König Surgical Instruments Instructions for Use, Cleaning, Sterilization, and Maintenance Guidelines

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General Instrumentation – Recommended Cleaning and Sterilization Instructions

Pre Cleaning
1. All devices should be cleaned in the open position to allow solution to contact all surfaces.
2. Contaminated instruments should be cleaned as soon as possible.
3. Rinse off device to remove any excess gross soil.
4. Submerge instruments in an enzymatic/ neutral pH detergent bath and allow soaking between 5 and 10 minutes.
5. Use a soft bristled brush and gently remove any visible soil still remaining on the device. Be sure to clean hinges, crevices and other difficult to reach areas. Lumens should be cleaned with a soft bristled pipe cleaner of corresponding width and length to ensure the entire lumen has been scrubbed.
6. Rinse instruments in purified water for a minimum of 2 minutes. Flush lumens, hinges, crevices and other difficult to reach areas until the water exiting the device is clear of soil and detergent. If soil still remains, repeat the steps above.

Manual Cleaning
1. Rinse under cool running tap water to remove gross soil.
2. Bathe in enzymatic detergent per manufacturer’s recommendation using lukewarm tap water for 1 minute.
3. Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with enzymatic detergent to remove soil.
4. Rinse under cool running tap water and aggressively flush lumens with a syringe to remove detergent residuals.
5. Bathe in a neutral detergent per manufacturer’s recommendation using warm tap water for 3 minutes.
6. Scrub thoroughly with a soft bristled brush to remove soil. Pass a stylet through lumens a minimum of 3 times and, using a syringe, aggressively flush lumens with neutral detergent to remove soil.
7. Rinse under running reverse osmosis/deionized (RO/DI) water to remove detergent residuals.
8. Sonicate in enzymatic detergent per manufacturer’s recommendation for 10 minutes.
9. Rinse under running RO/DI water and aggressively flush lumens with a syringe.
10. Dry with a disposable, lint free cloth.
11. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visibly clean.

Ultrasonic Cleaning
1. Follow Pre-Cleaning steps outlined above.
2. Submerge instruments fully opened in Ultrasonic Washer with cold distilled water and the minimum effective concentration of enzymatic cleaner per manufacturer’s recommendation.
3. Ultrasonically clean instruments at 45kHz for 10 minutes.
4. Rinse under cool running RO/DI water for 2 minutes and aggressively flush lumens with a syringe until water exiting instrument is clear of detergent.
5. Dry with a disposable, lint free cloth.
6. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

Automated Washer: Neutral pH Detergent
1. Follow Pre-Cleaning steps outlined above.
2. Load instruments into automatic washer per manufacturer’s recommended orientation.
3. Wash instruments per Mechanical Washer Parameters in Table 1.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time</th>
<th>Description</th>
<th>Detergent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash 1</td>
<td>2 min</td>
<td>Pre wash with cold tap water</td>
<td>None</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>1 min</td>
<td>Enzyme spray and soak with hot tap water</td>
<td>Enzymatic Detergent</td>
</tr>
<tr>
<td>Cold Tap Water Rinse</td>
<td>15 sec</td>
<td>Cold tap water rinse (2x)</td>
<td>None</td>
</tr>
<tr>
<td>Wash 1</td>
<td>2 min</td>
<td>Detergent wash with hot tap water</td>
<td>Neutral pH Cleaner</td>
</tr>
<tr>
<td>Rinse 1 Hot Tap Water</td>
<td>15 sec</td>
<td>Hot tap water rinse</td>
<td>None</td>
</tr>
<tr>
<td>Pure Rinse</td>
<td>10 sec</td>
<td>Hot purified water</td>
<td>None</td>
</tr>
<tr>
<td>Drying</td>
<td>7 min</td>
<td>Hot air dry</td>
<td>None</td>
</tr>
</tbody>
</table>

4. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

Automated Washer: Low Impingement/High pH Detergent
1. Follow Pre-Cleaning steps outlined above.
2. Load instruments into automatic washer per manufacturer’s recommended orientation.
3. Wash instruments per Mechanical Washer Parameters in Table 1.
4. Low motor setting (low impingement) requires Neutral pH Cleaner to be replaced with Alkaline Detergent with pH above 11 in Wash 1 Phase.
5. Visually inspect for cleanliness. Repeat cleaning process, as necessary, until visually clean.

