Instructions for Use	Reusable Device

Hercules™ 3 Universal Stabilizer Arm

Catalog Number 401-161

Instructions for Use

⚠ *Carefully read all instructions prior to use. Observe all contraindications, warnings and precautions noted in these directions. Failure to do so may result in patient complications. AtriCure relies on the physician to determine, assess and communicate to each patient all foreseeable risks of the procedure.*

DESCRIPTION

The Hercules 3 universal stabilizer arm is reusable and supplied non-sterile. It consists of a distal connection mechanism (standard Estech shaft Quick-Connect), an articulating arm, a handle for providing cable tension, and a mechanism to mount the device to a sternal retractor. *A wide variety of reusable and disposable attachments are available from AtriCure intended for use with the Hercules Universal Stabilizer Arm (USA).* Refer to Table 1 for the length and number of links found on the Hercules 3 USA.

Table 1

Model	Length	# of Links
Hercules™ 3 Universal Stabilizer Arm – Model 401-161	6.35 (16.1 cm)	18

INDICATIONS

The Hercules 3 is a universal stabilizer arm intended for use in cardiac surgery to provide stabilization and positioning of various anatomical structures during various 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 cable to fray, snap or break. If the Arm does not hold position, it should not be used and should be returned to AtriCure for replacement.
- Avoid repositioning the Arm when the Arm 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 unit.
- Visually inspect 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 or breakage to the Nylon bearing component. Please contact the equipment manufacturer prior to use to determine if the equipment's processing parameters are compatible with the arm.
- Strictly follow the manufacturer's instructions for concentration of the detergent solution and proper use to avoid high acidity or alkaline pH balances outside the validated pH range 7.8 – 8.8, which may cause corrosion and result in breakage.

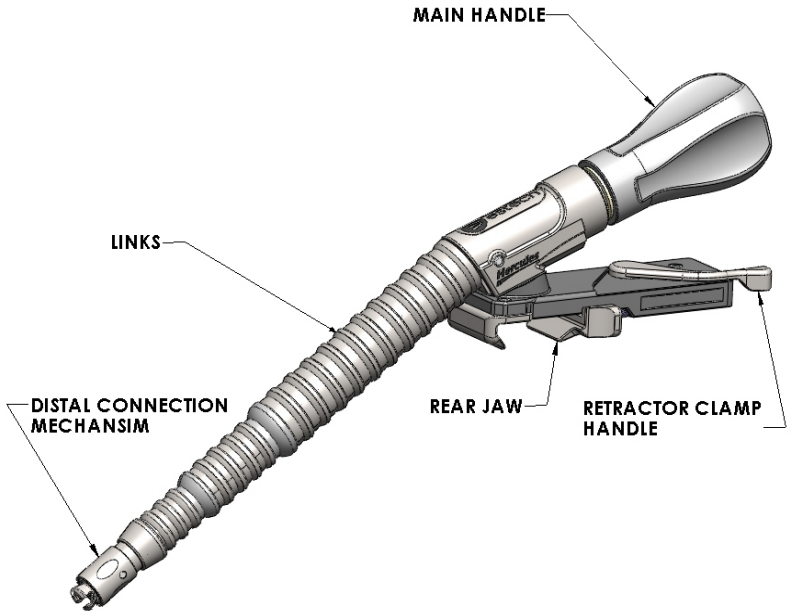


Figure 1 – Hercules Device

LIMITATIONS ON REPROCESSING

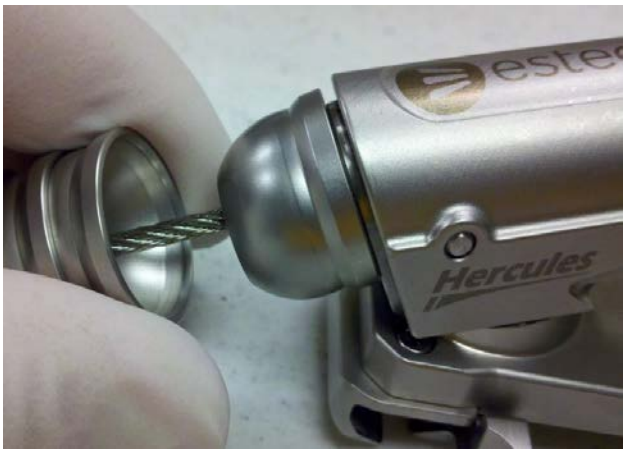
- Repeated processing has no significant influence on the length of life of the device.
- End of life shall be determined by wear and/or damage from use.

