Instructions for Use – HeartLine Universal Stabilizer Arms

DESCRIPTION

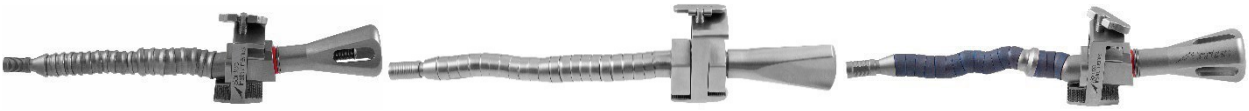
The HeartLine Universal Stabilizer Arm is reusable and supplied non-sterile. It consists of a distal connection mechanism, an articulating arm, a handle for providing cable tension, and a mechanism to mount the device to a sternal retractor. A variety of reusable attachments are available from Sontec for use with the HeartLine Universal Stabilizer Arm.

INDICATIONS

The stabilizer arm is intended for use in cardiac surgery to provide stabilization and positioning of multiple anatomical structures during a variety of cardiovascular procedures.

CONTRAINDICATIONS

Local or systemic infection.



⚠ WARNINGS

- United States Federal Law restricts this device to sale by or on the order of a physician or other licensed practitioner.
- Excessive torque might cause the cable to fray, snap, or break. If the arm does not hold position, it should not be used. Return the unit to Sontec for repair or replacement.
- Avoid repositioning the arm when it is tensioned. It will cause the cable in the flexible arm to fray and possibly break.
- Heavy or improper use of devices may cause damage requiring replacement of the unit.
- Visually inspect the cable for fray. Do not use fingers to check for cable fray.
- This unit is **not** to be reprocessed using Sterrad automatic washers/sterilizers which can cause damage to or break the nylon bearing component. Please determine if your sterilization equipment's processing parameters are compatible with the arm prior to reprocessing.
- Strictly follow the manufacturer's instructions for proper concentration of detergent solution to avoid highly acidic or alkaline pH balances, which may cause corrosion and result in breakage. The validated pH range is 7.8 - 8.8.

⚠ PRECAUTION

Cable fatigue and wear can be easily detected, and failure prevented, by examining the cable before each use. Prior to beginning each procedure, while the arm is fully loosened, look at the arm to determine if the cable shows signs of fraying. If so, it should not be used. A cable will not suddenly fail during a procedure if inspection is done to verify cable integrity prior to use.

PRE-INSPECTION BEFORE USE

Prior to use, the unit should be fully loosened and visually inspected. The cable should be inspected by examining the spaces between links. No signs of wear or fraying of the cable should be present. If any wear is found, it is recommended that the product be returned to Sontec for repair or replacement.

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PROCEDURE

1. Attach a Sontec accessory device to the distal connection mechanism. For connection of a standard Sontec quick-connect attachment, slide the sleeve backward and hold it in place, then insert the shaft into the connection with the flat on the shaft facing opposite the indentation on the sleeve (Figure 1). Return the sleeve to its original forward position to lock the accessory device into connection. Check for a secure connection (Figure 2).

   NOTE: Ensure that the sleeve is grasped during attachment insertion. Failure to grasp the sleeve may result in an inability to insert the attachment.

Figure 1 – Hold the sleeve back to insert the shaft.

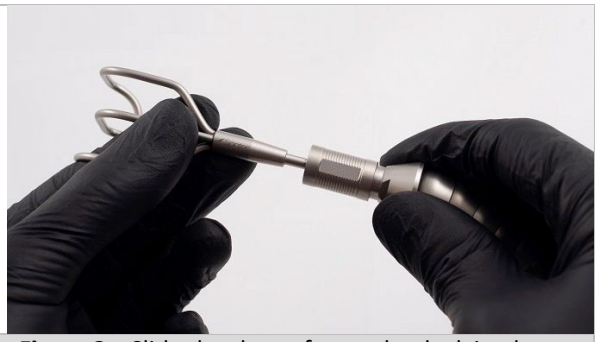

Figure 2 – Slide the sleeve forward to lock in place.

2. Attach the stabilizer arm to the retractor using the clamp at the base of the unit. First twist the clamp handle counterclockwise to loosen the jaw. Place the jaw over the retractor frame in the desired position, then rotate the clamp handle clockwise to tighten the clamp and secure the device.

3. Position the accessory device as required. Turn the main handle clockwise until the gap between the compression washers closes, as shown in Figure 4. The closing of the gap between the washers indicates that the recommended cable tension is reached.

   NOTE: Do not reposition the arm without first loosening the main handle.

