



Lead Hand

INTENDED USE:

Key Surgical® Lead Hand is sold non-sterile and is used to position and immobilize a patient's hand during surgery. The Lead Hand is not intended to come in direct contact with open wounds or mucous membrane.

CONTRAINDICATIONS:

No known contraindications and/or adverse effects.

INSTRUCTIONS FOR USE:

1. Lead Hand should be cleaned and sterilized before use according to the parameters detailed below.
2. Place lead hand on the surgical table and place the patient's hand on top.
3. Bend the wrist tabs over the patient's wrist and bend the immobilizer finger tabs over the patient's fingers as needed to immobilize.
4. After the procedure, straighten the immobilizer's finger and wrist tabs and reprocess according to the instructions below.

MANUAL CLEANING:

1. Pre-rinse under cold tap water for one (1) minute to remove gross debris
2. Soak for a minimum of two (2) minutes in a pH neutral detergent, prepared in according with the manufacturer's instructions for use.
3. If necessary, brush with a soft bristle cleaning brush to remove remaining soil
4. Rinse under cold tap water for one (1) minute.
5. Rinse with deionized water for one (1) minute.
6. Dry with a clean, lint-free towel and/or filtered compressed air.

AUTOMATED CLEANING

It may be necessary to manually clean prior to automated processing to improve the removal of adherent soil. Follow the previous instructions for manual cleaning.

Run the automatic wash cycle – minimum cycle parameters:

- 1 minute cold pre-rinse
- 5 minute enzyme wash at 43°C (109°F) minimum temperature
- 30 second hot rinse
- 1 minute thermal rinse at 82°C (180°F) minimum temperature
- 6 minute dry at 90°C (194°F) minimum temperature

CLEANING INSPECTION:

Visually inspect before sterilization or storage to ensure the complete removal of soil from surfaces. If soil is still present, re-clean.

STERILIZATION:

Validated for sterilization according to the following parameters:

Steam Sterilization		
Method	Cycle Temperature	Exposure Time
Pre-Vacuum	270°F (132°C)	4 minutes

STORAGE: Store in a clean, dry environment. Due to the nature of the material, oxidation may 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.

DISPOSAL:

Requires replacing if there are any signs of deterioration or loss of functionality. Dispose according to facility protocol.



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CATALOG NUMBER



CONSULT INSTRUCTIONS FOR USE



LOT NUMBER