PATTERSON DENTAL

Reprocessing of dental hand instruments and accessories

Fundamental Points

All non-sterile instruments are to be cleaned, disinfected, and sterilized prior to each use, and also prior to first use.

The person responsible for reprocessing (i.e., the operator) is responsible for proper instrument reprocessing using onsite equipment and safe procedures that are validated for cleaning, disinfection, and sterilization. The sterilization equipment must also be maintained and checked per the manufacturer's recommendation as well as the validated parameters applied to each cleaning and sterilization cycle.

Additionally, consider the legal provisions valid for your country as well as to the hygienic instructions of the doctors, practice, or hospital. Use only freshly prepared detergent solutions, as well as only low contaminated and deionized water (maximum 10 cfu/ml) as well as low endotoxin contaminated water (maximum 0.25 endotoxin units/ml), i.e., aqua purificata (highly purified water acc. Pharmacopeia), and HEPA-filtered air for drying, respectively.

Water quality may influence the result of the cleaning and disinfection of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. With the use of completely deionized or distilled water most water quality problems can be avoided beforehand.

Using an instrument management system gives you considerable benefits. It is the ideal solution for arranging your instruments in an organized manner, cleaning, disinfecting, sterilizing and storing in an efficient way, providing maximum security.

Receiving a New Instrument

After receiving a new instrument, make sure you follow the initial cleaning, disinfection and sterilization steps before using it for the first time. This step is essential for the patient's health.

Instrument Reprocessing Steps

If possible, an automatic procedure in a Washer/Disinfector unit should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automatic procedure is not available or if such a method is not compatible with specific materials; in this case, the significantly lower efficiency of a manual procedure must be considered. The pre-treatment has to be performed in both cases.

All assembled instruments must be disassembled before reprocessing (for further details, please see Special Procedures section). Effective cleaning and disinfection are an indispensable requirement for proper instrument sterilization.

Pre-Treatment

Before processing the instruments, remove coarse impurities on the instruments immediately after application and pre-treatment within one hour from the application. In case the instruments are transported to an external service provider, ensure the instruments remain soaked to avoid fixation of proteins, e.g., by using a pre-cleaning product such as Enzymax Spray Gel.

Use an enzymatic cleaner or a disinfectant solution during pre-soaking.

The disinfectant should...

- be free of aldehydes to prevent fixation of blood impurities
- possess a fundamentally approved efficiency
- be suitable for the disinfection of medical devices, and
- be compatible with the instruments (see Material Resistance section and Special Procedures section)

Consider that the disinfectant used in the pre-treatment step serves only for personal safety, and cannot replace the disinfection step, which should be performed later. Only use soft brushes.

Procedure:

1. Completely disassemble the instruments, if applicable.
2. Pre-soak the devices for at least 5 minutes* and make sure that all surfaces are wetted and lumens are filled with water.
3. Brush the instruments to remove residues from the surface, paying special attention to lumens and dead ends. Also make sure that movable parts are brushed in open and closed position.
4. Difficult-to-reach positions such as hinges, mating surfaces, lumens or dead ends shall be flushed at least 3 times with minimum 50 ml cold deionized water, using a syringe or a rinsing adapter.*

* These parameters are validated for Enzymax Liquid. For other cleaning agents and disinfectants, the instructions of the manufacturer must be observed.

Cleaning and Disinfection

Automatic Cleaning and Disinfection in a Washer-Disinfector Unit

When using a Washer-Disinfector unit, make sure that...

- the efficiency is fundamentally approved
- your process is validated, including equipment, detergents, temperatures, durations and loading, and
- regular maintenance and inspection/calibration is done

For the selection of detergents to be used with the Washer-Disinfector unit, consider the following items:

- Fundamental suitability for cleaning of medical devices
- Compatibility with the instrument materials (see Material Resistance section and Special Procedures section)
- Detergent manufacturer instructions regarding concentration and soaking time

Procedure:

1. Connect devices with lumen to flush ports in the Washer-Disinfector.
2. Load the Washer-Disinfector as validated.
3. Start the validated program.
4. Remove the instruments after end of program. Let the instruments dry.
5. Conduct post-disinfection steps.

The fundamental suitability of the instruments for an effective automatic cleaning and disinfection was demonstrated by an independent accredited test laboratory under the following conditions:

Washer-Disinfector	Miele Professional G 7836 CD
Racks	Mobile injector unit (Miele) E429, Four-level rack (Miele) E493
Cleaning Cycle	• 2 minute pre-cleaning with cold tap water • Draining • 5 minute cleaning with 55°C cleaning solution • Draining • 3 minute rinsing with cold deionized water • Draining • 2 minute rinsing with cold deionized water • Draining
Cleaning Solution	0.5% cleaning solution neodisher® Mediclean Dental (Chemische Fabrik Dr. Weigert, Hamburg)

The responsibility for reprocessing of instruments according to parameters which are not specified in this document lies with the customer.

