EN

tiologic TWINFIT

Surgery Manual.

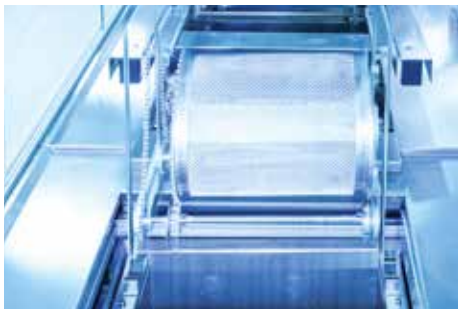
DENTAURUM

CONTENT.

High-tech in-house.

There is a high level of professional knowledge in our company that has been built up over the years in our own research and development facilities, both in Germany and in France. Highly qualified employees work together in interdisciplinary teams to find answers to the challenges the future poses. At the same time, long-standing cooperations with experts from universities and clinics contribute to finding new developments and innovations.

A further result of these efforts: a comprehensive product portfolio which is one of Dentaurum's strengths. No other dental company has such an extensive range of products offering a total of more than 8500 articles.



General information.

Manufacturer.
Dentaurum GmbH & Co. KG I
Turnstr. 31 I 75228 Ispringen I Germany

Brief description.

tioLogic® TWINFIT implants are designed for insertion in the endosteal region of the maxilla or mandible. Depending on the indication, appropriate transgingival abutments are secured on the implants and fitted with a prosthetic superstructure.

The tioLogic® TWINFIT implant system contains specially coordinated instruments, abutments and accessories for insertion of the implants and fabrication of the prosthetic restoration. Only original components of the tioLogic® TWINFIT implant system should be combined in accordance with the Instructions for use/manuals.

Further information.

Though placement of dental implants has a high rate of success and implants have a long durability, successful treatment cannot be guaranteed. The implantologist should note and document any problematic cases and inform the manufacturer Dentaurum.

An inadequate number of implants, implants with insufficient length or diameter, unfavorable positioning of the implants or a statically poor prosthetic restoration can cause premature implant loss and fatigue fractures in implants, abutments and prosthetic screws under biomechanical loading.

Placement of the implants and fabrication of the prosthetic restoration should take the situation of each individual patient into account to avoid overloading the components.

Using tioLogic® TWINFIT implant system components in combinations other than those stipulated in the Instructions for use/manuals can cause mechanical failure, damage to the tissue or unsatisfactory aesthetic results.

At the time of going to press, tioLogic® TWINFIT implants are not known to have any side effects or to cause interactions. It cannot, however, be ruled out that in rare cases allergies to components used in the materials of the tioLogic® TWINFIT implant system may occur or that there may be electrochemically-induced discomfort.

Use, availability, precautions, documentation.

The tioLogic® TWINFIT product range is supplied exclusively to doctors, dentists and dental technicians. It should only be used by doctors, dentists or dental technicians who are familiar with dental implantology, including diagnosis, preoperative planning, surgical techniques and prosthetic restorations.

Before use, implantologists should ensure that they have carefully read and understood all tioLogic® TWINFIT Instructions for use/manuals and check that these are up-to-date. As the instructions and manuals cannot provide all information for immediate use, we strongly recommend that, before using the system, implantologists attend a tioLogic® TWINFIT implant system training course offered by Dentaurum to learn the correct techniques.

- Refer to the Product Catalog and the Surgery Manual for further information on precautions and the selection of components for the surgical procedure.
- Refer to the Product Catalog and the Prosthetic Manual for information on precautions and the selection of components for the prosthetic procedure.

Before using this product, the patient must be thoroughly examined by the implantologist and given a detailed explanation of the product. Dentaurum recommends full clinical, radiological, photographic and statistical documentation.

The implantologist should ensure that the products cannot be aspirated during intra-oral use.

Note: Not all components are available in every country.

Quality, warranty and liability.

The development, clinical testing, manufacture and quality monitoring of the tioLogic® TWINFIT product range follow stipulations outlined in the Medical Device Regulation (EU) 2017/745 and Directive 93/42/EEC. Sections 9 and 10 of our General Terms of Delivery and Payment apply with regard to warranty or liability – unless stated otherwise in the Instructions for use/manual.

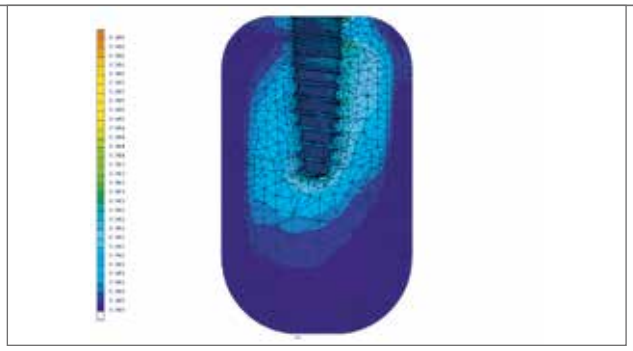
Warranty and liability are rendered void in particular if the products are not used by the dental professional or a third party in accordance with the Instructions for use; this also applies if the tioLogic® TWINFIT product range is used in combination with products from other manufacturers which have not been specifically recommended for use by Dentaurum.

Dentaurum has no control over processing and use of the product. These are the sole responsibility of the dental professional.

The tioLogic® TWINFIT implant system components can be documented, e. g. in the patient file or PatientPass (REF 989-961-20), using the additional labels.

Implant system.

The tioLogic® TWINFIT implant system offers you maximum flexibility from insertion to final restoration.



FEM analysis tioLogic® TWINFIT.

Implant shape.

The shape of the tioLogic® TWINFIT implant and the thread geometry were calculated using FEM analyses and documented in scientific studies. Tests show a uniform, gentle loading of the bone which prevents local overloading and stress peaks that could damage the bone.

Thread geometry.

The thread geometry of the tioLogic® TWINFIT implants enables a quick and atraumatic implant insertion and a high level of primary stability. The endosseous region of the implant surface is blasted and etched.

Internal geometry.

The design of the internal geometry of the implant was calculated and proven by FEM analyses and physical investigations carried out by the University of Bonn using a fatigue strength test in accordance with ISO 14801.

Its distinguishing features:

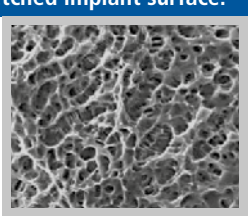
- 2 connector geometries – conical and platform
- high resistance to torsion and high bending strength when under permanent loading
- zero backlash transmission of bending moments
- maximum flexibility in the positioning of the system components

Abutment Switch.

Integrated Platform Switch.

Crestal fine thread.

Sandblasted/etched implant surface.



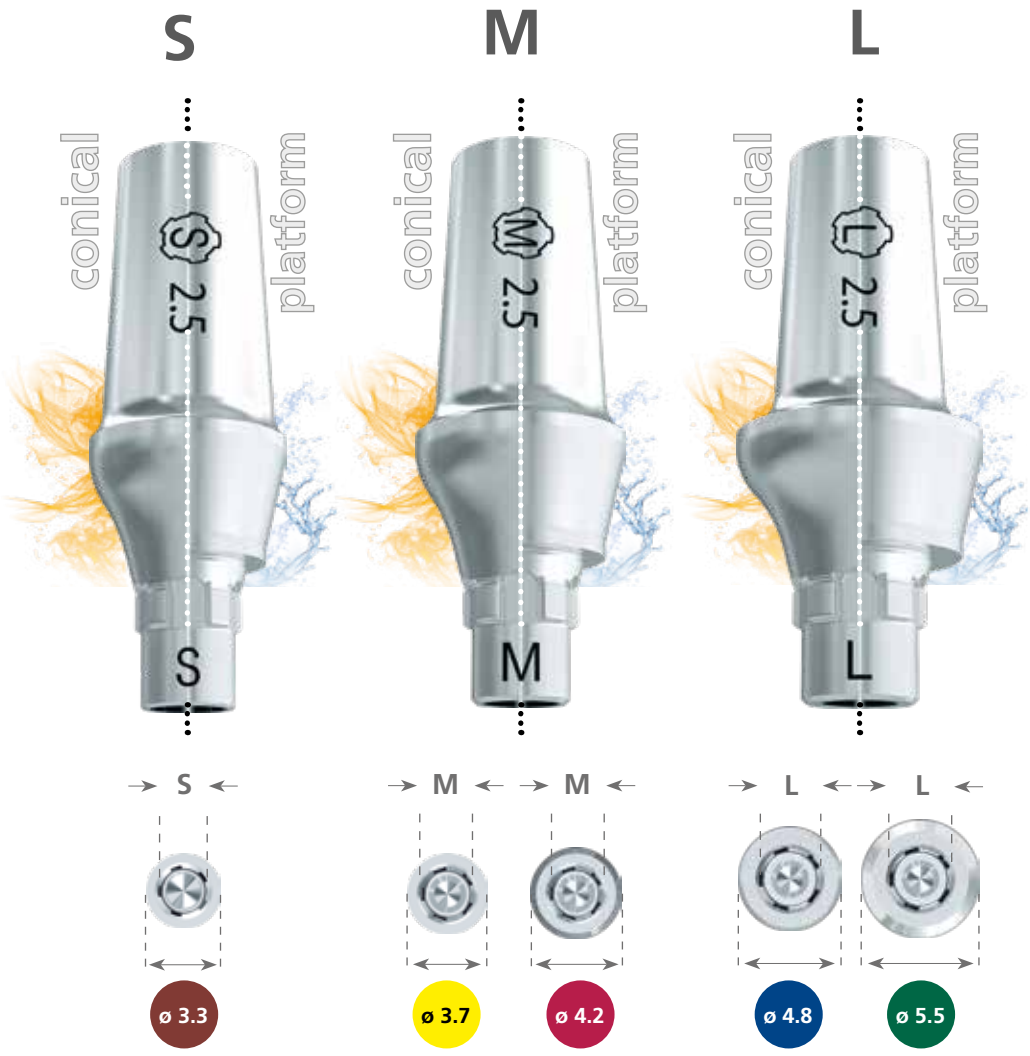
Progressive coarse thread.

Rounded apex.

S-M-L concept.

5 implant diameters. 5 implant lengths. 3 series of abutments. 2 connector geometries.

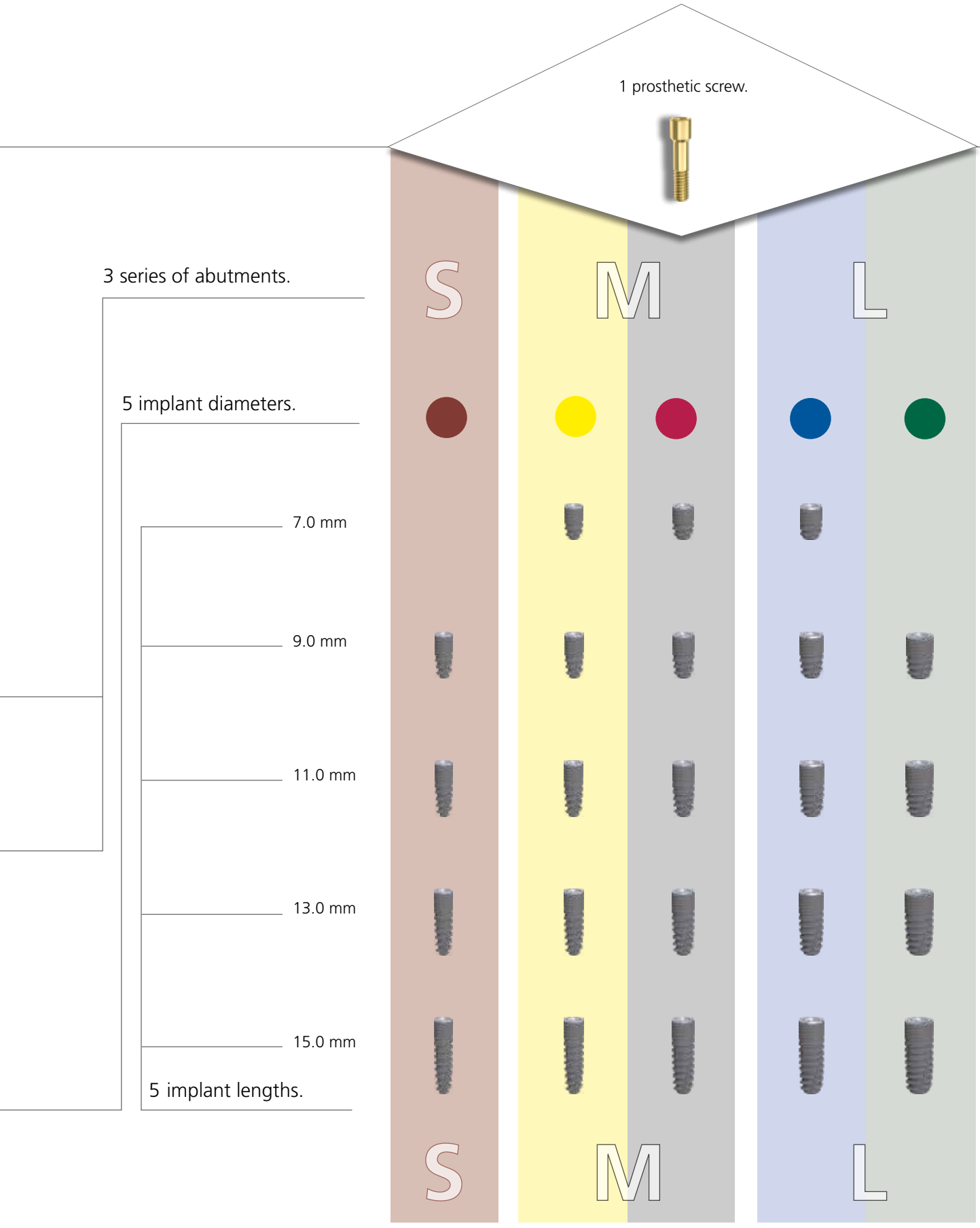
The optimal grading of implant diameters and lengths ensures that the appropriate implant is used for the indication. The three series of abutments are each available in the two connector geometries, conical or platform. The portfolio includes abutment components in plastic (temporary restorations) and titanium to suit the individual situation. CAD/CAM, ball, tioLOC and 4Base abutments complete the portfolio and enable the implantologist to offer restorations for all kinds of indications. The abutment components S are used for the implant diameter 3.3 mm, the abutment components M for the implant diameters 3.7 mm and 4.2 mm and the abutment components L for the implant diameters 4.8 mm and 5.5 mm. All components are laser-marked with S, M or L for exact identification.



2 connector geometries.

3 series of abutments.

5 implant diameters.


