Instructions for Use for Prosthetic Abutments of Implant System OT-F1

Introduction

Illustrations, indications and product catalog numbers referring to the prosthetic components mentioned below are contained in detail in the OT-F1 product catalog. Malocclusion and overloading of the implant abutment connection, the abutments and the complete prosthetic construction should be absolutely avoided.

Important instructions:

- All prosthetic components are supplied in non-sterile condition.
- Basically only new and non-used abutment screws should be used for final restoration in the mouth of the patient.
- All abutments (except for CreativeLine) should be fixed with 35 Ncm. CreativeLine should be fixed with 15 Ncm. The abutment screws may not be cemented or glued within the implant.
- Please observe the material specific minimum wall thickness for processing of the prosthetic abutments. The wall thickness may only be reduced partially – for titanium to 0.3 mm, for precious metal to 0.4 mm and for zirconium oxide to 0.5 mm
- Titanium abutments are color coded according to the color coding system in the area of the implant connection (complete or partial) and the model implant analogs in yellow (diameter 3.80) and blue (diameter 4.90 mm).
- The connection surfaces of the abutments to the implant may not be blasted or treated. The hazard of an invasion of bacteria as well as weakening of the components must be avoided.

Model preparation: Impression copings / implant analogs (Material Titanium grade 4)

Important:

Impression Copings and Implant Analogs are for single use only. Multiple use is not allowed due to technical reasons (loss of precision of the thread parts resp. of Implant-Abutment-Connection). For preparation of a master model in the dental lab, the pertaining implant analogs are screw-fixed to the impression copings after impression taking. We distinguish between an open and a closed impression.

Open impression:

- The impression copings are safely positioned and remained in the impression material of the (individually prepared) impression tray. Diameter-conform implant analogs are placed onto the hexagonal connection of the impression copings and screw-fixed with the long impression coping screw through the perforation of the individual tray.

Closed impression:

- Impression copings which will have loosened from the impression material, must be exactly repositioned in the impression. At first the impression copings are screwed onto the corresponding implant analogs and then repositioned into the impression by carefully observing the rotation position. We recommend to prepare a removable gingival mask. The model should be made from high-quality class 4 plaster.

Temporary abutment “CreativeLine” (Material titanium grade 5)

Indications:

Temporary crowns and bridges (time period is dependent on permitted durability of the acrylic material used)

Contraindications:

Primary connections of abutments on diverging implants, General contraindications for implant surgery: see instructions for use of the implant system.

- Fixation with abutment screw on the implant model analog
- The knurled shaft of the abutment can be reduced in length according to the prosthetic situation.
- The circular groove marks the maximum length reduction.
- The modified abutment is then covered with opaque material.

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- The slim funnel-shaped basic design favors a natural root profile in the surrounding gingival tissue by adding tooth-colored acrylic.
- The temporary abutment can be inserted immediately after exposure of the implant instead of a conventional non-rotation-safe titanium gingival healing abutment.
- A temporary crown can be inserted if the abutment is designed appropriately.

Titanium abutment „VersaLine“ (Material titanium grade 4)

Indications:

Preparation of primary parts in the telescope or conical crown technique, Cemented crown and bridge restorations

Contraindications:

Primary connections of abutments, Prosthetic angulation to implant axis of more than 25°, Cast-on technique, Double crowns on implant diameter 3.30 mm, Single tooth restorations with free-end cantilever

- The titanium abutment is used preferably for the crown and bridge technique, when standard restorations (as for instance with the NaturalLine Abutment) is not suitable.
- It is possible to prepare individual angulations between 0° and nearly 25° or to prepare circular shoulders which adjust to the natural contour of the gingival tissues.
- After a special modification it is possible to veneer the abutment directly with an adequate titanium ceramics.
- We recommend the use of titanium milling instruments for the preparation of this abutment.

Important note: Implants with 3.30 mm diameter are not suitable for a restoration with telescopic or conical crowns.

