Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

General Basics:

All instruments and abutments have to be cleaned, disinfected and sterilized prior to each use; this is especially essential for first use after delivery, since all instruments and abutments are supplied in non-sterile condition (Cleaning and disinfection after removal of the transport protection package; sterilization after packing). A thorough cleaning and disinfection is an indispensable precondition for an effective sterilization.

Please observe the following which is within your responsibility for sterility of the instruments and abutments during use:

- To use generally only validated processes for the cleaning/disinfection and sterilization which are sufficiently specific for instruments and products,
- To ensure maintenance and inspection of the equipment (such as disinfectant unit, sterilizer) at regular intervals, and
- To comply with the validated parameters for each cycle.

Please never reuse products labeled as single use. Otherwise, malfunctions such as jamming, unintentional loosening or infection may occur.

Please take care during use that contaminated instruments are gathered separately and do not get back into contact with the instruments tray in order to avoid a contamination of the clean instruments within the tray. Clean/disinfect the contaminated instruments and then place back into the instruments tray, and then sterilize the complete tray including instruments.

Please comply with the additional regulations valid in your country and hygiene regulations of the dental office or clinic/hospital. This is especially essential for the different specifications regarding an effective prion inactivation. **For some instruments there are several additional aspects for compliance (see table “Special handling”)!**

Cleaning and Disinfection

Basics: For cleaning and disinfection please use a mechanical process (disinfectant unit). A manual process – also when using an ultrasonic bath – should only be used if a mechanical process is not available sinceto the effectiveness and reproducibility is considerably lower. (The evidence of effectiveness of the manual process has to be provided by the user.) Pre-treatment has to take place in either case

Pre-Treatment: Directly after use (within maximum 2 hours) all contaminations have to be removed from the instruments. Please disassemble all parts of the instruments. Use cold desalinated running water (min. drinking water quality) or a disinfectant. The disinfection agent should be free of aldehyde (to avoid fixation of contamination with blood), should have a defined effectiveness (e.g. VAH/DGHM or FDA license / clearance or CE marking permit), suitable for disinfection of instruments and compatible with the instruments (see chapter “Material Resistance”). For manual removal of contaminations use only a soft brush (for small lumina and gaps: interdental brush) or a clean soft cloth which you use only for this purpose, but never use any metal brush or steel wool.

If applicable (see table “Special handling”): Rinse all lumina of the instruments and abutments for five times by using a disposable syringe (minimum volume 5 ml)/or a one-way cannula. Brush small lumina thoroughly. Move mobile parts back and forth during cleaning.

Please note that the pre-treatment with the disinfectant serves only for personal protection and does not replace the later disinfection phase after cleaning.

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Mechanical cleaning/disinfection (disinfectant/RDG-Cleaning and disinfection apparatus):

When selecting the mechanical disinfectant unit please observe the following:

- To ensure that the disinfectant equipment used has an approved effectiveness (e.g. DGHM or FDA license / clearance or CE marking permit according to DIN EN ISO 15883),
- To use an approved program for thermic disinfection (A0-value > 3000 or – if an old unit is used – minimum 5 minutes at 90°C) (with chemical disinfection there is a hazard of disinfectant remaining on the instruments),
- To ensure that the program used is suitable for the instruments and contains sufficient rinsing cycles,
- To take care that for final rinsing only desalinated and sterile or bacteria-free (max. 10 germs/ml) and endotoxin-free water (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) is used,
- To ensure that the air flow used for drying is filtered (grease-free, free of germs and particles), and
- To ensure maintenance and inspection of the disinfectant unit at regular intervals.

When selecting the cleaning agent system to be used, please observe the following:

- To ensure suitability for instruments of metal and acrylic
- To ensure that – if no thermic disinfection is used – in addition a suitable disinfection agent with approved effectiveness is used (e.g. VAH/DGHM or FDA license / clearance or CE marking permit) and is compatible with the cleaning agent used
- To ensure that the chemicals used are compatible with the instruments (see chapter “Material Resistance”).

The concentrations, temperatures and duration of use as well as specifications for final rinsing as stipulated by the manufacturer of the cleaning and disinfection agents must be strictly observed.

Course of action:

1. Place the disassembled instrument parts into the disinfectant unit. Use baskets for small parts and take care that the instruments have no contact with each other.
2. Start the program.
3. Remove the instruments from the disinfectant unit at the end of the program.
4. Control and package the instruments immediately (see chapter “Control”, “Maintenance” and “Packaging” at a clean place, if applicable after final drying.

