CENDRES+ MÉTAUX

prosthetic.line

# Reprocessing of surgical and prosthetic products

# Instructions for Use
# Reprocessing of surgical and prosthetic products

## 1 Scope of application of Instructions for Use

These Instructions for Use specify the reprocessing steps for both reusable products as well as for Cendres+Métaux SA products specified for single use. This includes cleaning and subsequent disinfection and/or sterilisation to ensure that the product is safe and effective for its intended purpose. The information given in this document is applicable to products intended for invasive or other direct or indirect contact with the patient. The reprocessing steps for products which are not intended for direct contact with the patient (e.g., instruments for laboratory use) are also described in these Instructions for Use.

The issuing of these Instructions for Use renders all previous versions invalid.
The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use.

## 2 Intended use

Auxiliary parts and instruments are used in the various product systems for activation, deactivation, preparation of a root canal and for correct processing and restoration of the corresponding product systems of a dental restoration.

## 3 Classification

The classification below depends on the intended purpose and its risk of transmitting pathogens (infections) for reusable products or products intended for single use only.

| Classification | Description | Example |
|---|---|---|
| Non-critical | Non-critical products only come into contact with intact skin or are products which are not intended for direct patient contact. | Products intended for laboratory use only e.g. parallelometer insert, transfer axis, analogs, duplicating auxiliary parts, burn-out parts, etc. |
| Semi-critical | Semi-critical products come into contact with mucous membranes or non-intact skin. | Products which are used for a short time in the patient's mouth e.g. aligner, handle, screwdriver invasive, female parts, retention and friction inserts, etc. |
| Critical | Critical products usually penetrate sterile parts of the human body. | Products which are used in invasive surgery, e.g. instruments for working in the root canal, root canal posts and root canal anchors, abutments, male parts, etc. |

| Work steps for reprocessing | Classification of product | | |
|---|---|---|---|
| | Non-critical[1] | Semi-critical | Critical |
| 1. Initial treatment at the place of use | | x | x |
| 2. Preparation prior to cleaning | | x | x |
| 3. Cleaning | (x) | x | x |
| 4. Disinfection | | x | x |
| 5. Drying | | x | x |
| 6. Inspection and maintenance | (x) | x | x |
| 7. Packaging | | x | x |
| 8. Sterilisation | | x | x |
| 9. Storage | (x) | x | x |
| 10. Transport | (x) | (x) | (x) |

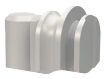
x = Work step mandatory
(x) = Work step applicable if the situation requires

[1] Non-critical products which are not intended for direct contact with the patient are not treated according to standard ISO 17664 with regard to reprocessing (cleaning, disinfection and sterilisation). Nonetheless, it is recommended to clean these instruments after use from work residues such as chips, dust and other materials.

## 4 Product description

These Instructions for Use specify the reprocessing steps for the following product families:

| Product | Description | Material | Classification | Single use | Labelling |
|---|---|---|---|---|---|
|  | **Abutments, implant adapter, bars, screws** | Titanium | Critical | Yes | CE 0483 |

| Product | Description | Material | Classification | Single use | Labelling |
|---|---|---|---|---|---|
|  | **Root canal posts** and **root canal anchors** | Ceramicor®, titanium | Critical | Yes | CE 0483 |
|  | **Female parts** | Titanium, Elitor®, Doral | Semi-critical | Yes | CE 0483 |
|  | **Retention inserts** | Pekkton® | Semi-critical | Yes | CE 0483 |
|  | **Retention and friction inserts**<br><br>**Important note**<br>All parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use.<br>Plastic parts may not be sterilised. | made of POM | Semi-critical | Yes | CE 0483 |
|  | **Duplicating aids** | made of POM | Non-critical | Yes | CE |
|  | **Burn-out parts** | made of POM | Non-critical | Yes | n/a |
|  | **Root canal instruments**<br>surgically invasive drills, root canal drills, milling cutters of the systems:<br>root canal posts CM, MP-Post, root canal posts Mooser, Rotex, Rotex-RD, Pirec, Dalbo®-Rotex | stainless steel | Critical | No | CE 0483 |
|  | **Handles** for the manual activation of products of the following systems:<br>root canal posts CM, root canal posts Mooser, Rotex, Rotex-RD, Dalbo®-Rotex | stainless steel | Semi-critical | No | CE |
|  | **Root post gauge** for checking the insertion depth and wall stability of CM root canal posts and Mooser root canal posts | stainless steel | Semi-critical | No | CE |
|  | **Case guide** for determining the implant axis and abutment height for the CM LOC® system | Titanium | Semi-critical | No | CE |

