

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Heart Stabilizers
Manufactured by SterilMed, Inc.
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SterilMed, Inc. Reprocessed Heart Stabilizers
 Models Octopus 3.0 (28400), Octopus 4.0 (29400) and Octopus 4.3 (29403)
 Original Manufacturer: Medtronic

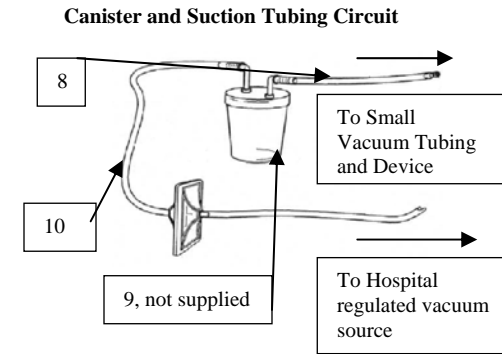
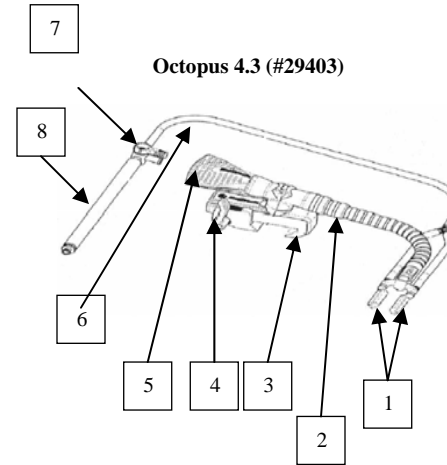
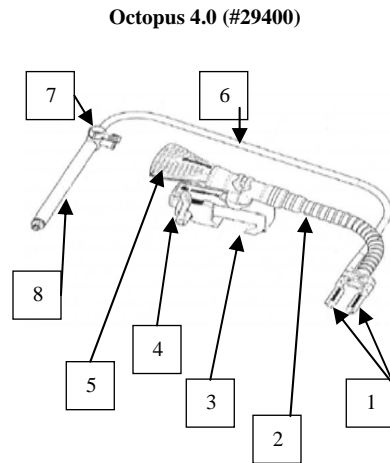
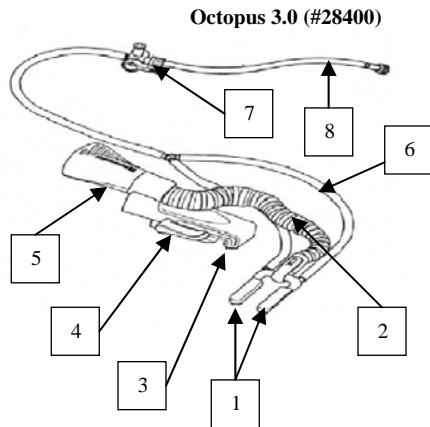


Diagram Legend

- | | |
|--------------------------------------|------------------------------------------|
| 1. Tissue Stabilizer/Stabilizer Fork | 6. Small Vacuum Tubing |
| 2. Articulating Arm | 7. Stopcock |
| 3. Rail Clamp | 8. Large Suction Tubing Assembly |
| 4. Rail Lock | 9. Canister (not supplied) |
| 5. Articulating Arm Lock | 10. Large Suction Filter Tubing Assembly |

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

INDICATIONS FOR USE

These devices are reprocessed heart stabilizers originally manufactured by Medtronic, Inc. Tissue Stabilizers are intended to stabilize and minimize the movement of localized areas of a beating heart during off-pump cardiac surgery.

Original Equipment Manufacturers (OEMs) provide an Instructions for Use document for each original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

The reprocessed heart stabilizer is a retractor-based system that consists of a stabilizing fork with eight suction pods attached to an articulating arm. The articulating arm fastens to a retractor by use of a mounting clamp. The arm is tightened and loosened by a large knob on the proximal end. As the arm tightens, the tissue stabilizers spread an arc fashion. With the pods placed on either side of the anastomosis site, suction is applied to stabilize the tissue. A stopcock provides control of suction.

