INSTRUMENT MANAGEMENT

Reprocessing Guidelines



Cleaning

If possible, **an automatic procedure in a dental instrument washer unit should be used** for cleaning 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.

NOTE:

- The pre-treatment step is to be performed in both cases.
- All assembled instruments must be disassembled before reprocessing (for further details, please see Special Procedures reference sheet).
- Puncture-/chemical-resistant utility gloves should be worn when handling contaminated instruments and when performing instrument cleaning and decontamination procedures.

Pre-treatment

Before processing the instruments individually or in a tray or cassette system, **remove coarse impurities** on the instruments immediately after application (within a maximum of 2 hours). Instruments with impurities have to be pre-treated within two hours of the application.

Use an enzymatic cleaner, like Enzymax™ Dual Enzyme Ultrasonic Detergent or a precleaning product such as Enzymax™ Spray Gel Ready to-Use Instrument Pre-Cleaner. When using Enzymax™ Enzymatic Cleaner, pre-soak for 3-5 minutes at 89.5°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.

If applicable: Rinse all lumens (the space in the interior of a hollow tube or area that can collect debris. Ex. Aspirator) of the instruments five times with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.

Automatic Cleaning (automated washer unit)

Make sure to place the cassettes so that rinse arms are not blocked.

Check the detergent manufacturer's instructions for soaking time and detergent concentration. Write the time and measurment below for quick reference.

Cycle time:	
Concentration:	

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 unit (no contact between the instruments). If applicable: Connect the instruments to the rinsing port of the washer-disinfector unit, e.g., stainless high volume suction tips.
3. **Start** the cycle.
4. **Remove the instruments** from the automated washer unit after end of the cycle.
5. **Inspect and package** the instruments immediately after removal.

PROPERLY LOADED AUTOMATED WASHER



HuFriedyGroup recommends the use of **Washer-Disinfector Cleaning Monitors** to assure your cleaning process achieves the highest quality results. (**IMS-1200W**, **IMS-1200H**)

Maintenance (automated washer unit)

Assemble disassembled instruments if necessary (see Special Procedures reference sheet).

Light corrosion on the surface can be removed with Shine reNEW™ Instrument Wipes (**IMS-1455**).

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 Shine reNEW™ Instrument Wipes, the instrument must be cleaned and sterilized. Repeat cleaning and sterilization.

Hinged instruments have to be lubricated with a lubricant suitable for steam sterilization, like Instrument Lubricant Spray (ILS).

Manual and Ultrasonic Cleaning

Consider the following when picking a cleaning detergent:

- Powder based cleaners have to be dissolved completely in water before immersing the instruments into the solution.
- Check the manufacturer's instructions for the appropriate concentration, time of exposure, and temperature. Write those below for quick reference.

Exposure time:		**Current Ultrasonic Gallon Capacity:**	
Concentration:			

Use only freshly prepared solutions and purified water. Only low contaminated and deionized water (max. 10 germs/ml) and low endotoxin contaminated water (max. 0.25 endotoxin units/ml) should be used. Keep air filtered for drying, with the same deionized and endotoxin levels as above.

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

MANUAL CLEANING

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. If applicable: Rinse all lumens of the instruments five times at the beginning and at the end of the soaking time with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.
3. **Remove** the instruments from the cleaning solution and post rinse them intensively with low contaminated and deionized water.
4. **Inspect the instruments** for proper cleaning.

ULTRASONIC CLEANING

Use appropriate baskets/racks as recommended by the equipment manufacturer.

5. 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. If applicable: Rinse all lumens of the instruments five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 50 ml).
6. If you are using the IMS 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 modus" if available.
7. For best results, **Remove the instruments** from the cleaning solution and post rinse them intensively with low contaminated and deionized water.
8. **Inspect the instruments** for a good cleaning result. Inspect all instruments for corrosion, damaged surfaces, and impurities. Do not use damaged instruments anymore! (For limitation of the numbers of re-use cycles, see 3.8 Reusability section). If instruments are still dirty, clean again. Resharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil.

HuFriedyGroup recommends the use of Ultrasonic Cleaning Monitors to assure your cleaning process achieves the highest quality results. (**IMS-1200U**, **IMS-1200H**)

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Packaging

Ensure all instruments and cassettes are dry before packaging for sterilization.

After cleaning, critical & semicritical instruments should be inspected for remaining debris.

- **An internal chemical indicator should be placed inside each instrument package** prior to sterilization. If the internal indicator is not visible from outside the package, an external indicator should be affixed to the pack.
- **Packages should be labeled** with the date and, if multiple sterilizers are used within the facility, the sterilizer used should also be labeled. (This simplifies retrieval of processed items in case of a sterilization failure.)