Manual and Ultrasonic Cleaning and Disinfection

For the selection of detergents to be used for manual cleaning and disinfection, consider the following items:

- Fundamental suitability for cleaning of medical devices.
- Approved efficiency.
- Compatibility with the instrument materials (see Material resistance section and Special Procedures section).
- Detergent manufacturer instructions regarding concentration, temperature and soaking time.

Combined cleaning/disinfection solutions should be used only in the case of extremely low contamination (no visible impurities), unless indicated explicitly otherwise by the manufacturer of the combined detergent/disinfectant.

Cleaning procedure:

1. Place the devices in an ultrasonic bath containing a cleaning solution at min. 45°C for at least 15 minutes.*
2. At the beginning of the soak time flush the lumens with 5 ml of the cleaning solution using a syringe.
3. Non-rigid components shall be operated during the immersion.
4. Difficult-to-reach positions such as hinges, mating surfaces, lumens or dead ends shall be flushed at least 3 times with minimum 50 ml cold deionized water, using a syringe or a rinsing adapter.*
5. Remove the instruments from the cleaning solution.
6. Rinse the instruments under running water for at least 1 minute.
7. Inspect optically for proper cleaning.

* These parameters are validated for Enzymax Liquid. For other cleaning agents and disinfectants, the instructions of the manufacturer must be observed.

Disinfection procedure:

1. Soak the devices in the disinfectant solution for the duration intended by the disinfectant manufacturer.
2. Make sure they are completely immersed.
3. Difficult-to-reach positions such as hinges, mating surfaces, lumens or dead ends shall be flushed with the disinfectant, using a syringe or a rinsing adapter.
4. Non-rigid components shall be operated during the immersion.
5. Remove the instruments from the disinfectant.
6. Rinse the instruments under deionized water for at least 1 minute.
7. Let the instruments dry.
8. Conduct post-disinfection steps.

The fundamental suitability of the instruments for an effective automatic cleaning and disinfection was demonstrated by an independent accredited test laboratory under the following conditions:

Cleaning Solution	0.8 % Enzymax Liquid

The responsibility for reprocessing of instruments according to parameters which are not specified in this document lies with the customer.

Post-Disinfection Steps

Inspection and Maintenance
If there are still contaminations attached to the instruments, clean and disinfect again.

Inspect all instruments after the cleaning and disinfection step for corrosion and damaged surfaces. Light corrosion on the surface can be removed. After treating an instrument with IPS, the instrument must be cleaned and sterilized once more. If the corrosion cannot be eliminated or other surfaces are identified, do not further use those instruments.

Keep in mind that instruments shall no longer be reused in case the labeling is fading.

Re-sharpen instruments if necessary. Afterwards, completely remove any residues, such as metal residue or sharpening oil. Assemble disassembled instruments if necessary (see Special Procedures section).

Hinged instruments have to be lubricated with a lubricant suitable for steam sterilization.

Packaging

All instruments must be completely dry before packaging. Then, package immediately.
We recommend the use of a cassette system and sterilization pouches, sterilization wrap, or suitable sterilization containers, if the following requirements are fulfilled:

> Conformity with EN ISO/ANSI AAMI ISO 11607-1 and -2 and applicable parts of EN 868 suitable for steam sterilization (temperature resistance up to at least 141°C (286°F), sufficient steam permeability), sufficient protection of the instruments and the sterilization packaging against mechanical damage, regular maintenance according to the manufacturer's instructions (Sterilization Containers: limitations; also see Special Procedures section).

Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.
Restrictions:

- The flash sterilization procedure must not be used!
- Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization!
- The application of dry heat sterilization is the responsibility of the user. For some products the dry heat sterilization procedure has been explicitly excluded (please see Special Procedures section).

Steam Sterilization

For sterilizing, please remember the following:

- Maximum sterilization temperature of 138°C (280°F)
- Minimum exposure time to sterilization temperature:
  - 20 minutes at 121°C (250°F), or
  - 5 minutes at 132°C (270°F)
  - 4 minutes at 134°C (273°F)
- The manufacturer's instructions with respect to routine inspection and the regular maintenance of the sterilizer must be observed.
- The sterilizer must be maintained per manufacturer's recommendation.
- Only low contaminated and deionized water (i.e., aqua purificata) should be used.
- The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

Sterilization procedure:

1. Use properly installed and validated sterilizers, following instructions of the manufacturer.
2. Load sterilizer as recommended by the manufacturer.
3. Run validated program.

