

Reprocessing of Hu-Friedy Dental Hand Instruments and Accessories



Contents

1. Instruments Intended Use 3

2. General Considerations 3

First use instructions: 3

Sterilizer and automatic cleaning equipment best practices 3

Water quality 3

PPE considerations 3

Instrument Expected Life and Disposal 3

3. Warnings 3

4. Instrument Reprocessing Steps 3

General Considerations 3

Pre-Cleaning 3

Cleaning & Disinfection 4

Inspection & Maintenance 5

Packaging 5

Sterilization 5

Storage 6

1. Instruments Intended Use

Hu-Friedy dental Instruments are intended to perform specific functions such as grasping, holding, cutting, probing, retracting, applying, condensing, or placing of dental materials and/or oral tissues.

2. General Considerations

First use instructions:

- After receiving a new instrument, make sure to follow initial cleaning, disinfection and sterilization steps before using for the first time. All non-sterile instruments are to be cleaned, disinfected, and sterilized prior to first use and each subsequent use.

Sterilizer and automatic cleaning equipment best practices

- Instruments can be reused, unless indicated otherwise on the packaging.
- Sterilization and cleaning equipment should be maintained and checked per the manufacturer's recommendation.
- Consider the legal provisions valid for your country as well as any hygienic instructions of the doctor's 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).

Water quality

- 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 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.
- The use of completely deionized or distilled water can help avoid most water quality problems.

PPE considerations

- Within the EU, all used and contaminated Instruments must be handled with protective gloves fulfilling the requirements of regulation (EU) 2016/425.
 - Hu-Friedy provides such protective gloves (Product codes: 40-060 (Size 7); 40-062 (Size 8); 40-064 (Size 9); 40-066 (Size 10).

Instrument Expected Life and Disposal

- The lifetime of instruments depends on the frequency of use, the care by the user and proper reprocessing methods. Please contact your local Hu-Friedy agent with questions about the expected life of any Hu-Friedy product.
- When an instrument has exceeded its life, dispose of instrument per local regulations.

3. Warnings

- The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments.
- Inspect instruments prior to each use for damaged or soiled instruments and dispose of or reprocess as necessary.
- Improper cleaning or sterilization may lead to patient infection and improper inspection of the instrument may lead to patient injury.
- Instrument breakage or improperly maintained instruments (ex. loose parts or inadequately sharpened) may lead to medical intervention.
- The responsibility for reprocessing Hu-Friedy instruments according to parameters which are not specified in this document lies with the user.
- Sterilized instruments should not be used if the integrity of the packaging is compromised (e.g., torn, wet, or punctured). In this event, reprocess and repackage instruments before use.
- 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.
- Do not use steel wool, wire brushes or abrasive detergents containing bleach or other corrosive chemicals.
- In case of a serious incident that has occurred in relation to Hu-Friedy instruments within the European Union, please report by either calling Hu-Friedy for assistance Tel 00800 4837 4339 or send an e-mail to info@hu-friedy.eu. In addition, please inform your national competent authority.

4. Instrument Reprocessing Steps

General Considerations

- Instruments must be disinfected as early as possible in the reprocessing process, in order to maximize safety for staff members when handling contaminated instruments.
- Manual cleaning should only be performed on instruments if automated cleaning equipment is not available. Manual cleaning might also be performed if there is debris remaining after automated cleaning or when automated cleaning equipment is not accessible.
- If possible, an automated 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 automated 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. Pre-treatment must be performed in both cases.
- Hu-Friedy's IMS™ Cassettes keep instruments organized and protected throughout the facility, allowing the instruments to go from point of use to cleaning to sterilization to storage without the need to touch contaminated instruments.
- Instrument maintenance protocol should include regular lubrication following cleaning and prior to sterilization.

Pre-Cleaning

- PROCEDURE:
 - Completely disassemble instruments, if applicable. Note: color coding rings do NOT need to be removed.
 - Pre-soak instruments for at least 5 minutes' and make sure that all surfaces are wetted and lumens are filled with water.
 - Brush instruments to remove residues from the surface, paying special attention to lumens and dead ends. Make sure that movable parts are brushed in open and closed position.
 - All hinged instruments should be reprocessed in the open position.
 - 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.
- CONSIDERATIONS
 - Use a neutral pH enzymatic detergent or a disinfectant solution during pre-soaking. The solution should:
 - Be free of aldehydes to prevent fixation of blood impurities