⚠ **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 (see below for fraying example). 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 the product be returned to AtriCure for replacement.



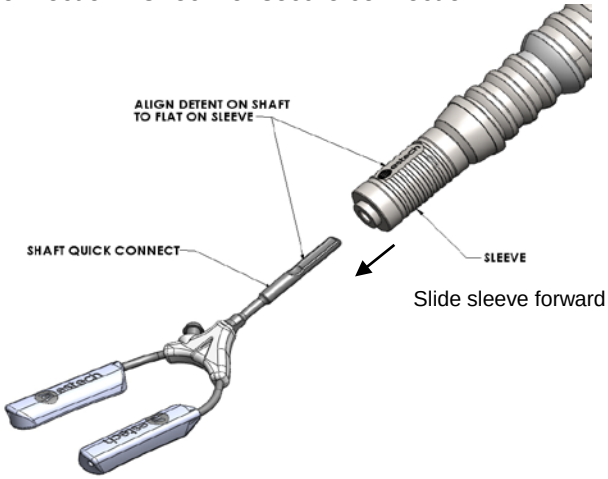
Appearance of a normal cable


Appearance of a fraying cable – Do not Use

1. Verify function of the device by tightening and loosening the cable by turning the Main Handle.

PROCEDURE

1. Attach an Estech accessory device to the distal connection mechanism. For connection of a standard Estech shaft quick connect attachment, slide the sleeve forward and insert the shaft into the connection with the detent on the shaft facing the flat on the sleeve (see Figure 2). Return sleeve to original position to lock accessory device into connection. Check for secure connection.



Slide sleeve forward to insert/remove attachments

Figure 2 – Hercules 3 Quick Connect (401-161)

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

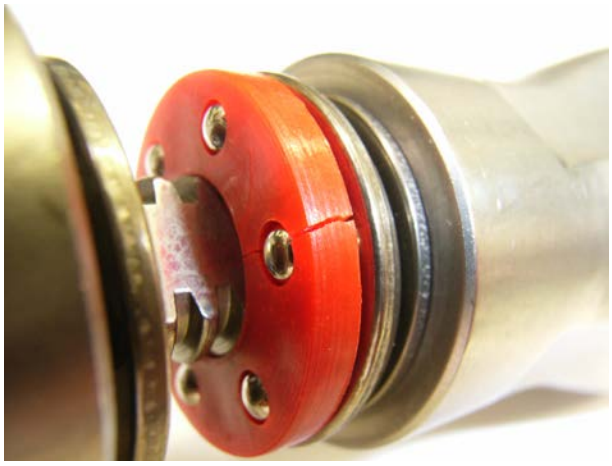
2. Attach the clamp of the Hercules to the retractor by sliding the rear jaw backward and placing the clamp onto the retractor arm. Allow the rear jaw to spring closed against the retractor arm before rotating the retractor clamp handle clockwise to clamp the Hercules.

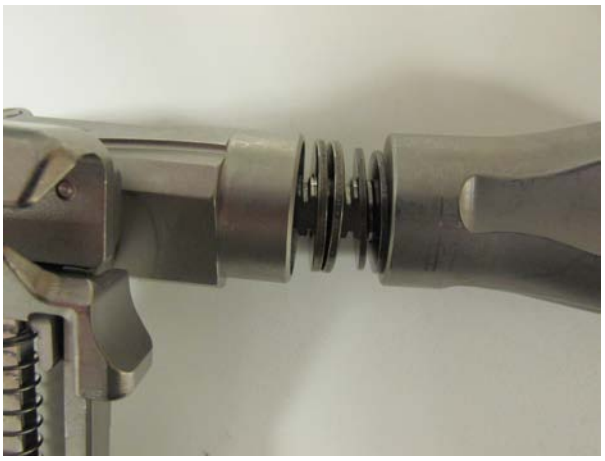
3. Position accessory device as required. Turn the main handle clockwise until the gap between the compression washers closes as depicted in the following picture. The closing of the gap between the washers indicates that the recommended cable tension is reached as shown in the following picture. Do not reposition the Arm without loosening the Main Handle.

