REPROCESSING GUIDE

for LM™ dental instruments

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 LM™ hand instruments, LM™ care and handling products, LM™ ultrasonic scaler tips and polisher nozzles as well as LM™ accessories that needs to be reprocessed before use.
Ask your LM™ distributor for a complete product code list.

INTRODUCTION

THE PROCESSING STEPS PROVIDED HEREIN

The following applies to the applicable LM™ products and their processing:

- All products are intended to be used in dental (or hospital) environments by qualified users.
- All products are supplied in a non-sterile condition. Processing prior to first use is required.
- All products mentioned in this guide are reusable products. Processing is required prior to reuse.
- Ask your LM™ distributor for a complete list of applicable products and corresponding product codes.

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 - washer-disinfector is the only method that is validated.

LM-Servo™ instrument cassettes and LM-ServoMax™ system

Use LM™ instrument cassettes to protect the instruments and avoid sharp injuries. LM-ServoMax™ system is an instrument handling and maintenance concept for dental professionals. It organizes and rationalizes the handling of dental instruments and accessories during the reprocessing procedures and maintenance. LM-ServoMax™ system facilitates a good hygiene control and saves your time by minimizing the handling of the individual items. The system prolongs the life span of instruments and protects the dental personnel. Read more at www.lm-dental.com/products/care and handling.

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.

WARNINGS

- Reusing these products without sterilization increases the risk of cross-contamination.
- Reusable products must be cleaned and sterilized prior to first use.
- The recommended maximum temperature of the steam sterilizer for reprocessing LM™ products is 134-137°C (273-278°F).
- A steel brush or any other sharp or abrasive tools are forbidden to be used for instrument cleaning as they will damage the metal blades and the silicone handles, thereby reduce the lifetime of the product.
- Do not use any abrasive tools for removing residue from LM Dark Diamond™ and LM Sharp Diamond™ instruments as they will damage the special coating and thus reduce the lifetime of the product.
- During the sterilization process, the residue may bake into the instrument handle resulting in discolorations.
- Do not soak any of LM™ products in lubricants.
- LM DTS™ product and the tagging might be damaged if it is heavily exposed to mineral oils.
- We don't recommend hot air sterilization but if anyway proceeding with this method note that the package of your product is marked with maximum sterilization temp of 180°C.
- Do not sterilize any of LM™ products in autoclaves that have oil residues in the chamber.

PRECAUTIONS

GENERAL

- Dispose of all sharp and 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 and exposure time impurity fixation).
- Always follow the instructions and concentrations provided by the manufacturer of the cleaning/disinfecting agent.
- Remove residue (especially filling materials residue) from instruments blades and handles while still soft.
- Avoid acidic detergents, use only neutral or (mildly) alkaline (pH 7–10) detergents.
- Protect instruments from abrasion and chafing when using cassettes. Use e.g. plastic, silicone, or comparable inserts in the cassettes, as applicable.
- Check the water softening settings of your thermo-disinfector and adjust them accordingly with the water hardness in your area. Avoid too high settings for the water softener.

FOR LM™ HAND INSTRUMENTS, LM™ ULTRASONIC SCALER TIPS AND POLISHER NOZZLES

Inspect the products before reuse and discard them in case of one of the following defects occurs:
breakage, loss of color coding or marking, bent instrument, damaged threads on scaler tips and polisher nozzles, damaged cutting surface, dull cutting blade, missing UDI code or product marking, or corrosion.

Note! LM-Dental™ does not specify a maximum number of reprocessing or usage cycles. As long as the condition of the instruments is adequate, as described above, their reprocessing and usage is safe.

MATERIAL RESISTANCE

Incorrect 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.

A non-exhaustive list of situations to avoid:

- NiTi products should not be fully immersed in NaOCl solution concentrate. Only the operative part, which is in contact with the patient, should be immersed. The NaOCl solution concentration shall not exceed 5%.
- Excessive concentrations or immersion / exposure times may cause corrosion or other defects in the products.
- Do not use detergents or soaking solutions that are incompatible with the products. Components to be avoided include: acids, aldehydes, amines, chlorine, lubricants, oxidizers, phenols.

