Strategic Business Holdings, Inc.
...Quality Products, Superior Customer Service, & Support

SBH ™ Kerrison Rongeurs
INDICATIONS FOR USE

Our Kerrison Rongeurs are manually operated instruments indicated for cutting or biting bone during surgery involving the skull or spinal column.

CONTRAINDICATIONS

Instruments should not be used for anything other than their intended use.

WARNINGS

• Discard instrument after suspected Creutzfeldt-Jakob disease (CJD) exposure; the rongeurs have not been validated to withstand the chemical and thermal exposures recommended to eradicate prions.

• DO NOT flash sterilize the rongeurs. The instruments have not been validated for flash sterilization.

PRECAUTIONS

• Check screws on instruments after ultrasonic cleaning. Vibration from ultrasonic cleaning may cause them to loosen or fall out.

• Inspect rongeur tips before use to ensure cutting surfaces meet evenly; ensure that Ejector rongeur pin/bar is not bent. Uneven meeting or bent pin/bar may indicate a weakened tip and may lead to tip failure.

• 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 instrument to fail.

• Inappropriate use of instruments will lead to damage that is usually not repairable.

DIRECTIONS FOR EJECTOR RONGEUR

• Examine Ejector tip pin/bar to ensure it smoothly retracts into instrument shaft.

• Squeeze handles to bite bone and retract pin/bar.

• Release handles (open position) to deploy tip and eject bone tissue from shaft.

INSPECTION OF ALL INSTRUMENTS

Instruments must be thoroughly inspected upon receipt and prior to use to assure proper functioning. Failure to make a complete inspection to assure proper operation and function of instrument may result in unsatisfactory performance.

HANDLING AND OPERATING INSTRUMENTS

Instruments should be handled and operated by personnel completely familiar with their use, assembly and disassembly.

• Before a new instrument is used and prior to each surgical procedure, instrument must be decontaminated, lubricated and sterilized.

• DO NOT use instrument if it does not appear to be functioning properly. Use of an instrument 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 insure warranties and guarantees, instruments in need of repair should be sent to sbh.

DECONTAMINATION AND STERILIZATION PROCEDURES

Personnel should follow accepted guidelines as recommended in ANSI/AAMI ST79:2006, A1:2008, A2:2009 -Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Instruments must be rendered safe for handling, inspection and assembly by wearing appropriate personal protection equipment (PPE) as promulgated 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 render instrument safe for handling or disposal.
2) Sterilization is a validated process to render an instrument free from viable microorganisms.

PRECLEANING: Remove gross debris from surgical instruments with a lap sponge and sterile water routinely during procedure to prevent drying on of blood and body fluids, etc.

NOTE: Perform "A. Manual Decontamination" or "B. Mechanical Decontamination"followed by "C. Terminal Sterilization" instructions.

A. MANUAL DECONTAMINATION

CLEANING: To prevent formation of biofilm, cleaning should occur as soon as possible after instrumentation is used.

Step 1. Maintain moisture: Immediately after surgical procedure, place instruments in an instrument tray/container and cover with a towel moistened with sterile water. Foam, spray or gel products, specifically intended for use with surgical instruments, are available to keep soil moist. Rinse foam, spray or gel products from instruments with distilled water prior to enzymatic soak.

Step 2. Enzymatic Soak: Immerse fully opened and/or disassembled instruments in an enzymatic solution, specific for use with surgical instruments. Prepare solution and use per enzyme manufacturer's recommendations / instructions for correct dilution, temperature and soak time.

Step 3. Rinse: Remove from enzymatic soak after time period recommended by enzymatic manufacturer and rinse thoroughly with lukewarm distilled water.

Step 4. Cleaning Instruments: Choose a cleaning solution appropriate for surgical instruments and follow manufacturer's instructions for use.

• The use of neutral pH detergents is recommended to avoid corrosion, pitting and breakage.

• Using a small, clean hand-held brush, remove soil from all surfaces of instrument while fully immersed in solution.

• Never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil as these will damage the instruments' protective surface and lead to corrosion.

• Use a clean, soft bristled brush to clean instruments with an accessible channel.

• Remove soil from jaws, tips and hinge mechanism. Vigorously flush channels with distilled water.

Step 5. Rinse: Thoroughly rinse instruments with distilled water and wipe with a clean, soft cloth.

Step 6. Ultrasonic Cleaning and Rinsing: Follow recommendations of ultrasonic manufacturer regarding cycle times, detergents, proper placement of instrument tray, and conditioning ("de-gassing") of cleaning solution.

• Use an ultrasonic cleaner to remove soil from hard to reach surfaces such as grooves, crevices and moving parts after gross soil has been removed.

• Open or disassemble instruments as appropriate.

• Keep different metal types separated, i.e., separate stainless steel from non-anodized aluminum, brass, copper and chrome-plating to avoid possible transfer of one metal plating to another.

• Place instruments in a mesh bottom stainless steel instrument tray. Place tray into ultrasonic cleaner.