The evidence of basic suitability of the instruments for an effective mechanical cleaning and disinfection was submitted by an independent accredited test laboratory by using the disinfector unit G 7836 CD (thermic disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg). The above-mentioned process was complied with.

Control: Please inspect all instruments and abutments after cleaning or cleaning/disinfection on possible corrosion, damaged surfaces, splitting off or contaminations and remove damaged instruments and abutments (number of reusability cycles permitted please see chapter “Reusability”). If instruments and abutments are still contaminated, it is essential to clean and disinfect them again.

Maintenance: An installation is not necessary. Instrument oils must not be used.

Packaging: When packing for sterilization, there are different procedures for instruments and abutments.

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Instruments

The packing of the instruments must be effected in a tray and in a sterilization container. The cleaned and disinfected instruments should be placed into the pertaining sterilization tray.

Please pack the instruments or the sterilization trays into a sterilization container which should comply with the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607 / FDA - clearance
- Sufficient protection of the instruments or sterilization packages to avoid mechanical damages
- Maintenance at regular intervals according to specifications by the manufacturer (sterilization containers)
- Filter: Please use preferably one-way filters. When using reusable filters the specifications of the manufacturer regarding number of sterilization cycles of textile filters should be complied with (replacement cycles to be stipulated).

Abutments

The packing of the abutments is effected in single or double packages (not in a tray). Please pack the abutments in one-way sterilization packages (single or double packages) which correspond with the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607 / FDA - clearance
- Suitable for steam sterilization (temperature resistance up to min. 138°C (279°C) with sufficient steam permeability)

Sterilization: For sterilization, please use only the following sterilization processes; other sterilization processes are not permitted.

Steam sterilization

- Fractional vacuum process or gravitation process[2] (with sufficient product drying[4])
- Steam sterilizer according to DIN EN 13060 or DIN EN 285 or ANSI AAMI ST 79 respectively
- Validated according to DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance evaluation (PQ))
- Maximum sterilization temperature 134°C (273°F; plus tolerance according to DIN EN ISO 17665)
- Sterilization time (exposition period at sterilization temperature) minimum 20 minutes at 121°C (250° F) or minimum 3[3] (fractional vacuum process)/8[3] (gravitational process) minutes at 132°C (270°F)/134°C (273°F)

[2] The use of the less effective gravitation process is only permissible at non-availability of the fractional vacuum process and requires an evidence of suitability and effectiveness at sole responsibility of the user.
[3] or 18 minutes (prion inactivation) respectively
[4] The additionally required drying time is directly dependent on parameters which are the sole responsibility of the user (loading configuration and density, condition of the sterilizer, ...) and must therefore be determined by the user. Nevertheless, the drying times should be not below 20 minutes

The evidence of suitability of the instruments for an effective steam sterilization was submitted by an independent accredited test laboratory by using the steam sterilizer Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractional vacuum process, under consideration of typical conditions in a dental clinic or practice as well as the above-mentioned process.

The quick sterilization process is basically not permissible.

Do not use hot air sterilization, radiation, formaldehyde or ethylene oxide sterilization, or any plasma sterilization.

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Transport & Storage: After sterilization, the instruments and abutments must be transported and stored dry, dust-free and protected from mechanical damage in the sterilization packaging. The tray content remains sterile under aseptic conditions of storage for 6 months, provided that the tray is closed and the filter is undamaged. The storage time depends on the storage conditions. At particularly high demands on sterility shorter storage periods or additional packaging may be required.

Recommended storage conditions: Temperature: 15-26 ° C, humidity: 30-50%, normal air pressure. We recommend storage of max. 6 weeks in a ventilated/open location and 3 months in a non-ventilated location (eg. in a closed cupboard). This information only applies when using the original filter.

Material resistance: Please take care when selecting the cleaning and disinfection agent that the following elements are not contained:

- Organic, mineral or oxidizing acids (minimum permissible pH value 5.5)
- Strong leaches (maximum permissible pH value 9.5; neutral/enzyme cleaning agent recommended)
- Organic solutions (such as alcohols, ethers, ketones, benzines
- Oxidation agents (e.g. hydrogen peroxide)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated carbon hydrides.

Never clean any instruments, abutments, sterilization trays and sterilization containers with a metal brush or with steel wool. All instruments, abutments and sterilization trays should not be exposed to temperatures higher than 138°C (280° F).