1 prosthetic screw.
3 series of abutments.
5 implant diameters.
7.0 mm
9.0 mm
11.0 mm
13.0 mm
15.0 mm
5 implant lengths.
S
M
L
S
M
L

ABUTMENT

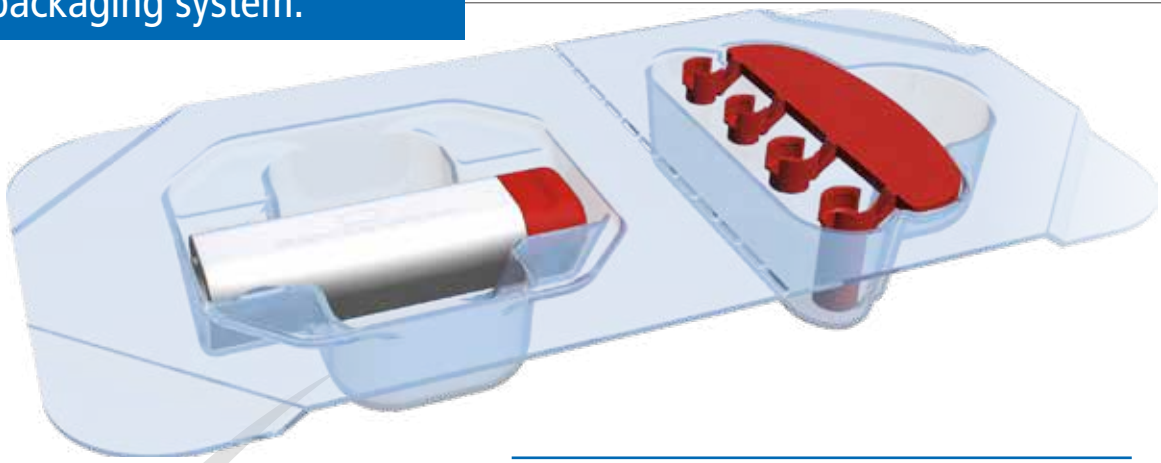
2 CONNECTOR GEOMETRIES – **1** IMPLANT

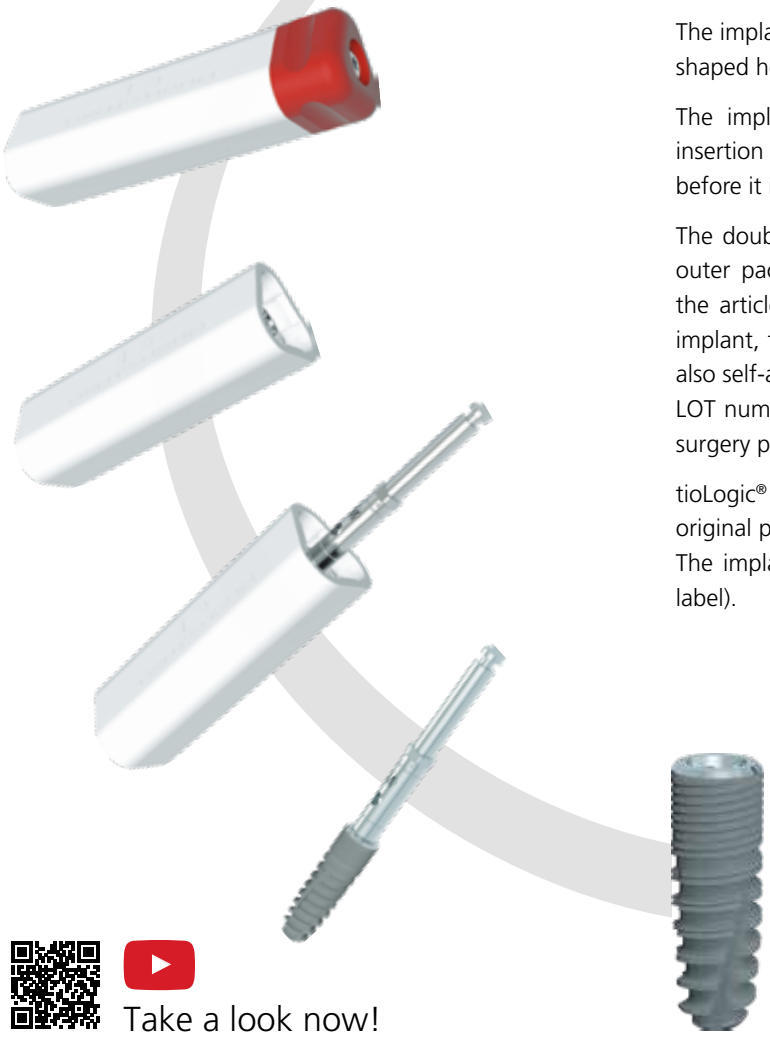
conical

T SWITCH

platform

Sterile packaging system.





Blister packaging.

The implant is optimally stored and protected in a triangular-shaped holder in the blister packaging.

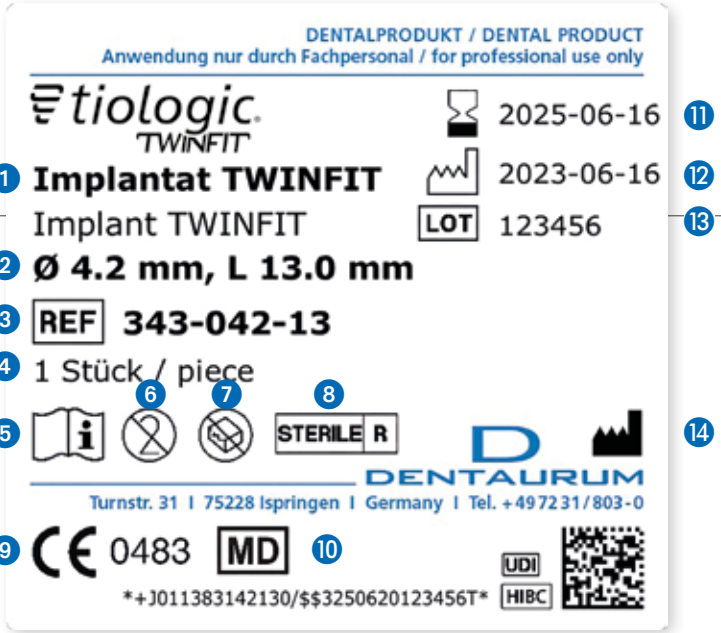
The implant can be removed from the holder using an insertion key. This ensures that the implant is not touched before it is inserted.

The double packaging (foil and blister) is also protected by outer packaging. The label on the outer packaging states the article number, the name, length and diameter of the implant, the sterility expiry date and LOT number. There are also self-adhesive labels in the outer packaging with REF and LOT numbers for documentation in the PatientPass and the surgery protocol.

tioLogic® TWINFIT implants should only be stored in the original packaging at room temperature in a dark, dry place. The implant should not be used after the expiry date (see label).

Take a look now!

1. Content
2. Diameter/length
3. Article no. (REF)
4. Quantity
5. Refer to Instructions for use
6. For single use only
7. Do not use if packaging is damaged
8. Symbol for gamma-sterilization
9. Identification number of the notified body in accordance with Directive 93/42 EEC
10. Medical device
11. Sterility expiry date
12. Date of manufacture
13. Batch number (LOT)
14. Manufacturer



Implant.

All tioLogic® TWINFIT implants are supplied singly with the appropriate closure screw and with depth-stop sleeves of appropriate length and width. They are intended for single use only. The gamma-sterilized double packaging (foil and blister packaging) protects the inner container with the sterile implant, the closure screw and the depth-stop sleeves against contamination. The contents only remain sterile as long as the packaging is undamaged. The product should not be used if the double packaging is damaged.

The blister packaging is perforated between the implant and the depth-stop sleeves and can be separated if the sleeves are not required.

Depth-stop sleeves.

The depth-stop sleeves are coordinated for the use and sequence of the rotating instruments for medium bone quality. Should the bone quality for the case in hand be different, the procedure should be adapted to follow the drilling protocol.

The drill is pushed into the depth-stop sleeve until it clicks into place. The lower half is then pushed backwards. The click function on the head of the drill ensures the drill is anchored safely.

The procedure is outlined in the images below.

Take a look now!

Depth-stop sleeves for optional use.

Torque ratchet

Description.

The torque ratchet is a precision instrument that can be disassembled. To ensure that it always functions perfectly, the torque ratchet should be disassembled, cleaned, disinfected and lubricated, and then sterilized after reassembly, in accordance with the Instructions for use, before using for the first time and immediately after each use (Torque ratchet).

Read the Instructions for use carefully. The function of the torque ratchet should be checked before each use to ensure the precision of the torque. The torque ratchet should make a uniform sound when functioning properly; the ratchet head should not be blocked. After use, the tension of the torque ratchet spring should be released by loosening the adjusting screw. The torque ratchet should be recalibrated annually.

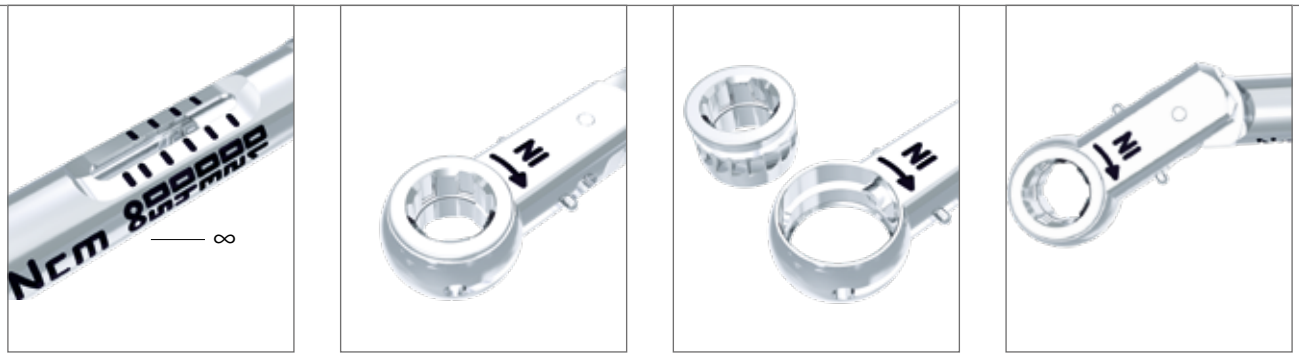
Accuracy of the torque ratchet: + / - 10 %.

Use.

The torque ratchet can be used for the surgical procedure, implant insertion, securing the closure screws, gingiva formers and impression posts and for temporary and final prosthetic restorations. There are different inserts available, depending on the application.

The ratchet is set to the required torque using the adjusting screw. The correct torque is set when the graduation line is at the required setting (see fig. ①).

The torque ratchet is additionally fitted with a blocking function. To set the blocking function, turn the adjustment screw to the '∞' symbol. For storage, turn the torque adjustment screw back until the spring is as relaxed as possible.



The pressure point for exact torque release is at the head of the torque adjustment screw. When the set torque has been reached, the scale sleeve will bend around the ratchet head axis. The release is audible and perceptible. After the torque release, **DO NOT** apply more pressure as this could damage the ratchet.

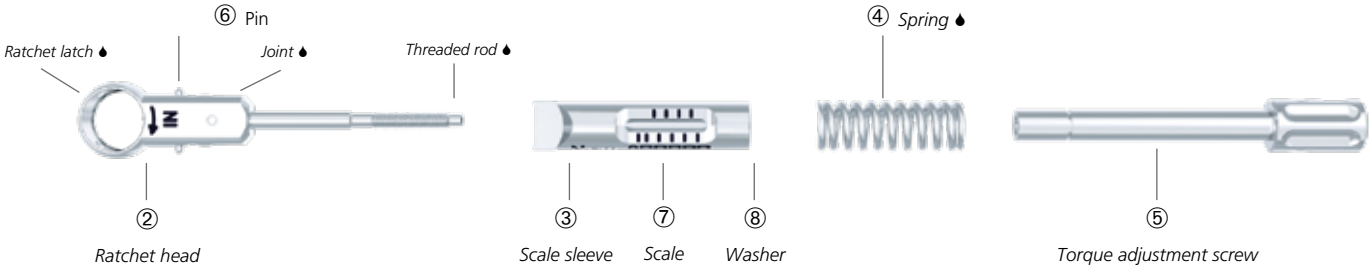
When you let go of the torque adjustment screw, the ratchet returns to its initial position.

Exceeding the torque specified by Dentaurum can cause mechanical damage to components, to the implants, and destruction of bone structures.

The blocking function mode should be used with extreme caution. After use, the torque adjustment screw ⑤ must be loosened and relieved to avoid subsequent errors.

The word 'IN' on the ratchet head (see Fig. ②) shows that the ratchet is in the correct position for tightening. The word 'OUT' stands for loosening the torque.

When fitting the final prosthetic restoration, all prosthetic screws should be tightened with the torque ratchet set at the relevant torque (see Table for torque ratchet settings) and then re-tightened after approx. 5 minutes using the same torque. It is important that the insertion key fits flush in the prosthetic screw. We recommend using a new AnoTite prosthetic screw for the final fitting.



The torque ratchet is intended for clinical use only.
Prosthetic screws should be tightened
with care manually in the laboratory.

