RECOMMENDATIONS

- Ensure that packaging is intact.
- Verify the dates on which the device was sterilized and the expiration date.
- Percutaneous catheter with peel-off sheath introducer must be stored and transported at room temperature away from heat and humidity.
- 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. This procedure must be monitored and carried out by a fully trained and qualified professional in accordance with established protocols at each institution.

STERILE EO Sterilized using ethylene oxide

Reprocessing is prohibited

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.

PACKAGING
The **GMI PERIPHERALLY INSERTED CENTRAL CATHETER – PICC WITH PEEL-OFF SHEATH INTRODUCER AND NO GUIDE WIRE** comes in thermally sealed packaging with blister and Tyvek paper.

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

ADVERSE EFFECTS
No adverse effects have been observed in the use of 100% silicone products; however, adverse effects related to the use of venous catheters have been reported, such as:
Mechanical phlebitis, dermatitis, arrythmia, and infections in the insertion site.

Technician Responsible - Dr. Josimara S. A. Possidonio – CRF - SP 54659 ANVISA REG.: 80423540006

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REF **650**

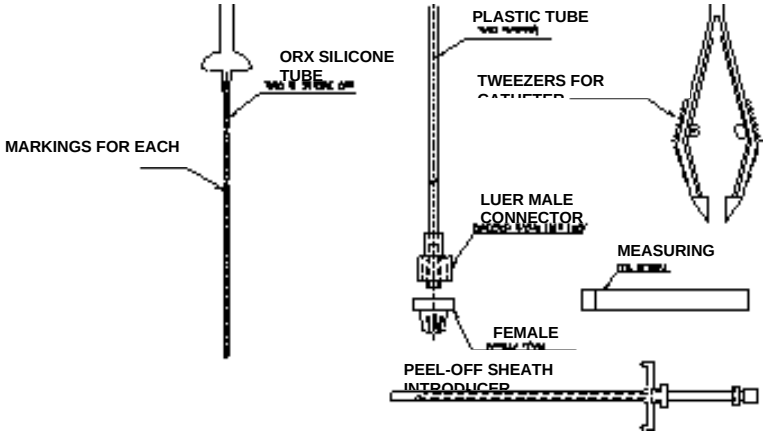
GMI PERIPHERALLY INSERTED CENTRAL CATHETER WITH PEEL-OFF SHEATH INTRODUCER AND NO GUIDE WIRE

INTRODUCTION

The following table presents the product's dimensions and code:

CODE	Fr/Ch	Introducer Gage	Int. D. X Ext. D. (mm)	Catheter length (mm)	Prime Volume	Velocity* (mL/hr)	Max. Volume (mL/sec)	Pressure (PSI)
650-19-50	1.9	24 G	0.25 x 0.65	500	0.15	> 20	0.2	170
650-02-30	2.0	24 G	0.25 x 0.65	300	0.10	> 30	0.2	170

***** Flow velocity with saline solution using gravity - Flow velocity may vary depending on the viscosity of the fluid used and the catheter length.



PRODUCT DESIGN

PRODUCT DESCRIPTION AND COMPOSITION

The GMI PERIPHERALLY INSERTED CENTRAL CATHETER – PICC WITH PEEL-OFF SHEATH INTRODUCER AND NO
GUIDE WIRE consists of:

- 100% Silicone Catheter with markings for each cm, radiopaque, with Luer-Lock connection at proximal end – this product is bio-based and hemocompatible.
- Split peel-off sheath introducer for ideal insertion of the needle/catheter when introduced into venous network.
- Measuring Tape – used to measure the catheter and act as a reference during cutting in accordance with previous measurements, when necessary.
- Tweezer – used to introduce catheter through peel away sheath introducer.
- Tourniquet – 100% silicone band facilitating location of peripheral access.
- PVC extension set with proximal connection and distal Luer-Lock for connection and clamp tweezers.
- Plastic Sheath – protects the catheter; perforated in order to facilitate opening.

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PURPOSE / RECOMMENDED USE

The GMI PERIPHERALLY INSERTED CENTRAL CATHETER – PICC WITH PEEL-OFF SHEATH INTRODUCER AND NO
GUIDE WIRE is recommended for use in facilitating prolonged venous access through peripheral pathways through means of venous puncture or another technique chosen by a professional that is fully trained and qualified to carry out this procedure.
For sure in patients requiring intravenous therapy, thereby avoiding repeating punctures. Also recommended for infusion of electrolytes, drugs, blood, hemoderivatives, and chemotherapy. Not recommended for use in collecting blood samples.

INSTRUCTIONS FOR USE:

While techniques for insertion, care, and removal of the percutaneous catheter may vary according to the specific characteristics of each usage, it is suggested that the following instructions be adhered to:
Gather the materials needed for the procedures and select the proper location.

Select the insertion site;

- The catheter may be inserted peripherally through the cephalic, median cubital, or basilic veins.

Insertion Procedure:

- Place the patient in the most convenient and comfortable position. Procedure must be carried out in accordance with established protocols;
- Assess the conditions at the puncture location and select the ideal insertion site.
- Open the protective plastic sheath along the perforated line in order to remove the catheter;
- Measure the approximate length between the insertion site and the superior vena cava (third right intercostal space) using the measuring tape and record the measurement;
- Prepare the area surrounding the location in which the puncture will be made, carrying out asepsis at the site;
- Attach the extension set to the catheter using the Luer-Lock connection for initiating intravenous therapy and hydrate the catheter before inserting;
- Apply tourniquet to member in order to distend blood vessels (use the silicone tourniquet provided with the unit);
- Puncture vein with Peel-Off Sheath Introducer;
- Remove the puncture needle from the peel-off introducer once blood return has been observed;
- 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;
- While introducing the catheter, note the number of centimeters of catheter that is being introduced in accordance with the measurements previously made at the start of the procedure.
- It is recommended that the tip of the catheter be positioned in the superior vena cava approximately 3 to 4 cm from the entrance to the right atrium;

- Aspirate the catheter and observe reflux;
- Remove Peel-Off Sheath Introducer (break the introducer and peel it away in a manner in which it splits into two parts, leaving the catheter positioned in the vein);
- Fasten the catheter;
- Prepare a dressing in accordance with the institution's standardized protocol;
- Request that radiography be carried out in order to confirm the catheter's position.

CONTRAINDICATIONS

- Changes in puncture site;
- Changes in patient coagulation;
- Administering of large bolus volumes under pressure;
- 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 by fully trained and qualified medical professionals.
- Select a large caliber vein whenever possible.
- Consistently assess the patient's condition.
- Patients subjected to the procedure must be hermodynamically stable.
- During the procedure, connect the patient to a saturation and heart rate monitor.
- Salinize channel before and after administering medication.
- 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

- Attention must be taken during the concomitant application of drugs involving the potential for chemophysical reactions which may contribute to the channel becoming obstructed.
- If the catheter becomes obstructed, do not apply excessive pressure with syringes or infusion pumps since this may cause a rupture.
- Care must be taken when using the catheter in a lower caliber vein since complications such as reduced blood flow and a significant reduction in the dilution of infused fluids may cause an irritation commonly known as **phlebitis.**
- The collecting of blood samples in low caliber catheters must be avoided due to the possibility of the device becoming obstructed or damaged.
- Do not use syringes with a volume of less than 10 mL.
- Take precautions when using perforating or cutting materials near the catheter.
- The device must be stored at room temperature in a well-ventilated, dry, clean area away from light and excess humidity.
- The maximum period of time for which the PICC can remain in the human organism is 29 days.