PROCESSING

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MANUFACTURER INFORMATION AND INSTRUCTIONS FOR CLEANING/STERILIZING SURGICAL INSTRUMENTS AND PROSTHETIC COMPONENTS OF MEDEALIS.

Instruments/prosthetic components are delivered non-sterile. They must be disinfected or sterilized before their first use. Instruments intended for repeated use must be cleaned, disinfected, and sterilized before each use. Single-use products are not intended for repeated use.

I. SINGLE USE PRODUCTS

1. Prosthetic components: Abutments, abutment retaining screws, impression posts

				
Abutment straight	Abutment angulated	Bar abutment/cap	Retaining screw	Impression post

The products must be sterilized before use on the patient.

Packaging, sterilization [1], [2] and storage

When selecting disposable sterilization packaging (single packaging), the following applies requirements according to material/process: - EN ISO/ANSI AAMI ISO 11607-1/-2 - suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F) and sufficient steam permeability) - Sufficient protection of the instruments or sterilization packaging against mechanical damage. The following requirements apply when selecting sterile containers (hereinafter referred to as "containers"): - EN ISO/ANSI AAMI ISO 11607-1/-2 as well as EN 868-8 - Maintain and check containers regularly. For sterilization, only the sterilization procedure listed below is to be used. Other sterilization procedures are not permitted.

The steam sterilizer used must be CE marked and comply with EN 13060 or EN 285 (Europe) or have FDA clearance (US).

Sterilization bags [7], [8], [9]

Pack the separately cleaned prosthetic parts and instruments in a disposable sterilization package suitable for steam sterilization (single or double package) and/or a sterilization container. Packaging suitable for steam sterilization must meet the requirements of DIN EN ISO 11607/ANSI/AAMI ST79/AAMI TIR, e.g. disposable sterilization packaging (single or double packaging) with a temperature resistance of at least 137 °C (279 °F) and sufficient steam permeability.

The sterilization parameters for prosthetic components can be found in the following table:

Method 1	Procedure	Temperature	Minimum holding time *	Drying time
Hot steam	Vacuum procedure (3x fractional pre-vacuum)	134°C	5 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary on different devices.

Validated procedure Europe: Steam sterilizer Systec HX-320 ; sterilization packaging SteriCLIN® bags (paper / foil) REF: 230212

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Method 2	Procedure	Temperature	Minimum holding time *	Drying time
Hot steam	Vacuum procedure (3x fractional pre-vacuum)	132°C	4 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary on different devices.

Validated procedure: Autoclave EHS 3870 from Tuttnauer; Sterilization packaging according ISO 11607-1 (e.g. 60g/qm)

Marking of sterile goods

For safe reuse of instruments/medical devices, the following information must be clearly visible to the user on the cleaned and sterilized packaged instruments/medical devices:

- Name of the contents, if not clearly recognizable (for sterilization in trays)
- Specifies the sterilizer if more than one is used.
- Batch identification (which sterilization run?)
- Date of sterilization
- expiry date, if applicable, until when safe use is possible

The cleaning and sterilization results must be documented in such a way that traceability of the respective batch of medical devices is possible at any time.

Requirements for storage according to DIN58953-8

Storage unprotected: On shelves in rooms that do not comply with room class II according to DIN 1946-4:

maximum 48 hours ***To be avoided as storage type!***

Storage protected: Dust-protected in closed storage systems, e.g. in cupboards, drawers or shelves in rooms of room class II According to DIN 1946-4

maximum 6 month

Once the storage period has expired, the medical device must be repackaged and sterilized.
Observe deviating specifications of the manufacturer of the sterile barrier system (sterilization bag)!

2. Prosthetic components: HPP (PA12-GB30) retention inserts, block-out spacer, scan cap

		
Retention inserts HPP	Scan cap	Block-out Spacer

The products must be sterilized before use on the patient.

Packaging, sterilization [1], [2] and storage

When selecting disposable sterilization packaging (single packaging), the following applies requirements according to material/process: - EN ISO/ANSI AAMI ISO 11607-1/-2 - suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F) and sufficient steam permeability) - Sufficient protection of the instruments or sterilization packaging against mechanical damage. The following requirements apply when selecting sterile containers (hereinafter referred to as "containers"): - EN ISO/ANSI AAMI ISO 11607-1/-2 as well as EN 868-8 - Maintain and check containers regularly. For sterilization, only the sterilization procedure listed below is to be used. Other sterilization procedures are not permitted.

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The steam sterilizer used must be CE marked and comply with EN 13060 or EN 285 (Europe) or have FDA clearance (US).

