EN

tioLogic®

Surgery Manual.

DENTAURUM IMPLANTS

Content.

Treatment procedure

General information

Reusability of surgical instruments

Safety instructions.

Manufacturer.

Dentaurum Implants GmbH I Turnstr. 31
75228 Ispringen I Germany

Brief description.

tioLogic® implants are designed for insertion in the endosteal region of the maxilla or mandible. Depending on the indication, appropriate transgingival abutments are secured on the implants and fitted with a prosthetic superstructure.
The tioLogic® implant system contains specially coordinated instruments, abutments and accessories for placement of the implants and fabrication of the prosthetic restoration. Only original components of the tioLogic® implant system should be combined in accordance with the Instructions for use / user manuals.

Further information.

Though placement of dental implants has a high rate of success and implants have a long durability, successful treatment cannot be guaranteed. The operator should note and document any problematic cases and inform the manufacturer Dentaurum Implants.
An inadequate number of implants, implants with insufficient length or diameter, unfavorable positioning of the implants or a statically poor prosthetic restoration can cause premature implant loss and fatigue fractures in implants, abutments and prosthetic screws under biomechanical loading. Placement of the implants and fabrication of the prosthetic restoration should take into account the individual oral situation to avoid overloading the components.
Using tioLogic® implant system components in combinations other than those stipulated in the Instructions for use / manuals can cause mechanical failure, damage to the tissue or unsatisfactory aesthetic results.
At the time of going to press, tioLogic® implants are not known to have any side effects or to cause interactions. It cannot, however, be ruled out that in rare cases allergies to components used in the materials of the tioLogic® implant system may occur or that there may be electrochemically-induced discomfort.

Use, 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 use, operators should ensure that they have carefully read and understood the full tioLogic® Instructions for use / manuals. As the instructions and manuals cannot provide all information for immediate use, we strongly recommend that, before using the system,

operators attend a tioLogic® system training course offered by Dentaurum Implants to learn the correct techniques.

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

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

The tioLogic® implant system components can be documented, e. g. in the patient file or PatientPass, (REF 989-961-10) using the additional labels.

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

Not all components are available in every country.

Quality, warranty and liability.

Development, clinical testing, production and quality control of the tioLogic® product range are completed 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 or liability – unless stated otherwise in the Instructions for use / manual.

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

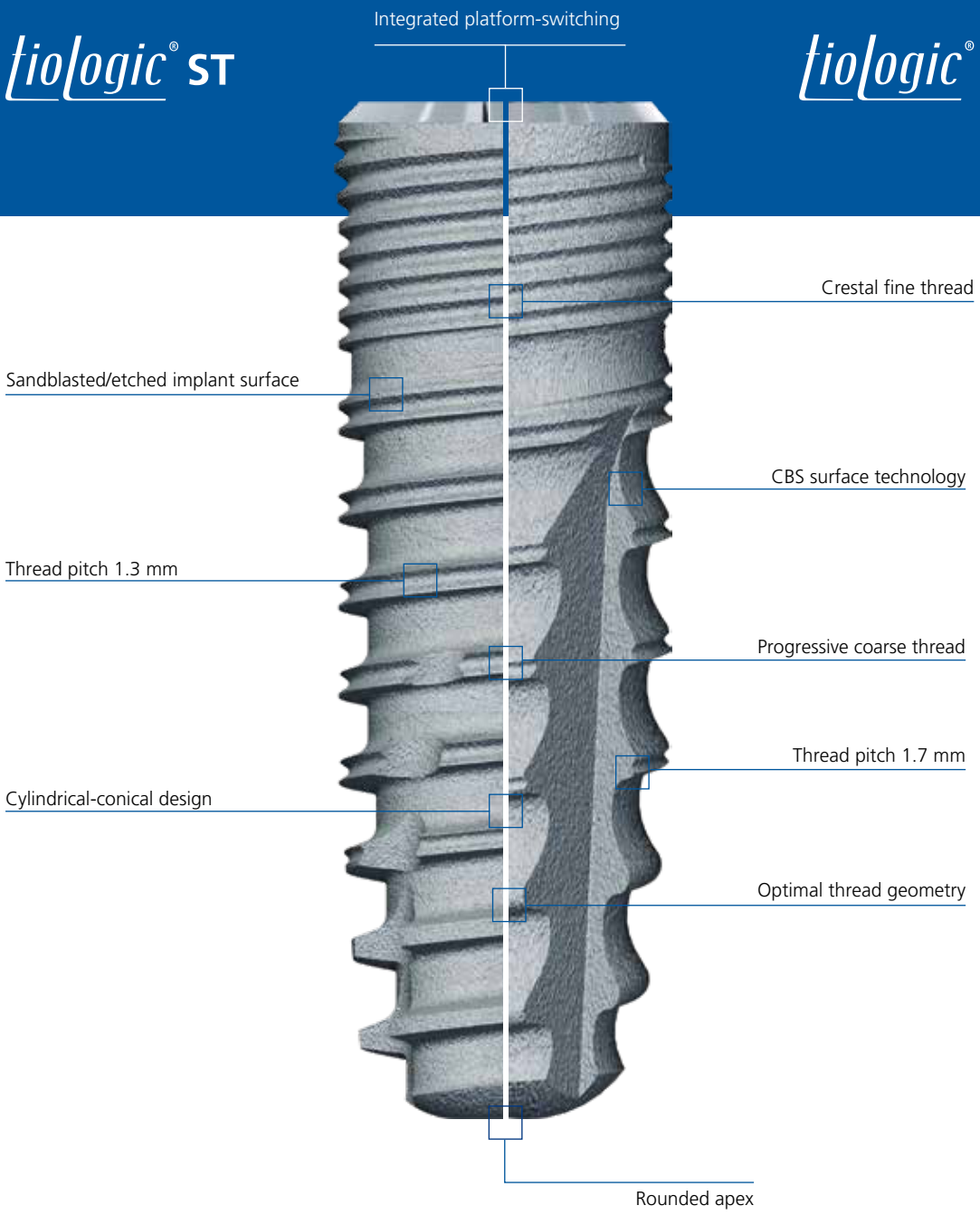
Dentaurum Implants has no control over processing and use of the product. These are the sole responsibility of the user.

The tioLogic® implant system.

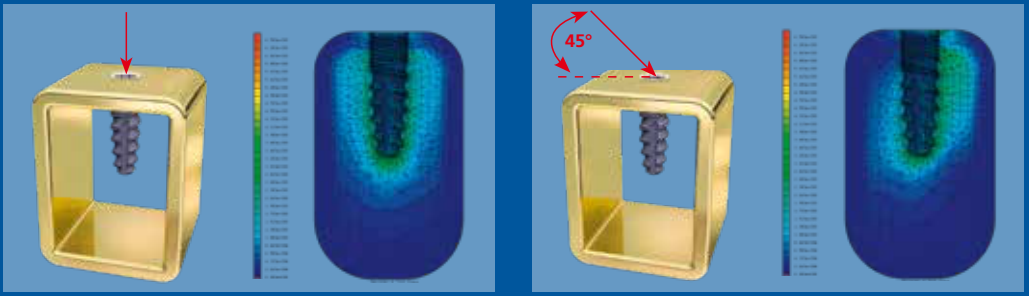
The tioLogic® implant types.

tioLogic® ST

tioLogic®



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



External geometry.

The shape of the tioLogic® implant type and the thread geometry were calculated using FEM analyses[1] and documented in scientific studies[2]. Tests show a uniform, gentle loading of the bone which prevents local overloading and stress peaks that could damage the bone.

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

tioLogic® – in the crestal region, the implant has a fine thread that is adapted to the cortical bone density. The progressive coarse thread, which follows on seamlessly from the fine thread, is tailored to the density of the cancellous 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 thread geometry and reduced thread pitch of the tioLogic® **ST** enable a quick and atraumatic implant insertion and a high level of primary stability. The endosseous region of the tioLogic® **ST** implant surface is blasted and etched. The tioLogic® **ST** 7.0 mm implant also extends the indication range with reduced vertical bone availability.

[1] A. Rahimi, F. Heinemann, A. Jäger, C. Bourauel: Biomechanische Untersuchungen des Einflusses von Geometrievarianten des tioLogic® Implantats (Biomechanical analyses of the influence of tioLogic® implant geometry variations); University of Bonn 2006.

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

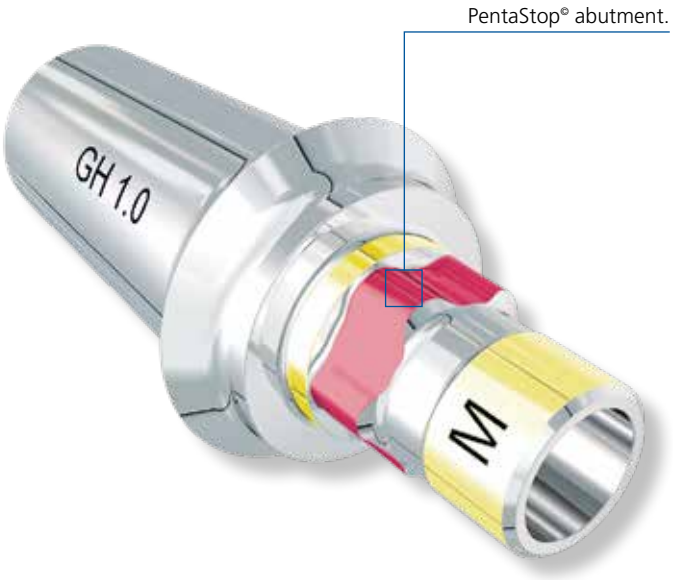
[3] I.Hasan, L. Keilig, H. Stark, C. Bourauel: Biomechanische Analyse der tioLogic® ST Implantate (Biomechanical studies on the tioLogic® ST implant); University of Bonn, Germany 2012

The tioLogic® implant system.

Internal geometry.

The design of the internal cylinders and 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 as well as a high flexural strength in the physical studies of the fatigue test under continuous load.

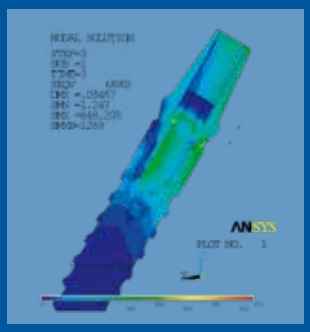
The internal geometry comprises an upper cylindrical contact surface, the PentaStop© rotational security, and a lower cylindrical contact surface.

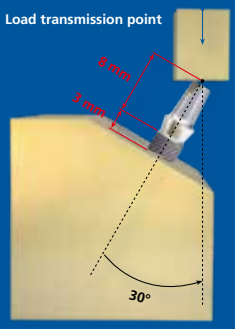


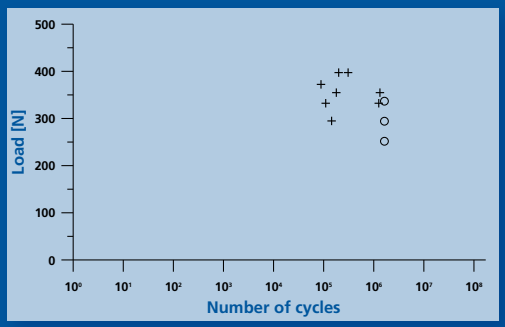
[4] F. O. Kumala: Analyse des tioLogic® Implantats mittels F EM (Analysis of the tioLogic® implant using FEM); CADFEM Stuttgart 2006.

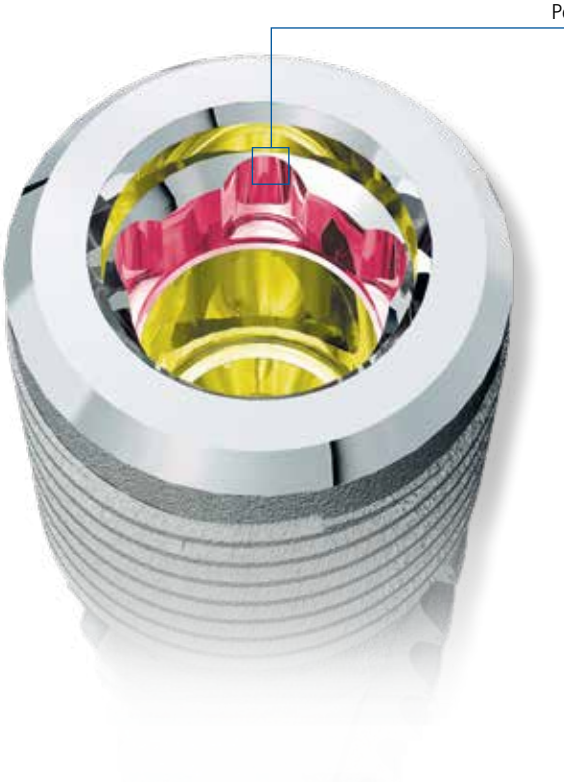
[5] R. Schäfer, R. Jaeger, D. Ulrich, U. Köster: Bestimmung der Ermüdungsfestigkeit eines Dentalimplantats (Determination of the fatigue strength of a dental implant); Fraunhofer Institut Werkstoffmechanik Freiburg, Germany, 2006.
DIN EN ISO 14801: 2003, Ermüdungsprüfung für enossale dentale Implantate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

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









The upper cylindrical contact surface is shortened. This precise cylindrical connection guarantees optimal centering 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 the 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.

