

REPROCESSING OF HU-FRIEDY DENTAL HAND INSTRUMENTS AND ACCESSORIES

1.0 Fundamental points

All instruments are to be cleaned and sterilized prior to each use. In addition, cleaning and sterilization is also required for the first use of non sterile instruments after removal from the protective packaging. Effective cleaning and 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 4.0 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 Instrument Cassettes - Hu-Friedy IMS® Instrument Management System

is an established and well thought out system, which gives you considerable benefits. It is the ideal solution for arranging your instruments in an organized manner, pre cleaning, cleaning, sterilizing and storing in an efficient way, providing maximum security.

3.0 Instrument Reprocessing Steps

3.1 Cleaning

3.1.1 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 4.0 Special Procedures section).

Protection of Staff Members:

All used and contaminated Instruments must be handled with protective utility gloves. Hu Friedy provides such protective gloves (Part codes: Size 7 = 40 060; Size 8 = 40 062; Size 9 = 40 064; Size 10 = 40 066). 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.

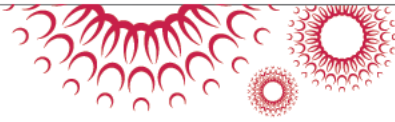
3.1.2 Pre-treatment

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, like Hu Friedy Enzymax and Enzymax Earth (Partcodes: Enzymax liquid: IMS 1222, IMS 1224, IMS 1226, IMS 1336, or Enzymax powder: IMS 1230, IMS 1232, IMS 1332, IMS 1333) or a precleaning product such as Enzymax Spray Gel (Part Code: IMS 1229). When using an enzymatic cleaner like Enzymax, 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, but in no case metal brushes or steel wool.

If applicable: Rinse all lumens of the instruments five times with a single use syringe (minimum volume 50 ml) or a suitable rinsing adapter.



3.1.3 Automatic Cleaning in an automated washer disinfector

Consider the following items, 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.

For the selection of detergents to be used with the automated washer disinfector, consider the following items:

- 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 3.7 Material resistance section and 4.0 Special Procedures section).

The use of a cassette system, like the Hu Friedy IMS System is recommended (limitations see 4.0 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 3.2 Inspection, 3.3 Maintenance, and 3.4 Packaging). If necessary allow post drying step in a clean place.

The fundamental suitability of the instruments for an effective automatic cleaning was demonstrated by an independent accredited test laboratory by application of the disinfectant G 7736, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the cleaning detergent Neodisher medizym.

3.1.4 Manual and Ultrasonic Cleaning

3.1.4.1 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 3.7 Material Resistance section and 4.0 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.

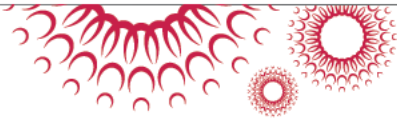
Hollow instruments, like aspirator tips or ultrasonic scaler tips have to be immersed at declined angle, in order to de-aerate the hollow channels.

3.1.4.2 Manual Cleaning

Procedure: **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 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.

The fundamental suitability of the instruments for an effective cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the cleaning detergent Enzymax (Hu Friedy Mfg. Co.) and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt) considering the specified procedure.



3.1.4.3 Ultrasonic Cleaning

The use of a cassette system like the Hu Friedy IMS System is recommended (limitations see 4.0 Special Procedures section).

Procedure: **Cleaning**

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. 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 a good cleaning result.
5. Thoroughly dry prior to packaging for sterilization.

The fundamental suitability of the instruments for an effective cleaning demonstrated by an independent accredited test laboratory by application of the cleaning detergent Enzymax (Hu Friedy Mfg. Co.) considering the specified procedure.

3.2 Inspection

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. Do not further use damaged instruments (for limitation of the numbers of re use cycles, see 3.8 Reusability section). If instruments are still visibly soiled, clean again. Re 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.

3.3 Maintenance

Light corrosion on the surface can be removed with Hu Friedy Penetrating Oil (IPS) or Shine reNew (IMS 1453 or 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 or IPS, the instrument must be cleaned and sterilized once more.

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

3.4 Packaging

We recommend the use of a cassette system, like the Hu Friedy IMS System and Hu Friedy Bagettes® sterilization pouches (IMS 1236, IMS 1237, IMS 1238, IMS 1239), Hu Friedy Sterilization Wrap (Hu Friedy IMS 1210, IMS 1211, IMS 1212, IMS 1213, IMS 1214, IMS 1215, IMS 1216, or IMS 1217), Hu Friedy Bonded Double Wraps (IMS 2215, IMS 2220, or IMS 2224) 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 (Sterilization Containers: limitations also see 4.0 Special Procedures section)
- make sure the devices are completely dry before packaging.