It is recommended to use an appropriate alkaline (pH 7–10) detergent with disinfecting and corrosion inhibiting properties.

LM SHARP DIAMOND™ COATED SHARPEN FREE INSTRUMENTS

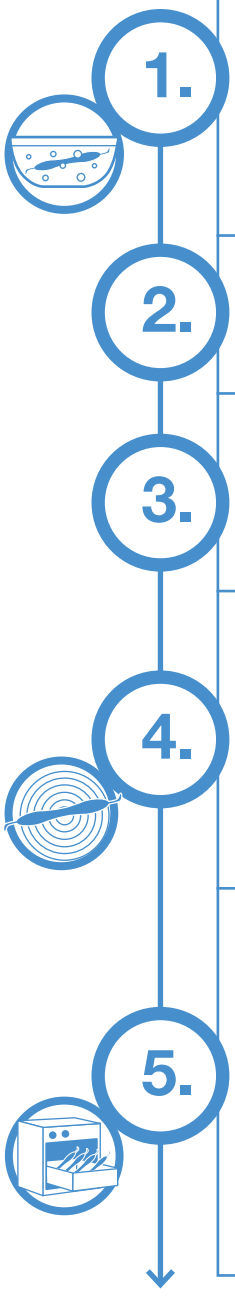
When processing LM Sharp Diamond™ instruments, the following precautions should be taken:

- It is recommended to clean the instruments immediately after use
- Avoid excessive brushing of the LM Sharp Diamond™ instrument tips. Only soft brushes should be used (e.g., nylon, polypropylene, or acrylic).
- Neutral to alkaline detergents (pH 7-10) should be used
- Chemicals containing acidic ingredients (e.g., citric- or phosphoric acid) should be avoided
- Neutralizing and rinsing agents should be avoided
- Rinse the instruments thoroughly after exposing them to any cleaning solutions
- Dry the instruments properly after washing. It is highly recommended to set the drying time and/or efficiency to as high as possible (when using e.g., a thermo-disinfector). If drying manually, use e.g., (medical) pressurized air or lint-free paper.

PROCESSING INSTRUCTIONS

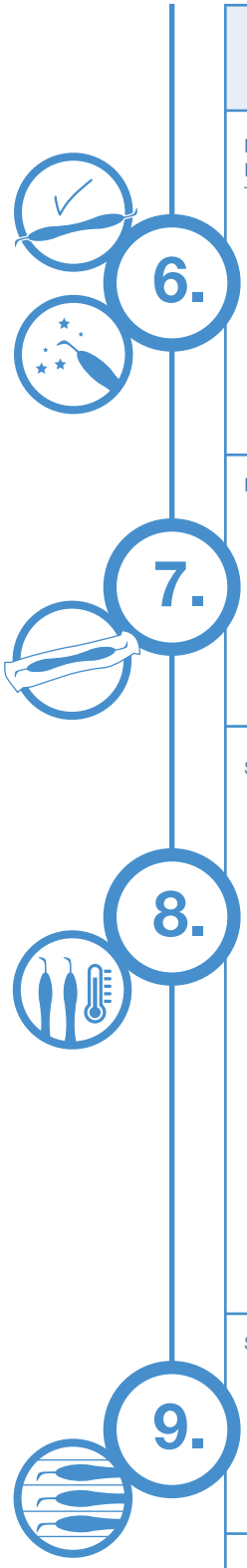
Processing instructions for LM™ hand instruments, LM™ care & handling products, LM™ ultrasonic scaler tips and polisher nozzles, and LM™ accessories.

All reusable products should be reprocessed before use (steps 1–9). Additionally, all products should be processed (steps 5–9) before first use.



