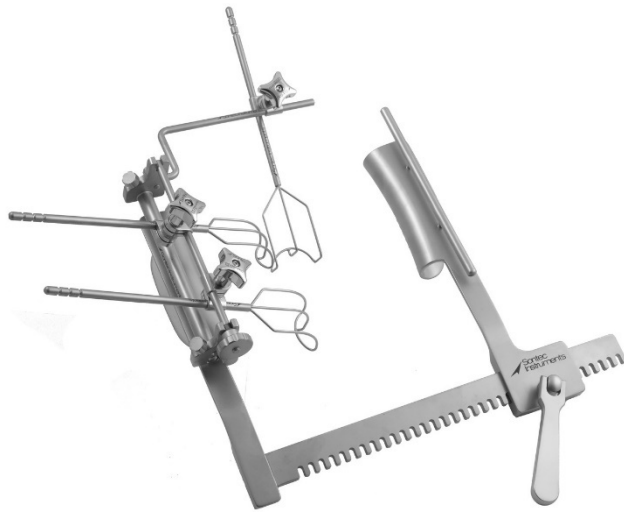


Cooley Mitral Rib Spreader Retractor Set – Instructions For Use –

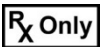


DESCRIPTION / INTENDED USE

The Sontec Cooley Mitral Retractor is intended for use in a sterile setting to hold and position bodily structures during cardio-thoracic surgery. It provides exceptional and consistent exposure of the left and right atrium, tricuspid and mitral valves while reducing the need for surgical assistance. The device requires placement only during the intracardiac portion of the procedure. It is mounted on a Cooley sternum retractor made from instrument-grade quality stainless steel and is available in both large and small sizes. Recommendations for cleaning and sterilization are included in these instructions.



CAUTION: This device is supplied non-sterile and must be cleaned and sterilized prior to use.



U.S. federal law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS

This product is not intended for use except as indicated.

PRE-SURGICAL ASSEMBLY

Position your modified chest spreader as shown (**Figure 1**). Slide the main bracket (**Figure 3**) onto the chest spreader with locking screws to the outside of the chest cavity opening by sliding it onto one of the pre-attached mounting bars (**Figure 2**). Secure the main bracket by tightening the left and right non-removable locking screws (A) (**Figure 3**).

Slide the retractor blade (D) through the universal clamp (C) (**Figure 4**).

Remove the transverse nut (E), then slide universal clamp(s) with attached retractor blade(s) (**Figure 5**) onto the support bar. Rotate the support bar down into the groove in the side support bracket and tighten the transverse nut to secure (**Figure 6**).

Adjust the retractor blades on the main bracket according to the surgeon's preference. Once they are in place, secure the retractor blades by tightening the wing nut on the universal clamp(s).

A third retractor blade can be mounted by attaching the side arm bar (F) as follows: Loosen the side arm locking screw (non-removable) on the main bracket (B) (**Figure 3**). Slide the flattened end of the side arm bar between the support bracket and the head of the locking screw. Tighten the locking screw. Slide a universal clamp with attached retractor blade in the bottom opening onto the side arm bar and secure it by tightening the wing nut on the universal clamp (**Figure 6**).

The Sontec Cooley Mitral Retractor assembly as shown on the first page is now complete.

NOTE: All screws on the Sontec Cooley Mitral Retractor are non-removable. These screws are peened over to prevent the screws from falling into the surgical field. The only item that is removable is the large transverse nut (E) located on the main bracket (**Figure 3 & 5**).

NOTE: The retractor blades may be easily readjusted during surgery by loosening the wing nut on the universal clamp(s).

NOTE: This product is normally intended to be used for less than 60 minutes.

CLEANING

Immediately after surgery, thoroughly rinse the instruments with warm distilled water to remove all blood, bodily fluids, and tissue. If delays prevent immediate rinsing, soak the instrument in a solution of water and pH-neutral detergent prior to cleaning. Never allow organic materials or other contaminants to dry or get encrusted on the instrument.

ULTRASONIC CLEANING

Separate the components and place them into the ultrasonic cleaner. Clean per instrument protocol. Rinse the instruments with warm distilled water immediately after ultrasonic cleaning.

AUTOMATIC WASHER STERILIZERS

Follow the sterilizer manufacturer's recommendations to ensure instruments are lubricated after the last rinse cycle and before the sterilization cycle. According to the Robert Koch Institute (RKI) recommendations, mechanical cleaning and disinfection should be conducted at temperatures greater than 93° C (200° F).

AUTOCLAVE STERILIZATION

Prior to autoclave sterilization, lubricate all instrument parts that have metal-to-metal contact using surgical lubricants such as instrument milk. Do not use industrial lubricants. Instruments must be unlocked before cleaning to prevent any cracks that may occur from heat expansion during the autoclave cycle. Do not overload the autoclave chamber.