Titanium abutment “NaturalLine” (Material titanium grade 4)

Indications:

Cemented crown and bridge restorations, Laterally screw-connected crowns and bridges (for individually prepared screw connections)

Contraindications:

Primary connections of abutments, Prosthetic angulation to the implant axis of more than 25°, Cast-on technique Double crowns on implant diameter 3.30 mm OT-F1, Single tooth restoration with free-end cantilever

- When selecting the appropriate abutment, the prosthetic direction with regard to the angulation in relation to the hexagonal connection to the implant should be observed. Version “A”: angulation over the flat side of the hex, Version “B”: angulation over the corner of the hex.
- The distinguished feature is the subgingival design. Starting from the implant shoulder, it extends circularly convex and ends in a surrounding gently curved chamfer. From the oral area it descends to the esthetic zone.
- The massive contour allows a special reduction by using suitable instruments (titanium drill, polisher) and to design an optimal emergence profile.
- The circular shoulder enables an exact transition to the crown to be prepared. The shoulder can be adjusted to the gingival contour.
- For single crowns an anti-rotation cementation should be made (especially for 0° NaturalLine abutments). It may be necessary to prepare an additional rotation protection into the abutment at an early stage.
- Abutment variations available: The straight 0° abutments in socket heights of 1.20 and 2.00 mm. The angulated abutments in 15° and 25° in versions A and B each.
- The abutments have an additional internal thread design which avoids loss of the abutment screw during processing.

Titanium abutment “BasicLine” (Material titanium grade 4)

Indications:

Fixed cemented crown and bridge restorations, Laterally screw-connected crown and bridge restorations (for individually prepared screw connections)

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Contraindications:

Primary connections of abutments, Prosthetic angulation to the implant axis of more than 25°, Cast-on technique, Double crowns on implant diameter 3.30 mm, Single tooth restoration with free-end cantilever

- For a dentist-removable construction, individual horizontal screw connections can be prepared.
- This abutment ends in the cervical region tangentially.
- Available in the straight 0° and the angulated 15° version in two gingival heights each.
- The abutment variations 15° and 25° are directed in their angulation towards the flat surface of the hex connection (version “A”).

Goldbase Abutment “GoldLine” [Material: Base Gold/platinum alloy Ceramicor®, manufacturer C&M Switzerland, furnace acrylic (POM)]

Indications:

Individual abutments for fixed crown and bridge restorations, Individual primary parts in the telescope and conical crown technique

Contraindications:

Single tooth restorations with free-end cantilever, Prosthetic angulation to the implant axis of more than 25°, Primary connections for abutments

- The base of the abutment consists of a highly precise manufactured cast-on Gold-platinum alloy and shows a perfect fit to the implant.
- The furnace fixed on the base is made of residue-free burn-out acrylic.

Processing:

The acrylic furnace of the abutment is shortened according to the prosthetic situation. The selected shape of the abutment is waxed onto the acrylic furnace. When preparing bridge or double crown constructions, a mutual insertion direction prior to modellation should be determined. Take care to prepare a circular functional surface of minimum 5 mm when designing the primary parts for the double crown technique. When investing the model, please be careful to keep a clean flow of the investing compound (containing phosphate) free of bubbles within the screw channel. Please note the instructions of the manufacturer of the investment compound. The final temperature for preheating should be kept for at least 30 minutes. A precious metal alloy is cast onto the existing precious metal basis using a regular process. The precious metal alloy should have a high level of consistency and observe the instructions of the manufacturer of the alloy.
Leave the muffle to cool off at room temperature. In order to minimize the mechanical stress when removing the invested material, the precious metal base should be carefully polished with blast pearls at a pressure of approx. 1.5 bar.
We recommend to use acid for removal of remaining investing material especially in the area of the implant-abutment interface (hex), or to steam-clean or to remove in an ultrasonic bath. During further processing (drilling, blasting, polishing) the connection interface must be protected from damage, therefore the abutment should be screwed onto an implant analog. When preparing a ceramics crown for direct veneering with occlusal screw connection, care must be taken that a minimum wall thickness of 0.5 mm is remaining. Due to the different thermal expansion coefficient (TEC) of the cast-on GoldLine base and the veneer ceramics, these should not have any contact. Please observe the instructions of the veneer ceramics manufacturer.