■ Tightening torques for implants and prosthetic components*

Implant insertion		max. 40 Ncm (depending on bone density)
Closure screw Implant tioLogic® TWINFIT		15 Ncm or manually
Closure screw 4Base abutment tioLogic® TWINFIT		15 Ncm or manually
Gingiva former tioLogic® TWINFIT		15 Ncm or manually
Screw for impression post		15 Ncm or manually
Screw for impression post		15 Ncm or manually
Retaining screw for closed impression		15 Ncm or manually
Screw for temporary abutment tioLogic® TWINFIT		15 Ncm or manually
AnoTite screw – L 9.0 mm		30 Ncm
4Base abutment tioLogic® TWINFIT		35 Ncm
AnoTite screw – L 6.0 mm		25 Ncm
Ball abutment tioLogic® TWINFIT		35 Ncm
tioLOC abutment tioLogic® TWINFIT		30 Ncm
AnoTite screw for angulated screw apertures		25 Ncm

■ Inserts for the torque ratchet**

Hex key
1.3 – ratchet,
L 26.0 mm

Hex key
1.3 – ratchet,
L 16.0 mm

Insertion key S –
ratchet, tioLogic® TWINFIT,
L 26.6 mm

Insertion key M –
ratchet, tioLogic® TWINFIT,
L 26.6 mm

Insertion key L –
ratchet, tioLogic® TWINFIT,
L 26.6 mm

Insertion key
tioLOC abutment – ratchet,
L 15.0 mm

Adapter – ISO shank
hexagon/ ratchet, L 15.0
mm

Adapter – ISO shank
hexagon/ ratchet, L 20.0
mm

■ ISO shank inserts for adapter ISO shank / ratchet

Insertion key S – ISO shank,
tioLogic® TWINFIT,
L 23.5 mm

Insertion key M – ISO shank,
tioLogic® TWINFIT, L 23.5 mm

Insertion key L – ISO shank,
tioLogic® TWINFIT, L 23.5 mm

PentaGrip insertion key,
ISO shank,
L 22.3 mm

Hex key,
ISO shank 1.3,
L 20.0 mm

Insertion key S – ISO shank,
tioLogic® TWINFIT,
L 26.5 mm

Insertion key M – ISO shank,
tioLogic® TWINFIT, L 26.5 mm

Insertion key L – ISO shank,
tioLogic® TWINFIT, L 26.5
mm

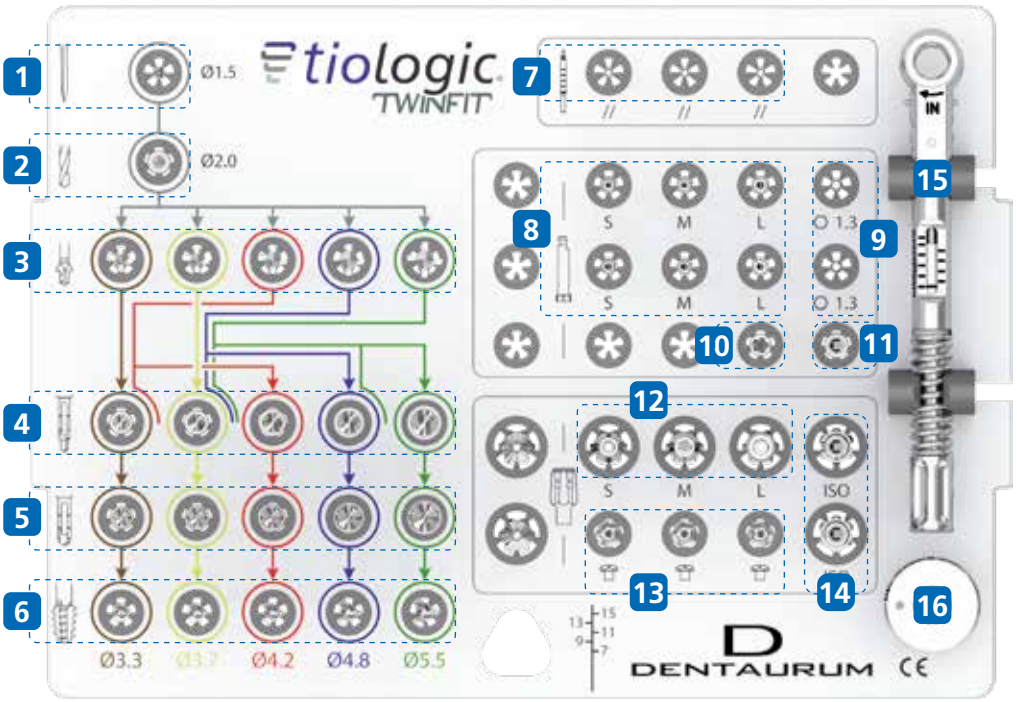
Drill extension –
ISO shank hexagon,
L 21.0 mm

Hex key,
ISO shank 1.3,
L 26.0 mm

* *Primary stable and osseointegrated*

** *There are different inserts available, depending on the application.*

The Surgical Tray for tioLogic® TWINFIT.



The Surgical Tray for tioLogic® TWINFIT.

The Surgical Tray for tioLogic® TWINFIT contains all the rotary instruments and accessory components needed for implantation. These are arranged in the order outlined in the operating procedure and provide maximum flexibility during implant site preparation while reducing the number of instruments.

The ADVANCED rotary instruments thus enable atraumatic preparation especially tailored to the bone quality, collection of bone chips and individual regulation for attaining maximum primary stability of the implant. The clear depth marking and inscription of the rotary instruments guarantee reliable, visual control throughout the entire surgical procedure. In addition, the ADVANCED instruments are color-coded according to the diameter of the respective implant and have a hexagonal chucking system for transferring high torques. The used instruments and accessory components are put back in the corresponding slots directly after each use. This increases safety during implantation as all instruments are always located in their intended place. After implantation, the fully packed Surgical Tray for tioLogic® TWINFIT is transferred to the machine treatment cycle.

Tray content

1.	Marking drill		Marking the insertion point
2.	Depth drill ADVANCED		Preparing the depth to the length of the implant, ø 2.0 mm, integrated depth stop
3.	Surface cutter ADVANCED		Preparing a flat bone surface to the diameter of the implant (optional)
4.	Stepped countersink ADVANCED		Preparing the implant site according to length and diameter of the implant, depth markings on drill
5.	Expander ADVANCED		Preparing the implant site according to length and diameter of the implant, depth markings on drill
6.	Thread tap ADVANCED		Tapping the thread to the length and diameter of the implant, depth markings
7.	Paralleling pin		Checking parallel alignment after depth drilling
8.	Insertion key, handpiece		Insertion instrument for handpiece implant insertion
9.	Hex key		Hex key 1.3 – long and short for ISO shank 1.3, L 20.0/26.0 mm, mechanical tightening and loosening of AnoTite screws
10.	Drill extension – ISO shank hexagon		Extension of handpiece instruments and accessories
11.	PentaGrip insertion key		Insertion key for handpiece insertion of the 4Base abutments
12.	Insertion key, manual		Insertion instrument for manual insertion of implant
13.	Counter screw insertion key, manual		Fixing manual insertion key in implant
14.	Adapter, ISO shank hexagon/ ratchet, L 15.0/20.0 mm		Manual operation of handpiece instruments and accessories with ratchet
15.	Torque ratchet		Manual operation with torque control for instruments and accessories
16.	Sure-grip wheel		Manual operation of instruments and accessories

Treatment procedure.

General.

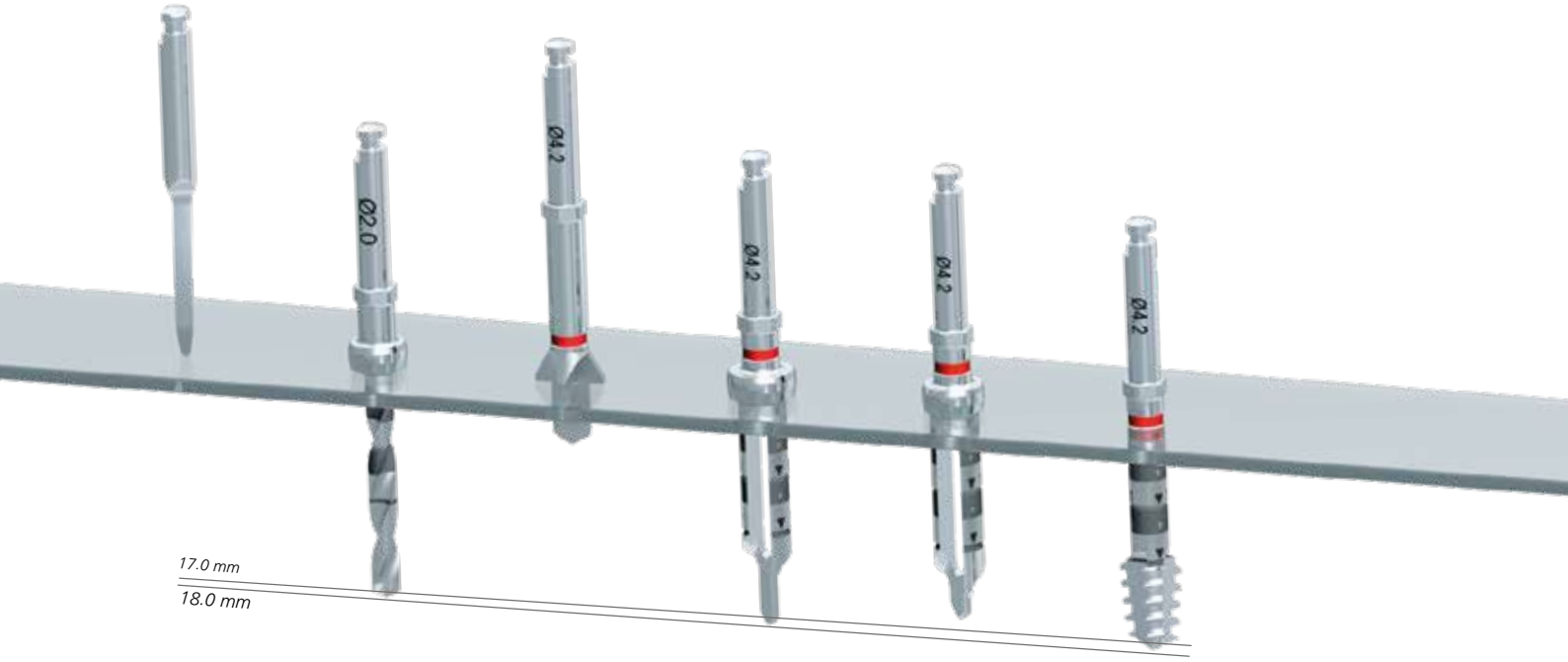
All tioLogic® TWINFIT implant types are supplied individually with a closure screw and depth-stop sleeves in appropriate length and diameter for the implant in gamma-sterilized double packaging.

The depth-stop sleeves are coordinated for the use and sequence of the rotating instruments for medium bone quality. Should the bone quality for the case in hand be different, the procedure should be adapted to follow the drilling protocol.

Coordinated instruments that can be re-used are available for the insertion of the tioLogic® TWINFIT implant types. Preparation takes place according to a preparation protocol (REF 989-501-15) for ideal bone compression and primary stability of the implant taking into account different bone qualities.

Preparation of the implant site.

- The **marking drill** is used for centering and marking the insertion point.
- The **depth drill** helps to determine the final depth and the orientation of the implant independently of the diameter. It has no integrated depth stop. Appropriate depth markings (7.0, 9.0, 11.0, 13.0 and 15.0 mm) on the cutting edges of the depth drill will indicate when the planned implant length has been reached.
- The **surface cutter** with four blades has an excellent cutting capacity, which ensures reliable handling without applying a lot of pressure. Even before implant insertion, the circular area on the bone indicates that the cervical area of the implant will be fully surrounded by bone. By using the surface cutter, the insertion depth may be larger than planned.
- The **stepped countersink** enlarges the implant site according to the implant contour. It has no integrated depth stop. It is inserted up to the laser-marked depth indication according to the planned diameter and length of the implant. All stepped countersinks have a special hollow space for collecting bone chips.
  The stepped countersinks have a laser marking indicating the diameter and are color-coded. Each instrument also has a hexagonal chucking system for transferring high torques.



- The **expander** prepares the implant site according to the diameter of the implant. It has no integrated depth stop. The expander ADVANCED is used for all bone qualities for expansion to a drill depth of 7.0 mm. It may be necessary to subsequently tap the thread if the bone is hard. All expanders have a special hollow space for collecting bone chips. The expanders have a laser marking indicating the diameter and are color-coded. Each instrument also has a hexagonal chucking system for transferring high torques.
- The **thread tap** diameter is equivalent to the implant diameters available. It has no integrated depth stop. Appropriate depth markings on the thread tap will indicate whether the planned implant length has been reached. The expander has a laser marking indicating the diameter and is color-coded. Each instrument also has a hexagonal chucking system for transferring high torques.

Note: The thread tap ADVANCED should only be used with tioLogic® ST and tioLogic® TWINFIT implants.

**For technical reasons, the depth drill and the stepped countersink are 1.0 mm longer than the given preparation length. This should be taken into account during diagnosis, planning and preparation.*

Design ADVANCED instruments.

All rotary instruments ADVANCED are supplied non-sterile and should be sterilized before use. They should be thoroughly cleaned, disinfected and conditioned before using for the first time (brand new) and immediately after each use. Rotary instruments should always be checked to ensure that they are sharp, in good condition and the markings are legible, as they have a limited service life. Instruments can become blunt as a result of use and cleaning. Only instruments that are sharp and free from defects should be used (General information).

Rotary instruments – used with proper care and provided that they are not damaged or contaminated – can be reused in dense bone 15 to 20 times; any further reuse or the use of damaged and/or contaminated instruments must be avoided. The dental professional bears responsibility. No liability is accepted if these instructions are disregarded.

Diagnosis and planning.

This section provides a general overview of diagnosis and planning. For more detailed information on these aspects, please refer to current literature. Implantologists and dental technicians with many years of experience are available to answer any questions that you may have.

Indications.

tioLogic® TWINFIT implant types can be used both in the mandible and maxilla for surgical immediate implantation, delayed immediate implantation and delayed implantation using either the one-stage or two-stage technique. Indications for implant insertion are small and large-bounded saddles (one-tooth restorations, increasing the number of abutments) in the maxilla and mandible, a shortened dentition and an edentulous jaw. The possible benefits and disadvantages as well as the risks involved in implant treatment and alternative treatments should be taken into account when considering whether implant treatment is indicated.

With all implantological cases, the implant diameter and length of the tioLogic® TWINFIT implant types should be in proportion to the prosthetic restoration.

If practical for the individual oral situation, implants with a minimum diameter of 4.2 mm should generally be used for restorations that subject the implant and superstructure to high mechanical loading.

The tioLogic® TWINFIT implant type S ø 3.3 mm is available for patients with narrow alveolar ridges. Due to the smaller diameter and lower load capacity (compared to the tioLogic® TWINFIT implant type M ø 4.2 mm), these implants have a limited range of indications (limited angulation compensation). In edentulous jaws, at least four tioLogic® TWINFIT implants S ø 3.3 mm with a splinted restoration must be inserted to ensure forces are evenly applied. Two tioLogic® TWINFIT implants ø 3.3 mm may be used for restorations on ball abutments as long as movement around the axis of rotation is guaranteed. With implant-borne restorations in a partially edentulous jaw, they should be used in conjunction with tioLogic® TWINFIT ø 4.2 mm or ø 4.8 mm/ø 5.5 mm implants and fitted with a fixed, splinted prosthetic restoration. With single-tooth restorations, tioLogic® TWINFIT ø 3.3 mm implants should only be used for lower incisors or upper lateral incisors and only with a length of minimum 11.0 mm. For single-tooth restorations on tioLogic® TWINFIT ø 3.7 mm to ø 5.5 mm implants, a minimum length of 9.0 mm should be planned.

The tioLogic® TWINFIT training program ensures that all dentists, dental technicians and dental assistants involved in the implant procedure are optimally prepared by experienced lecturers. Dentaurum provides numerous training courses at different levels tailored to suit the target group, the level of knowledge and individual interests.

Contraindications.

Implants with a diameter of 3.3 mm are not suitable for single-tooth restorations of the central incisor in the maxilla or the canines, premolars or molars in the maxilla or the mandible. It is not permitted to use telescope crown constructions on these implants. The use of tioLOC abutments for non-parallel abutments of 10° or more per implant is contraindicative.