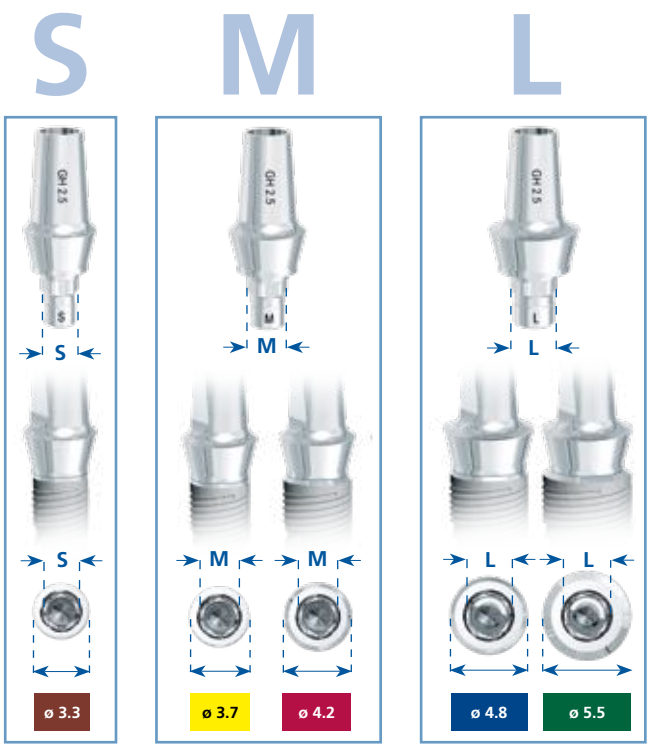
The tioLogic® implant system.

S-M-L concept.

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

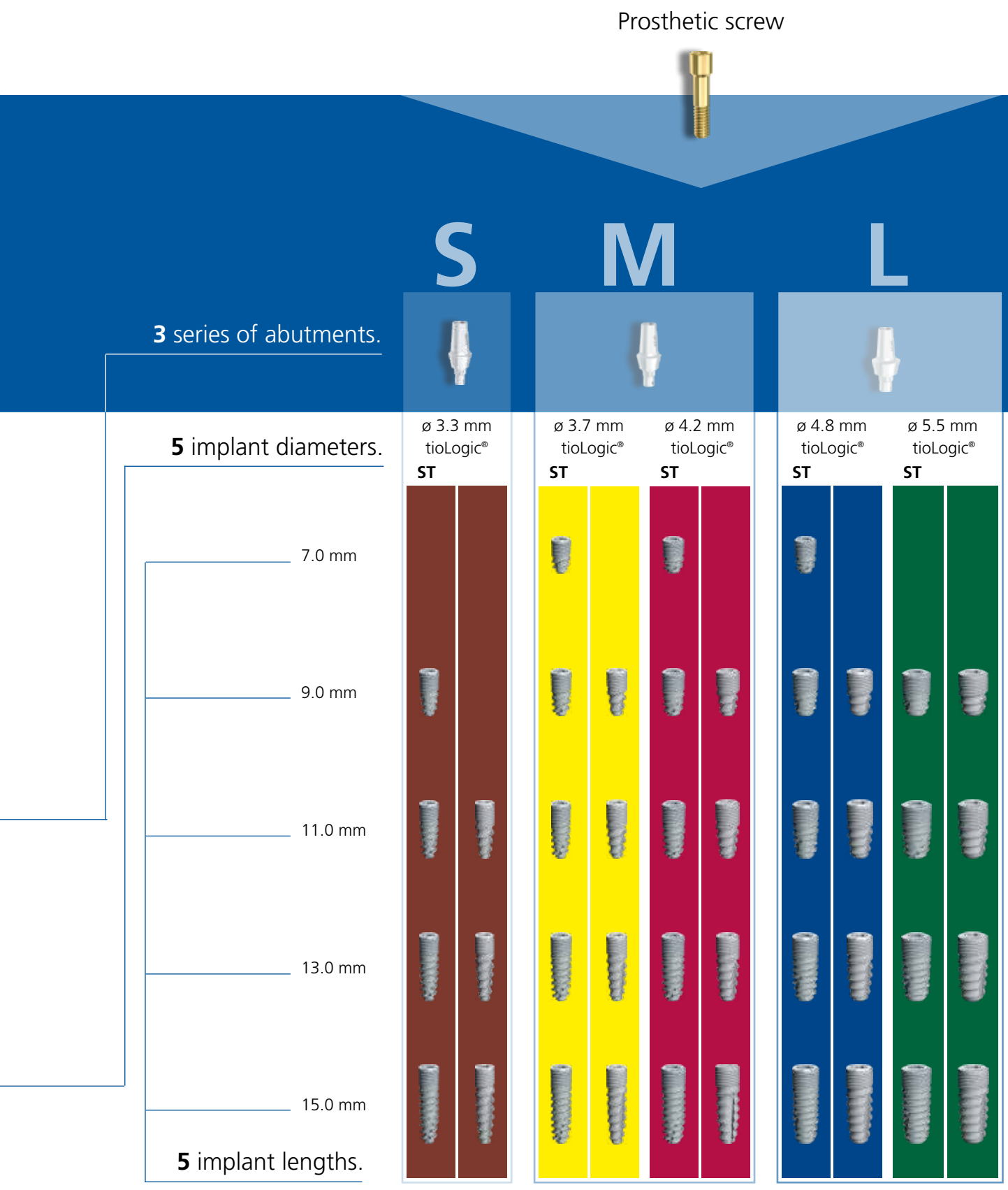
Integrated platform-switching.

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), titanium and precious metal and include CAD/CAM, bar, ball, bridge, AngleFix, and LOCATOR® abutments. 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 laser-marked with S, M or L.



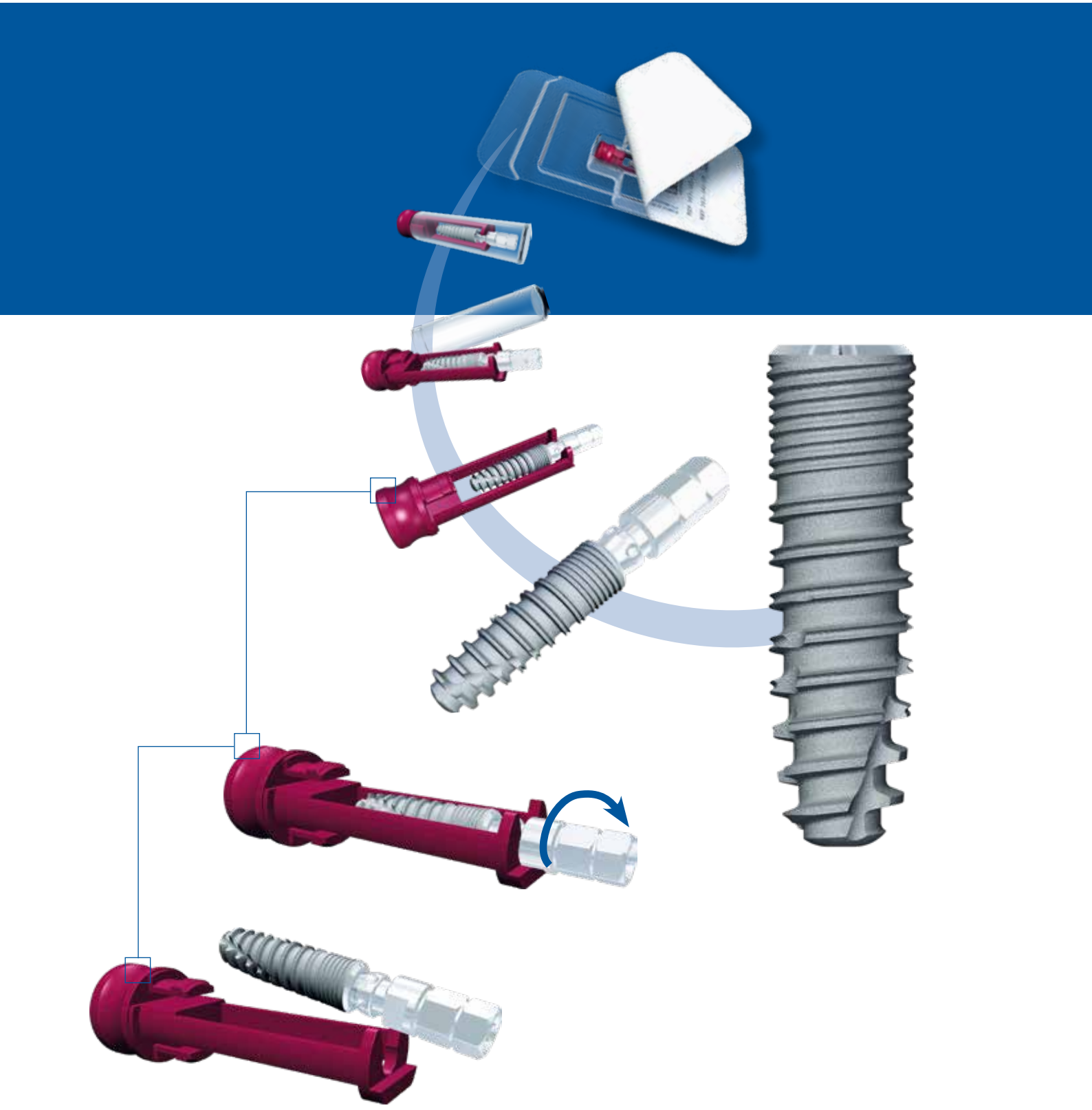
3 series of abutments.

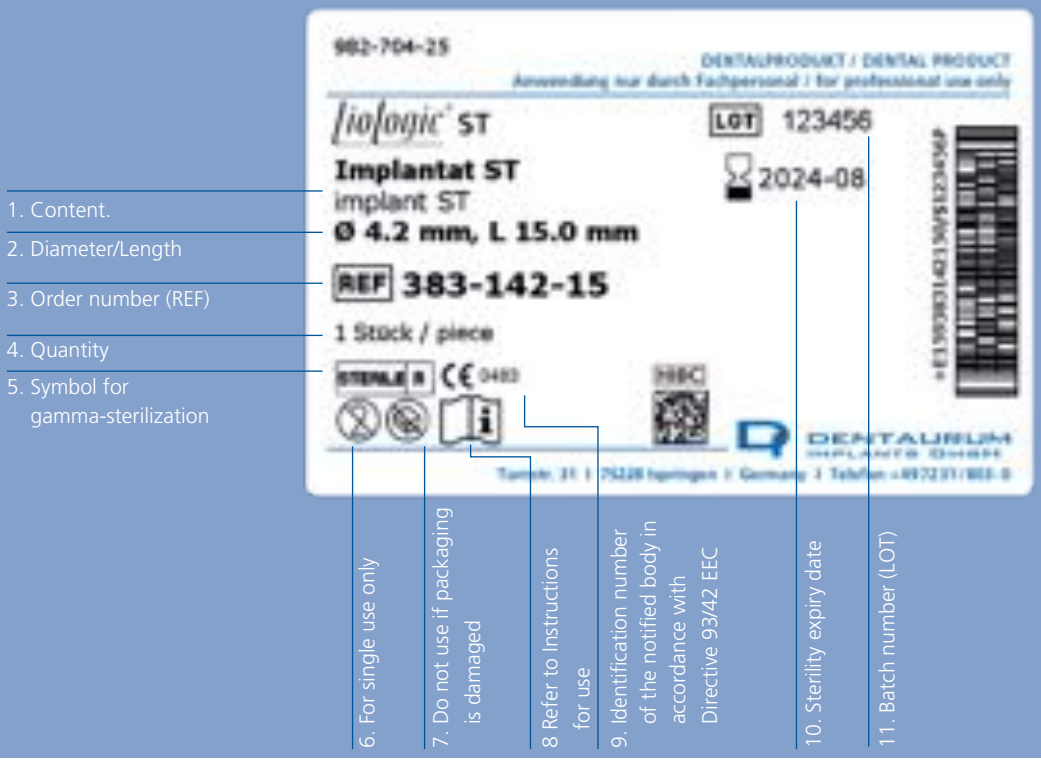
5 implant diameters.



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

Sterile packaging system.





All tioLogic® implant types are supplied individually with a closure screw and 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.

