

Care and maintenance

Surgical and Prosthetic Instruments

Instructions for use

1. Foreword

The use and periodic maintenance of surgical and prosthetic auxiliary instruments must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work. 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.

The batch numbers of all parts used must be documented to ensure traceability.

2. Fields of application

The auxiliary instruments are intended for activation, deactivation, root canal preparation and the correct processing and restoration of the appropriate design elements.

3. Definition of materials of the auxiliary instruments

- Stainless steel
- Plastic
- Titanium
- Aluminum
- Pekkton®

Detailed information on the materials and their classification is available in the specific material data sheets and the catalog. See website www.cmsa.ch/dental or the Cendres+Métaux Dental Documentation (available free of charge from all Cendres+Métaux subsidiaries, branches and dealers).

4. Definition of cleaning agents

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All components are supplied non-sterile to the customer. Therefore, all products need to be disinfected. Surgical instruments must be sterilized prior to use. Adhere strictly to the manufacturer's instructions for the use of disinfectants (duration of application and concentration).

Surgical instruments intended for multiple use must be disinfected immediately after use and then cleaned to remove any deposits (if necessary, use a nylon brush). Rinse thoroughly with water. Then place the instruments in an autoclave bag or a surgical cassette and sterilize them according to the abovementioned measures. The following are not recommended for stainless steel: chlorinated or chlorine-contaminated disinfection or cleaning agents (e.g. through physiological saline solution) as well as disinfection or cleaning agents containing oxalic acid.

Sterilization/disinfection

After any fabrication or modification and prior to use, the prosthetic work, including the female part components, must be cleaned, disinfected and, if appropriate, sterilized. Metal and Pekkton® components are suitable for steam sterilization (see below), while components made of plastic other than Pekkton® are not. Consider published national guidelines when selecting a disinfection and sterilization process. For re-usable surgical and prosthetic instruments, consult the dedicated documentation Care and Maintenance Surgical and Prosthetic Instruments (available for download on www.cmsa.ch/Dental/Download-Center), which provides detailed instructions and recommendations (partly instrument-specific) regarding, maintenance, cleaning, disinfection and sterilization.

Recommendation: Disinfection

All the parts must be disinfected before use with a high-level disinfectant. Follow the instructions of the manufacturer regarding dosage and exposure time.

When choosing the disinfectant, ensure that:

- it is suitable for the cleaning and disinfection of dental prosthetic components,
- it is compatible with the materials of the products to be cleaned and disinfected, and
- it has proven efficacy in disinfection.

We recommend using an ortho-phthaldehyde (OPA) solution like the Cidex® OPA Solution. Strictly follow the manufacturer's instructions.

Sterilization

After cleaning and disinfection, and prior to use, all metal and Pekkton® components must be sterilized. Plastic parts, except those made of Pekkton®, are not suitable for steam sterilization and are processed as indicated in the section Sterilization/Disinfection above.

Sterilization method

The original packaging shall not be used for the sterilization process. Steam sterilization for sterilization of system components was validated with the following parameters:

- Temperature of saturated steam: 132 °C (270 °F)
- Flash-gravity (gravity displacement according to ANSI/AAMI ST79: 2010)
- Sterilization time 10 min (components unwrapped in an unclosed container)
- Drying time: 1 min

According to material properties, metal and Pekkton® components are also compatible with prevacuum steam sterilization at 134 °C (273 °F) for 18 minutes. Do not exceed 140 °C (284 °F).

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.

Rx only

Medical devices (in accordance with MDD 93/42/EC are CE labeled. See packaging for details.

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5. Warnings for care:

The spanner key (order No. 070500) of the Dalbo®-Rotex® according to Prof. Brunner consists partly of plastic. This is heat resistant up to 134°C. At approximately 140°C it becomes brittle.

Cutting instruments must not be cleaned ultrasonically (the cutting edge will be dulled).

The following are not recommended for stainless steel (steel components, auxiliary instruments):
chlorinated or chlorine-contaminated disinfection or cleaning agents (e.g. through physiological saline solution) as well as disinfection or cleaning agents containing oxalic acid.