It should be taken into account that these contraindications may be long or short-term depending on the extent, duration and individual conditions. The current position of scientific implantological associations relating to indications and contraindications and current literature should be taken into consideration when planning implant treatment.

General contraindications for dental surgery procedures apply. These include:

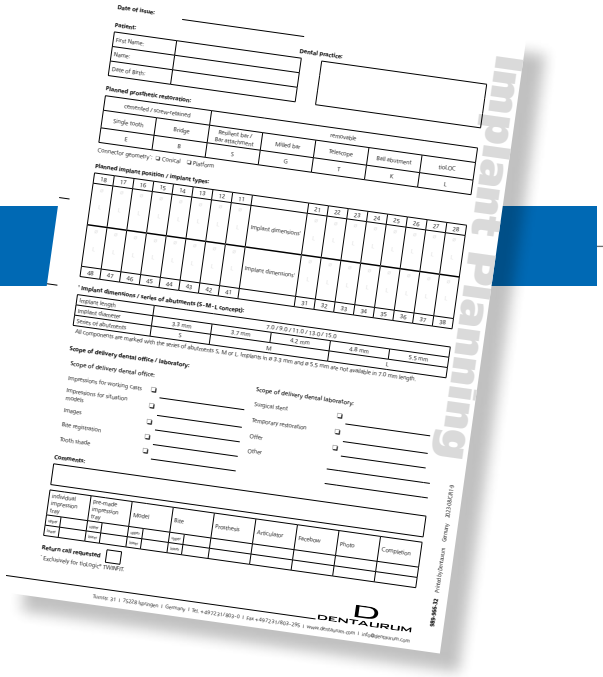
- reduced immunodeficiency
- steroid treatment
- blood coagulation disorders
- uncontrolled endocrine diseases
- rheumatic disorders
- bone system diseases
- cirrhosis of the liver
- drug, alcohol or tobacco abuse
- depression, psychopathic disorders
- poor patient compliance
- chronic inflammatory diseases
- incomplete physical growth of patient

Local/personal contraindications.

- osteomyelitis
- radiotherapy in the head region
- recurring mucosal diseases
- temporomandibular joint dysfunctions
- parafunctions
- lack of vertical or horizontal bone availability, jaw defects, inadequate bone quality
- poor oral hygiene

Diagnosis and planning.

All the relevant data for implant planning can be noted in the implant planning form (REF 989-966-32) and passed on to the dental technician for planning.



Standard planning / planning for template-guided implant placement.

Precise planning at the pre-prosthetic stage is the basis for successful implant treatment. The aim is to place the implants in a prosthetically optimal position to attain excellent aesthetics and function. This entails an implantological-related anamnesis, clinical and prosthetic planning and a final consultation with patients to ensure that the planned treatment meets their expectations.

Example: Diagnosis indicates a fixed restoration instead of a removable restoration due to the probable position of the implant and the resulting loading.

In the following sections different examples are given of planning options, including the planning for template-guided implant insertion (see pOsition for tioLogic®). The examples can serve as orientation for individual cases. Other procedures can also be used in pre-prosthetic planning.

Diagnostic model.

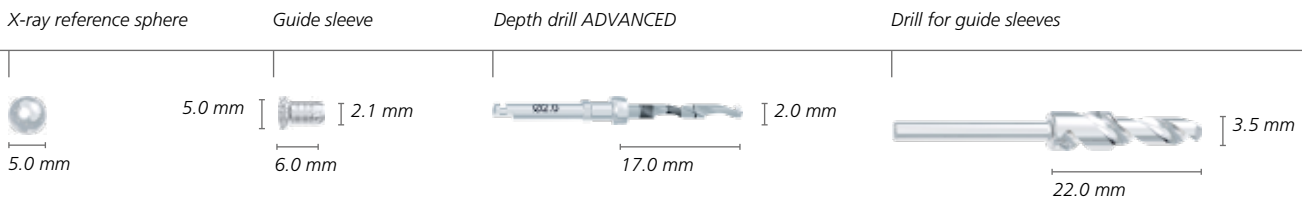
Impressions are taken of the upper and lower jaw for the diagnostic models, which are then mounted in an articulator after bite registration. The impression should be an optimum reproduction of the hard and soft tissue situation. Any hard or soft tissue defects give an indication of the implant inclination or augmentation measures required. These factors are already taken into consideration at the planning stage.

The main purpose of pre-prosthetic planning is to decide between a fixed, an operator-removable or a removable restoration.

Set-up / wax-up, planning template.

Fixed or operator-removable restorations.

Based on the planned prosthetic restoration, a set-up or wax-up is fabricated on the diagnostic model to represent the ideal prosthetic restoration. Remaining teeth and the opposing jaw are taken into consideration. The residual dentition should, for example, provide adequate support for the lips without adding a buccal acrylic flange or placing the teeth too far in front of the jaw. The length of the teeth should be waxed up anatomically, but missing papillae should not be waxed up. An acrylic template is fabricated over the tooth set-up or wax-up.



Removable restorations.

Based on the planned prosthetic restoration, a set-up is fabricated on the diagnostic model to represent the ideal prosthetic restoration. The set-up is adjusted until the patient is completely satisfied with the result. It is then waxed up as a denture base and processed in clear acrylic.

X-ray reference foil, surgical stent.

Guide sleeves are polymerized into the plastic template in the ideal implant and alignment position for the prosthetic restoration to fabricate the X-ray template or the surgical stent. The guide sleeve is available with a length of 6.0 mm. If the drill that corresponds to the outer diameter of the guide sleeve is used, the guide sleeve can be pressed directly into the planned position in the planned direction.

Orthopantomograph (OPG).

Model analysis for measuring the ridge height and width after initial examination can also be used for integrating the guide sleeves in the plastic template. When planning, it is important to take into account that a surface cutter, that removes bone material, may be used. During model analysis the relationship to the adjacent teeth and opposing dentition is assessed and transferred to a special sectioned model. The surgical stent is placed on the sectioned model and the implant alignment checked.

If the checks on the sectioned model are correct, an OPG can be taken with the X-ray template. The position, diameter, length of the implants and their alignment in relation to the adjacent teeth can be checked two-dimensionally and the position of the guide sleeves can be altered if necessary.

Instead of using guide sleeves, e. g. for an edentulous jaw, X-ray spheres (ø 5.0 mm) can be used as X-ray reference points, polymerized into a template. If they are positioned directly on the mucosa, the thickness of the mucosa can be calculated.

Planning foils are also available with all tioLogic® TWINFIT implants in the scale of 1:1 and in the standard enlargement scale of 1.25:1 and 1.4:1.

The OPG can be used to calculate the vertical bone availability:

Known data:

- Actual length of the guide sleeve or diameter of the X-ray sphere (Dr)
- OPG length of the guide sleeve or diameter of the X-ray sphere (Do)
- Alveolar ridge height on the OPG (Ko)

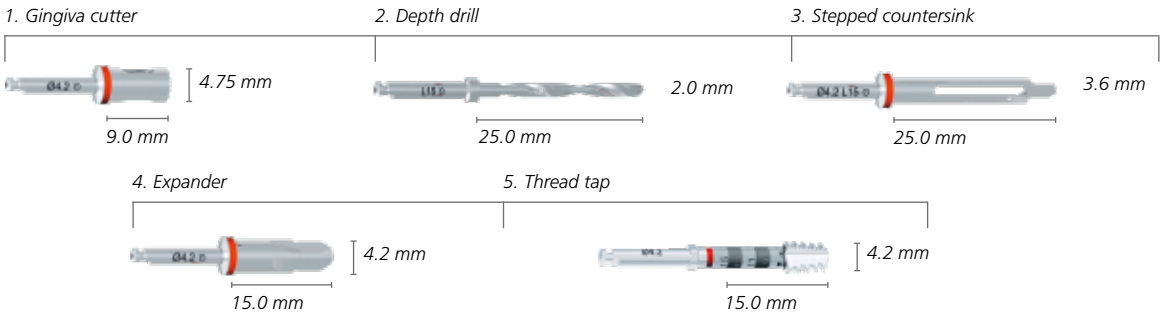
Data to be calculated:

- Actual alveolar bone height (Kr)

Formula:

$$Kr = \frac{Ko \times Dr}{Do}$$

Template-guided implant insertion – pOsition for tioLogic®.



Template-guided implant insertion.

Accurate three-dimensional diagnostic analysis of the relevant data is possible with the use of computer tomography (CT) or digital volume tomography (DVT). Using a CT/DVT and the relevant software programs, data such as bone quality, bone availability and gingival thickness can be determined. The relevant implant types can also be selected from the database of the respective software program and positioned three-dimensionally in the planned region.

All this information affects implant planning with regard to the number, position, diameter and length of the implants.

Data obtained from the three-dimensional diagnostic analysis is used for producing the relevant X-ray reference foil and surgical stent.

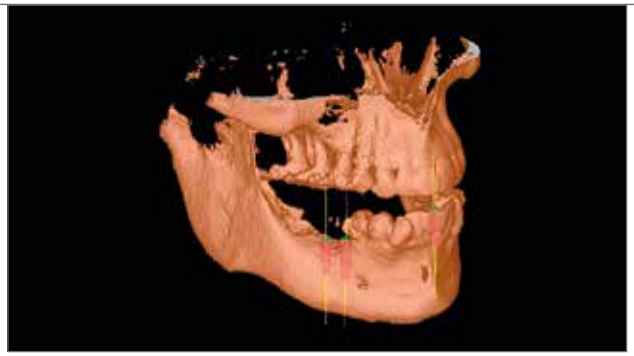
tioLogic® pOsition is a sleeve and drill system from Dentaurum that ensures reliable, minimally invasive and precise template-guided implant placement using coordinated planning software for accurate diagnosis and 3D planning. (see Surgery Manual pOsition for tioLogic®, REF 989-999-20).

Information obtained from clinical, prosthetic and radiological data should be checked during planning to ensure that it is practicable from a surgical point of view. In certain cases it may be concluded that the planned site does not have adequate bone availability and that a fixed restoration for example would be impractical without extensive augmentation measures.

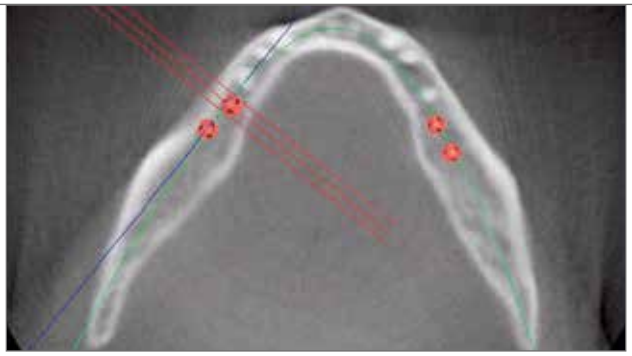
The planned implant restoration is discussed with the patient with regard to the patient's expectations (extent and cost of treatment) and a decision reached. The surgical stent is modified according to any adjustments made to the planned restoration.

The surgical stent should be cleaned and sterilized prior to surgery.

When using a surgical stent, the implantologist is still responsible for maintaining safety margins, exposing the mental foramen as well as checking the bone contour etc.



3D implant positioning.



Implant positioning.

Preparation for surgery.

Users of the tioLogic® TWINFIT implant system should have relevant experience in implantology and dentistry and be familiar with the product. Dental professionals should also note the specific aspects below relating to quality assurance in implant treatment:

- The treatment room should be divided into a sterile and non-sterile area.
- Ensure that hygiene measures are carefully followed, documented and validated throughout the surgical procedure. The treatment room, instrumentarium and patient should be prepared accordingly.
- All surgical instruments required for the operation should be checked to ensure that they are complete, functional and sterile. We recommend having several implants and preparation instruments available as a precaution.

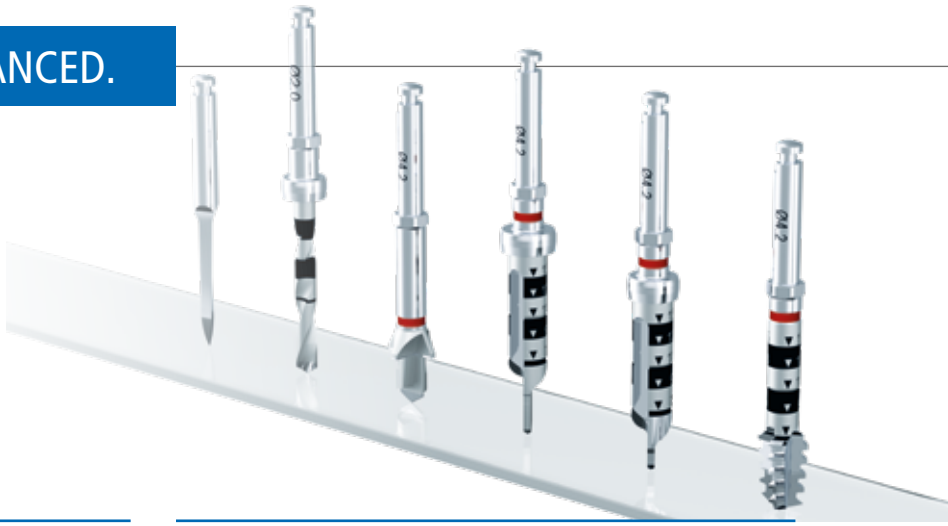
The patient should rinse with a disinfectant mouthwash solution immediately before treatment. In addition, the perioral area should be cleaned with a disinfectant solution. Implant insertion is then normally carried out under local anesthesia.

Other components are used in implant treatment apart from implant-specific products. Additional implant-related product ranges have been designed to facilitate implant treatment for the implantologist and ensure compatibility when extending the range of indications. These product ranges include components and instruments such as:

- special surgical instruments

Further information is available in the tioLogic® TWINFIT product catalog (REF 989-910-20).

Treatment procedure ADVANCED.



Instruments.

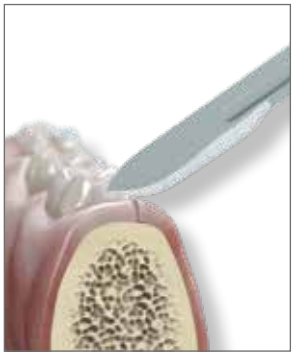
A handpiece extension and three manual hex keys are available for all rotary instruments. The handpiece instruments can also be used manually as required using an adapter (max. permitted torque 40 Ncm). The instruments should be inserted rotationally secure and the fit checked. The manual hex keys and adapter can be used with the torque ratchet set at the relevant torque.

Components should be secured with a sterile safety cord to prevent aspiration during use.

For the preparation of the implant site, the rotary instruments and their drilling sequence should be chosen depending on the bone quality. A preparation protocol for different bone qualities (soft, medium, dense) is available for the implantologist. Determination of the bone quality rests on the implantologist.

