Instructions for Use

English

DENTAL IMPLANTS

TA IMPLANT SYSTEM
Instructions for Use

SCOPE OF THE INSTRUCTIONS FOR USE

These instructions for use describe the handling and application of the TA Implant System.

The instructions apply to the dental implants as well as to all components belonging to the system, including:

- prosthetic abutments
- gingiva formers
- cover screws
- surgical drills
- screwdrivers
- other prosthetic and surgical accessories.

These instructions also contain information regarding the reprocessing (cleaning, disinfection and sterilization) of devices that are supplied non-sterile or intended for multiple use.

The TA Implant System must only be used by trained dental professionals with experience in dental implantology and prosthetic restoration.

Read these instructions for use carefully and completely before using the system. Keep the instructions for future reference.

Failure to observe these instructions may result in:

- injury to the patient
- implant failure
- damage to the device.

DEVICE INFORMATION

Intended Purpose

Dental Implants
Dental implants are sterile, threaded endosseous medical devices intended for surgical placement in the maxilla or mandible to support and retain dental prosthetic restorations.

The implants provide support for prosthetic solutions such as:

- single crowns
- bridges
- overdentures
- full arch restorations.

Their purpose is to restore chewing function, stability and esthetics in partially or fully edentulous patients.

Abutments

Abutments are prefabricated medical devices intended to be connected to dental implants in order to support and connect prosthetic restorations to the implant.

They serve as the interface between the dental implant and the prosthetic restoration.

Gingiva Formers

Gingiva formers are temporary components used during the healing phase following implant placement.

They are intended to shape and maintain the soft tissue contour around the implant site.

Implant Drills

Implant drills are surgical instruments used for the preparation of the implant bed in the jawbone.

They are used to create osteotomies of appropriate diameter and depth to facilitate the placement of dental implants.

Screwdrivers

Screwdrivers are dental instruments designed for tightening and loosening prosthetic and surgical screws during implant surgery and prosthetic procedures.

They are used in combination with manual handles or dental handpieces.

Prosthetic and Laboratory Components

Prosthetic and laboratory components are intended to support the prosthetic workflow of the implant system.

These components are used for:

- impression taking
- model fabrication
- digital or conventional prosthetic planning
- fabrication of implant-supported restorations.

Intended Users

The TA Implant System may only be used by trained dental professionals with appropriate theoretical and practical knowledge in dental implantology.

This includes:

- Dentists
- Oral surgeons
- Oral and maxillofacial surgeons.

Dental laboratories may only handle prosthetic components of the system and are not permitted to use the devices directly on patients.

Clinical Benefits

The TA Implant System is intended to restore oral function and aesthetics by replacing missing teeth and supporting dental prosthetic restorations.

The system contributes to:

- restoration of masticatory function
- improvement of speech
- restoration of dental aesthetics
- improvement of patient comfort and oral health-related quality of life.

Principle of Operation

Dental implants act as artificial tooth roots and are surgically inserted into the jawbone.

Following implantation, the implant achieves primary stability through mechanical engagement with the surrounding bone. During the healing phase, biological integration between the implant surface and the surrounding bone tissue occurs. This process is known as osseointegration.

Dental implants are used to support prosthetic components such as abutments and dental restorations, which restore oral function and aesthetics.

Treatment and loading protocols depend on the clinical situation and the treatment planning of the clinician.

General Device Description

The TA Implant System consists of dental implants and associated prosthetic and surgical components including:

- cover screws
- transmucosal abutments
- gingiva formers
- surgical drills
- screwdrivers
- other prosthetic accessories.

The components of the TA Implant System form a complete and coordinated system and must only be used in combination with the original components and instruments of

this system.

Implant drills and screwdrivers are equipped with shanks in accordance with EN ISO 1797 and are intended for connection to compatible dental handpieces.

TA implants are two-piece endosseous screw implants designed for dental implantation.

The implants feature:
- an internal hexagonal index
- a conical implant–abutment connection

designed to provide precise positioning of prosthetic components, rotational stability and secure fixation of the implant–abutment interface.

The implant surface is treated with a sandblasted and acid-etched surface designed to support and promote osseointegration.

Dental implants are supplied sterile by gamma irradiation.

Each implant is packaged in a sterile blister package and supplied in an outer carton containing patient identification labels.

The instructions for use are provided in electronic format (eIFU) and can be accessed via the website indicated on the product packaging.

Users should ensure that they have accessed the latest version of the instructions for use before using the device.

The connection dimensions depend on the implant diameter and ensure compatibility with the corresponding prosthetic components of the TA Implant System.

Implant Types

Two different implant designs are available within the TA Implant System.

The implant designs differ in their macro geometry in order to allow the clinician to select the appropriate implant according to bone quality and surgical requirements.

