Zoll Dental – Instructions for Use

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REPROCESSING DENTAL HAND INSTRUMENTS AND ACCESSORIES

1.0 Overview

All instruments must be cleaned and sterilized prior to each use, including the first use of non-sterile instruments after removal from the protective packaging. Effective cleaning is an indispensable requirement for proper instrument sterilization.

The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning and sterilization cycle.

Consider 3.0 Special Procedures section for processing exceptions of specific instruments.

Additionally, consider the legal provisions valid for your country as well as to the hygienic instructions of the doctor's practice or hospital.

2.0 Steps for Instrument Reprocessing

2.1 Cleaning

2.1.1 Basics

If possible, an automatic procedure in a dental instrument washer or ultrasonic bath should be used for cleaning of the instruments.

A manual procedure, such as hand scrubbing, should only be used if an automatic procedure is not available, if debris is remaining after automated cleaning, 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 step is to be performed in both cases.

All assembled instruments must be disassembled before reprocessing (for further details, please see 3.0 Special Procedures section).

For the protection of staff members, all used and contaminated Instruments must be handled with protective utility gloves. Contaminated instruments must be cleaned as early as possible in the reprocessing process, in order to maximize safety for staff members when handling contaminated instruments.

2.1.2 Pre-Treatment

Before processing the instruments single or in a tray or cassette system, remove coarse impurities on the instruments immediately after application (within a maximum of two hours). Instruments with impurities have to be pre-treated within two hours from the application.

Use an enzymatic cleaner or a precleaning product. When using an enzymatic cleaner, pre-soak for 3-5 minutes at 89.6°F (32°C). For other cleaning agents and disinfectants, the instructions of the manufacturer must be observed.

For manual removal of coarse impurities, use only a soft brush or a long handled soft brush. Never use metal brushes or steel wool.

2.1.3 Automatic Washer Disinfector

Items to consider when using an automated washer disinfector:

- fundamentally approved efficiency of the washer disinfector
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post rinse only with low contaminated and deionized water (max. 10 germs/ml, max. 0.25 endotoxin units/ml) for example purified water
- only use filtered air for drying
- regular maintenance and inspection/calibration of the washer disinfector.

Items to consider for the selection of detergents to be used with the automated washer disinfector:

- fundamental suitability for cleaning of instruments
- additional application
- if instruments are not compatible with the automated washer, please follow the recommended instructions for the manual cleaning
- compatibility of the detergents with the instruments (see 2.7 Material resistance section and 3.0 Special Procedures section).

The use of a cassette system is recommended (limitations see 3.0 Special Procedures section). Consider the instructions of the detergent manufacturers regarding concentration and soaking time.

Procedure:

1. Completely disassemble instruments if applicable.
2. Place the disassembled instruments in a cassette or any other tray system suitable for the instrument, and place it in the automated washer disinfector (no contact between the instruments). If applicable, connect the instruments by use of a suitable rinsing adapter to the rinsing port of the automated washer disinfector.
3. Start the program.
4. Remove the instruments from the automated washer disinfector after end of the program.
5. Inspect and package the instruments immediately after removal (see sections 2.2 Inspection, 2.3 Maintenance, and 2.4 Packaging). If necessary, allow post drying step in a clean place.

2.1.4 Manual and Ultrasonic Cleaning

2.1.4.1 General Information

Consider the following items during selection of the cleaning detergents:

- fundamental suitability for the cleaning of dental instruments
- compatibility of the detergents used with the instruments (see 2.7 Material Resistance section and 3.0 Special Procedures section)
- powder based cleaners have to be dissolved completely in water before immersing the instruments into the solution
- observe the instructions of the manufacturer with respect to the concentration of the cleaning solution, the time of exposure and the temperature.

Consider the instructions of the detergent manufacturers regarding concentration and soaking time. Please use only freshly prepared solutions as well as only low contaminated and deionized water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), i.e., purified water, and filtered air for drying, respectively.

Hollow instruments, like aspirator tips, have to be immersed at declined angle, in order to de-aerate the hollow channels.