Bone exposure.

The mucosa is cut through to the bone with a ridge incision and a mucoperiosteal flap is raised. The buccal flap section should be adequately mobilized and slightly retracted towards lingual. This exposes the actual contour of the alveolar process. It is generally necessary to make relief incisions mesially and distally. The position of the mental foramen should be clarified before placing implants in the mandible.

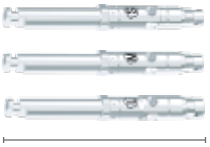


Alveolar ridge incision.

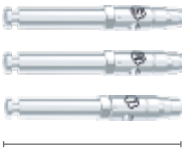
Handpiece ISO shank hexagon – Extension

21.0 mm

Insertion key, handpiece



26.5 mm



23.5 mm

Insertion key, manual

30.0 mm

30.0 mm

30.0 mm

Adapter ISO shank hexagon – Ratchet

15.0 mm

20.0 mm

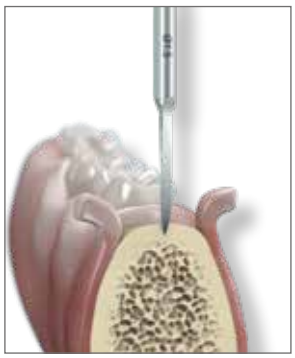
Drillpoint marking.

The following describes preparation regardless of the bone quality in order to show exactly how each of the rotary instruments work. The template-guided preparation and implant insertion with pOsition for tioLogic® is described in the Surgery Manual pOsition for tioLogic® (REF 989-999-20).

Thin crestal bone in the region of implant insertion can be smoothed slightly with a round bur (ø 6.0 mm).

The insertion point of the implant can be marked using the marking drill.

The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C/41 °F).



Drillpoint marking.

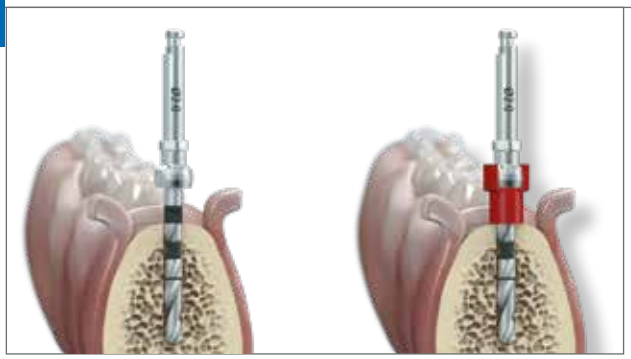
Surgical stent.

If tioLogic® guide sleeves have been integrated in the surgical stent, the relevant guide sleeve drill can be used. The drilling depth can be calculated by taking the drill length from pre-drilling and subtracting the height of the guide sleeves and the mucosa.

Either guide sleeve drill can be used for marking the insertion point as well as for initial pilot drilling for implant alignment so that the planned implant position and alignment are preset for further preparation. Both guide sleeve drills have an integrated depth stop. Surface cutting is not required if a surgical stent is used. Preparation is continued using the appropriate depth drill depending on the length of the implant.

The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C/41 °F).

Treatment procedure ADVANCED.



Depth drilling ADVANCED. *optional: incl. depth-stop sleeve.*

Depth drilling ADVANCED.

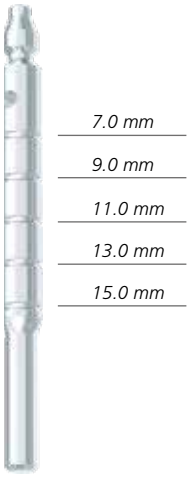
The depth drill ADVANCED prepares the final depth and direction of the implant site independent of the implant diameter. The depth drill does not have an integrated depth stop, but depth markings according to the implant length. The depth markings on the depth drill ADVANCED indicate when the previously determined implant length (here 13.0 mm as an example) has been reached. This guarantees keeping to the exact insertion depth determined in the treatment planning.

As an option, the sterile depth-stop sleeves that are delivered with every tioLogic® TWINFIT implant type can be used. These are coordinated to be used with the rotating instruments for medium bone quality. Should the bone quality for the case in hand be different, the procedure should be adapted to follow the drilling protocol.

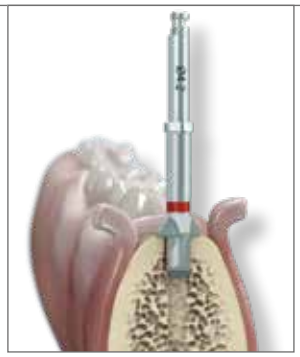
The depth drill has a diameter of 2.0 mm. For technical reasons, the depth drill is 1.0 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation. In addition, the depth drill ADVANCED is provided with a hexagon chucking system for the transmission of high torques.

The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C/41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

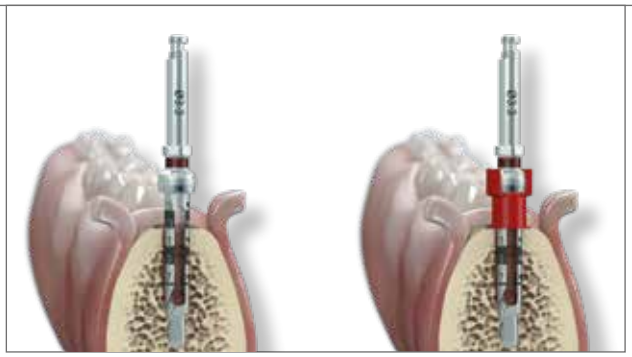
The paralleling pin can be used following depth drilling. This is used as orientation for subsequent depth drilling and as a depth gauge of the depth drilling made. It is available in two diameters: 1.4 mm (for pilot drills) and 1.9 mm (for depth drills). In addition, a paralleling pin with a short thread can be fixed in an implant that is already in place. The paralleling pin should be secured with a cord.



Paralleling pin tioLogic® TWINFIT.



Surface cutting ADVANCED.



Stepped countersinking ADVANCED ø 3.3 mm.

optional: incl. depth-stop sleeve.

Surface cutting ADVANCED.

The shape of the surface cutter ADVANCED has been specially designed for drilling through the compact bone and for preparing a flat bone surface cervically. It has a color-coded groove, which indicates the planned final implant diameter (here red for ø 4.2 mm) and is used for all lengths of implant. The implant diameter is also laser-printed on the surface cutter.

The surface cutter ADVANCED is drilled into the bone until a circumferential imprint of the cutting cylinder is visible on the compact bone. This ensures that the implant is surrounded by bone crestally. If the surface cutter is drilled deeper into the compact bone when there is adequate bone availability, the whole implant will be positioned deeper (adhere to the preoperative length measurement). Depending on the implant diameter, surface cutting can be omitted if there is enough flat bone surface in the crestal region.

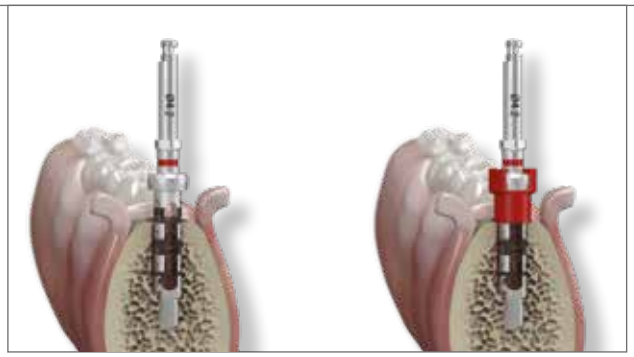
The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C/41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Stepped countersinking ADVANCED.

The stepped countersink enlarges the implant site according to the implant contour. The depth drill does not have an integrated depth stop, but depth markings according to the implant length. The implant diameter is indicated by a color-coded groove (here brown for ø 3.3 mm and red for ø 4.2 mm). The stepped countersink ADVANCED has laser-inscriptions of the implant diameter on the shank. In addition, the stepped countersink ADVANCED has a hexagon chucking system for the transmission of high torques.

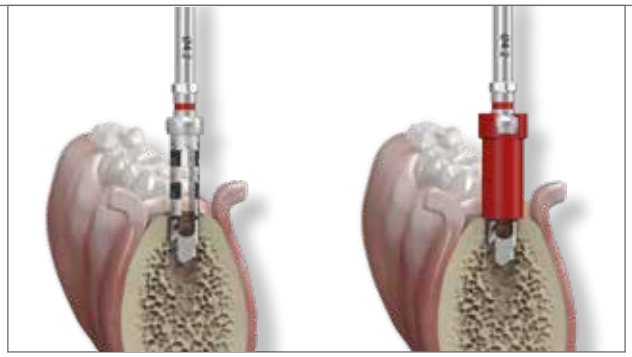
All ADVANCED stepped countersinks are provided with a special hollow space for collecting bone chips, which can be used as an autologous transplant.

The depth markings on the stepped countersink ADVANCED indicate when the previously determined length has been reached (here 13.0 mm length as an example). In accordance with the tioLogic® TWINFIT preparation protocol, the stepped countersink ADVANCED enlarges the implant site in steps, starting with the smallest available diameter until the determined diameter has been reached.



Stepped countersinking ADVANCED ø 4.2 mm.

optional: incl. depth-stop sleeve.



Expander ADVANCED ø 4.2 mm.

optional: incl. depth-stop sleeve.

For a determined implant diameter, e.g. ø 4.2 mm and 13.0 mm length, the implant site should be enlarged after the surface cutting in steps, first with the ø 3.3 mm stepped countersink ADVANCED, then with the ø 4.2 mm stepped countersink ADVANCED, each up to the 13.0 mm depth marking.

As an option, the sterile depth-stop sleeves that are delivered with every tioLogic® TWINFIT implant type can be used.

The depth-stop sleeves are coordinated for the use and sequence of the rotating instruments for medium bone quality. Should the bone quality for the case in hand be different, the procedure should be adapted to follow the drilling protocol.

For technical reasons, the stepped countersink is 1.0 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation.

Manual stepped countersinking using a torque ratchet adapter or sure-grip wheel is recommended for very soft or narrow bone.

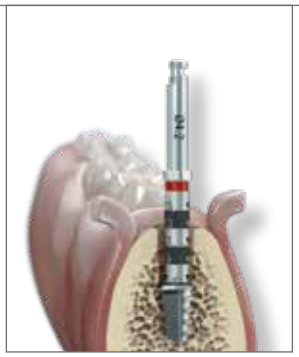
The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C/41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Expander ADVANCED

After using the stepped countersink ADVANCED, the fine thread part of the implant site is prepared according to the diameter of the implant with the expander ADVANCED. The depth drill does not have an integrated depth stop, but depth markings according to the implant length. The implant diameter is indicated by a color-coded groove (here red for ø 4.2 mm). The implant diameter is laser-printed on the shaft of the expander ADVANCED. In addition, the expander ADVANCED has a hexagon chucking system for the transmission of high torques.

All ADVANCED expanders are provided with a special hollow space for storing bone chips, which can be used as an autologous transplant. The expansion with the expander ADVANCED should take place according to the tioLogic® TWINFIT preparation protocol.

Thread tap ADVANCED depth scale.



Thread tap ADVANCED.

Expansion can be achieved for all bone qualities using the expander ADVANCED ø 4.2 mm to a drilling depth of 7.0 mm. It may be necessary to make a subsequent thread cut for hard bone quality.

Maximum primary stability can be individually regulated by the insertion depth of the expander ADVANCED (tioLogic® TWINFIT preparation protocol).

As an option, the sterile depth-stop sleeves that are delivered with every tioLogic® TWINFIT implant type can be used.

The depth-stop sleeves are coordinated for the use and sequence of the rotating instruments for medium bone quality. Should the bone quality for the case in hand be different, the procedure should be adapted to follow the drilling protocol.

Manual expanding using a torque ratchet adapter or sure-grip wheel may be helpful for very narrow bone.

The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C/41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Thread tapping ADVANCED

Depending on the bone quality, it is optionally recommended to finish the preparation with a thread tap. The thread tap ADVANCED is available for the insertion of a tioLogic® TWINFIT implant. It is available in the same diameters as the implants, has a color-coded groove (here red for ø 4.2 mm) and an additional marking on the shank. Appropriate depth markings on the thread tap will indicate whether the planned implant length has been reached. In addition, the thread tap ADVANCED is provided with a hexagon chucking system for the transmission of high torques.

Manual preparation using a torque ratchet adapter or sure-grip wheel may be helpful for very narrow bone.

The thread tap can also be used with a handpiece (max. 10 min^{-1}) in the same way as for the manual technique.

Preparation protocol – tioLogic® TWINFIT.

Adapt preparation protocol according to the indication and situation of each patient if required.

		Soft bone quality				
		ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
Marking drill		X	X	X	X	X
Depth drill[1]		X	X	X	X	X
Surface cutter[3]		X	X	X	X	X
Stepped countersink ø 3.3[1]		(X)[4]		X		
Stepped countersink ø 3.7[1]			(X)[4]		X	X
Stepped countersink ø 4.2[1]				(X)[4]		
Stepped countersink ø 4.8[1]					(X)[4]	X
Stepped countersink ø 5.5[1]						(X)[4]
Expander ø 3.3[2]		⑦				
Expander ø 3.7[2]			⑦			
Expander ø 4.2[2]				⑦		
Expander ø 4.8[2]					⑦	
Expander ø 5.5[2]						⑦
Thread tap[1,3]						

[1] *The insertion depth/length of the depth drill, stepped countersinks and thread tap depends on the implant length. Thread taps must be used if implant insertion torque exceeds 40 N cm.*
[2] *The insertion depth of the expander should not be less than 7.0 mm. The depth scales must be observed.*
[3] *Exemplary illustration of rotary instruments ø 4.2 mm (red).*
[4] *Can be used optionally to achieve improved primary stability in the cancellous bone.*

X Preparation depth in accordance with implant length

⑦ min. 7.0 mm preparation depth

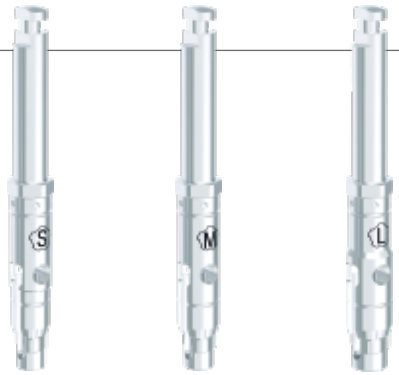
( ) Optional application
(taking into account the respective bone quality)

Medium bone quality				
ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
X	X	X	X	X
X	X	X	X	X
X	X	X	X	X
X		X		
	X		X	X
		X		
			X	X
				X
⑦				
	⑦			
		⑦		
			⑦	
				⑦

Hard bone quality				
ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
X	X	X	X	X
X	X	X	X	X
X	X	X	X	X
X		X		
	X		X	X
		X		
			X	X
				X
⑦				
	⑦			
		⑦		
			⑦	
				⑦
(X)	(X)	(X)	(X)	(X)

Treatment procedure.