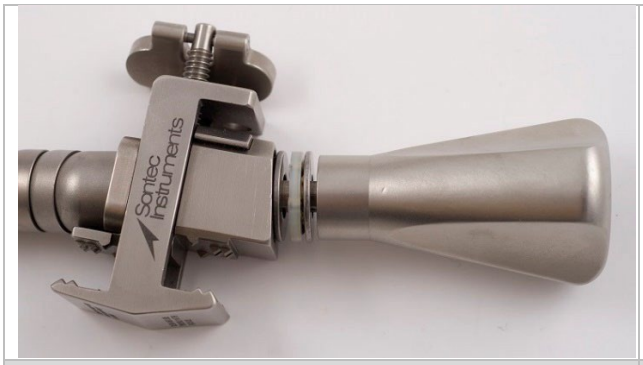

Figure 3 – Loosened, to inspect the washers.

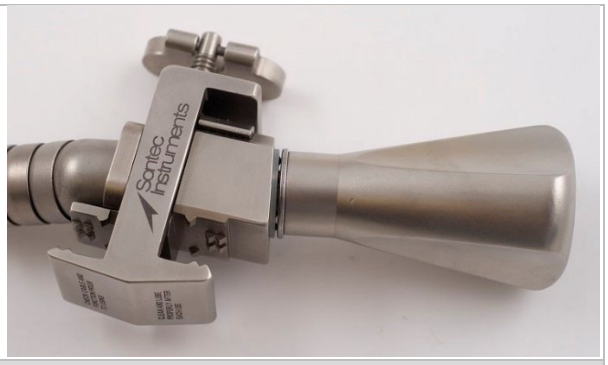

Figure 4 – Tightened, to rigidify the arm.

POST-INSPECTION AFTER USE

After every use, the arm should be fully loosened and visually inspected. Check between the last link and the clamp assembly for signs of cable fray. Cable fatigue and fraying typically occur in the same location, at the back end of the arm, nearest the retractor mounting clamp, making it very easy to detect early. There should be no signs of wear or fraying of the cable. In addition, check for a broken or missing nylon washer.

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Figure 5 – Inspecting the cable at the base.

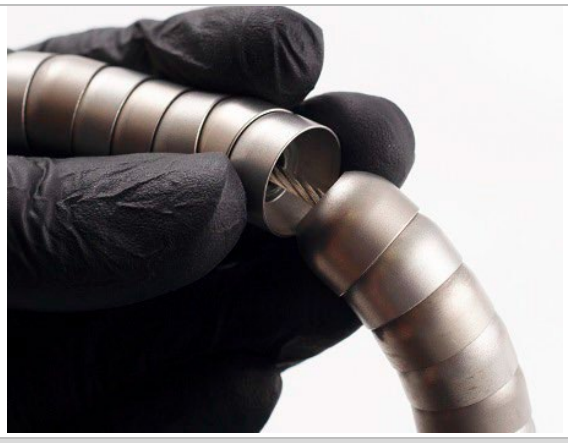

Figure 6 – Inspecting the cable between links.

⚠ If wear is observed, do not continue use, and contact Sontec Customer Service for repair or replacement. Again, the unit should never be used in the following conditions:

- Cable demonstrating fatigue and/or fraying.
- Broken or missing nylon washer.

REPROCESSING INSTRUCTIONS & LIMITATIONS

It is recommended to reprocess the device as soon as is reasonably practical following use. Repeated processing has no significant influence on the length of life of the device. End of life shall be determined by wear and/or damage from use.

PREPARATION FOR CLEANING

Remove excess soil with a disposable cloth or paper wipe. Ensure the main handle is fully loosened prior to cleaning, and that any attachments are disconnected from the distal end of the arm. Perform cleaning and decontamination using one of the manual or automated methods described below, followed by inspection, lubrication, and sterilization.

CLEANING AND DECONTAMINATION – MANUAL

- Rinse thoroughly under reverse osmosis/dionized (RO/DI) water for a minimum of 5 minutes to remove gross soil and debris. Flush any hard-to-reach areas with a 60 mL syringe.
- Immerse the device in an approved enzymatic detergent instrument cleaner using the recommended mixture concentration on the detergent's label and lukewarm tap water for a minimum of 5 minutes. Sontec recommends using Ruhof™ products, or a suitable equivalent. Ruhof™ is a brand of protein-resolving cleaner that removes all traces of blood and debris. Strictly follow the equipment manufacturer's instructions regarding temperature, concentration, and proper use.
- Actuate and tap the device to insure penetration of cleaner and release of trapped air bubbles.
- Scrub each link thoroughly using a soft brush or lint-free cloth and recommended enzymatic cleaner. Sontec recommends Whisk'R Brushes for this purpose. Remove all traces of blood and debris, and make sure all moving parts are cleaned thoroughly to prevent debris from interfering with movement.