Important note:

Implants with 3.30 mm diameter are not suitable for a restoration with telescopic or conical crowns.

Note for preparation:

Melting range: 1400 – 1490°C (2550-2710°F)
Cast-on temperature: up to 1350° C (2.462°F)
Thermal expansion coefficient (25-500°C): $11.9 \times 10^{-6}\ K^{-1}$,
Thermal expansion coefficient (25-600°C): $12.2 \times 10^{-6}\ K^{-1}$

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CAD/CAM abutments “HighLine” (Material: Base titanium grade 5, furnace acrylic)

Indications:

Cemented crown and bridge restorations of full ceramic, Preparation of primary parts in the telescopic and conical crown technique

Contraindications:

Primary connections of abutments, Prosthetic angulation to the implant axis of more than 25°, Cast-on technique, Double crowns on implant diameter 3.30 mm, Single tooth restorations with free-end cantilever

- The dental laboratory is responsible for the basic processing steps of a preparation with regard to the CAD/CAM or copy milling process used.
- For preparation and further processing of the zirconium abutment the instructions of the manufacturer of the system used should be observed. Please use only approved and certified CAD/CAM or copy milling systems and the pertaining materials.
- The connection to the implant is secured by a highly precise titanium base. The abutment screw transmits the tear strength for final fixation to the titanium base and not onto the zirconium part of the individualized abutment. The abutment is made for adhesion of the individual zirconium part on the prefabricated titanium base.
- The design of the base allows only a very precise positioning by adhesion so that transmission failures are avoided.
- The abutments have an additional internal thread design which avoids loss of the abutment screw during processing.

Processing:

The furnace of the abutment can be used as wax-up base according to the preparation process. The abutment is shortened according to the prosthetic situation. The abutment shape can be waxed onto the acrylic furnace. When preparing bridge or double crown constructions, a mutual insertion direction should be determined prior to modellation. The wax-up made on the acrylic furnace individually is transmitted to the zirconium according to the process. The predetermined wall thickness of the acrylic furnace of 0.5 mm should remain at the final processing of the zirconium part. The additionally available scan screw represents the final screw channel during the scan process. Please observe the instructions of the zirconium oxide manufacturer. The thickness of the adhesive for this phase should be taken from the adhesive manufacturer instructions.

Adhesion:

Basically the surfaces of both parts to receive the adhesive should first be blasted carefully with 50µm aluminum oxide. Protect the hexagonal connection of the titanium base from damage by screwing onto an implant analog prior to blasting and adhesion. Please use the laboratory screw and close the screw entrance of the titanium base with wax prior to applying adhesive.
For adhesion, please observe the instructions of the adhesive manufacturer.
Suitable adhesives are among others:

- Panavia F 2.0 OP (Opaque); Kuraray (permission of the manufacturer for using the Alloy Primer and the Ceramic Primer)
- RelyX™ Unicem white Opaque; 3M Espe (permission of the manufacturer so far only for Lava™ Zirconium oxide)
- Multilink Implant / Multilink Hybrid Abutment; Ivoclar Vivadent

Please make sure to perform an additional light curing !

Zirconium abutment “CeraLine” (Material: Base titanium grade 5, Abutment Zirconium oxide)

Indications:

Cemented crown and bridge restorations in full ceramics, Preparation of primary parts in the telescopic and conical crown technique

Contraindications:

Primary connections of abutments, Prosthetic angulation to the implant axis of more than 25°, Cast-on technique, Double crowns on implant diameter 3.30 mm, Single tooth restoration with free-end cantilever

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The connection to the implant is guaranteed by a highly precise titanium base. The abutment screw transmits the tear strength to the titanium base during final fixation, and not onto the zirconium part of the final abutment. The abutment is made of highly solid Yttrium stabilized zirconium oxide. These prefabricated moulds can be modified by trimming with a water cooled turbine. A veneering with suitable zirconium ceramics and color characterization is also possible. After these modifications have been made, the final zirconium part is fixed onto the titanium base by adhesive. The design of the base allows a precise positioning at adhesion so that transmission failures are avoided. The abutments have an additional internal thread design which avoids loss of the abutment screw during processing.

