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 instruments. All components of the TRI® Dental Implant System are made of titanium grade 5 (Ti-6Al-4V ELI), and the implants feature the TRI® SBA (**s**and**b**lasted **a**cid-etched) bone anchoring surface (unless otherwise indicated in the TRI® Product Catalog).

3. Intended Use

The TRI® Dental Implant System is intended to be used for replacing teeth, from single tooth gaps to fully edentulous jaws. The core components of the TRI® Dental Implant System are endosseous implants in different diameters and lengths, and various restorative components and auxiliaries. TRI® dental implants are intended to remain in the jawbone over the long term.

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. The prosthetic restorations used are single crowns, bars, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

5. Contraindications

Non-completed jawbone growth, drug or alcohol abuse, allergies or hypersensitivity to chemical ingredients of materials used (titanium grade 5 (Ti-6Al-4V ELI)), all conditions which would normally be contraindicated for oral surgery, patient situations in which adequate sizes, numbers or desirable positions of implants necessary to provide safe support of safe functional load are not achieved. The 6 mm implants are contraindicated for immediate loading.

6. Potential Side Effects

Temporary symptoms

Pain, swelling, phonetic difficulties, gingival inflammation.

More persistent symptoms

Chronic pain in connection with the dental implant, permanent paresthesia, dysesthesia, loss of marginal bone, localized or systemic infections, oroantral or oronasal fistulae, impairment to adjacent teeth, irreversible damage to adjacent teeth, implant fractures in the jaw, bone or prosthesis, esthetic problems, nerve damage, exfoliation, hyperplasia.

7. Operation technique with TRI® Dental Implants

7.1. General Warning and Cautions

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.

Cautions:

- Make sure that the internal configuration of the implant is correctly aligned. For more details, please consult chapter 7.4
- Implant Insertion.
- MRI safety information: Please note that the product has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.

7.2. 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.

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

Caution: 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.

7.3. Surgical Procedure

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 and TRI®-Octa (example 11.5mm implant).

Figure 2: Depth markings of TRI® surgical instruments used for TRI®-Narrow (example 11.5 mm implant)

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

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	TVSBD-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	TVDBD-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	TVSBD-4.7 S	Ø 3.6/4.0 mm	600
TVSBD-3.7 S	Ø 2.7/3.1 mm	800	TVSBD-4.7 L	Ø 3.6/4.0 mm	600
TVSBD-3.7 L	Ø 2.7/3.1 mm	800	TVDBD-4.7 L	Ø 3.8/4.5 mm	600
TVDBD-3.7 L	Ø 2.9/3.6 mm	800	TAP4.7	Ø 4.7 mm	15

Caution: 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.

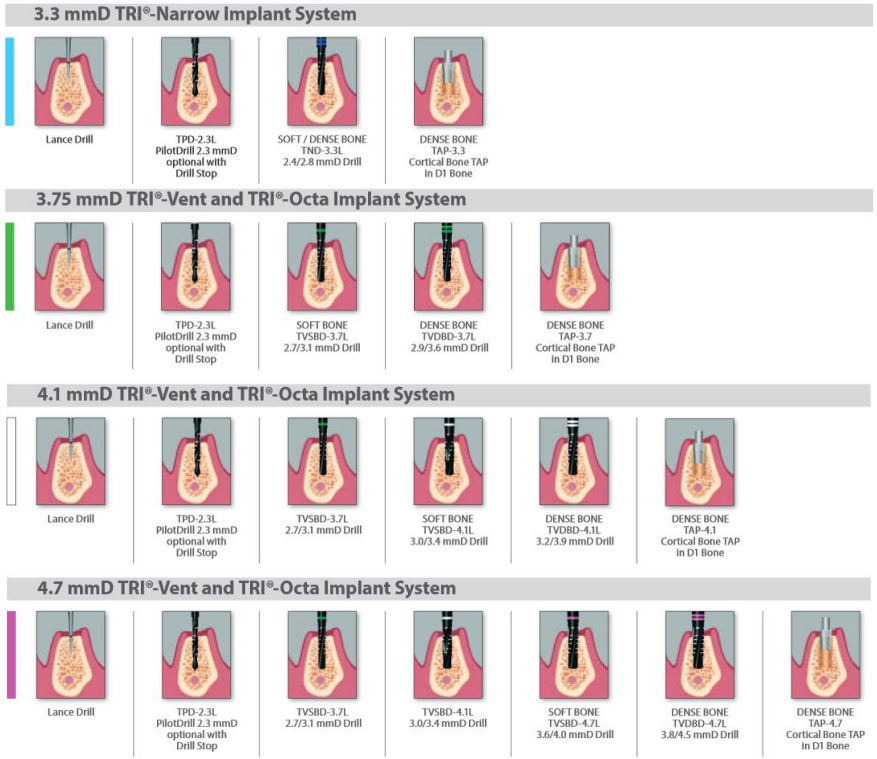

Figure 3: Drill sequence for the TRI® Dental Implant System

7.4. Implant Insertion

Remove the implant from the packaging without touching the non-sterile packaging exterior, and never touch the implant directly.

