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.

<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>
</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.