EN

tioLogic®

Surgery Manual **ADVANCED.**

DENTAURUM IMPLANTS

Content.

Treatment procedure

General instructions

Reusability of surgical instruments

Safety instructions.

Manufacturer.

Dentaurum Implants GmbH I Turnstraße 31
75228 Ispringen I Germany

Brief description.

The tioLogic© implant types are designed for insertion in the endosteal region of the maxilla or mandible. Depending on the indication, the relevant transgingival abutments are secured on the implants and fitted with a prosthetic restoration.
The tioLogic© implant system contains specially coordinated instruments, abutments and accessories for insertion of the implant and fabrication of the prosthetic restoration. Only original components of the tioLogic© implant system should be used in combination according to the instructions for use/manuals.

Further information.

Though insertion of dental implants has a high rate of success and implants have a high survival rate, successful treatment cannot be guaranteed. The operator should note and document any problem cases and inform Dentaurum Implants.
An inadequate number of implants, implants with an insufficient length or diameter, unfavourable positioning of the implants or an unstable prosthetic restoration can cause fatigue fracture in implants, abutments and prosthetic screws under biomechanical loading. The particular oral situation should be taken into account during implant insertion and fabrication of the prosthetic restoration to avoid overloading the components.

Use of tioLogic© implant system components in combinations that are not clearly defined in the instructions for use can also cause mechanical failure, damage to the tissue or unsatisfactory aesthetic results.
The tioLogic© implant types are not known to have any side effects or cause any interaction. It cannot, however, be ruled out that in rare cases allergies to components used in the materials of the tioLogic© implant system may occur or that there may be electrochemically induced discomfort.

Application, availability, precautions, documentation.

The tioLogic© 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 implantological procedures, including diagnosis, preoperative planning, surgical technique and prosthetic treatment.
Before using the system, operators should ensure that they have carefully read and understood all the information in the tioLogic© instructions for use/manuals. Operators are also strongly advised to attend one of the training courses on the tioLogic© system offered by Dentaurum Implants to learn the correct techniques because the instructions for use/user manuals cannot cover all possible clinical situations to allow immediate use.

SAFETY

- Refer to the Product Catalogue and Surgery Manuals for information on precautionary measures and the selection of components for the clinical procedure.
- Refer to the Product Catalogue and Prosthetic Manuals for information on precautionary measures and the selection of components for the prosthetic procedure.

Before using this product, the operator must give the patient a thorough examination and a detailed explanation of the procedure.

Dentaurum Implants recommends full clinical, radiological, photographic and statistical documentation. The tioLogic© implant system components used can be documented in the patient file or patient ID card with the additional labels.

The operator should ensure the products cannot be aspirated during intraoral use.

Several components are not available in all countries.

Quality, warranty and liability, development.

Development, clinical testing, production and quality control of the tioLogic© product range are in accordance with the Medical Device Directive 93/42/EEC.

Sections 9 and 10 of our General Terms of Delivery and Payment apply with regard to warranty and liability – unless otherwise stated in the instructions for use/manuals.

Warranty and liability are rendered void if the products are not used by the operator or a third party in accordance with the instructions for use; this also applies if the tioLogic© product range is used in conjunction with the products of other manufacturers, which have not been specifically recommended for use by Dentaurum Implants.

Dentaurum Implants has no control over processing and application of the product, which are the sole responsibility of the user.

Technical advice (oral and written) is based on the scientific and technical knowledge available when the product is put on the market. The user is still responsible for personally checking the suitability of the products for the intended indication and application. Advice is given only as non-binding recommendations, which do not imply any form of assurance or guarantee.

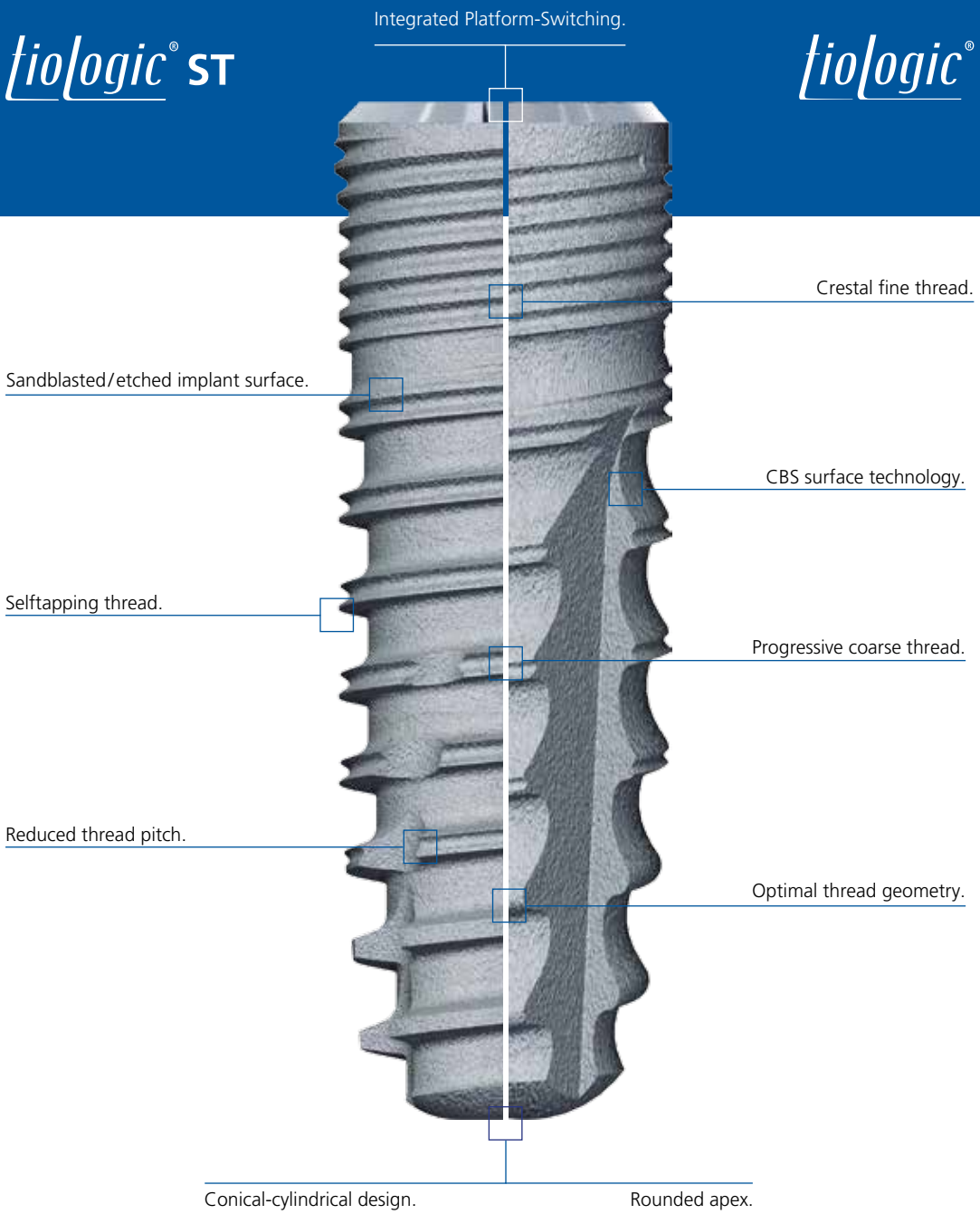
All products are subject to continuous development based on current scientific knowledge and we reserve the right to make changes in the construction, design or material of the products.

The tioLogic© implant system.

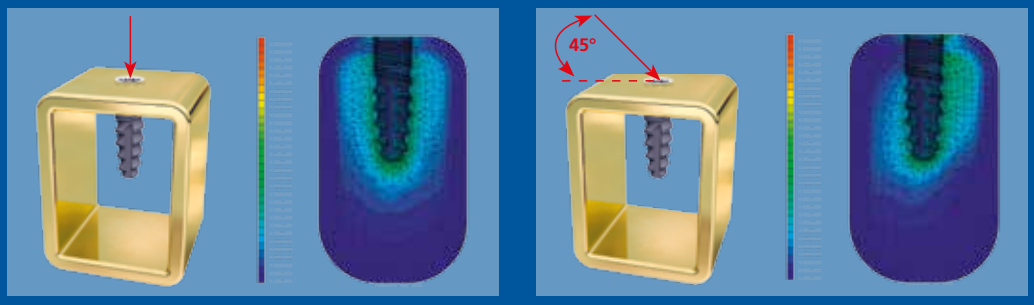
The tioLogic© implant types.

tioLogic® ST

tioLogic®



FEM-optimized implant shape and thread geometry.[1,2,3]



External geometry.

The design of the tioLogic© implant types shape and thread geometry were calculated and recorded based on FEM analyses[1]. These tests indicated uniform, gentle loading of the bone, which avoided stress peaks that could damage the bone and localized overloading.

The tioLogic© implant types have a cylindrical-conical external geometry and a rounded apex. The non-sandblasted polished cervical chamfer (integrated platform switching) of the implant shoulder is 0.3 mm and takes into account the biological width.

tioLogic© - In the crestal region, the implant is provided with a fine thread that is adapted to the cortical bone density. The progressive coarse thread, which follows seamlessly, is tailored to the density of the spongiosa bone and has three radial vertical grooves. The design of the thread flanks and the contour of the thread depth and pitch of the implant have been developed to provide optimum load distribution in the bone. The endosseous region of the tiologic© implant has a Ceramic Blasted Surface (CBS).

tioLogic© ST – The modified self-tapping thread geometry and reduced thread pitch of the tioLogic© **ST** enable a quick and atraumatic implant insertion at a steady insertion torque and a high primary stability. The endosseous region of the tioLogic© **ST** implant surface is blasted and etched. In addition, the tioLogic© **ST** 7.0mm implant extends the range of indications for limited vertical bone availability.

The implant site for the tioLogic© **ST** and tioLogic© implants is prepared with the same rotary instruments.

[1] A. Rahimi, F. Heinemann, A. Jäger, C. Bourauel: Biomechanical studies on the influence of thread versions of the tioLogic© implant, University of Bonn, Germany 2006.

[2] Bibliography (Studies and Publications) Dentaurum Implants, REF 989-767-10, 2011.

[3] I. Hasan, H. Stark, C. Bourauel: Biomechanical studies on the tioLogic© **ST** implant; University of Bonn, Germany 2012.

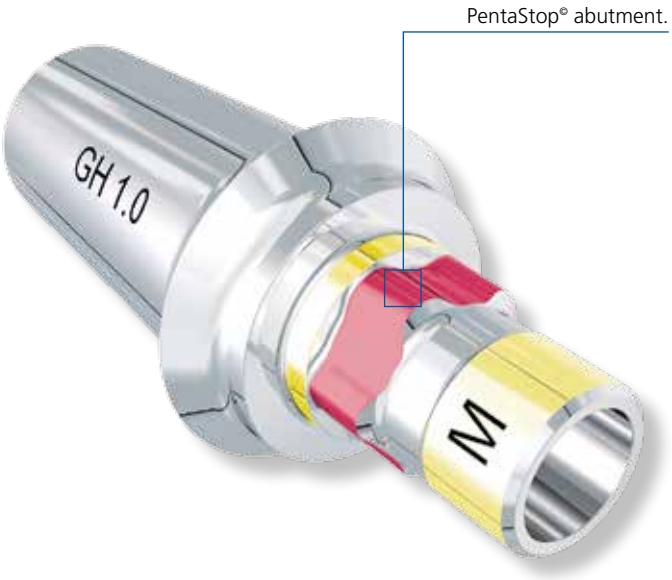
The tioLogic© implant system.

FEM-optimized internal geometry[4] and ISO-compliant fatigue strength.[5]

Internal geometry.

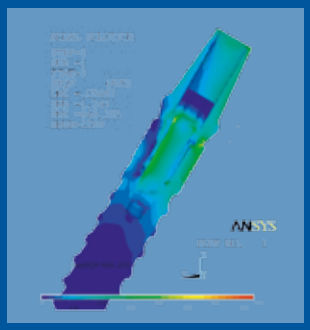
The design of the internal cylinders and of the rotationally secure internal geometry (PentaStop©) of tioLogic© implant types was calculated and verified in FEM analyses[4] and physical tests by the Fraunhofer Institute for Material Mechanics using an ISO 14801-compliant fatigue test[5]. In each of the FEM simulations the internal geometry, which was based on the results of the FEM analyses, shows a high distortional and flexural strength and a high flexural strength in the physical studies of the fatigue test under continuous load.

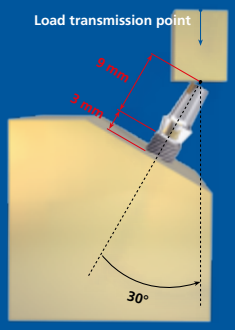
The internal geometry comprises an upper cylindrical contact surface, the PentaStop© rotational security and a lower cylindrical contact surface.

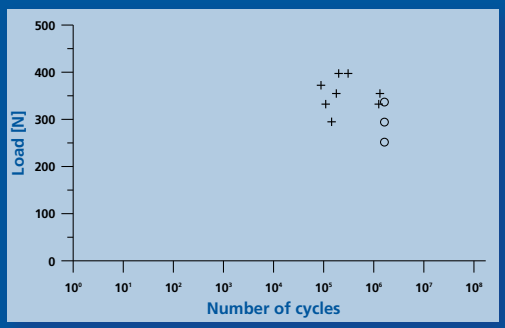


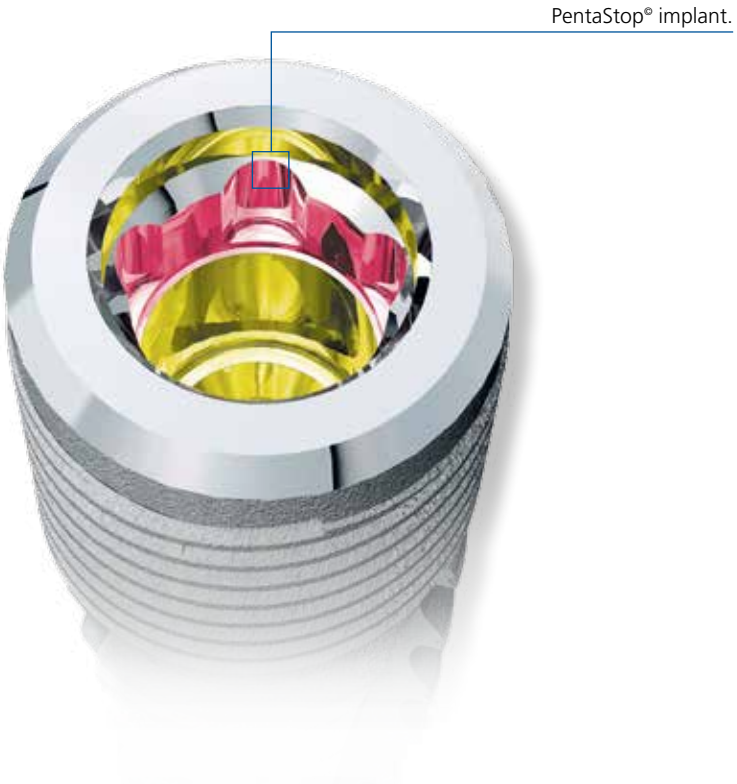
[4] F. O. Kumala: Analyse des tioLogic© Implantats mittels FEM (Analysis of the tioLogic© implant using FEM); CADFEM Stuttgart 2006.

