Y-Adapter

EN-US

Reprocessing information

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Usage

1 Reprocessing

1.1 Risk analysis and classification

A risk analysis and classification of medical devices that are common in dentistry must be performed before they are reprocessed by the operator. Comply with all national directives, standards and specifications such as e.g. the "Guidelines for Infection Control in Dental Health-Care Settings from the Centers for Disease Control and Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation given Intended Use of the product:
Non-critical to semi-critical B
Non-critical medical device:
A medical device that only comes into contact with intact skin.
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically changed skin.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

1.2 Reprocessing procedures

Perform the reprocessing procedure after each patient treatment and according to the reprocessing procedure:
– Pre-cleaning in accordance with AAMI TIR 30.
– Steam sterilization in accordance with ANSI/AAMI/ISO 17665-1, Annex D, ANSI/AAMI/ISO 14937, Annex D and ANSI/AAMI ST81.

Important information!

The reprocessing instructions in accordance with FDA Guidance "Reprocessing Medical Devices in Health Care Settings - Validation Methods and Labeling" have been independently tested by the manufacturer for the preparation of the device and its components for their reuse.

The person conducting the reprocessing is responsible for ensuring that the reprocessing is performed using equipment, materials and personnel that attains the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person conducting the reprocessing are the responsibility of the member of staff performing the reprocessing.
Frequent reprocessing has little effect on the components of the device. The end of the product life cycle is mainly influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing method was validated as follows:

- **Pre-cleaning**
  - Monarch Surface Disinfection Wipes
- **Manual cleaning**
  - Monarch Enzymatic Cleaner
  - Cleaning brush
  - Ultrasonic device: Elma Elmasonic S 300H
- **Automatic cleaning and disinfection**
  Was performed in accordance with ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - RDG: PG 8535 (Miele)
  - Programs: "Cleaning without neutralization" and "THERMAL DES"
  - Rinsing adapter (REF 0700-000-17)
- **Steam sterilization**
  Sterilization type: Dynamic-Air-Removal Steam Sterilization Cycles
  - Pre-vacuum: 3 x
  - Sterilization temperature: at least 270 °F
  - Sterilization time: 2 minutes (half-cycle)
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon bristles, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 0.9 and 3.35 in
  - Bristle length: 0.1 and 0.35 in

  Example: Hager & Werken Chiru-Cleaner (REF 4591517), Hager & Werken Mirasuc Brush (REF 4591160)

General information

› Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilization of medical devices as well as the specific specifications for dental practices and clinics.

› When selecting the cleaning and disinfectant agents to be used, the information provided (see above) must be followed.

› Comply with the concentrations, temperatures, residence times and post-rinsing specifications issued by the manufacturer of the cleaning agent and disinfectant.

› Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.

› Only use disinfectants that are aldehyde-free and display material compatibility with the product.

› Only use freshly-produced solutions.

› Only use distilled or de-ionized water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic micro-organisms (e.g. Legionella bacteria).

› Use clean, dry, oil- and particle-free compressed air.

› Do not exceed temperatures of 281 °F.

› Subject all devices used (e.g. ultrasonic bath, cleaning and disinfection device (washer-disinfector), sealing device, steam sterilizer) to regular maintenance and inspections.

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1.3 Preparation at the operating location

Wear hand protection.

Wear eye protection.

Use a mask.

Wear protective clothing.

WARNING

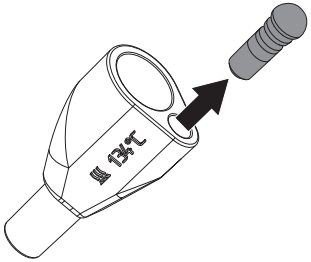
Risk of infection from contaminated products

Risk of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

› Directly after the treatment, aspirate at least 200 ml cold water.

› Take off the plug of the Y-Adapter.



› Wipe down the exterior surfaces of all components completely with two cleaning wipes to remove coarse organic and inorganic soiling.
› Note the action time of the cleaning agent.
› Protect the unit from contamination when transporting it from the treatment chair to the reprocessing location.