3.5 Sterilization

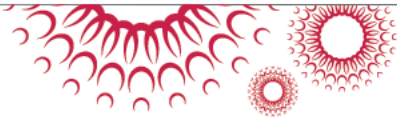
Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user. Hu Friedy recommends a minimum 30 minute dry time; however, defer to the manufacturer's instructions for the equipment used.

3.5.1 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 250°F (121°C)	Drying times
Wrapped instruments	30 minutes	Minimum 30 minutes



NOTE: This table represents the variation in sterilizer manufacturer’s recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer’s recommendations.

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

Item	Exposure time at 270°F (132°C)	Drying times
Wrapped instruments	4 minutes	Minimum 30 minutes

NOTE: This table represents the variation in sterilizer manufacturer’s recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer’s recommendations.

3.5.2 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.

3.5.3 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 4.0 Special Procedures section).

3.6 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.

3.7 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.

Do not expose any instruments, cassettes, trays or sterilization containers to temperatures higher than 141 °C (286 °F). Exposure to higher temperatures is the responsibility of the user. Please also consider the information under the 4.0 Special Procedures section.

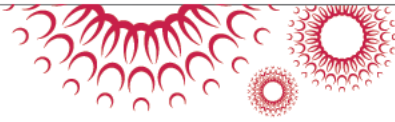
Water quality may influence the result of the cleaning of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in the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

3.8 Reusability

The instruments can be reused, unless indicated otherwise (see 4.0 Special Procedures section). 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). Re 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.

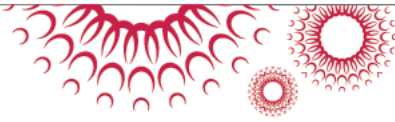
3.9 Single-Use Instruments

Single use instruments are intended and manufactured for one use only. They must not be reprocessed (exceptions: please see 4.0 Special Procedures section).



4.0 Special Procedures for Specific Hu-Friedy Instruments

<p>Aluminium Instruments</p>	<p>Cleaning: need special care. 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 disinfectant.</p> <p>Processing: Note: Anodized aluminium instruments, when processed with Stainless Steel instruments may cause an adverse chemical reaction.</p>
<p>Amalgam Carriers</p>	<p>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.</p> <p>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.</p> <p>Cleaning: Automated cleaning in an automated washer disinfectant is recommended. Do not use chemical disinfection (cold sterilization); these chemicals may damage the Amalgam Carrier. After the cleaning apply a lubricant (recommended lubricant: Hu Friedy ILS).</p> <p>Sterilization: For sterilization use steam sterilization (gravity or fractioned vacuum procedure) only.</p>
<p>Aspirators and Aspirator Tips</p>	<p>Processing: Clean and sterilize only in a completely disassembled state.</p> <p>Cleaning: For automated cleaning in an automated washer disinfectant 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!).</p>
<p>Sterilisation Container and Accessories</p>	<p>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.</p> <p>Cleaning: For the cleaning of anodized Aluminium Sterilization Containers only detergents can be used which are approved for this material.</p> <p>For the reprocessing in an automated washer disinfectant 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.</p> <p>Container made of Aluminium cannot be cleaned in an Ultrasonic Cleaner Unit.</p> <p>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.</p> <p>Sterilization parameters recommended: 273.2°F (134°C)/5min Sterilization parameters not validated: 249.8°F (121°C)/20min</p> <p>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.</p>



Osteotomes and Osteotom Handles	Processing: Clean and sterilize in a completely disassembled state if applicable.
Composite/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 #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. Hu Friedy IMS 1275). Cleaning: Pre treatment should be conducted outside the Endodontic stand. Automated cleaning in an automated washer disinfectant 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 and disinfection as well as steam sterilization can be effected in suitable Hu Friedy IMS Cassettes. Cleaning: For automated cleaning in an automated washer disinfectant consult dental instrument washer/disinfectant 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 135 °C (275 F).
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 effected in suitable Hu Friedy IMS Cassettes. Use 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 135 °C (275 F).
Ultrasonic Piezo Handpiece	Sterilization: The Piezo handpiece can be steam sterilized with all types of Steam Sterilizers at 273.2°F (134°C) for 15min. 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 Tel 800 HU FRIEDY.