ENGLISH

Reprocessing Guide for removable LM™ orthodontic appliances

LM feel the difference

REPROCESSING RECOMMENDATIONS
LM™
www.lm-dental.com/reprocessing

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LM feel the difference

This guide describes how to reprocess LM™ removable orthodontic appliances

LM-Dental™ recommends the use of validated cleaning, disinfection and/or sterilization procedures described in this processing instruction according to standard ISO 17664. This guide is applicable for removable LM™ orthodontic appliances and accessories: LM-Activator™, LM-Activator™ 2, LM-Trainer™, LM-OrthoSizer™, and LM-Activator™ 2 OrthoSizer™.
This guide is intended for doctors and other dental professionals working with LM™ orthodontic appliances.

CONTENT

1. INTRODUCTION

1.1 Instructions for home use - cleaning and use of the appliance

Make sure to provide the patient with adequate guidance on how to clean the appliance and on the use:

- **Before first use inspect the appliance for debris or flaws**. LM-Dental™ takes great care in the quality of the appliances. However, if debris or flaws are detected, discontinue the use and contact the prescribing doctor.
- **Cleaning is recommended before first use.** The appliance is delivered in a non-sterile condition. The appliance can be cleaned by brushing with a toothbrush without toothpaste. The appliance can also be cleaned by immersion in boiling water.
- **Daily use.** The appliance should be rinsed daily before placing it in the mouth and after removing it from the mouth. Use a toothbrush to clean the appliance. Using toothpaste is not recommended as the abrasive ingredients may scratch the appliance causing more favorable conditions for contamination. The appliance can be immersed in boiling water for cleaning.
- **Inspect the appliance.** If signs of abnormal wear or damage on the appliance are detected, the patient should discontinue the use and contact the prescribing doctor.

1.2 Reprocessing of device at dental health care facilities by professionals

As the appliance comes into contact with mucous membranes, it is considered a semi-critical item. The appliance is intended for single patient use only and then discarded. It may exceptionally be reprocessed (inspected, cleaned and high-level disinfected and 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.

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

If the appliance has been used by a patient at home, it shall not be reprocessed for use on another patient.

It is not recommended to use re-processed appliances in the actual treatment for the patients. It is advised that a separate set should be kept for fitting the appliances at the clinic.

1.3 The processing steps provided herein

Apply to the products indicated for removable orthodontic appliances for orthodontic treatment and eruption guidance.

The processing of products applies to the following situations:
- All LM™'s products are supplied in a non-sterile condition.
- All reprocessed products mentioned in this guide are products for transient use meaning to be used less than 60 min. (eg. for fittings and measuring). Processing is required prior to reuse.
  Note! LM-Activator™ and LM-Trainer™ appliances should not be reused if they have been used in treatment by a patient.

The table below summarizes the various existing situations and what type of processing action that are applicable:

Symbol on package or product	Device used to perform processing See Annex 1	Processing step
	Ultrasonic bath	Pre-cleaning
	Washer-Disinfector	Cleaning and disinfection
	Steam sterilizer	Sterilization

This guide is applicable to the products listed in Annex 1- List of products covered by this guide

Note! Regularly service the maintenance devices and follow all instructions in this guide.
Note! Pay special attention to correct dosage and exposure of disinfectants and cleaning agents.
Note! LM™ does not recommend manual cleaning at the clinic - washer-disinfector is the only method that is validated.

1.4 Disclaimer

The instructions for processing products before first use/reuse herein have been validated by LM-Instruments Oy. Users are solely responsible for any deviation from these instructions, and/or the use of alternative methods for processing. LM-Instruments Oy accepts no liability for damage, injury, or any legal responsibility incurred directly or indirectly by the user due to a deviation from the guide set forth below. The user shall observe safe and lawful practices including, but not limited to, those outlined in this document.