OPERATION	OPERATING MODE	PRECAUTIONS (in addition to what is stated in section Precautions)
INITIAL TREATMENT AT THE POINT OF USE	Rinse the lumen line for one minute with cold tap water (minimum drinking quality, 20 ± 2°C) if the instrument has a lumen. Do not leave dirty instruments to dry. If the instruments have dried, soak all products in a pre-cleaning solution according to the manufacturer's instructions (aldehyde-free, pH 7–10, and intended for pre-cleaning of medical devices).	The pre-cleaning solution should be changed regularly i.e. when it becomes soiled, or when efficacy is diminished due to exposure to microbial loads. Only use clean soft brushes designed for this purpose. Do not use metal brushes.
CONTAINMENT AND TRANSPORT	Safely transport to reprocessing area. It is recommended to reprocess the medical devices as soon as possible after use.	
PREPARATION PRIOR TO 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 product until visible impurities are removed.	
PRE-CLEANING AND RINSING (optional)	For visible impurities observed on products: manually brush the instruments for one minute until visible impurities are removed (use a soft brush made from either nylon, polypropylene or acrylic). If needed, LM™ ultrasonic scaler tips and polisher nozzles may be pre-cleaned in an ultrasonic bath. Follow the instructions of the (ultrasonic) manufacturer regarding detergents and modes of operations. Rinse the instruments thoroughly after the ultrasonic cleaning and process the instruments normally.	Always place the products in a cassette, support or container to avoid any contact between products.
AUTOMATED CLEANING WITH WASHER-DISINFECTOR CLEANING DISINFECTION DRYING	Use an appropriate (pH 7–10) detergent solution, as specified by the manufacturer. Place the products in a cassette, support or container to avoid any contact between products. LM-Servo™ and LM-Servo™ E cassettes, and LM-ServoMax™ system are recommended to reprocess LM™ products. And if the washer-disinfector has special lumen adapters*) use that for products with lumen. Place the products in a washer-disinfector in accordance with EN ISO 15883-1+-2 with thermal program (temperature 90-95°C (194-203°F) and perform the defined cycle A0≥3000.	Pay particular attention to cutting edges and sharp edges, both to avoid injury and damage to the products. Follow carefully the instruction provided by the disinfection solution manufacturer. If available, a distilled or ion-exchanged water rinse should preferably be used.

*) Here you can use special rinsing adapters from washer-disinfector manufacturers special designed for LM™ ultrasonic scaler tips (Miele, Melag, IC Medical)



OPERATION	OPERATING MODE	PRECAUTIONS (in addition to what is stated in section Precautions)
MAINTENANCE, INSPECTION & TESTING	Inspect the product functionality (check the sharpness of cutting parts if applicable). Visually inspect the product under appropriate lighting and discard if there are any defects (e.g. cracks, deformations, breakage, corrosion, colour fading, or loss of markings). Dirty products should be processed again. If visible signs of moisture are present (e.g., droplets on the instruments and/or accessories) at the end of the washer-disinfector drying cycle, the instruments/accessories may be manually dried by either medical compressed air or appropriate lint-free cloth/paper prior to sterilization. Adjust the washer-disinfector's drying time settings appropriately.	
PACKAGING	Place the products in a cassette, support or container to avoid any contact between products. Pack the products in "Sterilization pouches" (double-packaged using paper-plastic pouches for steam sterilization). For sharp products that are not contained within a box, silicone tubes should be placed around the products to prevent piercing of the packaging. 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 thermosealer must be calibrated and qualified.
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).
STORAGE	Keep sterilized packaged products in a clean environment, away from moisture and direct sunlight. Store at ambient temperature (typically 15-25°C (59-77°F). In case of damage to the pouch, a complete new processing cycle should be performed. Check the packaging and the medical devices before using them (packaging integrity, humidity, and 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.
	The processing of medical devices should be done with validated processes.	
Manufacturer contact	LM-Instruments Oy, Norrbyn rantatie 8, FI-21600 Parainen, Finland info@lm-dental.com, tel. +358 2 45 46 400, www.lm-dental.com	

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.