When packaging instruments and cassettes, **ensure packaging does not have open gaps**.

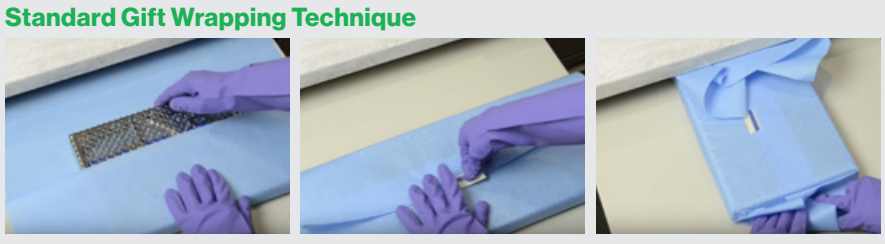
HuFriedyGroup recommends the use of Bagette™ Self-Sealing Sterilization Pouches, IMS™ Cassette Wrap, Crosstex™ Sure-Check™ and Duo-Check™ Self-Sealing Sterilization Pouches or suitable sterilization containers.

STERILIZATION PACKAGING REQUIREMENTS:

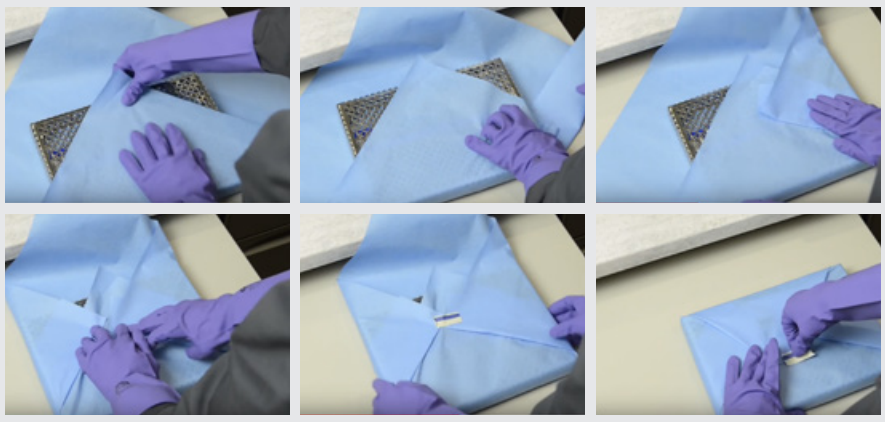
- FDA cleared medical device
- Suitable for steam sterilization (temperature resistance up to at least 286°F (141°C) with sufficient steam permeability)
- Sufficient protection of the instruments and the sterilization packaging against mechanical damage
- Sterilization wrap should be used in accordance with the recommendations of the following standards:
  - ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
  - CDC Guidelines for Infection Prevention in Dental Healthcare Settings

COMMON DOUBLE SIMULTANEOUS WRAPPING TECHNIQUES

Standard Gift Wrapping Technique



Hospital Style Wrapping Technique



Sterilization

Use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user. HuFriedyGroup recommends a **minimum 30 minute dry time**; however defer to the sterilizing manufacturer's instructions for the equipment used.

STEAM STERILIZATION

- Use fractionated vacuum or gravity procedure sterilizers.
- Sufficient product drying must be ensured after sterilization and before handling; see below for recommendations.
- Must follow AAMI/ANSI ST55 and AAMI/ANSI ST8
- Must use ANSI/AAMI ST 79 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))

Minimum Cycle Times for Wrapped Instruments:

Gravity-displacement steam sterilization*:

Exposure time at 250°F (121°C): 30 minutes

Drying time: Minimum 30 minutes

Fractionated vacuum/dynamic-air-removal steam sterilization*:

Exposure time at 270°F (132°C): 4 minutes

Drying time: Minimum 30 minutes

*This represents the variation in sterilizer manufacturers' recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer's recommendations.

Inspection and Maintenance Recommendations for Steam Sterilizers:

- The manufacturers' instructions with respect to routine inspection and the regular maintenance of the sterilizer must be observed.
- Follow the equipment manufacturer's recommendations for load/weight capacity.
- Cassettes and/or instrument packs are not recommended to be stacked on top of one another. Use appropriate racks as recommended by the equipment manufacturer.
- 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.

PROPERLY LOADED STERILIZER



Restrictions:

The flash sterilization procedure must not be used.

DO NOT use radiation sterilization, formaldehyde sterilization, ethylenoxide 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 reference sheet).

Storage & Reuse

STORAGE

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 nonsterile instruments strictly apart.