Reusability: The instruments and abutments can be – at corresponding care and in undamaged and non-contaminated condition and non impairment in function (with grip on tray fitting) – reused up to a maximum number of cycles stipulated (see table “Special handling”); each additional reuse or use of damaged and/or contaminated instruments and abutments is within the responsibility of the user.
Non-compliance to the above excludes any responsibility by OT medical.

Special Handling

Impression Coping and Healing Abutment for 4plus6Line OT-F2

Volume for rinsing	5 times minimum 5 ml
Brush	For internal: Interdental cyl. ISO 5 For external: small brush / toothbrush
Pre-treatment	Separate screw and abutment, brush internal thoroughly with interdental brush and rinse with one-way syringe/disposable cannula from both sides by using cold desalinated running water (min. drink water quality). External: brush thoroughly (especially also in between the external notches).
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position screw and abutment separately within the basket for small parts
Packaging	In single or double one-way sterilization package
Sterilization	In single or double one-way sterilization package
Maximum cycles permitted	15
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Impression coping open/closed (without 4plus6Line), Natural-, Basic-, Versa-, Profi- (OT-F1), Creative-, Gold-, High and CeraLine of systems OT-F1, OT-F2 and OT-F3, Scanbodies and Bar connector ProfiLine of systems OT-F2/OT-F3

Volume for rinsing	5 times minimum 5 ml
Brush	For internal: Interdental cyl. ISO 3 For external: Small brush/ toothbrush
Pre-treatment	Separate screw and abutment, brush internal thoroughly with interdental brush and rinse with one-way syringe/disposable cannula from both sides by using cold desalinated running water (min. drink water quality). Please be careful with the internal threads below the hex with systems OT-F2/F3. Brush externally thoroughly, for Scanbodies with soft brush! Special attention to the retention at the shaft (CreativeLine)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position screw and abutment separately within the basket for small parts
Packaging	In single or double one-way sterilization package
Sterilization	In single or double one-way sterilization package
Maximum cycles permitted	15
Classification recommended according to RKI regulation	Critical B

Angulated Abutments OT-F2 4plus6Line, Impression Caps, Healing abutments, abutment screws of all systems and adapter ProfiLine OT-F2, 4plus6Line straight for OT-F2

Volume for rinsing	5 times minimum 5 ml
Brush	For internal: Small bores Interdental cyl. ISO 2 and for large bores Interdental cyl. ISO 3 For external: Small brush/ toothbrush
Pre-treatment	Brush internal thoroughly with interdental brush rinse and with one-way syringe/disposable cannula (alternating) by using cold desalinated running water (min. drink water quality); for the small bores be careful with internal threads. External: brush thoroughly (especially the threads)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position screw and abutment separately within the basket for small parts
Packaging	In single or double one-way sterilization package
Sterilization	In single or double one-way sterilization package
Maximum cycles permitted	15
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

TecLine for all systems

Volume for rinsing	-
Brush	small brush/ toothbrush
Pre-treatment	brush thoroughly (especially also parallel to the external notches)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position within the basket for small parts
Packaging	In single or double one-way sterilization package
Sterilization	In single or double one-way sterilization package
Maximum cycles permitted	15
Classification recommended according to RKI regulation	Semi-critical B

Drills and Prosthetic Driver for contra-angle all systems, Implant Driver (mechanical Insertion)

Volume for rinsing	-
Brush	small brush/ toothbrush
Pre-treatment	Brush thoroughly
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position within the basket for small parts
Packaging	In sterilization tray and in sterilization container
Sterilization	In sterilization tray and in sterilization container
Maximum cycles permitted	Drills: 15 Drivers: 100 (or until damage visible)
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Osteotome Tips, Trial Fit Gauges, Insertion Tips, Tip wrench

Volume for rinsing	5 times minimum 5 ml
Brush	Internal: Interdental cyl. ISO 3 External: Small brush / toothbrush
Pre-treatment	Brush internal and rinse with one-way syringe / disposable cannula by using cold desalinated running water (min. drink water quality); brush external thoroughly
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position within the basket for small parts with opening showing downwards.
Packaging	In sterilization tray and in sterilization container
Sterilization	In sterilization tray and in sterilization container
Maximum cycles permitted	Osteotome Tips (cutting): 15 Others: 100 (or until damage visible)
Classification recommended according to RKI regulation	

