HENRY SCHEIN®

# Reprocessing of Hand Instruments and Accessories

## 1.0 Fundamental Points

All non-sterile instruments are to be cleaned, disinfected, and sterilized prior to each use and also prior to first use.

The person responsible for reprocessing (i.e. the operator) is responsible for proper instrument reprocessing using onsite equipment and safe procedures that are validated for cleaning, disinfection, and sterilization. The sterilization equipment must also be maintained and checked per the manufacturer's recommendation as well as the validated parameters applied to each cleaning and sterilization cycle. Additionally, consider the legal provisions valid for your country as well as to the hygienic instructions of the doctor´s practice or hospi-tal. 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), and HEPA-filtered air for drying, respectively. 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.

Within the EU, all used and contaminated Instruments must be handled with protective gloves fulfilling the requirements of regulation (EU) 2016/425. 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. Using an instrument management system like the Henry Schein cassettes system gives you considerable benefits. It is the ideal solu-tion for arranging your instruments in an organized manner, cleaning, disinfecting, sterilizing and storing in an efficient way, providing maximum security.

In case of a serious incident that has occurred in relation to our devices within the European Union, please report by either calling Henry Schein for assistance Tel +49 61037575000 or send an e-mail to cbproducts@henryschein.com. In addition, please inform your national competent authority.

## 2.0 Receiving a new Instrument

After receiving a new instrument, make sure you follow the initial cleaning, disinfection and sterilization steps before using it for the first time. This step is essential for the patient's health.

## 3.0 Instrument Reprocessing Steps

If possible, an automatic 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 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 has to be performed in both cases. All assembled instruments must be disassembled before reprocessing (for further details, please see 9.0 Special Procedures section). Effective cleaning and disinfection are an indispensable requirement for proper instrument sterilization.

## 3.1 Pre-Treatment

Before processing the instruments, remove coarse impurities on the instruments immediately after application and pre-treatment within one hour from the application. In case the instruments are transported to an external service provider, ensure the instruments remain soaked to avoid fixation of proteins e.g. by using a pre-cleaning product.

Use an enzymatic cleaner or a disinfectant solution during pre-soaking.
The disinfectant 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 devices and
- be compatible with the instruments (see 7.0 Material resistance section and 9.0 Special Procedures section)

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. Only use soft brushes.

### Procedure

Completely disassemble the instruments, if applicable.
Pre-soak the devices for at least 5 minutes* and make sure that all surfaces are wetted and lumens are filled with water. Brush the instruments to remove residues from the surface, paying special attention to lumens and dead ends. Also make sure that movable parts are brushed in open and closed position. Difficult to reach positions such as hinges, mating surfaces, lumens or dead ends shall be flushed at least 3 times with minimum 50ml cold deionized water, using a syringe or a rinsing adapter.*

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

## 3.2 Cleaning and Disinfection

### 3.2.1 Automatic Cleaning and Disinfection in a Washer-Disinfector Unit

When using a Washer-Disinfector unit, make sure that…

- the efficiency is fundamentally approved (e.g. EN ISO 15883, DGHM approval, CE marking),
- your process is validated, including equipment, detergents, temperatures, durations and loading, and
- regular maintenance and inspection/calibration is done.

For the selection of detergents to be used with the Washer-Disinfector unit, consider the following items:

- Fundamental suitability for cleaning of medical devices
- Compatibility with the instrument materials (see 7.0 Material resistance section and 9.0 Special Procedures section)
- Detergent manufacturer instructions regarding concentration and soaking time

### Procedure

Connect devices with lumen to flush ports in the washer-disinfector.
Load the washer-disinfector as validated.
Start the validated program.
Remove the instruments after end of program.
Let the instruments dry.
Conduct post-disinfection steps (see section 4.0)

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

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|---|---|
| Washer-Disinfector | Miele Professional G 7836 CD |
| Racks | Mobile injector unit (Miele) E429,<br>Four-level rack (Miele) E 493 |
| Cleaning Cycle | • 2 minute pre-cleaning with cold tap water<br>• Draining<br>• 5 minute cleaning with 55 °C cleaning solution<br>• Draining<br>• 3 minute rinsing with cold deionized water<br>• Draining<br>• 2 minute rinsing with cold deionized water<br>• Draining |
| Cleaning Solution | 0.5 % cleaning solution neodisher® Mediclean Dental (Chemische Fabrik Dr. Weigert, Hamburg) |
| Validation Report | Project Number: 00418-1<br>Examination of an Automated Cleaning Process using quantitative Detection of Protein and Hemoglobin and the Radionuclide Method |

The responsibility for reprocessing of Henry Schein instruments according to parameters which are not specified in this document lies with the customer.

