

822 Montgomery Ave #205 Narberth, PA 19072

(800) 600-0428

Instructions for Use Modular 3-Piece Lap Instruments

IFU-2015.01.20

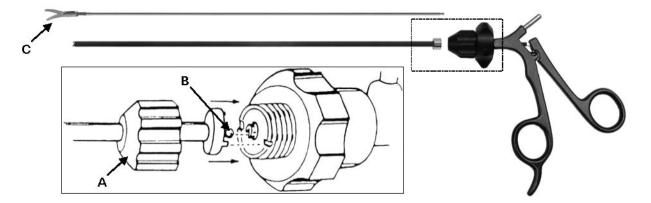
CLEANING AND CARE: Every instrument must be cleaned and sterilized before being used for the first time and after every subsequent use. Appropriate cleaning, inspection and maintenance help to ensure the serviceability of surgical instruments.

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

1) Turn the main screw cap (A) counterclockwise until it disengages from the handle.

- 2) Set the handle in the open position and release the ball (B) of inner rod out of its fixation in the handle port.
- 3) Turn the tip (C) counterclockwise out of the tube.

To reassemble, reverse the disassembly instructions.



HANDLING, STORAGE AND STERILIZATION: Extreme care must be exercised while using, transporting, cleaning, sterilizing, and storing. Damage to the function and safety of the instrument may occur if the instrument is handled roughly or improperly, or used for something other than its intended purpose.

CLEANING: The instrument is in three pieces: Handle, Insert and Outside Shaft. Rinse with deionized 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 solution. Thoroughly clean the inside of the outside shaft using a soft brush and flushing solution through it. Avoid the use of steel wool, wire brushes, and/or abrasive detergents. Clean entire surface of Insert, paying special attention to the tip area to be sure all blood and debris is removed. Thoroughly rinse instrument with deionized water after cleaning to remove any residual debris or cleaning solution.

Monopolar instruments are only to be activated at the respective area where they are to be used. Larger vertical movements within the trocar sleeve should not be made in an activated condition. Before each usage, insulated instruments should be checked once again for eventual damage to the insulation and if such is found, they should be replaced. The HF-cables used must fit perfectly onto the connector. The connector cable must be removed when cleaning and disinfecting the instrument.

IMPORTANT: Before each usage the instruments must be checked if they are correctly & functionally assembled.



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The instruments can be sterilized fully assembled (recommended) or it can be sterilized disassembled and reassembled in a sterile field in the operating room.

1. Steam Autoclaving: When using the wrap method, be certain that all complete instruments and all parts 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 sterilization unit instructions for steam sterilization:

	Sterilizing Temperature	Sterilizing Time	Drying Time* ³
Prevacuum	270°F (132°C)	5 minutes	30 minutes
Gravity/Wrapped	250°F (121°C)	30 minutes	45 minutes
Gravity/Wrapped	270°F (132°C)	15 minutes	45 minutes

2. ETO Sterilization: Instruments 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.

3. Sterrad Sterilization Process: Sterrad Sterilization is a multiple sterilization process that uses a combination of exposure to hydrogen peroxide vapor and plasma to affect sterilization. The Sterrad NX sterilizer can sterilize instruments which have diffusion restricted spaces, such as hinged portions of forceps and scissors. Adhere to the sterilization instructions provided by the manufacturer. (Advanced Sterilization Products a Johnson & Johnson company.)

4. Flash Autoclaving (fast heating/cooling cycle): Flash autoclaving will reduce the useful life of the instrument, particularly when it is constructed of various materials, encompassing different expansion rates.

Caution: Continued use of this process will cause premature failure of instruments, especially the insulation.

6. Chemiclaving – Soaking: Not Recommended – This is destructive to the insulating and silicone materials of electrosurgical accessories and can cause rapid deterioration and failure.

IMPORTANT: Adhere to proper drying cycle to make sure that instruments are completely dry on the inside (same applies for Cables). Moisture will prevent proper electrosurgical conductivity.

WARRANTY: These instruments are warranted against defects in material & workmanship for 1 year. Routine resharpening, reinsulating, and adjustments as well as repair of damaged instruments is available for a modest charge. Any servicing of these instruments performed by any source other than the manufacturer voids this warranty. The manufacturer and seller of the product, accept no liability for indirect damage or subsequent damages that result by improper usage, improper handling or through improper preparation, sterilization or maintenance. Instruments are only to be used as designated in their specialized medical fields by the respective trained and qualified personnel. They are not intended to be used on the central circulatory or central nervous system.

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!