Sterilization bags [7], [8], [9]

Pack the separately cleaned prosthetic parts and instruments in a disposable sterilization package suitable for steam sterilization (single or double package) and/or a sterilization container. Packaging suitable for steam sterilization must meet the requirements of DIN EN ISO 11607/ANSI/AAMI ST79/AAMI TIR, e.g. disposable sterilization packaging (single or double packaging) with a temperature resistance of at least 137 °C (279 °F) and sufficient steam permeability.

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Validated procedure Europe: Steam sterilizer Systec HX-320; sterilization packaging SteriCLIN® bags (paper / foil) REF: 230212

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Hot steam	Vacuum procedure (3x fractional pre-vacuum)	132°C	4 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary on different devices.

Validated procedure: Autoclave EHS 3870 from Tuttnauer; Sterilization packaging according to ISO 11607-1 (e.g. 60g/qm)

Marking of sterile goods

For safe reuse of cleaned and sterilized instruments/medical devices, the following information must be clearly visible to the user on the packaged instruments/medical devices:

- Name of the contents, if not clearly recognizable (for sterilization in trays)
- Specifies the sterilizer if more than one is used.
- Batch identification (which sterilization run?)
- Date of sterilization
- expiry date, if applicable, until safe use is possible

The reprocessing results shall be documented in such a way that traceability of the respective batch of medical devices is possible at any time:

Requirements for storage according to DIN58953-8

Storage unprotected: On shelves in rooms that do not comply with room class II according to DIN 1946-4:

maximum 48 hours ***To be avoided as storage type!***

Storage protected: Dust-protected in closed storage systems, e.g. in cupboards, drawers or shelves in rooms of room class II According to DIN 1946-4

maximum 6 months

Once the storage period has expired, the medical device must be repackaged and sterilized.
Observe deviating specifications of the manufacturer of the sterile barrier system (sterilization bag)!

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3. Prosthetic components: Retention inserts nylon, processing insert, retention housing, parallelisation post, spacer sleeve, impression coping, impression cap

						
Retention inserts nylon	Processing Insert	Parallelisation Post	Retention housing titanium/zirconium with processing insert	Spacer Sleeve	Impression Coping	Impression Cap

All products **cannot** be sterilized in an autoclave. The products must be chemically disinfected, otherwise the function of the products may be impaired.

Disinfection:

Use only disinfectants with tested efficacy (e.g., VAH/DGHM or FDA approval or CE marking). Always follow the information, instructions, and warnings of the respective manufacturer of the disinfectant.

Validated procedure for the disinfection of products that cannot be sterilized:

Disinfectant: **Cidex® OPA** from JOHNSON & JOHNSON GmbH.
(Cidex® OPA is a registered trademark of Johnson & Johnson)

Completely immerse the medical device in CIDEX® OPA solution at room temperature (20°C) for at least 5 minutes so that all lumens are filled and all air bubbles are eliminated. Remove the product from the solution and rinse thoroughly according to the following rinsing instructions.

• After removing the medical device from the CIDEX® OPA solution, immerse it completely in 1 litre of demineralized water. Then rinse the medical device under running water for 30 seconds.

• Repeat both steps: immersion and rinsing, once more so that the disinfectant is completely removed.

• After the second rinse, proceed with a final rinse for 10 seconds in isopropanol 70%.

Drying process

Subsequently, complete drying must be carried out with compressed air or a clean, lint-free disposable cloth.

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II. PRODUCTS FOR MULTIPLE USE

4. Instruments: Instruments with shank for contra-angles, universal instruments, angle measuring aid

			
A0022 screwdriver for System Abutments with shank for contra-angle handpieces	A0023 screwdriver with holding sleeve for Docklocs abutments with shaft for contra-angle handpieces	A0025 hexagon screwdriver 1.25mm for Docklocs abutments and retaining screws with shaft for contra-angle handpieces	A0027 screwdriver with holding sleeve for Docklocs Zeramex abutments with shank for contra-angle handpieces and ZrCN coating

		
A0019 Two-piece Universal instrument practice	A0020 Four-piece Universal instrument	A0013 Angle measuring aid

Basic information

The instruments should always be cleaned by machine. This is the only way to achieve a reproducible result. The use of manual methods is not recommended as it is clearly less effective and reproducible.

Preparation at the point of use

Coarse uncured contaminants on instruments should be carefully removed with a lint-free cellulose cloth immediately after use on the patient. The transport of the instruments from the place of use to the place of reprocessing can either take place in an instrument tub (dry disposal) or directly immersed in the combined detergent/disinfectant (see below) (wet disposal). In any case, after the instruments have been used, rapid forwarding for reprocessing is recommended. Waiting times of several hours between use and reprocessing must be avoided at all costs.

