Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed Cardiac Stabilization and Positioning Devices

Reprocessed Device for Single Use

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

- **STERILE**
- **NON-PYROGENIC**

Explanation of Icons

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Product Code
	Do Not Reuse
	See Instructions For Use

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Cardiac Stabilization and Positioning Device Description
Cardiac stabilization and positioning devices are specially designed devices used in minimally invasive cardiac surgery for coronary artery bypass grafting. The devices offer a retraction as well as a stabilizing function to control the movement of the beating heart. The cardiac stabilization and positioning devices consist of a combination of one or more of the following components: tissue stabilizer, heart positioner, and sternum retractor blades

Indications for Use
Reprocessed Cardiac Stabilization and Positioning Devices are indicated for use during performance of minimally invasive cardiovascular surgery through a sternotomy incision approach on the non-arrested heart.
- Sternum retractor blades are used to provide access to the thoracic cavity and to provide a mount for the tissue stabilizer and heart positioner. It also facilitates the positioning of pericardial sutures.
- The tissue stabilizer is used to stabilize and minimize the motion of selected sites on the beating heart.
- The heart positioner aids in positioning the heart by the application of vacuum suction when positioned on the heart.

Contraindications for Use
- Do not attach the device to newly infarcted tissue, aneurysmal tissue, and fragile tissue or directly over a coronary artery.

Warnings
- Prior to use, read and follow these instructions as well as those of any necessary devices used during the procedure.
- This device is only intended for use by individuals with adequate training and familiarity with techniques associated with the cardiac surgery procedures employed, the system's use, and its assembly and disassembly. For further information about techniques, complications and hazards, consult the medical literature.
- Many variables including techniques, patient pathology, and patient anatomy may influence surgical outcomes. Procedure and patient selection is the responsibility of the medical professional.
- Restrict the amount of retraction to the lowest possible setting that provides the desired effect and appropriate visualization.
- Begin grafting procedure on the vessels only after adequate heart stabilization is achieved.
- Do not move and reposition the platform while sutures are still attached.
- Do not adjust the platform while the stabilizer foot is on the epicardium or when a vessel is engaged.
- Take special precautions when removing stabilizing devices from the heart so as not to disrupt the anastomotic site.
- Suture features are designed for size '0' sutures.
- The heart positioner is to be used only on the apex and on the left ventricle immediately proximal to the apex.
- Anastomosis should only be performed on a site that is properly immobilized with a properly seated stabilizer.
- Do not use on atrial tissue or on the right ventricle.
- Always support the heart when repositioning the heart.

Precautions
- Store device in a dry, cool place.
- Inspect the packaging before opening. The contents of the package are sterile if the packaging has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the instrument and package to Stryker Sustainability Solutions.
- Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted.
- Ensure that positioners and/or stabilizers are compatible with the sternum retractor being used prior to beginning the procedure.
- Do not attempt to resterilize.
- Do not expose to organic solvents (such as alcohol).
- Use the device prior to its 'Expiration Date' on the package label.
- Features of the suture holders (if applicable) are for "0" size sutures.
- Apply only moderate downward pressure to the heart with the stabilizer in place.
- Remove the stabilizer with care to prevent unintentional contact with, and damage to, the surgical site.
- Do not use excessive force when assembling and disassembling the device to avoid permanent damage to the system.
- Retract with care. Too much retraction may result in malfunction of the retraction mechanism.
- When using the stabilizer or positioner, ensure that the mount and mount lever are clear of tissue when the devices are placed on the sternum retractor.
- ***Medtronic Urchin™, Urchin™ EVO, Starfish®, Starfish®2 and Starfish® EVO:*** Do not use device as a suction

source to remove blood from the operative field. 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.

Adverse Reactions
None.

Directions for Use
The package label is detachable and may be affixed to the medical record of the patient.

Medtronic Urchin™, Urchin™ EVO, Starfish®, Starfish®2 and Starfish® EVO
Suction Circuit hook-up