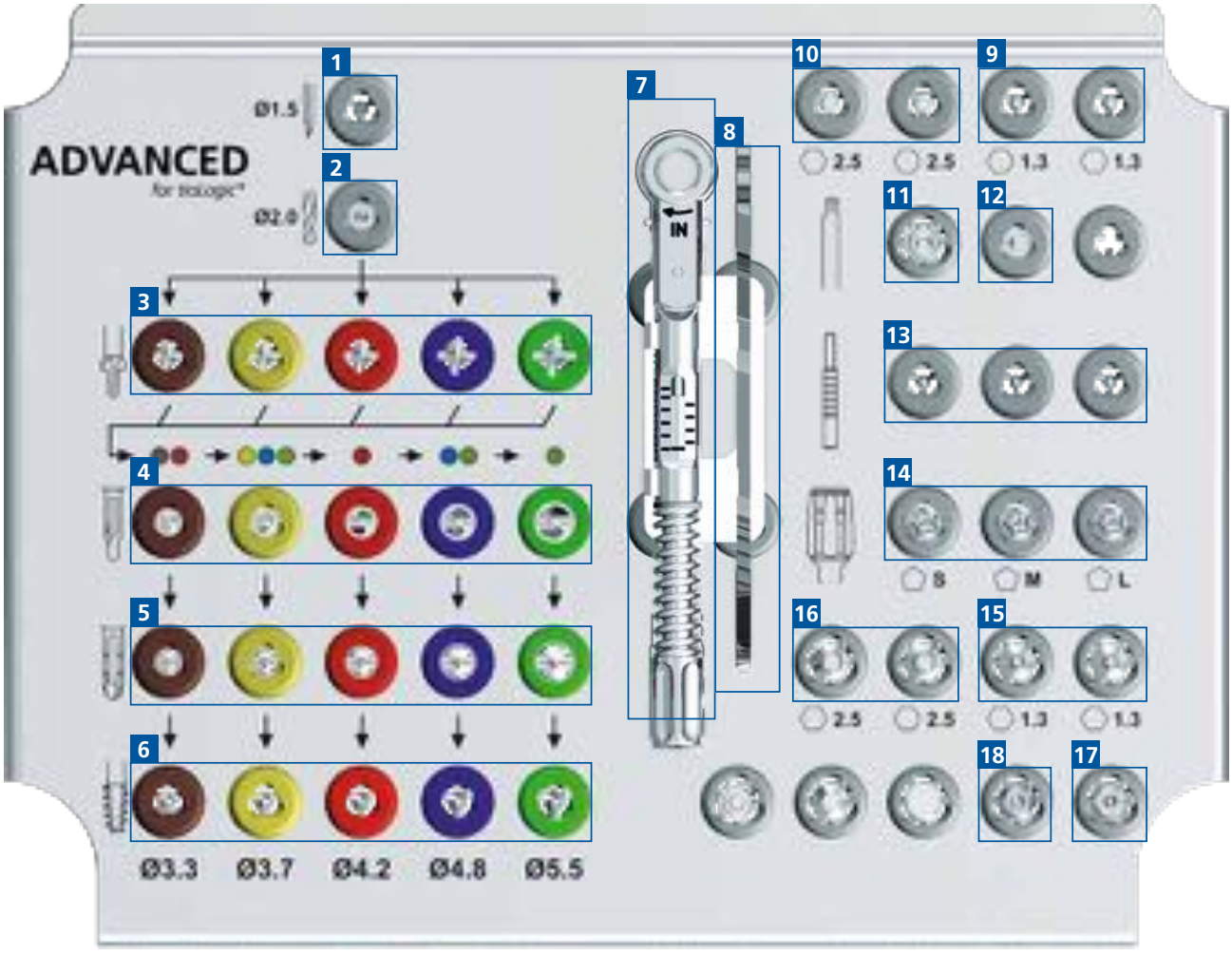
The implant is also safely stored and protected in a glass vial in the blister packaging. The implant has an integrated insertion aid and is attached to a color-coded implant holder. It can be removed and placed directly contact-free or with a manual or power-assisted handpiece extension.

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 blister packaging with peel-off REF and LOT numbers for documentation in the PatientPass (REF 989-961-20) and the surgical protocol.

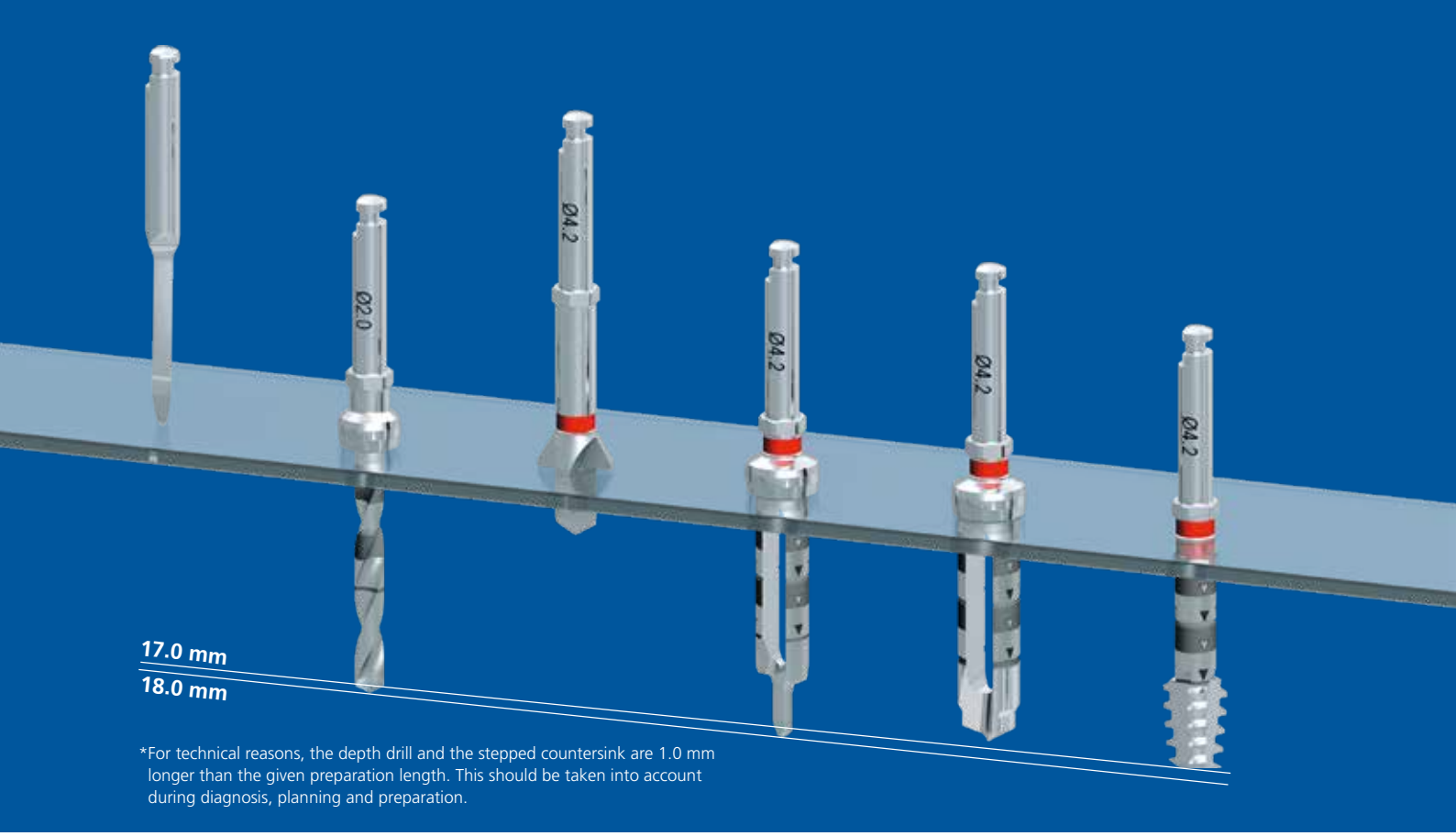
Surgical tray ADVANCED for tioLogic®.

The newly developed instrument set of the **surgical tray ADVANCED for tioLogic®** provides maximum flexibility during preparation of the implant site while reducing the amount of different instruments. The ADVANCED rotary instruments thus enable atraumatic preparation especially tailored to the bone quality, collection of bone chips and individual regulation for attaining maximum primary stability of the implant. The clear depth marking and inscription of the rotary instruments guarantee reliable, visual control throughout the entire surgical procedure.

In addition, the ADVANCED instruments are color-coded according to the diameter of the respective implant and have a hexagonal chucking system for transferring high torques. The surgical tray ADVANCED for tioLogic® is designed for the insertion of tioLogic® implants.



1. Marking drill		Marking the insertion point
2. Depth drill ADVANCED		Preparing the depth to the length of the implant, 2.0 mm diameter, integrated depth stop
3. Surface cutter ADVANCED		Preparing a flat bone surface to the diameter of the implant (optional)
4. Stepped countersink ADVANCED		Preparing the implant site according to length and diameter of the implant, depth markings on drill
5. Expander ADVANCED		Preparing the implant site according to length and diameter of the implant, depth markings on drill
6. Thread tap ADVANCED for tioLogic® ST		Cutting the thread according to length and diameter of the implant, depth markings on drill
7. Torque ratchet		Manual operation with torque control for instruments and accessories
8. Locking key Insertion aid		Securing the insertion aid for loosening the retention screw in the implant in the case of unfavorable primary stability
9. 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
10. 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
11. Adapter – ISO shank hexagon/ ratchet		Manual operation of handpiece instruments and accessories with sure-grip wheel or ratchet
12. Drill extension – ISO shank hexagon		Extension of handpiece instruments and accessories
13. Paralleling pin		Checking parallel alignment after pilot or depth drilling
14. Insertion key		Additional insertion key for implant insertion
15. 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
16. Hex key ratchet, SW 2.5, L 8.0/13.0/23.0 mm		Hex key SW 2.5 - long, medium and short, for implant insertion
17. Insertion key Bar/bridge/AngleFix – ratchet		Insertion key for manual insertion of the bar, bridge and AngleFix abutments
18. Insertion key Ball abutment – ratchet		Insertion key for manual insertion of the ball abutment



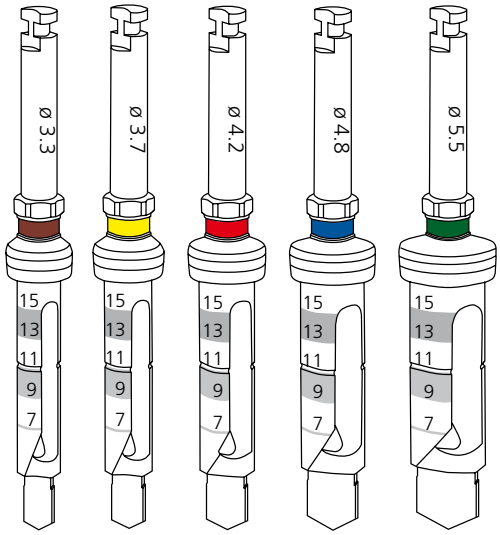
*For technical reasons, the depth drill and the stepped countersink are 1.0 mm longer than the given preparation length. This should be taken into account during diagnosis, planning and preparation.

Coordinated instruments that can be re-used are available for the insertion of the tioLogic® implant types. Preparation takes place according to a preparation protocol for an ideal bone compression and primary stability of the implant taking into account different bone qualities (p. 46).

Preparing the implant site.

- The marking drill is used for centering 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 (7.0, 9.0, 11.0, 13.0 and 15.0 mm) on the cutting edges of the depth drill will indicate whether the planned implant length has been reached.
- The surface cutter with four blades has an excellent cutting capacity, which ensures reliable handling without applying a lot of pressure. Even before implant 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. By using the surface cutter, the insertion depth may be larger than planned.
- The stepped countersink enlarges the implant site according to the implant contour. It has no integrated depth stop. It is inserted up to the laser-marked depth indication according to the planned diameter and length of the implant. All stepped countersinks have a special hollow space for collecting bone chips.

Stepped countersink ADVANCED



Instruments ADVANCED.

- 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 have a special hollow space for collecting bone chips.
- The thread tap diameter is equivalent to the implant diameters available. It has no integrated depth stop. Appropriate depth markings on the thread tap will indicate whether the planned implant length has been reached. The depth drill, surface cutter, stepped countersinker, expander and thread tap have a laser marking indicating the diameter and are color-coded. Each instrument also has a hexagonal chucking system for transferring high torques. **The thread tap ADVANCED should only be used with tioLogic® ST implants.**

Design ADVANCED instruments.

All rotary instruments ADVANCED are supplied non-sterile and should be sterilized before use. They should be thoroughly cleaned, disinfected and conditioned before using for the first time (factory new) and immediately after each use. Rotary instruments should always be checked to ensure that they are sharp, in good condition and the markings are legible, as they have a limited service life. Instruments can become blunt as a result of use and cleaning. Only instruments that are sharp and free from defects should be used (p. 70, General Information).

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.

Surgical trays.

There are two different surgical trays available for the tioLogic® implant system, the **surgical tray STANDARD for tioLogic® and the surgical tray easyClean for tioLogic®**. Each of the surgical trays for tioLogic® contains all surgical, re-sterilizable instruments and all essential accessories which are necessary for the preparation of the implant site and for the insertion of tioLogic® implants. The components are arranged according to the operation sequence, they are color-coded and marked with symbols.

The **STANDARD tray** contains a stainless steel insert which is fitted with colored silicone inserts and laser-printed symbols for optimum orientation.

The surgical trays are delivered non-sterile and must be sterilized prior to use. All components should be thoroughly cleaned, disinfected and conditioned before being used for the first time (factory new) and immediately after each use (Processing Instructions for easyClean for tioLogic® REF 989-998-20). The sterilization container and stainless steel tray insert have been designed in accordance with cleaning and sterilization guidelines.

The sterilization container has integrated hydrophobic PTFE permanent filters, which can be steam-sterilized using an EN 554 validated sterilization procedure. The permanent filters are designed to withstand up to 1000 sterilization cycles. If required, they can be removed by unclipping the mesh tray and replaced in sets of two. For further information on cleaning, disinfection and sterilization refer to the Instructions for use for the sterilization container and Aesculap permanent filters.