## 3.2.2 Manual and Ultrasonic Cleaning and Disinfection

For the selection of detergents to be used for manual cleaning and disinfection, consider the following items:

- Fundamental suitability for cleaning of medical devices.
- Approved efficiency (e.g. VAH/DGHM, RKI approval or CE marking).
- Compatibility with the instrument materials (see 7.0 Material resistance section and 9.0 Special Procedures section).
- Detergent manufacturer instructions regarding concentration, temperature and soaking time

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.

## Cleaning procedure

Place the devices in an ultrasonic bath containing a cleaning solution at min. 45°C for at least 15 minutes*.
At the beginning of the soak time flush the lumens with 5 ml of the cleaning solution using a syringe.
Non-rigid components shall be operated during the immersion.
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.*
Remove the instruments from the cleaning solution.
Rinse the instruments under running water for at least 1 minute.
Inspect optically for proper cleaning.

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

## Disinfection procedure

Soak the devices in the disinfectant solution for the duration intended by the disinfectant manufacturer.
Make sure they are 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 adapter.
Non-rigid components shall be operated during the immersion
Remove the instruments from the disinfectant.
Rinse the instruments under deionized water for at least 1 minute*.
Let the instruments dry.
Conduct post- disinfection steps (see sections 4.0)

* These parameters are validated (Validation Report: 10918-1)

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

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|---|---|
| Cleaning Solution | 0.8 % Enzymax Liquid (Henry ScheinMfg. Co., LLC, USA) |
| Validation Report | Project Number: 00418-2<br>Examination of a Manual Cleaning Process using quantitative Detection of Protein and Hemoglobin and the Radionuclide Method |

The responsibility for reprocessing of Henry Schein instruments according to parameters-which are not specified in this document lies with the customer.

## 4.0 Post- Disinfection Steps

## 4.1 Inspection and Maintenance

If there are still contamination attached to the instruments, clean and disinfect again.
Inspect all instruments after the cleaning and disinfection step for corrosion and damaged surfaces, Light corrosion on the surface can be removed with Henry ScheinPenetrating Oil (IPS) or similar appropriate oils. After treating an instrument with IPS, the instrument must be cleaned and sterilized once more. **If the corrosion cannot be eliminated or other surfaces are identified, do not further use those instruments**.
Keep in mind that instruments shall no longer be reused in case the labelling is fading.

Re-sharpen instruments if necessary. Afterwards, completely remove any residues, such as metal residue or sharpening oil. Assemble disassembled instruments if necessary (see 9.0 Special Procedures section).

Hinged instruments have to be lubricated with a lubricant suitable for steam sterilization.

## 4.2 Packaging

All instruments must be completely dry before packaging. Then, package immediately.
We recommend the use of a cassette system, like the Henry Schein cassettes, Henry Schein Pouches, Sterilization Rolls or CSR Wrap. or suitable sterilization containers, if the following requirements are fulfilled:

- 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 (Sterilization Containers: limitations also see 9.0 Special Pro-cedures section)

## 5.0 Sterilization

Please use only the recommended sterilization procedures listed below. Other sterilization procedures are the responsibility of the user.
**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 9.0 Special Procedures section).

## 5.1 Steam Sterilization

For sterilizing, please remember the following:

- maximum sterilization temperature of 138 °C (280 °F)
- minimum exposure time to sterilization temperature:
- 20 minutes at 121 °C (250 °F) or
- 5 minutes at 132 °C (270 °F)/
- 4 minutes at 134 °C (273 °F)
- the manufacturer's instructions with respect to routine inspection and the regular maintenance of the Sterilizer must be observed.
- the sterilizer must be maintained per manufacturer's recommendation.
- 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 pro-gram are recommended.

## Sterilization procedure

Use properly installed and validated sterilizers, following instructions of the manufacturer.
Load sterilizer as recommended by the manufacturer.
Run validated program.

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

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

The responsibility for reprocessing of Henry Schein instruments according to parameters which are not specified in this document lies with the customer.

## 6.0 Transport and Storage of Reprocessed Instruments

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. In case the reprocessed instrument is transported, make sure to use air-conditioned vehicles in order to avoid condensate formation. For safety reasons, keep sterile and non-sterile instruments strictly apart.

## 7.0 Material resistance

We recommend not to 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.

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 9.0 Special Procedures section.

## 8.0 Reusability and Single Use

**Reusability**
The user is responsible for inspecting instruments prior to each use, and for the use of damaged and dirty instruments. The instruments can be reused, unless indicated otherwise (see 9.0 Special Procedures section). The lifetime of instruments depends on the frequency of use, the care by the user and proper reprocessing methods. Please contact your local Henry Schein agent with questions about the expected life of any Henry Schein product.