Implant Types and Dimensions

Implant Type	Diameter [mm]	Length [mm]
TA-switch plus Passive	3.3 / 3.8 / 4.1 / 4.8 / 5.5	6 / 8 / 10 / 12 / 14
TA-switch plus Aggressive	3.3 / 3.8 / 4.1 / 4.8 / 5.5	8 / 10 / 12 / 14

The different implant designs allow the clinician to select the most suitable implant depending on:
- bone quality
- bone density
- surgical technique
- anatomical conditions.

Whenever anatomical conditions permit, the use of larger diameter and longer implants is recommended to improve mechanical stability and load distribution.

Specific indication restrictions or extensions for certain implant types or dimensions are described in the Indications section.

Platform Configuration

Implants with the following diameters are supplied with a Regular Platform (RP) connection:
- Ø 3.3 mm
- Ø 3.8 mm
- Ø 4.1 mm

Implants with the following diameters are supplied with a Wide Platform (WP) connection:
- Ø 4.8 mm
- Ø 5.5 mm

Exception:

The implants Ø 4.8 × 6 mm and Ø 5.5 × 6 mm of the TA Switch Plus Passive design are supplied with a Regular Platform (RP) connection.

The platform configuration determines the compatibility with prosthetic components of the TA Implant System.

Patient Population

The TA Implant System is intended for use in patients who have completed skeletal and alveolar bone growth.

The system is intended for use in adult patients with fully erupted permanent dentition and sufficient bone volume to support dental implants.

The clinician must ensure that no contraindications for dental implant treatment are present.

Pregnant or breastfeeding women should be excluded from treatment with the TA Implant System due to the lack of sufficient clinical data regarding the effects of implant surgery and medical devices on the patient and the unborn child.

Indications

The TA Implant System is intended for the replacement of missing teeth in the maxilla and mandible by means of endosseous dental implants supporting prosthetic restorations.
Depending on the available bone volume and anatomical conditions, the implants may be used for functional and aesthetic oral rehabilitation.

The prosthetic restoration can be performed using implant-supported prosthetic restorations such as:
- single crowns
- bridges
- partial dentures
- complete dentures

These restorations are connected to the implants via compatible abutments.

The implants may be used for:
- replacement of single missing teeth
- replacement of multiple missing teeth
- rehabilitation of partially edentulous jaws
- rehabilitation of fully edentulous jaws

The selection of implant type, diameter and length depends on:
- bone volume and bone quality
- anatomical conditions
- prosthetic treatment planning.

Whenever the anatomical conditions permit, the use of implants with larger diameters and lengths is recommended to improve primary stability and load distribution.

Indication Restrictions for Reduced Diameter Implants

Reduced diameter implants (Ø 3.3 mm) have lower mechanical strength compared to implants with larger diameters and may therefore be associated with an increased risk of mechanical complications, including implant fracture, particularly under high occlusal loading.

For this reason, implants with a diameter of Ø 3.3 mm should primarily be used in clinical situations with limited mechanical loading, such as:
- replacement of maxillary lateral incisors or mandibular incisors
- cases with limited interdental space where placement of implants with a larger diameter is not possible
- situations with reduced bone volume where augmentation procedures are not indicated or not desired.

Reduced diameter implants should be used with caution in posterior regions, especially in areas with high occlusal forces.

In situations with increased mechanical loading, it is recommended to:
- use implants with larger diameters, or
- ensure load distribution through splinted prosthetic restorations supported by multiple implants.

Careful prosthetic treatment planning and occlusal load

management are required to minimize mechanical complications.

Contraindications

Implant placement with the TA Dent Implant System is contraindicated in patients with:

• Insufficient bone volume and/or bone quality that does not allow stable implant placement
• Local root remnants or untreated pathological conditions at the intended implant site
• Serious internal medical diseases or conditions that contraindicate oral surgical procedures
• Uncontrolled bleeding disorders
• Insufficient wound healing capacity
• Incomplete maxillary or mandibular growth
• Poor general state of health that may compromise surgical treatment
• Patients who are uncooperative, unmotivated, or unable to comply with treatment instructions
• Alcohol or drug abuse
• Severe psychiatric disorders
• Prolonged treatment-resistant functional disorders
• Xerostomia
• Weakened immune system
• Diseases requiring periodic use of corticosteroids
• Uncontrolled endocrine disorders
• Known allergy or hypersensitivity to titanium or titanium alloys

Warnings

• Products must be secured against aspiration or swallowing when handled intraorally. Aspiration or ingestion of components may result in infection or physical injury.