The mounting clamp has been designed to be compatible with most adult median sternotomy retractors. Compatibility should be confirmed prior to the beginning of any procedure.

Reprocessed heart positioners have been cleaned, evaluated for continued integrity, and re-sterilized prior to use. These devices were shipped from a health care facility and reprocessed for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times the device has been reprocessed.

This device has been reprocessed for a single use. If the device is to be used again, it must undergo reprocessing prior to use.

CONTRAINDICATIONS

1. Do not place the tissue stabilizer over a coronary artery, newly infarcted or aneurismal heart tissue.
2. Procedures associated with the use of these devices should be performed only by persons having adequate training and familiarity with applicable techniques. Consult literature relative to techniques, complications and hazards prior to performing any procedure.

WARNINGS

1. The user of the device should have adequate training and a thorough understanding of the use and application of these devices.
2. Inspect the packaging and device prior to use. If sterility appears compromised or the package/product appears damaged, do not use.
3. Equipment may vary with each manufacturer. Verify appropriate compatibility of all equipment and accessories prior to use.
4. Patient and procedure selection is the responsibility of the medical professional and the outcome is dependent on many variables, including patient anatomy, pathology and surgical techniques.

PRECAUTIONS

1. The directions are furnished for information purposes only.
2. The initial spacing between the right and left tissue stabilizers is important for optimal performance.
3. The initial spacing between the tissue stabilizers will affect stabilization and tension on the tissue and should be chosen at the surgeon's discretion.
4. The Canister (not supplied) must be orientated in the vertical position. Do not fill past Full line on canister.
5. Do not exceed (-) 400mm Hg of suction.

GENERAL INSTRUCTIONS AND INFORMATION

1. Inspect package and product for signs of damage or sterility compromise. Remove the product using appropriate sterile field technique.
2. Suction circuit hook-up:



- a. Attach Suction filter tubing assembly (supplied in separate pouch) from the operating room regulated vacuum source to the canister (not supplied). Turn the regulated vacuum pressure on and set vacuum to (-) 400mm Hg.
 - b. Using sterile field technique, attach the small vacuum tubing on the device to the large suction tubing. Connect the other end of the large suction tubing to the canister (not supplied). Note: The canister (not supplied) must be in the vertical positioner. Do not fill past the full line on the canister. Use the stopcock in the sterile field to control vacuum on-off during the procedure.
3. Attach the device to the retractor.
 - a. With rail lock rotated towards the articulating arm lock, slide open the rail clamp.
 - b. Place the rail clamp onto the retractor, assuring the clamp contact is flush with the retractor.
 - c. While pressing the rail clamp together on the retractor, lock in place by rotating the rail lock lever forward away from the articulating arm lock. Check that the clamp is securely fastened to the retractor.
 4. Position tissue stabilizers onto designated anastomotic site. The following steps are recommended:
 - a. Shape tissue stabilizers to conform with the heart, maximizing capture at the desired location.
Caution: Do not exceed a 25 degree bend in any axis. Exceeding this angle may occlude the lumen. Repeated bending of the tissue stabilizers may compromise device performance.
 - b. Turn on suction by turning stopcock to the off-to air position and gently position tissue stabilizers in the desired location on the surface of the heart.
 - c. Turn the articulating arm lock to immobilize the arm. As the arm tightens, the tissue stabilizers will gradually spread.
 5. The tissue stabilizers can be removed by supporting the heart and terminate suction by turning the stopcock to the off-to-vacuum position.
 6. Turn the articulating arm lock counterclockwise to loosen the arm and gently lift the tissue stabilizers from the heart.
 7. When finished, remove the device from the retractor.

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, routine sterilization. inspection and pre-release testing are used to ensure the device integrity and function of each device prior to release of product.



Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.