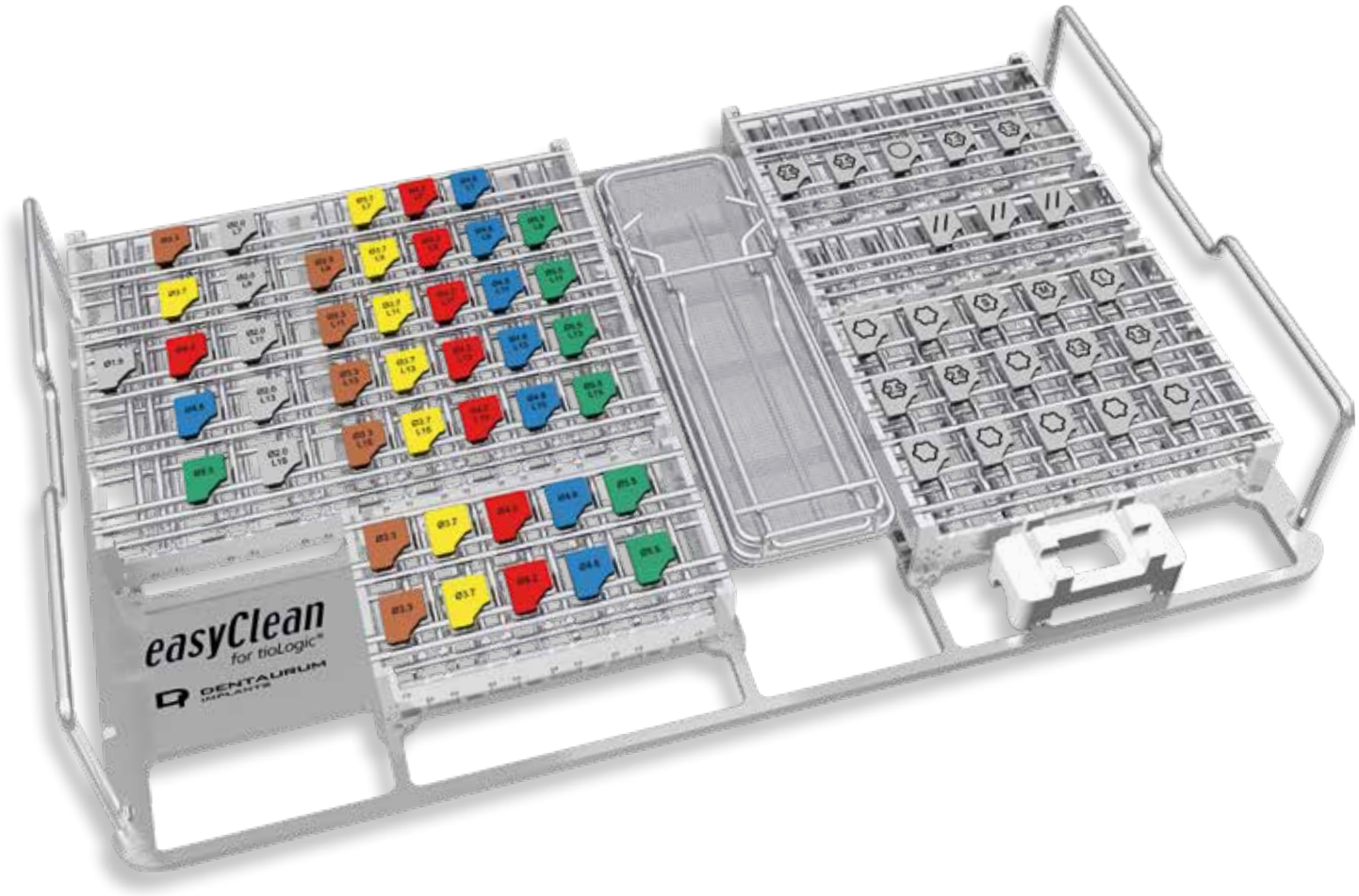
Components surgical tray STANDARD for tioLogic®

1. Marking drill		Marking the insertion point
2. Surface cutter STANDARD		Preparing a flat bone surface to the diameter of the implant (optional)
3. Depth drill STANDARD		Preparing the depth to the length of the implant, 2.0 mm diameter, integrated depth stop
4. Conical former STANDARD		Preparing the implant site according to length and diameter of the implant, integrated depth stop
5. Thread tap ADVANCED for tioLogic® ST		Tapping the thread to the length and diameter of the implant, depth markings
6. Conical former DB* dense bone		Preparing the implant site in dense bone to the length and diameter of the implant, no integrated depth stop 9.0 / 11.0 / 13.0 / 15.0 mm
7. Sure-grip wheel		Manual operation of instruments and accessories
8. Torque ratchet		Manual operation with torque control for instruments and accessories
9. Locking key Insertion aid		Securing the insertion aid for loosening the retention screw in the implant in the case of unfavorable bone conditions
10. 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
11. Hex key SW 2.5 – ISO shank, L 19.0 / 25.0 mm		Hex key SW 2.5 – long and short for machine thread tapping and implant insertion
12. Adapter – ISO shank hexagon / ratchet		Manual operation of handpiece instruments and accessories with sure-grip wheel or ratchet
13. Drill extension – ISO shank hexagon		Extension of handpiece instruments and accessories
14. Paralleling pin		Checking parallel alignment after pilot or depth drilling
15. Insertion key		Additional insertion key for implant insertion
16. 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
17. 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
18. Insertion key Bar/bridge/AngleFix – ratchet		Insertion key for manual insertion of the bar, bridge and AngleFix abutments
19. Insertion key Ball abutment – ratchet		Insertion key for manual insertion of the ball abutment

Surgical trays.

The easyClean for tioLogic® is a wash tray that contains all the rotary instruments and accessory components needed for implantation. They are arranged according to the operation sequence. For optimal orientation there is a color-coded and laser-labeled plastic clip beside each instrument. The used instruments and accessory components are put back in the corresponding slots directly after each use. This increases safety during implantation as all instruments are always located in their intended place. After implantation, the fully packed easyClean for tioLogic® is transferred to the machine treatment cycle. Small parts and accessory components to be disassembled are placed in the mesh tray.

easyClean for tioLogic® – the tray for machine processing.[1,2]



[1] Cleaning investigation surgical tray easyClean for tioLogic® SMP GmbH, 2010.
[2] Cleaning investigation easyClean for tioLogic® AFIP, 2012.

easyClean
for tioLogic®

Innovative lattice structure.

Stable double springs.

Clear guidance system.

Reproducible machine-treatment results.

Developed in collaboration with:

Miele PROFESSIONAL

Cleaning investigation[1] by:

SMP GmbH
Prüfen Validieren Forschen

Advantages: Machine treatment of the fully packed surgical tray.

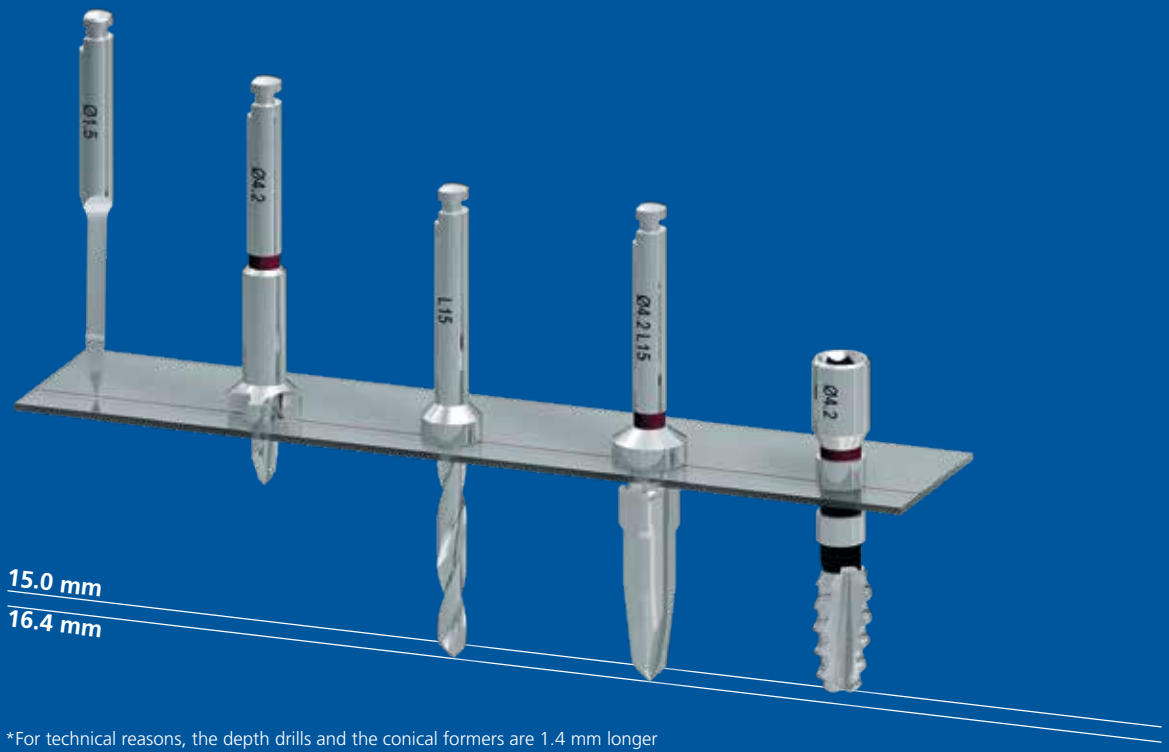
Guaranteed by:

- optimal washing of the components
- minimal contact surface
- innovative lattice structure
- fine mesh tray

Added value for the practice:

- no time-consuming manual treatment necessary
- reproducible machine-treatment results
- saves working time
- no sorting of components necessary

Suitable for doctors' surgeries and central treatment centres.



*For technical reasons, the depth drills and the conical formers are 1.4 mm longer (conical former DB for dense bones 0.2 mm) than the given preparation length. This should be taken into account during diagnosis, planning and preparation.

Coordinated instruments that can be re-used are available for the insertion of the tioLogic® implants. Preparation takes place according to a preparation protocol taking into account different bone qualities for an ideal bone compression and primary stability of the implant (p. 54).

Preparing the implant site.

- The marking drill is used for centering and marking the insertion point.
- The surface cutter prepares a flat bone surface and is used for all lengths of implants with the same diameter (optional). The drill tip has a diameter of 2.0 mm.
- The depth drill helps to determine the depth and the orientation of the implant. An integrated depth stop ensures that it does not exceed the planned insertion depth.
- The conical former contours the implant site to the implant diameter. It has an integrated depth stop and is available for each diameter and length. The integrated depth stop ensures that it does not exceed the planned insertion depth. The cutter grooves allow bone chips to be collected.

A conical former (dense bone) is also available for use with high-density bone. It is available according to implant diameter and does not have an integrated depth stop. The depth marking allows alignment at the relevant implant site.*

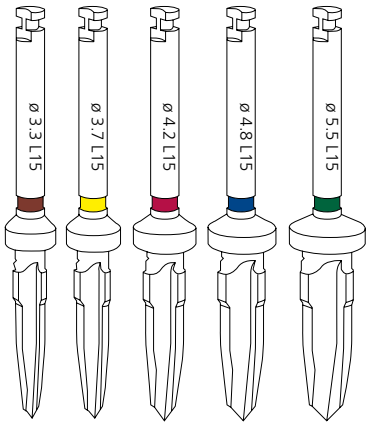
- The thread tap is used manually in the case of high-density bone (torque ratchet). It is used for the final preparation stage and has the same diameter as the implant. **The thread tap STANDARD should only be used with tioLogic® implants.** The depth markings allow alignment at the relevant implant site. All STANDARD rotary instruments have a laser marking on the shank to indicate the diameter and/or the length. In addition, the instruments with a specific diameter are color-coded.

  Various extensions are available for handpiece and manual instruments to allow preparation in restricted areas.

Instruments STANDARD.

All rotary instruments 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 always be checked to ensure that they are sharp, in good condition and the markings are legible, as they have a limited service life. Instruments can become blunt as a result of use and cleaning. Only instruments that are sharp and free from defects should be used (p. 70, General Information).

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. 76 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.

Accuracy of the torque ratchet according to manufacturer + / - 10 %.

Use.

The torque ratchet can be used for the surgical procedure, implant insertion, securing the closure screws, gingiva formers and impression posts and for temporary and permanent prosthetic restorations. Different inserts are available depending on the application (p. 26).

The ratchet is set to the required torque using the adjusting screw. To set the correct torque, the adjusting screw is turned to the required torque line.

The torque ratchet is additionally provided with a blocking function. To set the blocking function, turn the adjustment screw to the '∞' symbol. Do not turn too tightly. For storage, turn the torque adjustment screw back until the spring is as relaxed as possible.

The pressure point for exact torque release is on the head of the torque adjustment screw. When the adjusted torque has been reached, the scale sleeve will bend around the axis in the ratchet head. The release is audible and perceptible. After the torque release, do not apply more pressure; this could damage the ratchet.