| Product | Description | Material | Classification | Single use | Labelling |
|---|---|---|---|---|---|
|  | **Screwdriver** for CM LOC®, CM LOC® Flex, Dalbo® Abutment and CM screw system<br>**Coupling** for extending the root canal instruments of the following systems: root canal posts CM, root canal posts Mooser, Rotex, Rotex-RD, Dalbo®-Rotex<br>**Gauge** for Dalbo®-PLUS | stainless steel | Semi-critical | No | CE |
|  | **Activator for Dolder® System and round bar with rider** | stainless steel | Non-critical | No | CE |
|  | **Activator and deactivator for Dolder® System and Dalbo®-B, Dalbo®-Classic, Dalbo®-Z**<br><br>**Important note**<br>As the handle is not made of heat resistant plastic this instrument may not be sterilised, but only disinfected using suitable methods. | Brass chrome plated / steel, stainless, plastic | Non-critical | No | CE |

## 5 Qualification of the specialist

Expertise in professional dentistry and dental technology is assumed. The current Instructions for Use must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.

Only original tools and parts may be used for this work. For information and additional details, please contact your Cendres+Métaux SA representative.

Important information for the specialist

⚠ Warning symbol for increased caution

## 6 Prescription

Federal laws in the USA prohibit the use by or sale to unlicensed dentists.

## 7 Side effects

⚠ This product must not be used in patients with allergies or suspected allergies to materials used in the product (see Section 19), or only after prior allergological clarification.
Auxiliary instruments may contain nickel.
If applied as intended, side effects can be excluded.

## 8 Warnings

⚠ **Magnetic resonance (MR) environment**
The device has not been evaluated for safety and compatibility in the MR environment.
The product has not been tested for heating or migration in the MR environment.

## 9 General information

These Instructions for Use must be taken into account together with the Instructions for Use of the respective product system before application.

## 10 Preventive measures

All reusable products (e.g. instruments) and products for single use (e.g. construction elements) are supplied non-sterile.
Prior to use in the patient's mouth, the products must be cleaned, disinfected and sterilised. Cendres+Métaux recommends the following procedure for cleaning, disinfecting and sterilising reusable products (e.g. instruments) before use.

Note on chemical resistance
The following:
– oxidising components ($H_2O_2$) in a detergent or cleaning additive
– active chlorine
– phosphoric acid as neutralising agent
– caustic soda
– strong alkaline detergents
must not be used.

## 11 Procedure

### 11.1 Initial treatment at the place of use

After use, coarse contamination must be removed to prevent organic matter from drying on the surface. For the protection of the environment and medical personnel, the products must be transported in suitable containers.

**During surgery (e.g. endodontic treatment)**
Place soiled instruments in suitable containers.

**Following surgery (e.g. endodontic treatment)**
Remove residual blood, secretion, tissue or root dentine immediately.

**Important note**
Do not allow organic residue to dry up.

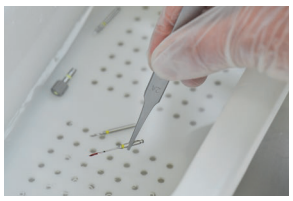
### 11.2 Preparation and cleaning

All products must be disassembled into their individual parts as far as possible prior to cleaning/disinfection and sterilisation. Automated procedures are recommended for cleaning/disinfection.

The instruments must be cleaned subsequently. Use nylon brushes for manual cleaning. Use only suitable cleaning agents. Follow the manufacturer's instructions precisely.

**Important note**
Use adequate protective clothing (protective goggles, face mask, gloves, etc.) during all working steps with contaminated instruments.

**Manual precleaning**



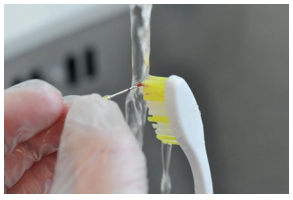
Place the (disassembled) products in cold water for 5 min. (<40°C/104°F). Brush the outside and inside with a soft nylon brush while adding fresh water, and remove all contamination (use a magnifying glass with 3x magnification). Rinse the products with cold tap water until all visible accumulation of soiling is removed. Avoid drying of the product before or during cleaning. Dried biological material is difficult to remove.

**Ultrasonic precleaning**

The (disassembled) products are placed in a suitable accessory container and cleaned in deionised water with cleaning solution in an ultrasonic bath at room temperature.
Perform an ultrasonic cleaning cycle according to the parameters below. The (disassembled) products are placed in a suitable accessory container and rinsed in deionised water with cleaning solution in an ultrasonic bath at room temperature.
Perform an ultrasonic cleaning cycle according to the parameters below.