Processing:

At first, the zirconium part is modified according to the prosthetic situation. Please use only water-cooled turbine handpieces and suitable diamond trimmers. When preparing a bridge or double crown construction, a mutual insertion direction should be determined first. A minimum wall thickness of 0.5 mm should remain at the final trimming of the zirconium part.

Adhesion:

Basically the surfaces of both parts for adhesion should first be blasted carefully with 50µm aluminum oxide. Protect the hexagonal connection of the tanium base from damage by screwing the basis onto an implant analog prior to blasting and adhesion. Use only the laboratory screw and close the screw entrance of the titanium base with wax prior to adhesion.

For adhesion please observe the instructions for use of the adhesive by the manufacturer. Suitable adhesives are among others:

- Panavia F 2.0 OP (Opaque); Kuraray (permission of the manufacturer for using the Alloy Primer and the Ceramic Primer)
- RelyX™ Unicem white Opaque; 3M Espe (permission of the manufacturer so far only for Lava™ Zirconium oxide)
- Multilink Implant / Multilink Hybrid Abutment; Ivoclar Vivadent

Please make sure to perform an additional light curing.

Bar connection “ProfiLine” [Material: Adapter titanium grade 4, bar connection acrylic (POM), bar connector titanium grade 4, bar connector precious metal (Ceramicor®)]

Indications:

Confectioned or individually milled bar constructions for anchoring of implant-supported complete prosthetic constructions in the edentulous maxilla and mandible.

Contraindications:

Combination of periodontal (tooth) and implant-supported constructions, Combinations with other anchoring elements (for instance ball head attachment)

- Two-piece abutment to prepare confectioned as well as individually milled bar constructions.
- First step is to select the adapter corresponding to the implant diameter and the prevailing gingival height. The adapter with the hex is the connection to the implant.
- Second step according to the following preparation (direct casting, cast-on, soldering, laser welding, or adhesion) is the selection and insertion of the bar connector of acrylic, of titanium or of precious metal.
- The conical connection between adapter and bar connector allows an adjustment of divergences between the implants of up to 40°.
- The corresponding abutment screw is supplied with the adapter. The bar is fixed directly onto the implant by placing the screw through the adapter.

Note:

- Please observe to keep an absolutely tension-free fit for all bar constructions (passive fit; Sheffield test) in the mouth of the patient.
- Bilateral extensions of the bar beyond the posterior implants may be useful for static reasons. These should not, however, extend over a length of max. 5 mm (premolar width). Please consider the number of implants inserted for such extensions.
- If only two implants are placed, the bar shape (round bar; drop-shaped) should permit a slight rotation of the anchored prosthetic construction parallel to the jaw articulation axis.

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- An off-central loading of the implants by an unfavorable bar connection is to be avoided.
- Please observe basically to design a suitable dimension of the bar construction.
- When using an adhesive, please follow the instructions of the manufacturer of the adhesive.

Bar Connector Acrylic (POM):

- Made of burn-out acrylic.
- This element is included in the complete individual bar modellation and casted.
- When investing the modellation please take care that a clean blister-free flowing from the screw channel with (phosphate based) investing compound is possible.
- Please observe the instructions of the manufacturer of the investing material. The final temperature for preheating should be kept for at least 30 minutes.
- Please make sure to select a precious metal alloy of high stability property. The instruction of the alloy manufacturer should be observed.
- Leave the muffle to reduce to room temperature.

