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**TRIPOD™ Heart Stabilizer**

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**Stabilisateur cardiaque TRIPOD™**

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**TRIPOD™ Herzstabilisator**

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**Stabilizzatore TRIPOD™**

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**Estabilizador TRIPOD™**

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**TRIPOD™ szívstabilizátor**

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Product Code	Description
STB-30C4S	TRIPOD Heart Stabilizer - Nylon Foot Pads
STB-30C6S	TRIPOD Heart Stabilizer - Light Metal Foot Pads
STO-30C4S	TRIPOD Heart Stabilizer - Nylon Foot Pads + Occluder Clips
STO-30C6S	TRIPOD Heart Stabilizer - Light Metal Foot Pads + Occluder Clips
STB-30C6S-C02	TRIPOD Heart Stabilizer+2cm - Light Metal Foot Pads
STB-30C4S-C03	TRIPOD Heart Stabilizer+2cm - Nylon Foot Pads

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**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.

**Models with Integral Occluders:**

On this model, the occluder gates are mounted distal and proximal 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 off pump coronary artery bypass surgery.

**Contraindications:**

- This device is not intended for use except as indicated above.

**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.

**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.

**Adverse Effects:**

None known.

**Directions for Use:**

**TRIPOD™ Stabilizer – All Models:**

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.

**Attaching Tripod™ Stabilizer to the Retractor – All Models:**

1. Attach the TRIPOD™ stabilizer base to the Chase Sternal Retractor.
  - 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.**

2. Adjust the stabilizer arm and place the foot pads on the anastomotic site.
3. Slowly rotate the tabs on the foot pads inward to gently stabilize the heart tissue.
4. 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.**
5. 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.
6. 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 Occluders:**

1. 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.**
2. If required, occlude both the proximal and 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.**
3. Upon completion of the anastomosis, use forceps to unhook the locking side of the occluder gate.

**Removal/Disposal of the Tripod™ Stabilizer – All Models:**

1. 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.
2. When finished, remove the TRIPOD™ stabilizer from the retractor and discard according to approved hospital procedures.

**LIMITED WARRANTY AND DISCLAIMER OF LIABILITY**

Chase Medical products ("Product") are manufactured under carefully controlled conditions and Chase Medical warrants the Product will perform in accordance with its labeling, and will be free from defects in material and workmanship under normal use for one year from the date of shipment.

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