[5] R. Schäfer, R. Jaeger, D. Ulrich, U. Köster: Bestimmung der Ermüdungsfestigkeit eines Dentalimplantats (Determination of the fatigue strength of a dental implant); Fraunhofer Institut Werkstoffmechanik Freiburg 2006
DIN EN ISO 14801: 2003, Ermüdungsprüfung für enossale dentale Implantate (Fatigue test for endosseous dental implants), DIN – Deutsches Institut für Normung, Berlin.
DIN – Deutsches Institut für Normung, Berlin.









The upper cylindrical contact surface is shortened. This precise cylindrical connection guarantees optimal centring of the system components and transmits the transversal forces into the internal geometry. The integrated PentaStop© rotational security is designed to ensure maximum rotational stability and excellent flexibility when positioning system components. The prosthetic components can be optimally aligned using the 5 positioning options; incorrect positioning is easily detected. The lower cylindrical contact surface is positioned directly below the rotational security and is longer. Any bending moments are smoothly transmitted by this contact surface. The cylinder also allows accurate guidance and quick, reliable orientation in the longitudinal axis of the implant before the PentaStop© rotational security engages.

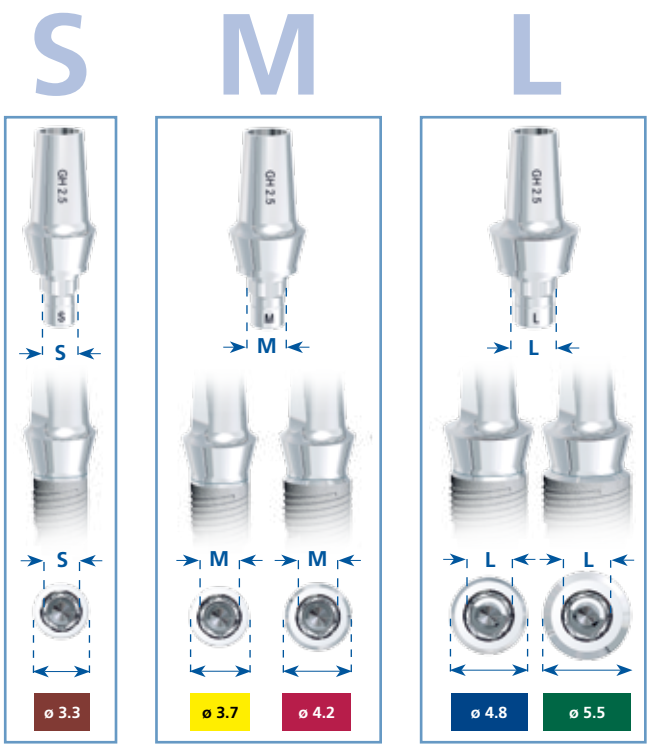
The tioLogic© implant system.

The S - M - L concept.

5 implant diameters. **6** implant lengths. **3** series of abutments.

Integrated platform-switching.

The optimal grading of implant diameters and lengths ensures that the appropriate implant is used for the indication. Components of the 3 series of abutments are made of plastic (temporaries), zirconia, Titanium and precious metal and include CAD/CAM, bars, ball abutment, AngleFix, SFI-Bar®, LOCATOR® and magnets. The construction components S are used for the implant diameter 3.3 mm, the construction components M for the implant diameters 3.7 mm and 4.2 mm and the construction components L for the implant diameters 4.8 mm and 5.5 mm. For exact identification all components are marked with S, M or L by laser.



3 series of abutments.

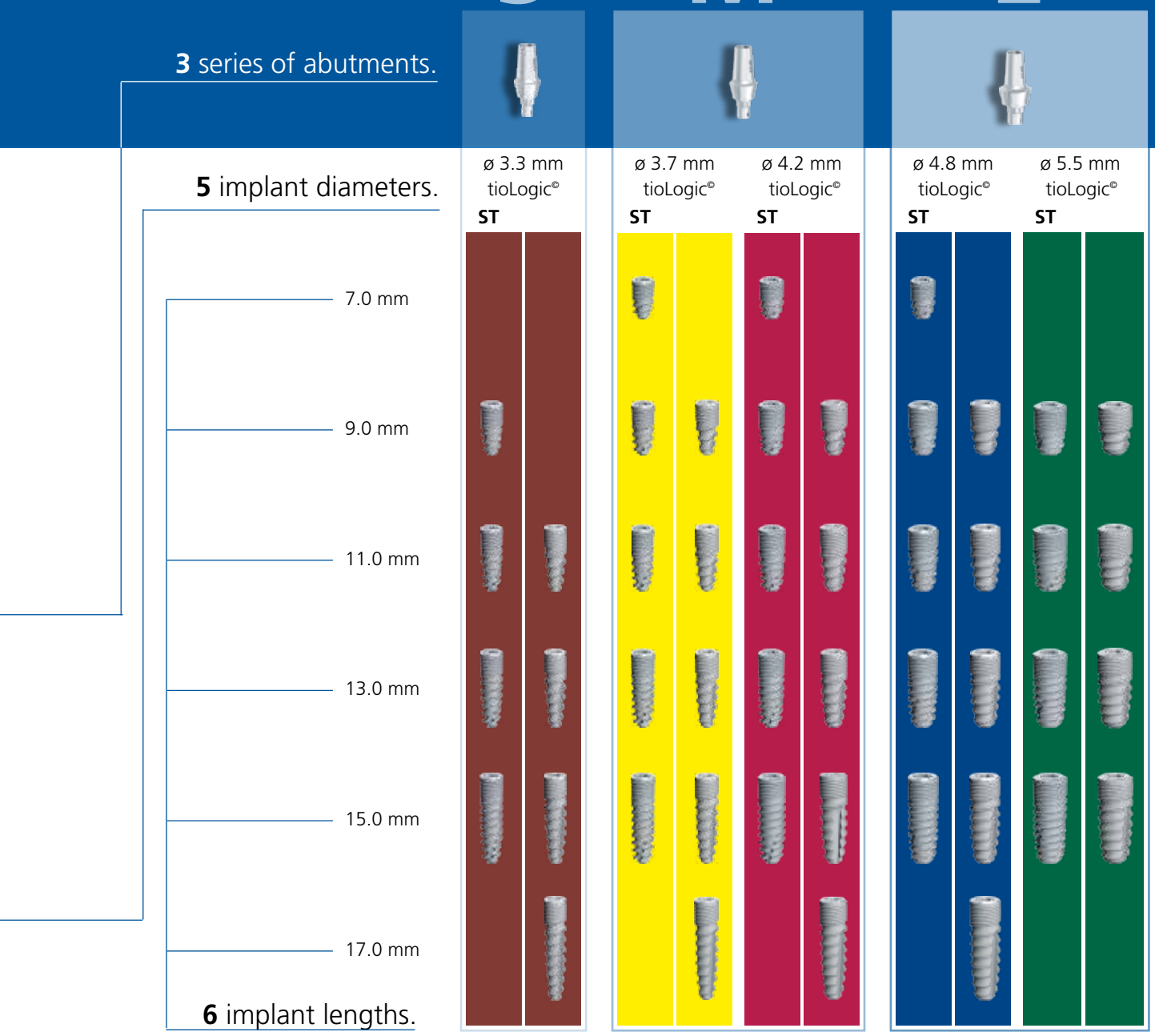
5 implant diameters.

Prosthetic screw

3 series of abutments.

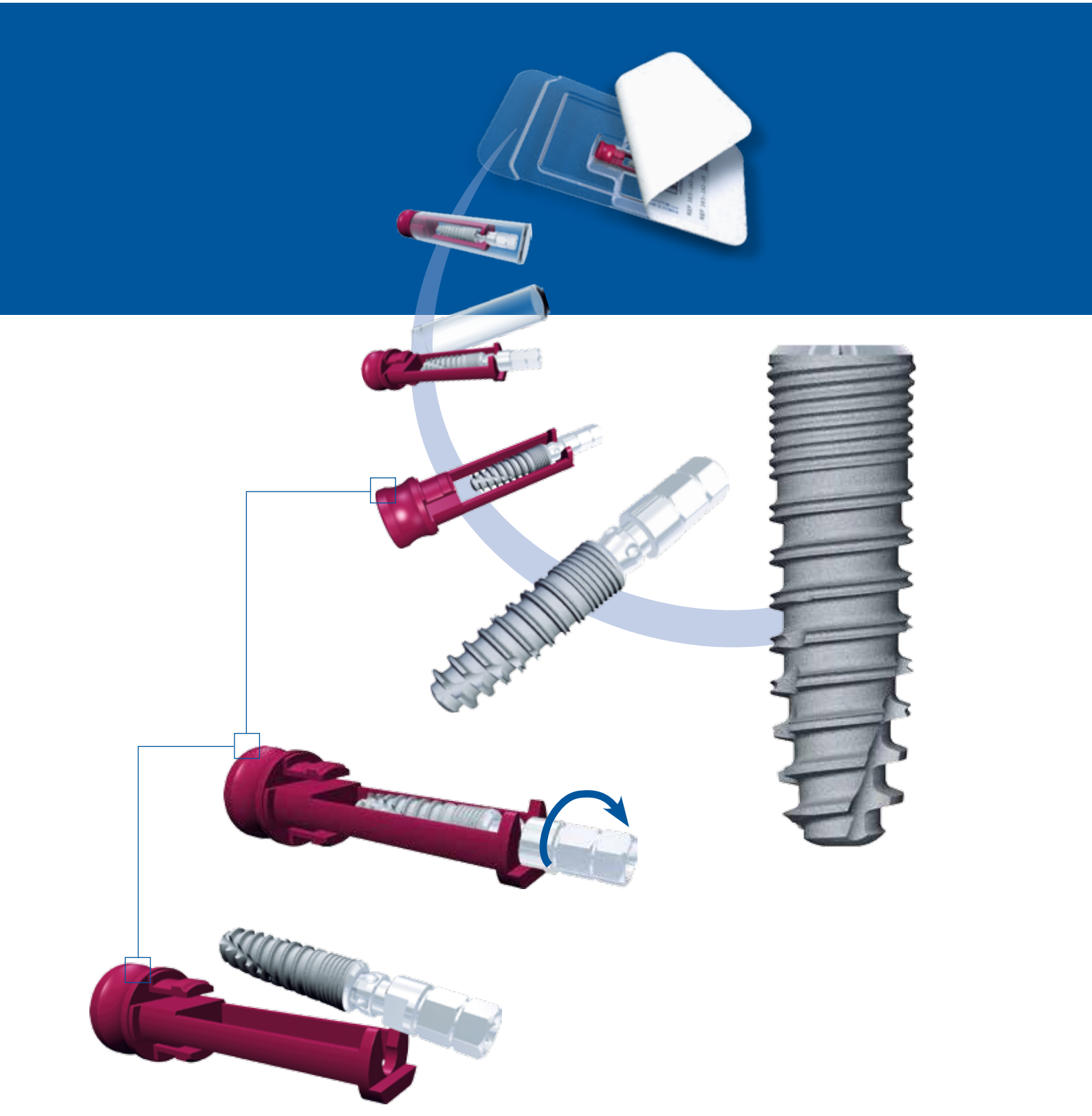
5 implant diameters.

6 implant lengths.

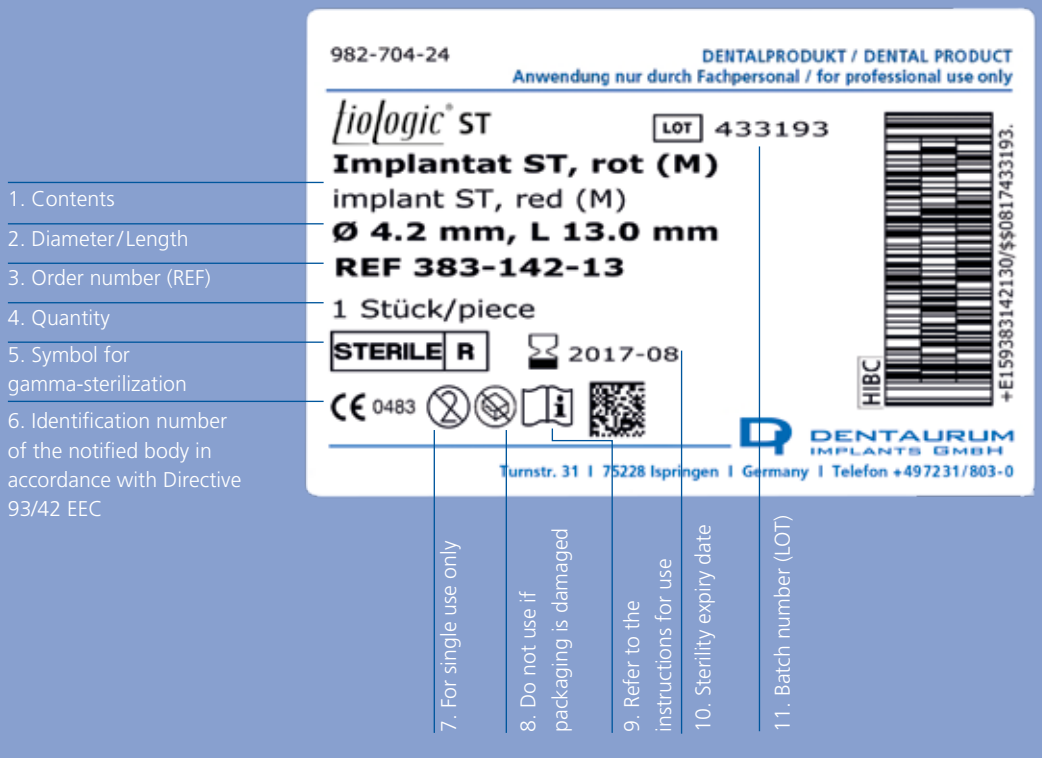


All abutments and implants on a scale of 1:1.

Sterile packaging system.



LABEL



All tioLogic© implant types are supplied individually with the respective closure screw 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 and closure screw against contamination. The contents remain sterile as long as the packaging is undamaged. The product should not be used if the double packaging is damaged.

The implant is also safely stored and protected in a glass vial in the blister packaging. The implant has an integrated insertion aid and is attached to a colour-coded implant holder. It can be removed and placed directly contact-free or with a manual or handpiece extension.

The double packaging (foil and blister packaging) is also protected by outer packaging. The label on the outer packaging gives the order number, the description, length and diameter of the implant, the sterility expiry date and LOT number. There are also self-adhesive labels in the outer packaging and four additional labels in the packaging with peel-off REF and LOT numbers for documentation in the PatientPass (REF 989-961-20) and the surgical protocol.

