepsis.

SPECIAL PRECAUTIONS

- If the catheter becomes obstructed, do not apply excessive pressure with syringes or infusion pumps since this may cause a rupture.
- Take special care to always precisely measure distance to cover the patient's body;
- Adhere to all standardized/universal precautions with all patients in order to reduce potential exposure to bloodborne pathogens;
  necessary for reaching the final location of the catheter in the cephalic vein through the median cubital or basilic vein.
- If the catheter is inserted into a vein of a lower caliber than that previously used, complications commonly result since the catheters is subsequently housed in low caliber peripheral vessels in which the space between the external wall of the catheter is significantly reduced, resulting in a reduction in
  blood flow and significantly diminishing the dilution of infused fluids, causing an irritation commonly known as phlebitis.
- Never remove the catheter while the sheath introducer is positioned since this may rupture the catheter.
- Do not use syringes with a volume of less than 10 mL.
- Take precautions when using perforating or cutting materials near the catheter.
- Store the product in a dry, well-ventilated area protected from solar rays with an ambient temperature between 15 to 30 ºC and 20% to 80% humidity.
- Do not use the member in which the catheter has been inserted to measure pressure and unintended puncture for collecting blood samples.

RECOMMENDATIONS

- Ensure that packaging is intact.
- Verify the dates on which the device was sterilized and the expiration date.
- Store the product in a dry, well-ventilated area protected from solar rays.
- Respect the distances marked on the catheter for each case.

The specifications described in this document are presented in a schematic fashion in order to properly explain the manner in which the apparatus is used. They must be accompanied by the professional training received by the individual carrying out the procedure and a bibliography on the subject area.

ADVERSE EFFECTS

- Hematoma
- Arrhythmia
- Chemical phlebitis
- Mechanical phlebitis , Mechanical phlebitis and Dermatitis

The PICC catheters' distal end must be inserted into the lower third of the superior vena cava up to the junction between the superior vena cava and the right atrium.

- The lower extremity must have its distal end inserted into the thoracic inferior vena cava, above the level of the diaphragm.
- Follow the aseptic technique approved by the institution. Aseptic techniques and proper preparation are essential to correct use of the apparatus.
- The manufacturee recommends that the maximum possible number of sterile barriers are used during insertion of the catheter in order to prevent infection related to the catheter, including the use of aprons, masks, surgical cap, gloves, and large sterile fields

INSERTING THE CATHETER

1. Select a vein that is appropriate for puncture;

The catheter may be inserted peripherally through the cephalic, median cubital, or basilic veins. The basilic vein is recommended since access through the median cubital or cephalic vein is more difficult to obtain, An access point established through another surgical incision made at an alternative site may be carried out by a physician in accordance with each institution's protocol.

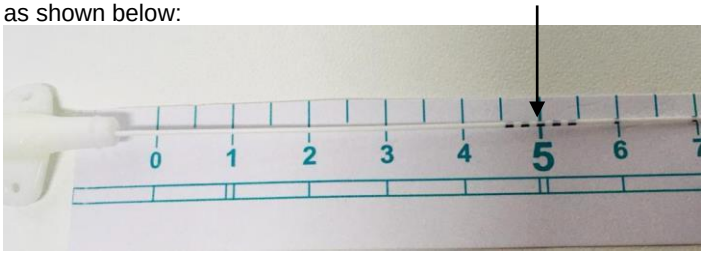
2. Position and measure the patient;

- To implant the PICC in upper extremities: position the arm at a 90° angle and measure from the insertion point to the right clavicular head and afterwards downwards to the third palpable intercostal space for fastening to the superior vena cava (SCV);
- To implant the PICC in a lower extremity: measure from the location intended to be used for fastening to the right of the umbilicus upwards to the xiphoid process for implantation in the Inferior Vena Cava (ICV);

NOTE: external measurements made using measuring tape will never equal the internal anatomy of the vein.

3. Measure catheter;

- The GMI polyurethane double lumen Peripherally Inserted Central Catheter is 30 cm in length, with markings starting at 5 cm;
- To measure correctly, position the catheter at the third 5 cm marking, as shown below:



4. Prepare sterile field;

- Opening packaging to access the contents of the tray;

- Separate and prepare the necessary equipment, adhering to appropriate aseptic techniques.