2.1.4.2 Manual Cleaning

Procedure:

1. Completely disassemble the instruments, if applicable.
2. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed.
3. Remove the instruments from the cleaning solution and post rinse them extensively with low contaminated and deionized water (i.e., purified water).
4. Inspect the instruments for proper cleaning.
5. Thoroughly dry prior to packaging for sterilization.

2.1.4.3 Ultrasonic Cleaning

Procedure:

1. Completely disassemble the instruments if applicable. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed. Use the processing time recommended by the manufacturer of the detergent and/or the cassette system. Note: There should not be any contact between the instruments.
2. If you are using a cassette system, the ultrasonic cleaning time has to be at least 16 minutes, unless a longer exposure time is required by the manufacturer of the detergent. Do not overload the ultrasonic cleaning unit. Use “Sweep Mode” if available.
3. Remove the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water (i.e., purified water) for best results.
4. Inspect the instruments for proper cleaning.
5. Thoroughly dry prior to packaging for sterilization.

2.2 Inspection

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. Do not further use damaged instruments. If instruments are still visibly soiled, clean again. Sharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil. In case sharpening is done, remember to repeat the cleaning and sterilization process.

2.3 Maintenance

Light corrosion on the surface can be removed with low-viscosity, penetrating oil. If the corrosion cannot be completely eliminated, the instruments should be removed from use. Otherwise, such corrosion could damage other instruments. After treating an instrument with penetrating oil, the instrument must be cleaned and sterilized once more.

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

2.4 Packaging

We recommend the use of a cassette system and sterilization pouches, or suitable sterilization containers, if the following requirements are fulfilled:

- FDA approved
- 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 (also see 3.0 Special Procedures section)
- make sure the devices are completely dry before packaging.

2.5 Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user. Zoll Dental recommends a minimum 30-minute dry time; however, defer to the manufacturer's instructions for the equipment used

2.5.1 Steam Sterilization

- fractionated vacuum or gravity procedure
- sufficient product drying must be ensured after sterilization and before handling, see table below for recommendations.
- steam sterilizer according to or AAMI/ANSI ST55 and AAMI/ANSI ST8
- validated according to or ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))

Minimum cycle times for gravity-displacement steam sterilization cycles

Item	Exposure time at 250ºF (121ºC)	Drying time
Wrapped instruments	30 Minutes	Minimum 30 minutes

Minimum cycle times for dynamic-air-removal steam sterilization cycles

Item	Exposure time at 250ºF (121ºC)	Drying time
Wrapped instruments	4 Minutes	Minimum 30 minutes

NOTE: These tables represent the variation in sterilizer manufacturer's recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

2.5.2 Inspection and Maintenance Recommendations for Steam Sterilizers

- The manufacturer's instructions with respect to routine inspection and the regular maintenance of the sterilizer must be observed.
- The sterilizer must be cleaned on a regular basis.
- Only low contaminated and deionized water (i.e., purified water) should be used.
- The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

2.5.3 Restrictions

- Immediate-use sterilization (flash sterilization) should not be a facility's primary source of sterilization. When used follow manufacturer's instructions for use.
- 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 3.0 Special Procedures section).

2.6 Storage

Please store the instruments after sterilization in a dry and dust-free place in the clean section of the instrument processing area. Sterilization can only be maintained if the instruments remain packaged or wrapped—impermeable to micro-organisms—following validated standards. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers. For safety reasons, keep sterile and non-sterile instruments strictly apart.

2.7 Material Resistance

Detergents or disinfectants containing the following substances must not be used:

- strong alkalines (> pH 9)
- strong acids (< pH 4)
- phenols or iodophors
- interhalogenic agents/halogenic hydrocarbons/iodophors
- strong oxidizing agents/peroxides
- organic solvents.

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool.

Please also consider the information under the 3.0 Special Procedures section.

Water quality may influence the result of the cleaning 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 the area. With the use of completely deionized or distilled water most water quality problems can be avoided beforehand.