⚠ **POST USE INSPECTION**

After every use, the arm should be fully loosened. A visual inspection should be conducted between the last link and the clamp assembly for cable fray. Cable fatigue and fraying typically occurs 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. See the picture below with a cable demonstrating fatigue and fraying.
In addition, check for broken or missing nylon (orange) washer.
If wear is observed, do not continue use, and contact your local AtriCure Representative or call Customer Service for replacement. Again, the unit should never be used in the following conditions:

Cable demonstrating fatigue and fraying – Return to Estech





Broken or missing nylon washer – Return to Estech

REPROCESSING INSTRUCTIONS

It is recommended that the device is reprocessed as soon as is reasonably practical following use.

POINT OF USE

Remove excess soil with disposable cloth/paper wipe.

PREPARATION FOR CLEANING

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 device in an approved suitable enzymatic detergent instrument cleaner under recommended mixture concentration on the detergent's label using lukewarm tap water for a minimum of 5 minutes. AtriCure recommends using ENZOL™ manufactured by Johnson and Johnson, or a suitable equivalent. ENZOL™ is a brand of protein resolving cleaner to remove all traces of blood and debris. Strictly follow the manufacturer's recommended instructions regarding temperature, concentration and proper use.
- Actuate and tap 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. Remove all traces of blood and debris. Make sure all moving parts are cleaned thoroughly to prevent debris from interfering with movement.
- Rinse device thoroughly for a minimum of 1 minute in RO/DI water to remove dislodged surgical debris and the detergent solution. Flush any hard to reach areas with a 60 mL syringe.
- Immediately after rinsing, gently drain off excess water. Blow dry using compressed air. Wipe device with a clean, lint-free soft cloth.
- Rinse device completely with purified water running between each link to remove all signs of enzymatic cleaner.

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

CLEANING AND DECONTAMINATION: AUTOMATED (ULTRASONIC CLEANING)

- Place device on proper perforated trays or in wire baskets.
- Avoid any "wave shadows" or covering surfaces caused by wire baskets or perforated trays or by large or bulky instruments.
- Add ENZOL 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 concentration of the solution and proper use, avoiding acidic or alkaline pH balances, which can cause corrosion and damage the device.
- Follow recommendations of the ultrasonic cleaner manufacturer 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 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 and lumen, etc.) for cleanliness to assure residue has been removed. If any tissue, blood, pus or soil is still present, repeat 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 AtriCure for 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 continued revolutions 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 per Table 1 of this IFU.

Check for smooth movement of jaw handle, back 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 replacement if any defects are found.

After cleaning, completely dry the Arm for a minimum thirty minutes before storage.

LUBRICATION

For optimal device performance and to maximize useful life, lubrication of the device using Steris® Hinge-Free® instrument lubricant (or equivalent) per manufacturer's instructions is recommended prior to each device sterilization cycle. Ensure the handle is fully loosened to expose the screw prior to lubrication.

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.

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

PREVENTIVE MAINTENANCE

After use the arm must be properly maintained following these instructions. When the arm shows wear and tear it is recommended that the arm should be replaced.

HOW SUPPLIED

The Hercules Arm is supplied non-sterile. Each unit is packaged and sold individually.

CONTENTS

The packaging configuration consists of one unit (1) per box.

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 properly disposed and replaced with a new unit. If the unit performance fails while still under warranty, please contact your local AtriCure sales representative or customer service for a RGA number to return the unit.

DISPOSAL

After use, dispose of product and packaging in accordance with hospital, administrative and/or local, state, federal and international laws and regulations.

WARRANTY AND LIMITATIONS

AtriCure 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 AtriCure control directly affect the instrument and the result obtained from its use. AtriCure's obligation under this warranty is limited to the repair or replacement of this instrument and AtriCure shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. AtriCure neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. AtriCure 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.

GRAPHIC SYMBOLS FOR DEVICE LABELING

Catalogue Number 	Caution-See instructions for Use 	Manufacturer/Company Address 	Authorized Representative in the European Union 
Serial Number 	Does not contain Natural Rubber Latex 	Contains no di (2-ethylhexyl) phthalate (**DEHP**) released from polyvinyl chloride (PVC) 	
Quantity 	Date of Manufacture 	Non-sterile reusable device 	
Consult Instructions For Use 	CE Mark - class I medical devices comply with EC Directive 93/42/EEC 	For USA Only: "Caution: Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner." 	

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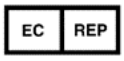

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