REUSABILITY

The instruments can be reused, unless indicated otherwise (see Special Procedures reference sheet) The life time 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).

Single use instruments are intended and manufactured for one use only. They must not be reprocessed (exceptions: please see Special Procedures reference sheet).

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Special Procedures

Some instruments require special care due to their unique shape or material. Please become familiar with this list and check to be sure your instruments are cared for properly.

360 KNIFE (K360)

Processing: **Clean, disinfect and sterilize with fixation screw unscrewed.**

ALUMINIUM INSTRUMENTS

Cleaning: Use neutral cleaning agents suitable for Aluminium. Check cleaning agent label for precautions for use with Aluminium. **Do not clean in an ultrasonic cleaner.** Clean by hand or in an automated washer disinfector.

Processing: Note: Anodized aluminium instruments, when processed with Stainless Steel instruments may cause an adverse chemical reaction.

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 (recommended lubricant: ILS).

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, DRILLS, DIAMOND COATED BURS

Processing: We **recommend the use of a bur stand** for reprocessing (i.e. IMS-1372S or IMS-1372T also available in Trephines half size.

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. Reprocessing of diamond burs should be validated by the end user facility in accordance with local laws and regulations.

CARBON STEEL INSTRUMENTS

Processing: Clean and sterilize separately. **Do not clean or sterilize with other stainless-steel instruments.** Do not clean in an automated washer-disinfector. After cleaning and prior to sterilization, use a proclave emulsion.

CHU'S AESTHETIC TOOL KIT TIPS

Processing: **Clean and sterilize with tip and handle disassembled.** The tip will last for approximately 5 reprocessing cycles. Tips with fading markings should be replaced. **Do not disinfect with phenols or iodophors. Do not use dry heat.**

COLORVUE™ PROBES

Processing: **Clean and sterilize with tip and handle disassembled.** The tip is disposable and will last about 30 reprocessing cycles. Tips with a fading black marking should be replaced. **Do not disinfect with phenols or iodophors. Do not use dry heat or rapid heat sterilization.**

CROWN REMOVER (CRL AND CRU)

Cleaning: **Do not disinfect with phenols or iodophors.**

Sterilization: **Do not sterilize with dry heat.**

HINGED INSTRUMENTS

Processing: **Process (clean and sterilize) in an open state and lubricate prior to sterilization.**

IMPLACARE

Sterilization: **IMPLACARE disposable resin tips can be steam sterilized prior to use. They are intended for one use only.**

MGA / MGC / MGI

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. If the mouth gag does not fit in an available cassette, please contact HuFriedyGroup for help finding the proper cassette size.

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.

O-RINGS

Sterilization: **O-Rings cannot be dry heat sterilized.**

ORTHO-INSTRUMENTS

Cleaning: **Not recommended to be cleaned in an automated washer.**

Sterilization: The use of **Steam Sterilization is recommended**.

OSTEOTOMES AND OSTEOTOM HANDLES

Processing: **Clean and sterilize in a completely disassembled state if applicable.**

OVERSIZE INSTRUMENTS

Processing: **If instruments do not fit in cassettes, other systems should be considered for reprocessing.** Please call HuFriedyGroup for assistance (1-800-HU-FRIEDY)

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 a better handling with composite materials. Scratches that are not visible might cause composite materials to stick to the rougher surface.

PLASTIC RETRACTORS (CRPC AND CRPA)

Cleaning: **Can only be disinfected by chemical disinfection.** Do not clean / disinfect in an automated washer or washer-disinfector.

Sterilization: **Do not sterilize** (steam, dry heat, etc.)

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Special Procedures (continued)

RESIN INSTRUMENTS AND RESIN COMPONENTS OR RESIN CASSETTES

Cleaning: For resin or silicone products **do not use detergents or disinfectants containing phenols or iodophors**.

Sterilization: Dry Heat is explicitly not compatible with Instruments with resin handles (handle #8 and C8), with resin or silicone components such as cassette rails, instrument rings or grips, inserts on any instruments, or with resin cassettes. The sterilizer equipment manufacturer's compatibility with specific materials must be observed.

RETRACTORS

Processing: Removable retractor tips must be disassembled from the handle before cleaning and sterilization.

ROOT CANAL INSTRUMENTS

Processing: Reprocess in suitable endodontic stands (i.e. IMS-1275).

Cleaning: Pre-treatment should be conducted outside the Endodontic stand. **Automated cleaning in an automated washer disinfector is recommended.** Ultrasonic cleaning in the Endodontic stand is not recommended.

STERILIZATION CONTAINER AND ACCESSORIES

Processing: For reprocessing, **the lid of the Container and the filter holding devices in the base and the lid have to be removed.** If single use paper filters have been used, they must be removed before reprocessing. Indicators have to be removed from the label holding device.