Do not clean any cutting instruments in the ultrasonic cleaner as this could blunt the instruments.

| Process step | Parameters | Operating material / quality |
|---|---|---|
| Concentration | 8 ml per litre (0.8%)<br>15 min.<br>< 40°C (140°F) | Cidezyme® ASP |
| Rinsing | Cold, 2x 10 sec. | Deionised water |



All internal cavities, threads and drill holes must be rinsed with a water gun for 10 seconds. Then rinse the entire precleaned product again.

## 11.3 Cleaning, disinfection and drying

### Automated process

Place the precleaned product in a suitable accessory container and clean/disinfect the product in a washer disinfector. Select a suitable programme according to the manufacturer's instructions. Cleaning / disinfection was performed with a Miele washer disinfector, programme DES-VAR TD. The cleaning and disinfection cycle was validated with the following parameters.

| Process step | Parameters | Operating material / quality |
|---|---|---|
| Rinsing / prewashing | Cold, 3 min. | Tap water |
| Washing | 5 ml per litre (0.5%)<br>55 °C (131 °F), 10 min. | Thermosept® X-tra<br>Soft or deionised water |
| Rinsing | >40 °C (104 °F), 2 min. | deionised water |
| Disinfection | >90 °C (194 °F), 5 min. | Please observe the national requirements concerning the A0 values (ISO 15883) |
| Drying | <120 °C (248 °F)<br>Airflow, customised duration | According to the manufacturer's recommendations for the washer disinfector. |

**Recommended detergent:**

Thermosept® X-tra.

Manual drying can be performed with a lint-free cloth. Dry all cavities with sterile compressed air.

### Manual process

Important: read the Instructions for Use on the detergent label and packaging before using the detergent solution. Prepare a cleaning bath according to the manufacturer's instructions.

| Process step | Parameters | Operating material / quality |
|---|---|---|
| Cleaning | 8 ml per litre (0.8%)<br>1-3 min.,<br>< 40°C (140°F) | Cidezyme® ASP |
| Rinsing | Cold, 3x | Tap water |

a. Fully immerse the precleaned products in the detergent solution. Follow the manufacturer’s instructions on exposure time.
b. Clean the product manually with a soft brush in the bath containing detergent. All surfaces must be brushed several times.
c. The following steps only apply to canals and the insides of drill holes: brush in and out of the drill holes at least six times. Rinse the drill holes/ canals with distilled water and repeat the procedure.
d. Rinse the products thoroughly with running tap water to remove the detergent without leaving any residues. Repeat this procedure twice for a total of 3 rinses.

Remove excess moisture from the products. This prevents excess water from diluting the disinfection solution below its minimum effective concentration.
Dry the products with a lint-free cloth and use oil-free compressed air, in particular for cavities and recesses.

**Recommended detergent**

Cidezyme® ASP. The detergent must be renewed daily or if there are any signs of contamination.

Cidex® OPA Solution is compatible with enzymatic detergents (e.g. Cidezyme® ASP), which have a weak pH, produce little foam and which are easy to rinse from the product surfaces. Strongly acidic or alkaline detergents must not be used.

**Disinfection**

Important: read the Instructions for Use on the disinfectant label and packaging before using the disinfectant solution. Prepare a disinfectant bath according to the disinfectant manufacturer's instructions. It is recommended to test the disinfectant solution before each use (e.g. with a test strip) to ensure that the correct concentration is assured.
A highly effective (high-level) disinfectant is required for all products.

| Process step | Parameters | Operating material / quality |
|---|---|---|
| Disinfection | Undiluted, 5 min.<br>> 20°C (68°F) | Cidex® OPA |
| Rinsing | Cold, 3x (1 min., 0.1 litre) | Deionised or sterile water |

Fully immerse the cleaned and dried products in the disinfectant solution.
Ensure that the products are fully covered with disinfectant solution and fill all cavities if necessary. Cover the disinfectant container securely with a lid. Allow the disinfectant to act on the products according to the parameters given below to achieve a high level of disinfection.
After disinfection, rinse the products thoroughly with deionised or sterile water, in particular also all canals and cavities. Repeat this procedure twice for a total of 3 rinses.
Each rinse should last at least 1 minute with a sufficient amount of fresh water (e.g. 0.1 litre).

**Drying**

Dry the products with a lint-free cloth and use oil-free compressed air for cavities and drill holes.
Disinfected products should be used immediately, sterilised, or stored in a manner which minimises recontamination.

**Recommended disinfectant**

Cidex® OPA, ASP. A highly effective (high-level) disinfectant is recommended.
Cidex® OPA. The disinfectant solution must be disposed of after 14 days, even if the test indicates a concentration above the minimum effective concentration.

## 11.4 Inspection and maintenance

Inspect the products visually for cleanliness. If necessary, repeat the reprocessing process until the product is visually clean. Any apparent defects such as deformation, breakage, corrosion, loss of colour coding or marking are indications that the products can no longer fulfill their intended use with the necessary level of safety and must therefore be disposed of.