1. Attach tubing from the operating room suction source to the back of the regulator. Turn regulator on and set vacuum to (-) 250 mm Hg for Urchin™ and (-) 400 mm Hg for Starfish® devices.
2. Using aseptic technique, connect the tubing from the heart positioner to the non-filter tubing set. Connect other end of the non-filter tubing set to a fluid collection container (not supplied). Use filter tubing set to connect fluid container to regulator. Utilize the stopcocks to control the vacuum (on-off) during the procedure. The vacuum "on" mode is achieved by rotating the stopcock perpendicular to the tubing leading to the vacuum source. The vacuum "off" mode is achieved by rotating the stopcock parallel to the tubing leading to the vacuum source. Note: Canister must be oriented in a vertical position. Do not fill past *Full* line on the canister.
3. Attach device to the retractor. With clamp lever rotated toward the knob, slide open the mounting clamp. Place mounting clamp onto the retractor, assuring clamp contact is flush to the retractor. While pressing the mounting clamp together on the retractor, lock in place by rotating clamp lever forward, away from the knob. Check that the clamp is securely fastened to the retractor. For devices Urchin™ and Starfish®2, rotate turret to desired position.
4. The arm can be made more mobile by turning the knob counter-clockwise and more rigid by turning the knob clockwise. ***Urchin™ EVO and Starfish® EVO***: Maximum tension has been reached when the tension indicator appears red.
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" vacuum position. Position the heart only after the device has reached full vacuum (-) 250 mm Hg for Urchin™ and (-) 400 mm Hg for Starfish® devices.
6. Position the heart by holding onto the headlink with one hand while supporting the heart with the other hand.
7. To disengage, support the heart and terminate suction by turning the stopcock to the "off" vacuum position.
8. Upon completion, remove device from retractor. Immediately follow decontamination procedure described in Decontamination section in this Instructions for Use Manual.

Medtronic Octopus 3.0™, 4.0™, 4.3™, and Evolution™

1. Attach tubing (not supplied) from the operating room suction source to the back of the regulator. Turn regulator on and set vacuum to (-) 400 mmHg.
2. Using aseptic technique, connect the tubing from the tissue stabilizer to the non-filter tubing set. Connect other end of the non-filter tubing set to a fluid collection container (not supplied). Use filter tubing set to connect fluid container to regulator. Utilize the stopcocks to control the vacuum (on-off) during the procedure. The vacuum "on" mode is achieved by rotating the stopcock perpendicular to the tubing leading to the vacuum source. The vacuum "off" mode is achieved by rotating the stopcock parallel to the tubing leading to the vacuum. Note: Canister must be oriented in a vertical position. Do not fill past *Full* line on the canister.
3. Attach device to the retractor. With clamp lever rotated toward the knob, slide open the mounting clamp. Place mounting clamp onto the retractor, assuring clamp contact is flush to the retractor. While pressing the mounting clamp together on the retractor, lock in place by rotating clamp lever forward, away from the knob. Check that the clamp is securely fastened to the retractor.
4. Position tissue stabilizers onto designated anastomotic site. It is recommended to adhere to the following steps: Contour the pliable area of the tissue stabilizer to conform with the heart. Warning: Do not bend any axis past 25 degrees. Surpassing a 25 degree bend could result in occlusion of the lumen. Repetitive bending may fatigue the material and subsequently compromise device performance.
    a. ***Octopus 4.0™, 4.3™, and Evolution™***: Rotate turret to preferred position.
    Note: Do not apply excessive force or torque during any manipulation of tissue stabilizers. Excessive force and or torque potentially cause the device to lose suction, and may cause serious injury to the patient.
    b. ***Evolution™***: If it is desired to obtain spread of tissue stabilizers, approximate tissue stabilizers medially utilizing flexibility of wire-loop headlink prior to contact with epicardial surface. Once tissue stabilizers are in place on epicardial surface, commence suction by turning stopcock to "on" vacuum position. Release tissue stabilizers, allowing tension in wire-loop headlink to provide lateral traction to anastomotic site. To immobilize the arm, turn knob clockwise. Maximum tension has been reached when the tension indicator appears red.
    c. ***Octopus 3.0™, 4.0™, 4.3***: Commence suction by turning stopcock to the "on" vacuum position and carefully

apply tissue stabilizers to ideal location on epicardial surface. To immobilize the arm, turn knob clockwise. Tissue stabilizers will steadily move laterally.

5. ***Octopus 3.0™, 4.0™, 4.3™, and Evolution™***: For tissue stabilizer removal, support the heart and cease suction by turning stopcock to "off" vacuum position.
6. To loosen arm, turn knob counterclockwise. Carefully remove tissue stabilizers from heart.
7. Upon completion, remove device from retractor. Immediately follow decontamination procedure described in Decontamination section in this Instructions for Use.