• During implant bed preparation and implant placement, care must be taken to avoid damage to anatomical structures such as nerves, blood vessels, maxillary sinus, and adjacent teeth. Injury may result in anesthesia, paresthesia, dysesthesia, or bleeding.

• Do not exceed the recommended insertion torque during implant placement, as excessive torque may lead to bone necrosis or implant failure.

Precautions

• A thorough clinical and radiological examination must be performed prior to implant placement to evaluate the patient's anatomical conditions and general health status.

• Particular caution should be exercised in patients with systemic or local risk factors that may impair bone healing or osseointegration.

These risk factors may include:

•smoking
•severe parafunctional habits such as bruxism
•uncontrolled systemic diseases (e.g., diabetes mellitus)
•radiation therapy in the head and neck region
•treatment with bisphosphonates or other medications affecting bone metabolism
•poor oral hygiene

• Patients taking proton pump inhibitors (PPIs) may present a potential risk for impaired osseointegration. Although a definitive causal relationship has not been scientifically confirmed, clinicians should carefully evaluate patients using PPIs and consider consultation with the treating physician. Premature implant loss due to insufficient osseointegration cannot be completely excluded.

• Adequate treatment planning and proper patient selection are essential to minimize complications and improve treatment outcomes.

• Small diameter implants require careful case selection and should not be used in regions exposed to high occlusal forces unless appropriate clinical conditions are present.

• All products must be handled under sterile conditions. The sterile packaging must be checked for integrity prior to use.

• Products intended for single use must not be reused. Reuse may lead to infection, loss of sterility, or mechanical failure.

• Only original components and instruments of the TA Dent Implant System should be used in combination with the implants.

Complications and Side Effects

The implantation of a dental implant always carries a risk of complications and side effects due to the surgical nature of the procedure. These complications may occur intraoperatively or postoperatively.

Intraoperative complications

Intraoperative complications and side effects may occur due to injury to anatomical structures, including:

• mandibular nerve (N. alveolaris inferior)
• lingual nerve (N. lingualis)
• neighbouring teeth
• soft tissues
• maxillary sinus
• blood vessels (haemorrhage)

In addition, the use of medical devices or anaesthetic agents may lead to allergic reactions. An overview of the materials used in the TA Dent Implant System can be found in the material information section. When handling the selected anaesthetic, the relevant information provided by the manufacturer of the anaesthetic must be taken into account.

Postoperative complications

Postoperative complications and side effects may be divided into early and late complications.

Early complications may include:

• postoperative bleeding or hematoma formation
• swelling
• infection of the implant site and surrounding structures
• wound healing disorders

Late complications may include:

• peri-implantitis
• implant loss or implant fracture
• bone loss around the implant
• loosening or fracture of prosthetic screws
• prosthetic restoration failure or fracture
• local or systemic allergic reactions or rejection of medical devices

SAFETY INFORMATION

General Information

The TA Implant System may only be used by trained dentists or oral and maxillofacial surgeons who possess the necessary theoretical knowledge and practical experience in dental implantology.

The components of the TA Implant System are supplied exclusively to qualified medical professionals or dental laboratories. Dental laboratories are not permitted to use the devices directly on patients.

Before starting treatment, each patient must be carefully assessed from both a general medical and dental perspective by taking a detailed medical history and performing a comprehensive clinical examination.

Prior to implant placement, all pathological conditions in the jaw and remaining dentition must be treated. Adequate bone quality and bone quantity as well as the absence of local infections are important prerequisites for successful osseointegration.

To select the appropriate implant diameter and length and to minimize the risk of damage to anatomical structures such as nerves or blood vessels, the available bone volume and anatomical situation must be carefully evaluated using suitable diagnostic imaging methods.

The selection of the appropriate implant type, diameter, and length must be carried out by qualified medical professionals based on the individual anatomical and physiological conditions of the patient.

The Summary of Safety and Clinical Performance (SSCP) of implantable medical devices (dental implants, abutments, gingiva formers) can be viewed in the European database of

medical devices (EUDAMED).

If the database is not yet fully functional, the SSCP can be requested using the contact details provided in the Manufacturer section.

Please report any serious incident that occurs in connection with the TA Implant System in a country of the European Union to TA Zahnimplantate GmbH using the contact details provided in the Manufacturer and Distributor sections and additionally to the competent authority in your country.

A serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following:

a) the death of a patient, user or other person;

b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health;

c) a serious public health threat.

You can find the contact details for your country at the following internet address:

https://health.ec.europa.eu/document/download/900ad9e7-fc79-4617-93be-f6712a3e3306_en

Presentation of Safety Information

Safety-related information in this document is presented using specific symbols and signal words to highlight important instructions and potential hazards.

Note — Notes are general precautionary measures that may lead to impairment or temporary discomfort if not observed.

