INSTRUCTIONS FOR USE

Catalog Number 401-152/401-152L

Universal Stabilizer Arm (USA)™

Hercules

INTRODUCTION

These instructions are designed to help you understand the capabilities and operation of your USA. The information includes options available to use with the USA instrument. The applicability depends on the particular model. Please read these instructions before use.

PRODUCT DESCRIPTION/INDICATIONS FOR USE

The USA Hercules is a reusable flexible arm, capable of providing extremely rigid positioning. It is comprised of various links and a quick connection with mounting clamp at the end of the proximal end for attachment to standard sternotomy retractors or other thoracic access devices. The quick connection can be easily mounted with disposable and reusable stabilization and retraction devices. A wide variety of reusable and disposable attachments are available from ESTECH intended for use with the USA. Refer to Table 1 for available versions of the USA.

<table>
<thead>
<tr>
<th>Table 1</th>
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<tbody>
<tr>
<td>Model</td>
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<tr>
<td>USA Hercules</td>
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<td>USA Hercules, Extended Length (as shown)</td>
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GENERAL WARNINGS

1. United States Federal Law restricts this device to sale by or on the order of a physician or other licensed practitioner.

⚠ 2. 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 ESTECH for refurbishment.

3. Avoid repositioning the Arm when the Arm is tensioned. It will cause the cable in the flexible Arm to fray and possibly break.

4. Heavy use of devices or use of high alkaline detergents may require more frequent service.

5. Inspect for cable fray visually. Do not use fingers to check for cable fray.
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 ESTECH for replacement.

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

2. Attach an accessory device e.g., an ESTECH Coronary Artery Stabilizer product to the Quick Connect by sliding sleeve of connection towards the arm while inserting accessory device into connection. Detent in connecting shaft of accessory attachment allows attachment to fit into connection in correct orientation. While inserting shaft into connection, align attachment Detent to the ESTECH Logo located on the Stabilizer Arm connector. Slide shaft fully into connector. Return sleeve to original position to lock accessory device into connection. Check for secure connection.

3. Attach the clamp of stabilizer arm to sternotomy retractor or other access device. Tighten butterfly handle to affix clamp to retractor or access device.

4. 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 indicated that the recommended cable tension is reached. Do not reposition the Arm without loosening the Arm.
POST-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. There should be no signs of wear or fraying of the cable. If some wear is observed, return to ESTECH for refurbishment.

Please refer to ESTECH Instructions for Reprocessing of Reusable Devices, 440-11975-01 located at our Website: www.estech.com for care and handling instructions to augment the following instructions on cleaning, lubrication, sterilization and storage.

CLEANING
Break up each binding link by light taping with a plastic handle. Manually 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. After manual cleaning rinse Arm 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.

POST-CLEANING
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.

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

STERILIZATION
After following the above cleaning recommendations, the device may 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.

<table>
<thead>
<tr>
<th>Steam Sterilizer</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
<tr>
<td>Pre-vacuum</td>
<td>132°C (270°F)</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Gravity Displacement (Wrapped)</td>
<td>121°C (250°F)</td>
<td>30 minutes</td>
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</table>
LUBRICATION

Lubrication on the screw is required for every use. A water-soluble, a biodegradable grade is recommended. Turn the handle all the way back to expose the screw. Apply an approved instrument lubricant on the thread portion of the screw as shown in follow. This will increase the life of the device.

PREVENTIVE MAINTENANCE

Every 12 months or when used frequently it is recommended that high wear components should be replaced. When returning for maintenance or repair, please contact your local ESTECH sales representative or customer service for a RMA number.

WARRANTY

The USA Hercules has a 1 year warranty on parts and workmanship. ESTECH warrants that the instruments are free from defects in both materials and workmanship. Suitability for use of the instruments for any surgical procedure shall be determined by the user. ESTECH shall not be liable for incidental or consequential damages of any kind. The above warranties are in lieu of all other warranties either expressed or implied including any warranty of any merchantability or fitness for use.

BIBLIOGRAPHY

Sterilization of Medical Devices – Information to be Provided by the Manufacturer for Processing of Resterilizable Medical Devices, ISO 17664, First Edition 2004
Estech Cleaning Validation Report, Nelson Laboratory No. 389165, September 4, 2007
Mediflex – Vernick Positractor PN 69072, 69073 Qualification Test Report #645C, October 31, 1996

TECHNICAL SUPPORT

For more information about any ESTECH product or technical support, contact ESTECH customer service:

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