

IMPORTANT PRODUCT INFORMATION - PLEASE REVIEW BEFORE USING

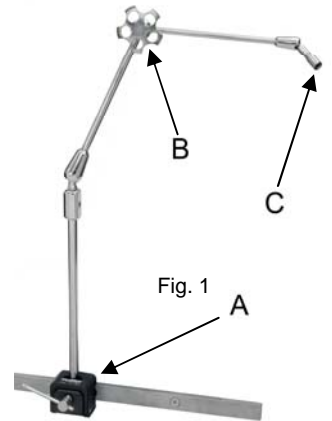
MEDIFLEX StrongArm™ Surgical Holders and Positioners

Single Arm Models 73000, 73000-ST, 73000-DT, 73000-QG10, 73000-QG5 and 73000-RBA

PRODUCT DESCRIPTION

StrongArm Surgical Holders and Positioners are designed to hold, stabilize and easily reposition various surgical instruments during both open and minimally invasive surgery. They are identical except for the distal tip design, which further defines specific function. Figure 1 shows the device as it might appear attached to an OR Table Rail.

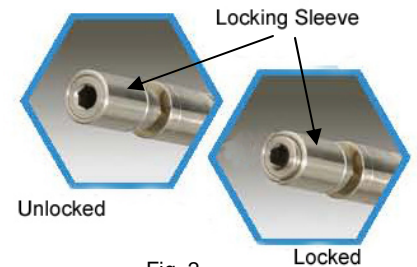
- “A” is the O.R. Table Rail Clamp with tightening lever.
- “B” is the Ergonomic Tightening Knob
- “C” is the Quick Disconnect feature found on all versions of the 73000 series. Any Mediflex Device featuring a Hex fitting can be attached to this device.
- The 73000 is supplied with just the Quick Disconnect feature “C”. The other models come with one of 5 removable instrument or scope holders as shown below



The Stainless Steel tip can be used to hold the shaft of laparoscopic or open instruments with a diameter ranging from 3 to 12mm. The Delrin Tip holds laparoscopes ranging from 3 to 12mm in diameter. The Quick Grip Tips hold endoscopes of the indicated diameter. The Ratchet tip holds Bookler™ Brand Retractor Blades for open procedures.

INSPECTION

Inspect upon receipt, during the cleaning process and immediately before use. Test to see that the tightening lever on the Rail Clamp, the Ergonomic Tightening Knob and the Quick Disconnect Locking Sleeve (Fig. 2) all move freely. Visually inspect for loose or missing parts, cracks and broken components. If one of the above tips is included, check to see if it opens and closes easily. 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.
- Other than removing the post from the Rail Clamp and the tip from the Quick Disconnect fitting, StrongArm Holders and Positioners are **not** designed to be disassembled. Do **not** attempt to disassemble them.
- 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.

STERILISATION

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 Rail Clamp should be placed on the OR Table rail with the Mediflex name facing upward. Generally the device is placed on the side of the table opposite the primary surgeon and in such a position that will allow the arms to reach the intended instrument position. Both jaws of the clamp should be loose enough to easily slide both over and under the rail. (Loosen by turning the tightening lever counterclockwise.

The Vertical Post of the StrongArm Device (easily identified by its one flat surface) is inserted through the opening of the Rail Clamp with the flat portion facing away from the patient. When the desired position (along the rail and height) is reached, turn the Rail Clamp Tightening lever clockwise as far as possible.

Attach the desired tip into the Quick Disconnect Fitting:

- Be sure that the Locking Sleeve (Fig. 2) is in the unlocked position.
- Insert the device's Hex end into the opening. A slight rotation may be necessary to align the fit.
- When completely inserted, slide the locking sleeve into the locked position (Fig. 2).
- Always check to assure that the tip is locked in place by pulling on the tip. If the tip comes out of the fitting, slide the locking sleeve back to the unlocked position and repeat the steps above.

When the chosen tip is securely installed on the arm, move the arm so that the Tip is approximately where the device will be used and the arm segments are as out-of-the-way as possible. Tighten the Ergonomic Tightening Knob by turning it clockwise. During the procedure, if the tip needs to be adjusted, turn the Ergonomic Tightening Knob counter clockwise until the arm can be moved; adjust the tip position and re-tighten the Ergonomic Tightening Knob.

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

Mediflex StrongArm Surgical Holders and Positioners 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 info@mediflexeurope.com or phone us at +44 1494 712333