



**MILLENNIUM
SURGICAL**

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UNMATCHED SERVICE · UNLIMITED INSTRUMENTS

822 Montgomery Ave #205
Narberth, PA 19072
(800) 600-0428

Silastic Ring Applicator Maintenance Instructions

IFU-2014.07.21

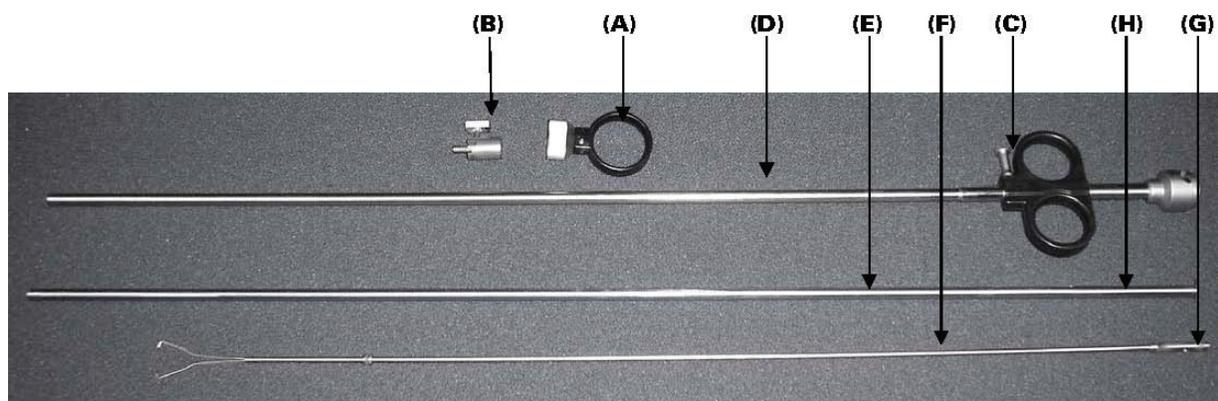


CLEANING AND CARE

Every instrument must be cleaned and sterilized before being used for the first time and after every subsequent use. Appropriate cleaning, inspection and maintenance help to ensure the serviceability of surgical instruments.

Clean, inspect and test all instruments thoroughly, and sterilize before use. Effective cleaning and maintenance will prolong their service life.

Cleaning and rinsing should be done promptly after every use, with the instrument disassembled, otherwise tissue particles or dried secretions may adhere to it, which may make subsequent cleaning and sterilization difficult, if not impossible. Instruments must be entirely free of any foreign bodies.



DISASSEMBLY

Unscrew (A) Handle on assembly from outer shaft (D) Remove (B) Selector Handle from the rear housing of Outer Shaft (D) Lift up Spring Loaded Set Pin on Ring Handle, release inner shaft (E) and slide out inner shaft (E) toward the rear of outer shaft (D) Push inner tong (F) (assist with blunt probe if necessary) out the front of inner shaft (E)

REASSEMBLY

Reverse steps of disassembly instructions. Important – When reinserting inner Tong into inner sheet – Hole (G) on rear of inner tong shaft with slot (cut out) (G) on inner shaft (Lock Pin – (C) fits into slot (G))

HANDLING, STORAGE AND STERILIZATION

All surgical instruments should be treated with the utmost care when being carried, cleaned, serviced, sterilized or stored. This applies particularly to cutting edges, fine tips and other delicate parts.



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CLEANING

Once the instrument is in 5 pieces: Rear Handle, Selector Handle, inner tong assembly (tip), Inner shaft and outer shaft, rinse it with demonized water to remove any debris. Hand-wash all parts using neutral pH detergent or enzymatic cleaner and a soft brush, being sure to flush all lumens and channels with the solution. Thoroughly clean inside of the outer shaft using a soft brush and flushing solution through it. Avoid the use of steel wool, wire brushes, and/or abrasive detergents.

Clean the entire surface of the instrument, paying special attention to the jaw and hinged area to be sure all blood and debris are removed.

Thoroughly rinse the instrument with deionized water after cleaning to remove any residual debris or cleaning solution. Immediately after the instrument has been cleaned and rinsed, it must be carefully dried. Tubes must be blown out.

After cleaning, inspect all components for broken or worn parts that may inhibit the function. Specifically, check for nicks, cracks or exposed metal on the shaft and handle insulation. Careful and frequent inspections during use for functional integrity are recommended as a safeguard against possible injury to patient or operator.

Note: After cleaning and before sterilization, all instruments must be treated with physiologically harmless oil (liquid paraffin complying with DAB 8, Ph. Eur. or USP). This applies particularly to cutting edges, closing faces, ratchets, locking catches and all moving parts.

STERILIZATION

The instrument can be sterilized fully assembled or disassembled (to be reassembled later in a sterile field in the operating room prior to use). The instrument can be sterilized using steam autoclave, heat sterilization or gas sterilization.

RECOMMENDED AUTOCLAVING METHODS:

1. ETO Sterilization

Instrument can be sterilized by ethylene oxide in any standard cycle. Pressure reading should not exceed 12 PSI. Temperature should not exceed 68.3°C (155°F). It is recommended to follow the manufacturer's instructions for the ETO sterilization unit concerning humidity, vacuum, cycle time, gas concentration and temperature.

2. Steam Autoclaving

When using wrap method, make certain that all instruments are individually wrapped or sealed in a sterile pack. Metal objects should never come in contact with the insulating material of forceps and handles, or with RF-connection cables. Such points of contact will cause severe melting. We recommend the following values/parameters, but also suggest following the manufacturer's instructions for steam sterilization:

Cycle	Sterilizing Temperature	Sterilizing Time	Drying Time
Prevacuum	270°F (132°C)	5 minutes	20 minutes
Gravity	250°F (121°C)	30 minutes	15 minutes



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INSPECTION AND FUNCTION TESTING

It is essential for every surgical instrument to be inspected for fractures, cracks or malfunctions before use. In particular, areas such as insulation, cutting edges, tips, ratchets and locking catches and all moving parts must be carefully inspected.

Never use damaged instruments or attempt to repair them yourself. Service and repairs should only be carried out by suitably trained and qualified technicians.

Like the electrosurgical generators, all accessories must undergo technical inspections at regular intervals.

WARRANTY supplies only fully tested, fault-free products. They are designed and made to the highest quality standards. No liability is accepted for products that have been modified in any way, used for a purpose other than specified or treated or used in an important manner.

SILASTIC RING APPLICATOR: RING RELOADING INSTRUCTIONS



Guide cone

Applier



Step 1: Take the ring applicator and introduce the guide cone into the applicator, make sure it is completely flushed and slide the silastic ring on the guide cone.



Step 2: Slide the ring applicator with the guide cone and the silastic ring into the applier.



Step 3: Push the ring applicator slow and steadily till the silastic ring appears to move towards the tip.



Step 4 & 5: Slowly pull the applier off the guide cone, until it touches the Outer Shaft.



Warning: If this device is/was used in a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!