English **Instructions for use:** TRI® Dental Implant System

Important: please read.

1. Disclaimer of Liability

Practitioners must have knowledge of dental implantology and the handling of the TRI® Dental Implant System in order to use TRI® products safely and properly in accordance with these instructions for use. It is the practitioner's responsibility to use the device in accordance with these instructions for use and to determine if the device is suited to the individual patient's situation. TRI® dental implants must only be used with original TRI® components and instruments.

TRI® Dental Implants Int. AG accepts no liability, express or implied, and no responsibility for any direct, indirect, punitive or other damages arising as a result of or in connection with any errors in professional judgement or practice related to the use of TRI® products.

2. Product Description

The TRI® Dental Implant System is an integrated system of endosseous dental implants with corresponding abutments, healing abutments, closure screws, surgical and prosthetic parts and the TRI® Dental Implants Instruments. All implants of the TRI® Dental Implant System are made of titanium grade 5 ELI (Titanium Grade 23), and the implants feature the TRI® SBA (**s**and**b**lasted **a**cid-etched) bone anchoring surface.

The table below shows the materials used for the implants and abutments of the TRI® Dental Implant System:

Implants	**Healing components**	**Provisional Abutment**	**Final Abutment Titanium**	**Final Abutment Gold**
TRI®-Vent TRI®-Narrow TRI®-Octa TRI®-matrix®	Healing Collars Cover Screws	Peek Provisional Abutments, scan bodies	TRI®-Vent TRI®-Narrow TRI®-Octa TRI®-matrix®	TRI®-Vent TRI®-Narrow
				
Material: Titanium Grade 5 ELI (Titanium Grade 23)	Material: Titanium Grade 5 ELI (Titanium Grade 23)	Peek ClassiX	Material: Titanium Grade 5 ELI (Titanium Grade 23)	Ceramicor
Single use only (incl. Cover screw)	Single use only	Single use only	Single use only	Single use only
Delivered sterile.	Delivered sterile.	Delivered non-sterile.	Delivered non-sterile.	Delivered non-sterile.

All implant-lines of the TRI® Dental Implant system support the digital workflow.

The surgical drills are manufactured of stainless steel 1.4614 including DLC coating. The implant drivers are manufactured of stainless steel 1.4034.

3. Intended Use

The TRI® Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI® Dental Implant System allows for one and two stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI® Dental Implant System 6.5 mm implants are intended for delayed loading only.

The TRI® Dental Implants Instruments are intended to be used for planning and placement of the implants from the TRI® Dental Implant System. The cassettes are used to store and sterilize instruments.

4. Indications

TRI® dental implants are suitable for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TRI® dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Prosthetic restorations such as single crowns, bars, bridges and partial or full dentures are connected to these implants either directly or indirectly via other components.

TRI® Dental Implants Instruments are used for planning, preparing and performing surgical and prosthetic procedures for placing TRI® products of the TRI® Dental Implant System. The dense bone drill and the tap are indicated for dense bone class 1 only.

5. Contraindications

Non-completed jawbone growth; drug or alcohol abuse; allergies or hypersensitivity to chemical ingredients of materials used; patients where primary stability cannot be achieved due to bone type, bone situation or co-morbidities; all conditions which would normally be contraindicated for oral surgery; patient situations in which appropriate sizes, numbers or desirable positions of implants necessary to provide safe support of safe functional load are not achieved; radiotherapy of the jaw bone; untreated intraoral pathology or malignancy; untreated or uncontrolled periodontal disease; uncontrolled psychiatric disorders; recent myocardial infarction (MI) or cerebrovascular accident (CVA) or valvular prosthesis surgery; intravenous bisphosphonate (anti-resorptive) therapy, Immunosuppression - for example following organ transplant or treatment of systemic disease; inability to maintain high levels of plaque control (e.g. reduced manual dexterity or mental capacity); periapical pathology or untreated periodontitis.

The 6 mm implants are contraindicated for immediate loading.

Small diameter implants (3.3mm) and angled abutments are contraindicated for the posterior region.

6. Warnings Related to Patient Selection

Warning: A lower implant survivorship or a higher rate of complications must be expected when treating the following patients:

- Smoking: heavy smokers
- Uncontrolled diabetes
- History of periodontal disease
- Intravenous bisphosphonate (anti-resorptive) therapy
- Cancer
- Abnormal occlusional loading i.e. bruxism

Warning: in the case of dental treatment/implantology of pregnant or breast-feeding women, please consult a medical professional. Please consider the limitations of the medical treatment with regards to the state-of-the-art clinical knowledge.