Preparation for cleaning/disinfection

For infection prevention reasons, pre-treatment of the instruments is expressly recommended for both the mechanical and the manual reprocessing procedure to protect the staff! To prevent drying of residues and for pre-disinfection, the instruments are placed bubble-free, completely covered in a disinfectant tub (with sieve insert and lid) filled with alkaline, aldehyde-free disinfectant solution. The disinfectant ** used must be suitable for the instruments and have a tested effectiveness (e.g. DGHM or FDA approval, CE marking). For correct application of the disinfectant (e.g. concentration, temperature, and exposure time), please be sure to follow the manufacturer's instructions.

Disassembly: Completely disassemble all instruments that can be disassembled: See chapter Disassembly

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Machine cleaning [6]

In the case of machined cleaning and sterilization, the instruments are carefully rinsed under running tap water after pre-disinfection so that no residues of the cleaning agent and disinfectant get into the WD. For mechanical cleaning and disinfection of the instruments, use an instrument stand according to the manufacturer's instructions that is suitable for the cleaning and disinfection device used. Add a cleaning and disinfection agent intended for the application to the cleaning and disinfection device in accordance with the product and instrument manufacturer's instructions and start a cleaning and disinfection program validated for the instrument type.

If possible, use the following validated procedure:

Validated with a Miele PG8535 and neodisher MediClean forte from Dr. Weigert, Hamburg.

- Rinse for 1 minute with cold water <40°C
- Wash for 10 minutes with 0.5% neodisher MediClean forte at 55°C
- Rinse with deionised water <40°C for 1 minute
- Thermal disinfection at 93°C for 5 min
- Dry at 110°C for 20 minutes

Drying

After the cleaning and disinfection programme has been completed, the instruments or prosthetic components are removed from the disinfection device and any moisture residues are dried completely with compressed air or a clean, lint-free cloth.

Maintenance, inspection, and testing

Finally, the instruments are visually inspected for integrity, functionality, and cleanliness. If there is macroscopically visible residual contamination, they must be repeatedly subjected to the cleaning and disinfection process. If only automated cleaning is carried out (without mechanical disinfection), thermal disinfection in an unwrapped steam sterilizer is mandatory!

Packaging, sterilization [1], [2] and storage

When selecting disposable sterilization packaging (single packaging), the following applies requirements according to material/process: - EN ISO/ANSI AAMI ISO 11607-1/-2 - suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F) and sufficient steam permeability) - Sufficient protection of the instruments or sterilization packaging against mechanical damage. The following requirements apply when selecting sterile containers (hereinafter referred to as "containers"): - EN ISO/ANSI AAMI ISO 11607-1/-2 as well as EN 868-8 - Maintain and check containers regularly. For sterilization, only the sterilization procedure listed below is to be used. Other sterilization procedures are not permitted.

The steam sterilizer used must be CE marked and comply with EN 13060 or EN 285 (Europe) or have FDA clearance (US).

Sterilization bags [7], [8], [9]

Pack the separately cleaned prosthetic parts and instruments in a disposable sterilization package suitable for steam sterilization (single or double package) and/or a sterilization container. Packaging suitable for steam sterilization must meet the requirements of DIN EN ISO 11607/ANSI/AAMI ST79/AAMI TIR, e.g. disposable sterilization packaging (single or double packaging) with a temperature resistance of at least 137 °C (279 °F) and sufficient steam permeability.

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The sterilization parameters for instruments and prosthetic components can be found in the following table:

Instruments should only be placed in the autoclave or sterilized in a disassembled state.

Disassembly: See chapter Disassembly

Method 1	Procedure	Temperature	Minimum holding time *	Drying time
Hot steam	Vacuum procedure (3x fractional pre-vacuum)	134°C	5 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary on different devices.

Validated procedure: Steam sterilizer Systec HX-320; sterilization packaging SteriCLIN® bags (paper / film) REF: 230212

Method 2	Procedure	Temperature	Minimum holding time *	Drying time
Hot steam	Vacuum procedure (3x fractional pre-vacuum)	132°C	4 minutes	20 minutes

* The minimum holding times are indicated. The operating times are longer and can vary on different devices.

Validated procedure: Autoclave EHS 3870 from Tuttnauer; Sterilization packaging according ISO 11607-1 (e.g. 60g/qm)

Marking of sterile goods

For safe reuse of reprocessed instruments/medical devices, the following information must be clearly visible to the user on the packaged reprocessed instruments/medical devices:

- Name of the contents, if not clearly recognizable (for sterilization in trays)
- Specifies the sterilizer if more than one is used.
- Batch identification (which sterilization run?)
- Date of sterilization
- expiry date, if applicable, until which safe use is possible

The reprocessing results shall be documented in such a way that traceability of the respective batch of medical devices is possible at any time:

Requirements for storage according to DIN58953-8

Storage unprotected: On shelves in rooms that do not comply with room class II according to DIN 1946-4:

maximum 48 hours ***To be avoided as storage type!***

Storage protected: Dust-protected in closed storage systems, e.g. in cupboards, drawers, or shelves in rooms of room class II According to DIN 1946-4

maximum 6 month

Once the storage period has expired, the medical device must be repackaged and sterilized.
Observe deviating specifications of the manufacturer of the sterile barrier system (sterilization bag)!