Guidant Acrobat™ SUV Vacuum Stabilizer and Acrobat™ V Vacuum Stabilizer

1. Before use, close the Activator Drive Mechanism by turning the drive handle clockwise.
2. Assemble the AccessRail onto an Activator Drive Mechanism, matching the correct left and right platforms to the correct drive attachment side. Fully engage the drive platforms.
3. Properly seat the AccessRail Platform blades on the sternum.
4. Begin spreading the sternum to the desired opening by slowly counter-clockwise turning the drive handle.
5. If using sutures, slide the sutures into the suture holder slots. Engage only one suture strand per slot to ensure proper hold.
6. Release engaged suture from the platform by concurrently pulling back and up on the suture while pulling the suture through the holder slot.
7. Make sure that the stabilizer arm moves freely before installing the stabilizer.
8. ***Acrobat™ V Vacuum:*** Assemble the stabilizer onto the AccessRail Platform by hooking and re-hinging the mount onto the rail at the desired location.
   Acrobat™ SUV Vacuum: Assemble the stabilizer onto the AccessRail Platform by pulling backwards on the mount lever and hooking the mount onto the desired location of the AccessRail. Slide the mount lever 90° to the left or right to lock mount into place.
9. Attach stabilizer tubing from device to a fluid collection canister (not included). Assure stopcock is in the "off" vacuum position, and attach remaining vacuum tubing from the fluid collection canister (not supplied) to a regulated vacuum source. The vacuum "on" mode is achieved by rotating the stopcock perpendicular to the tubing leading to the vacuum source. The vacuum "off" mode is achieved by rotating the stopcock parallel to the tubing leading to the vacuum source. Vacuum Regulator should be set to 400mmHg.
10. Carefully adjust shapeable feet to conform as needed to the heart. Do not bend feet past 25 degrees on any axis. Do not apply excessive force or torque to malleable feet during manipulation of tissue stabilizers. Excessive force and or torque cause the device to lose suction and potentially cause patient injury. Once stabilizer foot is properly placed on epicardial surface, commence vacuum by turning stopcock "on" vacuum position.
11. After positioning the device, turn mount knob clockwise to stabilize the interlinking arm. Turn knob carefully while device is mounted.
12. To release the stabilizer from the AccessRail Platform, turn the stopcock to "off" vacuum position to disengage suction. Loosen by rotating mount knob counter-clockwise.
13. Unhinge mount, therefore releasing device from AccessRail Platform.
14. To remove the AccessRail Platform from an Activator Drive Mechanism, turn the release latches in the direction indicated by arrows and pull platform away from drive mechanism.
15. Immediately follow decontamination procedure described in the Decontamination section of this Instructions for Use Manual.

Guidant Ultima™ Mechanical Stabilizer and Acrobat™ Mechanical Stabilizer

1. Before use, turn drive handle clockwise to close Activator Drive Mechanism.
2. Place the AccessRail Platform onto the Activator drive mechanism, assuring the right and left platforms are matched to the corresponding drive attachment side. Make certain that the drive and platforms are fully engaged.
3. Verify that the AccessRail Platform blades are correctly seated on the sternum.
4. After correctly placing AccessRail Platform, spread sternum to desired width by slowly turning the drive handle counter-clockwise.
5. When using sutures, glide sutures into the suture holder slots. To ensure proper hold, engage only one suture strand in each slot.
6. Release engaged suture from the slot by simultaneously pulling back and up on the suture while pulling the suture through the holder slot.
7. Assemble Mechanical Stabilizer onto AccessRail Platform.
   a. ***Acrobat™ Mechanical Stabilizer***: Prior to installing the stabilizer, confirm the stabilizer arm moves freely by rotating knob counter-clockwise and loosening stabilizer arm. Place stabilizer onto AccessRail by pulling back on mount lever and hooking mount onto AccessRail at optimal position. Slide mount lever 90° to the left or

right to lock mount into place.
Ultima™ Mechanical Stabilizer: Place stabilizer onto AccessRail (or Activator Drive Mechanism) by hooking base of stabilizer device onto rail at optimal position. Move base lever clockwise to close position.

8. Position stabilizer on epicardium. Gently move the arm/ shaft of device while guiding the foot of the device with opposite hand to target area. Apply pressure to foot of stabilizer on epicardium in small increments until stabilization is acquired.
9. To secure, loosen, and/or remove apparatus:
    a. ***Acrobat™ Mechanical Stabilizer***: Secure stabilizer foot and arm by turning grey mount knob clockwise. Loosen stabilizer by grasping arm of device with one hand and turning grey mount knob counter-clockwise. Cautiously remove stabilizer foot from anastomostic site. Remove stabilizer device from AccessRail by sliding mount lever to center position and pulling back.
    b. ***Ultima™ Mechanical Stabilizer***: Secure stabilizer mount and shaft by applying lateral (inward) pressure to the light grey knob and rotating it clockwise while also supporting the light grey base. Secure stabilizer foot by turning dark grey shaft knob clockwise. When removing stabilizer device, support shaft with one hand while turning light grey side mount knob counter-clockwise. Cautiously remove stabilizer foot from anatomostic site. Remove stabilizer device from AccessRail (or Activator Drive Mechanism) by moving base lever counter-clockwise to open position.
10. To remove AccessRail Platform, close apparatus by carefully turning drive handle clockwise. Cautiously remove apparatus from incision.
11. Remove AccessRail Platform from Activator Drive Mechanism, turn release latches on platform in direction indicated by arrows and pull platform away from Activator Drive Mechanism.
12. Immediately follow decontamination procedure described in Decontamination section in this Instructions for Use Manual.