7. Complications

The following complications may occur: implant loss or loosening; soft tissue complications of excessive swelling, fistula or suppuration,

hyperplasia requiring surgical therapy; periodontal disease; gingivitis, periodontitis gingivitis, periodontitis; bone loss above the defined threshold; implant fracture; abutment screw loosening; abutment screw fracture; abutment failure; complications with suprastructures, i.e. chipping of the veneer, cement failure; fracture of suprastructure/overdenture; nerve injury; penetration of the sinus floor; compromised esthetic result; compromised functional result; lack of primary stability; impairment to adjacent teeth; irreversible damage to adjacent teeth; infections; aspiration of components; explantation.

8. Operation Technique With TRI® Dental Implants

8.1. General Warnings

General Warnings:

- Products must be secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.
- Avoid proximity to the mandibular nerve channel during implant bed preparation and implant insertion. Nerve damage may result in anesthesia, paresthesia and dysesthesia.
- Please ensure all surgical instruments and TRI® surgical Kit-Tray must be cleaned, disinfected and sterilized prior to use (see Section 9. Processing (cleaning, disinfection and sterilization))
- Products of the TRI® Dental Implant System must only be used according to the indications described in this IFU.
- Do not re-use or re-sterilize any products of the TRI® Dental Implant System that carry the single use symbol on the label.
- Make sure that the internal configuration of the implant is correctly aligned. Ensure the proper alignment of the implant, see details in Section 8.4.
- Prior to a Magnetic Resonance Imaging (MRI) procedure, the patient should consult their medical physician and the MRI technician. The TRI® Dental Implant Systems (excluding drills) have been validated to be conditionally safe if used for standard MRI procedures using 1.5 and 3.0 Tesla. For third party restorative components and materials (e.g. materials for creating crowns on top of TRI® abutments), please check their informational materials, including their IFU in terms of their safety.

8.2. Preparation and Planning of the Surgical Procedure

The planning of the surgical procedure requires profound knowledge in dental implantology. Please use the TRI® X-Ray template for implant planning or any software system that is compatible with TRI+ Digital Solutions.

Warning: Allow for 1mm of pilot drill overlength when planning your implant position.

Warning: Wrong planning of the length for drilling can result in damage to the alveolar nerve of the patient. Make sure to read your x-ray dimensions correctly.

Note: Make sure that the ordered components are identical with the components planned and used.

8.3. Surgical Procedure

Use appropriate surgical instruments such as round burs or lance drills to prepare the ridge for the surgical procedure with the TRI® Dental Implants Instruments.

Before starting the drilling procedure, make sure that the depth markings of the TRI® surgical instruments are understood correctly:

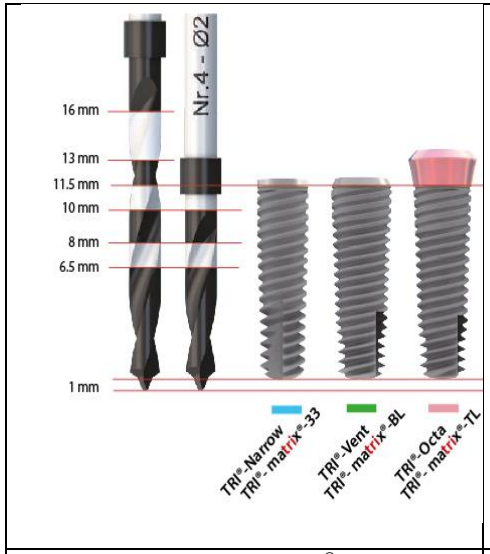


Figure 1: Depth markings of TRI® surgical instruments
Used for TRI®-Vent, TRI®-Narrow, TRI®-Octa and
TRI®-matrix®
(example 11.5mm implant)

Figure 2: Depth markings of TRI® surgical instruments used for TRI®-Narrow and TRI®-matrix® (example 11 mm implant)

TRI® Dental Implants instruments have an ISO 1797 instrument shank. Make sure that the surgical instruments are connected to a drilling unit that is compatible with ISO 1797 instruments shanks.

