

Cleaning and Disinfection

All single-use products (i.e. Abutments) are non-sterile when delivered. Before placing the restoration in the patient's mouth, the products must be cleaned, disinfected and sterilized. Cendres+Métaux recommends the following procedure for cleaning, disinfection and sterilization of single-use products (i.e. Abutments) prior to use.

Note: as far as possible, all products must be disassembled into their single parts prior to the cleaning/disinfection and sterilization procedure. Automated procedures for cleaning/disinfection are recommended.

Caution: Information on chemical resistance

No oxidative components (H₂O₂) may be used in a cleaner or cleaner additive

No active chlorine may be used

No phosphoric acid as neutralizing agent may be used

No caustic soda may be used

Do not use strong alkaline cleaners

1. Pre-cleaning (Manual and automated procedure):
The products outer and inner side are pre-cleaned with a soft nylon brush under fresh water until no contamination is seen (use magnifying glass 3x).
2. Cleaning (Manual procedure):
Before using the detergent solution, be sure to read the directions for use on the detergent label and package. Soaking the pre-cleaned products according to the parameters below within a detergent solution.

| | |
|---------------|----------------|
| Concentration | 8 ml per liter |
| Duration | 1- 3 min. |
| Temperature | Max. 40 °C |
| Water quality | de-ionized |

Alternatively:

The pre-cleaned products can be placed in an appropriate accessory tray and cleaned in an ultrasonic bath in de-ionized water with a detergent solution at room temperature. Run an ultrasonic cleaning cycle according to parameters below.

| | |
|---------------|----------------|
| Concentration | 8 ml per liter |
| Duration | 15 min. |
| Temperature | Max. 40 °C |
| Water quality | De-ionized |

Following cleaning, rinse products outer and inner side with adequate amounts (e.g., 0,1 liter) of fresh water to remove residual detergent. Be sure to repeat twice, for a total of 3 rinses.

Remove excess moisture from the products, this will help prevent excess water from diluting the disinfectant solution below its Minimum effective concentration.

Recommended detergent Cidezime[®], ASP. The cleaning solution must be renewed daily or by any signs of contamination.

Note: Cidex[®] OPA Solution is compatible with enzymatic detergents (e.g., Cidezime[®] ASP), which are mild in pH, low foaming, and easily rinsed from products. Detergents that are either highly acidic or alkaline are contraindicated as cleaning agents.

Instruction for use

Single-use (Abutments)

3. Disinfection (Manual procedure):

Before using the disinfectant solution, be sure to read the directions for use on the disinfectant label and package. For all products, a high-level disinfectant is required.

Immerse cleaned and dried products completely in the disinfectant solution. Ensure the products are completely submersed in the disinfectant solution and if applicable fill all lumens.

Cover the disinfectant solution tray with a secure lid. Soak products according to the parameters below to achieve high level disinfection.

| | |
|---------------|---------|
| Concentration | pure |
| Duration | 12 min. |
| Temperature | > 20 °C |
| Water quality | sterile |

Following disinfection, rinse products thoroughly, flushing channels and lumens with potable or sterile water. Be sure to repeat twice, for a total of 3 rinses. Each rinse should be a minimum of 1 minute in duration, and an adequate volume of fresh water (e.g., 0,1 liter) must be used for each rinse.

Dry the products. Disinfected products should be used or sterilized immediately or stored in a manner to minimize recontamination.

It is recommended that the disinfectant solution be tested before each usage (e.g. with test stripes) to verify that the appropriate concentration is guaranteed.

Note: Cidex OPA solution must be discarded after 14 days even if the test indicates a concentration above the minimum effective concentration.

Recommended disinfectant Cidex® OPA, ASP.

4. Cleaning/Disinfection (Automated procedure):

The pre-cleaned product can be placed in an appropriate accessory tray and cleaned/disinfected in an automated washer-disinfector.

Select the appropriate program according to the manufacturer`s instructions. The cleaning/disinfection is validated with the Miele washer-disinfector, program Vario TD Dental

The disinfection cycle is validated according the parameters below.

| Process step | Parameter | Agent/condition |
|---------------------|--|---|
| Flushing / pre-wash | Cold / 3 min. | potable water |
| Washing | 5 ml per liter 40 – 55 °C / 10 min. | Thermosept Xtra Soft or de-ionized water |
| Rinse | - | De-ionized water |
| Disinfection | >90 °C / 5 min. | - |
| Rinse | 93 °C / 5 min. | De-ionized water |
| Drying | 99 °C / 35 min. | - |

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5. Sterilization

The products may be sterilized unwrapped. Put the products in appropriate sterilizer tray. Only steam sterilization cycles as listed below may be used for sterilization. Other sterilization methods are not allowed. Do not exceed the maximum load according the manufacturers instruction for use of the sterilizer.

Steam sterilization according to the parameters below:

| Material | Method (validated) | Conditions |
|---|--|--|
| Abutments : (Titan, Zirconia) Inserts: (Pekkton, Elitor) | Autoclave (moist heat) flash-gravity displacement | 132°C (270°F) 3 min. Drying time: 1 min. |

| Material | Method (alternative) | Conditions |
|---|---|--|
| Abutments : (Titan, Zirconia) Inserts: (Pekkton, Elitor) | Autoclave (moist heat) Fractioned pre-vacuum | 134°C (273°F) 18 min. Drying time: 15 min. |

Note: Allow system components to cool before use. Only use approved sterilizers, sterilization containers, sterilization pouches, biological indicators, chemical indicators and other sterilization accessories appropriately identified and recommended for sterilization and the sterilization cycle.

Caution: Use device immediately after sterilization. Do not store sterilized devices.

The following devices, material and machines have been used in the cleaning/disinfection and sterilization validation study:

Manual procedure:

Detergent: Cidezyme®; ASP
Disinfectant: Cidex® OPA, ASP

Automated procedure:

Cleaning agent: Thermosept Xtra® Schülke+Mayr
Washer/Disinfectant: Steelco DS500CL
Accessory tray: Std.