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Reusability

The instruments can be cleaned and sterilized repeatedly and reused provided they are undamaged and fully functional and appropriate care is taken. The service life is limited by damage and deterioration; these products must be discarded. MEDEALIS does not specify a maximum number of uses and reprocessing cycles for reusable instruments.
The lifetime depends on many factors including the type and duration of use, as well as handling, storage, and transport of the instruments. Careful inspection and functional testing before the next use is the best way to identify and discard an instrument that is no longer functional. We would like to point out that the biological compatibility of the instruments may also no longer be given due to the accumulation of detergent residues. This is the responsibility of the user. In case of disregard, any liability is excluded.

Disposal of medical devices

Unless otherwise stated, devices must be disposed of as medical devices in accordance with the facility's procedures.

[1] DIN EN ISO 17664 Sterilisation von Medizinprodukten
[2] RKI Richtlinie Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten
[3] Leitlinie von DGKH, DGSV und AKI für die Validierung und Routineüberwachung maschineller Reinigungs- und thermischer Desinfektionsprozesse für Medizinprodukte,
[4] Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,
[5] AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
[6] DIN EN ISO 15883-1 Reinigungs- Desinfektionsgeräte – Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren
[7] ISO 11607-1: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems;
[8] DIN 58953-7: Use of sterilization paper, nonwoven wrapping material, paper bags and heat and self-sealable pouches and reels;
[9] ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities;
[10] VAH – Verbund für Angewandte Hygiene e.V.
[11] DGHM – Deutsche Gesellschaft für Hygiene und Mikrobiologie
[12] FDA – U.S. Food and Drug Administration

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Disassembly/Assembly of MEDEALIS Instruments

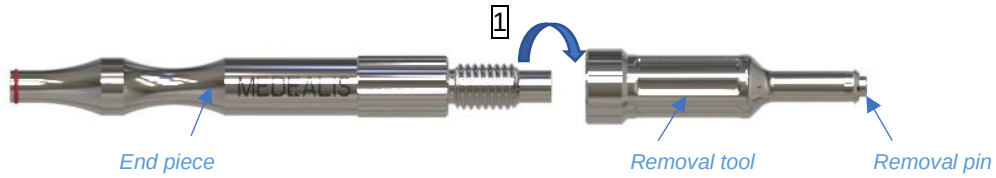
A0023 and A0027 Screwdriver with Holding sleeve

Disassembly: The holding sleeve is connected to the screwdriver by a thread. Turn the holding sleeve counterclockwise from the screwdriver.

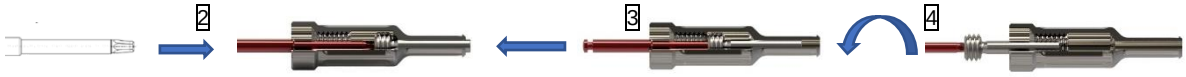
Assembly: The assembly is carried out in reverse order.
Note: Do not tilt the retaining sleeve when it is unscrewed. Increased resistance is a sign of this.

A0019 Two-piece Universal Instrument

Disassembly: The removal tool is connected to the end piece by a thread. 1 Turn the removal tool counterclockwise from the end piece.



Disassembly Removal pin from Removal tool
The removal pin is screwed into the removal tool. To unscrew the removal pin, use the A0025 instrument or an existing instrument with a 1.25 mm hexagon. 2 Insert the instrument into the removal pin. The removal pin will grip the instrument. 3 Carefully pull the instrument back to the stop of the removal pin in the removal tool. 4 Turn the removal pin counterclockwise to disengage the removal tool.



Assembly: The assembly is carried out in reverse order.

A0019 Two-piece Universal Instrument (Version 2 available since January 2023)

Version 2 without separate removal pin

A0020 Four-piece Universal Instrument

Disassembly: The removal tool and the end piece are both connected to the middle section by a thread. The holding sleeve is screwed onto the end piece. Turn the removal pin and the end piece counterclockwise from the middle section and the holding sleeve counterclockwise from the end piece.

Disassembly: Removal pin from Removal tool: Please see Two-piece Universal Instrument

Assembly: The assembly is carried out in reverse order.
Please also observe the instructions for screwing on the holding sleeve for the screwdriver with holding sleeve as described in section: A0023 and A0027 Screwdriver with Holding sleeve.

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