Bioptimal™

INSTRUCTIONS FOR USE OF EMBOLECTOMY CATHETER


Read Instruction Manual Before Use

Sterile And Non-Pyrogenic


For Single Use Only

Do Not Re-sterilize


Keep Dry


Do Not Use If Package Is Damaged


Keep From Direct Sunlight

Presence of Phthalates (DEHP)


Non-Pyrogenic

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

DEVICE DESCRIPTION

BIOPTIMAL Embolectomy Catheters are made of polyvinylchloride (PVC) single lumen tubing with latex balloon attached at the distal tip. Proximal end of the catheter is attached with a female luer connector for syringe attachment. 2F and 3F embolectomy catheters are made of Nylon tubing. The catheter has 10cm increments marked along its length that allow physician to determine depth of catheter insertion. A removable stylet for catheter stiffening is provided with each catheter, with exception for 2F and 3F embolectomy catheters.

INDICATIONS AND INTENDED USE

BIOPTIMAL Embolectomy Catheters are indicated for use in the removal of fresh, soft emboli from the peripheral arterial system. Embolectomy catheters are intended to be used with liquid prime which is sterile and blood compatible and are intended to be used only by physician with surgical skill in the vascular system.

CONTRAINDICATIONS

1. Not intended for use outside the peripheral arterial system.
2. Should not be used in endarterectomy procedures.
3. Should not be used as a vessel dilator.
4. Should not be used in grafts, shunts or the venous system.
5. Not recommended for the removal of fibrous, adherent, or calcified material.
6. Catheter with natural latex balloon is contraindicated for patient with known or suspected allergy to natural rubber latex.

PRECAUTIONS

1. Rx only.
2. This product is designed for single use only. Do not reuse or resterilize the catheter.
3. Do not use catheter after indicated expiration date on the package.
4. Do not use catheter if package is opened or damaged as contents may lose sterility.
5. Used catheter must be properly disposed as biohazard material and processed accordingly to facility protocol.
6. Purge air from the catheter prior to use by inflating and deflating the catheter balloon with the medium to be used in the procedure.

WARNINGS

1. Air should not be used to inflate catheter balloon to avoid air embolism when balloon rupture. Carbon dioxide is the only recommended gas.
2. Balloon rupture and catheter separation is common risk associated with embolectomy procedures (**See Complications**).
3. To minimize risk of damage to the blood vessel, balloon rupture, or tip detachment, do not exceed maximum recommended inflation volume and pull force for each size of catheter (**See Specifications**). In clinical use, balloon size and removal force are dictated by clinical conditions. During use, the balloon diameter and pull force should be adjusted based upon the sensitive touch of the surgeon performing the procedure.
4. Use of highly viscous or particulate contrast media for balloon inflation is not recommended as it may result in the occlusion of the inflation lumen.
5. This device is intended for single patient use only.
6. **DO NOT** resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient.

COMPLICATIONS

The following complications have been associated with the use of all types of vascular catheters:

Air embolus	Aneurysms
Vessel dissection	Vessel thrombosis
Arteriovenous fistula formations	Vessel spasms
Balloon rupture or tip separation with fragmentation	Distal embolization of blood clots atherosclerotic plaque
Distal embolization	Hemorrhage
Intimal disruptions	Local hematomas
Perforation and rupture	Systemic infection

Experience and recognition of the procedural and device limitation significantly reduce the incidence of complications.

INSTRUCTION FOR USE:

1. Using sterile technique, remove the cap and stiffening stylet (except 2F and 3F catheters) from the catheter luer hub.
2. Purge all air from catheter lumen and balloon by inflating and pulling a vacuum repeatedly on the balloon. Use sterile fluid or Carbon Dioxide to the maximum recommended volume (**see Specifications**). Use the smallest syringe capable of holding the stated maximum fluid capacity.
3. Inspect the inflated balloon at maximum recommended volume. Leaking or grossly asymmetric balloons should not be used.

CAUTION: Do not exceed recommended maximum inflation volume, as specified in this instruction For Use and on the catheter. Check fluid volume in the syringe prior to each inflation.

4. With the balloon deflated, insert the catheter through arteriotomy into the vessel and manoeuvre the catheter tip into position just beyond the embolus.
5. Inflate the balloon only with sterile fluid until the balloon can be felt to have engaged the vessel wall, indicated by an increase in the resistance to continual inflation of balloon at the syringe plunger.

CAUTION: Inflation of the balloon should be associated with a feeling of increasing resistance to continued advancement of the inflation syringe plunger. When no resistance is encountered, inflation should be discontinued and the catheter withdrawn and inspected.

6. Gently withdraw the catheter to remove occlusion. Uniform contact with the vessel wall at narrow segments through displacement of the fluid within the balloon enables atraumatic withdrawal of the occluding material. Physician controlling balloon inflation should also control withdrawal of the catheter to avoid excessive traction that may damage the vessel wall. Balloon diameter can be adjusted to varying vessel diameters during the procedure based upon the sensitive touch of the physician performing the case.

Due to the complexity and variation of the embolectomy catheters procedure, catheter selection, the choice of surgical technique as appropriately modified in accordance with the previously described warnings, cautions and instructions, is left to the discretion of the individual physician.

PACKAGING AND STERILITY

Product is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Catheters are for single use only. Do not clean or resterilized a used catheter.

STORAGE

Catheters should be stored unopened in its original packaging in dark, cool dry places to avoid exposure to fluorescent or sunlight, which will prematurely deteriorate the latex balloon.

SHELF-LIFE

The recommended shelf-life is indicated on each package.

SPECIFICATIONS:

Catalogue Number	Catheter Size	Length (cm)	Color Code	Max. Liquid Volume (cc)	Max CO_2 Volume (cc)	Inflated Balloon Diameter (mm)	Maximum Pull Force Inflated Balloon (lb)
EL3260	2Fr	60	Purple	0.08	0.2	4	0.5
EL3280	2Fr	80	Purple	0.08	0.2	4	0.5
EL3340	3Fr	40	Green	0.20	0.6	6	0.7
EL3380	3Fr	80	Green	0.20	0.6	6	0.7
EL1440	4Fr	40	Red	0.75	1.7	9	1.5
EL1480	4Fr	80	Red	0.75	1.7	9	1.5
EL14100	4Fr	100	Red	0.75	1.7	9	1.5
EL1540	5Fr	40	White	1.50	3.0	11	2.0
EL1580	5Fr	80	White	1.50	3.0	11	2.0
EL1640	6Fr	40	Blue	2.00	4.5	13	2.5
EL1680	6Fr	80	Blue	2.00	4.5	13	2.5
EL1740	7Fr	40	Yellow	2.50	5.0	14	3.5
EL1780	7Fr	80	Yellow	2.50	5.0	14	3.5

WARRANTY

BIOPTIMAL warrants all its products free from defect in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

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