Strictly follow the drilling sequence and maximum amount of revolutions per minute (RPM) described in Table 1 and Figure 3 below and use appropriate irrigation:

Table 1: Maximum RPM

Art. No.	Dimension / Description	Max. RPM	Art. No.	Dimension / Description	Max. RPM
LD-1.6	Lindemann drill	800	TAP3.7	Ø 3.75 mm	15
RB-2.3SK	Round bur	800	SBD-4.1 S	Ø 3.0/3.4 mm	600
TPD 2.3 S	Ø 2.3 mm	800	TVSBD-4.1 L	Ø 3.0/3.4 mm	600
TPD 2.3 L	Ø 2.3 mm	800	DBD-4.1 L	Ø 3.2/3.9 mm	600
TND-3.3L	Ø 2.4/2.8 mm	800	TAP4.1	Ø 4.1 mm	15
TAP3.3	Ø 3.3 mm	15	SBD-4.7 S	Ø 3.6/4.0 mm	600
SBD-3.7 S	Ø 2.7/3.1 mm	800	SBD-4.7 L	Ø 3.6/4.0 mm	600
SBD-3.7 L	Ø 2.7/3.1 mm	800	DBD-4.7 L	Ø 3.8/4.5 mm	600
DBD-3.7 L	Ø 2.9/3.6 mm	800	TAP4.7	Ø 4.7 mm	15

Warning: Excessive drilling depth can lead to permanent damage to the alveolar nerve of the patient. Make sure that the depth markings are clearly visible during the entire surgical process or use the TRI® Drill Stop System. Replace the drills after a maximum use of 30 times.

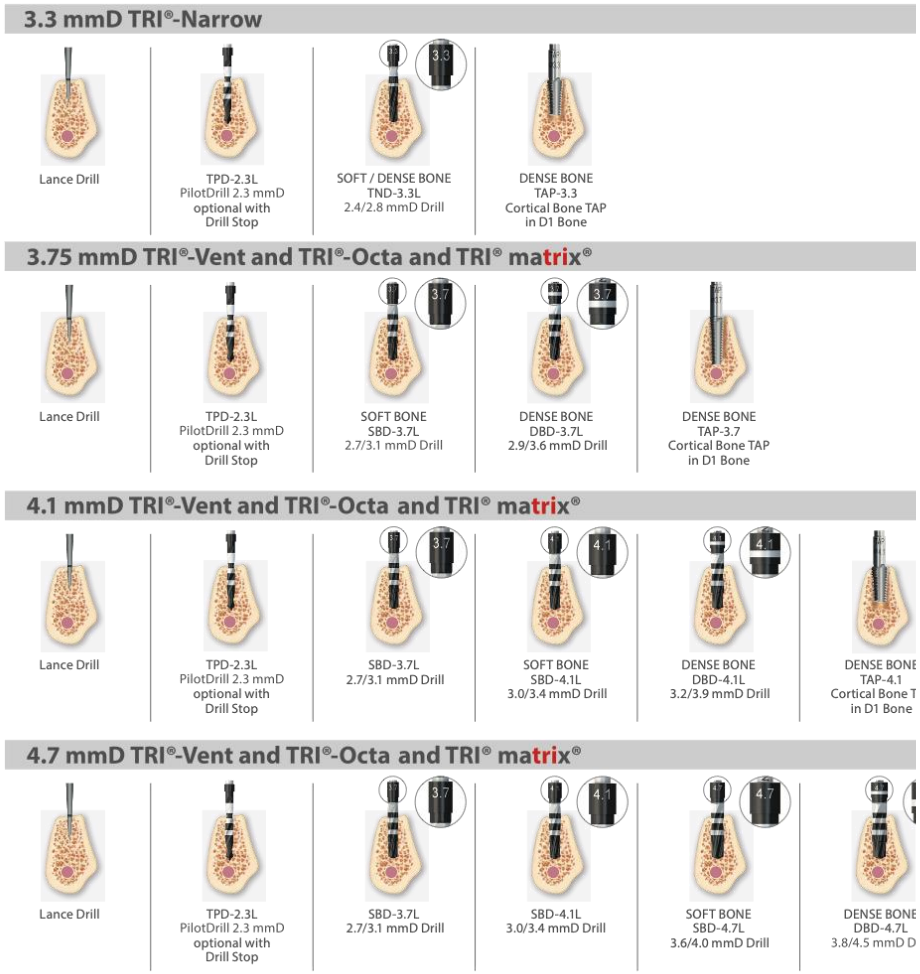


Figure 3: Drill sequence for the TRI® Dental Implant System

8.4. Implant Insertion

Remove the implant from the packaging without touching the non-sterile packaging exterior, and never touch the implant directly. Do not proceed if the packaging is damaged.

Insert the implant either with the TRI® implant driver, the surgical hand piece or the torque ratchet.

Figure 4: Handling of TRI® Pod implant packaging.

Warning: Align the flat side of the hex buccally, except when using TV50-17 or TV50-30 abutments. Matrix® implants do not need any specific alignments of the internal configuration.

Warning: Never exceed an insertion torque of **40 Ncm**. Over-tightening an implant may lead to implant damage, fracture or necrosis of the bone site.

