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CE 2803

INSTRUCTIONS FOR USE

ARTERIAL EMBOLECTOMY CATHETER SINGLE AND DOUBLE LUMEN

CE marking = 2000

READ CAREFULLY INSTRUCTIONS BEFORE USE.

PRODUCT REFERENCES:
- Single lumen catheters: range 300000
- Double lumen catheters: range 500000

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 has not been opened, damaged or broken.
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 arterial embolectomy catheter should not be used outside the arterial system (e.g. venous system).
- The arterial embolectomy 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.
- Do not use out of the arterial system
- Do not use for endarterectomy procedures
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

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.
- Considering the forces applied during fistula declotting, it is not recommended to use catheter smaller than 4F.

COMPLICATIONS
As with all catheterization procedures, complications may occur. These may include local or systemic infection, local haematomas, intima disruption, arterial dissection, perforation and vessel rupture, hemorrhage, arterial thrombosis, distal embolization of blood clots and atherosclerotic plaque, air embolus, aneurysm, arterial spasm, arteriovenous fistula formation and balloon rupture with fragmentation, tip separation and distal embolization.

EMBOLECTOMY CATHETER USE:
The embolectomy catheter is indicated for the removal of fresh, soft emboli in the peripheral arterial system. The catheter is intended to be passed through an arteriotomy and advanced along the artery until the suspected occlusion site is reached.
For the double lumen catheters, the embolus can be made radio-visible by first inflating the balloon and then injecting medium contrast product through the distal lumen.
If visualization is not desired, the catheter tip may be advanced further with the balloon deflated through any suspected embolus.
Emboli removal is achieved by inflating the distal balloon with sterile liquid and subsequently withdrawing the catheter tip through the arteriotomy.
For the double lumen catheters, irrigation of the embolectomized segment may be performed by reinserting the catheter, injecting sterile liquid through the distal lumen and with the balloon inflating, removing the residual emboli through the arteriotomy. Infusion of any sterile liquid may be performed, with the balloon inflated or deflated, through the distal lumen.
We advise you to irrigate with a fibrinolytic agent if the embolus is too hard thus in order to pass the catheter tip without damage.

EMBOLECTOMY CATHETER DESCRIPTION:
The single or double lumen embolectomy catheters are 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.
For the double lumen catheters, the derivation branch (white) is connected to the balloon and the main branch (which is coloured to indicate the catheter size) allows the injection of the necessary solutions.

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 arterial diameters and lengths (see table A).
WARNING: The 40 cm embolectomy catheters must be used just for the peripheral arterial system of upper limbs. The 80 cm embolectomy catheters must be used just for the peripheral arterial system of lower limbs.

DIRECTIONS FOR USE: CATHETER PRIMING
Remove the stiffening stylet from the catheter hub. 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 liquid). 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.
For the double lumen, connect it to the white derivation branch hub.
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. (It is recommended that the 2F catheter be inflated with carbon dioxide gas)
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.
9- With the balloon deflated, insert the catheter into the vessel and beyond the obstructing material. Inflate the balloon with sterile fluid or gas.

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.

10- Remove the occlusive material by gently withdrawing the catheter. During withdrawal, it is important to adjust the balloon diameter to the varying arterial diameters by controlling the inflation volume

WARNING: SOLUTION INJECTION (only for double lumen catheters)
In the event successive injections of different liquids are necessary, it is recommended to rinse the catheter and the syringe with sterile liquid, to avoid any medicinal interaction risk.

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 ®

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TABLE A : STANDARD EMBOLECTOMY CATHETERS

Other dimensions available upon request
We recommend to use a 3 ml syringe capacity to inflate our catheters

REFERENCE	COLOUR CODE	OUTER DIAMETER	USEFUL LENGTH	MAXIMUM RECOMMENDED LIQUID VOLUME	MAXIMUM RECOMMENDED PULL FORCE ON INFLATED BALLOON (N)	APPROXIMATE DIAMETER OF INFLATED BALLOON	COMPATIBLE GUIDEWIRE (INCH)
SINGLE LUMEN EMBOLECTOMY CATHETER							
300240 – 300260 - 300280	Grey	2F (0,70 mm)	40 cm - 60 cm - 80 cm	0,05 ml (gas = 0,2 ml)	3	4 mm	-
300340 – 300360 - 300380	Green	3F (1,00 mm)	40 cm - 60 cm - 80 cm	0,20 ml	5	5 mm	-
300440 – 300460 - 300480	Red	4F (1,35 mm)	40 cm - 60 cm - 80 cm	0,75 ml	9	8 mm	-
300540 – 300560 - 300580	White	5F (1,70 mm)	40 cm - 60 cm - 80 cm	1,50 ml	11	10 mm	-
300640 – 300660 - 300680	Blue	6F (2,00 mm)	40 cm - 60 cm - 80 cm	2,00 ml	12	13 mm	-
300740 – 300760 - 300780	Yellow	7F (2,35 mm)	40 cm - 60 cm - 80 cm	2,50 ml	15	14 mm	-
300840 – 300860 - 300880	Brown	8F (2,70 mm)	40 cm - 60 cm - 80 cm	3,00 ml	15	15 mm	-
DOUBLE LUMEN EMBOLECTOMY CATHETER							
500440 – 500460 - 500480	Red	4 F (1,35 mm)	40 cm - 60 cm - 80 cm	0,75 ml	9	8 mm	-
500540 – 500560 - 500580	White	5 F (1,70 mm)	40 cm - 60 cm - 80 cm	1,50 ml	11	10 mm	.018
500640 – 500660 - 500680	Blue	6 F (2,00 mm)	40 cm - 60 cm - 80 cm	2,00 ml	12	13 mm	.018
500740 – 500760 - 500780	Yellow	7 F (2,33 ml)	40 cm - 60 cm - 80 cm	2,50 ml	15	14 mm	.025

References without natural latex rubber: add “LF” at the end.

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	REF 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
STERILE EO 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	LOT EN: Batch code FR: Numéro de lot DE: Chargennummer ES: Número de lote	