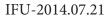
# Cholangiogram Forceps Instructions for Use



#### IMPORTANT:

These instruments are for minimal invasive surgery. They are non-sterile, reusable. The manufacturer and seller of the product accept no liability for indirect damage or preparation, sterilization or maintenance.

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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.

#### MAINTENANCE 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 and prolong service life.

Clean, inspect and test all instruments thoroughly, and sterilize before use.

Cleaning and rinsing should be done promptly after every use. 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.

#### 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:

Rinse with deionized water to remove any debris. Hand-wash the complete outside, handle and shaft using pH detergent or enzymatic cleaner and a soft brush, being sure to flush all lumens with the solution. Thoroughly clean outside shaft using a soft brush and flushing solution. Avoid the use of steel wool, wire brushes, and/or abrasive detergents.

Since the Cholangiogram Forceps have no flushport we suggest cleaning the instrument shaft from its distal end. Slide a piece of silicone tubing\*4 over the jaw assembly and make sure the hinge part is covered – about 2" from the distal end. Use a syringe and flush with deionized water to soften any debri or use the ELMED Water Jet Cleaning Gun\*3. After flushing inject air to blow out any debri and dry. The ELMED Water Jet Cleaning Gun uses either water or pressurized air this means the cleaning process

is quick, efficient and inexpensive. The Selectra Spray Gun features a new type of internal flow control mechanism. It permits the smooth and simple adjustment of the water or air flow across the entire range of the trigger movement. Rinsing, suction or drying in every area of application is made possible through the set of 8 attachments.

\*<sup>3</sup> Recommended ELMED Water Jet Cleaning Kit, List No. 52003- & 52003-81
\*<sup>4</sup> Recommended ELMED Cleaning Tube with Luer Fitting List No. 52-5473

### IMPORTANT: BEFORE EACH USAGE THE INSTRUMENTS MUST BE CHECKED IF THEY ARE CORRECTLY & FUNCTIONALLY ASSEMBLED.

STERILIZATION: The instrument is to be sterilized fully assembled.

IMPORTANT: The flushport or rinsing channel cap MUST BE REMOVED when the instrument is being sterilized to keep the inner instrument cavity open at both ends.



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### IFU-2014.07.21

1. Steam Autoclaving: When using the wrap method, make 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:

Cycle Sterilizing Temperature Sterilizing Time Drying Time\*\*

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Prevacuum/Wrapped	270°F	(132°C)			4 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 including Sterrad NX: The sterilization process is a multible sterilization process that utilizes 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.

5. 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: This instrument is 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 this instrument performed by any source other than the manufacturer voids the 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!