8.5. Soft Tissue Management

Warning: Surgical cover screws and healing components must not be re-used.

The healing components of the TRI® Dental Implant System allow for one-stage or two-stage surgery.

For two-stage surgery, mount the surgical cover screw to the implant after implant placement. Tighten the surgical cover screw with a torque of 15 Ncm.

The TRI® Dental Implant System contains various healing components for soft tissue management. Use these components according to the patient's anatomy and your selected treatment approach. For one-stage surgical procedures, mount the healing collar directly after implant placement. Tighten all healing collars with a torque of 15 Ncm.

Warning: Never exceed an insertion torque of **15 Ncm**. Over-tightening a healing collar may lead to implant loss.

Fabrication of individual healing collars with the TRI®-matrix® system: Use appropriate materials for the fabrication of individual healing collars. Please see matrix® suprastructure reference table for detailed specifications.

8.6. Impression Taking

The TRI® Dental Implant System allows for both an open-tray and closed-tray impression technique.

Note: Ensure a good retention of the impression post in the impression material to ensure high precision to avoid any prosthetic misfit.

Digital impressions can be taken both with the scan bodies (Art. No. TX70-Scan) or the open tray impression posts (Art. No. BLM-05-XX-PXX & TX05-XX).

8.7. Prosthetic Procedures

State-of-the-art prosthetic and dental technician procedures shall be followed for the fabrication of the prosthetic restoration on the TRI® Dental Implant System.

Warning: Temporary crown should be out of occlusion in order to protect the implant during the healing phase. Make sure to use appropriate prosthetic design and materials to ensure proper loading of the implant and avoid fracture of the prosthetics.

8.7.1. Standard Prosthetic Procedures

This section describes the standard prosthetic procedures for the TRI®-Vent/Narrow/Octa/matrix® implant lines.

State-of-the-art prosthetic and dental technician procedures shall be followed when restoring the TRI® dental implants.

The TRI® Dental Implant System allows for the following prosthetic options:

Table 2: Prosthetic options

Type of restoration	TRI® product series	Warnings and Notes
Temporary restoration	10-series	**Warning:** Temporary crown should be out of occlusion in order to protect the implant during the healing phase.
Final cement-retained restoration with titanium abutments.	10-series straight abutments 20-series angled abutments	**Warning:** Use correct torque of 30Ncm in order to prevent screw loosening or inappropriate abutment positioning. **Warning:** Try to avoid excess cement when placing the abutment.
Screw-retained restoration with gold or platinum abutment.	30-series gold abutments 35-series platinum NEM abutments	-
Screw-retained multi-unit restoration.	40-series straight and angled (All-on-TRI®)	**Warning:** Place the flat side of the implant mesially for 17° and 30° angled abutments (unlike all other abutments). **Warning:** Use 20 Ncm for restorations on top of 40 series abutments.
Removable restoration with LocatorTM	Locator™	-
Removable restoration with ball abutments	60-series	-
CADCAM abutments with titanium base.	70-series	**Note:** Request TRI+ files at digital@tri-implants.com for compatibility with CADCAM systems.

The following torques must be used for the various components of the TRI Dental Implant System:

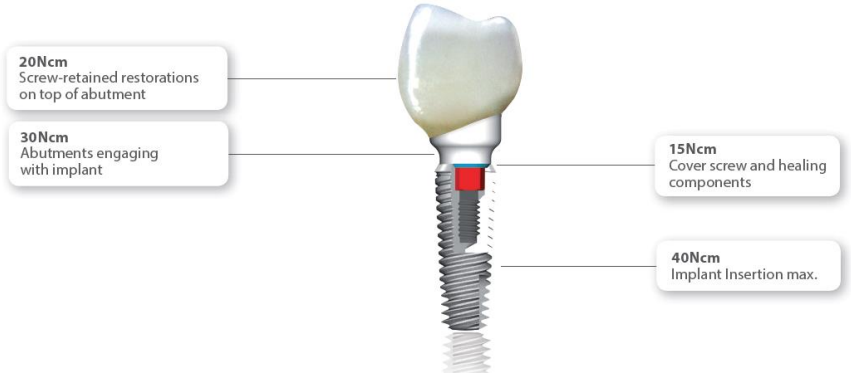


Figure 5: Torques for the TRI® Dental Implant System.

Warning: The healing time required for osseointegration (and full loading of the implant) is very individual and treatment-dependent. It is the sole responsibility of the surgeon to decide when the implant can be loaded. TRI® dental implants are suitable, within the scope of application, for immediate and early restoration in single-tooth gaps and in an edentulous or partially edentulous jaw. Good primary stability and an appropriate occlusal load are essential.

