Sterisharp®
Reusable Kerrison Rongeur Instrument

INDICATIONS
The Sterisharp® Kerrison rongeur is a manually operated, instrument indicated for cutting or biting bone during surgery involving the skull or spinal column.

The instrument is supplied non-sterile, it is to be cleaned and sterilized for use in a single surgery, prior to reprocessing. Use the instrument until it no longer provides a clean sharp cut, then discard.
The product has demonstrated acceptable cleaning in accordance with ANSI/AAMI ST98 and autoclave sterilized in accordance with ANSI/AAMI ST79. Instructions are included in this document for the clinical site reprocessing.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician

DESCRIPTION
The Sterisharp® Kerrison rongeur is constructed of stainless steels and anodized aluminum handle. It is available in footplate widths of 1, 2, 3, 4, and 5mm.

INSTRUCTIONS FOR USE
Prior to use:

- Inspect the instrument for damage or rust. Do not use the device if damage or rust is apparent.
- Inspect the colored handle for chips or discoloration. Do not use the device if the coloring is flaked.
- Clean the device before first use in accordance with this instruction.
- Sterilize the device by autoclave steam sterilization in accordance with this instruction.
- Irrigate and lubricate metal shaft prior to use.

Only use this instrument for its intended purpose. Avoid misuse and rough handling. Do not bend or twist the instrument or use it as a pry bar. It should cut cleanly without requiring excessive force. Should it fail to do so for any reason, do not use it. The cutting tip is sharp; exercise extreme caution to avoid injury to the user and patient.

Do not attempt to alter the Sterisharp® instrument in any way. Unpredictable failure modes and hazards may result.
Do not attempt to disassemble the Sterisharp®.
Do not re-sharpen.

Steribite, LLC is not responsible for damages or injury resulting from misuse or failure to follow instructions provided.

WARNINGS AND PRECAUTIONS
The Sterisharp® materials of construction and manufacturing methods are specifically tailored to a reusable instrument.
Known risks associated with Kerrison rongeurs include:

- Cutting tip breakage
- Cutting tip deformation
- Handle breakage
- Disassembly during use
- Dull cutting tip
- Screws falling out

Avoid the use of excessive force. Follow user instructions and take care to avoid situations in which these risks might occur. Warn the patient of all potential risks.

LABEL SYMBOL DESCRIPTIONS

Reference number and symbol	Title of symbol	Description of symbol per Standard[1]
5.1.1 	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
5.1.5 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
5.1.6 	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
5.4.3 	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
[1] Reference numbers and descriptions from ISO 15223-1:2016, Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements, FDA recognized standard # 5-118		

DISPOSAL

Dispose of the instrument in an approved sharps container per local regulations.

WARRANTY

All Steribite LLC products are guaranteed to be free from defects in workmanship and materials when used properly for their intended surgical purpose. Any product proving to be defective will be replaced at Steribite, LLC discretion, at no charge to the customer.

United States Patent Numbers: 10092299, 10925618. Foreign patents pending and applied for.

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CLEANING & STERILIZATION INSTRUCTIONS FOR REUSABLE INSTRUMENTS

INSPECTION AND HANDLING

- Instruments must be inspected prior to use to ensure function. Failure to make a complete inspection and test proper operation may result in unsatisfactory performance.

- Instruments should be handled and operated by personnel knowledgeable with their intended use and these instructions.
- This reusable instrument must be decontaminated, lubricated and sterilized prior to the first use and prior to each respective surgical procedure.

DECONTAMINATION AND CLEANING

- Cleaning is performed in accordance with ***ANSI/AAMI ST98:2022, Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices***.

- Instruments must be cleaned and processed to be safe for handling, inspection and assembly by wearing appropriate personal protection equipment (PPE) as required per clinical site procedures, conforming to OSHA & AORN as required.

PRECLEANING OF USED INSTRUMENT

- Remove gross debris, tissue, and bone fragments from the instruments using approved brushes, lap sponge, and deionized and/or sterile water routinely during procedure to prevent drying. Irrigate as needed. This precleaning should be performed as soon as possible after use, prior to storage where possible.

STORAGE AWAITING REPROCESSING

- Immediately after precleaning, place instruments in an instrument tray/container. Include a towel moistened with sterile water as covering, or use approved foam, spray, or other products intended for storage applications to keep the soiled instrument as moist as possible.

CLEANING INSTRUCTIONS

1) Perform preliminary rinse of the soiled instruments with distilled water prior to enzymatic soak.
2) Prepare solution and use per enzyme manufacturer's instructions for correct dilution, temperature and soak time.
3) Fully immerse the instrument in the solution
4) Immerse the instrument in the open position in an enzymatic solution.
5) Remove the instrument from enzymatic soak after manufacturer recommended by enzymatic soak time and and rinse thoroughly with warm distilled water.
6) Prepare a neutral or mildly alkaline detergent in accordance with the manufacturer's instructions for use. Use a mildly alkaline or neutral detergent to minimize pitting and corrosion to this instrument.
7) Use a small, approved cleaning brush to scrub the soil from all surfaces. This may be performed above the bath for progress inspections and scrubbed within the bath water to promote cleaning as needed.

   Note: Do not use wire brushes, blades, steel wool, or other abrasive cleaners

CLEANING INSTRUCTIONS (CONTINUED)

8) Brush scrubbing should include careful attention to the instrument jaws, crevices, and instrument surfaces. Flush with water as needed during manual brushing of the instrument.
9) Thoroughly rinse instruments with distilled water and wipe with fibre-free wiper or approved cloth to avoid contamination.
10) As needed, prepare a subsequent ultrasonic cleaning tanks in accordance with the manufacturer recommendations of the detergent. Ensure the processing considers all parameters and degassing of the cleaning solution prior to use.
11) Perform final rinsing with sterile or other pyrogen-free water where possible
12) Visually inspect instrument for cleanliness
13) Lubricate the product handles and verify device function
14) Dry the product thoroughly before preparation to autoclave sterilization

STERILIZATION INSTRUCTIONS

Sterilization by autoclave (moist heat, steam sterilization) is performed in accordance with ***ANSI/AAMI ST79:2006, A1:2008, A2:2009 - Comprehensive guide to steam sterilization and sterility assurance in health care facilities.***

1) This instrument shall be cleaned and sterilized before first use.
2) This instrument shall be cleaned and sterilized between each clinical use as a reusable instrument.
3) This instrument is not designed to be disassembled for cleaning or sterilization Verify the product is in the open position.
4) Refer to the ANSI/AAMI ST79 standard and the autoclave sterilizer manufacture's manual for the required parameters. Ensure to meet or exceed the recommended temperature and exposure times as needed. As general guidance, the following cycles, and additional cycles as recommended by the sterilizer manufacturer may be considered:

Cycle Type	Packaging	Temperature	Dwell Time	Dry Time
Prevacuum	Instrument Tray, Multiple Devices	275°F (135°C)	3 minutes	16 minutes
Flash	Instrument Tray, Single or Multiple Devices	270°F (132°C)	10 minutes	1 minutes
Gravity	Wrapped / Pouched, Multiple Devices	270°F (132°C)	15 minutes	30 minutes

5) It is the responsibility of the clinical user site to select the steam sterilization parameters and demonstrate a Sterility Assurance Level (SAL) of 10^{-6} is achieved for each processing of this reusable instrument.