Warning — Warnings indicate dangers which, if ignored, can lead to minor or serious injury or to impairment of therapy.

General Safety Information, Liability and Warranty

There is no 100% guarantee of success for treatment with dental implants. The long-term success of implant therapy depends on correct case selection, proper surgical technique, appropriate prosthetic planning and patient compliance. Failure to observe the specified restrictions for the use of the TA Implant System may lead to functional failures, complications or loss of the implant.

Complications and side effects may occur during the insertion of implants.

The use of non-system components can impair the function and safety of the TA Implant System and excludes any warranty or replacement by the manufacturer.

Check the medical devices for damage before each use. Damaged medical devices must not be used and must be disposed of immediately.

Medical devices supplied in sterile condition must not be used if the packaging is damaged, has already been opened, or if the use-by date has been exceeded. In all these cases, sterile provision cannot be guaranteed.

Medical devices supplied in non-sterile condition must be reprocessed in accordance with the procedure validated by the manufacturer before first use. Further information can be found in the *Cleaning, Disinfection and Sterilisation* section.

If the actual drilling depth is not correctly determined in relation to the diagnostic imaging, permanent injury to nerves or other vital structures may occur. This can, for example, lead to permanent paraesthesia of the lower lip or chin during procedures on the mandible.

Material Information

All components of the TA Implant System are manufactured from biocompatible materials commonly used in dental implantology. The following table provides information on the materials used in all device groups.

Device Group	Materials
Dental implants	Titanium grade 4
Cover Screws	Titanium grade 5
Abutments	Titanium grade 5 Polyoxymethylene (POM)
Gingiva Formers	Titanium grade 5
Implant Drills	Medical stainless steel (1.4112)
Screw Drivers	Medical stainless steel (1.4035)

Even though the materials used in the TA Implant System have been widely used in the medical device industry and in dental implant systems for many years and are generally considered biocompatible, allergic reactions or hypersensitivity to the materials may occur in individual cases.

Therefore, possible material intolerances should be carefully evaluated during the patient's medical history and discussed with the patient prior to treatment.

Information on MRI Safety

The TA Implant System has not been tested for safety and compatibility in the magnetic resonance (MR) environment.

It has not been tested for heating, migration, or image artefacts in the MR environment.

Therefore, the safety of the TA Implant System in the MR environment is unknown. Scanning a patient with dental implants or abutments that are part of the TA Implant System may result in injury to the patient.

According to currently available scientific literature, titanium as a material is considered non-ferromagnetic and therefore generally compatible with magnetic resonance imaging. However, individual components of the implant system may cause imaging artefacts.

The decision to perform magnetic resonance imaging in patients with implants of the TA Implant System should be made by the responsible physician or radiologist based on the individual clinical situation.

APPLICATION DESCRIPTION

Implantation is a surgical procedure and must be carried out in accordance with the generally accepted rules of dental surgery and implantology.

The procedure must be performed under sterile conditions using appropriate surgical instruments and techniques.

Proper treatment planning, including clinical and radiological examination, is essential to determine the appropriate implant type, diameter, length and position.

During implantation, care must be taken to avoid damage to anatomical structures such as nerves, blood vessels and neighbouring teeth.

All procedures should be performed by qualified dental professionals egxperienced in implant surgery.

Preparatory Measures

⚠ Due to the small size of the individual components of the TA Implant System, small parts may be swallowed or aspirated.

Aspiration can lead to respiratory distress and, in the worst case, to suffocation. Ensure that small parts are secured against swallowing and aspiration during intraoral use.

Before the surgical procedure, inform the patient about the generally applicable precautions, rules of behaviour and possible complications and side effects.

Clinical and radiological examination of the patient as well as model analysis are mandatory prerequisites to increase the chances of treatment success.

⚠ Deficiencies in the patient's medical history, preoperative diagnostics or treatment planning may lead to premature implant loss.

Dental implants of the TA Implant System are supplied exclusively in sterile condition.

All other components of the implant system are supplied in non-sterile condition.

⚠ Dental implants supplied sterile by the manufacturer must not be re-sterilised by the user.

In the event of re-sterilisation, contamination of the devices cannot be excluded.

⚠ Medical devices supplied by the manufacturer in a non-sterile condition must be cleaned, disinfected and sterilised by the user before first use and, in the case of reusable devices, before each subsequent use.

A validated reprocessing procedure is described in the Cleaning, Disinfection and Sterilisation section.

Consumables and Accessories

All rotary instruments of the TA Implant System are equipped with a shank in accordance with EN ISO 1797.

These instruments are intended to be used with dental handpieces (e.g. contra-angle handpieces) and shank extensions that are compatible with the above-mentioned standard.

