

CLEANING AND CARE: EVERY INSTRUMENT MUST BE CLEANED AND STERILIZED BEFORE BEING USED 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: ELMED 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:

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 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 PATIENTS HAND AND THE LEAD HAND TO AVOID DIRECT CONTACT.
3. AFTER THE PROCEDURE, CAREFULLY STRAIGHTEN THE LEAD HAND'S FINGER AND WRIST TAPS.
4. 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.

1. PREPARE AN ALKALINE OR NEUTRAL CLEANING SOLUTION IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS.
2. IF NECESSARY, SOAK SOILED LEAD HAND IN CLEANING SOLUTIONS FOR 3-5 MINUTES TO LOOSEN OR REMOVE SOIL.
3. RINSE THE LEAD HAND IN TAP WATER.
4. DRAIN WATER AND RINSE FOR SECOND TIME WITH TAP WATER.
5. WASH PER AUTOMATIC WASHING PROCEDURE.
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 INSURE THE COMPLETE REMOVAL OF SOIL.
9. PREPARE ITEM FOR STERILIZATION IN PEEL POUCH, STERILIZATION WRAP OR OTHER APPROVED STERILIZATION PACKAGING.

STERILIZATION

THE ELMED LEAD HAND IS PROVIDED NON-STERILE. CHEMICAL STERILIZATION IS NOT RECOMMENDED DUE TO DANGER OF CORROSION.

CYCLE	STERILIZING TEMP.	STERILIZING TIME	DRYING TIME* ³
PRE VACUUM/WRAPPED	270° F (132° C)	4 MINUTES	30 MINUTES

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. THE LEAD HAND HAS A LIFE SPAN AND WILL REQUIRE REPLACING IF THERE ARE ANY SIGNS OF DETERIORATION.

STORAGE: 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.

IMPORTANT: THE LEAD HAND MUST NOT COME IN DIRECT CONTACT WITH OPEN WOUNDS OR MUCOUS MEMBRANE.

NOTE: 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.

WE DESIGN, MANUFACTURE, & SELL THE TOOLS THE SURGEONS USE

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WE SUBSCRIBE TO COST
CONTAINMENT AND
PROTECTION OF THE
ENVIRONMENT



THEREFORE, WE
MANUFACTURE
REUSABLE PRODUCTS
FOR A CLEANER
WORLD

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