2. WARNINGS

- The recommended maximum temperature of the steam sterilizer for reprocessing LM™ products is 134°C-137°C (273°F-278°F).
- Liquids containing chlorine, phenol or amines are not permitted to use for reprocessing LM™ products.
- A steel brush or any other sharp or abrasive tools are forbidden as they may scratch the appliance and thus reduce the lifetime of the product.

3. PRECAUTIONS

3.1 General

- Dispose of all contaminated products in accordance with accepted local regulations.
- Always wear protective clothes for your safety (gloves, eye protection wear, and mask).
- Do not use labels or identification markers directly on the product.
- Only use properly maintained processing equipment and materials approved by national laws and regulations. The reprocessing equipment should be used according to the manufacturer's instructions (including calibration, cleaning, loading weight, shelf life, operating time and functional testing).
- Only use a detergent solution with disinfecting action approved for its efficacy (VAH/DGHM listing, CE marking, FDA approval) and in accordance with the IFU of its manufacturer.
- Detergent should be aldehyde-free (to avoid blood impurity fixation).
- Always follow the instructions and concentrations provided by the manufacturer of the cleaning/disinfecting agent.

3.2 Material resistance

- The use of cleaning and disinfecting agents can damage the products.
- Consult the instructions for use provided by the legal manufacturer of the cleaning/disinfection agent and check compatibility with the material of the products covered by this guide.
- Do not use solutions containing phenol or any products which are not compatible with the products.

4. REPROCESSING INSTRUCTIONS

4.1 General

Instruction for processing prior to use/reuse

Type of product family	Condition	Instruction
LM-Activator™ (First generation)	Processing before reuse	Steps 1 to 8
LM-Activator™ 2	Processing before reuse	Steps 1 to 8
LM-Activator™ 2 Reinforced	Processing before reuse	Steps 1 to 8
LM-Trainer™	Processing before reuse	Steps 1 to 8
LM-OrthoSizer™ LM-Activator™ 2 OrthoSizer™	Processing before reuse	Steps 1 to 8

4. REPROCESSING INSTRUCTIONS

4.2 Processing instructions

Processing instructions for removable **LM™ orthodontic appliances and accessories: LM-Activator™, LM-Activator™ 2, LM-Trainer™, LM-OrthoSizer™, and LM-Activator™ 2 OrthoSizer™.**

	Operation	Operating mode	Precautions in addition to section 3) PRECAUTIONS
1.	Containment and transport	Safely transport to reprocessing area. It is recommended to reprocess the appliance as soon as possible after use.	
2.	Preparation before cleaning	For visible impurities observed on products, or when needed, mechanical pre-cleaning with a soft brush made from either nylon, polypropylene or acrylic is recommended. Manually brush the device for one minute until visible impurities are removed. Pay extra notice for the lumen on the device.	—
3.	Pre-cleaning and rinsing (option)	**Ultrasonic bath** - Immerse the device in the detergent solution with cleaning properties according to the manufacturer's instructions (a washing medium at 0,5% concentration including (according to Regulation (EC) No 648/2004) less than 5%: anionic/non-ionic surfactants and with pH 10 assisted by an ultrasonic device for at least 15 minutes in deionized water at temp 30°C. - For visible impurities observed on products: manually brush the product until visible impurities are removed (use a soft brush made from either nylon, polypropylene or acrylic). - Rinse thoroughly (at least 1 minute) under running tap water (ambient temperature).	—
4.	Automated cleaning with washer-disinfector **Cleaning** **Disinfecting** **Drying**	- Place the products in a kit, support or container to avoid any contact between products. 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. - Place the products in a washer-disinfector in accordance with EN ISO 15883-1+-2 with thermal program (temperature 90°C-95°C (194°F-203°F) and perform the defined cycle A0≥3000. - Use a detergent solution with cleaning properties (a washing medium at 0,5% concentration including (according to Regulation (EC) No 648/2004) less than 5%: anionic/non-ionic surfactants and with pH 10, was utilized for a minimum of 10 min. in deionized water at temp 55°C for Validation procedure).	Follow carefully the instruction provided by the disinfection solution manufacturer.
5.	Maintenance, inspection and testing	- Visually inspect the product with the naked eye under appropriate lighting (min. 500 lux) and discard if there are any defects (e.g. cracks, deformations, breakage, loss of marking). - Dirty products should be cleaned again.	

