

Laparoscopic Suturing Knot Pushers

Directions for Use

M4500P - Clarke-Reich Micro 6-0 and smaller sutures, 29cm working length, 5mm OD

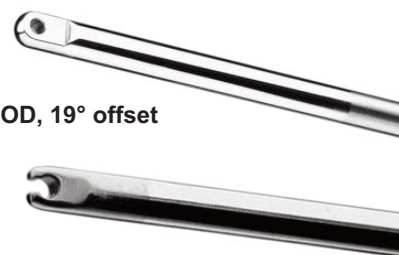
M4501P - Clarke-Reich Macro 5-0 and larger sutures, 29cm working length, 5mm OD

M4502P - Reddick-Saye Macro (Angled) 5-0 and larger sutures, 29cm working length, 5mm OD, 19° offset

M4503P - Closed Macro 5-0 and larger sutures, 29cm working length, 5mm OD

M4601P - Clarke-Reich Macro 5-0 and larger sutures, 45cm working length, 5mm OD

M4603P - Closed Macro 5-0 and larger sutures, 45cm working length, 5mm OD



DEVICE DESCRIPTION

A surgical knot pusher is a device for assisting with the placement and cutting of suture knots which have been tied extracorporeally during a laparoscopic procedure.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

WARNING & PRECAUTION

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to the performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.

INDICATIONS FOR USE

- These devices have application for extracorporeal knot tying in minimally invasive (laparoscopic) procedures.

CONTRAINDICATIONS

- These devices are not intended for use when minimally invasive (laparoscopic) techniques are contraindicated.

DIRECTIONS FOR USE

- Both ends of the cut suture are pulled out of the peritoneal cavity through the trocar
- Holding both ends, make a simple half-hitch and slid the knot pusher over the knot
- While maintaining tension with the index finger, the knot is pushed through the trocar to the level of tissue being secured.
- Repeat as indicated by type of suture material and application.

Note: If a closed loop design is utilized, pass through one limb of the suture material to affect displacement of the knot.

CARE, CLEANING, STORAGE AND STERILIZATION

These instruments are made of high grade quality stainless steel and are long-lasting. They should be immediately cleaned of blood, secretions and debris after use and be sterilized.

- Handle each instrument individually. Do not handle in groups or stacks.
- Replacement instruments should be kept on hand.
- Inspect instruments for integrity, signs of damage (broken or cracked) or missing hardware (screws).

CLEANING

Rinsing and cleaning must take place immediately following the instrument's use for decontamination. Adherent particles may resist cleaning and cause improper sterilization.

Instruments are to be completely cleaned of all foreign matter with special attention focused on channels and movable parts in contact with body and fluid. Thorough cleaning is essential prior to sterilization.

- Follow the instructions under "CARE" for proper handling of the instruments
- Wear protective gloves during the cleaning procedure
- **Never** use a corrosive cleaning agent (for example, bleach)
- Fully immerse instruments in cleaning agent

Cleaning Agents and Equipment

- Cleaning agents and rinses at or near a neutral pH (7.0) is recommended
- Use warm water and a mild soap
- Do not use an abrasive cleaning solution
- A soft bristle brush (toothbrush type) should be used
- Round bristle brushes should be used to clean inside channels near the tips
- An enzymatic cleaner is recommended to remove protein deposits on the instrument. Follow manufacturer's instructions and rinse thoroughly.

Note: Soak and thoroughly rinse the instruments in warm tap water to remove cleaning agents. A final rinse in distilled water is recommended.

Do not allow water to air dry on the instrument otherwise corrosion may occur.

Suturing Knot Pushers - Directions for Use (continued)

Cleaning Procedure (after each use)

1. Rinse and/or pre-soak
2. Manually clean with brushes using a mild soap and warm water
3. Using a round bristle brush, clean inside the tip channel as follows: use warm water, then a cleaning agent, and then warm water again
4. Rinse
5. Enzymatic cleaner
6. Rinse
7. Dry with cloth or gauze and filtered compressed air
8. Inspect
9. Prepare for storage and/or sterilization

Note: Dry instruments completely with compressed air (including inside channels) and/or a dry oven (maximum temperature 280 °F).

Sterilization with an Approved Liquid Chemical Sterilant

Instruments must be cleaned thoroughly following the steps in "Cleaning Agents and Equipment" and "Cleaning Procedure" prior to cold sterilization. Cold soak solutions with 2% glutaraldehyde solution can be used for sterilizing the instruments. Instruments are to be fully immersed.

Follow the manufacturer's instructions for sterilization times. Soak and rinse thoroughly in two separate sterile, deionized water baths. Dry the instruments.

STORAGE

Instruments should be stored dry in a moisture-free area. Instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect from damage if stored in drawers. Instruments should be stored with their jaws in the locked/closed position.

STERILIZATION

Recommended Steam Autoclave Sterilization Parameters

- The instrument should be thoroughly cleaned of all foreign matter prior to sterilization
- Follow the manufacturer's instructions for loading and operating the steam autoclave
- There must be direct steam exposure to all surfaces of the instrument being sterilized
- Autoclave temperatures should not exceed 280 °F; pressure should not exceed 32 psi
- Standard cycle of 270 °F for 10 minutes will vary depending on autoclave model, autoclave size, load size and load configuration

Allow longer times for lower temperatures. Allow instruments to cool down from autoclave to room temperature. Do not immerse in any fluid until the instrument has been allowed to cool.

Gravity Displacement Cycles

270 °F - 275°F / 10 -15 minutes or
250 °F / 15-30 minutes

Pre-Vacuum Cycles

270 °F - 275 °F / 3 -4 minutes

Recommended Hospital Ethylene Oxide Sterilization Parameters

- Items should be thoroughly cleaned of all foreign matter prior to sterilization, following the steps in "Cleaning Agents and "Cleaning Procedure"
- Follow the manufacturer's instructions for loading and operating the sterilizer. There must be direct exposure to all surfaces of the instruments being sterilized.
- Instruments should be sterilized in their "open" position
- Contact of plastic to bare metal should be avoided

The following are hospital Ethylene Oxide cycle settings:

Temperature	125°F - 130 °F
50% RH (pre-humidity)	60 minutes, -0/+10 minutes
Pre-Vacuum	24" Hg ± 2" Hg
Gas Pressure	6-8 psig
Exposure Time	4 hours minimum
Post-Vacuum	24" Hg 2X ± 2" Hg
Aeration	12 -0/+1 hours at 120 °F

Note: The particular EO cycle should be validated per the equipment manufacturer's requirements. It is recommended that each institution employ procedures which include the use of biological indicators in order to determine the effectiveness of the Ethylene Oxide process.

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EXPLANATION OF SYMBOLS

 Reorder Number



ATTENTION: See instructions for use.

CooperSurgical

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