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

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

The blocking function mode should be used with extreme caution. After use the value must be reset to standard torque to prevent mistakes next time it is used.

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

When fitting the permanent prosthetic restoration, all prosthetic screws should be tightened with the torque ratchet set at the relevant torque (p. 27 table for torque ratchet settings) and then re-tightened after approx. 5 minutes using the same torque. It is important that the insertion key fits flush in the prosthetic screw. We recommend using a new AnoTite prosthetic screw for the final fitting.

Torque ratchet.

Overview – Inserts for the torque ratchet.

There are different inserts available, depending on the application.

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, L 15.0 mm.

Insertion key LOCATOR® abutment, L 15.0 mm.

Insertion key bar/bridge/ AngleFix abutment, L 16.0 mm.

Adapter – ISO shank hexagon / ratchet.

Table – Tightening torques for implants and prosthetic components.*

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

Implant types		(depending on the bone density) max. 40 Ncm
Closure screw Implant		15 Ncm or manually
Closure screw bar abutment		15 Ncm or manually
Closure screw bridge abutment		15 Ncm or manually
Closure screw AngleFix abutment		15 Ncm or manually
Gingiva former		15 Ncm or manually
Screw for impression post		15 Ncm or manually
Screw for temporary abutment		15 Ncm or manually
AnoTite screw 9.0 mm		30 Ncm
Bar abutment		35 Ncm
Bridge abutment		35 Ncm
AngleFix abutment 0° GH 1.0 mm		35 Ncm
AnoTite screw Bar, bridge, AngleFix abutment L 6.0 mm		25 Ncm
Ball abutment		35 Ncm
LOCATOR® abutment		30 Ncm

* primary stable and osseointegrated

Diagnosis and planning.

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

The integrated tioLogic® training program 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 suit the target group, the level of knowledge and individual interests.

Indications.

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 (one-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 implantology in general, 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 patients with narrow alveolar ridges. Due to the smaller diameter and low load capacity (compared to the tioLogic® M ø 4.2 mm implants), these implants have a limited range of indications. In fully edentulous cases, four or more tioLogic® implants with a splinted bar restoration without extension must be inserted. In partially edentulous cases, implant supported restorations must be combined with tioLogic® ø 4.2 mm, ø 4.8 mm or ø 5.5 mm implants and a splinted fixed prosthetic restoration.

In single restorations, tioLogic® ø 3.3 mm implants should only be used for the lower incisors or the upper lateral incisors and only with a minimum 11.0 mm implant length. Single restorations on tioLogic® ø 3.7 mm, ø 4.2 mm, ø 4.8 mm or ø 5.5 mm implant types require a minimum 9.0 mm implant length.

Care should be taken to avoid an excessive mechanical loading when using ball head abutments together with ø 3.3 mm implants.

Contraindications.

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

General contraindications for dental surgery procedures apply. These include:

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

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.

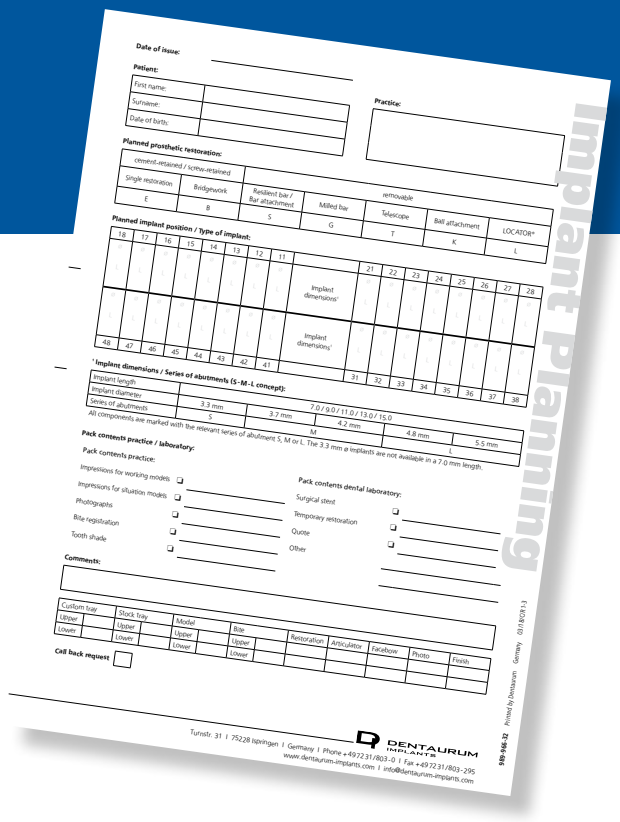
Diagnosis and planning.

Standard planning / planning for template-guided implant placement

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

Example: Diagnosis indicates a 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. 37 pOsition for tioLogic®). The examples can serve as orientation for individual cases. Other procedures can also be used in pre-prosthetic 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.

Diagnostic model

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

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

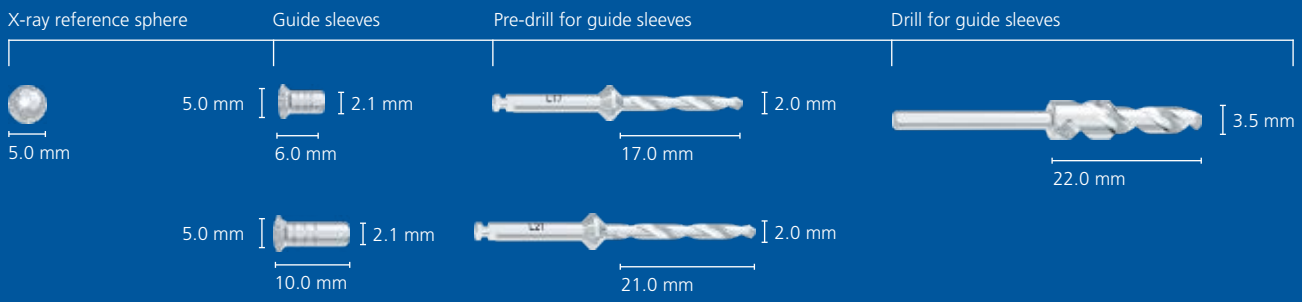
Set-Up / Wax-Up, planning template.

Fixed or operator-removable restorations.
Based on the planned prosthetic restoration, a Set-Up or Wax-Up is fabricated on the diagnostic model to represent the ideal prosthetic restoration, 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 not be waxed up. An acrylic template is fabricated over the tooth set-up or wax-up.

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

Diagnosis and planning.

Components used in planning STANDARD.



X-ray template, drilling template.

Guide sleeves are polymerized into the plastic template in the ideal implant and alignment position for the prosthetic restoration to fabricate the X-ray template or the drilling template. 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 pressed directly into the planned position in the planned direction.

Orthopantomograph (OPG).
Model analysis for measuring the ridge height and width after initial examination can also be used for integrating the guide sleeves in the plastic template. When planning, it is important to take into account that the surface cutter, if used, removes bone material. During model analysis the relationship to the adjacent teeth and opposing dentition is assessed and transferred to a special sectioned model. The drilling template is placed on the sectioned model and the implant alignment checked. If the checks on the sectioned model are correct, an OPG can be taken with the X-ray template. The position, diameter, length of the implants and their alignment in relation to the adjacent teeth can be checked two-dimensionally and the position of the guide sleeves can be altered if necessary.

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

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

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

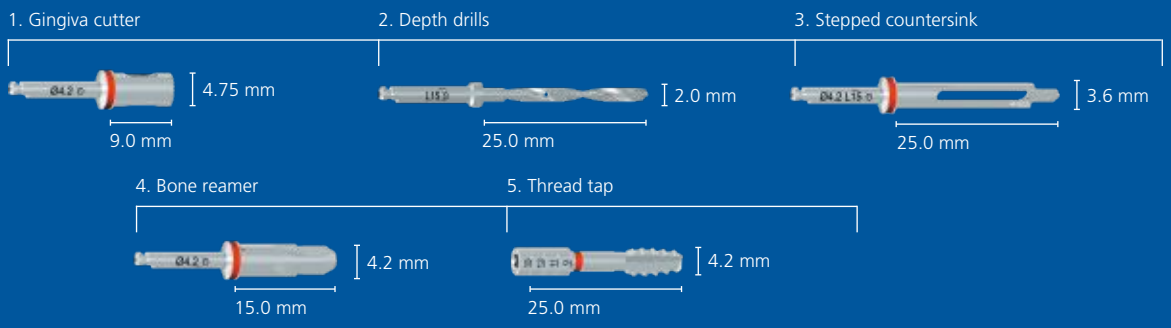
- Actual alveolar bone height (Kr)

Formula:

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

Diagnosis and planning.

Template-guided implant insertion – pOsition for tioLogic®.



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

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

Data obtained from the three-dimensional diagnostic analysis is used for producing the relevant X-ray foil and drilling template.

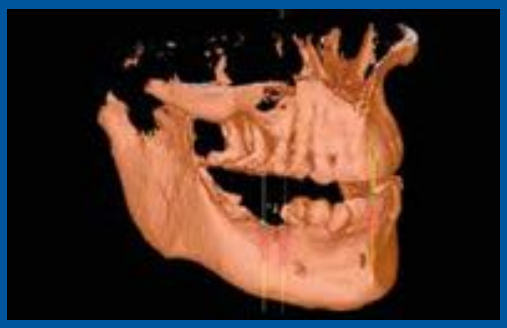
tioLogic® pOsition for tioLogic® is a sleeve and drill system from Dentaurum Implants that ensures reliable, minimally invasive and precise template-guided implant placement using coordinated planning software for accurate diagnosis and 3D planning. (see Surgery Manual pOsition for tioLogic® REF 989-999-20).

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

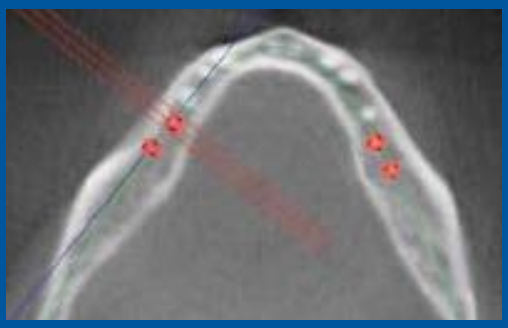
The planned implant restoration is discussed with the patient with regard to the patient's expectations (extent and cost of treatment) and a decision reached. The drilling template is modified according to any adjustments made to the planned restoration.

The drilling template should be cleaned and sterilized prior to surgery.

When using a drilling template, 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.

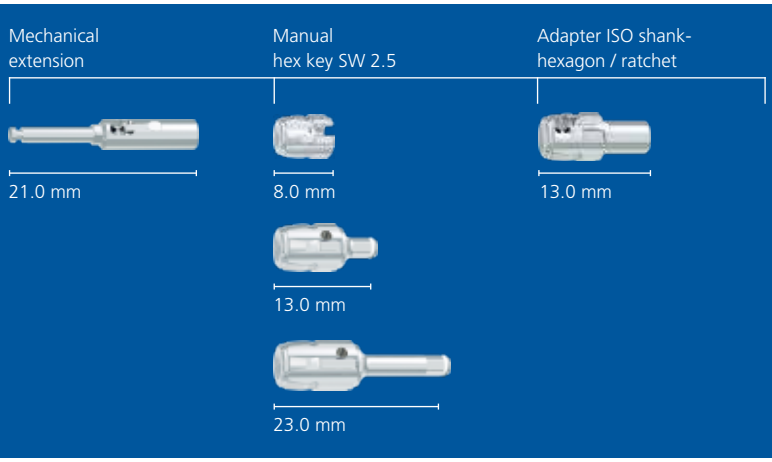
The patient should rinse with a disinfectant mouthwash solution immediately before the treatment. The perioral area should additionally be cleaned with a disinfectant solution. After that the implant insertion is normally conducted under local anesthesia.

Other components are used in implant treatment apart from implant-specific products. Additional implant-related product ranges have been 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
- special surgical instruments
- drapes

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

Treatment procedure ADVANCED & STANDARD.

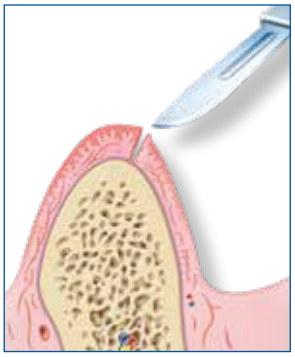


Instruments.

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.

Alveolar ridge incision.

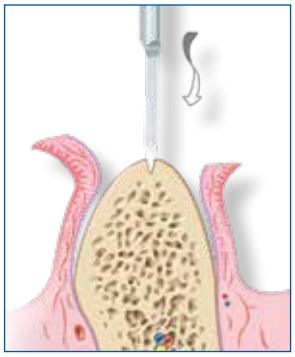


Bone exposure.

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

For the preparation of the implant site the rotary instruments and their drilling sequence should be chosen depending on the bone quality. A concerted preparation protocol (p. 46 and p. 54) for different bone qualities (soft, medium, dense) is available for the user. The determination of the bone quality rests on the user.

Drillpoint marking.



Drillpoint marking.

