



STERNAL RETRACTOR / 1 UNIT



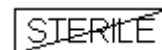
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Product Code	Description
RTC-1000	FasTract™ Sternal Retractor, Regular Blades (35mm), Suture Spring Inserts, Reusable
RTC-1000-C01	FasTract™ Sternal Retractor, Deep Blades (43mm), Suture Spring Inserts, Reusable
RTC-1000-C02	FasTract™ Sternal Retractor, Deep Blades (43mm), Flat Suture Inserts, Reusable
RTC-1000-C03	FasTract™ Sternal Retractor, Regular Blades (35mm), Flat Suture Inserts, Reusable

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Non-Sterile

STERNAL RETRACTOR / 1 UNIT

Product Description:

The Sternal Retractor is a stainless steel, mechanical device that has two arms with scallop shaped blades and cut outs for placement of a suture stay device (sold separately) to hold sutures. The device is reusable and is not sterilized as shipped.

Indications for Use:

The Sternal Retractor is intended to provide surgical access to the chest cavity by retraction. The Retractor also provides a stable mounting surface for the Chase Tripod™ and Viper OPCAB Stabilization System.

Contraindications:

This device is not intended for use except as indicated above.

Warnings:

- Proper surgical procedures and techniques are the responsibility of the medical professional. The surgical team must evaluate the appropriateness of the procedure based on their experience. The outcome is dependent on many variables, including patient anatomy, pathology, surgical technique and anesthesia management.
- Although product has been carefully designed, manufactured and inspected or tested prior to sale, the product may fail to perform its intended function satisfactorily for a variety of reasons. Warnings contained in the product labeling and in this document provide more detailed information and should be read by the user prior to use of product.

Precautions:

- Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.
- The Directions for Use are furnished for information purposes only.

Adverse Effects:

None known.

Directions for Use:

1. Carefully read instructions prior to use.
2. Inspect product for damage. DO NOT USE IF DAMAGED.
3. Prior to use, disassemble per Figure 1, clean and steam sterilize the Sternal Retractor per instructions below.
4. After sterilization, assemble the Sternal Retractor per Figure 2.
5. Place the Sternal Retractor in chest cavity per standard hospital procedure.
6. Insert suture stay(s) firmly into the slot(s) on the retractor arm(s) - optional.
7. Place a Tripod™ or Viper Stabilizer on the retractor arm where desired.
8. Immediately following use, disassemble, clean and steam sterilize the Sternal Retractor.

Steam Sterilization:

Warning: Thoroughly clean the device per hospital procedure to eliminate soil prior to sterilization. Examine the device for cracking or degradation prior to use. Do not use the device if components show signs of cracking or degradation.

Precaution: Do not exceed the sterilizer's maximum load if sterilizing more than one device at a time.

The following sterilization parameters have been validated by Chase Medical. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials, and personnel in the processing facility, achieves the desired result. Processing requires validation and routine monitoring. Likewise, any deviation by the processor from the following instructions should be properly evaluated for effectiveness and potential adverse consequences.

To Sterilize:

1. Lubricate per standard surgical instrument procedure.
2. Steam sterilize the device per the recommended parameters as follows:
Note: Chase Medical validated steam cycles with unwrapped devices.

Pre-Vacuum (Dynamic-Air-Removal) Steam Sterilization Cycle		
Temperature	Min. Exposure Time	Min. Drying Times
121°C (250°F)	15 minutes	15 minutes
132°C (270°F)	4 minutes	15 minutes
135°C (275°F)	3 minutes	15 minutes

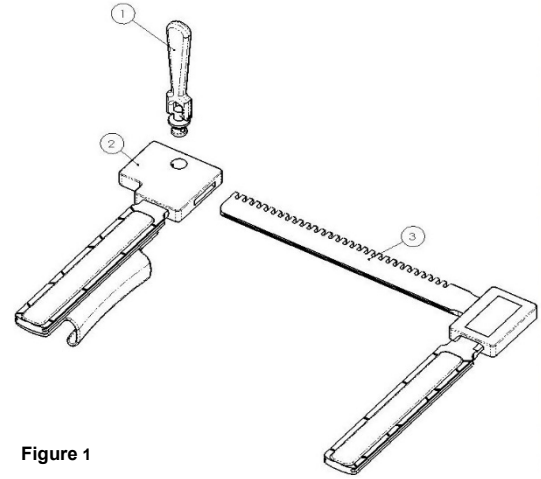


Figure 1

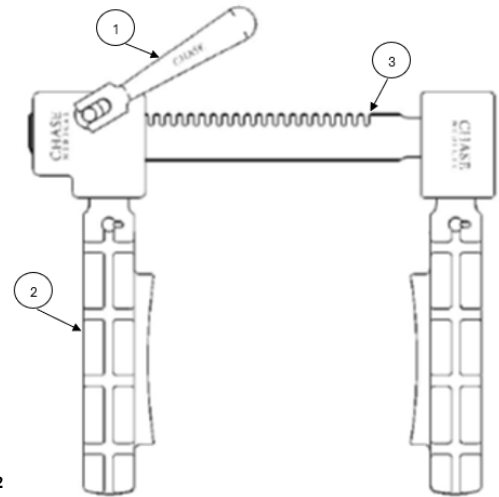


Figure 2

Figures 1, 2. Sternal Retractor
1. Retractor Handle
2. Adjustable Rail
3. Stationary Rail

LIMITED WARRANTY AND DISCLAIMER OF LIABILITY

Chase Medical products ("Product") are manufactured under carefully controlled conditions and Chase Medical warrants the Product will perform in accordance with its labeling and will be free from defects in material and workmanship under normal use for one year from the date of shipment.

Chase Medical's sole liability shall be limited to replacement of, or credit for, any Product returned to Chase Medical and which Chase Medical determines, in its sole discretion, to have been defective in either material or workmanship at the time of shipment.

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