8.7.2. Fabrication of patient-specific suprastructures with the TRI-matrix® implant line:

The TRI-matrix® implant line offers an interface specific for prosthetic restoration using the digital workflow with third-party planning software and materials.

Follow state-of-the-art prosthetic and dental technician restorative principles. Use appropriate materials and follow instructions from manufacturers. Only use materials with mechanical properties as described in table 3.

Warning: Make sure to use the appropriate screws and interface files as specified in tables

Table 3 and Table 4.

Warning: You must follow all instructions and respect limitations of third party equipment used. This may include scanners, design software, manufacturing equipment or materials.

Warning: Make sure that the interface is not covered with any veneering material.

Warning: Temporary crown should be out of occlusion in order to protect the implant during the healing phase. Make sure to use appropriate prosthetic design and materials to ensure proper loading of the implant and avoid fracture of the prosthetics.

Warning: Using of insufficient manufacturing precision for the production of suprastructures on the TRI-matrix® implants can lead to inadequate fit of the prosthetic restoration.

Warning: Usage of inappropriate materials for suprastructures on the TRI-matrix® implants can lead to fracture of the prosthetic restoration.

Warning: Worn CAM instruments may lead to insufficient precision of the suprastructure on the TRI-matrix® implants which can lead to fracture of the prosthetic restoration.

Warning: Inappropriate CAM strategies can lead to inadequate fit of the prosthetic restoration (see verification tool).

Warning: Usage of inappropriate CAM machines can lead to inadequate fit of the prosthetic restoration (see verification tool).

Warning: Do not proceed if you do not have appropriate measuring equipment to verify the specified production tolerances stated in the IFU (see verification tool).

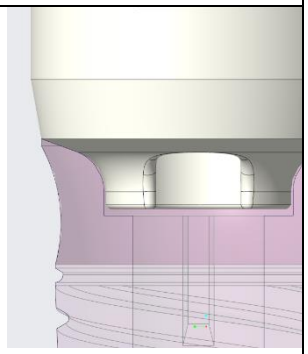
Table 3: TRI-matrix® suprastructure reference table

	Individual healing collars	**Individual single unit restorations**	**Individual multi-unit restorations**
Metal **Minimal tensile strength: 860 MPa.**	Screw: min. SCRW-2.25 or wider Interface File: RO or NE Torque: 15NCm	Screw: min. SCRW-2.25 or wider Interface File: EN Torque: 35 NCm	Screw: min. SCRW-2.25 or wider Interface File: NE Torque: 35 NCm
Zirconia **Minimal three point bending strength: 1200MPa.**	Screw: SCRW-2.8 Interface File: RO or NE Torque: 15NCm	Screw: SCRW-2.8 Interface File: EN Torque: 35 NCm	Screw: SCRW-2.8 Interface File: NE Torque: 35 NCm
Polymers **For provisional restorations only.** **Minimal three point bending strength:100 MPa.**	Screw: min. SCRW-2.8 or SCRW-3.25 Interface File: RO or NE Torque: 15NCm	Screw: min. SCRW-2.8 or SCRW-3.25 Interface File: EN Torque: 35 NCm	Screw: min. SCRW-2.8 or SCRW-3.25 Interface File: NE Torque: 35 NCm

Request the digital libraries files at digital@tri-implants.com for compatible third-party CAD software.

Warning: Do not modify the height of the pre-defined screw seat in the digital libraries.

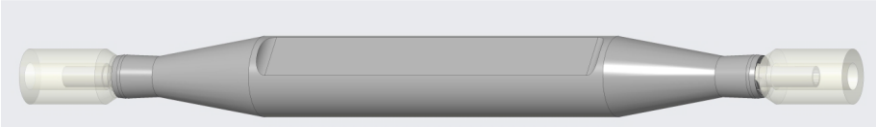
Table 4: matrix® interface files overview:

Rotational (RO)	**Non-engaging (NE)**	**Engaging (EN)**
		
Platform availability: P37 and P45 Description: interface is fully rotational. I shall only be used for healing collars that do not bear any occlusal loading.	Platform availability: P37 and P45 Description: interface is partially rotational. There is a support of the prosthesis on the horizontal surface. It shall be used for multi-unit restorations.	Platform availability: P37 and P45 Description: interface is engaging. There is a support of the prosthesis on the horizontal surface. It shall be used for single units.