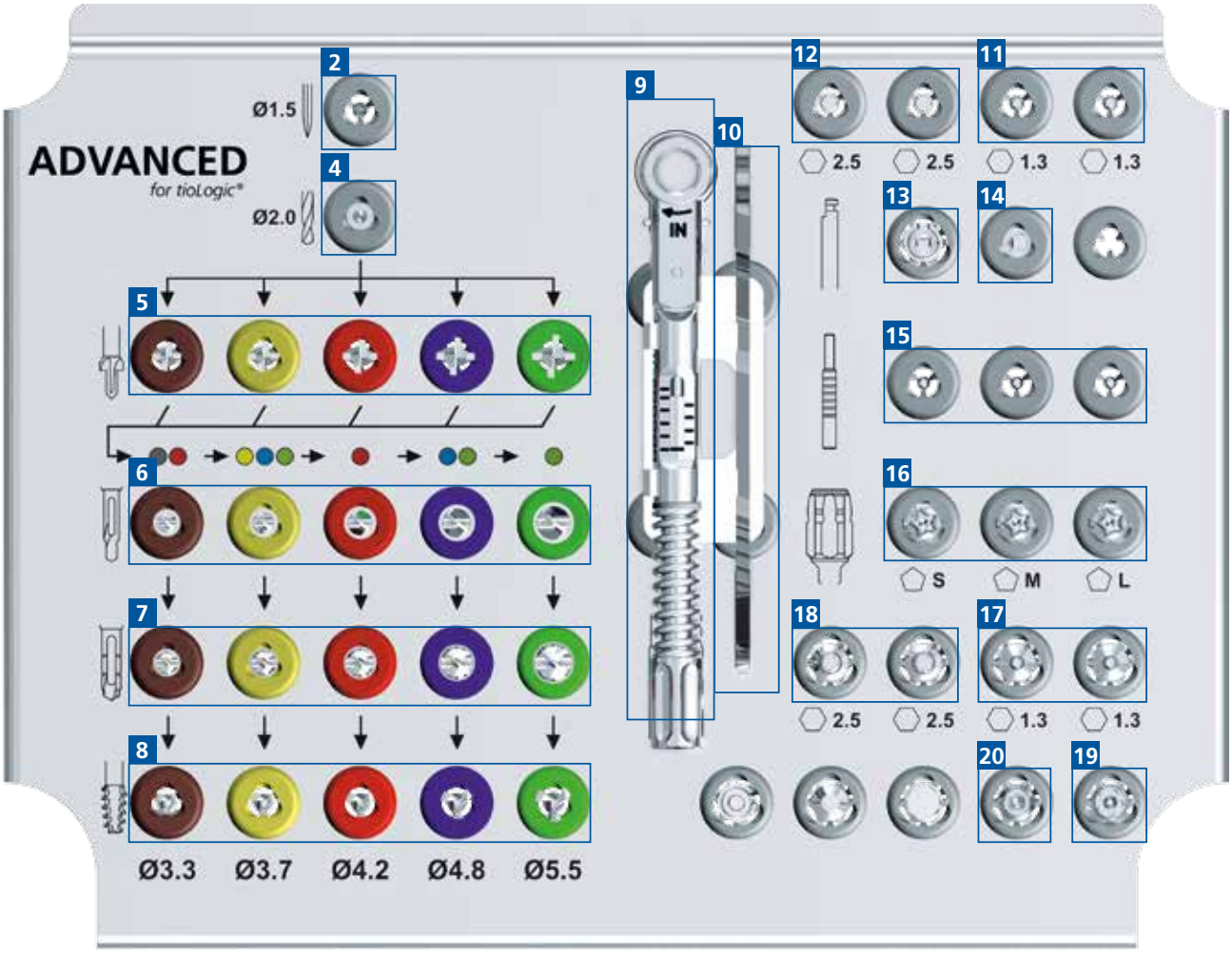
tioLogic© implants should only be stored in the original packaging at room temperature dry and in a dark place. The implant should not be used after the expiry date (see label).

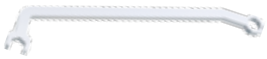
Handling the sterile packaging is described in detail in section implant insertion, p. 52.

tioLogic© surgical tray ADVANCED.

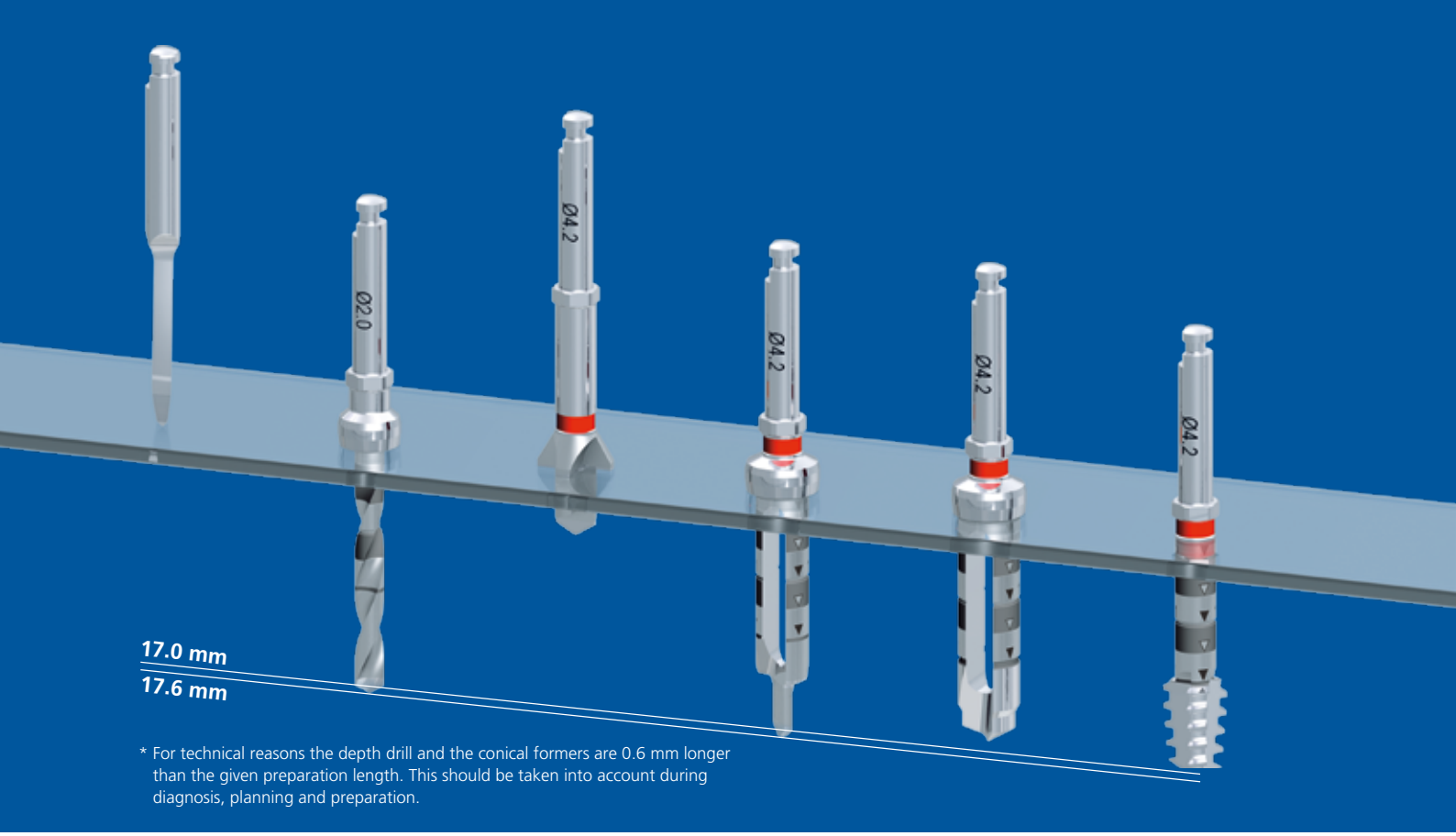
The newly developed instrument set of the **tioLogic© surgical tray ADVANCED** provides maximum flexibility during preparation of the implant site while reducing instrument diversity. The ADVANCED rotary instruments thus enable atraumatic preparation specially tailored to the bone quality collection of bone chips and individual regulation for attaining the 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 colour-coded according to the diameter of the respective implant and have a hexagonal fixation system for transferring high torques. The tioLogic© surgical tray ADVANCED is designed for placement of both the tioLogic© **ST** and the tioLogic© implants.



1. Pre-Drill for guide sleeves*		Determining implant position and alignment (L 17.0 mm and L 21.0 mm)
2. Marking drill		Marking the insertion point
3. Pilot drill*		Small diameter of 1.4 mm for pilot drilling with depth markings
4. Depth drill ADVANCED		Preparing the depth to the length of the implant, 2.0 mm diameter, integrated depth stop
5. Surface cutter ADVANCED		Preparing a flat bone surface to the diameter of the implant (optional)
6. Stepped countersink ADVANCED		Preparing the implant site according to length and depth of the implant, depth markings on drill
7. Expander ADVANCED		Preparing the implant site according to length and depth of the implant, depth markings on drill
8. Thread tap ADVANCED		Cutting the thread according to length and depth of the implant, depth markings on drill
9. Torque ratchet		Manual operation with torque control for instruments and accessories
10. Locking key		Securing the insertion aid for loosening the retention screw in the implant with unfavourable bone conditions
11. Hex key SW 1.3 – ISO shank, L 20.0/26.0 mm		Hex key SW 1.3 – long and short for tightening and loosening screws with the handpiece
12. Hex key SW 2.5 – ISO shank, L 19.0/25.0 mm		Hex key SW 2.5 – long and short for thread tapping and implant insertion with the handpiece
13. Adapter – ISO shank hexagon/ratchet		Manual operation of handpiece instruments and accessories with sure-grip wheel or ratchet
14. Drill extension – ISO shank		Extension of handpiece instruments and accessories
15. Paralleling pin		Checking parallel alignment after pilot or depth drilling
16. Placement aid		Additional placement aid for implant insertion
17. Hex key ratchet, SW 1.3 L 16.0/26.0 mm		Hex key SW 1.3 – long and short for manual loosening and tightening of screws
18. Hex key ratchet, SW 2.5, L 8.0/13.0/23.0 mm		Hex key SW 2.5 – long, medium and short for manual thread tapping and implant insertion
19. Insertion key bar abutment – ratchet		Insertion key for manual insertion of the bar abutment
20. Insertion key ball abutment abutment – ratchet		Insertion key for manual insertion of the ball abutment
21. Insertion key LOCATOR® abutment – ratchet*		Insertion key for manual insertion of the LOCATOR® abutment
22. Insertion key Titanmagnetics® x-Line – ratchet*		Insertion key for manual insertion of the Titanmagnetics® abutment

* Not supplied with the tioLogic© surgical tray ADVANCED.



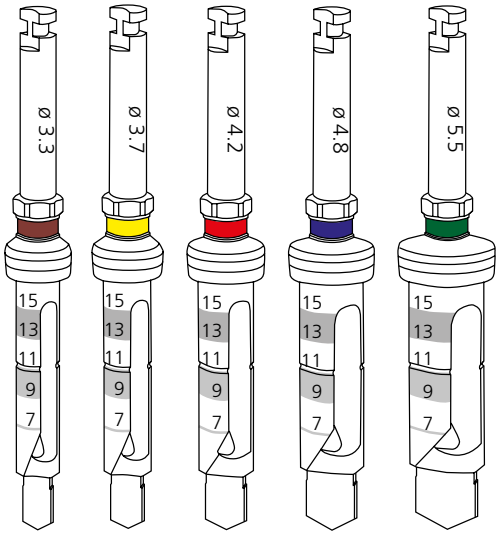
* For technical reasons the depth drill and the conical formers are 0.6 mm longer than the given preparation length. This should be taken into account during diagnosis, planning and preparation.

Coordinated instruments for reuse are available for placing tioLogic© implant types. The preparation takes place after a surgical preparation depending on the bone quality for an ideal bone compression and primary stability of the implant (p. 50).

Preparing the implant site.

- The marking drill is used for centring and marking the insertion point.
- The depth drill helps to determine the depth and the orientation of the implant independently of the diameter. It has no integrated depth stop. Appropriate depth markings (7, 9, 11, 13 and 15 mm) on the cutting edges of the depth drill will indicate whether the planned implant length has been reached. In addition, it is provided with a hexagon chucking system for the transmision of high torques.
- The surface cutter with four blades has an excellent cutting capacity, which ensures reliable preparation without applying a lot of pressure. Even before implant placement, the circular area on the bone indicates that the cervical area of the implant will be fully surrounded by bone. The surface cutter prepares the bone for the following stepped countersinking. In addition, it is provided with a hexagon chucking system for the transmision of high torques.
- The stepped countersink enlarges the implant site according to the implant contour. It has no integrated depth stop and has to be inserted up to the laser-marked depth indicators according to the diameter and length of the implant. All stepped countersinks are provided with a special hollow space for storing bone chips. The stepped countersinks are laser-marked and colour-coded according to the diameter. In addition, they are provided with a hexagon chucking system for the transmision of high torques.

Stepped countersink ADVANCED



ADVANCED Instruments.

- The expander prepares the implant site according to the diameter of the implant. It has no integrated depth stop. The insertion depth of the expander depends on the bone quality, the desired primary stability and the planned implant length. All expanders are provided with a special hollow space for storing bone chips. The expanders are laser-marked and colour-coded according to the diameter. In addition, it is provided with a hexagon chucking system for the transmision of high torques.
- The thread tap diameter is equivalent to the available implant diameters. It has no integrated depth stop. Depth markings on the thread tap will indicate whether the planned implant length has been reached. The thread tap and its diameter are laser-marked and colour-coded according to the diameter. In addition, they are provided with a hexagon chucking system for the transmission of high torques.

Design ADVANCED instruments.

All rotary instruments ADVANCED have the relevant diameter laser printed on the shank. The rotary instruments for the respective implant diameters are also colour-coded. 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 (factory new) and immediately after each use. Rotary instruments should be checked after use 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 clearly marked should be used (p. 66, section general instructions).

Rotary instruments – used with proper care and provided that they are not damaged or contaminated – can be reused in dense bone 30 to 40 times; any further reuse or the use of damaged and/or contaminated instruments should be avoided and the operator is responsible for ensuring the instruments are in good condition. No liability is accepted if these instructions are disregarded.

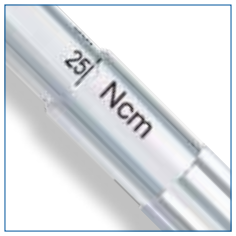
Torque ratchet.

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 (p. 72 Torque ratchet) before using for the first time and immediately after each use.

It is important to read the instructions for use carefully and check the function of the torque ratchet 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.

Accurancy of the torque ratchet according to manufacturer +/- 3 Ncm.



Application.

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 permanent prosthetic restorations. Different inserts are available depending on the application (p. 20).

The ratchet is set to the required torque using the adjusting screw. To set the correct torque, the adjusting screw is turned clockwise to the required torque line. The line on the ratchet handle should form a single line with the marking on the adjusting screw.

To decrease the torque, the adjusting screw should be set to two turns below the required torque and then turned to the correct setting.

The graduations are from 15 to 50 Ncm. As soon as the required torque is reached, the lock in the ratchet head disengages and the torque ratchet rotates freely. The recommended torques for inserting different components should not be exceeded (p. 21, table for starting torques).