Only compatible instruments and accessories should be used to ensure safe and proper operation of the system.

Description of the Application

⚠ Before using the devices, check whether they are suitable for the intended use.

Carefully check the product labeling to avoid confusion between instruments and implant components.

Ensure that the correct instruments and components are selected for the respective treatment step.

Drilling Protocol

The implant site must be prepared before inserting the dental implant. Follow the prescribed drilling protocol after appropriate diagnostic imaging and treatment planning.

In order to minimise the risk of injury to neighbouring anatomical structures, the surrounding tissue in the treatment area must be carefully assessed prior to the use of cutting instruments.

Perform local anaesthesia in the area to be treated. Incision and preparation of the mucosa and periosteum must be carried out according to standard surgical procedures in implant dentistry.

The drills are available in different lengths. The selection of the drill length depends on the available space in the patient's oral cavity. The length specified in the drilling protocol tables refers only to the length of the drill head and does not include the shank.

⚠ A bone temperature of more than 47 °C can lead to irreversible damage to bone cells and, in the worst case, to bone necrosis. Therefore, ensure that all drilling is performed intermittently and with continuous cooling using sterile physiological saline solution.

☞ When using the drills, ensure that the instrument does not tilt. Tilting the instrument may lead to instrument fracture. This also applies when drilling templates are used.

If the overall length of the drills is insufficient, they may be connected to a shank extension to increase the overall length by 15 mm. When connecting the drill to the shank extension, make sure that the locking hooks of the shank extension engage audibly.

The drilling direction and depth can be checked using direction and depth indicators. These instruments are inserted into the osteotomy site. During drilling, the depth can also be checked using the depth markings on the drills.

☞ The depth markings on the drills correspond to 7, 9, 11, 13 and 15 mm and include the length of the apical drill tip.

The dental implants of the TA Implant System are available in lengths of 6, 8, 10, 12 and 14 mm.

When determining the drilling depth, it must be taken into account that the overall implant length does not include the polished collar in the cervical region.

The height of the polished collar is approximately 0.3 mm for implants with a diameter of 3.3 mm and approximately 0.45 mm for implants with larger diameters.

All drilling procedures must be carried out at a rotation speed of 500–800 rpm.

The tap must only be used at a maximum rotation speed of 25 rpm.

⚠ Repeated use of surgical drills may lead to gradual wear of the cutting edges and reduced cutting efficiency. Worn drills may increase friction during drilling and may result in excessive heat generation in the bone.

Excessive bone temperature may impair osseointegration and, in the worst case, may lead to bone necrosis.

The drills of the TA Implant System are coated with DLC (Diamond-Like Carbon) to improve wear resistance and durability. Nevertheless, drills must be inspected regularly for signs of wear, deformation or reduced cutting performance.

If signs of wear or damage are detected, the drills must be replaced immediately.

The drilling sequence to be used for TA-switch plus Passive implants is described in the matrix below.

Drills	Implant Diameter Ø [mm]				
	3.3	3.8	4.1	4.8	5.5
PD 2.0	X	X	X	X	X
TD 2.9	X	X	X	X	X
TD 3.4	-	X	X	X	X
TD 3.7	-	-	X	X	X
TD 4.4	-	-	-	X	X
TD 5.1	-	-	-	-	X
CD 3.3	X	-	-	-	-
CD 3.8	-	X	-	-	-
CD 4.1	-	-	X	-	-
CD 4.8	-	-	-	X	-
CD 5.5	-	-	-	-	X
T 3.3	X	-	-	-	-
T 3.8	-	X	-	-	-
T 4.1	-	-	X	-	-
T 4.8	-	-	-	X	-
T 5.5	-	-	-	-	X

Explanation of Abbreviations in the Drilling Matrix

PD (Pilot Drill) TD (Twist Drill) CD (Cortical Drill) T (Tap)

After the final drilling, the implant can be inserted.

For the placement of passive implants, the use of the twist drills included in the surgical kit is recommended.

The twist drills are designed with a diameter approximately 0.4 mm smaller than the corresponding implant diameter. This drilling protocol generally allows the implant to be inserted without excessive compression of the surrounding bone.

However, in cases of high bone density (e.g. D1 bone), it is recommended to use the cortical drill (neck widening drill) and the tap drill in order to reduce insertion torque and avoid excessive stress on the bone and the implant.

The drilling sequence to be used for TA-switch plus Aggressive implants is described in the matrix below.