All oxidizing acids (nitric acid, sulphuric acid, oxalic acid, H₂O₂ (hydrogen peroxide)) will attack the surface.

These instructions for use are not sufficient for immediate use of the auxiliary instruments. Dental or laboratory knowledge is required, as well as an introduction to handling the auxiliary instruments by an experienced person.

Information: www.cmsa.ch/dental

Preventive measures:

The processing, use, repair and periodic maintenance of surgical and prosthetic auxiliary instruments must be carried out exclusively by skilled persons. Only original tools and parts may be used for this work.

All auxiliary instruments are supplied non-sterile and must be sterilized or disinfected prior to initial use.

Only use auxiliary instruments with a cutting function, e.g. drills, 10 times each. Then the part needs to be replaced.

Side effects:

No known side effects if used as intended.

General information:

Symbols



Warning symbol for increased caution

Labeling on packaging / symbols



Date of manufacture



Manufacturer



Catalogue number



Batch code



Quantity



Consult instructions for use

Rx only

Attention: According to US federal law, this product may only be sold by or on behalf of a physician.



Cendres + Métaux SA products with CE labeling meet the requirements of the Medical Device Directive 93/42/EEC.



Do not re-use



Non-sterile



Keep away from sunlight



Attention (observe accompanying documents)

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6. Product overview

Surgical: Instruments	Special note	Material
	<p>Fig. 01</p> <p>Drills and burs (e.g. Rotex® System)</p> <p>The drills and burs are supplied non-sterile to the customer. Surgical instruments must be sterilized prior to use. The use of disinfectants demands strict compliance with the manufacturer's instructions (period of application and concentration). Sterilization is performed as steam sterilization at 134 °C, duration: 18 min. (EN 13060:2004)</p> <p>Surgical instruments intended for multiple use must be disinfected immediately after use and then cleaned to remove any deposits (if necessary, use a nylon brush). Rinse thoroughly with water. Then place the instruments in an autoclaving bag or a surgical cassette and sterilize them according to the abovementioned measures. The following are not recommended for stainless steel: chlorinated or chlorine-contaminated disinfection or cleaning agents (e.g. through physiological saline solution) as well as disinfection or cleaning agents containing oxalic acid.</p> <p>Important note</p> <p>Cutting instruments must not be cleaned ultrasonically (the cutting edge will be dulled).</p> <p>Also see work instructions for the respective product.</p>	<p>Steel, stainless</p>
	<p>Fig. 02</p> <p>Spanner key (e.g. Rotex® System)</p> <p>The spanner key is supplied non-sterile to the customer. Surgical instruments must, if possible, be sterilized prior to use (also see work instructions for the respective product).</p> <p>Important note</p> <p>The spanner key (order No. 070500) of the Dalbo®-Rotex® according to Prof. Brunner consists partly of plastic. This is heat resistant up to 134 °C. At approximately 140 °C it becomes brittle.</p>	<p>Steel, stainless</p> <p>Steel, stainless Plastic</p>
	<p>Fig. 03</p> <p>Torque ratchet (e.g. SFI-Bar®)</p> <p>These are supplied non-sterile to the customer. Prior to surgical procedures, the torque ratchet must first be sterilized. Disassemble immediately after use, disinfect, clean and sterilize. Further information is given in the operating instructions of the torque wrench.</p>	<p>Steel, stainless Plastic</p>

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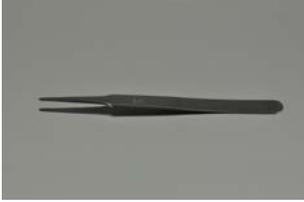
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Prosthetic / (chair- and labside): Instruments

