**IFU-Re-Processing Reusable Medical Devices**

**Universal Round Bar Table Mounted Retractor System**

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**PLEASE REVIEW BEFORE USING PRODUCT DESCRIPTION**

The Geister **Universal Round Bar Table Mounted Retractor** General Surgery Systems consists of a variety of Table Posts, Couplers, Frames, Tilt Clamps and Retractor Blades used in concert to provide retraction of tissue and organs during open surgery. The Starter Systems include all of the above except the Retractor Blades. Blades should be ordered separately based on specific requirements determined by surgeons.

**Inspection**
Inspect all parts upon receipt, during the cleaning process and immediately before use. Test to see that any moving or turning parts move freely. Visually inspect for loose or missing parts, cracks and broken components. Any device with missing parts, cracks or broken components should not be used and returned to Geister for repair or replacement.

**Cleaning**
These devices should be cleaned and sterilized before use. After use, they should be cleaned immediately according to recommended cleaning procedure below. Follow instructions and warnings as issued by the manufacturer of any decontaminants, disinfectants and cleaning agents used. Suggested steps in the cleaning process include but are not limited to:

- Wherever possible, do not allow blood, debris or bodily fluids to dry on devices. For best results and to prolong the life of the device, reprocess immediately after use. If they cannot be reprocessed immediately, use enzymatic foam spray cleaner or deionized (distilled) water to help prevent soil from drying.
- Components are **not** designed to be disassembled. Do not attempt to disassemble.
- Prepare enzymatic detergent (such as Kenzyme™) according to manufacturers’ recommendations at 40°C and soak device(s) for fifteen (15) minutes.
- Scrub the submerged device(s) with a soft bristled, non-metallic brush. Agitate the device(s) by hand while scrubbing. Maneuver any movable parts to loosen soil for one minute total, for each device.
• Rinse device(s) with warm tap water for thirty (30) seconds.
• Place device(s) into bath containing warm (38-49°C) water. Agitate the device(s) by hand for one (1) minute. Repeat two additional times.
• Sonicate device(s) for fifteen (15) minutes in 40°C water and a neutral P.H. detergent (such as Neutrad™). Prepare detergent according to manufacturers’ recommendations.
• Rinse the device(s) with clean tap water for one (1) minute.
• Dry the device(s) with a clean, lint-free cloth.
• Re-inspect for loose or missing parts, cracks and broken components. Inspect for visible soil or debris. Repeat cleaning procedure if the device(s) appear to be soiled.
• These devices should be lubricated after every cleaning. Any commercially available water soluble instrument milk or lubricant is acceptable. Follow instructions for lubricating surgical instruments as provided by the manufacturer of the lubricant used.

STERILIZATION
Minimum parameters for Pre-Vac cycles are 4 minutes at 132 Degrees C (270 degrees F). Validated hospital protocol for reusable surgical instruments including Gravity, Flash, Ethylene Oxide, Peracetic Acid (Steris) and Hydrogen Peroxide Gas Plasma (Sterrad) may also be used. Always follow the manufacturer’s recommendation for surgical instruments in the use of any sterilizing equipment or method.

SET-UP AND USE
The following are meant as general guidelines only. Operating room personnel should be familiar with general set-up and should adapt the following to case-specific needs considering type of procedure, size of patient, position of surgeons and assistants. If the device is being used for the first time, the OR Staff is urged to do a “dry-run” with the surgeons and OR personnel expected to be present during surgery.

• Mount the Field Post to the OR Table Rail. A scrubbed member of the team can do this by holding the upper part of the post and slipping the jaw over the rail. Lock by turning the tightening lever clockwise until firmly attached to the table rail. It is OK to mount the post over drapes but do not mount over blankets. Positioning is normally on the side opposite the primary surgeon. Do not allow the post to touch or exert pressure on the patient.
• Prepare the Retractor Frame for mounting by positioning the arms in such a manner that when attached to the Field Post they will not touch a non-sterile surface nor will they place any pressure on the patient. Lock the arms in place using the Cam Locks on the frame. The red handle in the Fig. 1 is in the unlocked position; the blue handle is in the locked position. If the angle of the entire frame needs to be changed, press and hold the silver and black button (yellow in the illustration) and rotate the frame to the desired position.

Fig. 1
Fig. 2
Fig. 3
• Open the coupler by turning the tightening knob fully counter clockwise. Place the coupler on the Handle of the Retractor Frame. Slide the opposite side of the coupler over the Field post and lower about half way. Tighten the coupler just enough to prevent further sliding on the field post.

• When retraction is required, position the frame over the operative site and 2-3” (5-7.5 cm) above the draped field. Height of the frame can be changed by adjusting the coupler while the angle of the frame and the positions of the individual arms are adjusted as described above. Be sure to support the weight of the frame any time either the coupler or one of the cam locks is released.

• Preload retractor blades into the snap clamps. The procedure and surgeon’s preference determine which blades are used. Figure 2 shows the parts of the Snap Clamp. The green section is the lock. It is shown vertical which is the unlocked position. The yellow section is the clamp. The “C” shaped opening is what snaps onto the Retractor Frame.

• The blue section has an opening (not visible) the handle of the blade slides into. Two things to note: enter the handle of the blade in, from the same side that the “C” of the yellow section faces. Make sure that the cam lock (the green section) will fold down away from the frame. The blade goes under the frame and is lowered into the incision. Next, snap the clamp onto the frame, reposition the blade and lock the clamp using the cam lock (green in Fig. 2.)

• If desired, the blades can be placed over the frame but the cam lock would then be beneath. Fig 3. Shows both options with the yellow section the part that is locked onto the frame. The upper blade in Fig. 3 is below the frame, the lower blade is above the frame.

• Protected-edge, Malleable Blades can be shaped as needed. We recommend The Bookler Blade Bender to assist in blade shaping. It is available from Geister.

• Intraoperatively, the Blades can be moved by unlocking the snap clamp and guiding the blade into the desired position.

• Postoperatively, remove components in the opposite sequence.

ROUTINE MAINTENANCE
If inspection, cleaning and lubrication are done on a regular basis, no other routine maintenance should be required on these devices. A detailed inspection instruction pamphlet and a DVD are available from your Geister Sales Representative.

⚠️ CAUTION
Geister does not define the maximum number of uses appropriate for re-usable medical devices. The useful life of these devices is dependent on many factors including the method and duration of each use, and the handling between uses. Careful inspection and functional testing of the device before use is the best method of determining the end of serviceable life for the medical device.

LIMITED PRODUCT WARRANTY
All Geister Universal Round Bar Table Mounted Retractor System Components are warranted to the original purchaser to be free from defects in material and workmanship for a period of one (1) year from the date of purchase. If this product proves to be defective, purchaser should obtain a Returned Goods Authorization from Geister and return it to the address above. Geister will repair or replace defective products at our option. Geister’s liability under this limited warranty does not extend to abuse or misuse of the product.

FOR SERVICE OR REPAIR
For any necessary service or repair, please contact your Geister Distributor or Geister Customer Service at the address shown above.