

Steribite®
Disposable Single Use Kerrison
DO NOT AUTOCLAVE

INDICATIONS

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

It is supplied sterile, may only be used in a single surgery, and cannot be reprocessed or resterilized.

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

DESCRIPTION

The Steribite Kerrison rongeur is constructed of stainless steels and fiber reinforced polyarylamide resin. It is available in footplate widths of 1, 2, 3, 4, and 5mm. For convenience the handles are color coded for size:

Handle Color	Footplate Width
Light Gray	1mm
Blue	2mm
Green	3mm
Dark Gray	4mm
Black	5mm

It is a single use, disposable device. This means that a Steribite Kerrison can only be used in a single surgery and must be disposed of after that surgery. It cannot be reprocessed or resterilized by any means.

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INSTRUCTIONS FOR USE

Prior to use:

- Inspect the packaging for damage and verify that package seals are intact. Do not use the device if package integrity has been compromised
- Inspect the instrument for damage or rust. Do not use the device if damage or rust is apparent.
- Verify that the expiration date has not been exceeded.
- Use sterile technique to open the packaging.
- Irrigate 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 Steribite instrument in any way. Unpredictable failure modes and hazards may result. Do not attempt to disassemble the Steribite.

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

WARNINGS AND PRECAUTIONS

The Steribite materials of construction and manufacturing methods are specifically tailored to a disposable device. Because it is made of multiple materials there is not a single method appropriate for resterilization.

Damage resulting from reprocessing and resterilization may not be visually apparent. The materials and functionality will be degraded, the device will not perform as intended, and injury may result.

Since the device cannot be resterilized open packages cannot be returned for exchange or credit.

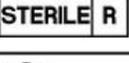
Known risks associated with Kerrison rongeurs include:

- 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.
5.1.4 	Use-by date	Indicates the date after which the medical device is not to be used.
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.
5.2.4 	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
5.2.8 	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
5.4.2 	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
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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