4. REPROCESSING INSTRUCTIONS

	Operation	Operating mode	Precautions in addition to section 3) PRECAUTIONS
6.	Packaging	- Place the products in a kit, support or container to avoid any contact between products. - Pack the products in “Sterilization pouches” (double-packaged using paper-plastic pouches for steam sterilization). - Seal the pouches according to the pouch manufacturer’s recommendations.	- Ensure that the pouches are suitable for steam sterilization (141°C, 286°F) and validated and manufactured as per ISO 11607 and EN 868-5. - If a thermo-sealer is used, the process must be validated and the thermo-sealer must be calibrated and qualified.
7.	**Sterilization**	- Place the pouches in the steam sterilizer according to the manufacturer’s recommendations. - Use one of the following sterilization cycles with the pre-vacuum air removal steam sterilizer (saturated steam and compliant with EN 13060 (class B, small sterilizer) and EN 285 (full-size sterilizer)): • 132°C-135°C (270°F-275°F), 4 minutes; • 134°C-137°C (273°F-278°F), 3 minutes; - We recommend steam sterilization at 134°C / 273.2°F for 3 minutes for deactivating potential prions. - Visually inspect the product with the naked eye under appropriate lighting (min. 500 lux) for packaging integrity, humidity, color change of packaging, positive physical-chemical indicators, and conformity of actual cycle parameters with the reference cycle parameters. - If visible signs of moisture are present (damp spots on sterile packaging, pooled water in the load) at the end of the sterilization cycle, repackage and re-sterilize using a longer drying time. - Store traceability records.	- Use a validated sterilization procedure according to ISO 17665 with a minimum drying time of 20 minutes. - Special attention should be paid to the packaging integrity if the 134°C (273.2°F) 3 minutes sterilization cycle is used. - Check the pouch’s validity period indicated by the manufacturer to determine the shelf life. - The owner is responsible for complying with the sterilizer’s maintenance procedure, which should be performed in accordance with the requirements on sterilizing medical devices (examples: planning for maintenance, qualification, acceptance criteria condensate and water as per EN 285, annex 2).
8.	Storage	- Keep sterilized packaged products in a clean environment, away from moisture and direct sunlight. Store at ambient temperature (typically 15°C-25°C (59°F-77°F). - In case of damage to the pouch, a complete processing cycle should be performed. - Check the packaging and the medical devices before using them (packaging integrity, humidity, and use by expiry date).	- After sterilization, the product should be handled with care to keep the packaging intact (sterile barrier). - Sterility cannot be guaranteed if the packaging is open, damaged, or wet.
	Additional information	The processing of medical devices should be done with validated processes.	
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The recommended instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as performed using equipment, materials, and personnel in the processing facility, achieves the desired results. This requires verification and/or validation and routine monitoring of the process.

ANNEX 1: LIST OF PRODUCTS COVERED BY THIS GUIDE

Type of product family	LM™ product code	Delivered in sterile condition	
LM-Activator™ (First generation)	**Ref . 94010LS** For a complete product code list ask your LM™ distributor	No	CE
LM-Activator™ 2	**Ref. 94235LSN** For a complete product code list ask your LM™ distributor	No	CE
LM-Activator™ 2 Reinforced	**Ref. 94235LSWR** For a complete product code list ask your LM™ distributor	No	CE
LM-Trainer™	**Ref. 94100T** For a complete product code list ask your LM™ distributor	No	CE
LM-OrthoSizer™	**Ref. 9400** For a complete product code list ask your LM™ distributor	No	CE
LM-Activator™ 2 OrthoSizer™	**Ref. 9402** For a complete product code list ask your LM™ distributor	No	CE

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