



Instruction for Use TA-Implant-System

1. Application:

This instruction for use applies to all components of the TA-implant-systems (including TA-switch / plus implants and corresponding components).

The individual components of the system are identified on the label of the package by the article number (REF) and the description.

2. General Instructions:

The acknowledgement of the relevant technical literature is a requirement for any implantological treatment. Experiences with the surgical procedure and in evaluating normal and pathological treatment outcomes are compulsory. The prosthetic planning must be conducted before the implantation – even when the surgical situation later necessitates a change of plans. This Instruction for use alone does not suffice for the immediate application of the TA-implant-system.

3. Description:

The TA-implant-system is a system for endosteal dental or oral surgical implantations. The system is made of implants, surgical and prosthetic instruments and abutments. The TA-implant-system is suitable for single-tier and two-tier procedures of implantation.

4. Essential elements:

All implants are made of alloyed titanium (implant steel). Abutments and screws remaining inside the mouth are also made of this alloy. The surgical drills are made of steel alloy. The plastic structure for the marking aid are made of polyethylene.

5. Indications:

For the adequate bone availability concerning bone quality, bone amplitude und bone height:

- Anchorage for bar and ball attachment prosthetics in toothed, partial toothed and toothless jaws
- Single tooth replacement
- Anchorage for orthodontic regulation systems

6. Contraindications

Absolute:

Patients, whose overall systemic condition does not permit implantation (for detailed comprehension concerning the extensive contraindication we refer to the studies of the relevant technical literature)

- Before, during or after tangential radiation therapy and/or malign diseases

- Psychological diseases, pain syndromes

- Uncompensated diabetes

- Inadequate oral hygiene

- Allergies to implant components

Relative:

- Diabetes

- Bruxism

- Allergies

- Alcohol and drug abuse

- Smoking

- Inadequate bone supply: during low vertical bone availability and/or imminent proximity of anatomical structures (nerve vicinity, maxillary sinus, among others) one should examine whether or not one resorts to conventional prosthetic solutions.

7. Diagnostics / Clarification:

Diagnostics is composed of the patient's medical history, the clinical examination, the radiological examination using conventional dental radiographs and orthopantomographs and, if necessary CT-examination. It is recommended to carry out a check-up by a general practitioner. Implantations allegorise an operation by choice the patient has to be well-informed about. Alternative treatments and the consequences of the implantations have to be highlighted. The importance of oral hygiene and cost for a post-treatment have to be depicted in particular. Manner and extent of the clarification are referred to in the relevant jurisdiction.

8. Side effects:

Transient complaints:

- Pain, swelling, difficulties with speaking and gingival inflammations.
- Persistent complaints:
- As with all dental implants, a horizontal and vertical bone loss may occur even with an appropriate methodical, surgical and prosthetic procedure. Manner and extent of the bone loss are not foreseeable.
- If implants come close to special structures (nerves, maxillary sinus, neighbouring teeth, among others) it may result in reversible or irreversible impairment.
- To prevent infections, an antibiotic prophylaxis is recommended.
- Chronic pain in conjunction with dental implants has been reported.
- If osseointegration is not successful, one has to reckon with the exfoliation (loss) of the implant.

9. Way of proceeding:

Preferably we work with rotating or displacing instruments and flap procedures under local anaesthetic. To prepare an adequate tray of bones we recommend obeying the following drill sequence and using the accompanying drill of TA-Implant-System (all details in mm):

TA - drill

TA - 3,6: DR 2,0 3,0 CS 3,6 T 3,6

TA - 4,6: DR 2,0 3,0 4,0 CS 4,6 T 4,6

TA - 5,6: DR 2,0 3,0 4,0 5,0 CS 5,6 T 5,6

TA-switch / plus-drill

TA-switch / plus- 3,3: DR 2,0 2,8 CS 3,3 T 3,3

TA-switch / plus- 4,1: DR 2,0 2,8 3,5 CS 4,1 T 4,1

TA-switch / plus- 4,8: DR 2,0 2,8 3,5 4,2 CS 4,8 T 4,8

(DR = Drill; CS = Countersink; T = Tap)

The length markers of the type DR apply to the work lengths without the 0,9 mm tip. An appropriate additional distance to endangered structures has to be kept. During the preparation of the bone cavity one has to cool the implant area continuously (with pre-cooled physiological salt solution). Never drill with more than 500-800 revolutions per minute. Always use sharp drills (maximum 10 uses). Utilize intermittent milling and drilling technique.

