Universal Cannula, Universal Cannula Protect, Universal Cannula Petito, Prophylaxis Cannula

EN

Reprocessing information

CE 0297

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DÜRR DENTAL

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Usage

Usage

EN

1 Reprocessing

1.1 Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives, standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".
Accessories of the medical device are also subject to reprocessing.
Classification recommendation given intended use of the product: **semi-critical B to critical B**
Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically affected skin.
Critical medical product:
a medical product which also comes into contact with injured skin and blood.
The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

1.2 Reprocessing procedure in accordance with EN ISO 17664

The reprocessing procedure after each patient treatment is carried out according to the reprocessing procedure established by EN ISO 17664.

Important information!

The reprocessing notes in accordance with EN ISO 17664 have been independently tested by Dürr Dental for the preparation of the device and its components for their reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.
Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially 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 procedure was validated as follows:

- **Pre-cleaning**
  - FD 350 disinfection wipes (Dürr Dental)
- **Manual cleaning**
  - ID 215 enzymatic instrument cleaner (Dürr Dental)
  - Cleaning brush
- **Manual disinfection**
  - ID 213 Instrument disinfection (Dürr Dental)
- **Automatic cleaning and disinfection**
  Was performed in accordance with EN ISO 15883 with tested efficacy.
  - Cleaning agent: Neodisher MediClean Forte
  - Washer-disinfector: PG 8535 (Miele)
  - Programmes: "Cleaning without neutralisation" and "THERMAL DES"
- **Steam sterilisation**
  was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.
  - Pre-vacuum: 3 x
  - Sterilisation temperature: 132 °C
  - Sterilisation time: 4 minutes
  - Drying time: min. 20 minutes
- **Cleaning brush**
  Cleaning brush with nylon hairs, double-sided
  - Number of brush heads: 2
  - Brush material: nylon
  - Brush head length: 25 and 35 mm
  - Brush length: 5 and 10 mm

  Example: Interlock cleaning brush, double-sided, green REF 09098, Interlock cleaning brush round REF 09318

General information

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

› Comply with the specifications (see "1.4 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "1.5 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying") when selecting the cleaning and disinfectant agents to be used.

› Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.

› 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.

› Do not use any rinse aid (danger of toxic residue on the components).

› Only use freshly-produced solutions.

› Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).

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

› Do not exceed temperatures of 138 °C.

› Subject all devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

1.3 Preparation at the operating location


Wear protective gloves.


Wear protective goggles.


Use a mask.


Use protective clothing.

WARNING

Risk of infection from contaminated products

Danger 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.

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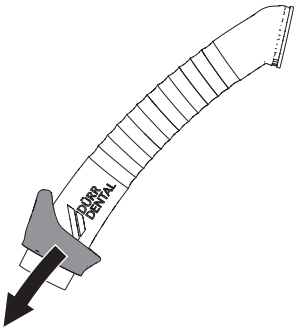
› Take off the rotating head of the prophylaxis cannula to the rear.



› Wipe down the exterior surfaces of all components completely with two cleaning cloths 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 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying

A disinfectant or combined cleaning and disinfectant agent is required for manual disinfection. It must have the following properties:
– certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)

For further information, see: "General information".

Cleaning

› Place the individual components in a disinfectant bath (non-fixing/aldehyde-free, see "General information") so that all parts are covered.
› Comply with the reaction times of the cleaning agent and disinfectant, see "General information")
› Brush all exterior and interior surfaces completely with a hygienic brush under the surface of the ready-to-use solution.

Intermediate rinsing

After the action time prescribed by the manufacturer:
› Rinse off all components under water for at least 1 minute (temperature < 35°C).

Disinfection

› Place individual components in a cleaning and disinfectant bath so that all parts are covered.
› Note the action time for the disinfectant.

Final rinse

After the action time prescribed by the manufacturer:
› Rinse off all components under water for at least 1 minute (temperature < 35°C).

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 EN ISO 15883
– Certified program for thermal disinfection (A_0 value ≥ 3000 or at least 5 minutes at 93°C)
– Programme is suitable for the components and provides 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
– Corresponds with the manufacturer's specifications of the CD

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 cannula to suitable holders in the washer-disinfector.
› Secure the removeable rotating head of the prophylaxis cannula with a suitable fixture of 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 sterilising

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 138°C
– Standards EN ISO 11607-1/2
– The applicable sections of the standard series EN 868

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

Steam sterilising

WARNUNG

Health risk due to incorrect sterilisation

If the sterilisation not performed correctly, it may not be effective. The use of instruments that have not been properly sterilised can pose a health risk to the patient..

› Only steam sterilisation must be used.
› Comply with all of the specified process parameters.
› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Do not use any other methods.

ACHTUNG

Damage to equipment due to incorrect sterilisation

If the sterilisation process is not performed correctly, this can cause damage to the product.

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

Requirements placed on the steam steriliser:

– Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
– Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
– Sufficient product drying
– Validated process in accordance with ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ))

Perform the following steps:

› Sterilise the parts for sterilisation (at least 20 minutes at 121°C, at least 4 minutes at 132°C or at least 5 minutes at 134°C).
Do not exceed 138 °C.

Marking

› Mark the packaged, treated medical product in such a way as to ensure safe application.

1.8 Issue clearance for the parts for sterilisation

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

› Document the clearance of the medical product after reprocessing.

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1.9 Storing parts for sterilisation

› 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

Packaging for a sterile medical device can suffer damage 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.

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