SPECIAL PRECAUTIONS

- If the catheter becomes obstructed, do not apply excessive pressure since this may cause a rupture.
- Never remove the catheter while the peel-off sheath introducer is positioned since this may rupture the catheter.
- Never open the peel-off sheath introducer before the catheter has been fastened with a dressing.
- Never use any type of staples with the catheter.

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 specific 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.

STERILE EO Sterilized using ethylene oxide.

Reprocessing is prohibited.

This product may 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 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. Product intended for single use only. Do not reprocess.

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.: 80423540011

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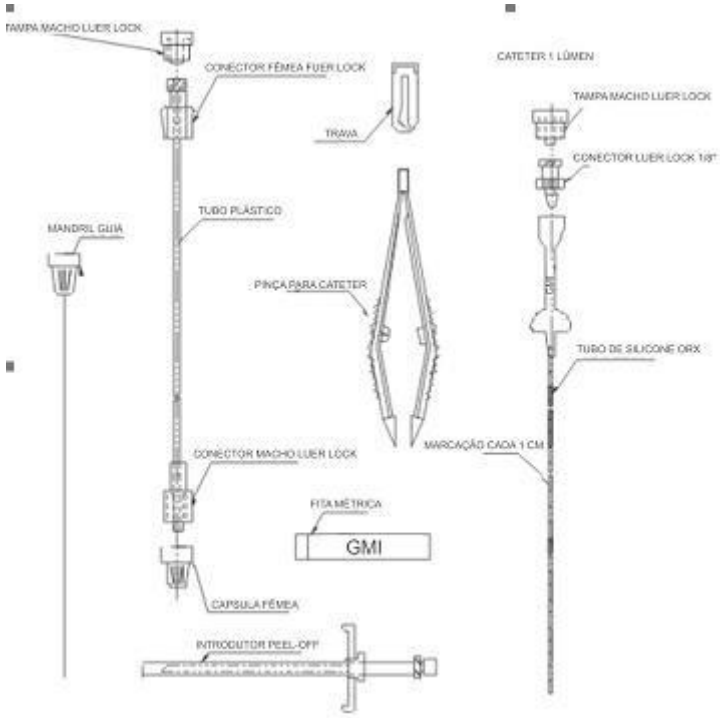
GABISA MEDICAL INTERNATIONAL

REF 650-G

GMI PERIPHERALLY INSERTED CENTRAL CATHETER - PICC WITH PEEL-OFF SHEATH INTRODUCER AND GUIDE WIRE

INTRODUCTION

- **Single lumen catheter**



PRODUCT DESIGN

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

CODE	Fr/ Ch	Introducer Gage	Lumen	Length (mm)	Int. D. x Ext. D. (mm)	Prime Volume	Velocity * (mL/hr)	Max. Volume (mL/sec)	Pressure (PSI)
650-03-50 G	3.0	20 G	1	500	0.50 x 1.00	0.30	> 100	1	75
650-04-65 G	4.0	18 G	1	650	0.75 x 1.35	0.45	> 200	3	100
650-05-65 G	5.0	16 G	1	650	0.80 x 1.70	0.50	> 500	3	100

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

PRODUCT DESCRIPTION AND COMPOSITION

The **GMI PERIPHERALLY INSERTED CENTRAL CATHETER - PICC WITH PEEL-OFF SHEATH INTRODUCER AND 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.
- Fixed connector with a Luer-Lock adapter with a sealing cover.
- Extension set made from PVC tubing with an external diameter of 2.00 mm and internal diameter of 1.00 mm with a universal connection at the proximal end with a cover for syringes. Clamp located on PVC extension set in order to restrict flow through the tube.
- Peel-off sheath introducer for ideal insertion of the needle/catheter when introduced into venous network.
- Metallic stainless-steel guide with different diameters to accommodate each silicone tube's FR (caliber).
- Insertion tweezers facilitating the introduction of the catheter.
- Measuring Tape for measuring the catheter as well as for use as a reference during cutting
- Plastic Sheath – protects the catheter; perforated in order to facilitate opening.

PURPOSE / RECOMMENDED USE

Use to facilitate central venous access for prolonged use, puncture through peripheral pathways, or other chosen techniques carried out by a fully qualified medical professional. Intended for adult, pediatric, and neonatal use.
Intended for use in patients requiring prolonged intravenous therapy, thereby eliminating the need for multiple punctures. Facilitates the venous administration of medication, chemotherapies, electrolytes, and hemoderivatives. Blood samples may also be collected using catheters greater than 3.0 FR (French) in size.

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 a 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. Do not pull the catheter inside the plastic sheath;
- 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; A sterile compress with aseptic solution is necessary for this procedure;
- Attach the extension set to the catheter using the Luer-Lock connection to initiate intravenous therapy;
- Salinize the catheter with physiological solution or distilled water;

- Whenever necessary, cut the catheter to the length indicated, pulling the guide wire so that it is positioned 1 or 2 cm in front of the measured cut;
- 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);
- Slowly remove the guide wire from the catheter;
- 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

- If the catheter becomes obstructed, do not apply excessive pressure with syringes or infusion pumps since this may cause a rupture.
- Take special care when measuring the distance necessary for reaching the final location of the catheter in the cephalic vein through the median cubital or basilic vein.
- 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.**
- Do not use syringes with a volume of less than 10 mL due to risk of the catheter rupturing.
- 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 time period for which the GMI PICC catheter can remain in the human organism is 29 days.