Cleaning: For the cleaning of anodized Aluminium Sterilization Containers only detergents can be used which are approved for this material.

For the reprocessing in an automated washer disinfector the components of the Container have to be placed securely in the washing baskets. Spraying nozzles and arms should not be blocked. Do not use acid neutralizers for the reprocessing of Aluminium Containers.

Container made of Aluminium cannot be cleaned in an Ultrasonic Cleaner Unit.

Sterilization: Sterilization Containers made of anodized Aluminium have been developed especially for sterilization in **Steam Sterilizers with pre-vacuum, fractioned vacuum or fractioned flow processes.** HuFriedyGroup Sterilization Containers cannot be used for other sterilization methods.

Sterilization parameters recommended: 273.2°F (134°C)/5min

Sterilization parameters **not validated**: 249.8°F (121°C)/20min

Maintenance: The surface of Aluminium Containers is very sensitive in respect to mechanical impact. For this reason **do not use metal brushes or scouring agents**. For the removal of stains, residues of inscriptions or adhesive tapes only a commercial cleaner for anodized Aluminium may be used (**no benzine or acetone**) After such treatment the Containers have to be cleaned once more.

SYRINGES—ALL TYPES

Processing: Completely disassemble including unscrewing of the cylinder.

ULTRASONIC INSERTS, MAGNETOSTRICTIVE

Processing: Ultrasonic cleaning as well as steam sterilization can be effected in suitable IMS™ Cassettes.

Cleaning: For automated cleaning in an automated washer disinfector, consult dental instrument washer/disinfector user manual and/or manufacturer.

Sterilization: For sterilization use steam sterilization (gravity or fractioned vacuum procedure) only. Do not expose to phenols or iodophors, do not use dry heat sterilization, or heat above 275° F (135°C).

ULTRASONIC PIEZO HANDPIECE

Sterilization: The Piezo handpiece **can be steam sterilized with all types of Steam Sterilizers at 273.2°F (134°C) for 15 min**. Other sterilization parameters are not permitted.

ULTRASONIC PIEZO TIPS/WRENCH WITH GUARDIAN

Processing: Piezo tips should remain in the wrench during the complete reprocessing cycle, also if reprocessed in cassettes.

Ultrasonic cleaning as well as steam sterilization can be affected in suitable IMS™ Cassettes.

Wrench to include Guardian and the EMS Combitorque.

Sterilization: For sterilization use steam sterilization (gravity or fractioned vacuum procedure) only. Do not expose to phenols or iodophors, do not use dry heat sterilization, or heat above 275°F (135 °C).

Enzymax™ Dual Enzyme Ultrasonic Detergent Application

PRODUCT / SKU	PRESOAK	LINEN PRESOAK	ULTRASONIC CLEANING	EVACUATOR
Enzymax™ Liquid Ultrasonic Detergent and Presoak Bottle IMS-1226	1 oz per gallon of water. Soak 3-5 min. Rinse thoroughly.	2 oz per gallon of water. Soak clothing 10 min. Proceed normal wash.	1 oz per gallon of water. After cleaning, rinse, and dry thoroughly.	2 oz per gallon of water. Insert evacuator hose, turn system on full open for one min. Suggested maintenance twice weekly.
Enzymax™ Liquid Concentrated Ultrasonic Detergent and Presoak IMS-1222	1 packet per gallon of water. Soak 3-5 min. Rinse thoroughly.	2 packets per gallon of water. Soak clothing 10 min. Proceed normal wash.	1 packet per gallon of water. After cleaning, rinse, and dry thoroughly.	2 packets per gallon of water. Insert evacuator hose, turn system on full open for one min. Suggested maintenance twice weekly.
Enzymax™ Powder Ultrasonic Detergent & Presoak IMS-1230	1 scoop per gallon of water. Soak 3-5 min. Rinse thoroughly.	1 to 2 scoops per gallon of water.	1 scoop per gallon of water. Rinse instruments thoroughly, dry and proceed with sterilization.	2 scoops per gallon of water. Insert evacuator hose, turn system on full open for one minute. Suggested maintenance twice weekly.
Enzymax™ Pax Ultrasonic Detergent and Presoak Powder IMS-1232, IMS-1233, IMS-1332, IMS-1333	1 packet per gallon of water. Soak 3-5 min. Rinse thoroughly.	1 to 2 packets per gallon of water.	1 packet per gallon of water. Rinse instruments thoroughly, dry and proceed with sterilization.	2 packets per gallon of water. Insert evacuator hose, turn system on full open for one minute. Suggested maintenance twice weekly.

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