The inscription "IN" should be facing upwards during insertion and "OUT" should be facing upwards during retraction. The individual inserts are inserted into the ratchet head according to the rotational security and click into place when fully engaged. The inserts are easily removed by applying light pressure to them with the thumb.

When fitting the permanent prosthetic restoration, all prosthetic screws should be tightened with the torque ratchet set at the relevant torque (p. 21 table for torque ratchet settings) and then retightened after approx. 5 minutes using the same torque. It is important that the insertion key fits flush in the prosthetic screw. We recommend using AnoTite new prosthetic screws for the final fitting.

Torque ratchet.

Overview – Inserts for the torque ratchet .

Depending on the application there are different inserts available.

Hex key SW 1.3 – ratchet, L 26.0 mm.

Hex key SW 1.3 – ratchet, L 16.0 mm.

Hex key SW 2.5 – ratchet, L 23.0 mm.

Hex key SW 2.5 – ratchet, L 13.0 mm.

Hex key SW 2.5 – ratchet, L 8.0 mm.

Insertion key ball abutment – ratchet, L 15.0 mm.

Insertion key LOCATOR® abutment – ratchet, L 15.0 mm.

Insertion key Titanmagnetics® x-Line – ratchet, L 15.0 mm

Insertion key bar/AngleFix abutment – ratchet, L 16.0 mm.

Adapter – ISO shank hexagon/ratchet.

Table – Starting torques for implants.*

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

Implant		(depending on the bone density) max. 45 Ncm	
Closure screws Implant		15 Ncm or manually	
Closure screws bar abutment		15 Ncm or manually	
Closure screws AngleFix abutment		15 Ncm or manually	
Gingiva former		15 Ncm or manually	
Adapter – ISO shank hexagon/ratchet		max. 45 Ncm	
Screw for impression post		15 Ncm or manually	
Screw for temporary abutment		15 Ncm or manually	
AnoTite prosthetic screw 9.0 mm		30 Ncm	
Bar abutment		35 Ncm	
AngleFix abutment 0° GH 1.0 mm		35 Ncm	
AnoTite screw L 6.0 mm		25 Ncm	
Ball abutment		35 Ncm	
LOCATOR® abutment		30 Ncm	
Titanmagnetics® Insert x-Line		30 Ncm	
SFI-Bar® implant Adapter		35 Ncm	

* primäry stable and osseointegrated

Overview.

Surgical treatment options and components.

Implants ø 3.3 mm, series of abutments S

Planning

X-ray reference sphere

ø 5.0 mm — **REF 330-560-00**

Guide sleeves

Length 6.0 mm — **REF 381-422-00**
Length 10.0 mm — **REF 381-420-00**

Pre-Drills guide sleeve

ø 2.0 mm
Length 17.0 mm — **REF 381-426-00**
Length 21.0 mm — **REF 381-424-00**

Rotary instruments ADVANCED reusable

Pilot drill

ø 1.4 mm
Length 17.0 mm — **REF 382-014-17**

Marking drill

ø 1.5 mm — **REF 382-015-00**

Depth drill ADVANCED

ø 2.0 mm
Length 17.0 mm — **REF 382-720-15**

Surface cutter ADVANCED

ø 3.3 mm — **REF 382-733-00**

Stepped countersink ADVANCED

ø 3.3 mm
Length 17.0 mm — **REF 382-733-15**

Expander ADVANCED

ø 3.3 mm
Length 17.0 mm — **REF 382-933-15**

Thread tap ADVANCED

ø 3.3 mm
Length 17.0 mm — **REF 382-933-00**

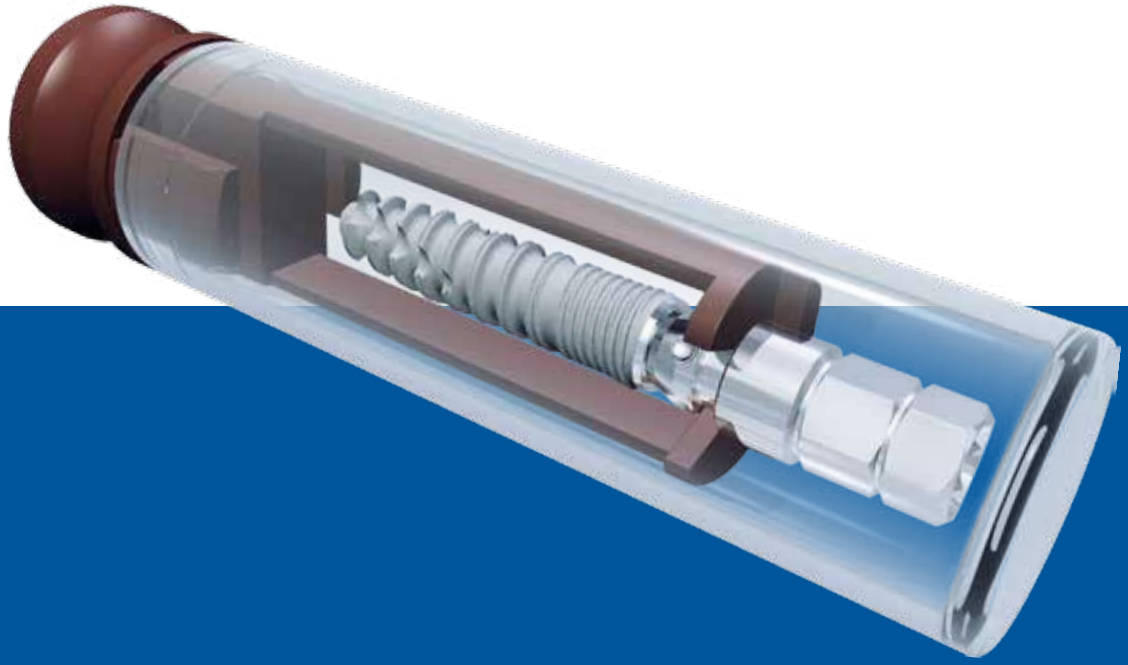
Implant types

tioLogic© ST

Length 9.0 mm — **REF 383-133-09**
Length 11.0 mm — **REF 383-133-11**
Length 13.0 mm — **REF 383-133-13**
Length 15.0 mm — **REF 383-133-15**

tioLogic©

Length 11.0 mm — **REF 383-033-11**
Length 13.0 mm — **REF 383-033-13**
Length 15.0 mm — **REF 383-033-15**
Length 17.0 mm — **REF 383-033-17**



Gingival forming S

Gingiva formers, conical

GH 1.5 mm	REF 384-110-00
GH 3.0 mm	REF 384-112-00
GH 4.5 mm	REF 384-114-00
GH 6.0 mm	REF 384-116-00

Gingiva formers, cylindrical

GH 1.5 mm	REF 384-120-00
GH 3.0 mm	REF 384-122-00
GH 4.5 mm	REF 384-124-00
GH 6.0 mm	REF 384-126-00

Temporary restoration S

Temporary abutment

GH 3.0 mm	REF 384-130-00

Impression S

Open impression

Length 10.0 mm	REF 385-110-00
Length 14.0 mm	REF 385-112-00

Closed impression

REF 385-120-00

Overview.

Surgical treatment options and components.

Implants ø 3.7 mm, series of abutments M

Planning

X-ray reference sphere

ø 5.0 mm	REF 330-560-00

Guide sleeves

Length 6.0 mm	REF 381-422-00
Length 10.0 mm	REF 381-420-00

Pre-Drills guide sleeve

ø 2.0 mm	
Length 17.0 mm	REF 381-426-00
Length 21.0 mm	REF 381-424-00

Rotary instruments ADVANCED reusable

Pilot drill

ø 1.4 mm	
Length 17.0 mm	REF 382-014-17

Marking drill

ø 1.5 mm	REF 382-015-00

Depth drill ADVANCED

ø 2.0 mm	
Length 17.0 mm	REF 382-720-15

Surface cutter ADVANCED

ø 3.7 mm	REF 382-737-00

Stepped countersink ADVANCED

ø 3.7 mm	
Length 17.0 mm	REF 382-737-15

Expander ADVANCED

ø 3.7 mm	
Length 17.0 mm	REF 382-937-15

Thread tap ADVANCED

ø 3.7 mm	
Length 17.0 mm	REF 382-937-00

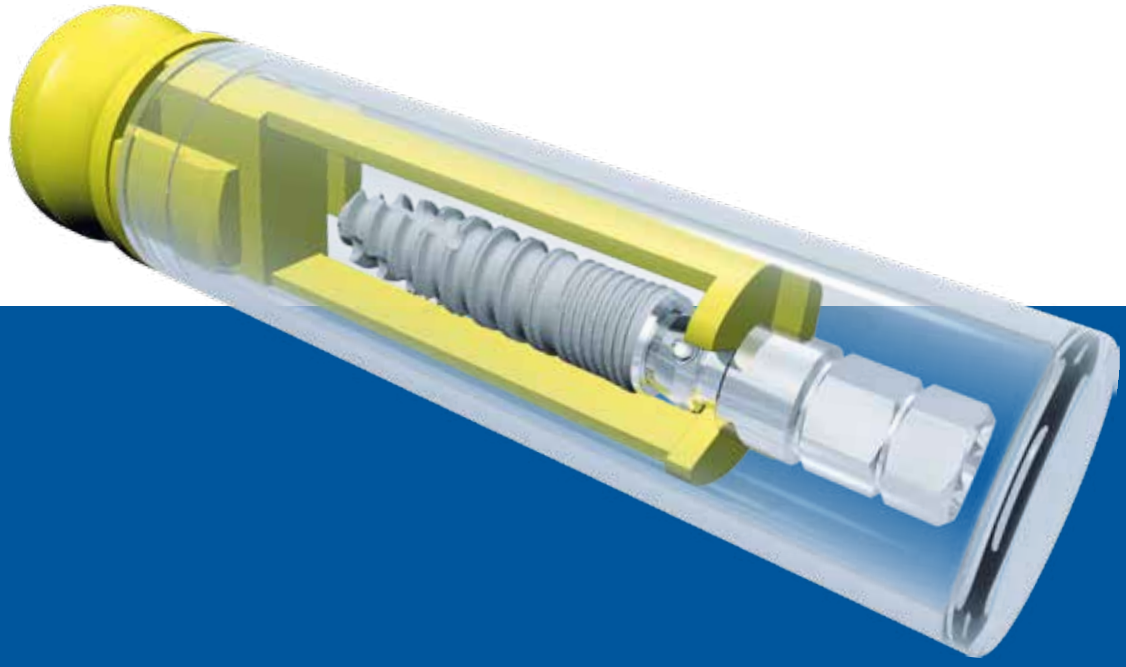
Implant types

tioLogic© ST

Length 7.0 mm	REF 383-137-07
Length 9.0 mm	REF 383-137-09
Length 11.0 mm	REF 383-137-11
Length 13.0 mm	REF 383-137-13
Length 15.0 mm	REF 383-137-15

tioLogic©

Length 9.0 mm	REF 383-037-09
Length 11.0 mm	REF 383-037-11
Length 13.0 mm	REF 383-037-13
Length 15.0 mm	REF 383-037-15
Length 17.0 mm	REF 383-037-17



Gingival forming M

Gingiva formers, conical	
GH 1.5 mm	**REF 384-210-00**
GH 3.0 mm	**REF 384-212-00**
GH 4.5 mm	**REF 384-214-00**
GH 6.0 mm	**REF 384-216-00**
Gingiva formers, cylindrical	
GH 1.5 mm	**REF 384-220-00**
GH 3.0 mm	**REF 384-222-00**
GH 4.5 mm	**REF 384-224-00**
GH 6.0 mm	**REF 384-226-00**

Temporary abutment M

Temporary abutment	
GH 3.0 mm	**REF 384-230-00**

Impression M

Open impression	
Length 10.0 mm	**REF 385-210-00**
Length 14.0 mm	**REF 385-212-00**
Closed impression	
	REF 385-220-00

Overview.

Surgical treatment options and components.

Implants ø 4.2 mm, series of abutments M

Planning

X-ray reference sphere

ø 5.0 mm — REF 330-560-00

Guide sleeves

Length 6.0 mm — REF 381-422-00
Length 10.0 mm — REF 381-420-00

Pre-Drills guide sleeve

ø 2.0 mm
Length 17.0 mm — REF 381-426-00
Length 21.0 mm — REF 381-424-00

Rotary instruments ADVANCED reusable

Pilot drill

ø 1.4 mm
Length 17.0 mm — REF 382-014-17

Marking drill

ø 1.5 mm — REF 382-015-00

Depth drill ADVANCED

ø 2.0 mm
Length 17.0 mm — REF 382-720-15

Surface cutter ADVANCED

ø 4.2 mm — REF 382-742-00

Stepped countersink ADVANCED

ø 4.2 mm
Length 17.0 mm — REF 382-742-15

Expander ADVANCED

ø 4.2 mm
Length 17.0 mm — REF 382-942-15

Thread tap ADVANCED

ø 4.2 mm
Length 17.0 mm — REF 382-942-00

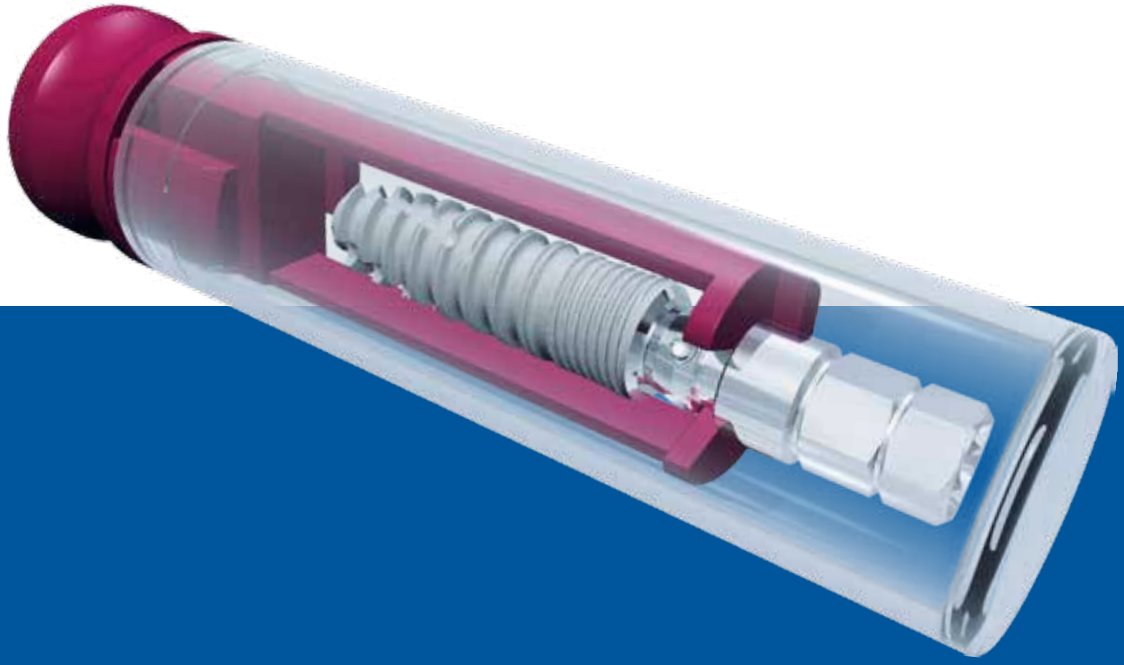
Implant types

tioLogic© ST

Length 7.0 mm — REF 383-142-07
Length 9.0 mm — REF 383-142-09
Length 11.0 mm — REF 383-142-11
Length 13.0 mm — REF 383-142-13
Length 15.0 mm — REF 383-142-15

tioLogic©

Length 9.0 mm — REF 383-042-09
Length 11.0 mm — REF 383-042-11
Length 13.0 mm — REF 383-042-13
Length 15.0 mm — REF 383-042-15
Length 17.0 mm — REF 383-042-17



Gingival forming M

Gingiva formers, conical

GH 1.5 mm	**REF 384-210-00**
GH 3.0 mm	**REF 384-212-00**
GH 4.5 mm	**REF 384-214-00**
GH 6.0 mm	**REF 384-216-00**

Gingiva formers, cylindrical

GH 1.5 mm	**REF 384-220-00**
GH 3.0 mm	**REF 384-222-00**
GH 4.5 mm	**REF 384-224-00**
GH 6.0 mm	**REF 384-226-00**

Temporary abutment M

Temporary abutment

GH 3.0 mm	**REF 384-230-00**

Impression M

Open impression

Length 10.0 mm	**REF 385-210-00**
Length 14.0 mm	**REF 385-212-00**

Closed impression

REF 385-220-00

Overview.

