ISOMed

CE 2803

INSTRUCTIONS FOR USE

OCCLUSION CATHETERS SINGLE LUMEN

CE marking: 2000

Products references: range 320000

Caution: this product contains natural rubber latex which may cause allergic reactions. Only the references ending with "LF" do not contain natural rubber latex.

Product sterilized by ethylene oxide. Sterile product as long as the packaging hasn't be opened, damaged or brake. Single use product.

CONTRAINDICATIONS:

- This catheter is not made to diagnose, to watch or correct a heart or central circulation system failure by direct contact with the central circulatory system.
- The occlusion catheter is not recommended for the removal of fibrous, adherent, or calcified material (e.g. chronic clot, atherosclerotic plaque). The catheter is not designed to withstand the additional pull force needed to remove these materials.
- Not for use as a dilation catheter.

WARNINGS:

- Balloon rupture and catheter separation as a result of excessive pull force applied to remove adherent material are the most frequent causes of reported failures. The possibility of balloon rupture must be taken into account when considering the risks involved in any embolectomy procedure.
- To minimize the risk of vessel damage, balloon rupture, or tip detachment, do not exceed the maximum recommended inflation volume and pull force for each size catheter (see Table A).
- Use of a highly viscous or particulate contrast medium is not recommended for balloon inflation because the inflation lumen may become occluded.
- To minimize the risk of infection, it is recommended to do preventive antibiotic therapy.

Must be excluded from the treatment, patients who present the followings status:
- Latex allergy or for whose the sensibility to latex is not known
- Identification of an atheroma plaque which may damage the catheter
- Pre-existing or induced cardiopathy
- Venous or arterial capital too fragile

OCCLUSION CATHETER USE:

The occlusion catheter is intended to temporarily occlude a blood vessel without using a clamp or ties.
The balloon conforms to the diseased interior wall of the vessel providing occlusion with less chance of damage to vessel wall and lining.
Check that the balloon diameter is constantly in contact with the vessel walls.
The indications are the occlusion of vessels both arterial and venous for the control of bleeding.

OCCLUSION CATHETER DESCRIPTION:

The occlusion catheters are composed of a tube and a Luer Lock hub.
The catheter is marked in 10 cm graduation to gauge the length of insertion and, noted on the tube at the hub proximity, its naming, size, and the maximal volume to inject in the balloon.
The distal portion of the catheter contains a latex section that inflates to form a balloon.

WARNING: Our catheter is designed to provide the surgeon with a variety of functional options for a wide range of surgical procedures. Therefore, the procedural approach, surgical technique, selection of infusate and method of use must be left to the discretion of the individual surgeon using the device: the medical judgement of the physician must be exercised at all time.

A size range of catheters is available in order to accommodate a variety of the venous diameters and length (see table A).

DIRECTION FOR USE: CATHETER PRIMING
The catheter should be primed before use.

1- Select the appropriate size Luer Lock syringe for use with the catheter (see the balloon maximal volume noted next to the hub).
2- Use liquid prime which is sterile and blood compatible (for example sterile physiological serum). Fill the syringe with liquid prime.

CAUTION: it is not recommended to use air to inflate the balloon

3- Fix the syringe to the catheter Luer Lock connection.
4- Hold the catheter vertically with distal tip toward the ground and slowly inject liquid prime into the catheter.
5- Remove air from the catheter by tapping it so that the air will return up into the syringe. Pull a vacuum on the syringe. Repeat until all air is removed.
6- The catheter should be inspected with the balloon inflated during purging. A balloon that does not inflate, leaks, or inflates in a grossly asymmetric manner should not be used.
7- Once the catheter is fully primed, the syringe is disconnected from the catheter and all residual contents are expelled from the syringe.
8- The syringe is then refilled with appropriate volume of liquid (see table A) and the syringe reconnected. The catheter is ready for use.
9- With the balloon deflated, insert the catheter into the vessel and inflate the balloon with sterile fluid to feel the balloon applies to the vessel.

WARNING: Exceeding the maximum recommended liquid volume for each size catheter greatly increases the possibility of balloon rupture. Balloon rupture is sensed by a decrease in resistance on the syringe during inflation procedures. If balloon rupture occurs, the catheter should be withdrawn.

WARNING: Air should not be used for inflation in instances where balloon rupture could produce a dangerous air embolus.

WARNINGS:
- Do not sterilize
- Store in a cool and dry place with ambient temperature. Avoid extreme temperatures and humidity. Avoid exposition to intense lights sources (solar light, fluorescent tube…) to preserve the balloon. Conserve in the original packaging.
- Shelf life - Use this catheter before the expiration date indicated on the packaging.

WARNING: Re-use of the device could result in inaccurate inflation, increased risk of infection or other improper functioning of the device.

WARNING: Comply with existing regulations for disposal of stained instruments.
The materials of the catheter are: tube & hub = TPE, balloon = latex or polyisoprene (for references LF), protector tube = PE, pouch = PGL + PET / PE, rod tube = ABS + MABS + Tyvek ®

OCCLUSION CATHETERS SINGLE LUMEN

TABLE A: STANDARD OCCLUSION CATHETERS

REFERENCES	COLOUR CODE	OUTER DIAMETER	USEFUL LENGTH	MAXIMUM RECOMMENDED LIQUID VOLUME	MAXIMUM RECOMMENDED PULL FORCE ON INFLATED BALLOON (N)	APPROXIMATE DIAMETER OF INFLATED BALLOON
320740	Yellow	7F (2,65 mm)	40 cm	15.00 ml	15	30 mm
320760	Yellow	7F (2,65 mm)	60 cm	15.00 ml	15	30 mm
320780	Yellow	7F (2,65 mm)	80 cm	15.00 ml	15	30 mm
320840	Brown	8F (2,70 mm)	40 cm	38.00 ml	15	40 mm
320860	Brown	8F (2,70 mm)	60 cm	38.00 ml	15	40 mm
320880	Brown	8F (2,70 mm)	80 cm	38.00 ml	15	40 mm

EN: Do not use if the packaging is damaged FR: Ne pas utiliser si l'emballage est endommagé DE: Nicht verwenden, wenn die Verpackung beschädigt ist ES: No utilizar si el embalaje está deteriorado		EN: Reference number FR: Numéro de référence DE: Bestellnummer ES: Número de referencia		EN : Manufacturing date FR : Date de fabrication DE :Herstellungsdatum ES : Fecha de fabricación
EN: See instruction for use FR: Lire la notice DE: Anleitung lesen ES: Consulte las intrucciones de uso		EN: Single use FR: Usage unique DE: Zum einmaligen Gebrauch ES: De un solo uso		EN: Use by FR: À utiliser avant la date DE: Verfallsdatum ES: Utilizar antes de
EN: Sterilized by Ethylene Oxide FR: Stérilisé à l'oxyde d'éthylène DE: Mit Ethylenoxid sterilisiert ES: Esterilizado con óxido de etileno		EN: Manufactured by FR: Fabriqué par DE: Hergestellt von ES: Fabricado por		EN: Batch code FR: Numéro de lot DE: Chargennummer ES: Número de lote