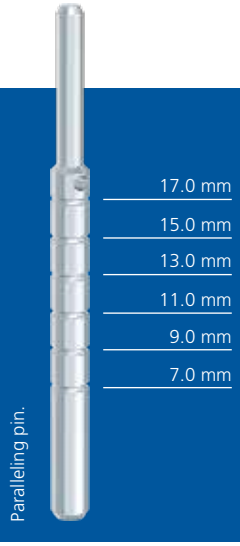
The following describes preparation regardless of the bone quality in order to show exactly how each of the rotary instruments works. The template-guided preparation and implant insertion with pOsition for tioLogic® is described in the Surgery Manual pOsition for tioLogic® (REF 989-999-20).

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

Drilling template.

The insertion point of the implant can be marked using the marking drill.
If tioLogic® guide sleeves have been integrated in the drilling template, the relevant guide sleeve drill can be used. The drilling depth can be calculated by taking the drill length from pre-drilling and subtracting the height of the guide sleeves and the mucosa.
Either guide sleeve drill can be used for marking the insertion point as well as for initial pilot drilling for implant alignment so that the planned implant position and alignment are pre-set for further preparation. Both guide sleeve drills have an integrated depth stop. Surface cutting is not required if a drill template is used. Preparation is continued using the appropriate depth drill depending on the length of the implant.
The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F).

Treatment procedure ADVANCED.

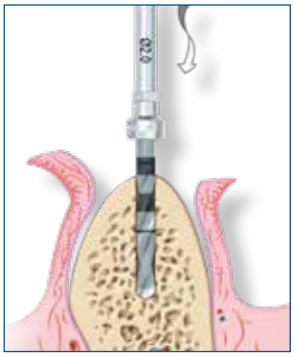


Paralleling pin.

The **depth drill ADVANCED** prepares the definitive depth and direction of the implant site independent of the implant diameter. The depth drill does not have an integrated depth stop, but depth markings according to the implant length. The depth markings on the depth drill ADVANCED indicate when the previously determined implant length (here 13.0 mm) has been reached. This guarantees keeping to 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 1.0 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation. In addition, the depth drill ADVANCED is provided with a hexagon chucking system for the transmission of high torques.

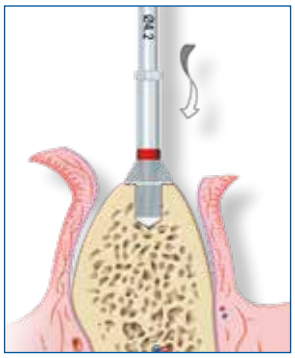
The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Depth drill ADVANCED.



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.



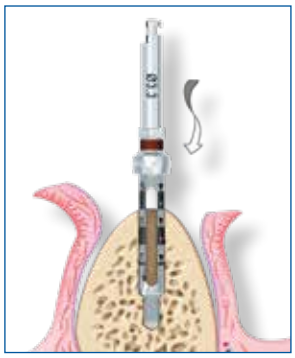
The shape of the **surface cutter ADVANCED** has been specially designed for drilling through the compact bone and for preparing a flat bone surface cervically. It has a color-coded groove, which indicates the planned final implant diameter (here red for ø 4.2 mm) and is used for all lengths of implant.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

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

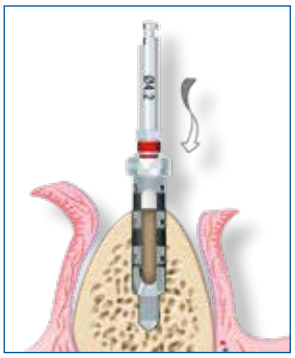
The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Treatment procedure ADVANCED.

Stepped countersinking
ADVANCED ø 3.3 mm.



Stepped countersinking
ADVANCED ø 4.2 mm.

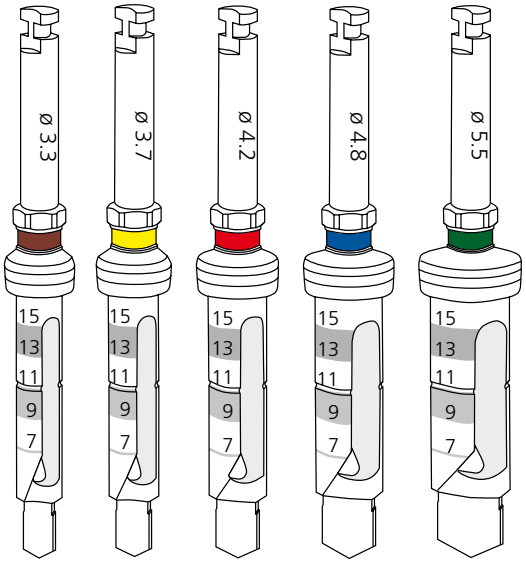


The **stepped countersink** enlarges the implant site according to the implant contour. The depth drill does not have an integrated depth stop, but depth markings according to the implant length. The implant diameter is indicated by a color-coded groove (here brown for ø 3.3 mm and red for ø 4.2 mm). The stepped countersink ADVANCED has laser-inscriptions of the implant diameter on the shaft. In addition, the stepped countersink ADVANCED is provided with a hexagon chucking system for the transmission of high torques. All ADVANCED stepped countersinks are provided with a special hollow space for collecting bone chips, which can be used as an autologous transplant.

The depth markings on the stepped countersink ADVANCED indicate when the previously determined length has been reached (here 13.0 mm length). In accordance with the preparation protocol, the stepped countersink ADVANCED enlarges the implant site in steps with the ADVANCED preparation instruments (p. 46), 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 1.0 mm longer than the given preparation length. This should be taken into account during diagnosis and preparation.

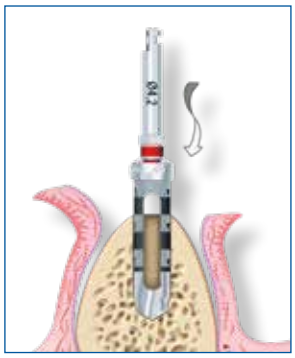


Manual stepped countersinking using a torque ratchet adapter or sure-grip wheel is recommended with very soft or narrow bone.

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.

Treatment procedure ADVANCED.

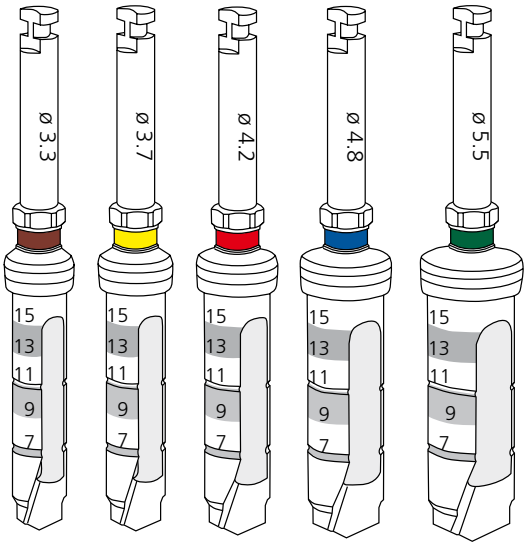
Expander ADVANCED ø 4.2 mm.



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**. The depth drill does not have an integrated depth stop, but depth markings according to the implant length. The implant diameter is indicated by a color-coded groove (here red for ø 4.2 mm). On the shaft, the expander ADVANCED has a laser inscription of the implant diameter. In addition, the expander ADVANCED is provided with a hexagon chucking system for the transmission of high torques. All ADVANCED 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. 46). 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 after stepped countersinking.

The primary stability can be individually regulated by the insertion depth of the expander ADVANCED. (p. 46 Preparation protocol with ADVANCED preparation instruments).

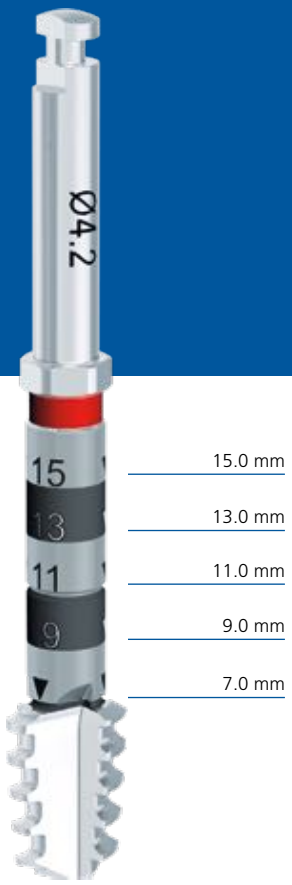


Manual expanding using a torque ratchet adapter or sure-grip wheel is recommended with very soft or narrow bone.

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.

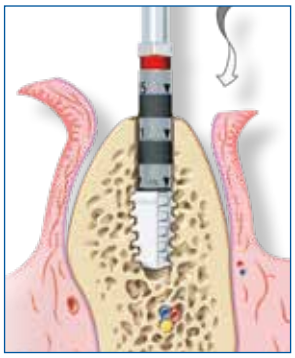
Treatment procedure ADVANCED.

Thread tap ADVANCED depth scale.

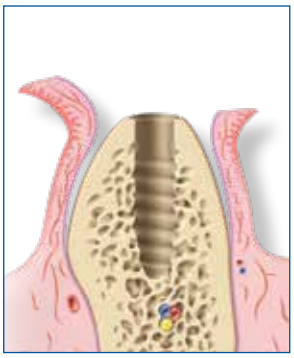


Depending on the bone quality, it is optionally recommended to finish the preparation with a thread tap. If a tioLogic® implant is to be inserted following preparation with the ADVANCED preparation instruments, the thread should be cut with a STANDARD thread tap in combination with a SW 2.5 hex key. For the insertion of a tioLogic® **ST** implant, the **thread tap ADVANCED** should be used. It is available in the same diameters as the implants, has a color-coded groove (here red for ø 4.2 mm) and an additional marking on the shank. The respective depth markings on the thread tap indicate when the previously determined implant depth has been reached. In addition, the depth drill ADVANCED is provided with a hexagon chucking system for the transmission of high torques.

Thread tapping ADVANCED
ø 4.2 mm.



Result, thread tapping.



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 gradually in several preparation stages using light axial finger pressure until the relevant depth mark is level with the upper edge of the bone.

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

Preparation protocol with ADVANCED preparation instruments.

Taking into account different bone qualities.

The preparation protocol may need to be adapted depending on indication and the individual situation of the patient.

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]		min. 7 mm				
Expander ø 3.7[1]			min. 7 mm			
Expander ø 4.2[1]				min. 7 mm		
Expander ø 4.8[1]					min. 7 mm	
Expander ø 5.5[1]						min. 7 mm
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 expanders depends on the requested primary stability. The maximum insertion depth of the expanders corresponds to the respective implant length. The thread taps must be used with insertion torque > 40 Ncm. The depth scales must be observed.

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

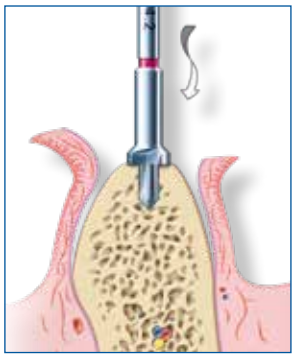
[3] Exemplary illustration of rotary instruments with ø 4.2 mm (red).

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

Hard bone quality				
ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
X	X	X	X	X
X	X	X	X	X
X	X	X	X	X
X		X		
	X		X	X
		X		
			X	X
				X
X				
	X			
		X		
			X	
				X
X	X	X	X	X

Treatment procedure STANDARD.

Surface cutting STANDARD.

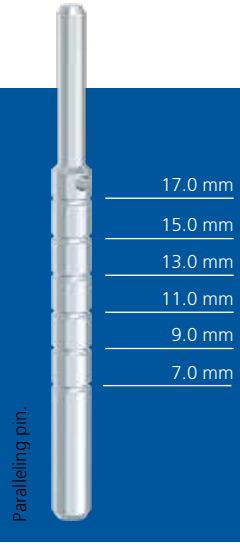


The shape of the **surface cutter STANDARD** has been specially designed for drilling through the compact bone and for preparing a flat bone surface cervically. It has a color-coded groove, which indicates the planned final implant diameter (here red for ø 4.2 mm) and is used for all lengths of implant.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

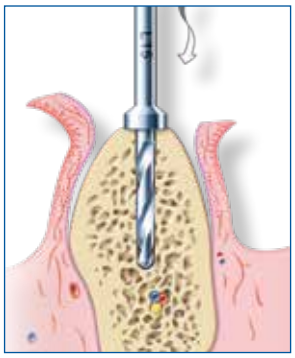
The surface cutter is drilled into the bone until a circumferential imprint of the cutting cylinder is visible on the compact bone. This ensures that the implant is surrounded by bone crestally. If the surface cutter is drilled deeper into the compact bone when there is adequate bone availability, the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

Depending on the implant diameter, surface cutting can be omitted if there is enough flat bone surface in the crestal region.

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



Depth drill STANDARD



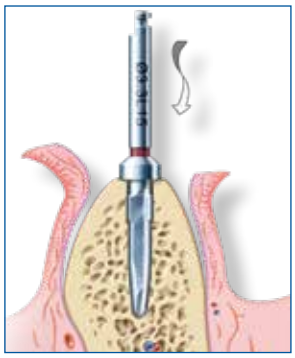
The **depth drill STANDARD** prepares the definitive depth and direction of the implant site independent of the implant diameter. The relevant depth drill is selected according to the planned length (here 15.0 mm) and inserted as far as the integrated depth stop. This guarantees keeping to the exact insertion depth determined in the treatment planning. All depth drills have a diameter of 2.0 mm and are laser-printed with the respective length. For technical reasons, the depth drill is 1.4 mm longer than the given preparation length. 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.