Implant packaging.



Handpiece insertion key S-M-L.

Sterile packaging.

All tioLogic® TWINFIT implants are supplied singly with the appropriate closure screw and with drill stops of appropriate lengths and diameters in gamma-sterilized double packaging. They are intended for single use only. The double packaging (foil and blister packaging) protects the inner container with the sterile implant, closure screw and depth stops against contamination. The contents only remain sterile as long as the packaging is undamaged. The product should not be used if the double packaging is damaged.

Handling.

The blister packaging, which is shrink wrapped in foil, is removed from the outer packaging. The foil is opened in the non-sterile area and the sterile blister packaging with the implant, closure screw and depth stops is transferred into the sterile area or taken by the clinician or qualified personnel.

The cover of the sterile blister packaging is peeled back and the sterile inner container removed.

The silicone seal with the closure screw is removed.

Note: Do not tilt as the implant lies loose in the inner container.

Implant insertion.

The implant is then grasped using the handpiece insertion key. The insertion key is designed to ensure contact-free insertion with all indications.

Direct manual insertion.

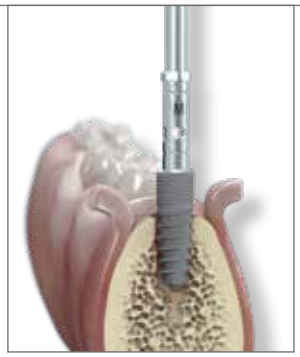
The adapter ISO shank/ratchet is placed on the insertion key. The key snaps into place on the implant by turning it slightly and can be inserted into the prepared implant site manually.

Handpiece insertion.

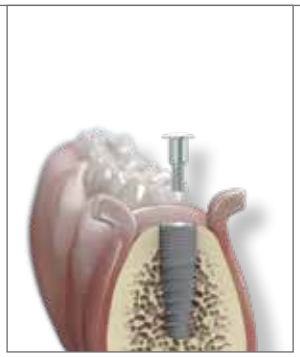
The insertion key is put into the tioLogic® TWINFIT implant. After making a slight turn, the insertion key snaps into place in the implant and can be inserted into the prepared implant site using the handpiece.

The insertion key can be extended using a drill extension.

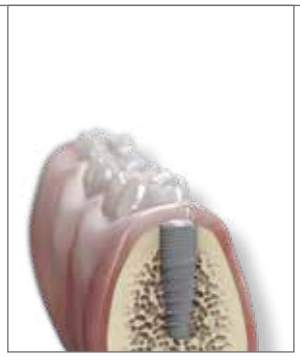
A torque of 40 Ncm should not be exceeded with any insertion procedure. The motor speed during handpiece insertion should not exceed 10 min^{-1}. Use of an excessive torque or motor speed can damage the implant site.



Implant insertion.



Inserting the closure screw.



Wound closure.

The five markings on the insertion key correspond to the five rotational security stops and allow alignment of the rotational security with regard to the subsequent prosthetic restoration.

The implant should be inserted into the bone as far as the lower edge of the polished cervical area, i.e. its final position is slightly transcrestal (0.3 mm).

The insertion key can be removed from the implant following implant insertion. (Removal should be done carefully in cases of horizontal bone loss).

Ensure that epithelial tissue does not enter the implant site during implant insertion.

Tightening torque

- depending on the bone quality, max. 40 Ncm

Temporary closure.

To remove the closure screw, press the hex key 1.3 into the closure screw and pull it from the silicone lid. The closure screw is then inserted into the implant and tightened. Closure screws should fit flush on the implant to ensure that bone tissue growth cannot penetrate into the implant. The closure screws are inscribed with S, M or L corresponding to the series of abutments. Closure screws are intended for single use only.

If open healing is planned or indicated, the relevant gingiva former (S, M or L) is inserted into the implant instead of a closure screw.

Tightening torque

- Closure screw: manually or 15 Ncm
- Gingiva former: manually or 15 Ncm

Wound closure.

After checking the operation site, the wound is closed by suturing. Simple interrupted sutures are normally used. Ensure that the wound closure is saliva-proof and that there is good blood circulation.

For open healing, ensure that the tissue is sutured close to the gingiva former.

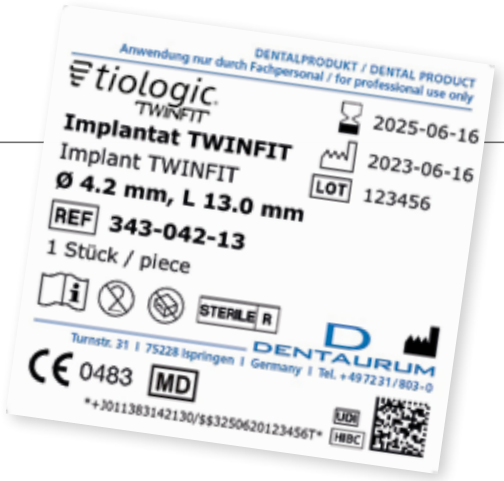
After the implant insertion is completed, an X-ray should be made to control the fit and position of the implant.

The following are indications of successful implant insertion:

- the implant is stable and a clear tapping sound is produced
- there are no signs of peri-implant inflammation
- the patient is symptom-free

Treatment procedure.

All tioLogic® TWINFIT prosthetic components should be used only in connection with tioLogic® TWINFIT implants.



Documentation.

There are four peel-off stickers with the REF and LOT numbers inside the blister packaging for documentation in the PatientPass (REF 989-961-20).

Surgical protocol.

All the important implant-related data for each case can be documented in the surgical protocol (REF 989-966-02).

Post-operative treatment, temporary restoration, healing stage, follow-up

Patients should attend regular recall appointments for checkups at brief intervals after implant insertion, during the healing stage and after implant exposure.

Post-operative treatment.

Following surgery, the first step should be immediate extra-oral cooling of the patient (avoid hypothermia) and the patient should rest for about an hour. The sutures are removed after 7 to 10 days. Further checks should be carried out after 14 and 21 days. Gingival healing and oral hygiene must be precisely monitored during the entire healing stage.

All instruments used during surgery should be thoroughly cleaned, disinfected and sterilized. Components such as the torque ratchet should be dismantled (see Reusability of surgical instruments).

Blunt or defect instruments should be discarded and replaced, as they can cause overheating of the bone, which can result in implant failure.

Temporary restoration.
Temporary denture (non-implant-borne).

A temporary prosthetic restoration should not be fitted until at least 14 days after implant insertion. Always ensure that there is no mechanical load on the placed implant. The restoration should be relieved over the implants and fitted with soft lining. If there are residual teeth, a temporary prosthetic restoration is generally fabricated on the abutment teeth prior to implant placement or an existing denture is converted.

Immediate restoration (temporary abutment).

It is possible to fit a long-term, non-functional immediate temporary restoration on implants if there is absolute primary stability and no recession of the implant site. In aesthetically relevant areas, the peri-implant structures are retained with a temporary abutment. After formation of the peri-implant structures, an optimal impression can be taken.

Temporary abutments with platform connector geometry are available for the S, M and L series of abutments. They are supplied non-sterile and are made from high-strength plastic (PEEK), which can be quickly and easily customized. The temporary abutment can be faced directly with composite or fitted with a temporary crown or bridge. In both cases the abutment is secured intra-orally with the screw for the temporary abutment; the contours are marked and adjusted extra-orally.

The restoration should only be shortened as far as the upper edge of the screw for the temporary abutment.

For a direct build-up of the facing, the temporary abutment is faced with composite extra-orally and then secured to the implant using the correct torque. The screw opening is sealed with composite.

With a crown restoration, the temporary abutment is fitted before sealing the screw aperture with wax and placing the temporary restoration. The crown should only be retained temporarily.

Tightening torque

- Temporary abutment on the model: manually
- Temporary abutment intra-orally: 15 Ncm

Healing stage.

The healing stage in the mandible is normally 3 months and in the maxilla 6 months. It can vary depending on the bone quality, the surgical procedure used and the patient's anatomy.

If examinations after the healing stage indicate osseo-integration of the implant, the prosthetic restoration can then be fabricated. Detailed information on this is contained in the Prosthetic Manual tioLogic® TWINFIT (REF 989-913-20).

Follow-up.

Patients should be entered into a regular recall program after the restoration has been fitted to ensure the long-term success of the implantological restoration. Patients should be given instructions on the appropriate hygiene regime for the implants and restoration.

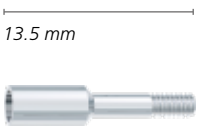
Further information is contained in the tioLogic® PatientPass (REF 989-961-20).

Safety information.

- Only use tioLogic® TWINFIT prosthetic components in combination with tioLogic® TWINFIT implants.
- Temporary restoration in situ up to 180 days
- No primary bracing of abutments
- No single restoration with cantilever unit
- Restoration with a maximum length ratio to the length of the implant 1:1.25
- The product should not be used if there is a known allergic reaction to one or more of the material components.
- The implant should not be subjected to mechanical stress
- Due to the small size, the article could be swallowed or aspirated. Aspiration could lead to difficulty in breathing or death due to asphyxiation. All articles used intra-orally should therefore be secured against swallowing and/or aspiration.
- All serious incidents arising from the use of the product should be reported to the manufacturer and the competent authority in the country in which the dental professional and/or the patient are resident.

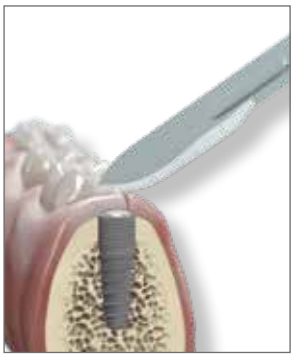
Implant exposure.

The implant is exposed after the healing stage. The patient should be prepared in the same way as for other surgical procedures. The patient is given a local anaesthetic. The implants can be bared using different techniques and aids, e.g. by using a scalpel or laser. If a scalpel or a laser is used, the peri-implant tissue (attached gingiva) is conserved and optimum aesthetic results are achieved (gingiva management).



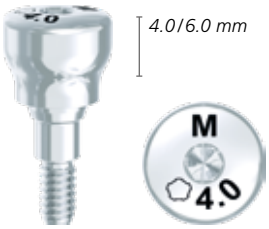
Screw, temporary abutment

Temporary abutment tioLogic® TWINFIT
tioLogic® TWINFIT, platform

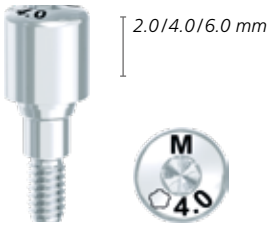


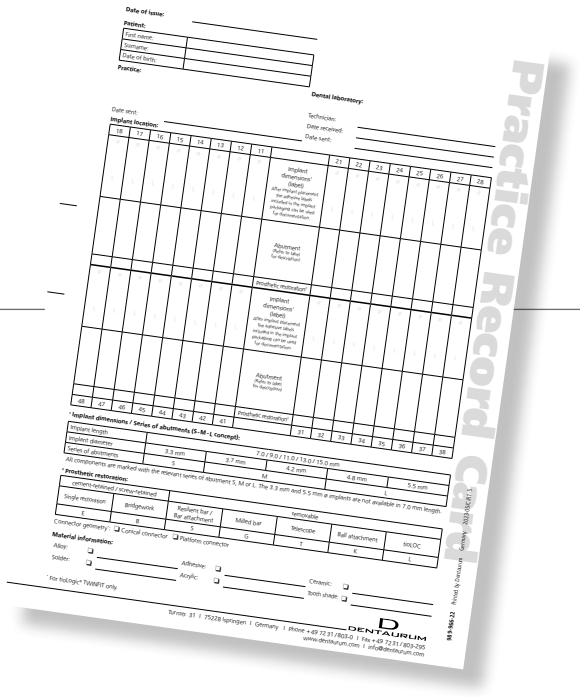
Implant exposure.

Gingiva former M, tioLogic® TWINFIT anatomical, platform



Gingiva former M, tioLogic® TWINFIT cylindrical, platform





Gingiva forming.

Gingiva formers, anatomically shaped or cylindrical, or 4Base abutments used directly – particularly gentle on the tissue – are available for the implantologist to ensure optimal gingiva management. The anatomical gingiva formers are designed to form a wide gingival contour. Depending on the type of prosthetic restoration, this can make it easier for the implantologist to fit the restoration. The gingiva formers are selected according to the series of abutments, gingival height and insertion depth of the implant. They are available with a platform connector geometry for the series of abutments S, M or L in different gingival heights (laser-marked).

Gingiva formers can also be used with open healing of the implant for specific indications and for preserving the soft tissue.

Important: The gingiva formers and 4Base abutments should be cleaned and sterilized before insertion in the implant.

If a temporary restoration is fitted, the denture should be relieved during gingiva forming. The impression should not be taken until the tissue is completely free of inflammation.

Tightening torque

- Gingiva former: manually or 15 Ncm

Impression taking.

The impression can be taken using either the open or closed technique. Relevant components are available for both impression techniques.

In the case of removable restorations (restorations with 4Base abutments, ball abutments, tioLOC abutments) the impression can also be taken with other special impression components over the respective primary abutments. These special impression techniques are described in the Prosthetic Manual (REF 989-913-20).

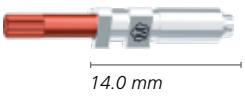
Silicone or polyether impression materials are recommended for impression-taking due to their high precision and elastic recovery.

As an alternative to the classic impression method, the intra-oral situation can also be digitally transferred via scan abutments in titanium or 4Base scan abutments in titanium.

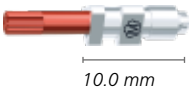
Practice record card.

To ensure optimal information flow between the implantologist and dental technician, all relevant data, e.g. the implant diameter, implant length and planned prosthetic restoration, are noted in a record card (REF 989-966-22). The card is kept with the prosthetic restoration during the entire fabrication procedure. At the fitting stage, it is given to the implantologist along with the finished prosthetic restoration. It contains all the important information for fitting the restoration.

Impression post M, tioLogic® TWINFIT, open, long



Impression post M, tioLogic® TWINFIT, open, short



Screw for impression post, long

Screw for impression post, short

Open impression technique.

Impression posts are available for the series of abutments S, M and L in lengths of 10.0 mm and 14.0 mm with the corresponding screws to cater for different occlusal spaces. The impression and the model are made using high-precision components (pre-fabricated, rotation-stable) on the basis of the platform connector geometry. The impression posts have S, M or L printed on the retention surface and at the interface.

