



Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432.5604 USA
www.medtronic.com

Description

The product is a disposable, retractor-based stabilizer that consists of two tissue stabilizers attached to an articulating arm. The articulating arm fastens to a retractor by use of a mounting clamp. A white stopcock provides on-off control of suction (see Figure 1). With the pods placed on either side of the anastomosis site, suction is applied to stabilize the tissue. The arm is tightened and loosened by the knob. As the arm tightens, the tissue stabilizers spread in an arc fashion.

Sterile, Non-pyrogenic, Disposable, Single use only.

Note: The mounting clamp has been designed to be compatible with most adult median sternotomy retractors. The 2 cm wide, spring-loaded clamp accommodates rectangular sections ranging in thickness from 0.150" (0.38 cm) to 0.320" (0.81 cm), and widths from 0.625" (1.59 cm) to 1.00" (2.54 cm). Retractor compatibility should be confirmed prior to beginning the procedure.

Indications

This product is intended to stabilize and minimize the motion of selected areas of the beating heart during cardiac surgery.

Contraindications

This product is not intended for use except as indicated above. Do not position the suction pods over a coronary artery, newly infarcted or aneurysmal heart tissue.

Warnings

Patient and procedure selection is totally a responsibility of the medical profession and the outcome is dependent on many variables, including patient anatomy, pathology and surgical techniques.

Precautions

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedures and techniques are necessarily the responsibility of the medical profession. The described procedure is furnished for information purposes only. Each surgeon must, of course, evaluate the appropriateness of the procedure based on their own medical training and experience and the type of surgical procedure.

The product is designed and intended for single use only: **DO NOT RESTERILIZE OR REUSE.**

The initial spacing between the right and left tissue stabilizers is important for optimal performance. The initial spacing between the tissue stabilizers will affect stabilization and tension on the tissue and should be chosen at the surgeon's discretion.

Do not exceed (-)400 mm Hg of suction.

Adverse Effects

None known.