Surgical treatment options and components.

Implants ø 4.8 mm, series of abutments L

Planning

X-ray reference sphere

ø 5.0 mm	REF 330-560-00

Guide sleeves

Length 6.0 mm	REF 381-422-00
Length 10.0 mm	REF 381-420-00

Pre-Drills guide sleeve

ø 2.0 mm	
Length 17.0 mm	REF 381-426-00
Length 21.0 mm	REF 381-424-00

Rotary instruments ADVANCED reusable

Pilot drill

ø 1.4 mm	
Length 17.0 mm	REF 382-014-17

Marking drill

ø 1.5 mm	REF 382-015-00

Depth drill ADVANCED

ø 2.0 mm	
Length 17.0 mm	REF 382-720-15

Surface cutter ADVANCED

ø 4.8 mm	REF 382-748-00

Stepped countersink ADVANCED

ø 4.8 mm	
Length 17.0 mm	REF 382-748-15

Expander ADVANCED

ø 4.8 mm	
Length 17.0 mm	REF 382-948-15

Thread tap ADVANCED

ø 4.8 mm	
Length 17.0 mm	REF 382-948-00

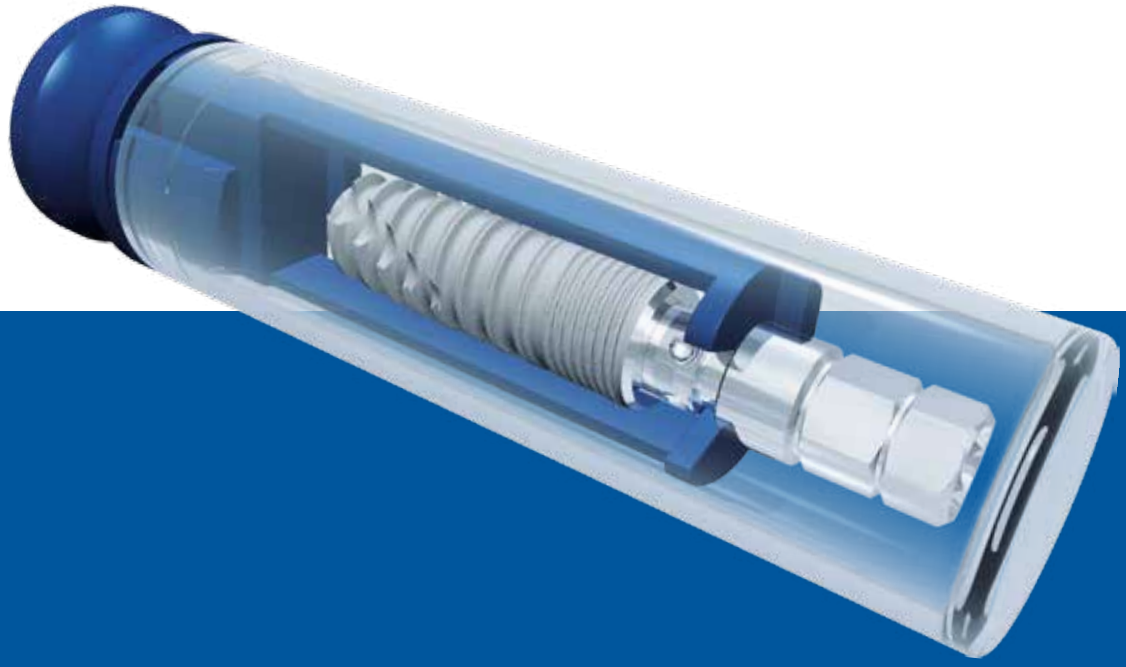
Implant types

tioLogic© ST

Length 7.0 mm	REF 383-148-07
Length 9.0 mm	REF 383-148-09
Length 11.0 mm	REF 383-148-11
Length 13.0 mm	REF 383-148-13
Length 15.0 mm	REF 383-148-15

tioLogic©

Length 9.0 mm	REF 383-048-09
Length 11.0 mm	REF 383-048-11
Length 13.0 mm	REF 383-048-13
Length 15.0 mm	REF 383-048-15
Length 17.0 mm	REF 383-048-17



Gingival forming

Gingiva formers, conical

GH 1.5 mm	**REF 384-310-00**
GH 3.0 mm	**REF 384-312-00**
GH 4.5 mm	**REF 384-314-00**
GH 6.0 mm	**REF 384-316-00**

Gingiva formers, cylindrical

GH 1.5 mm	**REF 384-320-00**
GH 3.0 mm	**REF 384-322-00**
GH 4.5 mm	**REF 384-324-00**
GH 6.0 mm	**REF 384-326-00**

Temporary abutment

Temporary abutment

GH 3.0 mm	**REF 384-330-00**

Impression

Open impression

Length 10.0 mm	**REF 385-310-00**
Length 14.0 mm	**REF 385-312-00**

Closed impression

REF 385-320-00

Overview.

Surgical treatment options and components.

Implants ø 5.5 mm, series of abutments L

Planning

X-ray reference sphere

ø 5.0 mm — REF 330-560-00

Guide sleeves

Length 6.0 mm — REF 381-422-00
Length 10.0 mm — REF 381-420-00

Pre-Drills guide sleeve

ø 2.0 mm
Length 17.0 mm — REF 381-426-00
Length 21.0 mm — REF 381-424-00

Rotary instruments ADVANCED reusable

Pilot drill

ø 1.4 mm
Length 17.0 mm — REF 382-014-17

Marking drill

ø 1.5 mm — REF 382-015-00

Depth drill ADVANCED

ø 2.0 mm
Length 17.0 mm — REF 382-720-15

Surface cutter ADVANCED

ø 5.5 mm — REF 382-755-00

Stepped countersink ADVANCED

ø 5.5 mm
Length 17.0 mm — REF 382-755-15

Expander ADVANCED

ø 5.5 mm
Length 17.0 mm — REF 382-955-15

Thread tap ADVANCED

ø 5.5 mm
Length 17.0 mm — REF 382-955-00

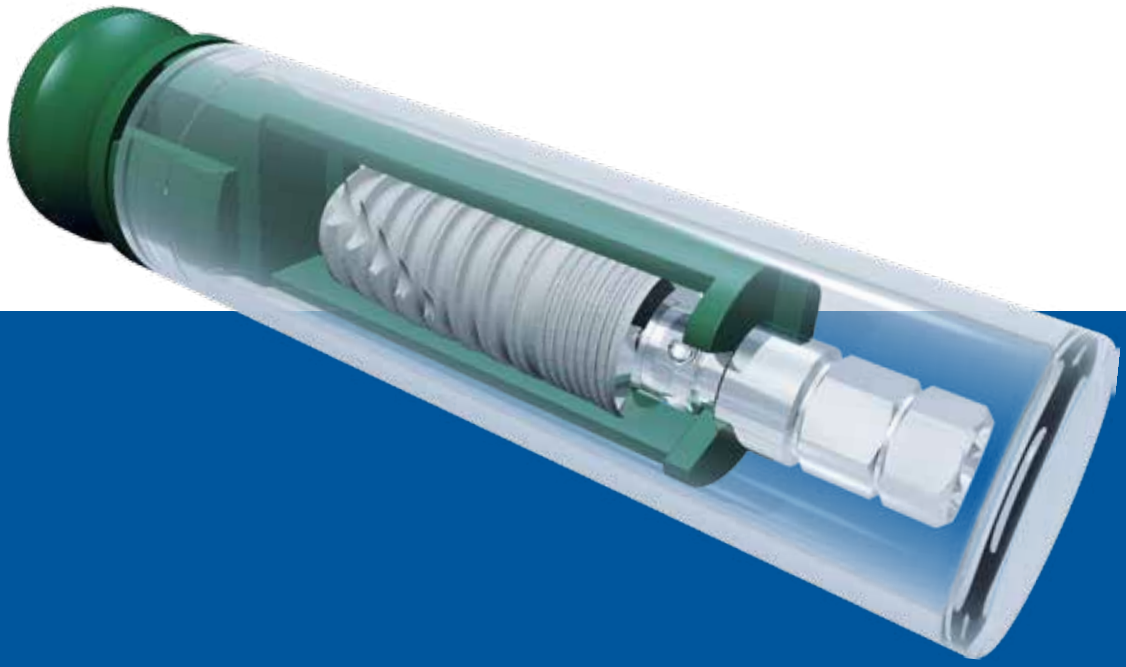
Implant types

tioLogic© ST

Length 9.0 mm — REF 383-155-09
Length 11.0 mm — REF 383-155-11
Length 13.0 mm — REF 383-155-13
Length 15.0 mm — REF 383-155-15

tioLogic©

Length 9.0 mm — REF 383-055-09
Length 11.0 mm — REF 383-055-11
Length 13.0 mm — REF 383-055-13
Length 15.0 mm — REF 383-055-15



Gingival forming L

Gingiva formers, conical

GH 1.5 mm	**REF 384-310-00**
GH 3.0 mm	**REF 384-312-00**
GH 4.5 mm	**REF 384-314-00**
GH 6.0 mm	**REF 384-316-00**

Gingiva formers, cylindrical

GH 1.5 mm	**REF 384-320-00**
GH 3.0 mm	**REF 384-322-00**
GH 4.5 mm	**REF 384-324-00**
GH 6.0 mm	**REF 384-326-00**

Temporary abutment L

Temporary abutment

GH 3.0 mm	**REF 384-330-00**

Impression L

Open impression

Length 10.0 mm	**REF 385-310-00**
Length 14.0 mm	**REF 385-312-00**

Closed impression

REF 385-320-00

Diagnosis and planning.

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

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

Indications.

The tioLogic© 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 (single-tooth restorations, increasing the number of abutments) in the maxilla and mandible, a shortened dentition or 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.

In any implantological case the implant diameter and length of the tioLogic© implant types should be in proportion to the prosthetic restoration. Implants with a minimum diameter of 4.2 mm should always be used for restorations that subject the implant and superstructure to high mechanical loading if this is practical with the particular oral situation.

The tioLogic© implant types S ø 3.3 mm are available for indications with a reduced bucco-lingual bone width. They have limited application due to their smaller diameter and lower loading capacity (compared with e.g. tioLogic© implant types M ø 4.2 mm).

In an edentulous jaw a minimum of four tioLogic© implants S ø 3.3 mm should be placed and fitted with a splinted bar restoration.

With implant-borne restorations in a partially edentulous jaw ø 3.3 mm implants should be used in conjunction with tioLogic© implant types M ø 4.2 mm and fitted with a fixed, splinted prosthetic restoration.

With single-tooth restorations, ø 3.3 mm implant types should only be used for lower incisors or upper lateral incisors and with a length of at least 11.0 mm. With single tooth restorations on ø 3.7 mm, ø 4.2 mm, ø 4.8 mm and ø 5.5 mm tioLogic© implant types, a minimum length of 9.0 mm must be used.

Contraindications.

General contraindications for dental surgery apply. These include:

- educed 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

Local contraindications / 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

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.

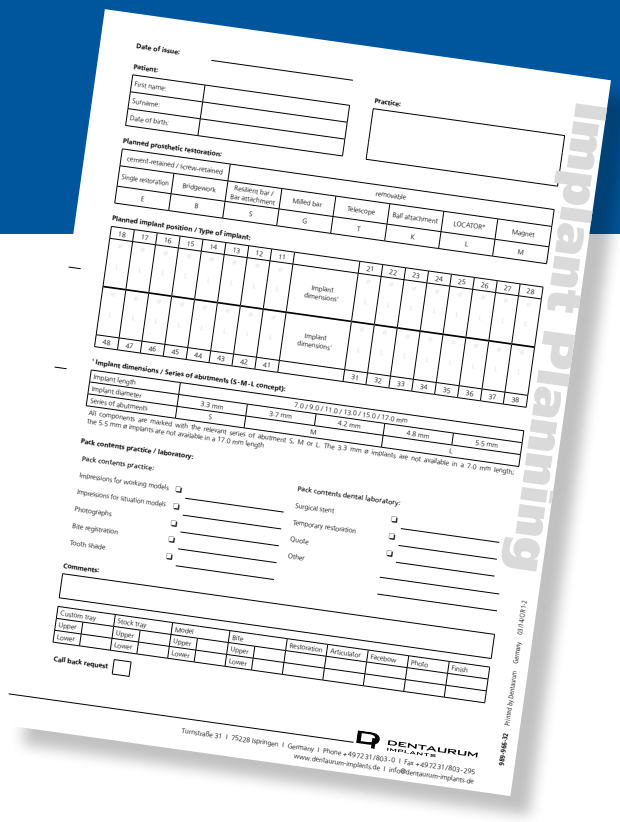
Diagnosis and planning.

Standard planning/ planning for template-guided implant insertion.

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

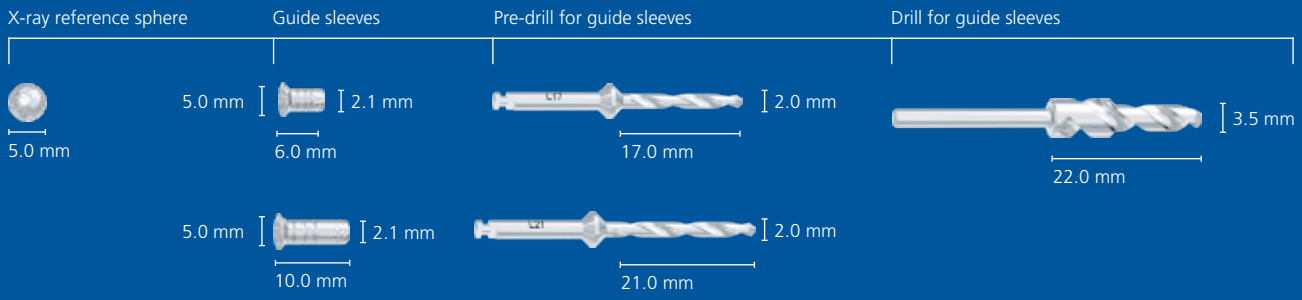
Example: Diagnosis indicates a removable restoration instead of a fixed restoration due to the probable position of the implant and the resulting loading.