Note: Ensure instruments are lubricated prior to sterilization and after last rinse cycle using a water soluble product intended for surgical instruments.

Sterilization
Sterilization should be performed in a medical grade instrument tray or disposable paper or plastic pouch. Make certain that the instrument container is sealed in an appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

Sterilization of instruments may be accomplished by Autoclave or Ethylene Oxide. Time and temperature parameters required for sterilization vary according to type of sterilizer, cycle design, and packaging material.

Autoclave Sterilization
- Testing should be conducted by each healthcare facility to ensure that the specific configuration of instrument sets is acceptable for the sterilization process.
- Do not sterilize instruments at temperatures over 141°C (285°F).
- All ring handled instruments must be autoclaved in the fully open position to prevent cracking of the box lock.
- All instruments must be sterilized in the completely open and disassembled (i.e. taken-apart) configuration. Note that
applicable instrument disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.).

- All flush ports shall remain in the fully open position.
- All devices shall be positioned to allow steam contact of all surfaces.
- All instruments with concave surfaces shall be placed so that the surfaces will drain water.
- Always verify parameters with sterilizer manufacturer’s written instructions.
- The use of “flash” sterilization is not recommended, as it may shorten the life of instruments.

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Temp</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Temp</td>
<td>275°F (135°C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>3 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity Displacement</td>
<td>Exposure Temp</td>
<td>270°F (132°C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>15 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

Storage
After sterilization, instruments should remain in sterilization wrap and be stored in a clean and dry environment. The devices are manufactured from non-degradable materials. When stored under the recommended conditions, the shelf life of this product is not limited.

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 instrument should only be repaired by an authorized service agent only.

All 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 originals.

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 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.
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.

(Nota: 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.

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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 only 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.

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**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**

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Rongeurs – Recommended Cleaning, Sterilization, and Instructions for Use

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

Caution: Federal U.S. laws restrict this device 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 reusable 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 only 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.

Decontamination and Cleaning
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 below.

Warning - Risk of infection!
Before use, the entire device, including its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create serious risk of infection in patients and/or users.

Cleaning
Clean the instrument externally with a soft sponge and a soft brush. If appropriate, take the instrument apart prior to decontamination.

1. Immediately after use: 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. Do NOT use a saline solution as it might damage or corrode the instrument. Flush the instrument’s internal channels to remove gross soil and debris from inside the shaft. Place the instrument back into the solution and cover the tray/container with a towel moistened with the solution.

2. Enzymatic detergents soak. Prior to manual cleaning, 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).

3. Manual cleaning. Flush the instrument's internal channels with enzymatic detergent with the jaws open to remove gross soil and debris from inside the shaft, clean each of the instrument's components (jaws, hinges, handles and shaft) with a clean, appropriately sized soft-bristle brush to remove all organic debris. Pay particular attention to the hinges, crevices and other hard to clean areas. Do NOT remove any screws and do NOT attempt to disassemble the instrument.

4. Rinse. Prior to sonication in an ultrasonic cleaning unit, rinse the instrument's components thoroughly with lukewarm water for a minimum of 1 minute to remove dislodged debris and the detergent solution. Flush the instrument's internal channels with the jaws open to remove dislodged gross soil and debris from inside the shaft. Wipe the instrument with a clean, soft cloth.

5. Ultrasonic cleaning. The cavitation action of ultrasonic cleaners can remove particles of debris from areas of the instrument inaccessible to a brush and is recommended as part of the reprocessing procedure. With the jaws in the open position, place the instrument in a mesh bottom instrument basket. Place the basket in the ultrasonic cleaner. Follow the recommendations of the ultrasonic cleaner manufacturer as to cycle times, cleaning solutions, suspension of the basket (e.g. the basket should not sit on the bottom of the ultrasonic cleaner), conditioning of the water, etc. Ensure that all instruments are fully submerged in the ultrasonic cleaner. Do NOT place dissimilar metals (stainless, copper, chrome-plated, etc.) in the same cleaning cycle.