The fundamental suitability of the instruments for an effective sterilization was demonstrated by an independent accredited test laboratory under the following conditions:

Sterilization Method	Pre-vacuum Mode
Sterilizer	W&H Lisa MB 17 Steam Sterilizer
Sterilization Temperature	134°C (273°F)
Pre-vacuum Phases	3
Holding (full cycle)	4 minutes
Drying Time	30 minutes*

The responsibility for reprocessing instruments according to parameters which are not specified in this document lies with the customer.

Transport and Storage of Reprocessed Instruments

Please store the instruments after sterilization in a dry and dust-free place.
Sterilization can only be maintained if the instruments remain packaged or wrapped – impermeable to microorganisms – following validated standards. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. In case the reprocessed instrument is transported, make sure to use air-conditioned vehicles in order to avoid condensate formation. For safety reasons, keep sterile and non-sterile instruments strictly apart.

Material Resistance

1. We recommend not to use detergents such as strong alkalines (> pH 9), strong acids(< pH 4) phenols or iodophors, interhalogenic agents/halogenic hydrocarbons/iodophors, strong oxidizing agents/peroxides and organic solvents.
2. Do not clean any instruments, sterilization trays, or sterilization containers using metal brushes or steel wool!
3. Do not expose any instruments, cassettes, trays, or sterilization containers to temperatures higher than 141°C (286°F)!
4. Exposure to higher temperatures is the responsibility of the user.

Please also consider the information under the Special Procedures section.

Reusability and Single Use

Reusability

1. The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments.
2. The instruments can be reused, unless indicated otherwise (see Special Procedures section).
3. The lifetime of instruments depends on the frequency of use, the care by the user and proper reprocessing methods.

Single Use

Single-use instruments are intended and manufactured for one use only.

Special Procedures for Specific Instruments

Hinged Instruments	Processing: Process in an open state and lubricate using instrument lubricant spray (ILS) prior to sterilization.
Oversized Instruments	Note: If instruments do not fit in cassettes, other systems should be considered for reprocessing.
Mouth Gags	Processing: When using a cassette system for cleaning/sterilization, the opening where the nylon tubing slips over the instrument tip must not be covered so as to allow the tips to properly drain. Clean, disinfect, and sterilize in a completely disassembled state.
Mouth Mirrors	Processing: To avoid scratches on the mirror surface from other pointed instruments, reprocess in an instrument cassette with instrument rails. Clean, disinfect, and sterilize in a completely disassembled state. Cleaning/Disinfection: Note: All types of rhodium-coated mouth mirrors should not be cleaned and disinfected in an ultrasonic cleaner.
Plastic Filling Instruments	Processing: Process in cassettes or trays with instrument rails to avoid scratches on the surface from other pointed instruments. Maintenance: Residues of filling materials and etching products must be removed immediately. Plastic filling instruments are designed with an extra smooth surface, in order to provide better handling with composite materials. Scratches that are not visible might cause composite materials to stick to the rougher surface.
Retractors, Metal	Processing: Removable retractor tips must be disassembled from the handle before cleaning/disinfection and sterilization.
Root Canal Instruments	Processing: Reprocess in suitable endodontic stands. Cleaning/Disinfection: Pre-treatment should be conducted outside the endodontic stand. Automated cleaning and disinfection in a washer-disinfector unit is recommended. Ultrasonic cleaning in the endodontic stand is not recommended.
Scalpel Handles	Processing: Clean, disinfect and sterilize in a completely disassembled state.
Scaler Marked with Color Coding Rings	Processing: For reprocessing, attached color coding rings do not have to be removed.
Syringes	Processing: Completely disassemble including unscrewing of the cylinder.

Ultrasonic Inserts, Magnetostrictive	Processing: Ultrasonic cleaning and disinfection as well as steam sterilization can be affected in suitable cassettes. Cleaning/Disinfection: For automated cleaning and disinfection in a washer-disinfector unit connecting rinsing adapters must be used, if the inserts are processed inside a cassette system. Otherwise open tray systems for the automated cleaning and disinfection or alternatively the manual cleaning and disinfection procedure are recommended. Sterilization: For sterilization use steam sterilization only. Do not expose to phenols or iodophors. Do not use dry heat sterilization, or heat above 135°C (275°F).
Ultrasonic Inserts, Piezo with Guardian	Processing: Piezo Ultrasonic Inserts remain in the Guardian during the complete reprocessing cycle, also if reprocessed in cassettes. Ultrasonic cleaning and disinfection as well as steam sterilization can be affected in suitable cassettes. Sterilization: For sterilization use steam sterilization only. Do not expose to phenols or iodophors. Do not use dry heat sterilization, or heat above 135°C (275°F).
Ultrasonic Piezo Handpiece	Sterilization: The Piezo handpiece can be steam sterilized with all types of steam sterilizers at 134°C/15 minutes. Other sterilization parameters are not permitted.

Manufactured for:
Fabriqué pour :

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