

1.0 Fundamental points

All instruments are to be cleaned, disinfected, and sterilized prior to each use. In addition, cleaning, disinfection and sterilization is also required for the first use of non-sterile instruments after removal from the protective packaging. Effective cleaning and disinfection is an indispensable requirement for proper instrument sterilization.

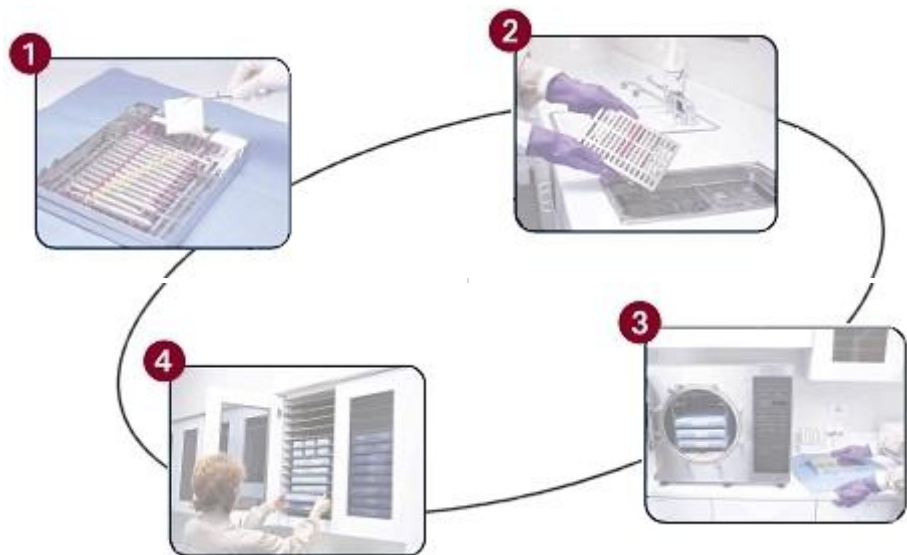
The user is responsible for the sterility of the instruments. Therefore, please ensure that only validated procedures are used for cleaning, disinfection and sterilization. The sterilization equipment must also be maintained and checked regularly, as well as the validated parameters applied to each cleaning 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, cleaning, disinfecting, sterilizing and storing in an efficient way, providing maximum security.



- 1 **Chairside**
- 2 **Cleaning and Disinfection**
- 3 **Sterilization**
- 4 **Sterile storage**

3.0 Instrument Reprocessing Steps

3.1 Cleaning and Disinfection

3.1.1 Basics

If possible, an automatic procedure in a Thermodisinfector unit (Washer / Disinfector) 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 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.

The pre-treatment step is to be performed in both cases.

Protection of Staff Members:

All used and contaminated Instruments must be handled with protective gloves fulfilling the requirements of Directive 89/686/EEC. Hu-Friedy provides such protective gloves (Partcodes: Size 7 = 40-060; Size 8 = 40-062; Size 9 = 40-064; Size 10 = 40-066). Contaminated Instruments must be disinfected 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 2 h). Instruments with impurities have to be pre-treated within two hours from the application.

Use an enzymatic cleaner, like Hu-Friedy Enzymax (Partcodes: Enzymax liquid: IMS-1222, IMS-1224, IMS-1226, IMS-1228 or Enzymax powder: IMS-1230, IMS-1232) or a disinfectant solution; the disinfectant should be aldehyde-free (otherwise fixation of blood impurities could occur), possess a fundamentally approved efficiency (i.e. DGHM, RKI approval or CE marking), be suitable for the disinfection of instruments and be compatible with the instruments (see 3.7 Material resistance section and 4.0 Special Procedures section). When using an enzymatic cleaner like Enzymax, pre-soak for 3-5 minutes at 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.

Consider, that the disinfectant used in the pre-treatment step serves only for personal safety and cannot replace the disinfection step, which should be performed later.

3.1.3 Automatic Cleaning / Disinfection in a Thermodisinfector unit (Washer/Disinfector)

Consider the following items, when using a Thermodisinfector unit (Washer/Disinfector):

- fundamentally approved efficiency of the Thermodisinfector unit (Washer/Disinfector) (for example EN ISO 15883, DGHM approval and/or CE marking)
- possibility for an approved program for thermal disinfection (at least 10 min at 93 °C / A⁰ >3000 and must follow equipment manufacturers guidelines). In the case of chemical disinfection there is a danger of remnants of the disinfectant on instruments.
- 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 aqua purificata (highly purified water acc. Pharmacopeia).
- only use filtered air for drying
- regular maintenance and inspection/calibration of the Thermodisinfector unit (Washer/Disinfector)

For the selection of detergents to be used with the Thermodisinfector unit (Washer/Disinfector), consider the following items:

- fundamental suitability for cleaning of instruments
- additional application – if instruments are not compatible with the thermal disinfection please follow the recommended instructions for the manual cleaning and disinfection
- 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 Thermodisinfector unit (Washer/Disinfector) (no contact between the instruments).
If applicable: Connect the instruments to the rinsing port of the Thermodisinfector unit (Washer/Disinfector).
3. Start the program.
4. Remove the instruments from the Thermodisinfector unit (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 and disinfection 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 and Disinfection

3.1.4.1 General information

Consider the following items during selection of the cleaning and disinfection detergents:

- fundamental suitability for the cleaning and disinfection of dental instruments
- application of a disinfectant with approved efficiency (for example DGHM, RKI approval or CE marking) compatible with the cleaning detergent used.
- compatibility of the detergents used with the instruments (see 3.7 Material Resistance section and 4.0 Special Procedures section)
- Powder based cleaners or disinfectants 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/disinfectant solution, the time of exposure and the temperature.