	Special note	Material
	<p>Fig. 04</p> <p>Oral screwdriver (e.g. Mini-SG® V) This is supplied non-sterile to the customer. The oral screwdriver must be disinfected prior to use for prosthetic procedures.</p> <p>Important note Due to its flexible center part, the special screwdriver may not be sterilized, but only disinfected using a suitable method.</p>	<p>Steel, stainless Plastic</p>
	<p>Fig. 05</p> <p>Oral screwdriver (e.g. CM screw system, internal hexagon) These are supplied non-sterile to the customer. The oral screwdrivers must be disinfected prior to use for prosthetic procedures.</p> <p>Important information for all steel components (instrument aids) The following are not recommended for stainless steel: chlorinated or chlorine-contaminated disinfection or cleaning agents (e.g. through physiological saline solution) as well as disinfection or cleaning agents containing oxalic acid.</p>	<p>Steel, stainless</p>
	<p>Fig. 06</p> <p>Activator (e.g. Dolder® System) These are supplied non-sterile to the customer. The activators must be disinfected prior to use for prosthetic procedures.</p>	<p>Steel, stainless</p>
	<p>Fig. 07</p> <p>Deactivator (e.g. Dolder® System) These are supplied non-sterile to the customer. The deactivators must be disinfected prior to use for prosthetic procedures.</p> <p>Important note As the handle is not made of heat resistant plastic it may not be sterilized, but only disinfected using suitable methods.</p>	<p>Brass chrome plated Plastic</p>
	<p>Figs. 08 and 09</p> <p>Activator and Deactivator (e.g. Dalbo®-B) These are supplied non-sterile to the customer. The activators must be disinfected prior to use for prosthetic procedures.</p> <p>Important note As the handle is not made of heat resistant plastic it may not be sterilized, but only disinfected using suitable methods.</p>	<p>Steel, stainless Plastic</p>

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Instruments	Special note	Material
	<p>Fig. 10</p> <p>Screwdriver / Activator (e.g. Dalbo®-PLUS) These are supplied non-sterile to the customer. The screwdrivers / activators must be disinfected prior to use for prosthetic procedures.</p>	<p>Steel, stainless</p>
	<p>Fig. 11</p> <p>Punch (e.g. Dalbo®-B) These are supplied non-sterile to the customer. The punches must be disinfected prior to use for prosthetic procedures.</p>	<p>Anodized Aluminum</p>
	<p>Fig. 12</p> <p>Insert positioner (e.g. SFI-Bar®) These are supplied non-sterile to the customer. The insert positioners must be disinfected prior to use for prosthetic procedures.</p>	<p>Steel, stainless</p>
	<p>Fig. 13</p> <p>Tweezers (e.g. Mini-SG® System) These are supplied non-sterile to the customer. The tweezers must be disinfected prior to use for prosthetic procedures.</p>	<p>Steel, stainless</p>

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7. Workflow / handling

The procedure was described using a laboratory case and is valid for use in the dental practice and the laboratory.

Intraoperative:



Fig. 14

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

Postoperative:



Fig. 15

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

Important note

Do not allow organic residue to dry up.



Fig. 16

2. Then place instruments in a suitable disinfection bath.
Please follow the manufacturer's instructions on dosage/
concentration, exposure and temperature precisely.

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Fig. 17

3. Following disinfection, rinse the instrument under running water.



Fig. 18

4. The instruments must be cleaned following disinfection. Only use nylon brushes for manual cleaning. Use only suitable cleaning agents. Follow the manufacturer's instructions precisely.



Fig. 19

5. Following cleaning, rinse the instrument under running water.
6. Then dry the instruments immediately, e.g. with a disposable cloth.
7. Place instruments in an autoclaving bag or surgical cassette. Sterilization is performed as steam sterilization at 134 °C, duration: 18 min. (EN 13060):
8. Following sterilization, store the packaging dry and dust-free at room temperature.

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Figs. 20 and 21

Important note

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

Handling / aftercare:

Further information on handling/aftercare of dentures is available in the patient information brochure. www.cmsa.ch/dental
For further information, please contact your Cendres+Métaux representative.

8. Disclaimer / disclaimer of liability

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.

The auxiliary parts are part 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 batch number.

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Dalbo®-Rotex®, Mini-SG®, Dolder®, SFI-Bar® and Pektkon® are registered trademarks of Cendres+Métaux Holding SA, Biel/Bienne, Switzerland.

Cidex® OPA Solution is a registered trademark of Advanced Sterilization Products. Irvine, Canada.