

LEAD HAND

Cleaning, Sterilization & Instructions

CLEANING AND CARE: Every instrument must be cleaned and sterilized prior to use for the first time and after every subsequent use. Clean, inspect and test all instruments thoroughly, and sterilize before use. Effective cleaning and maintenance will prolong service life.

INTENDED USE: Lead Hands are sold non-sterile and are made from malleable lead and used to position and immobilize a patient's hand during a surgical procedure.

INSTRUCTIONS FOR USE:

- Place the Lead Hand on the surgical table and place the patient's hand on top of the device.
- To immobilize, bend the wrist taps over the patient's wrist and bend the immobilizer finger taps 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.
- After the procedure, carefully straighten the Lead Hand's finger and wrist taps.
- Reprocess according to 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. It is not recommended to clean the Lead Hand manually.

- Prepare an alkaline or neutral cleaning solution in accordance with the manufacturer's instructions.
- If necessary, soak soiled Lead Hand in cleaning solutions for 3-5 minutes to loosen or remove soil.
- Rinse the Lead Hand in tap water.
- Drain water and rinse for second time with tap water.
- Wash per automatic washing procedure.
- Dry for 30 minutes under hot air at 100 °C (212 °F).
- Allow Lead Hand to cool at room temperature for 30 minutes.
- Visually inspect the Lead Hand before sterilization or storage to insure the complete removal of soil.
- Prepare item for sterilization in peel pouch, sterilization wrap or other approved sterilization packaging.

STERILIZATION

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

Reprocessing Parameters:

Washer Disinfectors:			Steam Sterilisation:		
Minimum temperature 90°- Max temperature 95° with a hold time of 1 minute (HTM 01-01 Part D: Washer Disinfectors)			Minimum temperature 134°- Max temperature 137° with a hold time of 3 minutes (HTM 01-01 Part C: Steam Sterilisation)		
Disinfection Temperature (°C)	Maximum Allowable Temperature (°C)	Exposure Time Period	Sterilisation Temperature (°C)	Maximum Allowable Temperature (°C)	Exposure Time Period
90	95	1 Minute	134	137	3 Minute

NOTE: 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 Lead hand. The Lead Hand will require replacing if there are any signs of deterioration. Store all devices in a clean 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.

It is the responsibility of the preprocessor to ensure 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 preprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.