Step 7. FINAL RINSE with distilled pyrogen-free water (preferred).

Step 8. Visual Inspection and Instrument Set Assembly: Visually inspect instrument for cleanliness and ensure all parts are in proper working order..

Step 9. Lubricate: The use of a water-soluble instrument lubricant that is compatible with pre-vacuum steam sterilization is recommended before instruments are sterilized.

• After thoroughly cleaning instruments, proper application of lubricants to all joints and movable mating surfaces will keep them moving freely and aid in protecting surface from mineral deposits.

• Proper lubrication is required for all instruments, regardless of surface coatings.

• Note that ultrasonic cleaners remove all lubrication; therefore, this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization.

Step 10. Drying: Before instruments are wrapped for sterilization, they must be thoroughly dry. Prepare instrument sets for sterilization using a wrapper, such as polypropylene wrap or cotton muslin, which is appropriate for pre-vacuum steam sterilization.

B. MECHANICAL DECONTAMINATION

Before using automatic washer:

• Perform PRECLEANING instructions

• Follow Steps 1-3 of A. Manual Decontamination CLEANING instructions to maintain moisture, perform enzymatic soak and rinse.

• Open or disassemble instruments as appropriate.

• Follow manufacturer's specifications when using automatic washers to process general surgical instrumentation.

• Recommended automatic washer parameters to remove gross amounts of soil:

Treatment	Time (mm:ss)	Temperature
Presoak	02:00	15-20°C (59-60°F)
Enzymatic Wash	04:00	60°C (140°F)
Wash (Cleaning)	02:00	50°C (122°F)
Rinse	02:00	70°C (158°F)
Dry	15:00	80°C (176°F)

• Remove instruments from automatic washer.
• Follow Steps 7-10 of A. Manual Decontamination CLEANING instructions to perform instrument final rinse, visual inspection, lubrication and drying before terminal sterilization.

C. TERMINAL STERILIZATION

After following manual or mechanical decontamination recommendations, reusable instruments are ready for terminal sterilization.
• Instruments must be sterilized in the open position or disassembled as appropriate.
• ANSI/AAMI ST79 standards recommend that sterilizer manufacturer's written instructions for cycle parameters should also be followed. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than minimum indicated by sterilizer manufacturer but must never be shorter. It is the responsibility of the user to establish whether sterilizer meets these minimum recommendations.
• Recommended steam sterilization parameters to achieve Sterility Assurance Level (SAL) of 10-6:

Sterilizer	Temperature	Exposure Time	Minimum Drying Time
Pre-vacuum (wrapped)	132°C (270°F)	4 min	20 min

MAINTENANCE PROCEDURES

Improper, ineffective and insufficient maintenance can reduce the life of an instrument and will invalidate the instrument's warranty.

Protect Instruments: The use of sterile water and distilled water, careful preliminary cleaning, use of neutralized pH solutions, adherence to manufacturer's instructions and visual inspection, will help to keep instruments performing accurately and free of stains.

• Certain compounds are highly corrosive to stainless steel and will cause serious damage. Instruments should never be exposed to:

Aqua regia	Iodine
Ferric chloride	Sulfuric acid
Hydrochloric acid	

• The following substances should be avoided whenever possible; rinse with copious amounts of water immediately if instruments are inadvertently exposed to any of the following substances:

Aluminum chloride	Mercury chloride
Barium chloride	Potassium permanganate
Bichloride of mercury	Potassium thiocyanate
Calcium chloride	Saline
Carbolic acid	Sodium hypochlorite
Chlorinated lime	Stannous chloride
Dakin's solution	

• Any kind of corrosion will lead to rust on steel. Rust particles can be transferred from one instrument to another, therefore, remove corroding instruments from service to prevent formation of rust on other instruments.

• Protect sharp cutting edges and fine working tips during all maintenance procedures. Avoid loading heavy items on top of delicate and hollow instruments.

Diagnosing Spots and Stains: It is common for instruments to become stained or spotted.

Adhering to proper technique during cleaning and sterilizing procedures will prevent most staining occurrences. The following identifies some of the various instrument-related problems hospitals may encounter.

Brown Stains: Detergents containing polyphosphates may dissolve copper elements in the sterilizer resulting in brown stains. A dull blue or brown stain is the result of oxidation on the surface.

Black Stains: Black stains may be the result of contact with ammonia.

Light or Dark Spots: Spots are often the result of the mineral content in the water used for rinsing, use of non-neutral instrument detergent or an unclean sterilizer chamber.

Rust Deposits: It is very unlikely for surgical grade steel to rust. Rust colored spots usually appear in localities where water has high iron content

RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by Sbh. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

REPAIRS AND MAINTENANCE

Should your instruments require repair or maintenance, contact Sbh for return authorization and address. Instruments returned to Sbh for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

PRODUCT INFORMATION DISCLOSURE

SBH AND ITS SUBSIDIARIES ("SBH") AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT SBH'S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER SBH NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER SBH NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

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