In the following sections different examples are given of planning options, including the planning for template-guided implant insertion (p. 18 pOsition for tioLogic which are intended as orientation for individual cases. Other procedures can also be used in preprosthetic planning.



Implant planning form.
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.

Components used in planning STANDARD.



Diagnostic model.

Impressions are taken of the upper and lower jaw for fabricating the diagnostic models, which are mounted in an articulator after bite registration. The impression should optimally reproduce 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 will already have been considered at the planning stage.

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

Set-Up/Wax-Up, planning stent.

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, taking into consideration the residual dentition and opposing dentition. 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 ridge. The length of the teeth should be waxed up anatomically, but missing papillae should be not 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. The set-up is then waxed up as a denture base and processed in clear acrylic.

Diagnosis and planning.

X-ray stent, surgical stent.

Guide sleeves are polymerized into the plastic template in the ideal implant position and alignment for the prosthetic restoration to fabricate the X-ray foil and surgical stent. tioLogic© guide sleeves are available in lengths of 6.0 mm and 10.0 mm. If the drill that corresponds to the outer diameter of the guide sleeves is used, the guide sleeves can be vacuum-formed directly in the planned position and alignment (depending on the technique used when integrating the guide sleeves).

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. 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 foil. The position, diameter, length of the implants and their alignment in relation to the adjacent teeth can be checked two-dimensionally.

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© implants in the scale of 1:1 and in the standard enlargement scale of 1.25:1 and 1.4:1.

An orthopantomograph (OPG) can be used to provide a two-dimensional check of the planned parameters based on the X-ray foil (guide sleeves or X-ray reference spheres) and to indicate whether the position of the guide sleeves requires adjustment.

The OPG can be used to calculate the vertical bone availability using the rule of three:

Known data:

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

Data to be calculated:

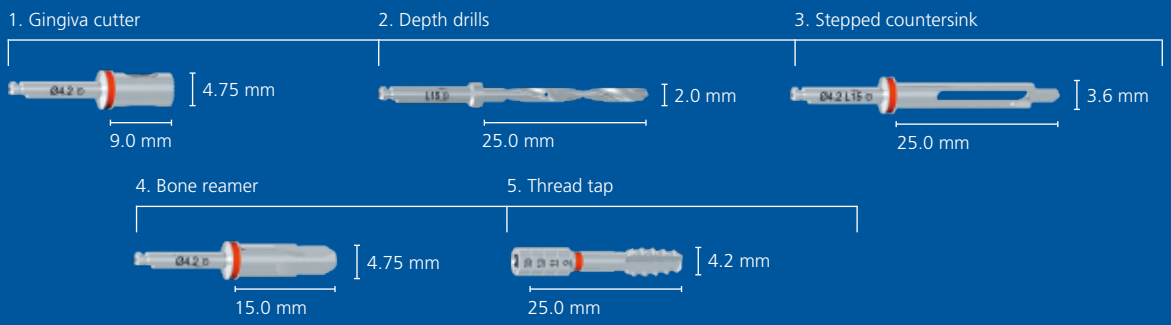
- Actual alveolar bone height (Kr)

Formula:

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

Diagnosis and planning.

Template-guided implant insertion – tioLogic© pOsition.



Template-guided implant insertion.
Accurate three-dimensional diagnostic analysis of the relevant data is only possible with the use of computer tomography (CT) or digital volume tomography (DVT). Using a CT/DVT and the relevant software programmes, data such as bone quality, bone availability and mucosal thickness can be recorded. The relevant tioLogic© implant types can also be selected from the database of the respective software programme 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 foil and surgical stent.

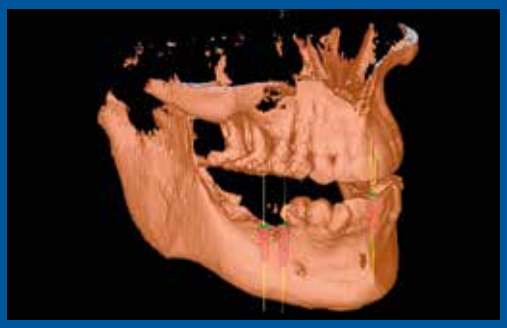
tioLogic© pOsition is a sleeve and drill system from Dentaurum Implants that ensures reliable, minimally invasive and precise template-guided implant placement using coordinated planning software for accurate diagnosis and 3D planning. (see surgery manual pOsition REF 989-999-20).

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.

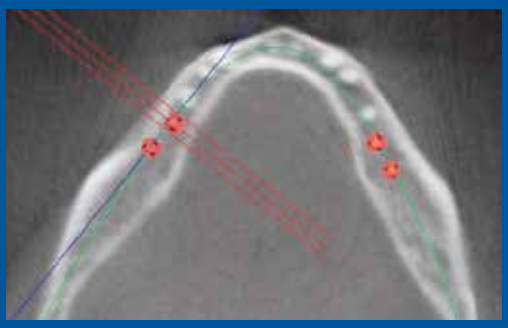
The planned implant restoration is discussed with the patient with regard to the patient's expectations (extent and cost of treatment) and a decision reached. The surgical stent is modified according to any adjustments made to the planned restoration.

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

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



3D implant positioning.



Implant positioning.

Preparation for surgery.

Users of the tioLogic© implant system should have relevant experience in implantology and dentistry and be familiar with the product. Operators 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 disinfected mouthwash solution immediately before the treatment. The perioral area should additionally be cleaned with a disinfectant solution. After that the implant insertion is normally conducted under local anesthesia.

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

- titanium membrane (TIOMESH)
- osteotomes (Osteotomie-Tray)
- special surgical instruments (TIOSET®)
- drapes (Tiodrape)

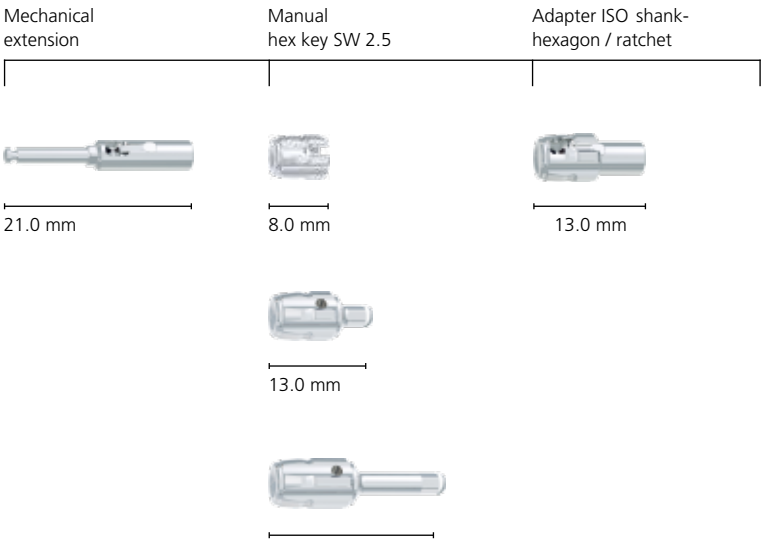
Further information is available in the tioLogic© product catalogue (REF 989-965-20).

Treatment procedure.

Instruments.

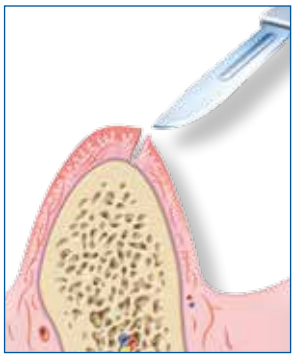
A handpiece extension and three manual hex keys are available for all rotary instruments. The handpiece instruments can also be used manually as required using an adapter (max. permitted torque 45 Ncm). The instruments should be inserted rotationally secure and the fit checked. The manual hex keys and 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. The silicone rings on the components should be replaced following surgery.



For the preparation of the implant site the rotating instruments and their drilling sequence should be chosen depending on the bone quality. A concerted preparation protocol for different bone qualities (soft, medium, dense) is available for the user (p. 50). The determination of the bone quality rests on the user.

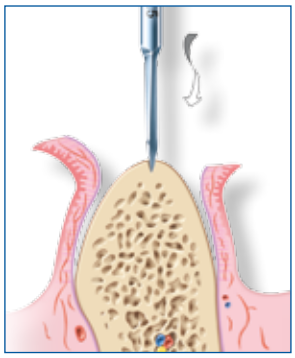
Alveolar ridge incision.



Exposing the bone.

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 the 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 foramina should be clarified before placing implants in the mandible.

Marking drill preparation.



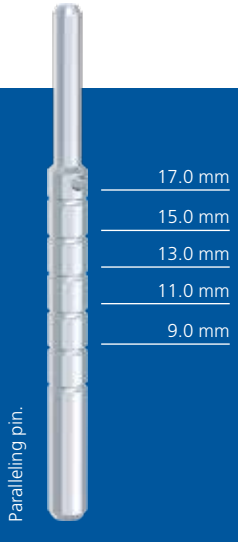
Preparing the implant site.

Preparation of the implant site is described using reusable instruments.

To illustrate the exact functionality of every rotating instrument, hereafter the preparation is explained independently to the bone quality. The template-guided preparation and implant insertion with tioLogic© pOsition is described in the Surgery Manual pOsition (REF 989-999-20).

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

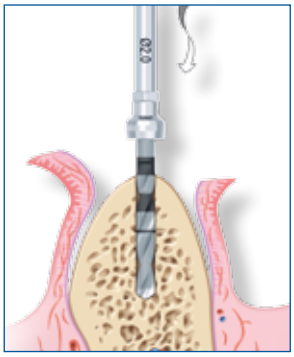
Treatment procedure.



The **depth drill ADVANCED** prepares the definitive depth and direction of the implant site independent from 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) has been reached. This guarantees reaching the exact insertion depth determined in the treatment planning. The depth drill has a diameter of 2.0 mm. For technical reasons, the depth drill is 0.6 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 transmision of high torques.

If a thinner drill is indicated due to the bone conditions, the **pilot drill** can be used prior to depth drilling. The pilot drill has a diameter of only 1.4 mm. It is used independent of diameter and can be used for any implant length, as it has depth markings corresponding to the implant lengths instead of an integrated depth stop. The respective depth markings on the pilot drill indicate when the prescribed implant length is reached.

Depth drilling ADVANCED.

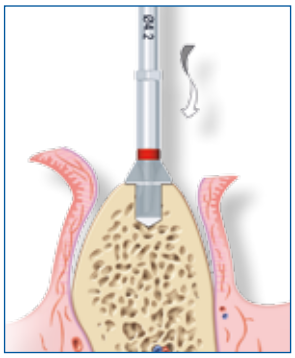


For technical reasons the pilot drill is 1.0 mm longer than the given preparation depth. This should be taken into account during diagnosis and preparation.

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. It is used as orientation for subsequent depth drilling and depth gauge of the depth drilling made. It is available in two diameters: 1.4 mm for pilot drills and 2.0 mm for depth drills. The paralleling pin should be secured with a sterile cord.

Surface cutting ADVANCED.

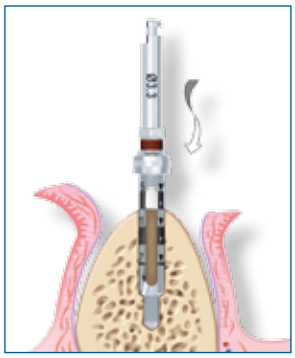


The shape of the **surface cutter ADVANCED** has been specially designed for drilling through the compact bone and for preparing a flat bone surface cervically. It has a colour-coded groove, which indicates the planned final implant diameter (here red for ø 4.2 mm) and is used for all lengths of implant.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

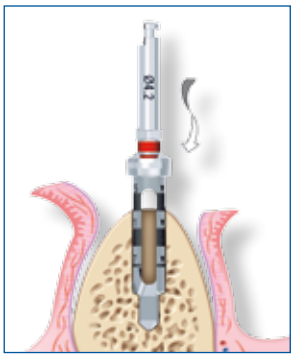
The surface cutter ADVANCED is drilled into the bone until a circumferential imprint of the cutting cylinder is visible on the compact bone. This ensures that the implant is surrounded by bone crestally. If the surface cutter is drilled deeper into the compact bone when there is adequate bone availability,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

Treatment procedure.

Stepped countersinking
ADVANCED ø 3.3 mm.



Stepped countersinking
ADVANCED ø 4.2 mm.

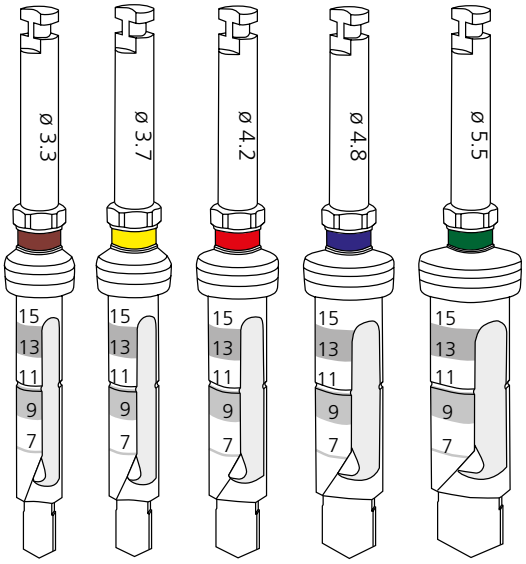


The **stepped countersink ADVANCED** enlarges the implant site according to the implant contour. It has no integrated depth stop, but depth markings according to the implant length. The implant diameter is indicated by a colour-coded groove (here brown for ø 3.3 mm and red for ø 4.2 mm). The stepped countersink ADVANCED has laser-inscriptions of the implant diameter on the shaft. In addition, the stepped countersink ADVANCED is provided with a hexagon chucking system for the transmision of high torques. All stepped countersinks are provided with a special hollow space for storing bone chips, which can be used as autologous transplant.

The depth markings on the stepped countersink ADVANCED indicate when the previously determined length has been reached (here 13.0 mm length). In accordance with the preparation protocol, the stepped countersink ADVANCED enlarges the implant site in steps with the ADVANCED preparation instruments (p. 50), starting with the smallest available diameter until the determined diameter has been reached.

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.

For technical reasons, the stepped countersink is 0.6 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation.



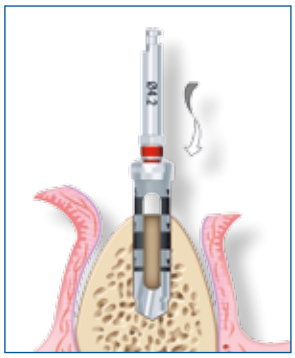
Manual stepped countersinking using a torque ratchet adapter or sure-grip wheel is recommended with very soft or narrow bone.

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.

Conical forming is completed by thoroughly rinsing the newly created alveolus with sterile, cooled physiological saline solution (5 °C / 41 °F).