Bar Connector Titanium (grade 4)

- For gluing or for laser welding with the individual casted titanium bar.
- Individually confectioned bars have to be separated from the bar connectors prior to investing and then casted separately. We recommend a welding on the master model or better an adhesion in the mouth of the patient. Please observe the instructions of the manufacturer of laser units.

Bar Connector Precious Metal (Ceramicor®)

- Confectioned bars can be directly soldered and individually prepared bars can be casted on directly.
- We recommend to invest and to cast the bar modellation separately from the precious metal elements. This enables the user to solder, weld or glue the parts.
- The investment of the modellation is made with a phosphate-containing investment material. The instructions of the manufacturer of the investment material must be followed. The final temperature for preheating should be held for at least 30 minutes.

Cast-on:

In general processes the precious metal alloy can be directly casted onto the prefabricated precious metal bar connector. When selecting the precious metal alloy the highest fixation abilities should be considered. Please follow the instructions of the alloy manufacturer.
The muffle should slowly cool off to room temperature. In order to minimize mechanical load at removal from investment, the area of the precious metal bar connector should be carefully blasted with beads by using a pressure of ≤ 1.5 bar. We recommend to either use acid or steam or an ultrasonic bath for removing any remaining investment material especially in the area of the connection to the ProfiLine Adapter (cone). For the following preparation of the ProfiLine abutment (milling, blasting, polishing) the connection area should be protected from possible damage by placing it on a model analog.

Note for preparation:

Melting range: 1400 – 1490°C (2550-2710°F)
Cast-on temperature: up to 1350° C (2.462°F)

Adhesion:

We recommend to separate individually prepared bars from the bar connectors prior to investing and to cast them separately. For achieving a passive fit, we recommend to weld/solder on the master model or rather use an adhesive in the mouth of the patient.

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Ball Head Abutment "TecLine" (Material: Ball head plus O-ring titanium grade 4, O-ring black FKM 75, O-ring red VMQ 40, Matrix Dalbo® Plus elliptic* titanium grade 4, lamella retention insert Elitor®)

Indications:

Anchorage of full prostheses in the edentulous maxilla and mandible in connection with two implants for achieving a transversal rotation axis, Anchorage of total prostheses in the edentulous maxilla and mandible in connection with four or also with six implants

Contraindications:

An uneven number of implants per jaw, Implants inserted in non-symmetrical position, A combination with other retention elements (for instance telescopes or also natural teeth), Disparallel implants of more than 20° divergence

- This abutment is screwed onto the implant with the octagon driver.
- For anchoring, the user can choose between O-Ring attachment and Retention Anchor Dalbo® Plus elliptic.

O-Ring Attachment

At first a red O-ring is inserted into a titanium metal housing. This ring remains in the housing during the laboratory processing and is replaced by the second red O-ring for final insertion of the denture. As an option, a black O-ring with higher retention ability is available.

Retention Anchor Dalbo® Plus elliptic*

This retention cap consists of two parts: a titanium housing with retention wings for fixation in the denture, and therein a Lamellae Retention Insert screw-in, made of precious metal (Elitor®), for which the forces can be individually adjusted by using an Activator Key (200-1,200 gram). Dalbo® Plus ellipti* can be used for up to 20° divergence of the implant.
For detailed information, please refer to the separate instructions supplied with the product.

Note:

The implants should be positioned in the corresponding jaw area symmetrically, for static reasons and for achieving a parallel rotation axis to the jaw articulation axis. An uneven number of implants should be avoided.

*Manufacturer Cendes & Métaux, Switzerland

Explanation of the symbols					
	Do not reuse		Consult Instruction for use	LOT	Lot Code
	Do not use if the packaging is damaged	CE 0482	CE Mark with the number of the Notified Body	CE	CE Mark of a medical device
	Caution		Manufacturer	MD	medical device
	Keep dry		Use by	REF	Device Number
	None sterile				

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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.

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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.

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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.

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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

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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

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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

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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

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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

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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

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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

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