The implant gets taken out of the sterile package immediately before firmly inserting it into the implant area according to the insertion aid (preinstalled by means of the package). Afterwards the implant is to be seated into the bone as deep as desired using the implant key. In case of strong bone resistance, the thread cutter may be used to cut it. Subsequently the implant gets sealed either at the vestibular side with the cover cap (two-tier process) or with a healing screw of adequate length (single-tier process). An adequate wound treatment and an radiographic analysis will occur if necessary. During the healing process (depending on the quality of bone, 3-6 months are recommended) the surgical procedure has to be checked at regular intervals. In case of incomplete healing of the mucosa membrane and/or premature penetration of the mucosa membrane we recommend to replace the cover cap with a healing screw. If the statics of the entire construction and the situation during the insertion allow it, implants can be strained directly after insertion. This is up to the attending dentist to decide.

In case of doubt a healing process of 3-5 months without straining

shall be maintained, depending on the available bone quality. At the end of the healing process radiographic and clinical examination takes place. Abutments of the TA-Implant-systems are available for prosthetic supply.

10. More clues:

- Implants may only be used within the expiration date given on the package.
- Implants with damaged aseptic package may not be used and must be returned to the producer.
- After implantation the type of the used implant and the number of the manufacturing batch (on the label LOT-number) has to be recorded on the patient card.
- Implants have to be stored dryly and closed. The closure may only be opened immediately before insertion. Any contact with foreign substances before insertion are to be avoided. The endosteal part of the implant may not be touched.
- In case of accidentally swallowing the implants, abutments or other materials the affected object has to be located (X-ray, etc.) and immediately the necessary medical measures have to be undertaken.
- The healing of the implants has to be checked regularly (e.g. radiographically). To prevent bone loss, the not osseointegrated or infected implants must be removed in time. The time of removal is determined by the dentist.

11. Permanency and instructions on sterilisation:

Provided that the permanency of single components of the TA-implant-system is restricted, the date of expiry is imprinted on the label (hourglass symbol).

The implants of the TA-implant-systems (incl. TA-switch-/plus-implants) are delivered as sterile products (gamma rays sterilisation) for one use only. Cover caps, healing screws and instruments get delivered unsterile in not autoclaved packages and can be autoclaved with the usual methods of the dental practice.

We recommend 15 minutes and 120°C for cover caps and healing screws and for the instruments we recommend 8 minutes and 134°C with 5 minutes cooling time afterwards. More instructions on how to clean and sterilise can be found on our web page.

12. Legend of the label:

	Sterilised using irradiation
	Batch Code
	Date of manufacture
	Manufacturer
	Do not re-use
	Use before expiry date
	Article number
	Serial number
	Consult instructions for use
	Unsterile

13. Form of delivery:

TA screwing implants

Intern Hex: SW 2,5

Diameter: 3,6 mm (lengths 8, 10, 12, 14 mm)

Diameter: 4,6 mm (lengths 8, 10, 12, 14 mm)

Diameter: 5,6 mm (lengths 10, 12, 14 mm)

TA-switch screwing implants

Intern Hex: SW 2,1 (3,3 and 4,1/3,3 mm implant)

SW 2,5 (4,1 und 4,8 mm implant)

Diameter: 3,3 mm (Lengths 8, 10, 12 mm)

Diameter: 4,1 mm (Lengths 6, 8, 10, 12 mm)

Diameter: 4,1/3,3 mm (Lengths 6, 8, 10, 12 mm)

Diameter: 4,8 mm (Lengths 8, 10, 12 mm)

TA-switch / plus screwing implants intern Hex: SW 2,1 (3,3 and 4,1 mm Implant)

SW 2,5 (4,8 mm Implant)

Diameter: 3,3 mm (Lengths 8, 10, 12 mm)

Diameter: 4,1 mm (Lengths 6, 8, 10, 12 mm)

Diameter: 4,8 mm (Lengths 8, 10, 12 mm)

Implants are delivered sterile.

The lengths refer to the entire lengths of the implants.

Deliverable products of the TA-implant-system may be found in the current product catalogue or rather the current price list or on the web site of the TA Zahnimplantate GmbH

TA Zahnimplantate GmbH reserves its right to change the design of the products and components and their package, to adjust application notes and to remake prices and delivery conditions. The accountability is restricted to the replacement of faulty products. Further claims of any kind are excluded.



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