TRIPOD™ Heart Stabilizer with Blower Mister and Occluder Clip

Product Code	Description
STO-3BC4S	TRIPOD Heart Stabilizer - Nylon Foot Pads + Occluder Clip + Blower/Mister

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900673 – Rev 2

STERILE EO

TRIPOD™ Heart Stabilizer with Blower Mister and Occluder Clip

Product Description:
The device consists of an articulating arm with two rotating stabilizing foot pads connected to a base which mounts onto the Chase Sternal Retractor. The stabilizer also has a large knob, which when tightened, will lock the articulating arm in place. The device contains an integral blower mister and integral occluder.

Integral Blower/Mister:
The distal end of the TRIPOD™ stabilizer has a blower/mister mounted to irrigate the anastomotic site. The blower is malleable to facilitate ease of positioning to direct the mist at the anastomotic site. The proximal end of the blower is separated into two CO_2 lines and a saline line. The saline line ends in a spike to fit an IV bag, while the CO_2 lines end in a luer lock, to fit a Chase foot pedal (Cat.# FTV-1020, not included).

Integral Occluder:
The occluder gate is mounted distal on the stabilizer foot pads. The occluder gate can rotate perpendicular to the axis of the foot pad. When engaged it is held against the opposite foot pad and applies downward pressure on the artery. The occluder gate has notches to lock it in place. As the gate is pushed past each notch progressively, more occlusion pressure is applied.

All Models: Sterile, Nonpyrogenic, Disposable, Single use only.

Indications for Use:
- This device is intended to stabilize and minimize the motion of selected areas of the beating heart to facilitate coronary anastomosis during beating heart coronary artery bypass surgery.
- The integrated blower/mister is also intended to irrigate the anastomotic site where enhanced visibility can be maintained by non-contact means.

Contraindications:
- This device is not intended for use except as indicated above.
- Blower/Mister should not be used where the effects of an air stream or irrigation mist are contraindicated.
- Not intended for use on pregnant women, nursing women, or children.

Warnings:
- **DO NOT REUSE OR RESTERILIZE.** Reuse or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience. The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
- Although product has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.
- DO NOT USE OXYGEN WITH THIS DEVICE.
- Do not allow blower tip to directly contact tissue.
- Do not use CO_2 pressure greater than 50 psi.

Precautions:
- Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.
- The Directions for Use are furnished for information purposes only.
- Product is Ethylene Oxide sterilized.
- Sterile unless package is opened or damaged.
- Use caution when moving blower tip closer than 3 cm to the surgical site
- Do not use pressure cuff on the IV bag. Hang the IV bag at the same level as the operating table. Excess pressure will compromise mist quality.

PHT
DEHP Contains phthalates

Adverse Effects:
None known.

Directions for Use:
1. Carefully read instructions prior to use.
2. Inspect package and product for damage and expiration date prior to opening the package.
3. If undamaged and unexpired, open the package and transfer the product onto the sterile field utilizing aseptic technique.

Integral Blower/Mister Hook-Up:
4. Connect the CO_2 line from device to the foot pedal (which is preconnected to a regulated CO_2 source of USP Medical grade CO_2.) Tighten the luer connection. Initially adjust regulated flow control to 30 psi. DO NOT USE CO_2 PRESSURE GREATER THAN 50 PSI.
5. Aseptically connect the spike of the IV set pre-connected to the device to a saline bag of sterile normal saline. Fully open the roller clamp to prime the saline line if needed raise the bag to help it prime faster.
6. Hang the bag at the same level as the operating table. DO NOT USE PRESSURE CUFF. Excessive pressure on saline bag will compromise mist quality.
7. Depress the left, right, or both foot pedals to activate the desired blower tip(s). Adjust the pressure of the CO_2 line to vary the mist pattern.

Attaching Tripod™ Stabilizer to the Retractor – All Models:
8. Attach the TRIPOD™ stabilizer base to the Chase Sternal Retractor (Cat# RTC-1000, not included)
   - Ensure the metal knob is underneath the large plastic knob.
   - Position the TRIPOD™ base onto the Chase retractor, using a toe-to-heel approach, assuring the base is flush with the retractor. Slide the metal knob to the left until it locks.

   Note: The protruding hook on the left side of the base is used to help lock the base with one hand by placing the left forefinger over the hook while using the left thumb to slide the metal knob to the left.
9. Adjust the stabilizer arm and place the foot pads on the anastomotic site.
10. Slowly rotate the tabs on the foot pads inward to gently stabilize the heart tissue.
11. Turn the large plastic knob ***clockwise*** **to tighten** the articulating arm. Turn the large plastic knob ***counterclockwise*** **to loosen** the articulating arm.
    Note: When loosening the articulating arm, do not turn the large plastic knob counterclockwise more than 3 complete turns. Doing so will cause the device to malfunction.
12. If motion is detected between the links in the articulating arm after tightening, ensure the foot pads are still correctly positioned on the heart, then continue turning the large plastic knob ***clockwise*** until all motion in the articulating arm is eliminated.
13. Gently turn the tabs on the rotating foot pads to allow for the tissue between the rotating pads to gently stretch - further minimizing the motion at the target site.

Models with Integral Occluder:
14. Swing the occluder gate over the artery and gently push it down to lock.
    Note: It is important to obtain proper exposure of the vessel prior to engaging the occluder gate, as it is difficult to rotate the pads after the occluder gate is engaged.
15. If required, occlude distal side of the anastomosis.
    Note: Certain vessels, such as deep myocardial arteries or highly calcified coronaries, may not allow complete occlusion. Use alternate occlusion methods if adequate occlusion cannot be attained using the Integral Occluders.
16. Upon completion of the anastomosis, use forceps to unhook the locking side of the occluder gate.

Removal/Disposal of the Tripod™ Stabilizer – All Models:
17. After performing the anastomosis, turn the tabs back to their original positions. Turn the large plastic knob ***counterclockwise*** to loosen the arm and gently remove the rotating foot pads from the heart surface.
18. When finished, remove the TRIPOD™ stabilizer from the retractor and discard according to approved hospital procedures.

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