5. Prepare puncture site and apply sterile fields;

- Prepare the site designated for puncture in accordance with institutional protocol.
- Apply the sterile field.

6. Prepare and cut the catheter;

- Open the plastic sheath using the central perforation and remove the catheter from its protective area.
- Connect a 10 mL syringe containing normal saline solution and wash the catheter.

Note: The 10 mL syringe is not supplied together with the product.

7. Apply the tourniquet;

- Apply tourniquet to member in order to distend blood vessels (use the silicone tourniquet provided with the unit).

8. Once the vein is punctured remove the introducer needle

- Use the peel-off sheath introducer while adhering to the following instructions:
- Remove the protective cover;
- Secure the introducer by the base and puncture the vein. Once blood return is observed, remove the metallic needle that guides the introducer, leaving only the peel-off cannula;

9. Advance the catheter;

- Remove the tourniquet from the member;
- Slowly introduce the catheter through the sheath introducer using the metallic tweezers. If resistance is encountered, remove catheter and repeat procedure;
- Continue to advance the catheter slowly in small increments;
- For positioning in the superior vena cava: as the tip of the catheter passes the shoulder, turns the patient's head to the side on which the insertion site is located, with the jaw above the shoulder in order to avoid poor positioning of the catheter within the jugular vein;
- Continue advancing the catheter until the desired position for implanting its tip is reached;
- Remove the sheath introducer by carefully engaging the peel-off in order to not pull on the catheter that has been introduced;

10. Clean the insertion site;

- Remove the sterile fields;
- The entire product must be applied under the direct supervision of a qualified health care professional. This professional must carry out monitoring during the application of the catheter as well as throughout patient treatment.
- The product must be used in accordance with the practices defined by the institution;
- It is important to note that the techniques for use, special care taken with the product, and removal may vary in accordance with the specific

circumstances of each usage;

- Monitor the patient (F.C, SPO2, F.R. (respiratory rate)
- Continuously assess color of skin and abdominal tension;
- Adhere to all medical recommendations and institutional protocols;

11. Fasten the catheter and apply a sterile bandage;

- The external part of the catheter must be properly fastened. Any change in the length of the external part of the catheter at the insertion site indicates that the location of the tip has also changed.
- Apply dressing in accordance with standards and institutional protocols.

12. Radiographic confirmation of positioning;

- Confirm the positioning of the tip of the catheter through means of radiography. Radiographic confirmation of the positioning of the catheter tip is necessary for all centrally implanted catheters.

REMOVING THE CATHETER

1. Remove the dressing; secure the catheter near the insertion site.
2. Slowly remove the catheter. NOTE: do not use an excessive amount of force.
3. If resistance is encountered, interrupt removal. Apply a warm compress and wait for 20 to 30 minutes before reinitiating the removal procedure.

CONTRAINDICATIONS

- Changes in puncture site; Changes in patient coagulation;
- Administering of large bolus volumes under pressure;
- Use of pumps with a high flow volume;
- Difficult peripheral venous access due to repeated punctures resulting in the formation of hematoma and thrombosis;
- Cutaneous lesions at the insertion site; atrophy in the member selected for implantation.

WARNINGS AND PRECAUTIONS

- The procedure must be carried out under the direct supervision of a qualified health care professional;
- Select a large caliber vein whenever possible;
- Consistently assess the patient's condition;
- Patients subjected to the procedure must be hermodynamically stable.
- Monitor the patient's vital signs throughout the entire procedure.
- Store product in a dry well-ventilated area;
- Carry out subsequent care in accordance with institutional/professional criteria.
- Disposable product intended for use on a single patient;
- Clean the insertion site;
- Apply a protective dressing to the skin or another item allowing the catheter to be fastened; Salinize both of the catheter's channels before and after medication is administered. The improper positioning of the catheter may result in heart arrhythmia**.** Carry out procedure in strict adherence to aseptic standards; contamination of the catheter may result in phlebitis, infections, and sepsis.