ELIZABETH
MITRAL VALVE EXHIBITOR

INTENDED USE
The device is intended for use in invasive heart surgeries, with the patient subjected to extracorporeal circulation and a stationary heart, is introduced into the valve annulus and can be wrapped around itself and kept closed by pliers. Once released by opening the clamp, returning to its original shape, the retractor expands the annulus and the valve leaflets exposing the underlying tendon cords and papillary muscles to the surgeon's view.
The device therefore allows an optimal exposure facilitating the surgeon in the approach and correction of the subvalvular apparatus of the heart.

WARNINGS
Read the instructions for use carefully before using the device. The device must be inserted, handled and removed, only by a qualified and authorized doctor or under its instructions.
The medical techniques described in these instructions are provided for information purposes only. The surgeon must establish the adequacy of the suggested procedure based on his / her experience and the patient's condition. The surgical team is solely responsible for managing the appropriate surgical techniques.

CONTRAINDICATIONS
- This device is not intended, sold or used in any other way than the one indicated;
- Do not reuse and / or re-sterilize as the product is disposable, re-use of the device leads to a high risk of bacterial contamination and cross infection.

PRECAUTIONS
- The contents of the package, if still closed and intact, are sterilized and non-pyrogenic;
- If the package 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 carefully: do not use it if you find defects;
- Where available, choose the model and measurement based on your application;
- Unintentional damage to the body of the device caused by blades or needles can significantly reduce the tensile strength of the device. Pay great attention during insertion, use and removal;

SPECIFICATIONS
The device is made entirely with medical grade resin to ensure maximum biocompatibility.

DISPOSAL
After use, dispose of the product according to the regulations in force for infected materials.

DISCLAIMER OF LIABILITY
We declare under our responsibility that the product complies with Directive 93/42 / EEC for medical devices.
In consideration of the patient's biological differences, the efficiency of the product cannot be 100% guaranteed. MED EUROPE® does not guarantee the success of the product, nor does it exclude the possibility of side effects, as the diagnosis, indications, application and use of the product are outside our scope. control.
MED EUROPE® carries out an accurate check during the development, the selection of the components, the production and the final testing.
MED EUROPE® is not responsible for any kind of loss, damage or injury of any kind, directly or indirectly, or for damages resulting from the use of its products.
In particular, MED EUROPE® is not required to reimburse the expenses incurred by the purchaser or third parties following the use of the device. This is also applicable to any medical expenses, hospital treatment, medication or consequential damage.

INSTRUCTIONS FOR USE
- Use the aseptic procedure to remove the device from the package;
- the device must be wrapped on itself and stopped by a clamp;
- The rolled device is introduced from the left atrium into the mitral valve at the valve plane level and is released by opening the clamp;
- At this point the device will open dividing the valve flaps;
- the flange on the device ensures that it is anchored to the natural annulus and prevents it from slipping into the ventricle;
- Make sure that the device does not interfere with the underlying papillary muscles, to eliminate this problem the device is asymmetrical and specially shaped;
- If you want to do a complete spreading over the entire ring, you can use two devices side by side;
- If you do not want to reach the maximum gap, it is possible to place stitches at the level of the holes in the device and to limit their expansion;
- The time of use of the device during surgery varies from 30 minutes to 1 hour;
- During the procedure, be careful not to damage the subvalvular apparatus;

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