



Lead Hands – Recommended Cleaning, Sterilization, and Instructions for Use:

EMPIRE 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 on NEXT PAGE.


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

**GENERAL INSTRUCTIONS & RECOMMENDATIONS
FOR THE USE, CARE AND MAINTENANCE OF
LEAD HANDS**



INTENDED USE: Lead Hands supplied by EMPIRE MEDICAL are re-usable devices intended for hand fixation during hand surgery procedures

HOW SUPPLIED: Lead Hands are supplied non-sterile and must be cleaned and sterilised before each use according to the instructions and recommendations outlined below.
Lead Hands are made from Lead conforming to BS EN 12588:2006 (PB810M).

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

INSTRUCTIONS & RECOMMENDATIONS

FROM POINT OF USE:

- Lead Hands must be used only by appropriately qualified surgical practitioners.
- Oxidation of lead is a normal process. Consideration should be given to the minimisation of risk of surgical wound contamination or foreign body reaction resulting from the transfer of lead particles to surgical wounds via the surgeon's gloves or other surgical instruments (eg. by covering the lead hand with an impervious sterile drape).
- We recommend immediate rinsing of all instruments after use to prevent biological residues becoming encrusted.
- Keep instruments moist and do not allow blood and/or bodily fluids to dry on them. If necessary, consider covering with a damp cloth to avoid drying out of the soil.

CLEANING:

- Avoid damage to the lead hand and/or other instruments during transportation for reprocessing (e.g. do not mix heavy devices with delicate items). Transport for reprocessing as soon as possible after use.
- **Lead Hands should be cleaned separately to other instruments to minimise the risk of transfer of lead particles.**
- Remove gross contaminants with a steady stream of lukewarm/cool water (below 43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.
- Keep Lead Hands separate from other instruments to avoid surface and/or mechanical damage during processing and to minimise the risk of transfer of lead particles to other items.
- Where necessary, remove blood and general grime by washing the lead hand in water and a neutral pH detergent. Manual or automated cleaning methods can be used although whenever possible, automated cleaning is recommended to provide greater process reliability and repeatability as well as reducing risks associated with staff exposure to contaminated devices and cleaning agents used.
- Whichever cleaning method is used, suitable protective clothing and equipment (PPE) should be used at all times.
- Care must be taken to ensure cleaning agents are used in accordance with the manufacturer's instructions.
- To minimise abrasion damage to the surface of the lead hand use only soft brushes or non-abrasive scouring pads. Do not use steel wool, wire brushes, or abrasive detergents.
- Rinse in running water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the steps above if necessary
- Allow to drain on absorbent wipes or transfer immediately to inspection step

 **CLEANING**

- **Avoid using chemical cleaners as they can cause severe corrosion of the lead surface.**

DISINFECTION:

- Lead Hands can be disinfected in accordance with HTM01-01 at 90° - 95°C for 1 minute
- Chemical Soaking must not be applied.

DRYING:

- Care must be taken to ensure that the Lead Hand is dried thoroughly before storage. When drying is achieved as part of a washer disinfector cycle, do not exceed 127°C.

STERILISATION:

- **It is recommended that Lead Hands are wrapped separately as supplementary items during sterilisation** in order to minimise the risk of cross-contamination caused by transfer of lead particles.
- **STEAM AUTOCLAVING is recommended:** Lead hands should be sterilised in accordance with HTM01-01 at 134°C - 137°C for three minutes or, where practicable, to prolong their service life for twenty minutes at 121° - 124°C.
- **Note:** Sterilisation times are for exposure and do not include ramp up times or drying cycle times needed. Follow the manufacturer's instructions for loading and operation of steam autoclaves.
- **CHEMICAL STERILISATION: Should not be used** as this can result in severe corrosion of the lead surface.
- **Note:** The responsibility for validation of sterilisation techniques and equipment lies with the healthcare facility. To ensure optimal processing, all cycles and methods should be validated for different sterilisation chambers, wrapping methods and/or load configurations.

SERVICE LIFE, INSPECTION AND DISPOSAL

- Before each use, inspect for any damage. If the lead hand is nicked, cracked or severely corroded it must be replaced.
- Damaged or defective instruments should not be used. For replacement, contact your Empire Medical Sales Consultant (or your local agent if outside the UK).
- Lead hands are re-usable for several uses but have limited service life due to the natural effects of metal fatigue with repeated use and need to be replaced at the first signs of unacceptable functionality loss. As such, Lead Hands are excluded from our standard terms of guarantee.
- Lead Hands cannot be economically repaired. If they are returned to Empire Medical for inspection/replacement or disposal, a certificate of decontamination must be supplied. Failure to supply evidence of decontamination will result in the products being returned untouched for reprocessing.



• Please note that the CE mark for these instruments is applied to the original packaging label & this IFU document only.



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Manufactured under an ISO 13485 registered quality management system.