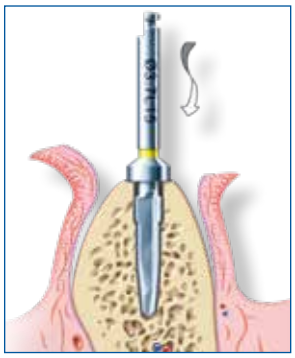
The **paralleling pin** can be used following depth drilling. It is used as orientation for subsequent depth drilling and depth gauge of the depth drilling made. It is available in two diameters: 1.4 mm for pilot drills and 2.0 mm for depth drills. The paralleling pin should be secured with a sterile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

Treatment procedure STANDARD.

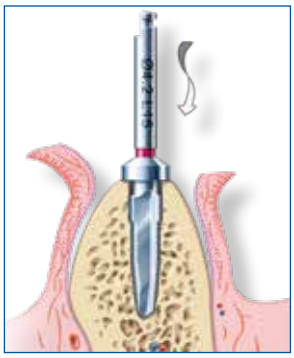
Conical forming STANDARD
ø 3.3 mm.



Conical forming STANDARD
ø 3.7 mm.

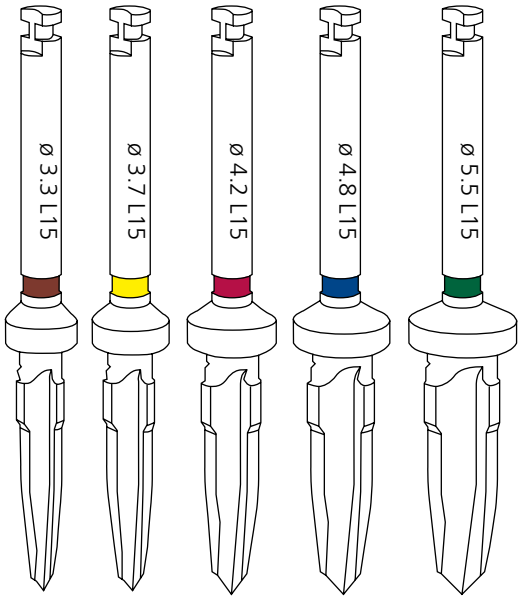


Conical forming STANDARD
ø 4.2 mm.



The conical former STANDARD widens the implant site according to the implant contour. This instrument also has an integrated depth stop and is available for different diameters and lengths of implants. The implant diameter is indicated by a color-coded groove (here red for ø 4.2 mm) and the implant length and diameter are laser-printed on the shank.

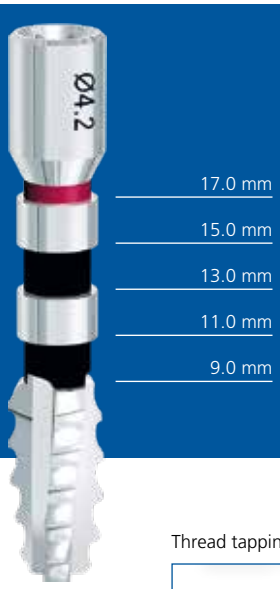
The conical former should be inserted as far as the integrated depth stop. At this working stage the integrated depth stop also ensures that the planned insertion depth is not exceeded. The site is widened gradually according to the implant length with the conical former, beginning with the smallest diameter available until the prescribed implant diameter is attained. To attain the prescribed implant diameter, for example ø 4.2 mm and a length of 15.0 mm, the implant site is widened gradually after depth drilling according to the preparation protocol with the STANDARD preparation instruments (p. 54) with the conical former ø 3.3 mm L 15.0 mm, conical former ø 3.7 mm L 15.0 mm and conical former ø 4.2 mm L 15.0 mm. A conical former is also available for high-density bone (dense bone). It is available according to implant diameter and does not have an integrated depth stop. The depth markings allow alignment at the relevant implant site (application see section on thread tapping). For technical reasons the conical former is 1.4 mm longer than the given preparation depth (conical former for dense bone 0.2 mm longer). This should be taken into account during diagnosis and preparation.



Bone chips can be collected with the cutter grooves of the conical former and used as autograft material. Manual conical forming using a torque ratchet adapter or sure-grip wheel is recommended with very soft or narrow bone.

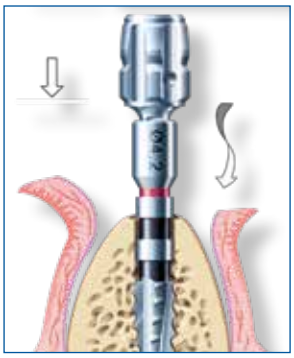
The green handpiece (500 – 800 min^{-1}) is used for drilling with external cooling using a sterile, cooled physiological saline solution (5 °C / 41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.

Treatment procedure STANDARD.

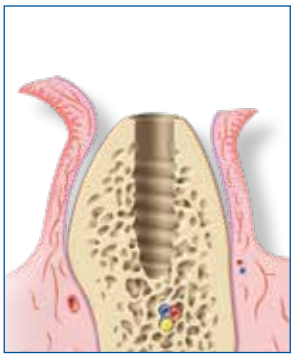


Thread tap depth scale STANDARD.

Thread tapping STANDARD.



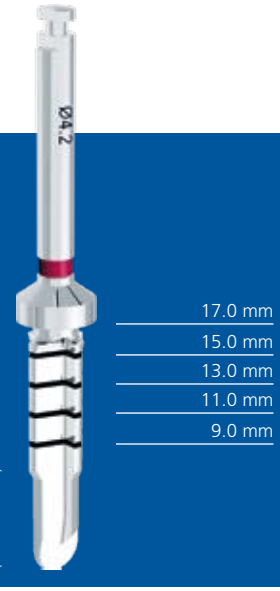
Result, thread tapping STANDARD.



Preparation of the implant site for tioLogic® implants is completed using the **thread tap STANDARD**. It is available in the same diameters as the implants, has a color-coded groove (here red for ø 4.2 mm) and an additional marking on the shank. The respective depth markings on the thread tap indicate when the previously determined implant depth has been reached.

The thread should be tapped manually using the torque ratchet. Depending on the indication, hex keys of different lengths, which are used for connecting the torque ratchet, can be inserted into the socket of the thread tap. In accordance with the preparation protocol using the STANDARD preparation instruments (p. 54), the thread is tapped gradually in several preparation stages using light axial finger pressure until the relevant depth mark is level with the upper edge of the bone.

The thread tap can also be used with a handpiece (max 10 min^{-1}) with the relevant attachments in the same way as with the manual technique. The protocol for high-density bone should be followed if more than 50 Ncm is required.



Conical former DB STANDARD (dense bone) 15.0 mm.

If a torque of 50 Ncm is exceeded during thread tapping and the relevant depth mark is not level with the upper edge of the bone, the thread tap should be removed and the implant site prepared further with the conical former DB (dense bone).

The **conical former DB STANDARD** (dense bone) is specially designed for additional preparation of the implant site in the case of dense bone. It is available according to implant diameter (9.0 / 11.0 / 13.0 / 15.0 mm) and does not have an integrated depth stop. The implant diameter is indicated by a color-coded groove (here red for ø 4.2 mm) and laser printed on the shank of the conical former. The respective depth markings on the conical former DB (dense bone) indicate when the previously determined implant depth has been reached.

The conical former DB STANDARD (dense bone) should be inserted until the relevant depth mark is level with the upper edge of the bone. For technical reasons the conical former DB STANDARD (dense bone) is 0.2 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.

Preparation protocol with STANDARD preparation instruments.

Taking into account different bone qualities.

The preparation protocol may need to be adapted depending on indication and the individual situation of the patient.

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
Surface cutter[4]		X	X	X	X	X
Depth drill[1]		X	X	X	X	X
Conical former 3.3[1]		X	X		X	
Conical former 3.7[1]			X	X		X
Conical former 4.2[1]				X	X	
Conical former 4.8[1]					X	X
Conical former 5.5[1]						X
Thread tap[2,3,4]						
Conical former DB[2,4]						

[1] The insertion depth / length of the depth drill and the conical formers depends on the implant length.
[2] The insertion depth of the thread tap and the conical former DB depends on the implant length.The depth scales must be observed
[3] For the insertion of tioLogic® ST implants, please use the thread taps ADVANCED.
[4] Exemplary illustration of rotary instruments with ø 4.2 mm (red).

STANDARD

for tioLogic®

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	X
				X
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	X
				X
X	X	X	X	X
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. The 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. 12).

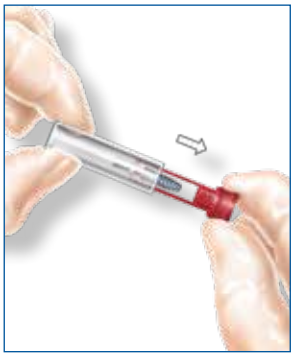
Foil packaging.

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

Removing glass vial with implant.

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

Removing implant from glass vial.



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

Implant insertion.

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

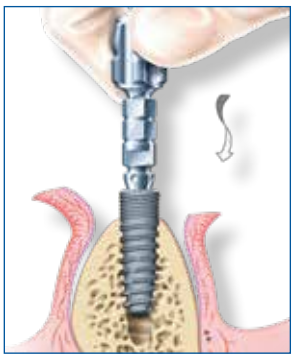
Manual insertion with the insertion key for the torque ratchet or sure-grip wheel.

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 quarter-turn of the insertion key and inserted into the prepared implant site using a handpiece.

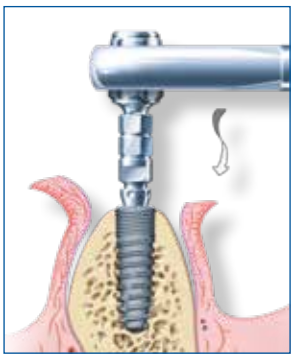
The markings on the insertion aid correspond to the five PentaStop® rotational security stops on the implant and allow alignment of the rotational security with regard to the subsequent prosthetic restoration.

Releasing the implant.

Manual insertion.



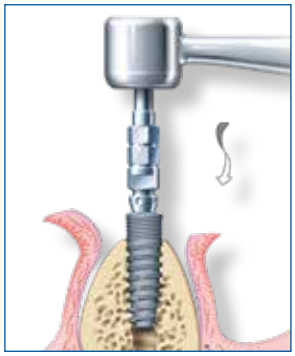
Manual insertion with the ratchet.



Treatment procedure.

Handpiece insertion with the insertion key.
The insertion key SW 2.5 (available in 2 different lengths) is inserted into the implant insertion aid, the implant is released from the implant holder by a quarter-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 40 Ncm should not be exceeded with any insertion procedure.

Handpiece insertion.



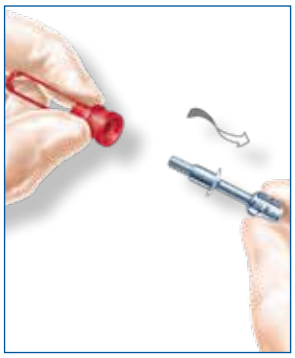
The motor speed during handpiece insertion should not exceed 10 min-1. Use of an excessive torque or motor speed can damage the implant site.

The five markings on the insertion aid correspond to the five PentaStop© rotational security stops on the implant 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 insertion aid removed. If the implant turns when the screw is loosened (e.g. with reduced horizontal bone), the locking key for the insertion aid should be used to provide rotational security. Alternatively, the insertion key ratchet can be used to finalize the positioning of the implant. Ensure that epithelial tissue does not enter the implant site during implant insertion. If the implant is difficult to insert, the thread of the implant site should be re-tapped or the conical former (dense bone) used.

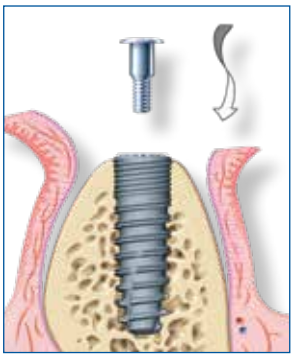
Tightening torque
- depending on the bone quality max. 40 Ncm

Closure screws S, M and L.

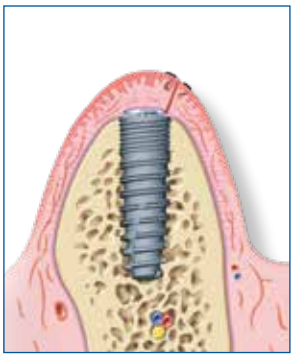
Removing the closure screw.



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.

Tightening torque

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

Wound closure.

After checking the operation site, the wound is closed by suturing. 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, an X-ray should be made to control the fit and position of the implant.

The following are indications of successful implant insertion:

- the implant is stable and a clear tapping sound is produced
- there are no signs of peri-implant inflammation
- the patient 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 PatientPass (REF 989-961-20).