Drills	Implant Diameter Ø [mm]				
	3.3	3.8	4.1	4.8	5.5
PD 2.0	X	X	X	X	X
SD 2.8	X	X	X	X	X
SD 3.2	-	X	X	X	X
SD 3.5	-	-	X	X	X
SD 4.2	-	-	-	X	X
SD 4.9	-	-	-	-	X
CD 3.3	X	-	-	-	-
CD 3.8	-	X	-	-	-
CD 4.1	-	-	X	-	-
CD 4.8	-	-	-	X	-
CD 5.5	-	-	-	-	X
T 3.3	X	-	-	-	-
T 3.8	-	X	-	-	-
T 4.1	-	-	X	-	-
T 4.8	-	-	-	X	-
T 5.5	-	-	-	-	X

Explanation of Abbreviations in the Drilling Matrix

PD (Pilot Drill) SD (Step Drill) CD (Cortical Drill) T (Tap)

After the final drilling, the implant can be inserted.

For the placement of aggressive implants, the use of the step drills included in the surgical kit is recommended.

The step drills are designed with a diameter approximately 0.6 mm smaller than the corresponding implant diameter. The stepped geometry of the drills corresponds to the macro-design of the implant.

This drilling protocol allows the implant to achieve high primary stability during insertion.

For implants with a diameter of 3.3 mm, the drill diameter is approximately 0.5 mm smaller than the implant diameter.

Depending on bone quality and clinical conditions, the use of a crestal drill (neck widening drill) or tap drill may be recommended to control insertion torque and prevent excessive compression of the surrounding bone.

Implant Placement

Any contamination of dental implants must be avoided.

Dental implants of the TA Implant System are supplied sterile and are intended for single use only. The implant should be inserted directly after removal from the sterile packaging.

The outer packaging is not sterile and must not be opened within the sterile field.

The blister pack is removed from the folding box and opened by a non-sterile assistant. The following steps are to be carried out exclusively by the sterile surgical assistant or the user, taking sterile working practices into account.

Remove the sterile container from the blister. Ensure that the container is held upright to prevent the implant from falling out during opening. Slide the lid off the side of the container.

To prevent the implant from rotating, the container can be pressed together to remove the implant. Insert the screwdriver into the connection geometry of the implant and turn it clockwise until the instrument engages in the indexing of the implant.

Then apply light pressure to bring the screwdriver into the intended end position. This can be felt by a slight click. The implant is now secured on the screwdriver and can be removed from the container.

Prior to implant insertion, the prepared osteotomy site may be rinsed with sterile physiological saline solution to reduce possible contamination.

Insert the implant into the prepared implant bed at a maximum rotation speed of 25 rpm.

For conventional or delayed loading protocols, the resulting insertion torque should not exceed 35 Ncm.

For cases where immediate loading is planned, an insertion torque of approximately 35–45 Ncm is recommended to

achieve sufficient primary stability. In such cases, the use of aggressive implant designs may be beneficial.

⚠ Insertion torque values exceeding 50 Ncm are not recommended, as excessive compression of the peri-implant bone may occur.

If insertion torque exceeds 50 Ncm, the clinician should consider additional osteotomy widening or cortical bone relief. The decision to perform immediate loading should not be based solely on insertion torque values but must take overall clinical conditions into account.

Excessive insertion torque may damage the implant or cause excessive compression of the surrounding bone.

Rotational alignment of the implant is not required. It is recommended to place the implant at a crestal or slightly subcrestal level.

For optimal later positioning of the abutments, it may be helpful to orient one rounding of the screwdriver toward the buccal/labial direction.

Remove the screwdriver by gently pulling it out of the implant. A slight axial movement of the screwdriver may facilitate removal.

Wound Closure

Before closing the gingiva with sutures after implant insertion, the implant must be sealed.

Check the interior of the implant for blood or tissue residues. If present, these must be removed before closure.

Remove the cover screw from the underside of the container using the corresponding screwdriver by turning it counterclockwise.

The screwdriver has a conical tip to ensure secure engagement between the screwdriver and the cover screw.

Insert the cover screw into the implant and tighten it carefully.

Alternatively, the implant may be closed using a gingiva former (healing abutment).

The recommended tightening torque for the cover screw is approximately 5 Ncm.

Subsequently perform a tension-free and saliva-tight wound closure.

If soft tissue healing proceeds normally, the sutures can usually be removed after 8–10 days.

If wound dehiscence occurs, prompt surgical revision with adequate coverage should be performed.

Connection of the Dental Suprastructure

Connect the selected abutment to the implant. Ensure that the abutment is correctly positioned in the implant connection.

The TA implant system features a conical implant–abutment connection with internal hexagonal indexing, which ensures precise positioning and rotational stability of the prosthetic components.

Insert the abutment into the implant and align it carefully with the internal indexing.

The abutment must seat passively and completely in the implant connection. Any obstruction that prevents full seating must be eliminated before tightening the retaining screw.

