Retractors – Recommended Cleaning, Sterilization, and Instructions for Use

König Surgical retractors are manual orthopedic devices intended to provide minimally invasive access to the surgical site by ensuring the placement, and positioning of the retractor, with its attachment to a flexible arm to provide a self-locking method of access to the site through which tubes, endoscopes and surgical instruments can be manipulated.

Caution: Federal U.S. laws restrict these devices to sale, distribution, and use, by, or on the order of a physician.

Instructions for Use

Warning
Remove all protective caps and sheaths carefully. Prior to surgical use, the retractor and accessory instruments must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are reusable and supplied as non-sterile.

Attention
Risk of damage - The retractor is a precision device. Careful handling is important for the accurate functioning of the product. Improper external handling (e.g. bending, banging, dropping, etc.) can cause product malfunction.

Control function before use
Before using, the general functioning and preparation of the retractor and accessories must be controlled. Please confirm prior to use.

Final preparation for use
Place the retractor in the compatible position and secure the locking mechanism respectively. Confirm once again to ensure that the device is secure and ready for use according to indication.

Operation
Neurosurgical procedures should be performed only by persons having adequate training and familiarity with neurosurgical techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performance of any neurosurgical procedure.

Before using the product, all instructions regarding its safety features as well as surgical techniques must be read carefully. The sterile retractor with the shaft is inserted into the body. The retractor must be operated only by trained personnel. Please observe general operating room technique.

Decontamination and Cleaning

Decontamination
Take the device with the adapter(s) and accessories to the decontamination area. Clean, decontaminate, and sterilize the device, adapter(s), and accessories following the instructions in the IFUs.

WARNING - Risk of infection!
Before use, the entire device, including adapter(s) and accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning

Clean the instrument externally with a soft sponge and a soft brush (See General Instruments - Pre Cleaning). Unscrew the retractor adapter(s) before decontamination. Perform Manual or Automated cleaning per the General Instruments IFU. Do not clean in an ultrasonic bath to avoid risk of damage. Screw the adapter(s) on, only immediately before the next usage of the retractor. Be sure that the threading is completely dry.

Sterilization

Autoclave sterilization - Use steam autoclave sterilization only.

Standard autoclave cycle
Steam sterilize at 270°F for fifteen (15) minutes. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature.

(Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.)

Caution: Autoclave temperatures should not exceed 280°F or handles, insulation or other nonmetallic parts may be damaged.

Make certain that the instrument container is sealed in appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene. König Surgical instruments are reusable and meet AAMI standards for sterilization. Please clean the retractor individually and separately from other instruments.

Maintenance

Attention
Apply lubricant only on the connecting elements (locking mechanism) and moving parts.

Repair
To ensure that all repairs are completed according to the manufacturer's specifications, the precision retractor should be repaired by Medline or by an authorized service agency only.

Warranty
All König Surgical products are guaranteed to be free from defects in material and workmanship at the time of shipping. All of our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their original design.

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY TO ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKewise, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.
Open Up Kerrison Rongeurs –
Recommended Cleaning, Sterilization, and
Instructions for Use

König Surgical Kerrison rongeurs are devices intended to access, cut and bite soft tissue and bone during surgery.

Caution: Federal U.S. laws restrict these devices to sale, distribution, and use, by, or on the order of a physician.

WARNING! If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!

Instructions for Use

Warning
Remove all protective caps and sheaths carefully. Prior to surgical use, rongeur must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are re-usable and supplied as non-sterile.

Attention
Risk of damage - The rongeur is a precision device. Careful handling is important for accurate functioning of the product. Improper external handling (e.g. bending, banging, dropping, etc.) can cause product malfunction.

Control function before use
Before using, the general functioning and preparation of the rongeur and accessories must be controlled. Please confirm prior to use.

Operation
Neurosurgical procedures should be performed by persons having adequate training and familiarity with neurosurgical techniques. In addition, consult medical literature relative to techniques, complications and hazards prior to performing any neurosurgical procedure.

