



# Clear Flush

PATENTED & VALIDATED CLEAN TECHNOLOGY

## VALIDATED INSTRUCTIONS FOR USE (IFUS) WITH AN FDA APPROVED AUTOMATED WASHER

### INDICATIONS FOR USE:

Elmed Clear Flush® Kerrison Rongeurs are intended for cutting or biting bone and tissue during surgery involving the skull or spinal column.

### CONTRADICTIONS:

Elmed Clear Flush® Kerrison Rongeurs should only be used for the above indicated uses.

### WARNINGS:

Discard instrument after suspected Creutzfeldt-Jakob disease (CJD) exposure; the Elmed Clear Flush® Kerrison Rongeurs have not been validated to withstand the chemical and thermal exposures recommended to eradicate prions.

### PRECAUTIONS:

- Check the screws on the Elmed Clear Flush® Kerrison Rongeurs after ultrasonic cleaning to ensure they did come lose.
- Inspect Rongeur tips before use to ensure cutting surfaces meet evenly; ensure that Rongeur pin/bar is not bent. Uneven meeting or bent pin/bar may indicate a weakened tip and may lead to tip failure.
- Elmed Kerrison Rongeurs are supplied non-sterile and must be cleaned, lubricated and sterilized prior to use. Failure to follow these procedures will invalidate instrument's warranty and can cause the instrument to fail.
- Inappropriate use of instruments will lead to damage that is usually not repairable and will void the warranty.

### HANDLING AND OPERATING INSTRUMENTS:

- Elmed Clear Flush® Kerrison Rongeurs should only be handled and operated by personnel completely familiar with their use. These Rongeurs are designed to be cleaned by flushing the instrument through the flush port. **DO NOT** disassemble the instrument. Disassembly of the Kerrison Rongeurs by hospital personnel will void the product Warranty.
- Before a new instrument is used and prior to each surgical procedure, the Elmed Clear Flush® Kerrison Rongeurs must be decontaminated, lubricated and sterilized.
- **DO NOT** use the instrument if it does not appear to be functioning properly. Use of the Clear Flush® Kerrison Rongeurs for a task other than that for which it is intended could result in a damaged or broken instrument, or one which provides an unsatisfactory performance.
- In order to maintain the new product Warranty, instruments in need of repair must be sent back to Elmed Incorporated. Call 224.353.6446 to get an RGA and shipping instructions. Repair by a third party will automatically void the Warranty.

### DECONTAMINATION AND STERILIZATION PROCEDURES:

When reprocessing the Elmed Clear Flush® Kerrison Rongeurs, we recommend that you follow accepted guidelines as recommended in ANSI/AAMI ST79:2017/ A.3-202x, "*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*" in conjunction with your institution's published guidelines and policies.



# INSTRUCTIONS FOR USE



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While cleaning, handling, lubricating and inspecting the instruments personnel should wear appropriate personal protection equipment (PPE) as required by OSHA & AORN.

Sterilization is a two-step process involving thorough cleaning, rinsing and decontamination and then terminal sterilization:

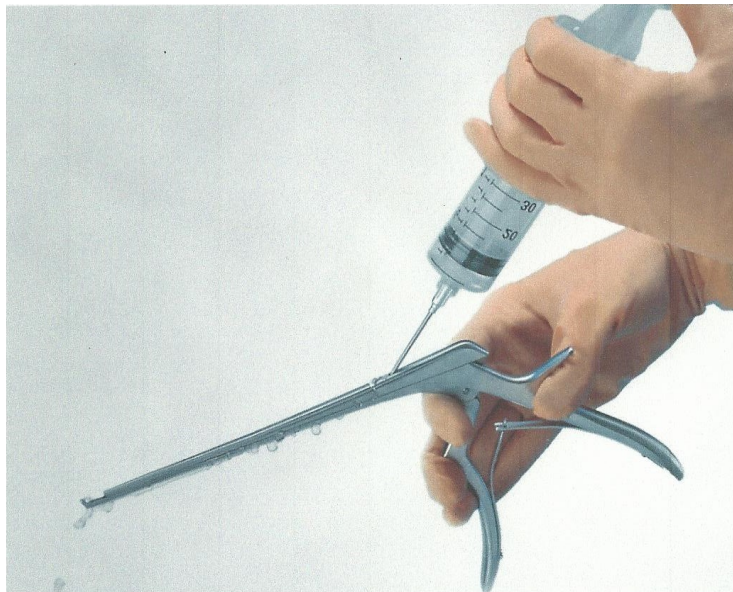
1. Decontamination is thorough cleaning and rinsing using physical or chemical means to remove, inactivate, or destroy blood-borne pathogens so they are no longer capable of transmitting infectious particles and instrument is safe for handling or disposal.
2. Sterilization is a validated process to render an instrument free from viable organisms that are no longer capable of transmitting infectious particles and the instrument is safe for handling or disposal.