Osteotome handle straight and bended

Volume for rinsing	-
Brush	small brush/ toothbrush
Pre-treatment	Brush with soft brush (especially the threads and knurling)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Position within the basket for small parts
Packaging	In sterilization tray and in sterilization container
Sterilization	In sterilization tray and in sterilization container
Maximum cycles permitted	100 (or until damage visible)
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Center Punch

Volume for rinsing	5 times minimum 5 ml
Brush	For the small bore of the centering pin and the thin bore in the housing: Interdental cyl. ISO 2 For large bore in housing: Interdental cyl. ISO 5 For external: small brush / toothbrush
Pre-treatment	Separate punch and housing and treat separately: interrnal brush thoroughly with interdental brush and rinse with one-way syringe / disposable cannula by using cold desalinated running water (min. drink water quality). External with soft brush, especially the knurl.
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Place housing with opening downwards and punch separately in basket for small parts.
Packaging	In sterilization tray and in sterilization container
Sterilization	In sterilization tray and in sterilization container
Maximum cycles permitted	100 (or until damage visible)
Classification recommended according to RKI regulation	Critical B

Direction indicator, Depth Gauge

Volume for rinsing	-
Brush	small brush/ toothbrush
Pre-treatment	Brush with soft brush (especially also parallel to the external notches / grooves)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Place into basket
Packaging	In sterilization tray and in sterilization container
Sterilization	In sterilization tray and in sterilization container
Maximum cycles permitted	100 (or until damage visible)
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

Finger Keys

Volume for rinsing	5 times minimum 5 ml
Brush	For internal: round brush with 10 mm diameter, For external: small brush / toothbrush
Pre-treatment	internal and external brush thoroughly and rinse internal with one-way syringe (external parallel to the cross-hatched knurling) by using cold desalinated running water (min. drink water quality)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Place into basket for small parts with opening showing downwards.
Packaging	In sterilization tray and in sterilization container
Sterilization	In sterilization tray and in sterilization container
Maximum cycles permitted	100 (or until damage visible)
Classification recommended according to RKI regulation	Semi-critical B

Prosthetic, Insertion (manual Insertion) and Octa-Drivers, Drill stops, Adapter

Volume for rinsing	5 times minimum 5 ml
Brush	for grooves: Interdental cyl. ISO 1, for Drill stops, Octa driver + Adapter internal: Interdental cyl. ISO 4, for cap internal: Interdental cyl. ISO 5 for external: small brush / toothbrush
Pre-treatment	Remove cap (by slight pressure laterally between cap and driver), clean cap and external notch with interdental brush and rinse with one-way syringe or disposable cannula (including undercut in cap) by using cold desalinated running water (min. drink water quality); brush lateral groove with interdental brush and rinse with one-way syringe/disposable cannula by using cold desalinated running water (min. drink water quality). External: brush thoroughly. Octa Driver + Adapter: internal brush thoroughly with interdental brush and rinse with one-way syringe / disposable cannula by using cold desalinated running water (min. drink water quality)
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Place screw cap and driver separately with opening showing downwards into the basked for small parts.
Packaging	In sterilization tray and in sterilization container
Sterilization	Assembled, in sterilization tray and in sterilization container
Maximum cycles permitted	100 (or until damage visible)
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482

Preparation (Cleaning, Disinfection and Sterilization) of instruments and abutments

All Trays

Volume for rinsing	-
Brush	for the silicone stoppers: large: cyl. ISO6 small: cyl. ISO5 Remaining areas: small brush / toothbrush
Pre-treatment	Remove all instruments and clean and disinfect separately; Remove all silicone parts and brush thoroughly on all sides; Brush all metal surfaces thoroughly.
Manual cleaning / disinfection	Please contact the manufacturer.
Mechanical cleaning/ disinfection	Clean all instruments as described; place silicone stoppers and retentions into basket for small parts with openings showing downwards.
Packaging	Place silicone stoppers back into tray (according to color guides), including retentions and instruments.
Sterilization	With instruments inserted in tray
Maximum cycles permitted	500 (or until damage visible. If silicone stoppers and retentions show discoloration, replace by new ones)
Classification recommended according to RKI regulation	Critical B

OT medical GmbH
Am Tabakquartier 62
28197 Bremen
Germany
Phone +49 (0)421 557161-0 | Fax +49 (0)421 557161-95 | sales@ot-medical.de

09-615000000 | 06-2023/8

CE 0482