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

Align the flat side of the hex buccally, except when using TV50-17 or TV50-30 abutments.

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

7.5. Soft Tissue Management

Caution: 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.

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

7.6. Impression Taking

The TRI® Dental Implant System allows for both an open-tray and closed-tray impression technique. Please refer to the TRI® Product Catalog for a detailed overview of available components.

Caution: Make sure that the marking of the TRI®-Octa ITC impression abutments (TO10-35-ITC and TO10-50-ITC) are aligned buccally, both in patient and model situations.

7.7. Prosthetic Procedures

A torque of 30 Ncm must be used for all TRI® abutments.

A torque of 20 Ncm must be used for all prosthetic restorations screwed on to TRI abutments (e.g. 40 series).

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

Table 2: Prosthetic options

Type of restoration	TRI® product series	Cautions and notes
Temporary restoration	10-series	**Caution:** 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	**Caution:** Use correct torque of 30Ncm in order to prevent screw loosening or inadequate abutment positioning. **Caution:** 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®)	**Caution:** Place the flat side of the implant mesially for 17° and 30° angled abutments (unlike all other abutments). **Caution:** 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.

Caution: 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.

7.8. Patient Record

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

8. Compatibility Information

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

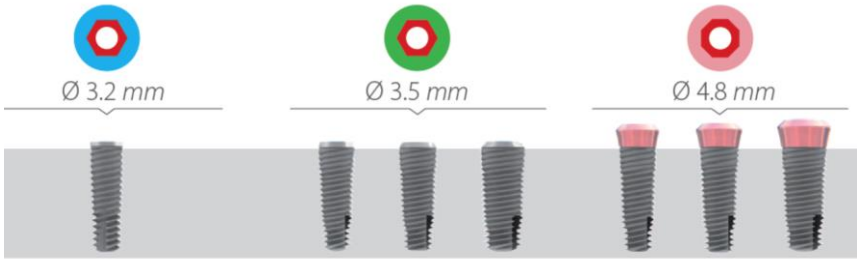

Figure 4: Compatibility information

9. Disinfection, Cleaning and Sterilization

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

All surgical instruments must be cleaned, disinfected and sterilized prior to use.

Cleaning

1. Place the disassembled instruments in the cleaning bath for the specified time (make sure that the instruments are completely covered). If necessary, brush carefully with a soft brush. Make sure that the instruments do not come into contact with one another. Rinse out all instrument cavities three times (3x) at the beginning or end of cleaning period, using a disposable syringe (minimum volume 20 ml).
2. Remove the instruments from the cleaning bath and rinse them thoroughly with water at least three times (3x).

Disinfection

3. Place the disassembled, cleaned instruments in the disinfection bath for the specified time. Ensure that the instruments are sufficiently covered by the disinfection solution and that the instruments do not come into contact with one another. Rinse out all instrument cavities three times (3x) at the beginning or end of disinfection period, using a disposable syringe (minimum volume 20 ml).
4. Remove the instruments from the disinfection bath and rinse them thoroughly with water at least five times (5x).
5. Dry the instruments internally and externally with filtered compressed air.

Sterilization

6. Sterilize the instruments according to the following specifications:

Table 3: Different sterilization methods

Sterilization method		
Fractionated vacuum method	Gravitation method	Comments
at least 20 min. at 121 °C (250 °F) OR at least 3 min. at 132 °C (270°F) up to 134 °C (273 °F)	at least 5 min. at 132 °C (270 °F) up to 134 °C (273 °F)	Maximum sterilization temperature 134 °C (273 °F) Make sure to use sufficient time for drying

10. Validity

Upon publication of these instructions for use, all previous versions are superseded.

11. Availability

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

12. Explanation of abbreviations and symbol


Consult Instructions for Use


Manufacturer


See Instructions for Use


Do not re-use

Use-by date

Batch code

Catalog number

Sterilized using radiation

CE 1023 TRI® Dental Implants products with the CE mark fulfil the requirements of the Medical Devices Directive 93/42 EEC
1023 identifies the notified body of manufacturers

RxOnly Caution: U.S. federal law restricts this device to sale by or on behalf of a dental professional

Manufacturer:

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