- Possess a fundamentally approved efficiency (i.e. DGHM, RKI approval or CE marking)
- Be suitable for the disinfection of medical instruments
- Be compatible with the instruments
- Remove coarse impurities on the instruments immediately after use and perform pre-treatment within one hour.
- The disinfectant used in the pre-treatment step serves only for personal safety and does not replace the disinfection step, which should be performed later.
- In case the instruments are transported to an external service provider, ensure the instruments remain wetted to avoid fixation of proteins e.g. by using a pre-cleaning product, such as Enzymax Spray Gel (Product Code IMS-1229).
- Only use soft brushes such as Art. No. 1003414000 (Schellenberger), Art. No. MED100.33, MED100.43, MED100.18, or MED100.17 (Insitumed)

Cleaning & Disinfection

- Automated Cleaning and Disinfection in a Washer-Disinfector
 - PROCEDURE:
 - Connect instruments with lumen to flush ports in the washer-disinfector.
 - Load washer-disinfector as validated for the intended cycle, being careful not to overload.
 - Start the cycle.
 - Ensure instruments are dry prior to handling.
 - Remove instruments following cycle completion.
 - Conduct post-disinfection steps
 - CONSIDERATIONS:
 - Use accessories such as instrument washer-disinfector baskets and instrument cassettes to hold instruments during the automated cleaning process.
 - Ensure the efficiency of equipment is fundamentally approved (e.g. EN ISO 15883, DGHM approval, CE marking).
 - Regular maintenance and inspection/calibration is conducted.
 - For the selection of detergents to be used with the Washer-Disinfector unit, consider the following:
 - Fundamental suitability for cleaning of medical instruments.
 - Compatibility with the instrument materials
 - Detergent manufacturer instructions regarding concentration and soaking time.
 - For resin or silicone products do not use detergents or disinfectants containing phenols or iodophors.

The fundamental suitability of the instruments for effective automated 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) E 493
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)
Validation Report	Project Numbers: 00418-1; 23919 Examination of an Automated Cleaning Process using quantitative Detection of Protein and Hemoglobin and the Radionuclide Method

- Manual and Ultrasonic Cleaning and Disinfection:
 - CLEANING PROCEDURE:
 - Place the instruments in an ultrasonic bath containing a cleaning solution, at a minimum of 45°C for at least 15 minutes.¹
 - At the beginning of the soak time flush lumens with 5ml of the cleaning solution using a syringe.
 - Ensure all instrument surfaces are exposed to the cleaning solution.
 - 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 adaptor.
 - Remove the instruments from the cleaning solution and rinse under deionized water for at least 1 minute.
 - Dry instruments.
 - Perform a visual inspection to ensure proper cleaning. If visible soil remains, repeat the cleaning process for impacted items.
 - Disinfection Procedure:
 - Soak instrument in disinfectant solution for the duration intended by the disinfectant manufacturer.
 - Ensure instrument is completely immersed.
 - 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 adaptor.
 - Ensure all instrument surfaces are exposed to the cleaning solution.
 - Remove instrument from disinfectant.
 - Rinse under deionized water for at least 1 minute.
 - Dry instruments.
 - Conduct post-instrument disinfection steps.

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

Cleaning Solution	0.8 % Enzymax Liquid (Hu-Friedy Mfg. Co., LLC, USA)
Validation Report	Project Number: 00418-2 Examination of a Manual Cleaning Process using quantitative Detection of Protein and Hemoglobin and the Radionuclide Method

- **CONSIDERATIONS:**
 - For the selection of detergents to be used for manual cleaning and disinfection, consider the following items:
 - Fundamental suitability for cleaning of medical instruments.
 - Approved efficiency (e.g. VAH/DGHM, RKI approval or CE marking).
 - Compatibility with the instrument materials.
 - Detergent manufacturer instructions regarding concentration, temperature and soaking time.
 - It is recommended to not 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.
 - 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.
 - Utilize HEPA-filtered air for drying.

Inspection & Maintenance

- **PROCEDURE**
 - If there is still visible contamination on the instruments, clean and disinfect again.
 - Inspect all instruments after the cleaning and disinfection for corrosion and damaged surfaces. If corrosion cannot be eliminated, the instruments should be removed from use. Otherwise, such corrosion could damage other instruments.
 - Re-sharpen instruments if necessary. After, completely remove any residues, such as metal residue or sharpening oil. Assemble disassembled instruments if necessary.
- **CONSIDERATIONS**
 - Light corrosion on the surface can be removed with a product such as Shine reNew (Product Code IMS-1455). After treating an instrument with Shine reNew, the instrument must be cleaned and sterilized once more.
 - Instruments shall no longer be reused if markings are fading.
 - Hinged instruments should be lubricated with a lubricant suitable for steam sterilization, like Hu-Friedy Instrument Lubricant Spray (Product Code ILS).

