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 Hu-Friedy Enzymax or a precleaning product such as Enzymax Spray Gel. When using Enzymax enzymatic cleaner, pre-soak for 3-5 minutes at 37°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) with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.

**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:**

**Concentration:**

**Current Ultrasonic Gallon Capacity:**

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

**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.

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. 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).
2. 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.
3. For best results, **Remove the instruments** from the cleaning solution and **post rinse** them intensively with low contaminated and deionized water.
4. **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.

**Manufature recommends the use of Hu-Friedy Ultrasonic Cleaning Monitors to assure your cleaning process achieves the highest quality results.**

IMS-1200U, IMS-1200H
HU-FRIEDY REPROCESSING GUIDELINES

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.

Hu-Friedy recommends the use of Hu-Friedy Bagette® sterilization pouches, Hu-Friedy Sterilization wrap or suitable sterilization containers.

STERILIZATION PACKAGING REQUIREMENTS:
- FDA cleared medical device
- Suitable for steam sterilization (temperature resistance up to at least 141°C / 286°F 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

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 non-sterile instruments strictly apart.

STORAGE & REUSE

Minimum 30 minutes for one use only. (see Special Storage & Reuse Sterilizer Management)

Drying time:

Exposure time (at 132°C / 270°F):
- Fractionated vacuum/dynamic-air-removal steam sterilization*: 4 minutes
- Minimum Cycle Times for Wrapped Instruments:
  - Gravity-displacement steam sterilization*: Exposure time (at 121°C / 250°F): 30 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.

Minimum Cycle Times for Wrapped Instruments:

COMMON DOUBLE SIMULTANEOUS WRAPPING TECHNIQUES

Dental Healthcare Settings

ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities

STD FOR STERILIZATION

- CDC Guidelines for Infection Prevention in Dental Healthcare Settings

STORAGE

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. Please see the “Life Expectancy of Instruments by Category” list for dental products. 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).

How the best perform

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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.

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 unit.

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 unit is recommended. Do not use chemical disinfection (cold sterilization); these chemicals may damage the Amalgam Carrier. After the cleaning / disinfection apply a lubricant (recommended lubricant: Hu-Friedy 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 unit 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).

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 unit 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. Hu-Friedy Sterilization Containers cannot be used for other sterilization methods.

Sterilization parameters recommended: 134°C/5min

Sterilization parameters not validated: 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.

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. For further information see the Hu-Friedy IMS Catalog).

Cleaning: In a suitable bur stand the burs, drills and trephines can also be reprocessed in an automated washer unit 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.

CROWN REMOVER (CRL AND CRU)

Cleaning: Do not disinfect with phenols or iodophors.

Sterilization: Do not sterilize with dry heat.

PLASTIC RETRACTORS (CRPC AND CRPA)

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

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

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 unit. After cleaning and prior to sterilization, use a proclavate 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

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.

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.

360 KNIFE (K360)

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

**MOUTH MIRRORS**
Processing: To avoid scratches on the mirror surface from other pointed instruments, reprocess in an instrument tray with instrument rails. 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.

**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.

**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 4B), with resin or Silicone components, 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. Hu-Friedy IMS-1275).
Cleaning: Pre-treatment should be conducted outside the Endodontic stand. Automated cleaning in an automated washer unit is recommended. Ultrasonic cleaning in the Endodontic stand is not recommended.

**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 Hu-Friedy IMS-Cassettes.
Cleaning: For automated cleaning in an automated washer unit connecting rinsing adapters have to be used, if the inserts are processed inside a cassette system. Otherwise open tray systems for the automated cleaning or alternatively the manual cleaning procedure is recommended.
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 135 °C (275 °F).

**ULTRASONIC INSERTS, PIEZO WITH GUARDIAN**
Sterilization: The Piezo handpiece can be steam sterilized with all types of Steam Sterilizers at 134 °C/15 min. Other sterilization parameters are not permitted.

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

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**ENZYMIX APPLICATION**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>ITEM</th>
<th>PRESOAK</th>
<th>LINEN PRESOAK</th>
<th>ULTRASONIC CLEANING</th>
<th>EVACUATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzymax Liquid IMS-1226, IMS-1224 IMS-1236</td>
<td>1 scoop per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 oz per gallon of water</td>
<td>Insert evacuator hose, turn system on full open for one minute. Suggested maintenance twice weekly.</td>
</tr>
<tr>
<td>Enzymax Liquid IMS-1222</td>
<td>1 packet per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>Insert evacuator hose, turn system on full open for one minute. Suggested maintenance twice weekly.</td>
</tr>
<tr>
<td>Enzymax Powder IMS-1230</td>
<td>1 scoop per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>Insert evacuator hose, turn system on full open for one minute. Suggested maintenance twice weekly.</td>
</tr>
<tr>
<td>Enzymax Pax</td>
<td>1 packet per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>2 packets per gallon of water</td>
<td>Insert evacuator hose, turn system on full open for one minute. Suggested maintenance twice weekly.</td>
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</table>