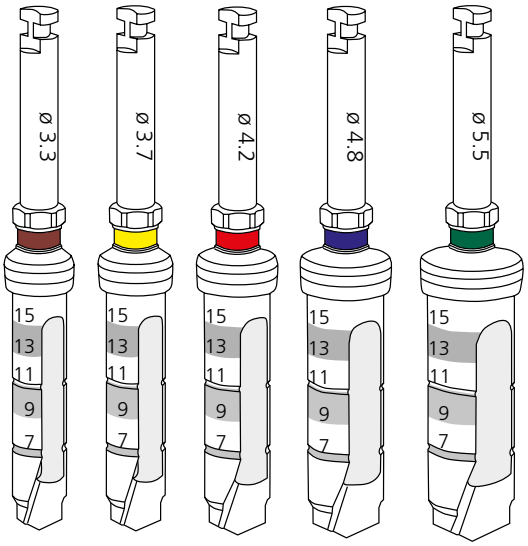
Treatment procedure.

Expanding ø 4.2 mm.



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**. It has no integrated depth stop, but depth markings according to the implant lengths. The implant diameter is indicated with a colour-coded groove (here red for ø 4.2 mm). On the shaft, the expander ADVANCED is provided with a laser inscription of the implant diameter. In addition, the expander ADVANCED is provided with a hexagon chucking system for the transmision of high torques. All stepped countersinks are provided with a special hollow space for storing bone chips, which can be used as autologous transplant. The depth markings on the expander ADVANCED indicate when the previously determined length has been reached (here 13.0 mm length). The expansion with the expander ADVANCED should take place according to the preparation protocol with the ADVANCED preparation instruments (p. 50). For a determined implant diameter, e.g. ø 4.2 mm and 13.0 mm length with a medium to dense bone quality, the implant site is prepared with the ø 4.2 mm expander ADVANCED with a minimum implant length of 7.0 mm after the stepped countersinking.

The primary stability can be individually regulated through the insertion depth of the expander ADVANCED (p. 50 Preparation protocol with ADVANCED preparation instruments). For technical reasons, the expander is 0.6 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation.



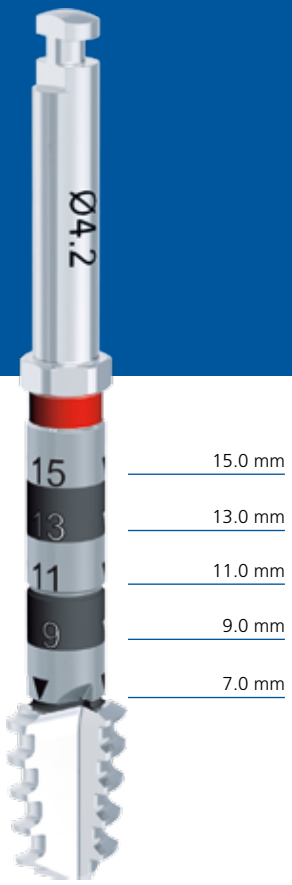
Manual expanding using a torque ratchet adapter or sure-grip wheel is recommended with very soft or narrow bone.

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.

Conical forming is completed by thoroughly rinsing the newly created alveolus with sterile, cooled physiological saline solution (5 °C / 41 °F).

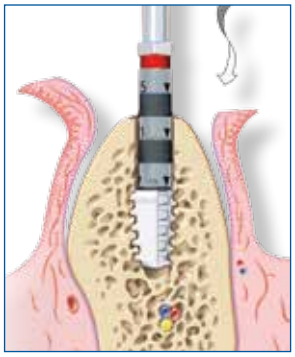
Treatment procedure.

Thread tap ADVANCED depth scale.

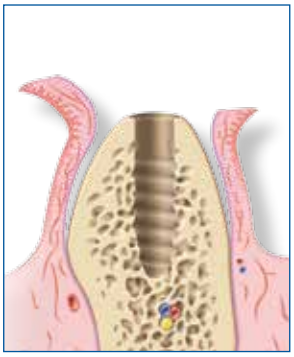


Depending on the bone quality, it is optionally recommended to finish the preparation with a thread tap. For the insertion of a tioLogic© implant with the ADVANCED preparation instruments after the preparation, the thread should be cut with a STANDARD thread tap in combination with a SW 2.5 Hex key. For the insertion of a tiologic© **ST** implant, the **thread tap ADVANCED** should be used. The thread taps have the same diameters as the available implant diameters and are provided with colour-coded grooves (here red for ø 4.2 mm) and additional markings on the shaft. The indicated depth markings on the thread tap indicate when the previously determined implant depth has been reached. In addition, the thread tap ADVANCED is provided with a hexagon chucking system for the transmision of high torques.

Thead tapping ADVANCED.



Result thead tapping ADVANCED.



The thread tap ADVANCED can be tapped manually with the torque ratchet. The Adapter – ISO shaft-Hexagon/ratchet can be used to connect the thread tap and the ratchet. The thread is tapped with a slight axial finger pressure in several preparation cycles until the determined depth marking is flush with the upper edge of the bone. Two to three preparation cycles could be necessary in order to clearly define the thread and reach the determined depth.

The thread tap ADVANCEDcan also be used mechanically (max. 10 min^{-1}) analogous to the manual procedure.

Upon conclusion of the thread tap, the alveole must be flushed with sterile, cooled phisiological saline solution (5 °C).

Preparation protocol with ADVANCED preparation instruments.

Taking into account different bone qualities.

Depending on indication and the individual situtation of the patient the preparation protocol has to be adapted.

X Optional application taking into account the respective bone quality.

		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		X		
Stepped countersink ø 3.7[1]			X		X	X
Stepped countersink ø 4.2[1]				X		
Stepped countersink ø 4.8[1]					X	X
Stepped countersink ø 5.5[1]						X
Expander ø 3.3[1]						
Expander ø 3.7[1]						
Expander ø 4.2[1]						
Expander ø 4.8[1]						
Expander ø 5.5[1]						
Thread tap[1,2,3]		X	X	X	X	X

[1] The insertion depth/length of the depth drill, stepped countersinks and thread tap depends on the implant length. The insertion depth of the bone reamers depends on the requested primary stability. The maximum insertion depth of the bone reamers correspond to the respective implant length. The thread taps must be used over 60 Ncm insertion torque. The depth scales must be observed.

[2] For the insertion of tioLogic® implants, please use the STANDARD thread taps.

[3] Exemplary illustration of rotary instruments with ø 4.2 mm (red).

Middle 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
minimum 7 mm				
	minimum 7 mm			
		minimum 7 mm		
			minimum 7 mm	
				minimum 7 mm
X	X	X	X	X

Dense 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
minimum 7 mm				
	minimum 7 mm			
		minimum 7 mm		
			minimum 7 mm	
				minimum 7 mm
X	X	X	X	X

Treatment procedure.

Implant packaging.

Sterile packaging.

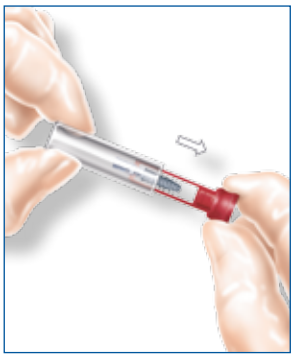
All tioLogic© implant types are supplied individually with the respective closure screw in gamma-sterilized double packaging. They are intended for single use only. The double packaging (foil and blister packaging) protects the inner container with the sterile implant and closure screw against contamination. The contents remain sterile as long as the packaging is undamaged. (p. 10).

Foil packaging.

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

Opening the blister packaging.

The cover of the sterile blister packaging is peeled back and the sterile glass vial removed.

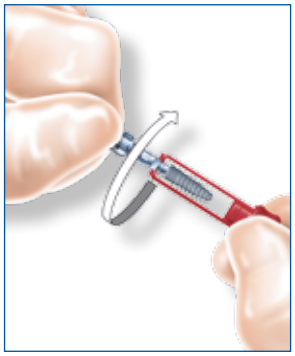


The implant holder with the implant and closure screw is removed from the glass vial.

Implant insertion.

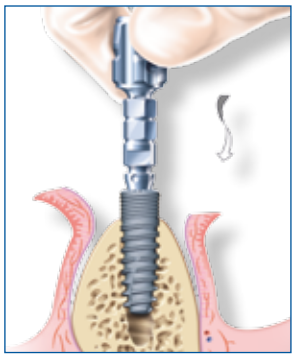
The implant holder and the placement aid attached to the implant are designed to ensure contact-free insertion with all indications.

Releasing the implant.



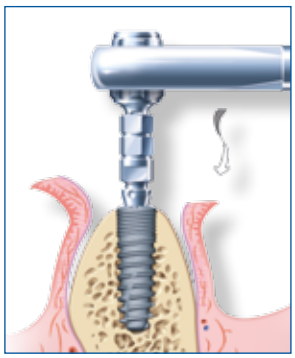
Direct manual insertion without an insertion key.
The implant is gripped with the placement aid, released from the implant holder by a ¼ turn and manually inserted into the prepared implant site.

Manual insertion.



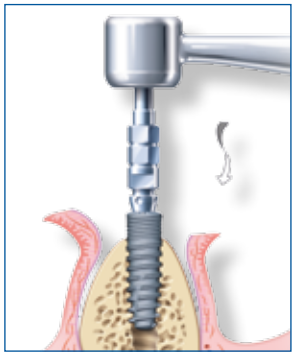
Manual insertion with the insertion key for the torque ratchet or sure-grip wheel.
The insertion key SW 2.5 (available in 3 different lengths) is inserted into the insertion aid, the implant is released from the implant holder by a ¼ turn of the insertion key and inserted into the prepared implant site using a handpiece.

Manual insertion with the ratchet.



Treatment procedure.

Handpiece insertion.



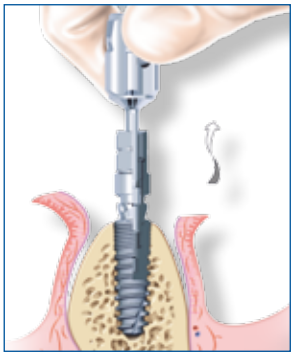
Handpiece insertion with the insertion key.
The insertion key SW 2.5 (available in 2 different lengths) is inserted into the placement aid, the implant is released from the implant holder by a ¼ turn of the insertion key and inserted into the prepared implant site using a handpiece. The handpiece insertion key can be extended using a drill extension.
A torque of 45 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 min^{-1} can damage the implant site.
The 5 marks on the placement aid correspond to the 5 PentaStop© 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 screw in the insertion aid is loosened with the hex key SW 1.3 (available in 2 different lengths) and the placement aid removed. If the implant turns when the screw is loosened (e.g. with reduced horizontal bone), the locking key for the placement aid should be used to provide rotational security. Ensure that epithelial tissue does not enter the implant site during implant insertion. If the implant is difficult to insert, the implant site should be rinsed again and the thread retapped or the conical former (dense bone) used.

Starting torque

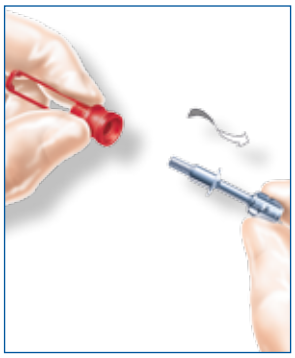
- depending on the bone quality max. 45 Ncm

Loosening screw of placement aid.

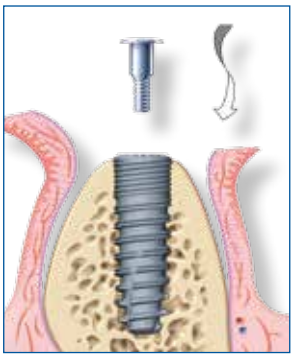


Closure screws S, M and L.

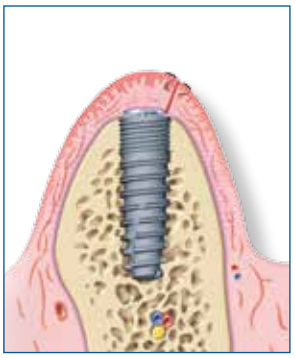
Removing the closure screw.



Inserting the closure screw.



Wound closure.



Temporary closure.

The closure screw is unscrewed from the implant holder using the hex key SW 1.3 mm and inserted into the implant. 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.

Starting torque

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

Wound closure.

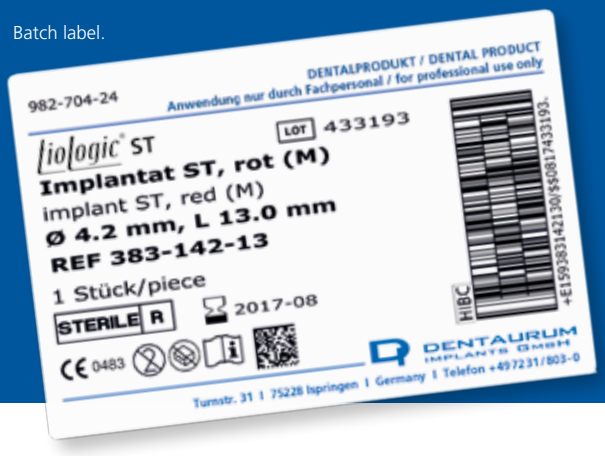
After checking the operation site, the wound is closed by suturing. Interrupted button sutures are normally used. Ensure that the wound closure is saliva proof and that there is good blood circulation.
When using open healing, ensure that the tissue is sutured close to the gingiva former.
After the implant insertion is completed, a 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
- here are no signs of peri-implant inflammation
- the patient does not have any problems

Treatment procedure.

Batch label.



Documentation.

There are also four peel-off stickers with the REF and LOT numbers inside the blister packaging for documentation in the Patient**Pass** (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).

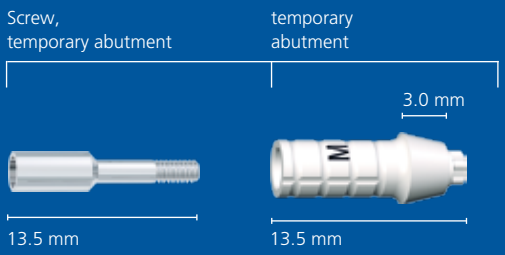
Postoperative treatment, temporary restoration, healing stage, follow-up.

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

Postoperative treatment.
Following surgery, the first step should be immediate extraoral 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 have to be precisely monitored during the entire healing stage.

All instruments used during surgery should be thoroughly cleaned, disinfected and sterilized. Components like the torque ratchet should be dismantled. The silicone rings used with the instruments should be replaced. Blunt instruments should be discarded and replaced, as they can cause overheating of the bone, which can result in implant failure.

All existing prosthetic lines are compatible with the tioLogic© and tioLogic© **ST** implants.



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 loading on the placed implant. The restoration should be relieved over the implants and relined with soft acrylic. If there are residual teeth, a temporary prosthetic restoration is generally fabricated on the abutment teeth prior to implant insertion 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 obtained with a temporary abutment. After formation of the peri-implant structures an optimal impression can be taken.

Temporary abutments are available for the S, M and L series of abutments. They are supplied non-sterile and 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 intraorally with the screw for the temporary abutment; the contours are marked and adjusted extraorally. The operator can use the polishing aid and AnatomicHold for a better grip. The restoration can only be shortened as far as the upper edge of the screw for the temporary abutment.