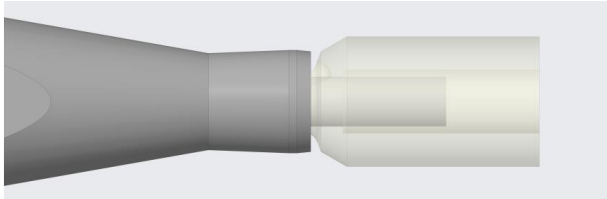
Verification of matrix® suprastructures:

Warning: Verify every matrix® suprastructure with the corresponding verification tool. Do not proceed upon successful verification of each suprastructure.

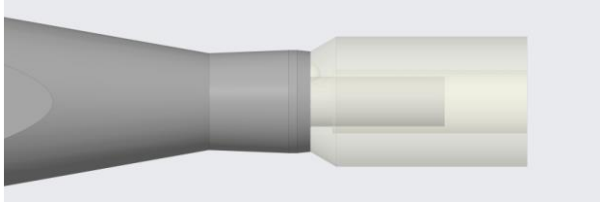
In order to check the appropriate fit of the suprastructure, use the verification tool. Art. No. VTool-P37 for P37 platform and VTool-P45 for P45 platform:



Right side: no-go



Left side:go



Left side: make sure that the crown can be fully inserted into the verification tool. There must be no gap visible under the microscope between verification tool and crown. This way, you can ensure the proper fit of the horizontal surface and make sure that the rotation element is not too narrow.

Right side: make sure that the crown cannot be moved all the way down into the verification tool This way, you can ensure that the rotation element is not too wide what would lead to an insufficient rotational stability of the crown.

8.8. Patient Record

Note: Keep the patient labels in your records to ensure proper traceability in case of notifications or recalls by TRI Dental Implants Int. AG.

8.9. Patient After-Care

Please follow appropriate and state-of-the art after-care after treatment.

9. Compatibility Information

The TRI® Dental Implant System comprises the implant lines TRI®-Narrow, TRI®-Vent, TRI®-Octa and TRI-matrix®. Each line has its own components and abutments. For TRI®-Narrow implants, only use components and abutments with Article Number TN-XXX (colour code blue), for TRI®-Vent TV-XXX (colour code green), TRI®-Octa TO-XXX (colour code pink) and for TRI-matrix® M-XXX, BLM-XX and TLM-XX.

10. Processing (cleaning, disinfection and sterilization)

10.1. Implants and Abutments

TRI® dental implants are provided in sterile condition and for single use only. They must not be cleaned or sterilized.

Abutments that are treated in the dental lab are delivered non-sterile. They must be appropriately disinfected and sterilized by the user. Please sterilize the non-sterile abutments using the following validated full cycle parameters and dry time:

Sterilizer Type: Gravity

Minimum Temperature: 121°C

Full Cycle Time: 30 minutes

Minimum Dry Time: 30 minutes

Healing collars that can be inserted during the surgical procedure are delivered in sterile condition. The sterile symbol on the product label indicates whether a product is sterile or not.

Warning:

- Visually inspect packaging that there is no physical damage.
- Implants must not be resterilized.

10.2. Instruments

All TRI Dental Implants Instrumnets are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Please pay attention to avoid a higher contamination of the complete sterilization tray during application by separate collection of contaminated instruments (without laying back into the sterilization tray). Pre-clean the contaminated instruments, then sort them back into the sterilization tray and clean, disinfect and sterilize the completely equipped sterilization tray.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the doctor´s practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA).

In case of some instruments additional or deviating procedure are required (see “Table 4: Specific aspects”).

10.2.1. Cleaning and disinfection

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered.

The pre-treatment step is to be performed in both cases.

Pre-treatment

Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h).

Procedure:

1. Remove the instruments of the tray and disassemble the instruments and tray as possible (see “Table 4: Specific aspects”).
2. Rinse the instruments and the tray at least 1 min under running water (temperature < 35 °C/95 °F). Agitate movable parts at least three times during pre-rinsing.
   If applicable (see “Table 4: Specific aspects”):
   Rinse all lumens of the instruments at least three times with a syringe (specific volume and further aids see section see “Table 4: Specific aspects”).
3. Soak the disassembled instruments and the tray in the pre-cleaning solution1 (ultrasonic bath, ultrasound not activated) so that the instruments and tray are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at beginning of soaking, further aids see section (see “Table 4: Specific aspects”). Agitate movable parts at least three times during pre-cleaning.
   If applicable (see “Table 4: Specific aspects”):

Rinse all lumens of the instruments at least three times with a syringe (specific volume and further aids (see “Table 4: Specific aspects”).

4. Activate ultrasound for the given soaking time (but not less than 5 min).
5. Then, remove the instruments and the tray of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Agitate movable parts at least three times during post-rinsing.
   If applicable (see “Table 4: Specific aspects”):
   Rinse all lumens of the instruments at least three times with a syringe (specific volume and further aids (see “Table 4: Specific aspects”).

