Snake Suture Organizer

DESCRIPTION

The SUTURE ORGANIZER device, which includes a frame that can be positioned on the patient close to the wound that requires suturing and/or to anatomical or prosthetic tissue edges that require uniting, is basically an assistance tool and instrument guide for surgical sutures during cardiac surgery or thoracotomy operations.

DIRECTIONS FOR USE

The device is designed to protect and manage surgical sutures during cardiac surgery, thoracotomy and mini thoracotomy, when it is necessary to substitute or reinforce anatomical structures with prosthetic material, or for blood vessel reconstruction or anastomosis, and in general for operations on the circulatory system (or on other internal organs within the rib cage).
It is a sterile surgical device, for short term use (more than 60 min. but less than 30 days).

WARNINGS

Before using the device, carefully read the instructions for use. The product must only be used in healthcare settings and must be placed, managed and removed exclusively by qualified and authorised medical doctors or under a doctor's instructions. The medical techniques described in these instructions are supplied only as information. The surgeon must decide on the adequacy of the suggested procedure based on personal experience and the conditions of the patient. The surgical team is solely responsible for the management of the appropriate surgical techniques used.

CONTRAINDICATIONS

- This device must not be intended, sold or utilised in any way other than that for which it was designated;
- Do not reuse and/or resterilize, as this is a single use product. Reuse of the device determines a high risk of bacterial contamination and cross infection.

PRECAUTIONS

- The contents of the package are sterile and antipyrogenic, if sealed and intact;
- If packaging is not intact, the device must not be used;
- The product must be used immediately after opening the package;
- Once the package has been opened, examine the product attentively: do not use if defects are found;
- When available, choose the product code according to the surgical procedure to be performed.

SPECIFICATIONS

Materials used: polyethylene, thermoplastic rubber, steel, double adhesive pvc

DISPOSAL

After use, dispose of the product according to standards of law for contaminated material.

RESPONSIBILITY WAIVER

We declare under our sole responsibility that the product conforms to medical device directive 93/42/CEE.
Due to biological differences between patients, the efficiency of the product is not guaranteed 100%. MED EUROPE® does not guarantee the success of the product, nor does it exclude the possibility of complications, as the diagnosis, indications, application and use of the product are beyond its control.
MED EUROPE® makes precise controls during development, component selection, production and final testing.
MED EUROPE® accepts no liability for leaks, damages or wounds of any type either direct or indirect, or damages that result from the improper use of its products.
MED EUROPE® will not be held responsible for reimbursement of expenses sustained by the purchaser or by third parties following improper use of the device. This also applies to medical expenses, hospital treatment, medicines or consequent damages.

INSTRUCTIONS FOR USE

- Remove the device from the package using the antiseptic procedure to guarantee sterility of the product.
- If required for the specific case, flex and bend the device based on the necessities of the operation to be performed.
- Position the device over the breast of the patient, in proximity with the wound to be sutured, and anchor the product to the surgical sheet by the double adhesive tape on the back of the product.
- During the surgical procedure, position the various suture threads in each of the interstices between the blocks and the respective adjoining spacers, with the added assistance of the numbering printed on each segment.