

INSTRUCTIONS FOR USE

Catalog Number 340-7475

Least Invasive Valve Instruments™

Suture Catcher

External view



340-7475 (Suture Catcher)

Tip area



INTRODUCTION

These instructions are designed to provide general instructions and suggestions on how to use the Estech Suture Catcher. The instructions are intended for use to advance surgeon controlled Suture Catcher placement in cardiothoracic procedures requiring remote suture catcher placement. The operation of a suturing thread or similar item is caught on the suture hook at the tip and can thereby be moved to a desired location during surgery.

PRODUCT DESCRIPTION/INDICATIONS FOR USE

The Suture Catcher is comprised of stainless steel. The overall length is 350 mm (13.75 inches) and the tip is approximately 5 mm (0.72 inches) long. The device is used to facilitate manipulation of suture during surgery. The principal use of the Estech Suture Catcher is to capture a suture placed deep in the thoracic cavity, which is to be retrieved. It is most commonly used to pull the suture through tissue out of the chest wall for pericardial and/or tissue retraction. This product is non-sterile.

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. Improper usage may damage this product. Excessive force may cause the instrument tip to fracture, which may lead to breaking off during the surgical procedure.
3. Do not modify, or otherwise alter this product (intended function may no longer be maintainable).
4. Do not use hydrochloric acid, sulfuric acid, nitric acid, or other mineral acids (inorganic acids) or strong abrasive agents on this product (usable life may be shortened).
5. No element of the process temperature must not reach 140° C (284° F) or higher.
6. Check for damage or other problems before use. Do not use a device showing any wear, deterioration, corrosion, deformation, pitting or other damage.
7. Before use, always wash/sterilize. Follow the "Instructions for Use" and the sterilizer processing parameters for appropriate method, temperature and time.

PRECAUTIONS

1. Handle with care; damage to the tip or deformation or damage caused by contact with hard surfaces will substantially reduce the life of the product.
2. This product is only for use by physicians skilled in the procedure.
3. To avoid unforeseen injury when handling this product, use utmost care with areas such as the sharp tip, and always wash/sterilize these areas.
5. When washing, do not polish the surfaces of the product with visually coarse polishing powders or metallic wools.
6. To avoid rusting, adhere strictly to the following practices.
7. Wash promptly after use.
8. Do not sterilize or disinfect the product when any debris remains after washing.
8. Use distilled or deionized water for washing and sterilization.
10. Avoid using strongly acidic or alkaline detergents; use a neutral detergent.
11. For ultrasonic washing, use an appropriate detergent; do not use a household detergent.
12. After washing, do not leave the product in a damp state.
13. To protect the tip and similar areas of the product, store the product in proper sequence in a partitioned, sterile case.
14. This device should not be directly placed through the chest wall without some type of guidance of a lead or catheter, (i.e., 12 gauge angiocatheter or red rubber catheter) used to protect the surrounding tissue and to prevent the tip from breaking off inside the chest wall cavity as it is a delicate instrument.



PRE-INSPECTION BEFORE USE

Prior to use, visually inspect the Suture Catcher for proper function. If any wear is found, it is recommended the product be returned to ESTECH for replacement. The tip area is smooth and free from irregularities. Do not use a device that is worn, deteriorated, corroded, deformed, pitted, or otherwise damaged.

USE OF DEVICE

1. This product is a reusable, manually operated, stainless steel instrument for facilitating manipulation of suture during surgery.
2. Ideally, the device should be directly placed through the chest wall using a lead or catheter, (i.e., 12 gauge angiocatheter or red rubber catheter, 2 ½ to 4" length) as a trocar to protect the surrounding tissue and to prevent the tip from breaking off inside the chest wall cavity. This is the safest option to repeatedly use the suture catcher in a procedure without damage. Note: This device is very delicate. Do not retract the suture catcher against high loads as it may be caught on tissue and doing so can cause damage to tissue and instrument.
3. If using an angiocatheter, once placed, the angiocatheter stylet is removed, leaving the catheter body in place.
4. The suture catcher is inserted and brought out through the angiocatheter and secured with optimum retraction.
5. Repeat step 4 as needed for the number of retraction sutures required.