Before using the product, all instructions regarding its safety features as well as surgical techniques must be read carefully. The sterile shafted rongeur is inserted into the body. The rongeur must be operated only by trained personnel. Please observe general operating room technique.

Squeeze handle to cut/bite bone. Medline König Open Up Kerrison Rongeur shaft should operate smoothly. When attached, shaft should be perfectly aligned.

Caution: For Open Up Kerrison Rongeurs avoid engaging the gold button while operating the rongeur.

Decontamination and Cleaning

Decontamination
Take the device with the adapter(s) and accessories to the decontamination area. Clean, decontaminate, and sterilize the device, adapter(s), and accessories following the instructions in the IFUs.

WARNING - Risk of infection!
Before use, the entire device, including adapter(s) and accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Open Up Kerrison Rongeurs
Unlocking:
Step 1: Press the gold PUSH button and hold it.
Step 2: Pull the handle trigger downwards.
Step 3: Open up the instrument at the higher runner.

Locking:
Step 1: Insert the higher runner into the guide of the lower handle runner.
Step 2: Align the arrows in the same position.
Step 3: Move the handle trigger upwards until the locking system is engaged. Squeeze the handle to ensure normal operation.

Pre Cleaning
Remove gross debris from surgical instruments with a lap sponge and sterile water routinely during procedure to prevent drying of blood and body fluids. Follow Pre Cleaning Instructions used for General Instruments.

NOTE: Perform “Manual Decontamination” or “Mechanical Decontamination”

Manual Decontamination

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

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.
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.
3. Rinse: Remove from enzymatic soak after time period recommended by enzymatic manufacturer and rinse thoroughly with lukewarm distilled water.
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.
5. Rinse: Thoroughly rinse instruments with distilled water and wipe with a clean, soft cloth.
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.

7. **FINAL RINSE** with distilled pyrogen-free water (preferred).
8. **Visual Inspection and Instrument Set Assembly**: Visually inspect instrument for cleanliness and ensure all parts are in proper working order.

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**: Ultrasonic cleaners remove all lubrication; therefore, this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization.

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.

**Mechanical Decontamination**

Before using automatic washer
   - Perform Pre Cleaning instructions
   - Follow Steps 1-3 of **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.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time [mm:ss]</th>
<th>Temperature [°C(°F)]</th>
</tr>
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<tbody>
<tr>
<td>Presoak</td>
<td>02:00</td>
<td>15-20°C (59-68°F)</td>
</tr>
<tr>
<td>Enzymatic Wash</td>
<td>04:00</td>
<td>60°C(140°F)</td>
</tr>
<tr>
<td>Wash (Cleaning)</td>
<td>02:00</td>
<td>50°C(122°F)</td>
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<tr>
<td>Rinse</td>
<td>02:00</td>
<td>70°C(158°F)</td>
</tr>
<tr>
<td>Dry</td>
<td>15:00</td>
<td>80°C(176°F)</td>
</tr>
</tbody>
</table>

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

**Sterilization**

**Autoclave Sterilization**

Use steam autoclave sterilization only. Steam sterilize at 270°F for four (4) minutes and thirty (30) minutes dry time. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times). The rongeurs can be sterilized in an open or closed position.

**Caution**: Autoclave temperatures should not exceed 280°F, handles, insulation or other nonmetallic parts may be damaged.

Make certain that the instrument container is sealed in appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

König surgical instruments are re-usable and meet AAMI standards for sterilization. We guarantee our products to withstand a minimum of twenty (20) sterilization cycles when sterilized according to the criteria listed.

**Maintenance**

**Attention**

Apply lubricant only on the connecting elements (locking mechanism) and moving parts.

**Repair**

To ensure that all repairs are completed according to the manufacturer’s specifications, the precision rongeur should be repaired by Medline or by an authorized service agency only.

**Warranty**

All König surgical products are guaranteed to be free from defects in material and workmanship at the time of shipping. All of our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their original design.

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