## DECONTAMINATION

### Precleaning Recommendations

For best results, and to prolong the life of the instrument, reprocess immediately after use. Place the soiled instrument in an instrument tray/container that contains sterile distilled water or an enzymatic cleaning solution to moisten the soil and prevent blood, mucus, and other debris from drying on the instrument. Use of a spray foam enzymatic detergent may also be used. DO NOT use a saline solution as it might damage or corrode the instrument.

Attach a 16ga or 17ga blunt needle to a 50cc (or larger) luer lock syringe and then fill the syringe with sterile distilled water or an enzymatic cleaning solution. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensure a tight seal. Flush the instrument until the sterile distilled water or enzymatic detergent is free of gross soil and debris when it exits the distal tip of the instrument (see photo below). Place the instrument back into the solution and cover the tray/container with a towel moistened with the solution.



### MANUAL DECONTAMINATIONS:

Prior to placing the instrument into the automated washer, soak the instrument in an approved, neutral pH (7 or lower), enzymatic detergent solution. Use only low foaming, non-ionizing cleaning agents and detergents. Always follow the manufacturer's instructions for use, warnings, concentrations and recommended cycles. Be sure that the solution is at the correct temperature as per the detergent manufacturer's recommendations. Completely immerse the instrument, with the jaws open, into the solution for a minimum of 5 minutes (or longer if called for on the detergent manufacturer's label).



# INSTRUCTIONS FOR USE



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## CLEANING IN AN FDA APPROVED AUTOMATED WASHER:

After the enzymatic detergent soak, place the instruments into the automated washer. Once in the washer, connect the Kerrisons to the washer's pressure infusion hoses using Elmed's infusion fixation devices that hold the 16ga x 1/2" stainless steel blunt needle in the infusion port on the top of the Kerrison (see photo below). Once all of the automated washer's pressure infusion hoses are connected to the Kerrisons run the automated washer through the standard, automatic cannulated cycle. Always refer to and follow the automated washer manufacturer's IFUs for cannulated instruments .



## RINSE:

After removing from the automated washer, rinse all of the Kerrisons thoroughly with lukewarm, neutral pH (7 or lower) water, which is controlled for bacterial endotoxins, to remove any remaining debris or automated washer detergent residue that could interfere with the sterilization process. Wipe the instrument with a clean, soft cloth.

## DRY:

The Kerrisons 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. Residual moisture may contain waterborne pathogens and must be removed prior to sterilization. Additionally, any remaining moisture, especially in the internal areas, may result in corrosion that can cause the instrument to "bind-up" and shorten the life of the instrument.

## VISUAL INSPECTION:

Visually inspect the Kerrison for cleanliness and clean off any remaining moisture or debris. Visually inspect the instrument for damage. Open and close the jaws to ensure proper operation of the instrument.

## LUBRICATION:

Use a hospital approved instrument lubricant (instrument milk) on the instrument's moving parts to ensure that they move freely and will not "bind-up" during use. Attach a 16ga or 17ga blunt needle to a 10cc luer lock syringe and then fill the luer lock syringe with instrument lubricant. Insert the blunt needle into the open flush port on the top of the instrument shaft and apply downward pressure on the needle to ensue a tight seal. Flush the instrument's internal flush channel with the instrument lubricant with the jaws open. Automatic washers 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) gas, be sure it is thoroughly dried after lubrication.



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## STERILIZATION

After following the above cleaning recommendations, the Elmed Clear Flush® Kerrison Rongeurs are ready for sterilization. Independent laboratory testing

conducted under U.S. FDA REGULATIONS (21 CFR PART 58), has validated steam sterilization as an effective sterilization process for instruments.

