Clear Flush® Laparoscopic Instruments

Validated Instructions For Use

Cleaning, & Sterilization

The Instructions For Use (IFUs) For Elmed's Patented Clear Flush® Reusable Laparoscopic Instruments Have Been Validated By Independent Laboratory Testing To Provide Clean, Sterile, Moisture-Free Instruments On Every Reprocessing Cycle. The Validation Testing Was Done **By Nelson Laboratories** Using **AAMI** And **FDA** 'Worst Case' IFU Validation Testing Protocols. Copies Of The **Nelson Laboratories** Cleaning and Sterilization Validation Reports Are Available at http://www.elmed.com/

When Reprocessing Clear Flush® Reusable Laparoscopic Instruments, We Recommend That You Use The Following Validated Practices And Procedures In Conjunction With Your Institution's Published Guidelines And Policies. During Cleaning, Wear Appropriate Eye And Face Protection, As Well As Gloves And Other Protective Clothing, To Protect Against Exposure To Bloodborne Pathogens, As Recommended By **OSHA** In Its Blood Borne Pathogens Standard.

CLEANING RECOMMENDATIONS

For Best Results, And To Prolong The Life Of The Instrument, Reprocess Immediately After Use. **The Association of Surgical Technologists (AST)** Publication "*Standards of Practice for the Decontamination of Surgical Instruments*" States That "The Cleaning Of Instruments Should Begin During The Surgical Procedure To Prevent Drying Of Blood, Soil And Debris On The Surface And Within Lumens." **The Joint Commission (TJC)** States That "Pre-Cleaning At The Point-Of-Use Requires That Visible Bioburden Is Removed From The Instruments Prior To Transport To A Decontamination Area Where Pre-Cleaning Or Preparation For Transport To A Reprocessing Area Occurs." Pre-Cleaning Of The Instruments At Point-Of Use Is Also Covered In Sections 6.3 Thru 6.4 in **AAMI ST79** (2017).

1. **Immediately after use**. Place She Soiled Instrument In An Instrument Tray/Container That Contains Sterile Distilled Water Or A Hospital Approved Enzymatic Cleaning Solution. Open The Jaws Of The Instrument To Moisten The Soil And Prevent Blood, Mucus, And Other Debris From Drying On The Instrument. Open The Black Rubber Seal That Covers The Flush Port Luer On The Instrument Shaft. Fill A 50cc (Or Larger) Luer Lock Syringe With Sterile Distilled Water Or The Enzymatic Cleaning Solution And Attach It To The Luer On The Instrument Shaft. Irrigate The Instrument's Shaft With The Jaws Open To Remove Gross Soil And Debris From Inside The Shaft. Place The Instrument Back Into The Solution With The Black Rubber Luer Seal And Jaws In The Open Position. Cover The Tray/Container With A Towel Moistened With Sterile Distilled Water Or The Enzymatic Cleaning Solution.
2. **Enzymatic detergent soak and manual cleaning**. Soak The Instrument In A Hospital Approved Enzymatic Detergent Solution Before Cleaning. Make Sure That The Solution Is At The Correct Temperature And Proper Concentration As Per The Enzymatic Manufacturer's Recommendations And Instructions For Use. Completely Immerse The Instrument, With The Jaws Open, Into The Solution For The Amount Of Time Recommended On The Detergent's Label. Open The Black Rubber Seal That Covers The Flush Fort Luer On The Instrument Shaft. Fill A 50cc (Or Larger) Luer Lock Syringe With The Detergent Solution And Attach It To The Luer On The Instrument Shaft. Flush The Instrument's Shaft With The Luer Lock Syringe With The Jaws Open To Remove Gross Soil And Debris From Inside The Shaft. Flush The Instrument Three (3) Times Or Until The Enzymatic Detergent Is Free Of Gross Soil And Debris When It Exits The Distal Tip Of The Instrument. Clean Each Of The Instrument's Components (Jaws, Hinges, Handles And Shaft) With A Clean, Appropriately Sized Soft-Bristle Brush To Remove All Organic Debris. Pay Particular Attention To The Hinges, Crevices And Other Hard To Clean Areas. Do NOT Remove Any Screws And Do NOT Attempt To Disassemble The Instrument.
3. **Rinse**. Rinse All Of The Instrument's Components Thoroughly With Lukewarm Tap Water To Remove Dislodged Debris And The Detergent Solution. Fill A 50cc (Or Larger) Luer Lock Syringe With Lukewarm Tap Water And Attach It To The Luer On The Instrument Shaft (Do NOT Use The Same Luer Lock Syringe That Was Used To Flush The Instruments With The Enzymatic Detergent). Irrigate The Instrument's Shaft With The Luer Lock Syringe With The Jaws Open To Remove Dislodged Gross Soil And Debris From Inside The Shaft. Wipe The Instrument With A Clean, Soft Cloth.

