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.

These Instructions for Use apply together with the Instructions for Use of the respective product systems and apply to the products listed in the Instructions for Use of the product systems.

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** **Important note** All parts made of plastic must be disinfected with a high EPA-registered disinfectant prior to use. 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** surgically invasive drills, root canal drills, milling cutters of the systems: 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: 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
	**Screwdriver** for CM LOC®, CM LOC® Flex, Dalbo® Abutment and CM screw system **Coupling** for extending the root canal instruments of the following systems: root canal posts CM, root canal posts Mooser, Rotex, Rotex-RD, Dalbo®-Rotex **Gauge** for Dalbo®-PLUS	stainless steel	Semi-critical	No	CE

Product	Description	Material	Classification	Single use	Labelling
	**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** **Important note** As the handle is not made of heat resistant plastic this instrument may not be steril-ised, but only disinfected using suitable methods.	Brass chrome plated / steel, stainless, plastic	Non-critical	No	CE

5 User qualification

The expertise of a professional dentist or dental technician is required. 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 (USA) prohibit the use or sale by unlicensed dentists.

7 Side effects

⚠ This product may not be used in patients with allergies to one or more elements of the product materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy.
Auxiliary instruments may contain nickel.
No known side effects if applied as intended.

8 Warnings

⚠ The transmission of pathogens (infections) through cross-contamination cannot be ruled out by improperly reprocessed products.

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. Dental or laboratory knowledge is required. Information: www.cmsa.ch/docs

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

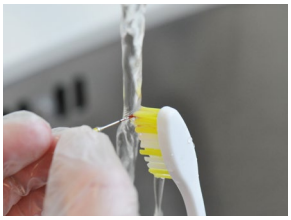
Place the (disassembled) products in cold water for 5 min. (<40°C/104°F). Brush the outside and inside with a soft nylon brush while adding fresh water, and remove all contamination (use a magnifying glass with 3x magnification). Rinse the products with cold tap water until all visible accumulation of 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%) 15 min. < 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%) 55 °C (131 °F), 10 min.	Thermosept® X-tra 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) 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%) 1-3 min., < 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. > 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) Gravitation process	132°C (270°F) 10 min. Drying: 1 min.
Stainless steel, titanium	Autoclave (moist heat) Fractionated vacuum process	134°C (273°F) 18 min. 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

Detailed information on the materials and their classification is given in the specific material data sheets, the catalogue or the section in the product list in the Instructions for Use of the product systems.
See website www.cmsa.ch/docs or the Cendres+Métaux SA Dental Documentation (available free of charge from all Cendres+Métaux SA subsidiaries, branches and dealers).

13 Complaint

Cendres+Métaux SA must be notified immediately of any incident that has occurred with regard to the product to all branches, offices and dealers of Cendres+Métaux SA and, in case of serious cases, to the competent authority where the user is registered.

14 Safe disposal

The product 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

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 SA, Biel/Bienne, 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. This product is part of an overall concept and may only be used or combined with the corresponding original components and instruments. Otherwise, the manufacturer rejects any responsibility and liability. In case of complaints, please always include the batch number.

The use of third party products not distributed by Cendres+Métaux SA in connection with the products listed in Table 1 will void any warranty or other express or implied obligations of Cendres+Métaux SA.

The user of Cendres+Métaux SA products is responsible for determining whether or not a product is suitable for a specific patient and a specific situation.

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 or installation of Cendres+Métaux SA products.

The user is also obliged to regularly study the latest developments of the Cendres+Métaux SA products listed in Section 4 and their applications.

Please note: the descriptions contained in this document are not sufficient for the immediate application of Cendres+Métaux SA products. Specialist knowledge of dentistry, dental technology and instructions in handling the products listed in Section 4 by an operator with appropriate experience is always required.

17 Symbols

	Important information for the specialist
	Warning symbol for increased caution

Labelling on packaging / symbols

	Date of manufacture
	Manufacturer
REF	Catalogue number
LOT	Batch code
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 0483 CE	Cendres+Métaux products with CE labelling meet the requirements of the relevant European requirements.
	Do not re-use
	Non-sterile
	Keep away from sunlight
	Attention, observe accompanying documents
UDI 	Unique Device Identification – UDI
EC REP	European Authorised Representative
	Importer in EU
MD	Medical device

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