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| <p>Manufacturer's recommended sterilization protocol:</p> <p>Sterilizer Type: Pre-vacuum</p> <p>Preconditioning Pulses: 3</p> <p>Minimum Temperature: 132°C (270° F)</p> <p>Full Cycle Time: 4 minutes</p> <p>Minimum Dry Time: 30 minutes</p> <p>Article Configuration: Instruments placed in a 11" x 26" x 3.5" (28 cm x 66 cm x 9 cm) surgical case without brackets or pin mat, with the tray wrapped in two layers of 1-ply polypropylene wrap using sequential envelope techniques.</p> | <p>The following cycle should be used when there is an immediate need for the device and no other alternatives:</p> <p>Sterilizer Type: Pre-vacuum</p> <p>Preconditioning Pulses: 3</p> <p>Minimum Temperature: 132°C (270° F)</p> <p>Full Cycle Time: 3 minutes</p> <p>Minimum Dry Time: N/A</p> <p>Article Configuration: Unwrapped</p> <p>Exposure time: Minimum 3 minutes</p> |
|---|--|

Equipment and procedures used for sterilization should comply with ANSI/AAMI ST79, AST-MF1744 and ISO 17665, www.a-k-i.org. Sontec Instruments, Inc. confirms that the processing recommendations related to machine cleaning and sterilization by the RKI may be used. Sterilization times and temperatures may be extended to 5 minutes and 134° C (273° F).

MAINTENANCE REQUIREMENTS

Every surgical instrument must be properly inspected, cleaned, lubricated, and sterilized before the initial use and all subsequent uses. Carefully examine each instrument for proper function and damage of any sort prior to and after each use. It is extremely important to check all working parts including blades, locks, points, screws, etc. Instruments that show any sign of damage or corrosion should be repaired or replaced prior to further use.

All Sontec Cooley Mitral Retractor sets and attachments should be serviced at least annually, and should be refurbished only by the original manufacturer, Sontec Instruments, Inc. There is no limit to the number of reuses of this device as long as it is appropriately maintained and serviced.

DO NOT SEND THIS INSTRUMENT OUT TO BE SERVICED BY YOUR LOCAL SURGICAL INSTRUMENT REPAIR COMPANY. PLEASE SEND ALL REPAIRS AND REFURBISHING BACK TO THE ORIGINAL MANUFACTURER, SONTEC INSTRUMENTS, INC.

WARRANTY

Sontec surgical instruments are guaranteed to be free from defects in workmanship and material. Any instrument that proves defective in workmanship or material will either be repaired or replaced at our discretion, without charge. Sontec Instruments, Inc. warrants the guarantee of this instrument for the life of the product under the normal surgical use for which it is intended.












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

Figure 1

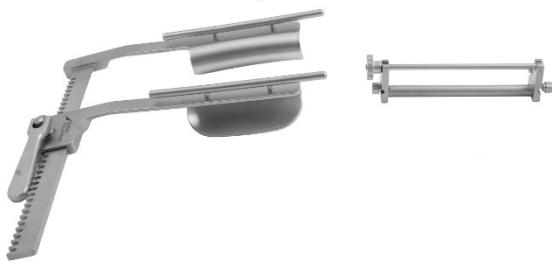


Figure 2



Figure 3



Figure 4

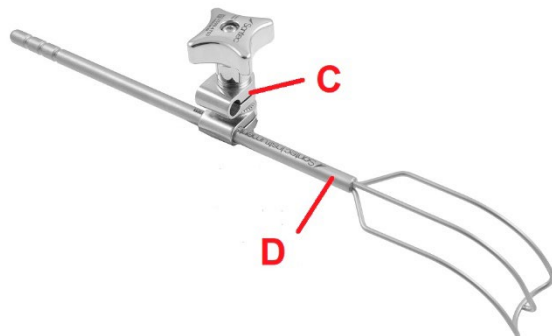


Figure 5

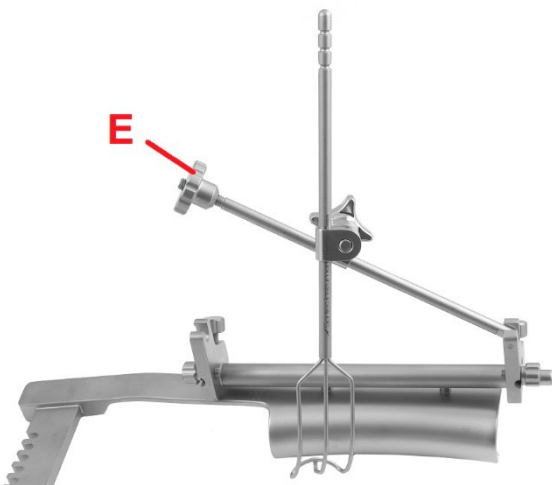


Figure 6