Guidant Xpose™ 3 Device and Guidant Xpose™ 4 Device

1. ***Xpose™ 3 Device:*** Attach the Xpose™ Device onto the AccessRail or Activator Drive Mechanism by hooking the medial edge of the green stabilizer mount on the rail and gently pushing down on the lateral edge of the rail mount to completely engage.
   Xpose™ 4 Access Device: Attach the Xpose™ Device onto the AccessRail or Activator drive mechanism by pulling backwards on the mount lever, then hooking the mount onto the Accessrail in the preferred location. Slide the mount lever 90° right or left to lock the mount into place.
2. Attach one end of the vacuum tubing to the Axius™ Xpose™ Device. Attach the other end of the vacuum tube to a fluid collection canister (not supplied). Make sure the stopcock is in the “off” vacuum position. The vacuum “on” mode is achieved by rotating the stopcock perpendicular to the tubing leading to the vacuum source. The vacuum “off” mode is achieved by rotating the stopcock parallel to the tubing leading to the vacuum source. The remaining vacuum tubing should then connect from the fluid collection canister (not supplied) to a regulated vacuum source.
3. Place the suction cup of the Axius™ Xpose™ Device onto the apex of the heart and gently apply a vacuum by turning the stopcock to the “on” vacuum position. Make sure there is a tight seal. The vacuum should be set at (-) 250 mmHg.
4. Positioning of the apex should be achieved by holding the grasping handle at the distal segment of the arm and cradling the heart into its desired location. Once positioned, lock the interlinking arm by turning the mount knob until the torque limiter is engaged.
5. Once positioned confirm that the Xpose™ Device cup and heart move freely with a natural movement.
6. To remove the Xpose™ Device, gently support the heart with one hand so it does not fall abruptly with the release of vacuum and cup disengagement. Vacuum will be released by turning the stopcock to the “off” vacuum position. .
7. ***Xpose™ 3 Device:*** Unhinge the stabilizer mount after a complete rotation of the mount knob has loosened the interlinking arm. Remove the rail mount by gently lifting the lateral edge of the mount to completely remove the device from the AccessRail or Activator Drive Mechanism.
   Xpose™ 4 Device: Rotate knob counter-clockwise to loosen the Flex-Link arm. To remove the Xpose™ device from the Accessrail, slide the mount lever to the center position and pull back.
8. Immediately follow decontamination procedure described in Decontamination section in this Instructions for Use Manual.

Storage and Handling

- Store device in a cool, dry environment.

Recommended Decontamination

1. **Segregation of Devices** - At the completion of each procedure, single-use devices to be reprocessed by Stryker Sustainability Solutions should be physically segregated from other devices. All devices to be reprocessed should be transported from the operating room to an adequate decontamination area.
2. **Decontamination** - All decontamination should take place in the appropriate areas of the facilities. After separating the devices from other devices in the collection bin, devices are to be rinsed with running water. For vacuum devices, remove and discard the ¼" tubing and canister. Flush devices by holding the 1/8" ID attached suction tubing end under running water to removed visible contaminants and debris. With a soft brush, clean the outer cavity. Avoid using a soiled brush on other devices. A soiled brush can deposit debris into small crevices that can be hard to clean. Areas susceptible to stains and debris without adequate decontamination include the suction apparatus, the flex links, the stabilizer feet, and in between the molded plastic and the metal of the head links. Irrigating the suction tubing provides an easy solution. For surgical areas without immediate source of running water, a disinfectant soak can be employed. If possible, use a syringe filled with water to irrigate attached vacuum tubing. Irrigate the device through the stopcock to avoid getting blood soil trapped into stopcock. Do not irrigate with saline solution due to potential residual build-up. If using central processing to decontaminate devices, send through the ultrasonic washer.
3. **Collection and Staging** – Devices should be individually placed in a quart size baggy with a tiny amount of water to keep them moist. **DO NOT DRY DEVICES**. This enables removal of debris from the "feet" that cannot be accessed with a brush and is also less destructive. Also, by keeping the moist, it is easier to remove the soil and debris in production. On a scheduled basis, the Account Service Representative will collect and identify all products in the containers and complete all necessary paperwork to facilitate shipment of the products to Stryker Sustainability Solutions for reprocessing.

The user facility is responsible for providing personal protective equipment (PPE) for all service personnel. Such equipment must comply with OSHA regulations, and can include protective gloves, liquid-resistant clothing, face shields, and surgical face masks. PPE should be worn whenever an individual is performing collection and initial decontamination procedures. Additionally, personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, the user facility should offer hepatitis B vaccinations to their service staff.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then 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.

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