Pay attention to following points during selection of the cleaning detergent[1]:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- in case of application of an ultrasonic bath: suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see section „material resistance“)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see section „material resistance“)

[1] In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see section „material resistance“).
Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

Procedure:

1. Disassemble the instruments as possible and remove the big holders of the tray (see “Table 4: Specific aspects”).
2. Transfer the closed tray equipped with the remaining instruments (as instructed “Table 4: Specific aspects”) and the disassembled instruments/holders (by use of a small pieces basket) in the WD (pay attention that the instruments have no contact).
3. Start the program.
4. Remove the instruments and tray of the WD after end of the program.
5. Check and pack the instruments immediately after the removal (see sections „check“, „maintenance“, and “packaging“, if necessary after additional post-drying at a clean place).

Manual cleaning and disinfection

Pay attention to following points during selection of the cleaning and disinfection detergents:

- fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material
- in case of application of an ultrasonic bath: suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible with the used cleaning detergent
- compatibility of the used detergents with the instruments (see section „material resistance“)

Combined cleaning/disinfection detergents should not be used.
Only in case of extremely low contamination (no visible impurities) combined cleaning/disinfection could be used.

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Procedure:
Cleaning

1. Disassemble the instruments and tray as possible (see “Table 4: Specific aspects”).
2. Soak the disassembled instruments and tray in the cleaning solution (ultrasonic bath, ultrasound not activated) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush. Agitate movable parts at least three times during cleaning.
   If applicable (see “Table 4: Specific aspects”):
   Rinse all lumens of the instruments at least five times by application of a single-use syringe (specific volume and further aids see “Table 4: Specific aspects”).
3. Activate ultrasound for the given soaking time (but not less than 5 min).
4. Then, remove the instruments and tray of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Agitate movable parts at least three times during post-rinsing.
   If applicable (see “Table 4: Specific aspects”):
   Rinse all lumens of the instruments at least five times by application of a single-use syringe (specific volume and further aids see “Table 4: Specific aspects”).
5. Check the instruments (see sections “check“ and “maintenance“).

Disinfection

6. Soak the disassembled instruments for the given soaking time in the disinfectant solution so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Agitate movable parts at least three times during disinfection.
   If applicable (see “Table 4: Specific aspects”):
   Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (specific volume and further aids see “Table 4: Specific aspects”).
7. Then, remove the instruments and tray of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water. Agitate movable parts at least three times during post-rinsing.
   If applicable (see “Table 4: Specific aspects”): Rinse all lumens of the instruments at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (specific volume and further aids see “Table 4: Specific aspects”).
8. Dry and pack the instruments and tray immediately after the removal (see section „packaging“, if necessary after additional post-drying at a clean place).

10.2.2. Check

Check all instruments after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged instruments (for limitation of the numbers of re-use cycles see section „reusability“). Still dirty instruments are to be cleaned and disinfected again.

10.2.3. Assembly/maintenance

Assemble disassembled instruments again. Return the holders back into the tray.

Instrument oils must not be applied (Exception Torque Wrench: Use only instrument oils (white oil without any further additives) admitted to steam sterilization considering the maximum possible sterilization temperature and with approved biocompatibility for this and apply only a small amount as indicated in Figure 7).

10.2.4. Packaging

Please insert the cleaned and disinfected instruments in the tray and pack them in single-use sterilization packagings (single or double packaging), which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packagings to mechanical damage

A maximum weight of 0.43 kg per equipped tray must not be exceeded.

10.2.5. Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[2] or gravity displacement procedure[3] (with sufficient product drying[4])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)

[2] at least three vacuum steps

[3] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure.

[4] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Table 3: Sterilization procedures

Area	**fractionated vacuum/dynamic air removal**	**gravity displacement**
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[4]	not recommended
Europe/other countries	at least 5 min[5] at 132 °C (270 °F) / 134 °C (273 °F)	not recommended

The flash/immediate use sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

10.2.6. Storage

Please store the instruments after sterilization in the sterilization packaging at a dry and dust-free place.

10.2.7. Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 5.5)
- lyes (maximum admitted pH-value 8.5, neutral/enzymatic cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.
Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments and sterilization trays by use of metal brushes or steel wool.

Please do not expose any instruments and sterilization trays to temperatures higher than 138 °C (280 °F)!