The instruments were 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°C (270°F) pre-vacuum sterilization cycle. The instruments were also validated as sterile after completing a 10-minute, 132°C (270°F) gravity sterilization cycle. Care should be taken to ensure that no part of the sterilization process exceeds 140 °C (284°F).

Hospital approved disposable paper wrap or cotton muslin wrap may be used for multiple instruments. Hospital approved paper or plastic sterilization pouches may be used to sterilize individual instruments. Make sure you use a wide enough pouch (6" or wider) so the instrument can be sterilized in the open and unlocked position. The Kerrisons may also be sterilized in a hospital approved sterilization case, container or tray. Place your heavy instruments at the bottom of the set (when two layers are required). Do not overload the sterilizer chamber. Pockets may form that do not permit steam penetration. 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 times.



# SERVICE AND REPAIR



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IN NEED OF INSTRUMENT REPAIRS? SEND THEM TO THE *ER!*

## ELMED REPAIR

60 YEARS OF EXPERIENCE AND KNOWLEDGE IN DESIGNING, ENGINEERING, MANUFACTURING AND REPAIRING FOR THE MEDICAL COMMUNITY HAS GIVEN ELMED, INC. ONE OF THE BEST REPUTATIONS IN THE INDUSTRY. WE REPAIR WHAT OTHERS ARE UNABLE OR UNWILLING TO DO AND WE REPAIR ALL COMPETITIVE BRANDS. OUR WORK IS PERFORMED BY SKILLED TECHNICIANS, ALL OF WHICH HAVE BEEN WITH ELMED FOR THE PAST 10-30 YEARS.

*COMPLETE IN-HOUSE MACHINE SHOP, POWDER COATING, LASER WELDING, & MARKING FINISHING, ELECTRONICS AND OPTICAL DEPARTMENTS*

### AREAS OF SPECIALTY

- LAPAROSCOPIC AND ENDOSCOPIC INSTRUMENTS
- ELECTROSURGICAL UNITS AND ACCESSORIES
- FIBER OPTIC LIGHT CABLES AND RETRACTORS
- RIGID ENDOSCOPES & FLEXIBLE SINUSCOPES
- STAINLESS STEEL HAND INSTRUMENTS
- LIGHT SOURCES AND HEADLIGHTS
- DEBRIDER UNITS, HAND PIECES AND BLADES
- SELF RETAINING RETRACTOR SYSTEMS

### HOW TO PACKAGE AND SHIP INSTRUMENTS

- **IMPORTANT:** ELMED CANNOT ACCEPT INSTRUMENTS THAT HAVE NOT BEEN PROPERLY CLEANED, DISINFECTED OR STERILIZED.
- INCLUDE CUSTOMER NAME AND ALL CONTACT INFORMATION (NAME, ADDRESS, PHONE NO., FAX NO., EMAIL ADDRESS, ETC.)
- INCLUDE CUSTOMER P.O. (PURCHASE ORDER), IF USED
- INCLUDE REASON FOR RETURN - BRIEF DESCRIPTION OF REPAIR PROBLEM IF AVAILABLE
- WRAP INSTRUMENT FOR PROTECTION DURING TRANSPORT
- USE A COMMON CARRIER SUCH AS UPS OR FEDEX
- INSURE THE PACKAGE AND RECORD THE TRACKING NUMBER

**PLEASE FILL OUT, DETACH, AND INCLUDE THE FORM BELOW WITH YOUR REPAIR:**

|                  |                 |
|------------------|-----------------|
| FROM:            |                 |
| FACILITY:        | CONTACT PERSON: |
| ADDRESS:         |                 |
| CITY, STATE, ZIP |                 |
| EMAIL:           | PHONE NO.       |
| PO. No.          | QTY.            |

INSTRUMENT DESCRIPTION:

(NOTE: PLEASE INCLUDE MODEL NO. AND SERIAL NO. IN INSTRUMENT DESCRIPTION FOR SCOPES)

FAST SERVICE: INCOMING REPAIRS COMING IN BY NEXT DAY AIR WILL BE COMPLETED WITHIN 24 HRS (WHEN PARTS ARE AVAILABLE)

SHIP TO: **ELMED** 35 N BRANDON DR., GLENDALE HEIGHTS, IL 60139