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- Rinse the device thoroughly for a minimum of 1 minute in RO/DI water to remove dislodged surgical debris and detergent solution. Flush any hard-to-reach areas with a 60 mL syringe.
- Immediately after rinsing, gently drain off the excess water. Blow dry using compressed air, and wipe the device clean with a soft, lint-free cloth.
- Rinse the device completely with purified water running between each link to remove all signs of enzymatic cleaner.

⚠ Incomplete rinsing after cleaning can cause the enzymatic cleaner to form a residue on the arm that may result in links binding together.

CLEANING AND DECONTAMINATION – AUTOMATED (ULTRASONIC CLEANING)

- Place the device on appropriate perforated trays or in wire baskets.
- Avoid any “wave shadows” or covering of surfaces by wire baskets, perforated trays, or large/bulky instruments.
- Add Ruhof™ or an equivalent enzymatic cleaner formulated for use by the manufacturer of the ultrasonic cleaner and lukewarm tap water. Strictly follow the manufacturer’s instructions for proper concentration of the solution to avoid overly acidic or alkaline pH balances, which can cause corrosion and damage the device.
- Follow the ultrasonic cleaner manufacturer’s recommendations as to the suspension of the basket (e.g., the basket should not sit on the bottom of the ultrasonic cleaner), conditioning of the water, etc. Allow to sonicate for a minimum of 10 minutes.
- After ultrasonic treatment, remove, rinse, and dry the device as described in the manual cleaning section above.

⚠ INSPECTION, MAINTENANCE, AND TESTING

Visually inspect the entire arm (i.e., surface, beads, joints, air pockets, channels, lumen, etc.) for cleanliness to assure residue has been removed. If any tissue, blood, pus, or soil is still present, repeat the cleaning process.

Ensure the arm is fully loosened and inspect the cable for damage between the last link and the clamp assembly. There should be no signs of wear or fraying of the cable. If wear is observed, return to Sontec for repair or replacement. Cable fatigue and wear is a gradual event that occurs over many arm-rigidifying cycles. As the cable begins to fatigue, the outer strands will begin to fray and break. The user can recognize onset of fatigue as continued revolutions of the handle do not rigidify the arm and an audible popping is heard. This sound indicates the individual cable wires breaking. Once cable fraying begins, the cable will eventually sever after numerous additional rotations of the handle. In the rare and unfortunate event where a cable completely severs and the articulating links disperse into the field, it is imperative to completely account for the distal assembly and all links.

Sontec Item Number	Quantity of Links
2800-810	17 links + tip
2800-810L	21 links + tip
2800-810T	17 links + tip

Check for smooth movement of the handles, jaw, and main body. Inspect the mated stainless steel and nylon thrust bearing washers near the main handle to verify all are intact. The instrument should be returned for repair or replacement if any defects are found.

After cleaning, completely dry the arm for a minimum of 30 minutes before storage.

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LUBRICATION

For optimal device performance and to maximize useful life, lubrication of the device is recommended prior to each device sterilization cycle. Ensure the handle is fully loosened to expose the screw prior to lubrication, following the lubricant manufacturer's instructions.

STERILIZATION

The device should be sterilized using the following processing parameters. Ensure the arm is not tightened during sterilization. To monitor the effectiveness of the sterilization process, a biological indicator containing Geobacillus stearothermophilus spores may be used.

Method	Temperature	Min. Exposure Time
Gravity Displacement (unwrapped)	132°C/270°F – 137°C/279°F	3 minutes
Pulsed Vacuum (wrapped)	132°C/270°F – 137°C/279°F	4 minutes
Pulsed Vacuum (wrapped)	134°C/273°F – 137°C/279°F	3 minutes

END OF LIFE

The arm can be used for up to 18 months or a maximum 150 uses, whichever comes first. At the end of life, the unit should be returned to Sontec for repair or replacement. Disposal of the unit, if necessary, should be performed in accordance with hospital, administrative and/or local, state, federal, and international laws/regulations. If the unit performance fails while still under warranty, please contact Sontec Customer Service for an RMA number to return the unit.

WARRANTY AND LIMITATIONS

Sontec warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. Handling, storage, cleaning, and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Sontec's control directly affect the instrument and the result obtained from its use. Sontec's obligation under this warranty is limited to the repair or replacement of this instrument and Sontec shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. Sontec neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Sontec assumes no liability with respect to instruments reused, reprocessed, or re-sterilized and makes no warranties expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such instrument.

SYMBOLS USED ON LABELING		
Manufacturer	Date of Manufacture	Consult Instructions for Use
REF Reference Number	LOT Lot Number	QTY Quantity
Caution! See Warnings and Precautions.	NON STERILE Packaged Non-Sterile	Rx Only U.S. Federal law restricts this device to sale by or on the order of a physician.
Handling & storage only in a dry location.	35°C 1°C Handling & storage only between 1°C – 35°C.	

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