## 11.5 Packaging and sterilisation

The products can be sterilised unpackaged. Place the products in suitable sterilisation containers. Only steam sterilisation cycles according to the methods or parameters given below are permissible. Do not exceed the maximum load specified by the manufacturer for the steriliser.

Information on steam sterilisation:

| Material | Method (validated) | Parameters |
|---|---|---|
| Stainless steel, titanium | Autoclave (moist heat)<br>Gravitation process | 132°C (270°F)<br>10 min.<br>Drying: 1 min. |
| Stainless steel, titanium | Autoclave (moist heat)<br>Fractionated vacuum process | 134°C (273°F)<br>18 min.<br>Drying: 15 min. |

Allow the products to cool before further use. Use only approved sterilisation equipment, sterilisation trays, sterilisation pouches, biological indicators, chemical indicators, and other sterilisation accessories which are labelled accordingly and recommended for sterilisation and the sterilisation cycle.

⚠ Use the products immediately after sterilisation. Store sterilised products only in packaging suitable for this purpose.

The following equipment, materials and machines were used for the validation of the cleaning, disinfection and sterilisation methods:

**Manual process:**
Detergents: Cidezyme®, ASP, Johnson & Johnson
Disinfectants: Cidex® OPA, ASP, Johnson & Johnson

**Automated process:**
Detergents: Thermosept® X-tra, Schülke+Mayr
Washer disinfector: Miele: G 7836 CD

**Sterilisation:**
Steriliser: HST 6x6x6 , Series No. 12/3259, Zirbus technology GmbH
Product packaging: Steriking® flat bag, REF S25, 100x150mm, sterilisation packaging, Wipak Medical

## 11.6 Storage

Store the products in the sterilisation packaging in a clean environment, protected against sources of moisture and direct sunlight. Store at ambient temperature (15-25 °C (59-77 °F)).

## 11.7 Transport

Insofar as the reprocessed medical device has to be transported to the place of use, it must be ensured that no damage occurs to the product and packaging and that its sterility is not impaired.

## 12 Materials

More detailed information on the materials as well as their compositions can be found in the product-specific material data sheets, the product information as well as the product list compiled in Section 29. All relevant documents can be found on the website www.cmsa.ch/docs by entering the relevant product name.

## 13 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product. To do this, please contact your customer advisor or send us your message by e-mail to the address complaints-cmbrand@cmsa.ch. In serious cases, also send a report to the competent authority where you are domiciled.

## 14 Safe disposal

The products must be disposed of in accordance with local laws and environmental regulations, taking into account the level of contamination. Cendres+Métaux Lux SA would be very pleased to accept precious metal waste. For information and additional details, please contact your Cendres+Métaux SA representative.

## 15 Trademarks

Registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland include:

Dalbo®, Dolder®, CM LOC®, Pekkton®, Elitor® and Ceramicor® are registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland.

Unless explained specifically, all products marked with “®” are not registered trademarks of Cendres+Métaux Holding SA, but registered trademarks of the respective manufacturer.

## 16 Disclaimer

The manufacturer rejects any liability for damages resulting from non-compliance with these Instructions for Use. Cendres+Métaux SA products are parts of an overall concept and may only be used or combined with the appropriate original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the lot number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products mentioned in the product list in Section 29 will void any warranty or other express or implied obligation of Cendres+Métaux SA.

Responsibility regarding the suitability of a product for the specific patient case is at the discretion of the specialist.

Cendres+Métaux SA disclaims any express or implied liability and shall not be responsible for any direct, indirect, punitive or other damages arising from or in connection with errors in professional judgement or practice in the use of Cendres+Métaux SA products.

The specialist is obliged to regularly study the latest developments of the products mentioned in the product list in Section 29 and their applications.

It should be noted that the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Expertise in dentistry, dental technology and instructions by an experienced specialist in the use of the products mentioned in the product list under Section 29 is always necessary.

In case of inconsistencies in translations, the English language version shall prevail.

## 17 Labelling on packaging / symbols

| | |
|---|---|
|  | Date of manufacture |
|  | Manufacturer |
| REF | Catalogue number |
| LOT | Lot number |
| QTY | Quantity |
|  www.cmsa.ch/docs | Observe the Instructions for Use, which are available in electronic form at the address specified. |
| Rx only | Attention: According to US federal law, this product may only be sold by or on behalf of a physician. |
| CE CE 0483 | Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements. |
|  | Do not re-use |
|  | Non-sterile |
|  | Protect from sunlight |
|  | Attention, observe accompanying documents |
| UDI  | Clear product identification |
| EC REP | European Authorised Representative |
|  | Importer |
| MD | Medical device |

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