Potential complications from arterial cannulation

- Vasospasms resulting in intense pallidness in lower members or buttocks. If patient's condition does not improve, the catheter must be removed.
- Vascular perforation - requires surgical intervention.
- Potential risk of thrombosis and accidental embolism.
- Hemorrhaging due to vascular perforation, accidental disconnection, accidental displacement of catheter, and catheter breakage may subsequently require that transfusions be carried out.
- Infection and necrotizing enterocolitis generally require that the catheter be removed.
- Arterial hypertension may develop if the end of the catheter is positioned near the start of the renal artery.
- Rarer complications: peritoneal perforation, hypogycemia when the catheter is positioned opposite to the celiac axis, false aneurysm, air embolism, paralysis of the sciatic nerve, and omphalocele.

RECOMMENDATIONS

1. Ensure that packaging is intact.
2. Verify the dates on which the device was sterilized and the expiration date. Do not use product after the expiration date.
3. Store the product in a well-ventilated area protected from solar rays.
4. Respect the distances marked on the catheter for each case.

THE MANUFACTURER RECOMMENDS A MAXIMUM DURATION OF USE FOR THE PRODUCT OF 7 (SEVEN) DAYS AND SUGGESTS THAT THE DEVICE BE REPLACED EVERY 5 (FIVE) DAYS

STERILE EO Sterilized using ethylene oxide. 2

Reprocessing is prohibited. Sterile and apyrogenic.

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
Envelope pouch with ETO sterilized paper on which product characteristics and production lot are printed, as well as labeling required by respective health authorities.

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

Adverse effects
There are no adverse effects associated with the use of this product provided that it is used in accordance with the instructions for use. However, all possible contraindications, precautions, warnings, and complications related to venous cannulation are described in this document.

Technician Responsible - Dr. Josimara S. A. Possidonio – CRF - SP 54659
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GABISA MEDICAL INTERNATIONAL

REF 544

GMI UMBILICAL CATHETER

INTRODUCTION

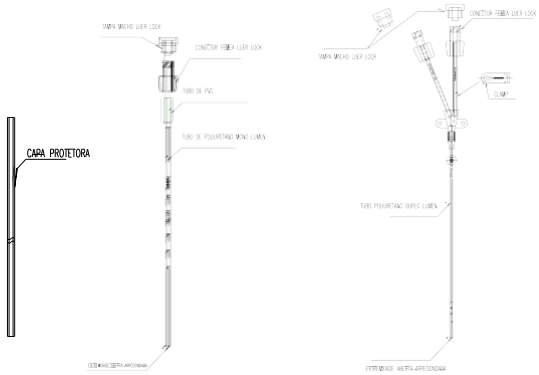
The **GMI UMBILICAL CATHETER** is available in both **SINGLE LUMEN AND DOUBLE LUMEN** models.

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

GMI SINGLE LUMEN (544) AND DOUBLE LUMEN (544D) UMBILICAL CATHETER

CODE	CH/FR	Ext. Diam. (mm)	Int. Diam. (mm)	Length (mm)
544-25	2.5	0.85	0.40	305
544-35	3.5	1.20	0.60	410
544-40	4.0	1.35	0.75	410
544-50	5.0	1.70	0.80	410
544-60	6.0	2.00	1.00	410
544-35-D	3.5	1.20	0.60	380
544-50-D	5.0	1.70	0.80	380

544 **544-D**



PRODUCT DESIGN

PRODUCT DESCRIPTION AND COMPOSITION

The **GMI SINGLE LUMEN** and **DOUBLE LUMEN UMBILICAL CATHETER** is made from medical-grade polyurethane, the measurements for length and caliber of which vary according to the product code.
Its polyurethane tube is radiopaque and graduated with markings from the 4th to the 24th cm up to the distal end.

GMI Single Lumen UMBILICAL CATHETER - product code 544

- Luer-Lock connection and a male Luer-Lock cover located at the proximal end of the polyurethane tube.
- Open distal end.
- Catheter comes with a protective cover.

GMI Double Lumen UMBILICAL CATHETER - product code 544-D:

- Single polyurethane tube divided into two lumens.
- Double channel extension with Luer-Lock connections and a protective male Luer-Lock cover located at the proximal end of the polyurethane tube.
- Includes 2 clamps for obstructing flow.
- Open distal end.
- Catheter comes with a protective cover.

PURPOSE

The GMI Umbilical Catheter is intended for use in umbilical vein or arterial catheterization.
Umbilical arterial catheterization is generally used to monitor pressure, collect blood samples, administer medications and blood products during therapy, and carry out volume replacement, among other activities.