POST-INSPECTION

After every use, the Suture Catcher should be visually inspected. If damaged, return to ESTECH for refurbishment.

CLEANING

Wash Suture Catcher manually or ultrasonically. Washing with an ultrasonic washer is recommended.

Manual washing

1. To remove blood or tissue fragments completely, soak the product for 5 minutes using an enzymatic detergent. Johnson and Johnson's ENZOL® Enzymatic Detergent is recommended. Use a soft brush and neutral detergent and wash with enough friction to remove blood/bodily fluids, etc. To ensure that no air bubbles remain, check that the detergent diffuses to delicate areas of the device. Though the product can withstand highly alkaline detergents (pH 7 or higher), use of highly alkaline detergents will increase the frequency of adjustment by the manufacturer. Discoloration will also occur but will not affect function.
2. Use a soft brush to wash the product thoroughly (at least 1 minute) and ensure that no tissue fragments remain on the device.
3. Rinse moving parts thoroughly (at least 1 minute) with distilled or deionized water to ensure that no tissue fragments remain on the device.
4. Use compressed air to blow off moisture, wipe with a soft cloth, and dry completely.

Ultrasonic washing

1. Place the device in an open state in a perforated tray or wire basket. Check that the device does not create "ultrasonic shadow areas" due to overlapping.
2. Add an enzymatic detergent as directed in the washing machine operating guide. Replace the detergent with a fresh supply periodically.
3. Set cycle time, washing solution, water, and other parameters according to the operating guide by the ultrasonic washing machine manufacturer.
4. After ultrasonic treatment, rinse with distilled or de-ionized water to prevent water spots. Check that there are no loose parts. Use compressed air to blow off moisture, wipe with a soft cloth, and dry completely.

STERILIZATION

Following are the recommended sterilization parameters.

Sterilization Method	Temperature and Time
Gravity displacement, high-pressure steam sterilization	132° C (270° F) 30 minutes
Prevacuum, high-pressure steam sterilization	132° C (270° F) 8 minutes

PREVENTIVE MAINTENANCE

To maintain optimum performance of the device, preventive maintenance once per year by the manufacturer is recommended. If the device is used frequently, or if a highly alkaline detergent is used, maintenance requirements may be more frequent.

When returning for maintenance or repair, please contact your local AtriCure sales representative or customer service for a RGA number.

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 these instructions.

WARRANTY

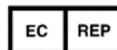
The LiV instruments have a 1 year warranty on parts and workmanship. AtriCure warrants that the instruments are free from defects in both materials and workmanship. Suitability for use of the instruments for any surgical procedure shall be determined by the user. AtriCure shall not be liable for incidental 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.

TECHNICAL SUPPORT

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



AtriCure, Incorporated
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Mason, Ohio 45040 USA
Customer Service:
1-866-349-2342 (toll free)
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Graphic Symbols for Device Labeling

<p>Catalogue Number</p> 	<p>Batch Code</p> 	<p>Quantity</p> 	<p>Date of Manufacture</p> 
<p>Attention: Read all warnings and precautions in instructions for use</p> 	<p>Manufacturer/Company Address</p> 	<p>Authorized Representative in the European Union</p> 	<p>Instrument supplied Non-Sterile</p> 
<p>Does not contain Natural Rubber Latex</p> 	<p>Contains no di (2-ethylhexyl) phthalate (DEHP) released from polyvinyl chloride (PVC)</p> 	<p>Consult Instructions For Use</p> 	
<p>CE mark, Product conforms with the essential requirements in the European Medical Devices Directive 93/42/EEC.</p> 		<p>Caution: U.S. Federal law restricts this device to sale by or on the order of a physician or other licensed practitioner.</p> 