6. Rinse. After removing from the ultrasonic cleaner, rinse all of the instrument's components thoroughly with lukewarm, neutral pH (7 or lower) water, which is controlled for bacterial endotoxins, to remove any remaining debris or ultrasonic, detergent residue that could interfere with the sterilization process. Flush the instruments internal channels with the jaws open to remove dislodged gross soil and remaining debris or ultrasonic detergent residue from inside the shaft. Wipe the instrument with a clean, soft cloth.

7. Dry. Instruments must be thoroughly dried with a clean, soft cloth. The use of pressurized air is recommended to aid in drying; especially in the crevices 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.

8. Visual Inspection. Visually inspect the instrument for cleanliness, and clean off any remaining debris. Visually inspect the instrument for damage. Open and close the jaws to ensure proper operation of the instrument.

9. Lubrication. Use a hospital approved instrument lubricant (instrument milk) on all of the instrument's moving parts to ensure that they move freely and will not bind up during use. Flush the instrument's internal channels with the instrument lubricant with the jaws open. Ultrasonic cleaners 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.

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.
Fiber Optic Laryngoscopes –
Recommended Cleaning, Sterilization, and Instructions for Use

Fiber Optic Features
These operating instructions pertain to both König brand integrated and non-integrated (Green System) Fiber Optic Laryngoscopes. These instructions should be followed to ensure the longevity and durability of this product. Please inspect all components before use to confirm all items are present and in perfect working condition.

Medline fiber optic laryngoscope blades are manufactured from a high quality AISI 303/304 stainless steel which is highly resistant to corrosion and conforms to ISO 7376.

Green System fiber optic laryngoscope blades are removable and interchangeable with other blades of the same size. By unscrewing the locking side screw as shown in Figure 1, the light guide can be disengaged and removed for cleaning, repairs or replacement.

The integrated fiber optic blades are built with an integrated fiber optic bundle with no cavities, thus allowing for easy decontamination. Integrated fiber optic blades are maintenance free and may be sterilized via autoclave up to 134˚ C/5 min approximately 4,000 times.

Operating Instructions
1. Engage the blade by aligning the slot of the blade on to the hook pin of the handle and apply a sufficient force (¼ – 1lb) as shown in Figure 2.
2. Apply force upward to bring the blade into operating position as shown in Figure 3.
3. To bring the blade into standby position apply force downward as shown in Figure.

Light Guide Replacement Procedure
1. Remove locking screw with a screw driver as shown in Figure 1.
2. Pull out the green block and slide out the light guide.
3. Fix new light guide of similar size and replace the locking screw.
4. Be sure the screw is properly tightened.

Caution: Great care should be taken while performing this procedure to avoid structural damage to the fiber blade.

Lamp Replacement Procedure for Xenon F.O. Handle
1. Unscrew the head from the barrel counter-clock wise as shown in Figure 5.
2. Remove the lamp from the head.
3. Replace the new lamp.
4. Screw the head clock-wise to the barrel.

Attention: Always try to keep the lens of the lamp clean for better performance.

NOTE: LED handles do not require replacement.
Battery Replacement Procedure

*2.5V Xenon & LED handles can be used with dry batteries as well as rechargeable batteries.

NOTE: In accordance with local regulations, rechargeable batteries should be disposed of as an electronic device separately.

Cleaning Procedure

Attention: Remove batteries before cleaning, high level disinfection or sterilization of the laryngoscope system.

Blades and Handles - Cleaning
1. Immediately after use, the laryngoscope system should be rinsed under cool running tap water until all visible soil is removed. Ensure that all hard to reach areas are flushed with the running tap water.
2. Immerse the sealed laryngoscope system in a presoak enzymatic cleaner solution, prepared in accordance to the manufacturer’s recommendations for a minimum of two (2) minutes.
3. Remove device from enzymatic cleaner solution and rinse with lukewarm running tap water for a minimum of one (1) minute to remove all residues and visible soils.
4. Immerse the device in enzymatic detergent. Remove bottom cap and brush items thoroughly using a soft bristle brush, ensuring all visible soils are removed.
5. Rinse under running reverse osmosis/deionized (RO/DI) water to remove detergent residuals.
6. Dry with a lint free cloth or filtered pressurized air.

WARNING! Ultrasonic cleaning is strictly prohibited.