INSTRUCTIONS FOR USE:

Umbilical arterial cannulation

- Positioning of child: In dorsal decubitis position and properly immobilized. Must receive an appropriate amount of heat;
- Properly measure the distance from the shoulder to the umbilicus or total body length in order to calculate the size of the catheter that is to be inserted; 2/3 of the distance from the shoulder to the umbilicus is generally appropriate;
- Establish parameters in accordance with institutional protocol;
- Check all necessary equipment;
- Connect syringe containing solution to three-way and the catheter and remove all air, injecting the solution into its interior;
- Ask assistant to raise the umbilical stump and carry out asepsis using antiseptic solution not only in the umbilicus, but also along the abdominal wall, using circular motions;
- Place fields onto umbilicus. Tie the base of the umbilicus with a wire, making a simple knot (prevents bleeding during passage of the catheter). Cut the cord horizontally 0.5 to 1 cm from the base. Pressure may be applied to the knot if bleeding occurs;
- Clean blood from the cut with gauze and identify the umbilical vessels: a vein with thin elliptical walls and arteries, with thick rounded walls;
- Secure the umbilical stump with one hand or a pair of hemostatic forceps, lightly everting its face. Avoid pinching the vessel;
- Introduce an ophthalmic probe into the arterial lumen, making gentle circular movements until a distance of 0.5 cm is reached;
- Keep the probe in the lumen for 30 seconds before removing it. Repeat this movement until the artery is sufficiently dilated to allow the catheter to enter;
- Hold the catheter 1 cm from the extremity with forceps or the thumb/pointer finger and insert into arterial lumen. Gently apply pressure, using a rotating motion to advance the catheter the necessary distance;
- Aspirate blood and introduce the catheter again to test its intraluminal positioning;
- The catheter must be fastened in accordance with institutional protocol;
- The catheter's position must be checked using radiography;
- No fastening should be carried out if the skin surrounding the umbilicus is compressed due to the risk of necrosis.

WARNINGS AND PRECAUTIONS

- Products must be used under the direct supervision of a qualified health care professional.
- This procedure requires that an analysis of the necessity of applying this type of product be carried out and must be monitored by the professional both during use and throughout patient treatment.
- The sterility of this product is guaranteed if the packaging is intact and properly sealed. Packaging preserving the product's original condition of sterility must only be opened in order to carry out the insertion procedure. Non-flammable.
- Special care must be taken while using cutting instruments since these items may cause tears or damage to product's external surface.
- This product must be used in accordance with procedures defined in manuals for standards and routines and by the medical team.
- Sutures used for fastening must not contain grooves in order to avoid damaging the catheter wall.
- It is important to note that techniques for insertion, special care taken with the product, and removal may vary in accordance with the specific circumstances of each usage.
- Consistently assess the patient's general characteristics.
- The patient's heart rate and saturation, at a minimum, must be monitored during the procedure.
- Assess bleeding during the procedure in order to contain and prevent possible complications.
- Carry out subsequent care in accordance with institutional protocols.
- Wash channel before and after removing blood samples.
- Improper placement of the apparatus may result in embolism, hemorrhaging, and vascular perforation.
- Carry out the procedure while adhering strictly to aseptic standards. Contamination of the catheter may result in infection and sepsis.
- If the catheter becomes obstructed, do not apply excessive pressure since this may cause it to rupture.
- Inspect the catheter's connections in order to ensure that they are secure.
- Do not carry out transfusions of blood or other blood products and do not aspirate blood for collection in catheters smaller than 3 FR.
- Avoid the use of organic solvents involving prolonged contact such as alcohol or acetone since these substances may cause irreversible damage to the polyurethane resulting in rupture or leakage.
- Do not use tweezers in catheters inserted into umbilical vessels.
- This is a disposable product intended for use on a single patient.

Do not resterilize the product.

Potential complications from venous cannulation

- General localized infections due to cannula remaining in position for long periods of time;
- Poor positioning in portal venous systems may cause hepatic necrosis and necrosing enterocolitis. May cause pericardial effusion, cardiac tamponade, arrythmia, and endocarditis when positioned in the heart;
- Thrombosis of the umbilical vein and the portal venous system may culminate in pulmonary embolism and hypertension in the portal system. Systemic embolism in the kidneys, liver, and brain may occur when the tip of the catheter is located in the left atrium;
- Perforation of the colon immediately after exchange transfusions have been carried out has been documented.