With a direct build-up of the facing, the temporary abutment is faced with composite extraorally and then secured to the implant using the correct torque. The screw access is sealed with composite.

With a crown restoration, the temporary abutment is fitted, then the screw access sealed with wax and the temporary restoration fitted. The crown should only be retained with temporary cement.

Starting torque
- temporary abutment intraorally: 15 Ncm

Treatment procedure.

All existing prosthetic lines are compatible with the tioLogic© and tioLogic© **ST** implants.

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

If examinations after the healing stage indicate osseointegration of the implant, the prosthetic restoration can then be fabricated. Detailed information on this is contained in the Prosthetic Manual (REF 989-960-20).

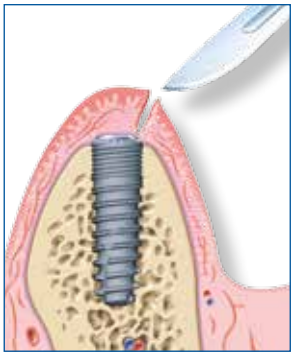
Follow-up.
Patients should be entered into a regular recall programme after the restoration has been fitted to ensure the long-term success of the implantological restoration. Patients should be given instructions on the appropriate hygiene regime for the implants and restoration.

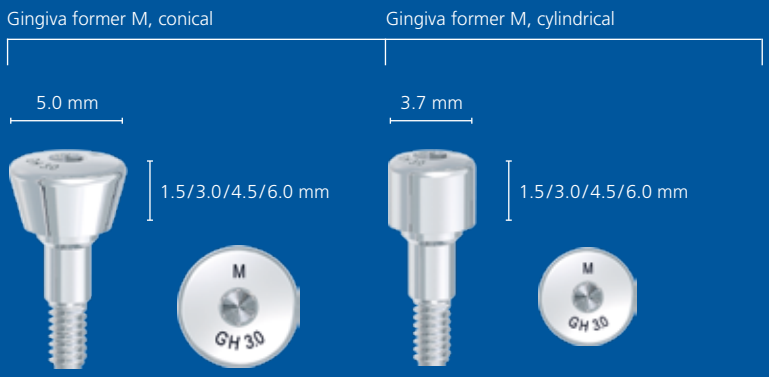
Further information is contained in the tioLogic© Patient**Pass** (REF 989-961-20).

Implant exposure.

After the healing stage the implant is exposed. The patient should be prepared in the same way as for other surgical procedures. The patient is given a local anaesthetic. Implants can be exposed using different techniques and aids, e.g. with a scalpel or laser. Using a scalpel or laser preserves peri-implant tissue (attached gingiva) and produces aesthetically optimal results (gingival management).

Implant exposure.





Gingival forming.

The operator has the choice of conical or cylindrical gingiva formers for optimal gingival management. The conical gingiva formers are designed to form a wide gingival contour. Depending on the type of prosthetic restoration, this can make it easier for the operator to fit the restoration. The gingiva formers are selected according to the series of abutments, gingival height and insertion depth of the implant. They have the series of abutments S, M or L and the gingival heights 1.5, 3.0, 4.5 or 6.0 mm laser printed on them.

Starting torque

- Gingival former: manually or 15 Ncm

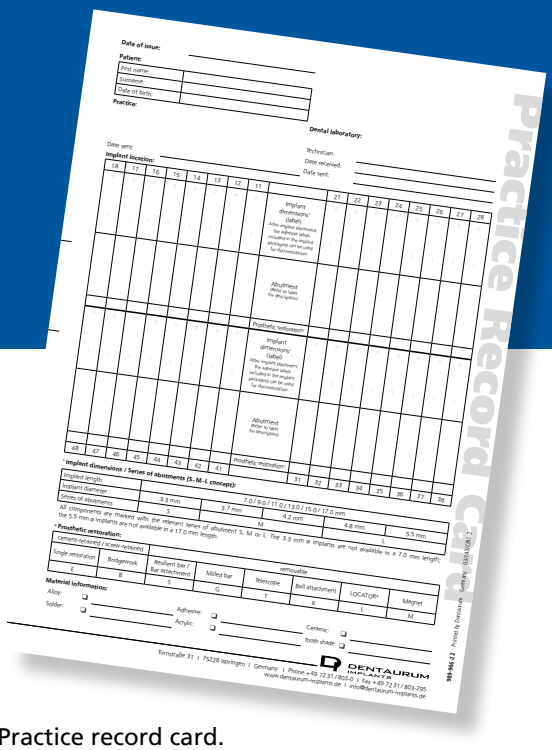
Gingiva formers can also be used with open healing of the implant for specific indications and for preserving the soft tissue.

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.

Treatment procedure.

All existing prosthetic lines are compatible with the tioLogic© and tioLogic© **ST** implants.

Practice record card.



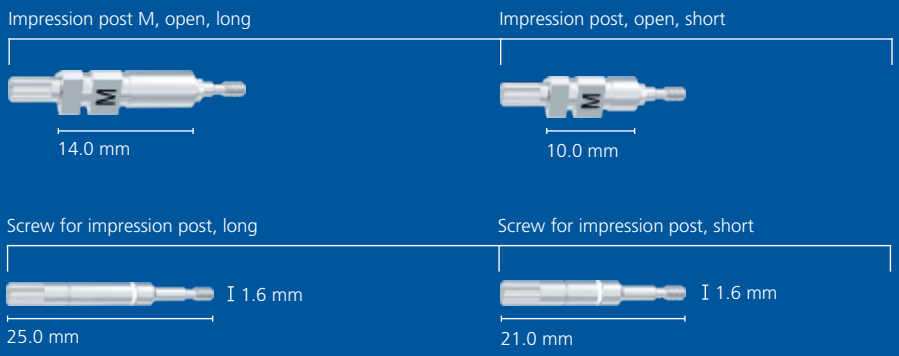
Impression taking.

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 bars, ball abutment, LOCATOR®, AngleFix, SFI-Bar® or magnets) the impression can also be taken with other special impression components over the respective primary abutments.

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

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



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 posts are laser printed with S, M or L on the retention surface and at the interface.

Starting torque

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

After the impression has been taken, a custom 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 to ensure a compression-free impression even with divergent axes.

Treatment procedure.

Groove sure-grip screw.

Markings impression at interface M.

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 impression post should be realigned and checked to ensure that it fits correctly (x-ray check).

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

Impression post M in situ.

Open impression post M with tray.

Impression post M prior to impression taking.

Loosening the sure-grip screw.

Impression post M at impression taking.

Impression post M in the open impression tray.

The impression should be taken with a silicone or polyether material. The impression posts are secured in the impression material with 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 laboratory.

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.

Treatment procedure.

Closed impression technique.

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

Starting torque

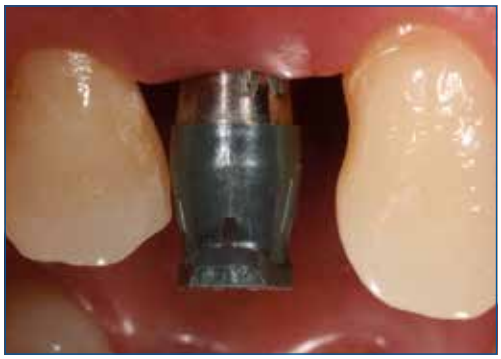
- Screw impression post intraorally: manually or 15 Ncm
- Screw impression post on the laboratory implant: manually or 15 Ncm

Exposed implant M.

Impression post M.

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 screw (here M).

Impression post M with cap M.



The corresponding impression aid S, M or L is fitted according to the vertical retention grooves until it clicks into place (here M).

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 p. 59). The tray is removed after the impression material has set. The impression posts are removed from the impression and sent along with the impression to the laboratory.

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

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

Impression tray with cap M.

Bite registration.

Bite registration caps are available for registering the bite before or after taking the impression. These caps, which are also marked with the series of abutment S, M or L (here M), click into place on the impression posts.

Impression caps and bite registration caps are single-use products. They are not suitable for sterilization. Multiple use results in transfer inaccuracies.

Starting torque

- sure-grip screw impression post intraorally: manually or 15 Ncm
- sure-grip screw impression post in the laboratory implant: manually or 15 Ncm

General instructions.

! Special measures are required with certain instruments. Please refer to section Reusability of surgical instruments p. 72!

Application.

For reuse 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 is essential for effective sterilization.

The operator 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 units used (disinfector, sterilizer) are regularly serviced and checked and that the validated parameters are maintained during each cycle.

When using the instruments, ensure that dirty instruments are collected separately and not replaced in the tray. This is to avoid heavier contamination of the loaded tray. Dirty instruments should be cleaned, disinfected and placed in position in the tray. The fully loaded tray should then be sterilized.

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.

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.

Preconditioning.

Loose dirt should be removed 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 compatible with the instruments (p. 69 section Material resistance). Only a soft brush or a clean, soft cloth should be used for removing dirt manually; metal brushes or steel wool should never be used.

If applicable: rinse all hollow sections of the instruments 5 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 cleaner/ disinfector).

When choosing 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 programme for thermal disinfection (minimum 5 min. at 194 °F or an A0 > 3000) is used (with chemical disinfection there is the risk of disinfectant residue on the instruments),
- the programme 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.

General instructions.

! Special measures are required with certain instruments. Please refer to section Reusability of surgical instruments p. 72!

Cleaning supplies.
When choosing a cleaning agent system, ensure that

- it is suitable for cleaning metal and plastic instruments,
- – provided that thermal sterilization is not used – an additional 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,
- the chemicals used are compatible with the instruments (p. 68 section Material resistance),
- the concentrations given by the cleaning agent and disinfectant manufacturer must be strictly adhered to.

Sequence.

1. Dismantle the instruments if applicable.
2. Place the dismantled instruments in the disinfector. Ensure that the instruments do not come into contact with one another.
3. Start the programme.
4. Remove the instruments from the disinfector when the programme is complete.
5. Check and pack the instruments in a clean area as soon as possible after removal (p. 68 section Care, checking, maintenance, packaging), if necessary after additional drying

Proof of basic suitability for effective automatic cleaning and disinfecting was provided by an independent, accredited test laboratory using a G 7836 GD disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and neodisher® Medizym cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg, Germany). The procedure described above was taken into account during the tests.

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,
- the chemicals used are compatible with the instruments (p. 69 section Material resistance),
- combined cleaning agents/disinfectants should not be used if possible. Combined cleaning agents/disinfectants can only be used if there is very little contamination (no visible dirt),

- 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.

Sequence – Cleaning.

1. Dismantle the instruments if applicable.
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 hollow sections of the instruments 5 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 hollow sections of the instruments 5 times using a disposable syringe (minimum volume 5.0 ml).
4. Check the instruments (p. 68 section Care, checking, maintenance, packaging).

Sequence – Disinfection.

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

   If applicable: rinse all hollow sections of the instruments 5 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 hollow sections of the instruments using a disposable syringe (minimum volume 5.0 ml).
7. Pack the instruments in a clean area as soon as possible after removal (p. 68 section Care, checking, maintenance, packaging), if necessary after additional drying.

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

General instructions.

! Special measures are required with certain instruments. Please refer to section Reusability of surgical instruments p. 72!

Care, checking.

Instruments should be checked after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipped edges and contamination. Damaged instruments should be discarded (limited reuse p. 17 section Surgical instruments ADVANCED and p. 72 section Reusability of surgical instruments). Instruments that are still contaminated should be cleaned and disinfected again.

Maintenance.

Reassembly of instruments (p. 70 section Reusability of surgical instruments).

If possible, instrument oils should not be used. If oil is to be used, ensure that only instrument oils (white oil) are used, which – depending on the maximum 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 ISO 11607)
- suitable for steam sterilization (temperature resistant to min. 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 procedures.[1]

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

Steam sterilization.

- fractional vacuum method or gravitational method[2] (with adequate product drying)
- 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; including 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) minimum 5 min at 134 °C/273 °F

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 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.

[1] Proof of basic suitability for effective steam sterilization was provided by an independent, accredited test laboratory using a EuroSelectomat steam sterilizer (MMM Münchener Medizin Mechanik GmbH, Planegg, Germany) and the fractional vacuum process as well as a Systec V-150 steam sterilizer (Systec GmbH Labor- Systemtechnik, Wettenberg, Germany) and the gravitationprocess. The procedure described above has been was taken into account during the tests.

Reusability of surgical instruments.

Rotary instruments can be reused up to 30 to 40 times – with proper care and provided that they are not damaged or contaminated; the operator is deemed responsible for any further reuse or the use of damaged and/ or contaminated instruments. We do not accept any liability if these instructions are disregarded.

Torque ratchet.

Disassembly.

Fully unscrew the adjusting screw from the torque ratchet handle and remove the springs. Leave the stopper on the spring.

Loosen the screw on the ratchet head with the hex key in the adjusting screw using light pressure.

Remove the cover from the ratchet head. Remove the two components, the ratchet core and ratchet wheel, from the ratchet head.

The ratchet head and handle are in one piece; the screw is secured in the ratchet head and can be removed if required.

Removing the adjusting screw.

Opening the ratchet head.

Cover removed.

Ratchet wheel.

Ratchet wheel and ratchet core.

Assembly.
To ensure that the torque ratchet functions perfectly, adhere strictly to the following sequence when assembling the ratchet.

First insert the ratchet wheel into the open ratchet head. This should fit flush in the round recess; turn it 180° if necessary.

Then insert the ratchet core. This can also only be placed in a defined position so that the pawl sits between the teeth of the ratchet wheel. The contact zones between the teeth of the ratchet wheel and the ratchet core are easily lubricated. Always use the "Instrument Lubricant" (USDA H1 approved) supplied with the ratchet for lubrication. Remove any excess lubricant on the outer surface of the torque ratchet.

After the components have been inserted, replace the cover on the ratchet head and hold it in position. Turn the torque ratchet over and tighten the screw with the hex key until the cover is securely retained.

Insert the spring with the stopper towards the front into the ratchet handle and tighten the adjusting screw slightly.

Check the function after assembly.

Sterilization.
The torque ratchet should be fully assembled for sterilization.

If there are signs of corrosion, the components should be conditioned in a 0.1 % sodium nitrite solution prior to sterilization. Dry-heat sterilization (hot-air sterilizer) is not approved, as this can accelerate wear and tear on the spring, which affects the torque.

Surgical tray ADVANCED.

The newly developed instrument set of the tioLogic© surgical tray ADVANCED provides maximum flexibility during preparation of the implant site while reducing instrument diversity. The ADVANCED rotary instruments thus enable atraumatic preparation specially tailored to the bone quality collection of bone chips and individual regulation for attaining the 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 colour-coded according to the diameter of the respective implant and have a hexagonal fixation system for transferring high torques. The tioLogic© surgical tray ADVANCED is designed for placement of both the tioLogic© **ST** and the tioLogic© implants.

tioLogic® surgical tray ADVANCED (REF 387-424-00).

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DENTAURUM IMPLANTS

Turnstr. 31 I 75228 Ispringen I Germany I Phone +49 72 31/803-0 I Fax +49 72 31/803-295
www.dentaurum-implants.com I info@dentaurum-implants.com