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.

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. aqua purificata (highly purified water acc. Pharmacopeia), 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 and Disinfection

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 intensively with low contaminated and deionized water (i.e. aqua purificata).
4. Inspect the instruments for proper cleaning.

Disinfection

5. Soak the disassembled instruments for the given soaking time in the disinfectant solution so 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.
6. Remove the instruments from the disinfectant solution and post rinse them five times with low contaminated and deionized water (i.e. aqua purificata).
7. All instruments must be completely dry before packaging. (see 3.4 Packaging section, if necessary allow post drying in a clean place).
8. Perform inspection and maintenance of the instruments (see 3.2 Inspection and 3.3 Maintenance sections).
9. Package the instruments immediately

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 and Disinfection

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. aqua purificata).
4. Inspect the instruments for a good cleaning result.

Disinfection

5. Soak the disassembled instruments for the recommended soaking time in the disinfectant solution and make sure that the instruments are sufficiently immersed. Use the complete processing time recommended by the manufacturer of the disinfectant. Note: There should not be any contact between the instruments.
6. Remove the instruments from the disinfectant solution and post rinse them intensively with low contaminated and deionized water (i.e. aqua purificata).
If applicable: Rinse all lumens of the instruments five times by application of a single-use syringe (minimum volume 50 ml) at the end of the soaking time.
7. All instruments must be completely dry before packaging. (see 3.4 Packaging section, if necessary allow post drying in a clean place).
8. Perform inspection and maintenance of the instruments (see 3.2 Inspection and 3.3 Maintenance sections).
9. Package the instruments immediately.

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 Cidezyme/Enzol and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt) considering the specified procedure.]

3.2 Inspection

Inspect all instruments after the cleaning and disinfection 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 dirty, clean and disinfect again. Resharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil.

3.3 Maintenance

Assemble disassembled instruments if necessary (see 4.0 Special Procedures section).

Light corrosion on the surface can be removed with Hu-Friedy Penetrating Oil (IPS). 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 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) or in case of dry heat sterilization Hu-Friedy High Heat Instrument Lubricant (ILHH).

3.4 Packaging

We recommend the use of a cassette system, like the Hu-Friedy IMS System and Hu-Friedy Bagettes™ (pouches) or Hu-Friedy Sterilization wrap (Hu-Friedy IMS-1210, IMS-1211, IMS-1212 or IMS-1213 or suitable sterilization containers, if the following requirements are fulfilled:

- Conformity with EN 868 / ANSI AAMI ISO 11607 (in future: EN ISO/ANSI AAMI ISO 11607)
- 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 manufacturers instructions (sterilization container)

3.5 Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.

3.5.1 Steam sterilization

- fractionated vacuum or gravity¹ procedure (with sufficient product drying)
- steam sterilizer according to EN 13060 and EN 285
- validated according to EN 554/ANSI AAMI ISO 11134 (in future: EN ISO/ANSI AAMI ISO 17665) (valid commissioning and product specific performance qualification)
- maximum sterilization temperature 138 °C (280 °F); plus tolerance according to EN 554/ANSI AAMI ISO 11134 (in future: EN ISO/ANSI AAMI ISO 17665)
- sterilization time (exposure time at the sterilization temperature) at least 20 min at 121 °C (250 °F) or 5 min at 132 °C (270 °F)/134 °C (273 °F)

¹ If possible, a fractionated vacuum procedure should be used for sterilization of the instruments. A gravity procedure should only be used if a fractionated vacuum procedure is not available; in this case, the significantly lower efficiency of a gravity procedure has to be considered.

The fundamental suitability of the instruments for effective steam sterilization was demonstrated by an independent accredited test laboratory by application of the steam sterilizer EuroSelectomat 666 (MMM Münchener Medizin Mechanik GmbH, Planegg), fractionated vacuum procedure, as well as the specified procedure.

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. 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.

3.5.3 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 4.0 Special Procedures section).

3.6 Storage

Please store the 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. 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 and disinfection 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 your 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).

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).

Special procedures for Specific Hu-Friedy/EI instruments:

DownPak Tips	<p>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).</p> <p>Ultrasonic cleaning and disinfection as well as steam sterilization can be effected in suitable Hu-Friedy IMS Cassettes.</p> <p>Remove all visible soil from the tips, then clean using ultrasonic cleaner or thermo-disinfector and steam sterilize before each use.</p> <p>Steam sterilize for a minimum of 3 minutes at 274°F (134°C). Do not heat above 275°F (135°C).</p> <p>Clean, disinfect, inspect and steam sterilize tips using an autoclave before each use. Follow the instructions provided with the cleaning/sterilization equipment.</p>
DownPak Handpiece	<p>Remove handpiece from charger for cleaning. Clean the outer surface of the handpiece by wiping with a soft cloth dampened with a pH neutral surface disinfection solution or mild detergent (not containing phenols). Do not spray cleaning solution directly on the handpiece. Do not saturate the controls, display, or front portion of the handpiece.</p>
Downpak Charger	<p>Remove the handpiece from the charger. Disconnect the charger from the power supply. Clean the outer surface of the charger by wiping with a soft cloth dampened with pH neutral surface disinfection solution that does not contain phenols. Do not spray disinfection solution directly on the charger base (do not saturate).</p>