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

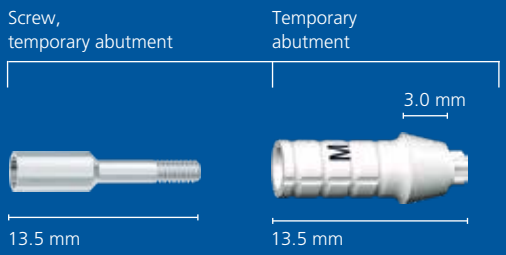
Post-operative treatment, temporary restoration, healing stage, follow-up.

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

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

All instruments used during surgery should be thoroughly cleaned, disinfected and sterilized. Components like the torque ratchet should be dismantled (p. 76 Reusability of surgical instruments) 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 fitted with soft lining. If there are residual teeth, a temporary prosthetic restoration is generally fabricated on the abutment teeth prior to implant placement or an existing denture is converted.

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

Temporary abutments 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 intra-orally with the screw for the temporary abutment; the contours are marked and adjusted extra-orally. 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 extra-orally 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 before sealing the screw aperture with wax and placing the temporary restoration. The crown should only be retained with temporary cement.

Tightening 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. It can vary depending on the bone quality, the surgical procedure used and the patient's anatomy.

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

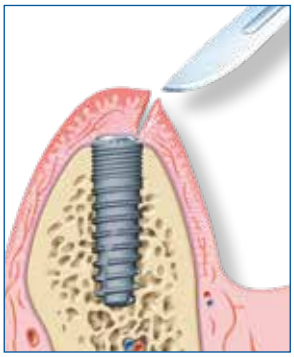
Follow-up.
Patients should be entered into a regular recall program after the restoration has been fitted to ensure the long-term success of the implantological restoration. Patients should be given instructions on the appropriate hygiene regime for the implants and restoration.

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

Implant exposure.

The implant is exposed after the healing stage. The patient should be prepared in the same way as for other surgical procedures.

Implant exposure



Gingiva 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 are available for the series of abutments S, M or L and the gingival heights 1.5, 3.0, 4.5 or 6.0 mm (laser-printed).

Tightening 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.

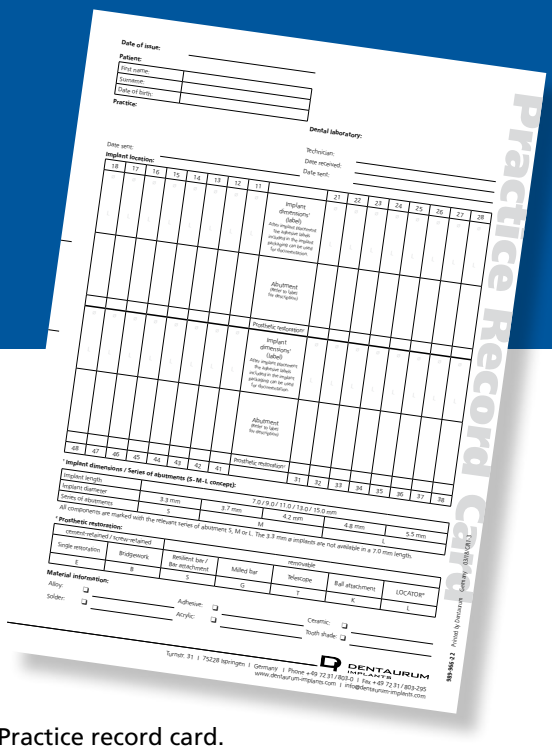
Impression taking.

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, bridges, ball abutments, LOCATOR®, AngleFix), the impression can also be taken with other special impression components over the respective primary abutments. These special impression techniques are described in the Prosthetic Manual (REF 989-960-20).

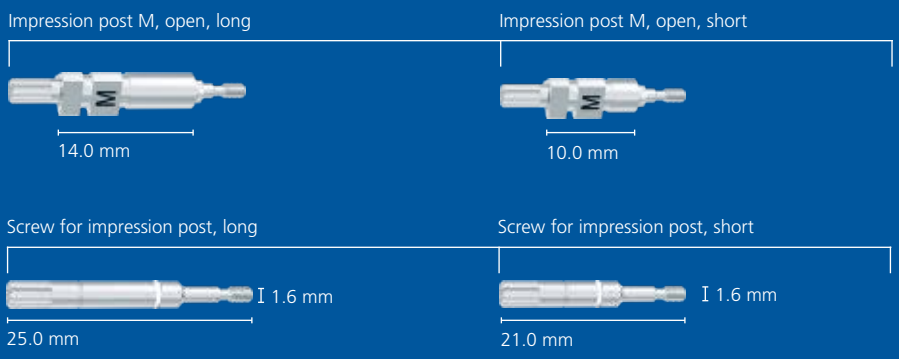
Silicone or polyether impression materials are recommended for impression-taking due to their high precision and elastic recovery.

Practice record card.



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 record card (REF 989-966-22). The card is kept with the prosthetic restoration during the entire fabrication procedure. At the fitting stage it is given to the 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.

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

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

Tightening torque

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

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

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

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

Treatment procedure.

Groove sure-grip screw.

Marking 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, open, 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.

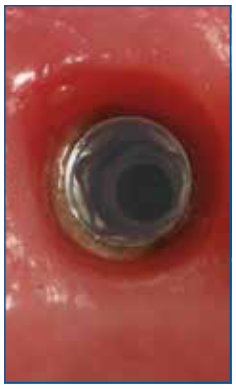
Closed impression technique.

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.

Tightening torque

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

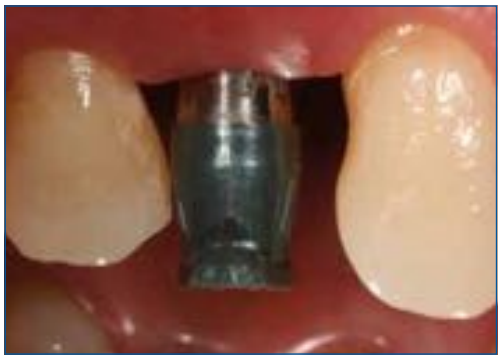
Exposed implant.



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). An x-ray can be taken to check if the impression post is positioned correctly.

Impression post M with cap M.



The corresponding impression aid S, M or L is fitted according to the vertical retention grooves until it perceptibly and audibly 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. 65). After the impression material has cured, the tray is removed. The impression posts with screws are delivered to the laboratory together with the impression.

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

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

Impression tray with cap M.

Bite registration.

Bite registration caps are available for registering the bite before or after taking the impression. These caps are also laser-printed with the series of abutment S, M or L (here M). They click, both perceptibly and audibly, into place on the impression posts.

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

Tightening torque

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

General information.

! Special measures are required with certain instruments. Please refer to section Reusability of surgical instruments p. 76.

Use.

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

The 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 equipment used (disinfector, sterilizer) is 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 put back into 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. Rotating instruments can be placed in the surgical tray easyClean for tioLogic® after use. 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 max. 2 hours).

Loose dirt should be removed under running water or using a disinfectant solution; the disinfectant should not contain aldehyde (may cause fixation of blood debris) and should have certified efficacy (e.g. DGHM or FDA approved and CE marking); it should also be suitable for disinfection of the instruments and be compatible with the instruments (p. 75 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 five times using a disposable syringe (minimum volume 5.0 ml).

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

Mechanical cleaning/ disinfection (disinfector or washer disinfector).

When choosing and using a disinfector, ensure that

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

General information.

! Special measures are required with certain instruments. Please refer to section Reusability of surgical instruments p. 76.

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

- it is suitable for cleaning metal and plastic instruments,
- an additional disinfectant with certified efficacy (e.g. DGHM or FDA approved and CE marking) is used – provided that thermal sterilization is not used – and that it is compatible with the cleaning agent used,
- the chemicals used are compatible with the instruments (p. 75 Material resistance),
- the concentrations given by the cleaning agent and disinfectant manufacturer are strictly adhered to.

Procedure.

1. Dismantle the instruments as far as possible.
2. Place the dismantled instruments in the disinfector. Ensure that the instruments do not come into contact with one another.
3. Start the program.
4. Remove the instruments from the disinfector when the program is complete.
5. Check and pack the instruments in a clean area as soon as possible after removal (p. 74 Care, monitoring, 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 the cleaning agent Sekumatic FR (ECOLAB, 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. 75 Material resistance),
- combined cleaning agents / disinfectants should not be used if possible.

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

Procedure – cleaning.

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

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

   If applicable: rinse all hollow sections of the instruments five times using a disposable syringe (minimum volume 5.0 ml).
4. Check the instruments (p. 74 Care, monitoring, maintenance, packaging).

Procedure – disinfecting.

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

   If applicable: rinse all 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. 74 Care, monitoring, 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 information

! Special measures are required with certain instruments. Please refer to section Reusability of surgical instruments p. 76.

Care, monitoring.

Instruments should be checked after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipped edges and contamination. Damaged instruments should be discarded (limited reuse p. 17 Instruments ADVANCED, p. 23 Instruments STANDARD and p. 76 Reusability of surgical instruments). Instruments that are still contaminated should be cleaned and disinfected again.

Maintenance.

Reassembly of instruments (p. 76 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 AAMI 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
- 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 a Systec V-150 steam sterilizer (Systec GmbH Labor- Systemtechnik, Wettenberg, Germany). The procedure described above was taken into account during the tests.

Torque ratchet.

Torque ratchet.

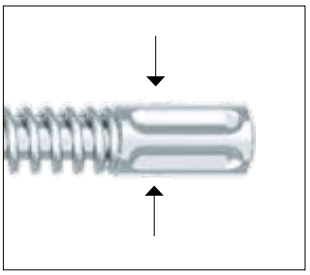
Disassembling.
Completely loosen torque adjustment screw ⑤ and remove the spring ④. Pull ratchet head ② with the threaded rod from the scale sleeve ③.

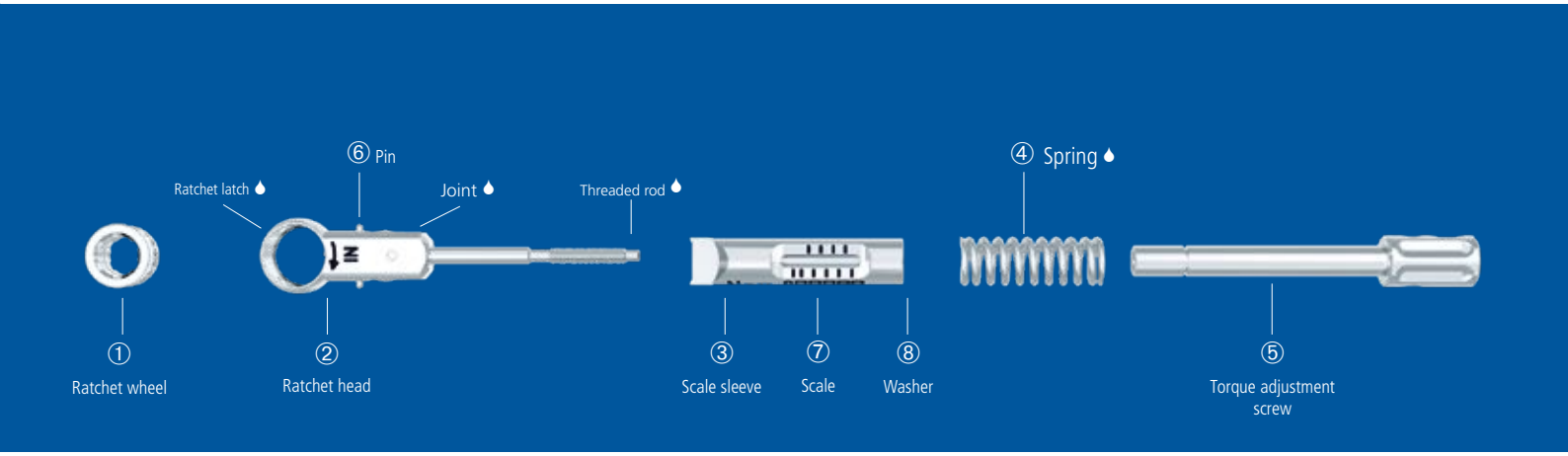
Remove ratchet wheel
Pull back the pin ⑥ in the direction of the arrow using your thumb and index finger and remove the ratchet wheel ①.

Blocking function – „∞" mark.


Ratchet head, assembled.


Ratchet head, disassembled.


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



Assembling.

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

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

Lubricating points (♦)

Lubricate the areas marked with the drop symbol with oil for handpieces. Then assemble the ratchet components as described below and perform a function test.

Slide the spring ④ over the torque adjustment screw ⑤. Pass the ratchet head ② with the threaded rod through the scale sleeve ③ and screw to torque adjustment screw ⑤.

After assembly and before each use, check the correct function of the torque ratchet. If there is an audible regular ratchet noise and the mechanism of the torque limit functions, the instrument is functioning correctly.

Sterilization.

The instrument must be sterilized with steam at 134 °C / 273 °F for 20 minutes.

Apply the regulations in force in the country where the instrument is used.

Before sterilization, the torque ratchet must be completely assembled and set to the lowest torque.

Sterilize according to cycles of sterilization recommended by the manufacturer of the autoclave. We recommend the use of devices equipped with a vacuum pump (type B) to decrease the risk of formation of air pockets.

We advise against the use of a hot air sterilizer because it can lead to ageing of the spring and subsequently impair instrument precision. Find more information on the preparation of medical devices at www.rki.de or www.a-k-i.org.

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