TRUE FLOW RDB

CANNULA FOR SELECTIVE ANTEGRADE CEREBRAL PERFUSION WITH PRESSURE SIGNAL LINE

DESCRIPTION

The cannula for selective antegrade cerebral perfusion has a double silicone lumen. The main lumen channel is for blood infusion from the external circulation circuit to the brain via the anonymous artery and the left carotid artery and the left subclavian artery. The second lumen consists of an inflation channel for the positioning balloon, which is located in proximity to the distal extremity of the cannula. The third lumen allows the pressure reading. The cannula is made of silicone, with a bendable steel wire inside to model the cannula according to the surgeon's needs. The cuff positioned on the inflation line of the balloon allows visibile verification of the condition of the balloon. When the balloon is inflated, the cuff will be full of sterile saline solution.

INDICATIONS FOR USE

The cannula for selective antegrade cerebral perfusion is used for the perfusion of blood to the brain for surgical operations on the aorta arch.

WARNINGS

Before using the device read the instructions for use carefully. The cannula must be inserted, managed and removed only by a qualified and authorised doctor under his or her instructions.
The medical techniques described in these instructions are supplied only information. The surgeon must establish the appropriateness of the suggested procedure based on his or her own experience and the patient's conditions. The surgical team is solely responsible for the management of the appropriate surgical techniques.

Counterindications

- This device is not intended to be sold or used in any way other than as indicated;
- Do not use this device on patients with a proven allergy to silicone;
- Do not reuse and/or resterilise, as the product is disposable

PRECAUTIONS

- The contents of the package, if still closed and intact, are sterile and anti-pyrogenic;
- In the event the package is not intact, the device must not be used;
- The product must be used immediately after the package is opened;
- After opening the package, examine the product attentively: do not use if any defects are found;
- When available, choose the charier (CH) according to:

⇒ The characteristics of the surgical operation;
⇒ The type of perfusion to be performed.

- Involuntary damages to the body of the cannula caused by scalpels or needles can notably reduce the tensile force of the device. Use extreme attention during insertion, use and removal. If a cannula is perforated by error, do not use;
- The cannula must be positioned and removed manually (the use of instruments could cause breakage), with light and constant pressure;
- Do not over inflate the balloon. Generally, 5cc of sterile physiological solution is necessary;
- Do not attempt to insert the cannula with the balloon inflated;
- Do not attempt to remove the cannula if the balloon is inflated.
- Maximum system working pressure not above 150 mmHg.
- In the case the pressure reading line is not in use make sure the luer cap is closed;

SPECIFICATIONS

Numeric grading: 5-10-15-20 cms.
Shore: 57
Centimetre scale
Infusion line flow: 266ml./min.– CH14, 400 ml./min.– CH17, 645 ml./min. - CH20

DISPOSAL

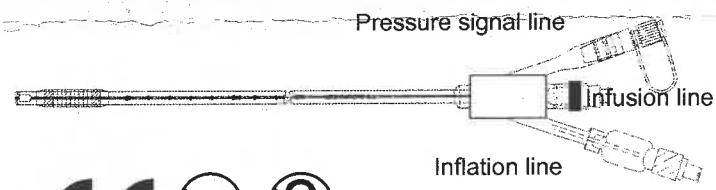
Following use, dispose of the product according to current laws for infected materials.

EXCLUSION OF RESPONSIBILITY

Under our responsibility we declare that the product conforms to Directive 93/42/CEE for medical devices.
In consideration of the biological differences of patients, the efficiency of the product cannot be 100% guaranteed. MED-EUROPE° does not guarantee the success of the product, nor excludes the possibility of complications, as the diagnosis, indications application and use of the product are not under our control.
MED-EUROPE° performs an accurate control during the development, selection of components, production and final testing.
MED-EUROPE° is not responsible for any type of leak, damage or wound of any type, either direct or indirect or for damages derived from the use of its products.
In particular, MED-EUROPE° shall not reimburse expenses on the part of the customer or by third parties following use of the device. This also applies to any medical expenses, hospital treatments, medications or consequent damages.

INSTRUCTIONS FOR USE

- Use the anti-septic procedure to remove the cannula from the package;
- Introduce air or physiological solution into the balloon to verify that the balloon is intact;
- Remove the air/physiological solution and deflate the balloon;
- Connect the cannula to the appropriate circuit for cerebral perfusion which itself is inserted in the external circulation pump and connected to the coronary outlet of the oxygeniser;
- Proceed as is standard to purge air from the circuit and from the cannula;
- The cannulae are to be inserted into the epiaortic trunks according to the techniques in use by the single surgical teams and according to the standard reference procedures.



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