In some cases, excess bone around the implant platform may interfere with the passive seating of the abutment. If this occurs, the surrounding bone should be carefully removed using a bone profiler drill in order to allow correct seating of the abutment.

Insert the retaining screw through the abutment and tighten it using a torque ratchet or a dental handpiece with torque control.

The recommended tightening torque for the abutment retaining screw is 30 Ncm.

Once the screw has been tightened, the screwdriver can be gently removed from the retaining screw.

When using a dental handpiece, the applied torque must be carefully controlled. If the handpiece does not support torque measurement, the use of a manual torque ratchet is recommended.

Before the final prosthetic restoration (e.g. crown or bridge) is placed, the retaining screw should be checked again to ensure that it is properly seated and tightened.

This procedure reduces settling effects and contributes to the long-term stability of the prosthetic connection.

Platform Compatibility

The TA implant system provides two prosthetic platform types:

Regular Platform (RP)

Implant diameters:

- 3.3 mm
- 3.8 mm
- 4.1 mm

In addition, all implants with a length of 6 mm are manufactured exclusively with the Regular Platform (RP), regardless of the implant diameter.

Wide Platform (WP)

Implant diameters:

- 4.8 mm
- 5.5 mm

All prosthetic components of the TA implant system are available for both platform types (RP and WP). It is essential that the prosthetic component platform corresponds to the platform of the implant used. Incorrect platform selection may lead to improper seating of the abutment and mechanical complications.

Torque Recommendations for Prosthetic Components

Device type	Tightening torque	Notes
Final abutments	30 Ncm	Standard recommended torque
Temporary abutments	15-30 Ncm	Torque above 30 Ncm only recommended after complete osseointegration
Components mounted on abutments (tertiary parts)	15 Ncm	e.g. occlusal screws
Components on implant/ abutment analogues	Hand tightening	Laboratory use only

Warning

Tightening torques above 30 Ncm may lead to damage of the abutment screw or implant connection.

Torque values below the recommended range may result in screw loosening, which can lead to prosthetic complications or implant failure.

Precaution

Temporary abutments should not be tightened to the full torque of 30 Ncm before complete osseointegration of the implant.

Documentation

Each implant package contains removable patient labels.

The patient label includes important product information such as:

- product name
- article number
- lot number
- UDI information

One of the patient labels should be attached to the patient's medical record to ensure full traceability of the implanted device.

Additional labels may be used for laboratory documentation or treatment records.

Proper documentation of the implanted device is essential to ensure traceability and patient safety.

Follow-up Care

Regular follow-up examinations are recommended after implant placement and prosthetic restoration. The patient should be included in an appropriate maintenance and recall program in order to monitor the long-term stability of the implant and the health of the peri-implant tissues. Follow-up visits should include, where appropriate, clinical evaluation of the peri-implant soft tissues, assessment of oral hygiene, verification of implant stability, inspection of the prosthetic components for loosening or wear, and radiographic examination if indicated. Patients must be instructed on proper oral hygiene measures and the importance of regular professional maintenance. Inadequate oral hygiene or insufficient follow-up care may increase the risk of peri-implant diseases and may compromise the long-term success of the implant restoration.

CLEANING, DISINFECTION AND STERILISATION

These reprocessing instructions apply to all components of the TA Implant System that may be (re)processed (reusable instruments) in accordance with their intended purpose and labelling.

Safety Instructions

For reasons of hygiene and health protection, all reusable medical devices sold by Absolute Medical GmbH must be cleaned, disinfected and sterilised before and after each use on the patient or in the patient's mouth. This also applies to the first use after receipt of the products, which are supplied non-sterile and must therefore be sterilised before use.

The hygiene regulations of the applicable national and international legal provisions for dental and medical practices, hospitals and dental laboratories must be observed.

Only devices with a validated procedure may be used for cleaning, disinfection and sterilisation. The parameters specified for cleaning and sterilisation must be complied with, as these have been validated processes. The cleanliness of the product cannot be guaranteed if the reprocessing is carried out with deviating parameters.

The dental implants of the TA Implant System are intended for single use and are supplied sterile. They must not be cleaned, disinfected or sterilised again.

Do not resterilize


Do not reuse

Sterilized using irradiation

Instructions for Cleaning and Sterilisation

All reprocessing must be carried out by trained personnel in a room specially equipped for this purpose with clearly separated clean and contaminated zones.

The cleaning agents used must be suitable for medical instruments and compatible with the materials of the devices.

Successful sterilisation must be preceded by effective cleaning and disinfection. The instruments must be cleaned, disinfected and sterilised before and after each use on the patient.

Dirty or used instruments must be kept separate from clean instruments during use.

Manual Pre-Cleaning

Manual pre-cleaning does not replace automated cleaning and disinfection and serves, among other things, to protect personnel.

