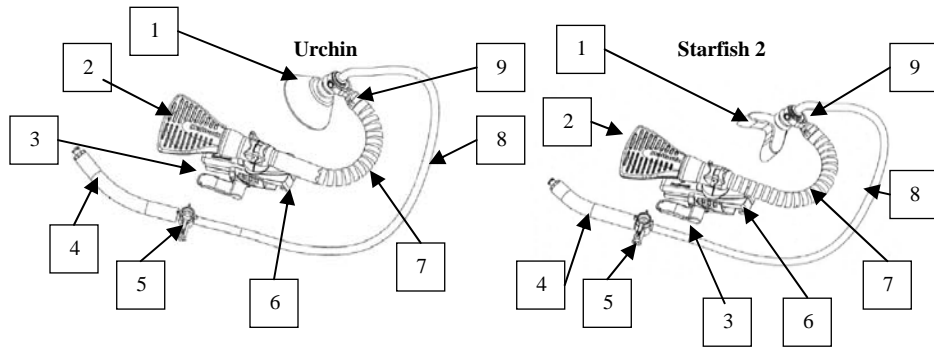


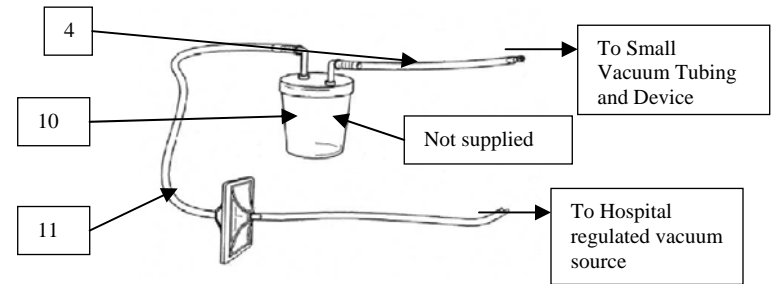
# INSTRUCTIONS FOR USE

**SterilMed, Inc.**  
**Reprocessed Heart Positioners**  
**Manufactured by SterilMed, Inc.**  
**11400 73<sup>rd</sup> Avenue North**  
**Maple Grove, MN 55369**  
**Toll Free 1-888-541-0078**  
[www.SterilMed.com](http://www.SterilMed.com)

**SterilMed Reprocessed Heart Positioners**  
 Models: Urchin (29700) and Starfish 2 (29800)  
 Original Manufacturer: Medtronic



Canister and Suction Tubing Circuit



### Diagram Legend

- |                                  |                                          |
|----------------------------------|------------------------------------------|
| 1. Positioning head              | 7. Articulating Arm                      |
| 2. Articulating Arm Lock         | 8. Small Vacuum Tubing                   |
| 3. Rail Lock                     | 9. Headlink                              |
| 4. Large Suction Tubing Assembly | 10. Canister (not supplied)              |
| 5. Stopcock                      | 11. Large Suction Filter Tubing Assembly |
| 6. Rail Clamp                    |                                          |

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

### INDICATIONS FOR USE

These devices are reprocessed heart positioners originally manufactured by Medtronic, Inc. Tissue Positioners are intended to lift, position and support the heart and maximize access of coronary arteries for off-pump grafting.

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

### DEVICE DESCRIPTION

The SterilMed reprocessed heart positioner is a single-use, retractor-based device that incorporates a silicone suction apparatus, an articulating arm and a mounting clamp. The silicone apparatus is attached to the surface of the heart by the application of regulated vacuum. The mounting clamp has been designed to be compatible with most adult median sternotomy retractors. Compatibility must 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 and ensure the number of times the device has been reprocessed.

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**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 positioner over a coronary artery, newly infarcted aneurismal or fragile 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 applications 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.
5. The Reprocessed Heart Positioner is to be used only on the apex and the left ventricle immediately proximal to the apex.
6. Always support the heart when re-positioning the heart.
7. Do not use on atrial tissue or on the right ventricle.

#### PRECAUTIONS

1. The directions for use are furnished for information purposes only.
2. Do not use this device as a suction source to remove blood from the operative field.
3. Avoid placing the device directly over a deep sulcus in the epicardial fat as this may disrupt the vacuum seal and lead to a loss of heart capture.
4. Canister (not supplied) must be oriented in a vertical positioner. Do not fill past Full line on canister.
5. Do not exceed 250mm Hg of suction for the Urchin positioner and 400mm Hg of suction for the Starfish 2 positioner.

#### GENERAL INSTRUCTIONS AND INFORMATION

1. Inspect package and product for signs of damage or sterility compromise. Open 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 (-) 250mm Hg for the Urchin positioner and (-) 400mm Hg for the Starfish 2 positioner.

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- 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 position. 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. Slide open the rail clamp with rail lock rotated towards the articulating arm lock.
  - b. Place the rail clamp onto the retractor, assuring the clamp contact is flush with the retractor.
  - c. Press 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. The arm of the device can be made more mobile by turning the articulating arm lock counter-clockwise and more rigid by turning the articulating arm lock clockwise.
5. Prior to turning on the vacuum, place the positioning head on the apex or on the left ventricle immediately proximal to the apex. Turn the suction on by turning the stopcock to the on position. Position the heart only after the vacuum has reached full vacuum pressure (-) 250mm Hg.
6. Position the heart by holding onto the headlink with one hand while supporting the heart with the other hand.
7. Support the heart and terminate suction by turning the stopcock to the off positioner in order to disengage the device
8. 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, and functionality testing. 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](http://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.*

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