**Single Use**
Single use instruments are intended and manufactured for one use only.

## 9.0 Special Procedures for Specific Instruments

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| **Aluminium Instruments** | **Cleaning / Disinfection:**<br>• Use neutral cleaning agents and disinfectants suitable for Aluminium.<br>• Check cleaning agent label for precautions for use with Aluminium.<br>• Do not clean in an ultrasonic cleaner.<br>• Clean by hand or in a Washer-Disinfector unit.<br><br>**Processing:**<br>Note: Anodized aluminium instruments, when processed with Stainless Steel instruments may cause an adverse chemical reaction. |
| **Carbon Steel Instruments** | **Processing:**<br>• Clean, disinfect and sterilize separately.<br>• Do not clean, disinfect or sterilize with other stainless-steel instruments.<br>• Do not clean / disinfect in a Washer-Disinfector unit. |
| **Hinged Instruments** | **Processing:**<br>• Process in an open state and lubricate using Instrument Lubricant Spray (ILS) prior to sterilization. |
| **Oversized Instruments** | **Note:** If instruments do not fit in cassettes, other systems should be considered for repro-cessing |
| **Aspirators and Aspirator Tips** | **Processing:**<br>• Clean, disinfect and sterilize only in a completely disassembled state.<br><br>**Cleaning / Disinfection:**<br>For automated cleaning and disinfection in a Washer-Disinfector unit connecting rinsing adapters must be used, if the inserts are processed inside a cassette system. Otherwise open tray systems for automated cleaning and disinfection or manual cleaning and disin-fection is recommended **(no Ultrasonic cleaning and disinfection!).** |
| **Crown Remover (CRL, CRU)** | **Processing:**<br>• Clean, disinfect and sterilize in a completely disassembled state.<br><br>**Cleaning / Disinfection:**<br>• Do not disinfect with phenols or iodophors.<br><br>**Sterilization:**<br>• Do not sterilize with dry heat. |
| **Mallet** | **Processing:**<br>Clean, disinfect and sterilize in a completely disassembled state. |
| **Mouth Mirrors** | **Processing:**<br>• To avoid scratches on the mirror surface from other pointed instruments, reprocess in an instrument cassette with instrument rails.<br>• Clean, disinfect and sterilize in a completely disassembled state.<br><br>**Cleaning / Disinfection:**<br>Note: All types of Rhodium coated Mouth Mirrors should not be cleaned and disinfected in an ultrasonic cleaner. |
| **O-Rings** | **Sterilization:**<br>O-Rings cannot be dry heat sterilized |
| **Osteotomes and Osteotome Handles** | **Processing:**<br>Clean, disinfect and sterilize in a completely disassembled state if applicable. |
| **Plastic Filling Instruments** | **Processing:**<br>Process in cassettes or trays with instrument rails to avoid scratches on the surface from other pointed instruments.<br><br>**Maintenance:**<br>• Residues of Filling Materials and etching products must be removed immediately.<br>• Plastic Filling Instruments are designed with an extra smooth surface, in order to pro-vide a better handling with composite materials. Scratches that are not visible might cause composite materials to stick to the rougher surface. |
| **Resin Instruments, Resin Components or Resin Cassettes** | **Cleaning / Disinfection:**<br>For resin or silicone products do not use detergents or disinfectants containing phenols or iodophors.<br><br>**Sterilization:**<br>Dry Heat is explicitly not compatible with Instruments with resin handles, with resin or Silicone components, inserts on any instruments, or with resin cassettes. |
| **Retractors, Metal** | **Processing:**<br>Removable retractor tips must be disassembled from the handle before clean-ing/disinfection and sterilization. |
| **Root Canal Instruments** | **Processing:**<br>Reprocess in suitable endodontic stands<br><br>**Cleaning / Disinfection:**<br>• Pre-treatment should be conducted outside the Endodontic stand.<br>• Automated cleaning and disinfection in a Washer-Disinfector unit is recommended.<br>• Ultrasonic cleaning in the Endodontic stand is not recommended. |
| **Scalpel Handles** | **Processing:**<br>Clean, disinfect and sterilize in a completely disassembled state. |
| **Syringes** | **Processing:**<br>Completely disassemble including unscrewing of the cylinder |

(manufacturer) HENRY SCHEIN INC.
135 DURYEA ROAD
Melville, NY 11747 USA
EC REP
HENRY SCHEIN SERVICES GmbH
MONZASTRASSE 2A
D-63225 LANGEN, GERMANY
WWW.HENRYSCHEINBRAND.COM
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