Disinfection

Soaking in solutions or thermo chemically in a washer sterilizer up to 65˚ C max may be used to perform disinfection. Manufacturer’s instructions regarding duration and concentration of solutions should be strictly adhered. After disinfection, rinse thoroughly in RO/DI water and dry with a lint free cloth.

Cold Soak Solution

To achieve a high-level disinfection, Cidex OPA or 2.4% Glutaraldehyde solution may be used according to the manufacturer’s instructions. Dry with lint free, clean cloth or filtered pressurized air. Reassemble all parts, load handle with batteries and test the system for proper function. If not functional, review the battery lamp testing instructions below.

WARNING! Do not immerse blades in Bleach, Betadine or Potassium Hydroxide solutions. Doing so will cause severe damage to the instruments. Avoid metal to metal contact during and after soaking.

Xenon and LED Handles

Xenon and LED handles may withstand the same cold soak solution outlined in the blade section. The batteries and lamp must be removed prior to disinfection/sterilization. Battery handles may withstand exposure to ethylene oxide. The Lamp may be cleaned with a cotton ball dampened in alcohol (IPA).

Note: The LED handles may be autoclaved/sterilized without removing the LEDs.

Attention: Do not allow excess fluid to seep into electrical contact; batteries must be removed before cleaning and sterilization.

Sterilization

Before performing any of the procedures described below, the blade and handle should be cleaned as described in the cleaning procedure.

Note: It is recommended to remove the fiber optic light guide from Green System blades before sterilization as it may adversely affect the polishing of the fiber and decrease light output.

Gas Sterilization

Gas sterilization by ethylene oxide may be used up to a maximum temperature of 65˚ C and 8p.s.i.

<table>
<thead>
<tr>
<th>Cycle Type</th>
<th>Parameter</th>
<th>Minimum Set Point</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevacuum</td>
<td>Exposure Temp</td>
<td>270˚ F (132˚C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>20 minutes</td>
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<td>Gravity Displacement</td>
<td>Exposure Temp</td>
<td>250˚ F (121˚C)</td>
</tr>
<tr>
<td></td>
<td>Exposure Time</td>
<td>30 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>15 minutes</td>
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</tbody>
</table>

Note: do not exceed a temperature of 135˚ C and a pressure of 28p.s.i.

WARNING! Flash autoclaving and hot air sterilization should be avoided as these processes will damage the instrument.

NOTE: THE ABOVE LISTED STERILIZATION GUIDELINES, PROVIDED BY MEDLINE INDUSTRIES, INC., ARE INTENDED AS PROCEDURES COMPATIBLE WITH SPECIFIC MATERIALS. STERILIZATION MUST BE PERFORMED TO APPROVED HOSPITAL PROTOCOL. MEDLINE INDUSTRIES, INC., CAN NOT GUARANTEE STERILITY. THIS WILL BE Validated BY THE HOSPITAL AND OR STERILIZATION EQUIPMENT MANUFACTURERS.
Standard Laryngoscopes – Recommended Cleaning, Sterilization, and Instructions for Use

Standard Laryngoscope Features

These operating instructions pertain to König brand standard laryngoscope systems. These instructions should be followed to ensure the longevity and durability of this product. Please inspect all components before use to confirm all items are present and in perfect working condition.

Medline standard laryngoscope blades are manufactured from high quality AISI 303/304 stainless steel which is highly resistant to corrosion and conforms to ISO 7376.

Operating Instructions

1. Engage the blade by aligning the slot of the blade on to the hook pin of the handle and apply a sufficient force ¼ - 1lb as shown in Figure 1.
2. Apply force upward to bring the blade in operating position as in Figure 2.
3. To bring the blade to standby position, apply force downward as in Figure 2.

Bulb Replacement Procedure

1. Unscrew the bulb counter-clock wise direction until free as shown in Figure 3.
2. Replace the bulb and verify that the bulb is sufficiently tight before use.

Battery Replacement Procedure

*2.5V battery handles can be used with dry batteries as well as rechargeable batteries.

NOTE: In accordance with local regulations, rechargeable batteries should be disposed of as an electronic device separately.

Cleaning Procedure

Attention: Remove batteries before cleaning, high level disinfection or sterilization of the laryngoscope system.