In order to make the abutment series more recognizable during impression taking, the interface is additionally marked with dots:

- 1 dot is equivalent to abutment S
- 2 dots are equivalent to abutment M
- 3 dots are equivalent to abutment L

Tightening torque

- Sure-grip screw impression post intra-orally: manually or 15 Ncm
- Sure-grip screw impression post in the laboratory implant: manually or 15 Ncm

After the impression has been taken, an individual tray is fabricated. This is strengthened and perforated in the region of the implants.

The temporary restoration and gingiva formers should be removed prior to taking the impression.

The screw is pushed down before fitting the impression post. This provides additional guidance when fitting the post. The inner connection is shorter with an open impression post to ensure a compression-free impression even with divergent axes.

The enclosed red sure-grip screw has a shortened thread which will only grip in the (laboratory) implant if the impression post has been inserted in the correct position into the connection.

Safety information.

- Impression post should fit on the inserted implant without any gaps
- The impression components should **NOT** come into contact with the individual impression tray.
- Due to the small size, the article could be swallowed or aspirated. Aspiration could lead to difficulty in breathing or death due to asphyxiation. All articles used intra-orally should therefore be secured against swallowing and/or aspiration.
- All serious incidents arising from the use of the product should be reported to the manufacturer and the competent authority in the country in which the dental professional and/or the patient are resident.
- Only use tioLogic® TWINFIT components in combination with tioLogic® TWINFIT implants.

Groove on sure-grip screw.

Marking at interface M.

Impression post M, tioLogic® TWINFIT, platform, closed,

9.5 mm

Impression cap M, tioLogic® TWINFIT

5.8 mm

For exact implant-supported registration of the maxillomandibular relationship, the impression should be taken only on the basis of the platform connector geometry.

The impression post corresponding to the series of abutments S, M or L (here M) is fitted until the rotational security engages. A congruent fit of the implant post on the implant shoulder is indicated when an optical mark on the screw is level with the upper edge of the impression post (screw should only be inserted and not tightened). If the rotational security is not engaged, the mark on the screw is not visible. The enclosed red sure-grip screw also has a shortened thread which will only grip in the (laboratory) implant if the impression post has been inserted in the correct position into the connection. The impression post should be realigned if necessary and checked to ensure that it fits correctly (x-ray check).

When preparing the impression tray, ensure that there is no contact between the impression posts or screws and the tray at the perforations.

The impression should be taken with a material based on silicone or polyether. The impression posts are secured in the impression material by the retention. Ensure that the peri-implant region is accurately reproduced in the impression.

The screws are loosened and retracted to remove the impression tray. The tray with the screws is sent to the dental technician.

The dental technician obtains all the relevant information from the practice record card (REF 989-966-22).

The respective gingiva formers are refitted after the impression has been taken.

Closed impression technique.

For exact implant-supported registration of the maxillomandibular relationship, the impression should be taken only on the basis of the platform connector geometry.

Components for the closed impression technique include impression posts, retaining screws and impression caps. They are laser-printed or marked with the series of abutments S, M or L.

Tightening torque

- Retaining screw impression post, intra-orally: manually, or 15 Ncm
- Retaining screw impression post on laboratory implant: manually, or 15 Ncm

The gingiva formers and temporary restoration are first removed and the relevant impression post S, M or L is secured on the implant with the retaining screw. An x-ray can be taken to check if the impression post is positioned correctly.

The red retaining screw has a shortened thread which will only grip in the (laboratory) implant if the impression post has been inserted in the correct position into the connection.

The corresponding impression cap S, M or L is fitted according to the vertical retention grooves until it perceptibly and audibly clicks into place.

Scan abutment titanium M,
tioLogic® TWINFIT

12.0 mm

4Base CAD/CAM scan cap, titanium,
tioLogic® TWINFIT

4.6 mm

10.0 mm

The design of the retention grooves ensures that they can be positioned without coming into contact with the adjacent teeth.

The impression is taken according to the standard criteria (open impression technique). After the impression material has cured, the impression tray is removed. The impression posts with screws are delivered to the laboratory together with the impression.

The dental technician obtains all the relevant information from the practice record card (REF 989-966-22).

The respective gingiva formers are refitted after the impression has been taken.

Digital impression (scan).

The surfaces of the scan abutment titanium and 4Base scan cap titanium are optimized for digital capture, both intra-orally and on the model without scanning spray.

Scan abutments tioLogic® TWINFIT with platform connector geometry are available in the S, M or L series of abutments. The scan abutment is placed on the tioLogic® TWINFIT implant (pay attention to the rotational security) and fixed with the red retaining screw.

4Base scan cap titanium are available for 4Base restorations. They can be scanned directly on the 4Base abutment in the mouth.

The subsequent matching process and design are carried out according to the instructions of the software manufacturer and according to dental prosthetic rules.

Safety information.

- Impression post should fit on the inserted implant without any gaps
- The impression components should **NOT** come into contact with the individual impression tray.
- Impression caps are single-use items. They are not suitable for sterilization. Multiple use results in transfer inaccuracies.
- Due to the small size, the article could be swallowed or aspirated. Aspiration could lead to difficulty in breathing or death due to asphyxiation. All articles used intra-orally should therefore be secured against swallowing and/or aspiration.
- All serious incidents arising from the use of the product should be reported to the manufacturer and the competent authority in the country in which the dental professional and/or the patient are resident.
- Only use tioLogic® TWINFIT components in combination with tioLogic® TWINFIT implants.

Cleaning and disinfection – Basic instructions.

A mechanical procedure (disinfector) should be used if possible for cleaning and disinfection.
Because of its inferior efficacy and reproducibility a manual procedure – even with an ultrasonic cleaner –
should only be used if a mechanical procedure is not an option. Preconditioning is required in both cases.
It is the responsibility of the dental professional to check if the description available on cleaning and disinfecting
is the currently valid version. Additional information can be found at www.dentaurum.com
(Processing Instructions Instruments and Accessories REF 989-801-09).

Use.

All instruments should be cleaned, disinfected and sterilized before each use. This applies in particular to initial use, as all instruments are supplied non-sterile (clean and disinfect after removing the transport packaging). Thorough cleaning and disinfection are essential for an effective sterilization.

The dental professional is responsible for the sterility of the instruments and should always ensure that only properly validated procedures relating to the unit and the product are used for cleaning, disinfection and sterilization, that the equipment used (disinfector, sterilizer) is regularly serviced and checked, and that the validated parameters are maintained during each cycle.

The current legal regulations in the relevant country as well as the hygiene regulations of the dental practice or hospital should be adhered to. This applies in particular to the different instructions regarding effective inactivation of prions.

Preconditioning.

Remove coarse impurities from the instruments immediately after use (within maximum 2 hours).

Loose dirt should be removed under running water or using a disinfectant solution; the disinfectant should not contain aldehyde (may cause fixation of blood debris) and should have certified efficacy (e.g. DGHM or FDA approved and CE marking); it should also be suitable for disinfection of the instruments and be compatible with the instruments (see Material resistance). Only a soft brush or a clean, soft cloth should be used for removing impurities manually; metal brushes or steel wool should never be used.

If applicable: rinse all cavities of the instruments five times using a disposable syringe (minimum volume 5.0 ml).

Note that the disinfectant used for preconditioning is only for personal protection and cannot be regarded as a substitute for subsequent disinfection after cleaning.

Mechanical cleaning / disinfection (disinfector or washer disinfector).

When choosing and using a disinfector, ensure that

- the efficacy of the disinfector has been certified (e.g. DGHM or FDA approved and CE marking according to DIN EN ISO 15883),
- a certified program for thermal disinfection (minimum 5 mins at 90 °C / 194 °F or an A0 > 3000) is used (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- the program used is suitable for the instruments and has an adequate number of rinse cycles,
- it uses only water that is sterile or has a low bacteria count (max. 10 bacteria/ml) and is low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) for rinsing,
- the air used for drying is filtered,
- the disinfector is regularly serviced and checked,
- the Instructions for use of the disinfector are observed.

Cleaning agents.

When choosing a cleaning agent system, ensure that

- it is suitable for cleaning metal and plastic instruments,
- an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used – provided that thermal sterilization is not used – and that it is compatible with the cleaning agent used,
- the concentrations given by the cleaning agent and disinfectant manufacturer are strictly adhered to.

Procedure.

1. Dismantle the instruments as far as possible.
2. Place the dismantled instruments in the disinfector. Ensure that the instruments do not come into contact with one another.
3. Start the program.
4. Remove the instruments from the disinfector when the program is complete.
5. Check and pack the instruments in a clean area as soon as possible after removal (see Care, monitoring, maintenance, packaging), if necessary after additional drying.

Manual cleaning and disinfection.

When choosing a cleaning agent and disinfectant, ensure that

- they are suitable for cleaning and disinfecting metal and plastic instruments,
- the cleaning agent, if used, is suitable for ultrasonic cleaning (no foaming),
- a disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used, and that it is compatible with the cleaning agent used,

Combined cleaning agents/disinfectants should not be used if possible.

The concentrations and reaction times given by the cleaning agent and disinfectant manufacturer should be strictly adhered to. Always use freshly prepared solutions, water that is sterile or has a low bacteria count (max. 10 bacteria/ml) and is low in endotoxins (max. 0.25 endotoxin units/ml) (e.g. purified water/highly purified water) and always use filtered air for drying.

Procedure – cleaning.

1. Dismantle the instruments as far as possible.
2. Immerse the dismantled instruments fully in the cleaning solution for the recommended reaction time (if required use an ultrasonic cleaner or brush carefully with a soft brush). Ensure that the instruments do not come into contact with one another.

   If applicable: rinse all cavities of the instruments five times at the beginning and at the end of the reaction time using a disposable syringe (minimum volume 5.0 ml).
3. Then remove the instruments from the cleaning solution and rinse thoroughly at least three times with water.

   If applicable: rinse all cavities of the instruments five times using a disposable syringe (minimum volume 5.0 ml).
4. Check the instruments (see Care, monitoring, maintenance, packaging).

Procedure – disinfecting.

5. Immerse the dismantled, cleaned and checked instruments fully in the disinfectant solution for the recommended reaction time. Ensure that the instruments do not come into contact with one another.

   If applicable: rinse all cavities of the instruments five times at the beginning and at the end of the reaction time using a disposable syringe (minimum volume 5.0 ml).
6. Then remove the instruments from the disinfectant and rinse thoroughly at least three times with water.

   If applicable: rinse all cavities of the instruments using a disposable syringe (minimum volume 5.0 ml).
7. Assemble, if appropriate, and pack the instruments in a clean area as soon as possible after removal (see Care, monitoring, maintenance, packaging), if necessary after additional drying.

Note: Proof of basic suitability for effective manual cleaning and disinfecting was provided by an independent, accredited test laboratory using Bododex® forte cleaning agent and Korsolex® plus disinfectant (Bode Chemie, Hamburg, Germany). The procedure described above was taken into account during the tests.

Care, monitoring.

Instruments should be checked after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipped edges and contamination. Damaged instruments should be discarded (limited reuse see Treatment procedure). Instruments that are still contaminated should be cleaned and disinfected again. Instruments and accessories must be replaced if they cannot be clearly identified or if the function is impaired due, for example, to poor readability of the markings or labels.

Maintenance.

Reassembly of instruments (chapter Reusability of surgical instruments).

Instrument oil should not be used if possible. If oil is to be used, ensure that only instrument oils (white oil) are used, which – depending on themaximum sterilization temperature used – are approved for steam sterilization and certified biocompatible.

Packaging.

Arrange the cleaned and disinfected instruments as required in the sterilization tray.

Wrap the instruments and sterilization tray in disposable sterilization packing (single or double wrap) and/or pack in sterilization containers that meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607-1/2
  (formerly: DIN EN 868/ANSI AAMI ISO 11607)

- suitable for steam sterilization (temperature resistant to min. 134 °C/273 °F adequate steam permeability) 134 °C/273 °F, adequate steam permeability)
- adequate protection of the instruments and sterilization packaging against mechanical damage
- regularly maintained according to the manufacturer's instructions (sterilization containers)

Sterilization procedure.

Sterilization should only be completed using the sterilization procedures listed below; other sterilization procedures are not approved.

Steam sterilization.

- fractional vacuum method
- steam sterilizer in accordance with DIN EN 13060 or DIN EN 285
- validated in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) (valid commissioning and product-specific performance evaluation)
- maximum sterilization temperature 134 °C/273 °F (plus tolerance in accordance with DIN EN ISO/ANSI AAMI ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134))
- sterilization time (exposure time at the sterilization temperature) max. 20 mins at max. 135 °C/275 °F 20 mins at max. 135 °C/275 °F
- max. pressure: 2.2 bar

Flash sterilization or gravitational method should never be used.

Do not use hot-air sterilization, X-ray sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization.

Correct storage.

After sterilization, the instruments should be stored dry and dust-free, away from the light, in the sterilization packaging.

Material resistance.

When choosing the cleaning agent and disinfectant, ensure that they do not contain the following components:

- organic, mineral or oxidizing acids (maximum permitted pH 9.5, a neutral/enzymatic cleaner is recommended)
- strong alkali
- organic solvents (e.g. alcohol, ether, ketones, benzene)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/ halogenated hydrocarbons
- heavy metal salts

Never clean instruments and sterilization trays with metal brushes or steel wool.

Torque ratchet

Ratchet wheel

After assembly and before each use check the correct function of the torque ratchet.

Disassembly.

Before cleaning (regardless of the selected cleaning method), the torque ratchet must be dismantled into the individual parts. This can be done without tools. Completely unscrew the torque adjustment screw ⑤, and remove the spring ④ and the ratchet head ② with threaded rod.

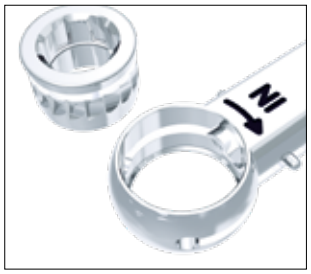
Take care not to lose the plastic washer ⑧ as this would have a negative impact on the instrument's precision. (The plastic washer needs only to be removed if there is visible contamination. It can be pulled off if necessary and replaced after cleaning).

