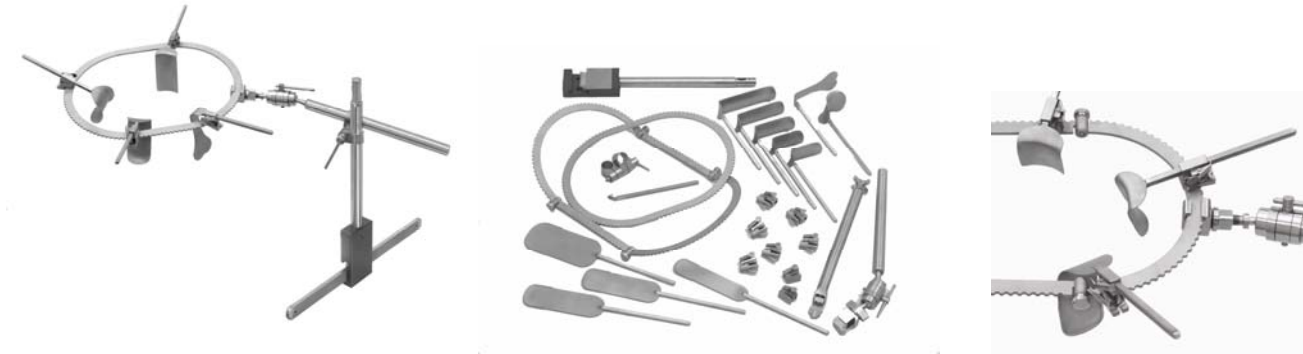


IMPORTANT PRODUCT INFORMATION - PLEASE REVIEW BEFORE USING

MEDIFLEX Bookler[™] Universal Table Mounted Retractor Systems and Devices

PRODUCT DESCRIPTION

The Bookler Universal Table Mounted Retractor System consists of a variety of Table Posts, Horizontal Bars, Couplers, Rings, Ratchets and Retractor Blades used in concert to provide retraction of tissue and organs during open surgery.



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 Mediflex for repair or replacement.

CLEANING

These devices should be cleaned and sterilized upon receipt. After use, they should be cleaned according to hospital protocol for reusable surgical instruments. 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 such as Ratchets, Tilt Ratchets, Horizontal Bars and Field Posts are **not** designed to be disassembled. Do not attempt to disassemble. Segmented rings will disassemble at the point of the Thumb Screws. The Thumb Screws themselves are **not** designed to be taken off the ring segments. Do not remove.
- Washer-sterilizers should be used according to the washer-sterilizer's manufacturer's recommendations
- Ultrasonic and/or mechanical (hand) cleaning is recommended. Hand cleaning should use a mild surgical instrument detergent and brushes. Do not use metal-bristled brushes as they can damage the instrument. Ultrasonic cleaning should be done according to the procedures provided by the ultrasonic cleaner's manufacturer
- Always rinse in distilled water and re-inspect for loose or missing parts, cracks and broken components. Also inspect for visible soil or debris. If present, repeat the cleaning process.
- 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

These products may be sterilized according to hospital protocol for reusable surgical instruments. Steam Autoclaving (Including gravity, pre-vac and flash), Ethylene Oxide, Peracetic Acid (Steris[®]) and Hydrogen Peroxide Gas Plasma (Sterrad[®]) systems may all be used. Always follow the manufacturer's recommendations for surgical instruments in the use of any sterilizer.

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.
- Open the coupler. Place the coupler on the Horizontal Bar. Slide the open 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.
- Roughly position the Horizontal bar so that the jaws are about where they must be to hold the ring in the appropriate position. It may be necessary to loosen the coupler and/or the double ball and socket joint to position the jaws. Be sure to position the jaws so that the open side faces up and make sure the jaws are open (If not; use the thumb screw to open all the way)
- Select the appropriate ring size, shape and configuration based on the procedure, size of patient, location of incision and surgeon preference. Position the ring over the anticipated surgical site and reposition the open jaw of the Horizontal bar under the ring at about the 11 o'clock or 1 o'clock (depending on which side the post is on) position. Again, it may be necessary to loosen the coupler and/or the double ball and socket joint to position correctly. Retighten both components. Close the jaws of the Horizontal Bar onto the ring by turning the thumb tab until it is tight. Test to be sure the ring is seated securely. Lower the entire Horizontal Bar/Ring Assembly until the ring sits parallel to and about 1-2" above the drapes.
- Preload retractor blades into the ratchets. The procedure and surgeon's preference determine which blades are used. Non-tilt or tilt ratchets will work while retraction is shallow. As the incision progresses, deeper blades will be used, usually with tilt ratchets. When loading the blade into the ratchet, be sure the teeth of the blade handle are positioned to engage the ratchet.
- Place the loaded ratchet onto the ring in the appropriate position. The notch on the ratchet slides onto the ring from the side away from the incision. The loaded ratchets will stay in place once the blade engages tissue (and tension). Place wet lap towels between the blade and tissue as hospital procedure or surgeon preference dictates. Lower the blade into the incision and, while holding the ratchet in place, pull the blade towards the ratchet until desired exposure is achieved. Add additional or deeper blades as the incision progresses. Use the system to create the best exposure to the operative site possible.
- Protected-edge, Malleable Blades can be shaped as needed
- Intraoperatively, the Blades can be moved by tilting or untilting the tilt ratchet (Tilt by simply angling down, untilt by releasing the tilt ratchet release, which is the lower, thinner tab on the right side of the ratchet.) Side to side movement can be achieved by sliding the ratchet along the ring. If too tight to slide, release tension on the blade by pressing the larger, upper tab on the right side of the ratchet.
- 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.

LIMITED PRODUCT WARRANTY

All Mediflex Bookler Universal 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 Mediflex and return it to the address below. Mediflex will repair or replace defective product at our option. Mediflex'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 Mediflex Distributor or Mediflex Customer Service at the address shown below.

MEDIFLEX Surgical Products

To find your authorised Distributor please visit:

www.mediflexeurope.com

To contact us, please send an email to:

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