4. **Ultrasonic cleaning**. The cavitation action of ultrasonic cleaners can remove particles of debris from areas of the instrument inaccessible to a brush and is recommended as part of the reprocessing procedure. With the black rubber luer seal and jaws in the open position, place the instrument in a mesh bottom instrument basket. Place the basket in the ultrasonic cleaner to which you have added a detergent solution formulated for use by the manufacturer of the ultrasonic cleaner. Follow recommendations of the ultrasonic cleaner manufacturer as to cycle times, cleaning solutions, suspension of the basket (e.g. the basket should not sit on the bottom of the ultrasonic cleaner), conditioning of the water, etc.
5. **Rinse**. Rinse all of the instrument's components thoroughly with warm tap water to remove any remaining debris or ultrasonic detergent residue that could interfere with the sterilization process. Fill a 50cc (or larger) luer lock syringe with warm tap water and attach it to the luer on the instrument shaft (do NOT use the same luer lock syringe that was used to flush the instruments prior to ultrasonic cleaning). Irrigate the instrument's shaft with the luer lock syringe with the jaws open to remove any remaining debris or ultrasonic detergent residue from inside the shaft.
6. **Visual inspection**. Visually inspect the instrument for cleanliness and clean off any remaining debris. Visually inspect the instrument for damage and open and close the jaws to ensure proper operation of the instrument. The **Association of periOperative Registered Nurses (AORN)** states that "*Technology should be used to conduct stray current leakage tests at the end of each decontamination cycle."* As the manufacturer, we support **AORN**'s recommendation to increase patient safety.
7. **Dry**. Instruments must be thoroughly dried with a clean, soft cloth. The use of pressurized air is recommended to aid in drying, especially in the flush port of the instrument with the jaws in the open position. Residual moisture may contain waterborne pathogens and must be removed prior to sterilization. Residual moisture, especially in the hinge areas, may result in corrosion that can potentially weaken the instrument and shorten the life of the instrument.
8. **Lubrication**. Use a hospital approved instrument lubricant (instrument milk) on all of the instrument's moving parts to ensure that they move freely and will not "freeze up" during use. Using a 10cc (or larger) luer lock syringe, flush the instrument's internal flush channel with instrument lubricant. Please ensure that the jaws of the instrument are in the open position while infusing the lubricant into the flush channel. Ultrasonic cleaners remove all of the lubrication from the instrument; therefore, proper lubrication during every reprocessing cycle before sterilization will extend the useful life of the instrument. If the instrument is to be stored or if it is to be sterilized by ethylene oxide (EtO), be sure it is thoroughly dry.

STERILIZATION RECOMMENDATION

After following the above cleaning recommendations, Elmed's Clear Flush® reusable laparoscopic instruments are ready for sterilization. Independent laboratory testing*, conducted under **FDA** regulations (21 CFR PART 58), has validated steam sterilization as an effective sterilization process for Elmed's Clear Flush® reusable laparoscopic instruments. The clean instruments were individually wrapped with the jaws and black rubber luer cap in the open position in two layers of 2-ply, approximately 140 count cotton muslin using sequential wrapping techniques. The instruments were then sterilized using one pre-vacuum steam sterilization method and one gravity steam sterilization method.

The instruments were validated as sterile after completing a 4 minute, 132 degree Celsius pre-vacuum sterilization cycle. The instruments were also validated as sterile after completing a 10 minute, 132 degree Celsius gravity sterilization cycle. As recommended by the **Association for the Advancement of Medical Instrumentation (A.A.M.I.) Standards and Recommended Practices**, the sterilizer manufacturer's written instructions for sterilization cycle parameters should be followed at all