IMPORTANT PRODUCT INFORMATION

PLEASE REVIEW BEFORE USING

NATHANSON FLEX ARM LIVER RETRACTION SYSTEM
69-7010

PRODUCT DESCRIPTION

Nathanson-Flex Arm Liver Retraction Systems are designed to hold, stabilize and easily reposition various surgical instruments during both open and minimally invasive surgery. They are supplied with supplemental devices (listed below) which further define specific functions. Figure 1 shows the device as it might appear attached to an OR Table Rail.

- "A" is the thumb knob for tightening the clamp to the rail.
- "B" is the O.R. Table Rail Clamp.
- "C" is the Vertical post, measuring 10" from the top of the Table Rail to the beginning of the flexible component.
- "D" is the tightening lever that is turned to tighten the flexible component "E". The tightening lever has an arrow etched into it to show the direction for tightening.
- The distal Tip "F" features a Quick Disconnect Hex Fitting that will accommodate any of the 5 supplemental products shipped with this arm::
  - Three sizes of Nathanson Hooks
  - One Stainless Steel Tip
  - One Delrin Tip

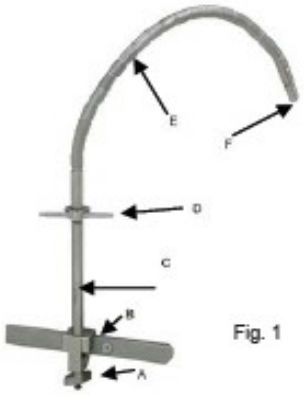

Fig. 1

Nathanson Hooks

Stainless Steel Tip

Delrin Tip

Fig. 2

INSPECTION Inspect upon receipt, during the cleaning process and immediately before use. Check that the Thumb Knob and Tightening Lever move freely and tighten the Table Rail Clamp and flexible component respectively. Slide the locking mechanism on the Quick Disconnect Tip back and forth to check its function. Check that the turning knobs on the Stainless Steel and Delrin Tips close the movable jaws when rotated. 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 Ackermann 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.
- Except for removing hooks or tips from the quick disconnect tip; Flex Arm Holders and Positioners are **not** designed to be disassembled. Do **not** attempt to disassemble them.
- However, all Flex Arm Holders and Positioners should be loosened prior to cleaning and sterilization to allow cleaner and sterilant to penetrate inside the arm. This is done by:
  - Turning the tightening lever as far as possible in the direction **opposite** the etched arrow.
  - Hold the entire arm vertically by the tip of the instrument
  - Turn the Vertical Post in the direction **opposite** the etched arrow.
  - As you turn, the flexible component will "open" slightly and you should be able to see the cable that's in the center.
  - Once 1/4" of the cable is visible, stop turning
- 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. Minimum parameters for Pre-Vac Cycles are 8 minutes at 134°C (270° F) Other methods Including gravity, flash, Ethylene Oxide, Peracetic Acid (Steris®) and Hydrogen Peroxide Gas Plasma (Sterrad®) systems may be used. Always follow the manufacturer's recommendations for surgical instruments in the use of any sterilizer.

SET-UP AND USE

Preparing the arm for use:

1. Hold the Arm vertically by the tip. Look at the junction of the vertical post and the tightening lever.
    a. If there is no gap skip to step 2
    b. If there is any gap below the tightening lever, turn the tightening lever in the direction **opposite** the arrow etched on the turning lever until the gap disappears
2. Check to see if the arm was loosened correctly for cleaning by holding it vertically by the distal end. With the other hand, grasp one of the knuckles near the tightening lever. Attempt to move the knuckles up and down. If there is no movement, skip to step 3. If there is up and down movement of the knuckles, the instrument must be retightened prior to use.
    a. Still holding the arm up right, turn the entire Vertical Post (C in Fig. 1) in the direction of the arrow etched on the tightening lever. Continue to turn until there is slight resistance.
3. Position the arm on the O.R. Table Rail. (Note: The device **may** be placed on the rail over drapes. Do **not** place over blankets or other thick coverings.)
    a. Open the Rail clamp by turning the Thumb Knob to the right until the Rail Clamp is open to its maximum position.
    b. If the surgeon's preference card does not specify the mounted location of this arm, consult with the surgeon regarding placement, prior to attaching it to the Table Rail.
    c. A scrubbed member of the O.R. team should hold the arm vertically while a circulator grasps the Rail Clamp portion of the arm and positions it on the rail at the selected location. (Note: Once the lower portion of the arm is lower than the upper plane (surface) of the table, the lower portion has left the sterile field and should no longer be considered sterile. **No** scrubbed person should touch any portion of the arm assembly that extends below the top of the table
    d. Once both upper and lower jaws are in position, the circulator should tighten the Thumb Knob by turning it to the left. Continue to tighten until the arm is very secure to the rail. A correctly mounted arm will display absolutely no movement at the point it is attached to the rail. If movement is detected, check to see if the Rail Clamp is correctly positioned; open the jaws, re position the rail clamp and tighten it again.
4. Attaching a Hook or Tip to the Quick Disconnect Sleeve.
    a. If one of the Nathanson Hooks will be used, under direct visualization with the laparoscope, create a Percutaneous Puncture in the midline, just below the Xiphoid Process. The puncture should be of a smaller diameter than the Hook to be used to minimize loss of pneumoperitoneum. The hook can then be threaded through the puncture and into the abdominal cavity. It should then be carefully placed under the liver and lifted to create the exposure required.
    b. Insert the hexagonal fitting of the hook or tip into the Quick Disconnect feature of the Flex Arm Device. The Locking Sleeve of the Quick Disconnect Fitting must be in the **unlocked** position as shown on the left side of Fig. 3.
    c. Slight rotation of the tip may be necessary to line up the fittings.
    d. Once inserted as far as possible, pull back on the Locking sleeve as shown in the right hand part of Fig. 3.
    e. Always check to assure that the tip or hook is locked in place by gently pulling on the device. If it comes out of the fitting, slide the locking sleeve back to the unlocked position and repeat the steps above.

Fig. 3

5. Tightening the arm
    a. Once the arm is positioned where desired, turn the tightening lever in the direction of the arrow etched onto the tightening lever. Tighten as much as desired. It is virtually impossible to over tighten the device by hand.
    b. Some movement of the arm, even when tight, is by design. This allows slight repositioning without having to loosen the device.

ROUTINE MAINTENANCE

We recommend an annual inspection and refurbishment to maintain your Flex Arm Device like new. This can only be done at a Ackermann Facility. Contact your distributor or Ackermann for further information.

LIMITED PRODUCT WARRANTY

All Flex Arm 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 Ackermann and return it to the address below. Ackermann will repair or replace defective product at our option. Ackermann'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 Ackermann Distributor or Ackermann Customer Service at the address shown below.

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