1. If the components can be disassembled, they must be separated into their individual parts.

2. Place all components to be cleaned in a suitable liquid instrument cleaner immediately after use according to the manufacturer's instructions.

3. Remove any visible residues with a nylon instrument brush and a lint-free disposable towel. Cavities, feedthroughs and constrictions must be cleaned carefully.

4. Rinse all components under cold, running water (drinking quality).

5. Visually check the cleanliness of all individual parts. Magnifying glasses may be used for inspection.

Repeat steps 1 to 4 if residues are still visible on the components

Automated Cleaning and Disinfection

1. Previously disassembled components must be reassembled if required according to the device design.

2. Place all components in an appropriately approved (small) parts holder (e.g., bur holder) in the washer-disinfector in accordance with EN ISO 15883.

All devices must be arranged in such a way that they can be directly reached by the spray jets.

3. Cleaning and disinfection must be carried out using a validated washer-disinfector programme with an A_0 value ≥ 3000 or an equivalent validated process (e.g. ≥ 90 °C for ≥ 5 minutes) using a suitable enzymatic detergent for medical instruments.

Pre-Cleaning	Cleaning	Disinfection		A_0-Value
		Duration	Temperature	
< 45 °C	≥ 55 °C	≥ 300 s	≥ 90 °C	≥ 3000

4. Visually inspect the cleanliness and integrity of all components. Magnifying glasses may be used for inspection.

⚠ Repeat steps 1 to 3 if residues are still visible on the components.

Maintenance, Inspection and Testing

After cleaning and sterilisation, the instruments must be checked for integrity. The devices must be free from corrosion, contamination, wear or damage.

⚠ Devices that show a loss of function and/or corrosion or defects must be removed from use immediately and must not be used on patients any longer.

Packaging

⚠ All non-sterile components supplied must not be sterilised in their original packaging.

1. The components must be packed individually in a sterile pouch (sterile barrier system) according to EN ISO 11607-1 and sealed using a suitable sealing device.

⚠ Care must be taken to ensure that the devices in the sterile pouch are not under tension. This may damage the sterile barrier system and lead to loss of sterility.

2. Sterilisation must be carried out in a Class B steam steriliser with fractionated pre-vacuum in accordance with EN 13060. Sterilisation parameters other than those listed below are not covered by the manufacturer's validation. Therefore, no guarantee can be given that a sterile status will be achieved.

Type	Temperature	Holding Time	Drying Time
B	134 °C	≥ 3 min	≥ 5 min

3. The labelling of the reprocessed and packaged components must include the following information:

a) designation of the device(s), including size if applicable

b) information on release

c) release decision

d) sterilisation cycle and sterilisation date

e) expiry date and sterile supply storage period

DEVICE LIFETIME

Dental implants and abutments are intended for long-term use. The actual service life depends on clinical conditions, prosthetic design, patient-specific factors and maintenance.

Reusable instruments such as implant drills must be inspected before each use. Instruments showing signs of reduced cutting efficiency, deformation, corrosion or other damage must be replaced immediately. The final judgement on continued use is the responsibility of the specialist user.

STORAGE

The implants are packaged in a hard blister sealed with a Tyvek® lid. The blister serves as a sterile barrier system.

Prosthetic components are packaged in a foil pack sealed by heat sealing.

The dental implants are sterilised using gamma radiation and must not be used after the expiry date printed on the folding box and the sterile barrier system.

The manufacturer accepts no liability for implants that have been sterilised by the user.

All components of the TA Implant System, including implants, prosthetic components and surgical instruments, must be stored in their intact packaging in a dry and clean environment at room temperature.

DISPOSAL

The devices must be disposed of in accordance with the applicable local regulations and environmental regulations.

The degree of contamination of the medical devices must be taken into account. Decontamination prior to disposal may therefore be necessary.

LIABILITY

The instruments and system components may only be used for the specified indications and in accordance with these instructions for use.

The user is responsible for checking the devices for functionality, integrity and suitability before use.

Failure to observe the instructions for use, warnings or intended use may result in a reduction or exclusion of liability on the part of the manufacturer.

The manufacturer shall not be liable for damages resulting from improper handling, misuse or use of the products outside the specified indications.

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CE 0297

English

EXPLANATION OF SYMBOLS


Manufacturer


Distributor

Medical Device

Catalogue Number

Batch Code

UDI Carrier

Do not resterilize


Do not reuse

Sterilized using irradiation


Do not use if pack-age is damaged


Keep away from rain


Single sterile barrier system


Date of manufacture


Use by date


Caution


Operator's manual; operating instructions

Non-sterile

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Date: 10.03.2026
Rev: 04