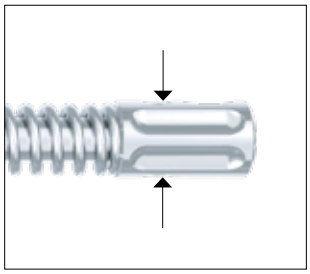
Remove ratchet wheel

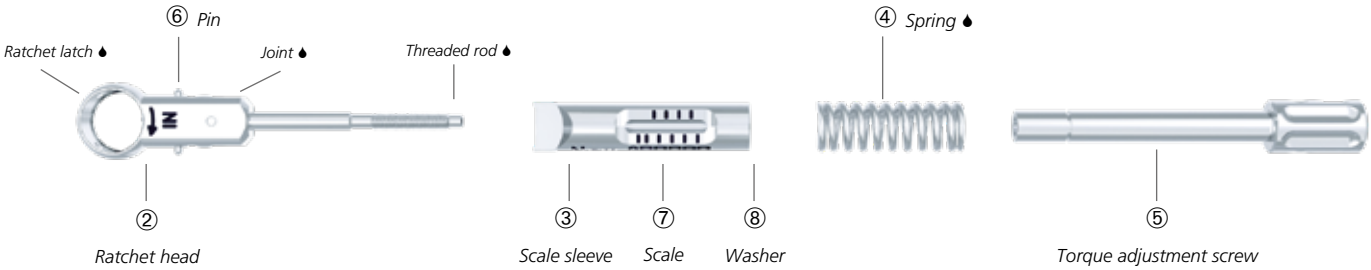
Pull back the pin ⑥ in the direction of the arrow using your thumb and index finger and remove the ratchet wheel ①.

Blocking function – „∞" mark.


Ratchet head, assembled.


Ratchet head, disassembled.


Never loosen these screws as the ratchet will lose its torque function.



Maintenance.

If several torque ratchets are in use, do not interchange the individual parts. Each individual part belongs to one instrument.

Lubricating point (♦)

Lubricate the areas marked with the "drop" symbol lightly with maintenance oil for instruments.

Ensure that only instrument oils (paraffinic white oil without corrosion inhibitor or other additives) are used, which – depending on themaximum sterilization temperature used – are approved for steam sterilization and are certified as biocompatible. The oil should be used sparingly.

Reassemble the ratchet and perform a function test.

Assembly.

To assemble the torque ratchet correctly, connect the components in the following order: first pull back the pin ⑥ as described above and insert the ratchet wheel ①.

Caution:
To avoid confusion, the ratchet wheel ① can only be inserted on one side.

Slide the spring ④ back over the torque adjustment screw ⑤.

Pass the ratchet head ② with the threaded rod through the scale sleeve ③ and screw to torque adjustment screw ⑤.

After assembly and before each use check the correct function of the torque ratchet. The instrument is ready for use when there is an audible regular ratchet noise and the mechanism of the torque limit functions.

After reassembly and before sterilization, the torque ratchet should be stress-relieved at max. 10 Ncm.

Additional information can be found at www.dentaurum.com (Processing Instructions Instruments and Accessories REF 989-801-09).

Material composition.

Implants ø 3.3, 3.7 and 4.2 mm	Titanium Grade 5
Implants ø 4.8 and 5.5 mm	Titanium Grade 4
Closure screw	Titanium Grade 5
Depth-stop sleeves	Polycarbonate USP Class VI
Gingiva former	Titanium Grade 5
Impression post:	
■ Impression post, open	Titanium Grade 5
■ Screw for impression post, open	Stainless steel, 1.4305
■ Impression post, closed and screw	Titanium Grade 5
■ Impression cap for impression post, closed	POM
Temporary abutment:	PEEK (polyether ether ketone)
■ Screw for temporary abutment	Titanium Grade 5
Titanium abutment:	Titanium Grade 5
■ Titanium abutment straight/angled	Titanium Grade 5
■ CAD/CAM titanium base	Titanium Grade 5
■ CAD/CAM titanium block	Titanium Grade 5
Scan abutment	PEEK (polyether ether ketone)
Scan abutment, titanium	Titanium Grade 5
4Base abutment	Titanium Grade 5
4Base cap:	
■ 4Base plastic cap	Polycarbonate
■ 4Base titanium cap, laser weldable	Titanium Grade 5
■ 4Base titanium cap, adhesive technique	Titanium Grade 5
■ 4Base closure screw	Titanium Grade 5
■ 4Base impression post, open	Titanium Grade 5
■ Screw for 4Base impression post, open	Stainless steel, 1.4305
■ 4Base impression post, closed	Titanium Grade 5
■ Impression cap for 4Base impression post, closed	POM
■ 4Base scan cap, titanium	Titanium Grade 5
4Base laboratory implant	Titanium Grade 5
4Base scan cap, titanium	Titanium Grade 5
Ball abutment	Titanium Grade 5
Ball abutment laboratory implant	Aluminum
tioLOC abutment	Titanium Grade 5
Prosthetic screws:	
■ AnoTite screw	Titanium Grade 5
■ Prosthetic screw	Titanium Grade 5
■ Retaining screw	Titanium Grade 5

■ Titanium Grade 4 DIN EN ISO 5832-2	
Chemical composition (% by mass)	
O	0.4 % max.
Fe	0.5 % max.
C	0.1 % max.
N	0.05 % max.
H	0.0125 % max.
Ti	Rest
Physical and mechanical properties	
0.2% yield strength	520 MPa min.
Tensile strength	680 MPa min.
Elongation at rupture	10 % min.

■ Titanium Grade 5 DIN EN ISO 5832-3	
Chemical composition (% by mass)	
Al	5.5 % – 6.75 %
V	3.5 % – 4.5 %
Fe	0.3 % max.
C	0.08 % max.
N	0.05 % max.
H	0.015 % max.
O	0.2 % max.
Ti	Rest
Physical and mechanical properties	
0.2% yield strength	780 MPa
Tensile strength	860 MPa
Elongation at rupture	10 % min.

■ PEEK	
Chemical composition (% by mass)	
Thermoplastic high-performance polymer	
Physical and mechanical properties	
Yield strength	95 MPa
Elongation	> 25 %
Modulus of elasticity	4.2 GPa
Operating temperature	260 °C / 300 °C (500 °F/572 °F) (continuous/temporary)

The SSCP is available at **https://ec.europa.eu/tools/eudamed** and **www.dentaurum.com**.

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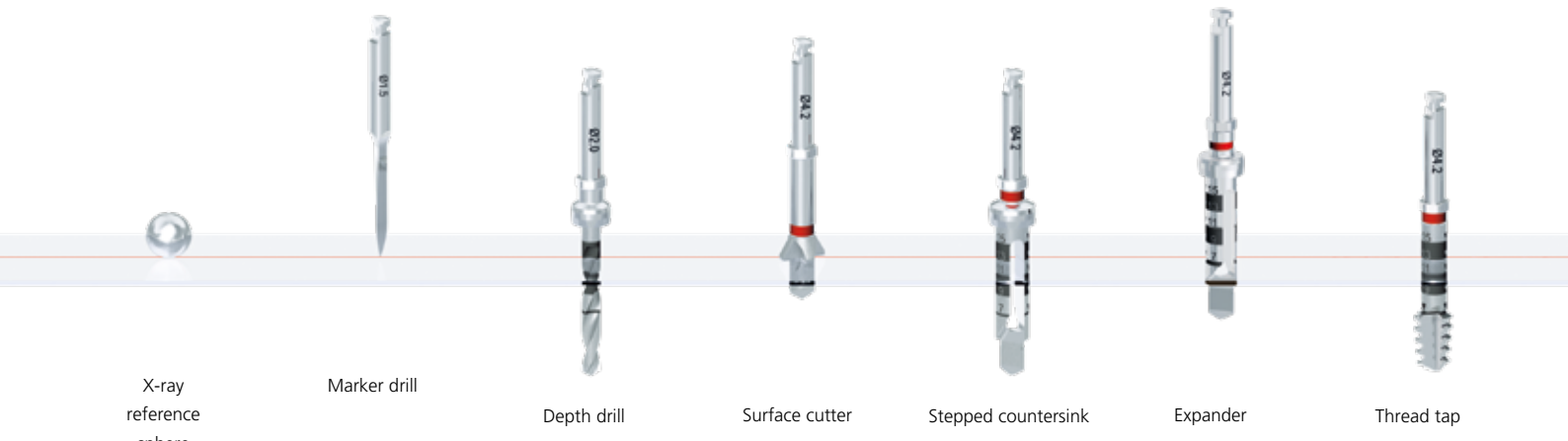


X-ray reference sphere

Marker drill

Depth drill

Surface cutter

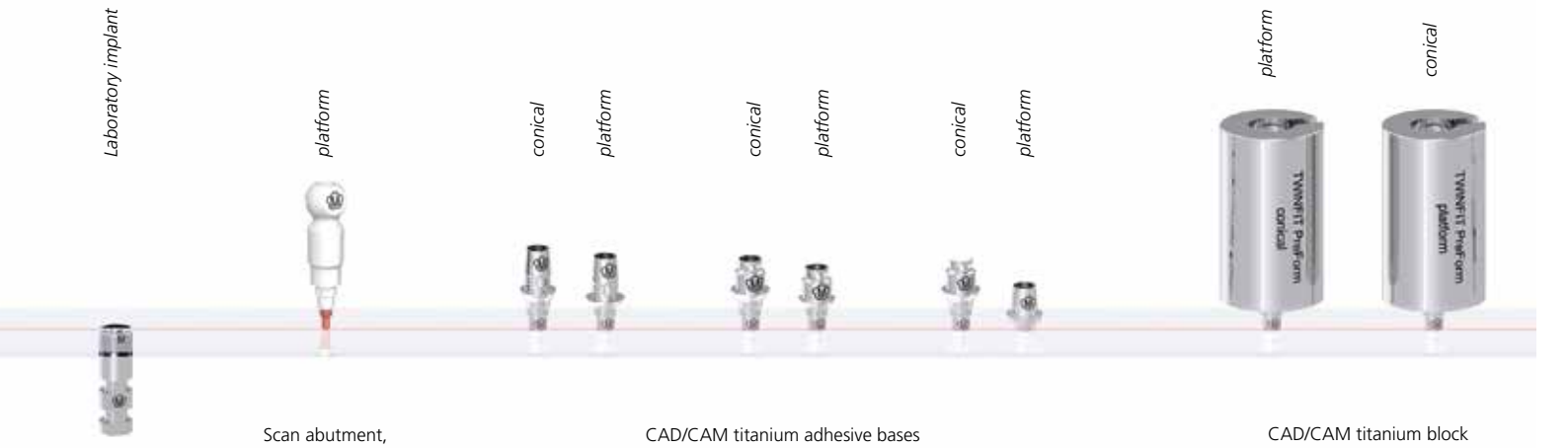
Stepped countersink

Expander

Thread tap

ADVANCED

Prosthetics – tioLogic® TWINFIT.



Scan abutment, titanium

CAD/CAM titanium adhesive bases

CAD/CAM titanium block

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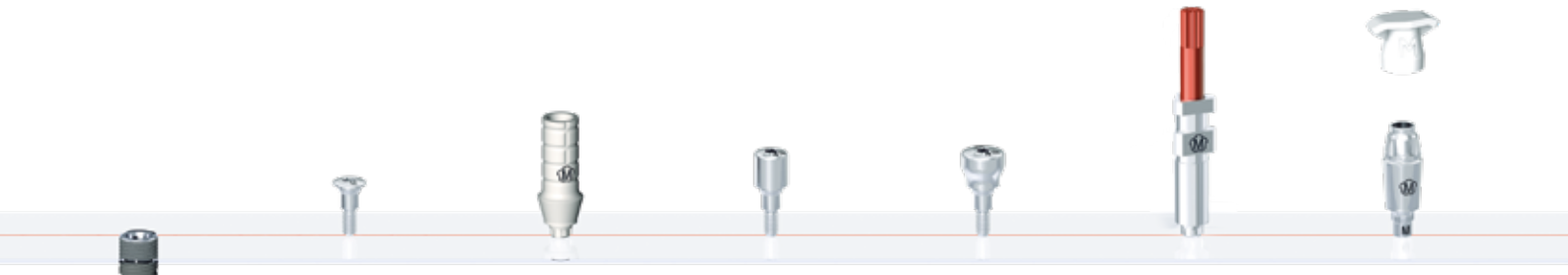
SURGERY.



Implant

Closure screw, platform

Temporary abutment, platform

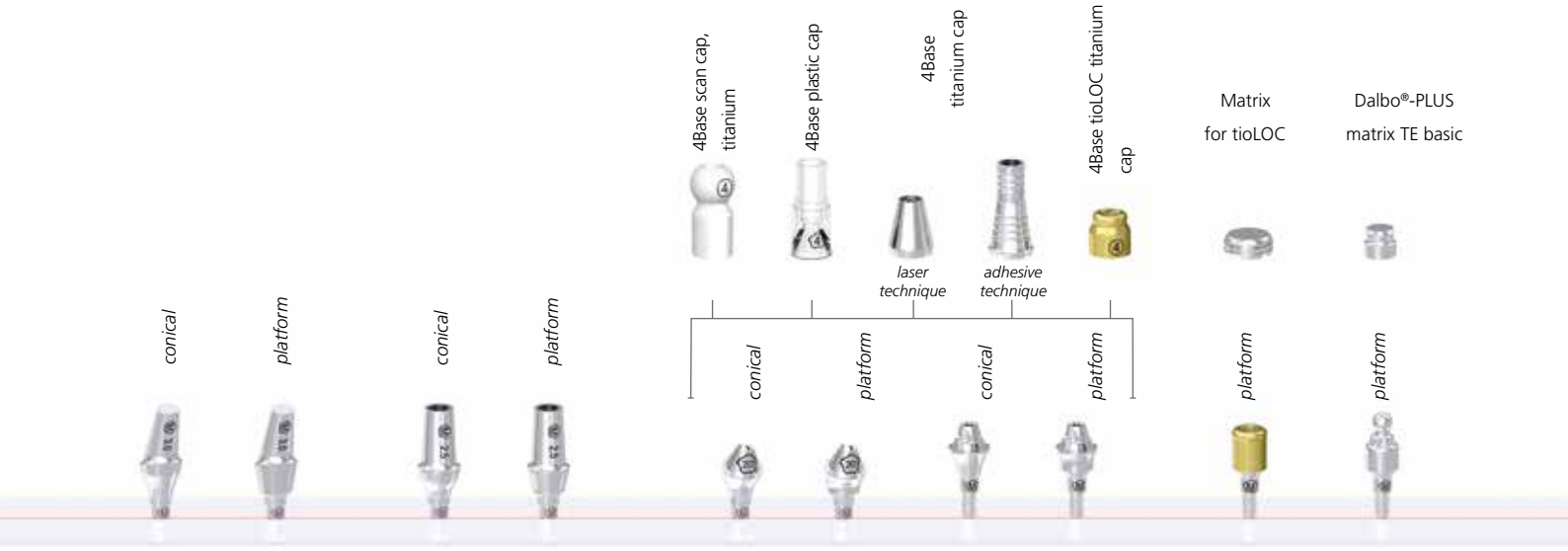
Gingiva former, cylindrical, platform

Gingiva former, anatomical, platform

Impression post, open and screw, platform

Impression post and cap, closed, platform

tiologic®
PROSTHETICS.



Titanium abutment, angulated

Titanium abutment, straight

4Base abutment, angulated

4Base abutment, straight

tioLOC abutment

Ball abutment

NOTES

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