Packaging

- **PROCEDURE:**
 - All instruments must be completely dry before packaging. Then, package immediately.
 - Place instruments into approved packaging materials for the sterilization method such as instrument cassettes, sterilization pouches, CSR wrap or other approved products.
 - Seal packing according to manufacturer's IFU's.
- **CONSIDERATIONS:**
 - We recommend the use of an instrument cassette system, like the Hu-Friedy IMS System in conjunction with packaging that meets the following requirements:
 - 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.
 - The following Hu-Friedy packaging solutions are suggested:
 - Hu-Friedy Bagette Pouches (Product codes: IMS-1236, IMS-1237, IMS-1238, IMS-1239, IMS-1345, IMS-1346, IMS-1347, IMS-1348)
 - Hu-Friedy Sterilization Wrap (Product codes: IMS-1210M, IMS-1211M, IMS-1212M)
 - Hu-Friedy Bonded Double Wrap (Product codes: IMS-22215, IMS-2220, IMS-2224)
 - Hu-Friedy Sterilization Containers (Product codes: IMDINCO0M, IMDINCO1M, IMDINCO2M, IMDINCO3M)

Sterilization

- **PROCEDURE**
 - Load sterilizer as recommended by the manufacturer, being careful not to overload. Follow the equipment manufacturer's recommendations for load/weight capacity.
 - Run validated program.
 - Validated steam sterilization cycle: Pre-vacuum 134 °C (273°F), 4 minutes.
- **CONSIDERATIONS**
 - Use only the recommended sterilization procedures listed above; other sterilization procedures are the responsibility of the user.
 - Maximum sterilization temperature of 138 °C (280 °F)
 - Minimum exposure time to sterilization temperature: 4 minutes at 134 °C (273 °F)
 - Use properly installed and validated sterilizers and follow manufacturer's instructions with respect to routine inspection and the regular maintenance.
 - Only low contaminated and deionized water (i.e. aqua purificata) should be used.
 - The sterilized items must be completely dried after sterilization and before handling.
 - Sterilizers with an automated drying program are recommended.

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
Validation Report	Project Numbers: 25517-1; 25517-2; 24219 Validation of a Sterilization Process using Steam Sterilization in Pre-vacuum Mode Method MD 4.0: Sterilization validation of medical products with moist heat Project Numbers: 10918-1; 10918-2 Determination of Residual Moisture after Sterilization using Steam Sterilization in Pre-vacuum Mode

Storage

- PROCEDURE
 - Store instruments after sterilization in a dry and dust free place. Sterilization can only be maintained, if the instruments remain packaged or wrapped - impermeable to micro-organisms - following validated standards.
 - Instruments should be stored and transported only in appropriate approved sterile packaging.
- CONSIDERATIONS
 - The status of the sterilization should be clearly indicated on the wrapped packages or the containers.

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



Hu-Friedy Mfg. Co., LLC
2501 Sanders Rd.
Northbrook, IL 60062 | USA



EU | REP Hu-Friedy Europe LLC & Co. KG
Bogenstrasse 6 - 8
78576 Emmingen - Liptingen
Germany

CH | REP MDSS CH GmbH
Laurenzenvorstadt 61
5000 Aarau
Switzerland

UK | REP MDSS-UK RP Ltd.
Parkway House, Palatine Rd,
Northenden, Wythenshawe,
Manchester M22 4DB
United Kingdom



Free Call: 00800 48 37 43 39 | **Free Fax:** 00800 48 37 43 40

E-Mail: info@hu-friedy.eu | **Website:** HuFriedyGroup.eu

[HuFriedyGroupEurope](https://www.hufriedygroup.eu)

Hu-Friedy Mfg. Co., LLC • European Headquarters • Lyoner Str. 9 • 60528 Frankfurt am Main, Germany • HuFriedyGroup.eu
All company and product names are trademarks of Hu-Friedy Mfg. Co. LLC, its affiliates or related companies, unless otherwise noted.
©2026 Hu-Friedy Mfg. Co., LLC. All rights reserved. HF-GB-17664 / REV1 - 2408