Blades and Handles – Cleaning

1. Immediately after use, the laryngoscope system should be rinsed under cool running tap water until all visible soil is removed. Ensure that all hard to reach areas are flushed with the running tap water.
2. Immerse the sealed laryngoscope system in a presoak enzymatic cleaner solution, prepared in accordance to the manufacturer’s recommendations for a minimum of two (2) minutes.
3. Remove device from enzymatic cleaner solution and rinse with lukewarm running tap water for a minimum of one (1) minute to remove all residues and visible soils.
4. Immerse the device in enzymatic detergent. Remove bottom cap and brush items thoroughly using a soft bristle brush, ensuring all visible soils are removed.
5. Rinse under running reverse osmosis/deionized (RO/DI) water to remove detergent residuals.
6. Dry with a lint free cloth or filtered pressurized air.
7. The bulb may be cleaned with a cotton ball dampened in alcohol (IPA).

WARNING! Ultrasonic cleaning is strictly prohibited.
Disinfection
Soaking in solutions or thermochemically in a washer sterilizer up to 65° C max may be used to perform disinfection. Manufacturer’s instructions regarding duration and concentration of solutions should be strictly adhered. After disinfection, rinse thoroughly in RO/DI water and dry with a lint free cloth.

Cold Soak Solution
To achieve a high-level disinfection, Cidex OPA or 2.4% Glutaraldehyde solution may be used according to the manufacturer’s instructions. Dry with lint free, clean cloth or filtered pressurized air. Reassemble all parts, load handle with batteries and test the system for proper function. If not functional, review the battery lamp testing instructions below.

WARNING! Do not immerse blades in Bleach, Betadine or Potassium Hydroxide solutions. Doing so will cause severe damage to the instruments. Avoid metal to metal contact during and after soaking.

Standard Handles
Standard handles may withstand the same cold soak solution outlined in the blade section. The batteries must be removed prior to disinfection/sterilization. Battery handles may withstand exposure to ethylene oxide.

Attention: Do not allow excess fluid to seep into electrical contact; batteries must be removed before cleaning and sterilization.

Sterilization
Before performing any of the procedures described below, the blade and handle should be cleaned as described in the cleaning procedure.

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</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>15 minutes</td>
</tr>
</tbody>
</table>

Gas Sterilization
Gas sterilization by ethylene oxide may be used up to a maximum temperature of 65° C and 8p.s.i. This method is preferred if sterilization is to be performed regularly.

Steam Sterilization
Steam sterilization can also be performed. Insert device inappropriate autoclave pouch.

Note: do not exceed a temperature of 135° C and a pressure of 28p.s.i.

WARNING! Flash autoclaving and hot air sterilization should be avoided as these processes will damage the instrument.

Blade and Handle Test Procedure
Laryngoscope blades and handles should always be tested after cleaning, disinfection, sterilization and prior to use. To test, connect the laryngoscope blade to the handle and pull it to the ON position as shown in Figure 1. If the unit fails to light or flickers, check the lamp/batteries and the electrical contacts. Be sure adequate supplies of spare lamps, batteries and replacement parts are readily available.

NOTE: THE ABOVE LISTED STERILIZATION GUIDELINES, PROVIDED BY MEDLINE INDUSTRIES, INC., ARE INTENDED AS PROCEDURES COMPATIBLE WITH SPECIFIC MATERIALS. STERILIZATION MUST BE PERFORMED TO APPROVED HOSPITAL PROTOCOL. MEDLINE INDUSTRIES, INC., CAN NOT GUARANTEE STERILITY. THIS WILL BE VALIDATED BY THE HOSPITAL AND/OR STERILIZATION EQUIPMENT MANUFACTURERS.
Gynecological Forceps – Recommended Cleaning, Sterilization, and Instructions for Use

König Surgical gynecological forceps are surgical instruments with two blades and handles used to seize tissue by compression or traction during gynecological surgery.

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

Caution: Surgical forceps should not be used by individuals who are not fully trained in proper gynecological surgical techniques. Consult relevant medical literature for the appropriate indications, techniques, and risks applicable to the corresponding gynecological procedure.

Read the instructions for Use prior to using this device.