[5] respectively 18 min (inactivation of prions, not relevant for USA)

10.2.8. Reusability

The TRI Dental Implants Instruments can be reused – in case of appropriate care and if they are undamaged and clean – 30times (or as indicated in “Table 4: Specific aspects”). The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

Table 4: Specific aspects

Art. no	article specification	rinsing volume	brush	specific/additional procedure in case of				packaging	sterilization	maximum admitted cycle number	recommended classification according to KRINKO/RKI/BfArM guidance (only Germany, with respect to intended use)
				pre-treatment	manual cleaning/ disinfection	automated cleaning/ disinfection	Assembly/ Maintenance				
TW	Torque Wrench	10 ml (single use syringe)	interdental brush conical (3-6.5 mm) , tooth brush	dismantled (see Figure 7)/outside the tray, brushing inside and outside, rinsing through	dismantled/outside the tray, brushing inside and outside, rinsing through	dismantled/outside the tray/in a small pieces basket	assembly und lubrication (see Figure 7)	mounted/in the tray	mounted/in the tray. Spring unloaded	Unrestricted maximum cycle number as long as the device does not show any signs of wear, damage or rust (no liability in case of disregard).	critical B
TW – Adapter	Torque Wrench Adapter	5 ml (single use syringe with cannula)	interdental brush conical (3-6.5 mm) , tooth brush	outside the tray, brushing inside and outside, rinsing through	outside the tray, brushing inside and outside, rinsing through	outside the tray/in a small pieces basket	lubrication not admitted	in the tray	in the tray	Unrestricted maximum cycle number as long as the device does not show any signs of wear, damage or rust (no liability in case of disregard).	critical B
TDS6 TDS8 TDS10 TDS11 TDS13	Drill Stops	5 ml (single use syringe with cannula)	interdental brush conical (3-6.5 mm) , tooth brush	outside the tray, brushing inside and outside, rinsing through	outside the tray, brushing inside and outside, rinsing through	outside the tray/in a small pieces basket	lubrication not admitted	in the tray	in the tray	Unrestricted maximum cycle number as long as the device does not show any signs of wear, damage or rust (no liability in case of disregard).	critical B
TPD-2.3S TPD-2.3L TND-3.3L TAP3.3 SBD-3.7S SBD-3.7L DBD-3.7L TAP3.7 SBD-4.1S SBD-4.1L DBD-4.1L TAP4.1 SBD-4.7S SBD-4.7L DBD-4.7L TAP4.7	Drills	-	tooth brush	outside the tray, brushing, check for remaining bone material (and repetition of pre-cleaning if required)	outside the tray, brushing	in the tray	lubrication not admitted	in the tray	in the tray	30	critical B

PP-L VD-S VD-L ND-S ND-L OD-S OD-L PD-S PD-L TRT TORT LD-1.6 RB-2.3 MD-L-ISO MD-S-ISO	further instruments	-	tooth brush	outside the tray, brushing	outside the tray, brushing	in the tray	lubrication not admitted	in the tray	in the tray	Unrestricted maximum cycle number as long as the device does not show any signs of wear, damage or rust (no liability in case of disregard).	critical B
TSK-Tray	TRI Surgical Kit – Tray	-	standard brush, tooth brush	removal of all instruments/removal of the big holders (for Torque Wrench, TW – Adapter, and Drill Stops)/removal out of the box, brushing inside and outside	removal of all instruments/removal of the big holders (for Torque Wrench, TW – Adapter, and Drill Stops)/removal out of the box, brushing inside and outside	without the big holders and the concerning instruments (Torque Wrench, TW – Adapter, and Drill Stops)/equipped with all further instruments/inside the closed box)	return the big holders back into the tray, lubrication not admitted	fully equipped, inside box	fully equipped, inside box	Unrestricted maximum cycle number as long as the device does not show any signs of wear, damage or rust (no liability in case of disregard).	not applicable

11. Storage of Packaged Products

Store the products of the TRI® Dental Implant System in the original packaging in a dry place and avoid direct exposure to sunlight.

12. Validity

13. Availability

Certain items of the TRI® Dental Implant System are not available in all countries.

14. Explanation of abbreviations and symbol

	Consult Instructions for Use
	Manufacturer
	Date of manufacture
	Caution, see Instructions for Use.
	Do not re-use
	Use-by date
LOT	Batch code
REF	Catalog number
STERILE R	Sterilized using radiation
	Keep away from direct sunlight
CE CE 0297	TRI® Dental Implants products with the CE mark fulfil the requirements of the Medical Devices Directive 93/42 EEC 0297 identifies the notified body.
RxOnly	Caution: U.S. federal law restricts this device to sale by, or on the order of, a licensed dentist or physician.
	Do not use if package is damaged.
	Keep dry
	Do not resterilize
	Non-sterile
MD	Medical Device

Manufacturer:

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