1.4 Clean manually, perform a final rinse, dry

Cleaning agents or combined cleaning and disinfection agents with the following properties must be used for manual cleaning:
– Only cleaning and disinfection products approved by EPA (United States Environmental Protection Agency)
– No aggressive or abrasive cleaning agents

For further information, see "General information".

Cleaning

› Place the components in a ultrasonic device with cleaning and disinfection bath (non-fixing/aldehyde-free) making sure that all parts are covered.
› Note the action times of the cleaning agents and disinfectants.
› Brush all exterior and interior surfaces with a hygienic brush below the surface of the ready-to-use solution for at least 5 minutes.

Final rinse

After the action time prescribed by the manufacturer has expired:
› Rinse all components with water for at least 1 minute (temperature < 95°F).

Drying

› If necessary, re-dry at a clean location using a hygienic, lint-free cloth.
› Blow dry the components with compressed air in a clean location.

1.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:
– Corresponds to and tested in accordance with ANSI/AAMI ST15883-1
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 382 °F)

Program is suitable for the components and includes sufficient rinsing cycles.
For more information: "General information".

Selection of the machine cleaning agents and disinfectants

The following properties are required:
– Material compatibility with the product
– Compliance with the washer-disinfector manufacturer's specifications

For further information, see "General information".

Automatic cleaning and disinfecting

When arranging the parts in the washer-disinfector, make sure there are no areas missed by rinsing.

› Attach the Y-Adapter to a suitable holder in the washer-disinfector.
› Place the plug in a basket for small parts in the washer-disinfector.

1.6 Check for function

› After the end of the cleaning and disinfection cycle, check the components for any residual soiling and residual moisture. If necessary, repeat the cycle.
› If necessary, replace any damaged parts.
› The components should be packaged as soon as possible after drying and checking.

1.7 Steam sterilization

Packing

For packaging of the components, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. This includes:
– Temperature resistance up to 281 °F
– Standards AAMI/ANSI/ISO 11607-1/2
– The applicable sections of the standard series EN 868
– Cleared by FDA under 21 CFR 880,6850, product code FRG

The sterile barrier system must be large enough. Once it is loaded, the sterile barrier system must not be under any strain.

Steam sterilization

WARNING

Health risk due to improper sterilization

If the sterilization is not performed correctly, it may not be effective. The use of insufficiently sterilized instruments can be a health risk to the patient.

› Only steam sterilization is permissible.
› Comply with all process parameters.
› Comply with the manufacturer‘s instructions regarding the use of the steam sterilizer.
› Do not use any other procedures.

NOTICE

Damage to equipment due to improper sterilization

Product damage may be caused if the sterilization process is not performed correctly.

› Comply with the manufacturer‘s instructions regarding the use of the steam sterilizer.
› Comply with all process parameters.

Process parameters
Sterilization type: Dynamic-Air-Removal Steam Sterilization Cycles
Min. temperature: 270 °F
Holding time: 4 min
Drying time: 20 - 30 min

Wear hand protection.

› Prior to use, subject the products to steam sterilization in a steam sterilizer at 270 °F for 4 minutes with 20 -30 minutes drying time.

Marking

› Mark the packaged, treated medical device appropriately such as to ensure its safe application.

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1.8 Issue clearance for the parts for sterilization

The reprocessing of the medical device ends with the documented clearance for storage and renewed use.

› Document the release of the medical device after reprocessing.

1.9 Storing parts for sterilization

› Comply with the stated storage conditions:
  – Store the parts protected against contamination
  – Dust-protected, e.g. in a locked cabinet
  – Protected against moisture
  – Protected against excessive temperature fluctuations
  – Protected against damage

  The integrity of the packaging of a sterile medical device be lost as a result of a particular incident and the passage of time.
  Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

› Store the product protected against contamination.

› Shelf life is determined and identified per instruction for use of sterilization packaging used.

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