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, 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 forceps 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 instrument and accessories must be controlled. Please confirm prior to use.

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 its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning
Follow the General Instruments cleaning guide found on page 2.

Sterilization

Autoclave Sterilization
Use steam autoclave sterilization only. 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.

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. 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 device should be repaired by Medline or by an authorized service agency only.

Warranty

All König 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.
Obstetrical Forceps – Recommended Cleaning, Sterilization, and Instructions for Use

König Obstetrical Forceps are intended to grasp and apply traction to the fetal head to facilitate delivery in cases of prolonged second stage, suspicion of immediate or potential fetal compromise, or shortening of the second stage for maternal benefit, provided that the cervix is fully dilated and the fetal head is positioned appropriately in the vagina.

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

Caution: Obstetrical forceps should not be used by individuals who are not fully trained in proper use of forceps and the potential complications associated with their use.

Consult relevant medical literature for the appropriate obstetric indications, prerequisites, techniques, and risks of operative vaginal delivery prior to the performance of any forceps delivery.

Read the Instructions for Use prior to using this device.

Caution: Obstetrical forceps should only be used in settings in which personnel are readily available to perform cesarean delivery in the event that operative delivery is unsuccessful.

Warnings:
1. König Obstetrical Forceps are not approved for use for > 45 degree rotation of the fetal head.
2. Use of forceps may result in maternal complications to include lacerations of the vagina and cervix, pelvic hematoma, episiotomy extension, hemorrhage resulting from these events, and possibly injury to the pelvic floor.
3. Use of forceps may result in fetal complications to include: minor lacerations, forceps marks, rare facial and brachial plexus palsies, cephalhematoma, skull fracture, and intracranial hemorrhage.
4. Use caution in attempting multiple efforts at vaginal delivery with different instruments, i.e., forceps and vacuum.
5. Use caution in performance of operative vaginal delivery in cases of presumed macrosomia.
6. Adhering to established obstetric guidelines for the use of forceps and careful placement of forceps helps minimize the risks of forcep assisted delivery.
7. 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!

Obstetrical forceps should not be used in the following situations:
1. If a live fetus is known to have a bone demineralization condition or bleeding disorder
2. The fetal head is unengaged
3. The position of the fetal head is unknown

Instructions for Use

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

Attention
Risk of damage - The forceps 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 instrument and accessories must be controlled. Please confirm prior to use.

Instructions for Placing the Forceps

1. Ensure that all prerequisites for operative vaginal delivery are met prior to performing forceps assisted delivery.
2. Insert the forceps one blade at a time. The blades should lie evenly against the sides of the head, reaching to and beyond the malar eminences, symmetrically covering the space between the orbits and the ears.
3. Lock the forceps and check their position to ensure even and symmetric placement.
4. Apply traction in a downward and outward direction to accomplish delivery of the fetal head.
5. An axis-traction device may be used to assist with the initial downward force.
6. Episiotomy may be performed at the discretion of the physician.
7. The forceps blades may be disarticulated during crowning or after delivery of the fetal head.
8. After delivery, closely inspect the cervix, vagina, and perineum for lacerations.
9. Inform neonatal care providers of the use of forceps during the delivery.

References
American College of Obstetricians and Gynecologists, Operative vaginal delivery.

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 its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning
Follow the General Instruments cleaning guide found on page 2.
Sterilization

Autoclave Sterilization

Use steam autoclave sterilization only. 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.

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. 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 device should be repaired by Medline or by an authorized service agency only.

Warranty
All König 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.
Vascular Clamps – Recommended Cleaning, Sterilization, and Instructions for Use

König Vascular Clamps are devices intended for temporary occlusion of blood vessels during open vascular or minimally invasive coronary surgical procedures.

Caution: Federal U.S. laws restrict this device 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, the instrument must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are reusable and supplied as non-sterile.

Attention
Risk of damage - The vascular clamp 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 instrument and accessories must be controlled. Please confirm prior to use.

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

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

Sterilization

Autoclave sterilization
Use steam autoclave sterilization only. 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.

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. 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 device should 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.