2.8 Reusability

The instruments can be reused, unless indicated otherwise. The lifetime of instruments depends on the frequency of use, the care of the user, and proper reprocessing methods. The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments (no liability in case of disregard). Sharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil. In case sharpening is done, remember to repeat the cleaning and sterilization process.

2.9 Single-Use Instruments

Single-use instruments are intended and manufactured for one use only. They must not be reprocessed.

3.0 Special Procedures

Amalgam Carriers	**Maintenance after Use:** Fully depress the lever, expelling unused amalgam. Submerge the barrel in isopropyl rubbing alcohol for 30 seconds and work the lever several times. All amalgam residues have to be removed. Special instructions if Amalgam is hardened in the Amalgam Carrier: If the above-mentioned measures fail to free the amalgam, grasp the barrel and gently twist it. Never apply any part of the carrier into a flame as this distorts the alignment of the instrument, tempers the metal and releases small amounts of vaporized mercury from the amalgam into the atmosphere. **Cleaning**: Automated cleaning in an automated washer disinfector is recommended. Do not use chemical disinfection (cold sterilization); these chemicals may damage the Amalgam Carrier. After the cleaning apply a lubricant. **Sterilization:** For sterilization use steam sterilization (gravity or fractioned vacuum procedure) only.
Aspirators and Aspirator Tips	**Processing:** Clean and sterilize only in a completely disassembled state. **Cleaning**: For automated cleaning in an automated washer disinfector connecting rinsing adapters have to be used, if the inserts are processed inside a cassette system. Otherwise, open tray systems for automated cleaning or manual cleaning is recommended (**no Ultrasonic cleaning!**).
Burs	**Processing:** We recommend the use of a bur stand for reprocessing. **Cleaning:** In a suitable bur stand the burs, drills and trephines can also be reprocessed in an automated washer disinfector if they are not single use only products. Pre-treatment should be conducted outside of the bur stands. Deterioration can rapidly occur on the bur cutting surface even after one single use and/or repeated re-processing cycles. Evaluate each bur prior to use for wear. Burs that are worn out will not cut efficiently and may generate excessive heat, vibration, and require the use of excessive force. Visually inspect burs for particle build up and/or debris. Remove all contaminants from the bur surface prior to sterilization; if necessary, mechanically clean using a nylon brush. Do not allow the burs to touch each other during cleaning. Corroded, worn out, and/or damaged burs should be discarded. Re-use of burs is at the sole discretion of the end user.

Composite 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. Composite Instruments are designed with an extra smooth surface, in order to provide a better handling with composite materials. Scratches that are not visible might cause composite materials to stick to the rougher surface.
Hinged Instruments	**Processing:** Process in an open state and lubricate prior to sterilization.
Implant Scalers	**Processing:** Clean and sterilize separately. Do not clean or sterilize with other stainless steel instruments.
Mouth Mirrors	**Processing:** To avoid scratches on the mirror surface from other pointed instruments, reprocess in an appropriate accessory such as a parts box or clip in a cassette. Clean and sterilize in a completely disassembled state.
Osteotomes with Stops	**Processing:** Clean and sterilize in a completely disassembled state if applicable.
Instruments or Cassettes with Resin or Silicone Components	**Cleaning:** For resin or silicone products, do not use detergents or disinfectants containing phenols or iodophors.
Retractors	**Processing:** Removable retractor tips must be disassembled from the handle before cleaning and sterilization.
Syringes (all types)	**Processing:** Completely disassemble including unscrewing of the cylinder.
Temporary Crown Removers	**Cleaning**: Do not disinfect with phenols or iodophors. **Sterilization:** Do not sterilize with dry heat.
Oversized Instruments	**Processing:** If instruments do not fit in cassettes, other systems should be implemented.

4.0 Legend of Symbols on Labels

Symbol	Symbol Title	Explanation
	Medical Device	Indicates the item is a medical device.
	CE marking	‘CE marking of conformity’ or ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing.
	Caution	To indicate that caution is necessary when operating the device.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Manufacturer	Indicates the medical device manufacturer.
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community / European Union.

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