

LMActivator and LMTrainer Cleaning and Reprocessing Instructions

Cleaning and disinfection at home by patients

Inspect your appliance before placing it in your mouth. If you detect signs of abnormal wear or damage, discontinue use and contact your dentist.

Rinse the appliance daily before placing it in your mouth and after removing it from your mouth.

Use a toothbrush to clean the appliance. Do not use toothpaste because abrasive ingredients in toothpastes may scratch your appliance.

The appliance can be disinfected if necessary by immersion in boiling water for at least 1 minute.

The box can be washed in a dishwasher.

Reprocessing at dental health care facilities by professionals

Adhere to guidelines for infection control in dental health-care settings in accordance with local regulations and recommendations. E.g. Centers for Disease Control and Prevention. Guidelines for Infection Control in Dental Health-Care Settings - 2003. MMWR 2003;52 (No.RR-17). (*)

Follow the instructions for use provided by the manufacturer of the washer-disinfector, autoclave, detergent and/or sterilant.

As the appliance comes into contact with mucous membranes, it is considered a semi-critical item.

(*) Available at http://www.cdc.gov/oralhealth/Infectioncontrol/guidelines/index.htm

The appliance is intended to be used on one patient and then discarded. It may exceptionally be reprocessed (inspected, cleaned and high-level disinfected or sterilized) for use on another patient in case the appliance has been used on a same-day procedure (e.g. fitting the appliance) under the monitoring of health care professionals. If the appliance has been used by a patient at home, it shall not be reprocessed for use on another patient.

Inspection

Inspect the appliance visually and discard if any signs of damage are detected.

Cleaning

Clean the appliance without delay. Do not presoak or use chemical disinfectants.

Recommendation: washer-disinfector

Clean in washer-disinfector using a mild pH-neutral enzymatic detergent that is intended for cleaning of medical devices made of silicone and that is not classified as a dangerous preparation under directive 1999/45/EC or other local regulations. (Check "Section 2: Hazards identification" of the

material safety data sheet provided by the detergent manufacturer.)

To avoid air bubbles and to ensure proper cleaning, rinsing and disinfection of the holes, place the appliance in an upright position with the holes vertically.

The temperature of the washer-disinfector programme can be freely chosen as silicone is heat tolerant (134 $^{\circ}$ C).

High-level disinfection / sterilization

Recommendation: Sterilization in steam autoclave at 134°C.

Alternative: High-level disinfection in washerdisinfector according to the section 'Cleaning' above.

Alternative: Chemical sterilization with DuPont Rely+On PeraSafe sterilant.

Alternative: manual cleaning

Scrub with a soft brush using a mild pH-neutral enzymatic detergent that is intended for cleaning of medical devices made of silicone and that is not classified as a dangerous preparation under directive 1999/45/EC or other local regulations. (Check "Section 2: Hazards identification" of the material safety data sheet provided by the detergent manufacturer.)

Rinse thoroughly.

After cleaning, inspect the appliance and repeat the above if necessary. Make sure the appliance and its holes are thoroughly cleaned and rinsed.

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