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 its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning
Follow the General Instruments cleaning guide found on page 2.
König Vessel Dilators – Recommended Cleaning, Sterilization, and Instructions for Use

König Vessel Dilators are devices used to enlarge or calibrate vessels during coronary artery bypass or angioplasty procedures. They are designed to locate orifices, to trace the course of abnormal vessels, and to perform various maneuvers of dilation and measurement of annulus and lumen diameters.

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

Caution: Surgical instruments should not be used by individuals who are not fully trained in proper cardiovascular surgical techniques. Consult relevant medical literature for the appropriate indications, techniques, and risks applicable to the corresponding cardiovascular procedure.

Read the instructions for Use prior to using this device.

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, the instrument must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are reusable and supplied as non-sterile.

Attention
Risk of damage - The instrument 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 instrument and accessories must be controlled. Please confirm prior to use.

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 its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning
Follow the General Instruments cleaning guide found on page 2.

Sterilization

Autoclave sterilization
Use steam autoclave sterilization only. 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.

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. 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 device 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.
Lead Hands – Recommended Cleaning, Sterilization, and Instructions for Use

König Lead Hands are made from malleable lead and used to position and immobilize a patient’s hand during surgical procedures.

Instructions for Use

1. Place the lead hand on the surgical table and place the patient’s hand on top of the device.
2. To immobilize, bend the wrist tabs over the patient’s wrist and bend the immobilizer finger tabs over the applicable fingers as needed. It is recommended to place a barrier or drape between the patient’s hand and the lead hand to avoid direct contact.
3. After the procedure, carefully straighten the lead hand’s finger and wrist tabs.
   NOTE: Due to the malleability of the material, continual bending of the tabs in the same location will cause the material to weaken and may crease or break.
4. Reprocess according to the cleaning and sterilization instructions below.

Caution: The Lead Hand must not come in direct contact with open wounds or mucous membrane.

Decontamination and Cleaning

Clean the lead hand immediately after each use using an automatic washer with integrated electronic controls. It is not recommended to clean the lead hand manually.

   1. Prepare an alkaline or neutral cleaning solution in accordance with the manufacturer’s instructions.
   2. If necessary, soak soiled lead hand in cleaning solution for 10 minutes to loosen or remove soil.
   3. Rinse the lead hand with tap water.
   4. Drain water and rinse for a second time with tap water.
   5. Wash per automatic washing procedure on page 2.
   6. Dry for 30 minutes under hot air at 100°C (212°F).
   7. Allow lead hand to cool at room temperature for 30 minutes.
   8. Visually inspect the lead hand before sterilization or storage to ensure the complete removal of soil.

Sterilization

The König Lead Hand is provided non-sterile. Chemical sterilization is not recommended due to danger of corrosion.

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<tr>
<td></td>
<td>Exposure Time</td>
<td>4 minutes</td>
</tr>
<tr>
<td></td>
<td>Dry Time</td>
<td>20 minutes</td>
</tr>
</tbody>
</table>

NOTE: Due to the nature of the material, oxidation will occur, leaving a film/coating on the lead hand that can be wiped away. The film/coating does not affect the performance of the hand immobilizer.

Storage

Store all devices in a clean and dry environment. The devices are manufactured from non-degradable materials. When stored under the recommended conditions, the shelf life of this product is not limited.

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 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.
Laparoscopes and Accessories –
Recommended Cleaning, Sterilization, and
Instructions for Use

König Laparoscopes and Accessories are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic closed and minimally invasive procedures.

Instructions for Use

Caution: Federal U.S. laws restrict this device to sale by or on the order of a physician only. Special safety precautions should be observed when using electrosurgical instruments. Electrosurgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly.

Caution: Please refer to the labelling and user manual for the electrosurgical generator for additional information on contraindications on electrosurgical or laparoscopic use.

Cautions & Warnings
Avoid touching or grounding electrosurgical instruments to non-insulated instruments, scopes, trocar sleeves, etc. All persons using such devices should be knowledgeable in the use and handling of laparoscopic instruments, laparoscopes, coagulation equipment, their accessories and other related equipment.

Test all instruments, accessories and equipment prior to each use. Written standard operating procedures for cleaning, sterilization, storage, inspection and maintenance of the instruments, accessories and equipment are recommended.

Caution: Do not use electrosurgical instruments on patients with pacemakers.
Caution: Do not use in presence of flammable liquids or anesthetics.

Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator.

The electrode tip must always be in full view before activating power. Apply power only when electrode tip is in full contact with the tissue selected for coagulation. Electrode tip must not come in contact with the laparoscope or other metal instruments during use.

Failure to observe these cautions and contraindications may result in injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient.

Contraindications

Contraindications to endoscopic procedures, not necessarily monopolar coagulation include:

Not intended for contraceptive coagulation of the fallopian tube but may be used to achieve hemostasis following transection of the tube.

As identified in the Manual of Endoscopy available from the American Association of Gynecologic Laparoscopists: The presence of large pelvic or pelvic-abdominal masses, hypovolemic shock and severe cardiac decompensation. Also, intestinal obstruction and marked bowel distention increase of possibility of pelvic and abdominal adhesions. A significantly elevated diaphragm contra-indicates the use of insufflation which may be necessary for proper surgical visualization and may increase the chance of inadvertent bowel injury. Pelvic abscess, chronic pulmonary disease, diaphragmatic hernia, obesity, and septic peritonitis may exclude some patients from surgical consideration depending on severity of these conditions.

Decontamination and Cleaning

Initial use of new instruments
Every instrument must be cleaned and sterilized before it is used for the first time. These instruments were developed for sterilization by autoclave.

Inspection and functional check
It is very important to carefully examine each surgical instrument/scope for breaks, cracks or malfunction before use. It is especially essential to check areas such as blades, points, ends, stops and snaps as well as all movable parts. Do not use damaged instruments. Never attempt to make repairs yourself. Service and repairs should be referred to trained qualified persons only.

Cleaning and Maintenance
Every surgical instrument should be disinfected and thoroughly cleaned after each use. Proper cleaning, inspection and maintenance will help ensure correct function of the surgical instrument. Clean, inspect and test each instrument carefully. Sterilize all instruments before surgery. A good cleaning and maintenance procedure will extend the useful life of the instrument.

Special attention must be paid to slots, stops, ends, hollow tubes and other highly inaccessible areas. Check insulation, cables and connectors for cuts, voids, cracks, tears, abrasions, etc.

Do not use damaged instruments. Cleaning and rinsing must take place immediately after each use for best results. Failure to clean promptly may result in adherent particles or dried secretions that may resist cleaning and complicate or resist future sterilization.

Instruments must be completely cleaned and rinsed of all foreign body matter. Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners must be used to remove protein deposits. Follow the enzymatic cleaner’s instructions and rinse thoroughly.

NOTE: Do not use corrosive cleaning agents (i.e. bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best. Do not use abrasive cleaners. Only a soft bristle brush should be used.

1. Immerse the entire device in detergent and clean while soaking.
2. Use a minimum of six strokes out with an instrument brush for all inside channels.
3. Rinse with sterile, deionized water. Repeat this procedure.
4. Instrument may be disinfected in an automated washer up to 203˚F.
5. Rinse thoroughly with distilled water.
6. Prepare for storage and/or sterilization.
After cleaning and rinsing, dry instruments completely and carefully with compressed air including inside channels and highly inaccessible areas.

NOTE: After cleaning and before sterilization, treat all instruments with oil which is considered as being physiologically safe, especially their blades, ends, stops, snaps, and all movable parts.

**Sterilization**

Thoroughly clean instruments of all debris, tissue and foreign matter prior to sterilization. Follow the sterilizer manufacturer’s instructions for operation and loading of steam autoclaves. There must be direct steam exposure to all surfaces of the instruments being sterilized including the internal surface and tube channels. Allow instrument to air cool to room temperature before use.

Use steam autoclave sterilization only. 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 as handles, insulation or other non-metallic parts may be damaged.

**Storage**

Instruments must be stored in a clean, dry, moisture free area. The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips with cloth, gauze or tubing if stored in drawers.

**Handling**

All surgical instruments must be handled with the greatest care when being transported, cleaned, treated, sterilized and stored. This is especially true for blades, fine points and other sensitive areas. Surgical instruments corrode and their functions are impaired if they come into contact with aggressive materials. The instruments must not be exposed to acids or other aggressive cleaning agents.

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