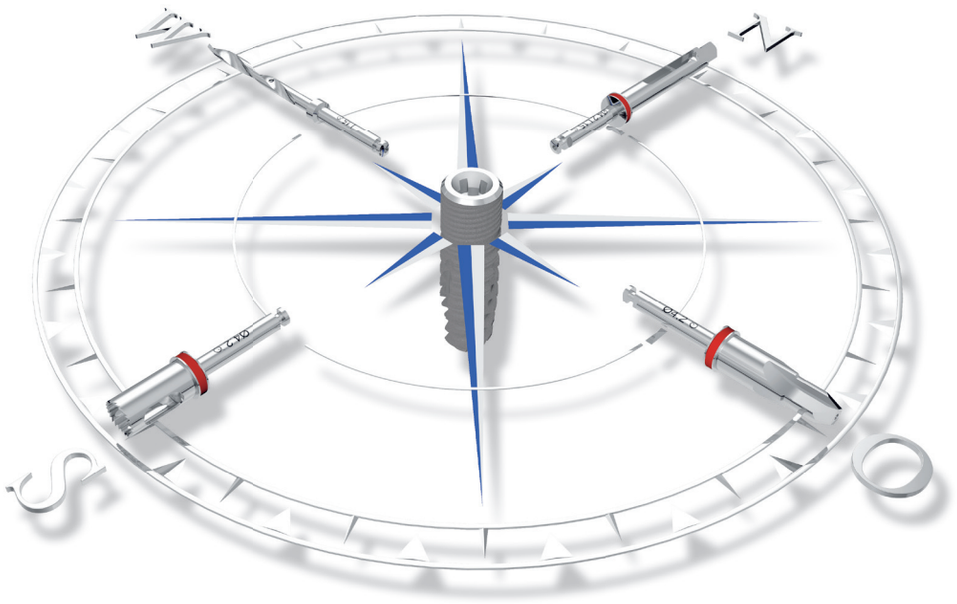
EN



tiologic TWINFIT

tiologic ST

POSITION
for tioLogic®

Surgery Manual.

DENTAURUM

CONTENT.

More than 25 years of science, innovation and service.

Dentaurum has more than 25 years of experience in implantology and more than 130 years of expertise in the fields of dental prosthetics, titanium technology and orthodontics. The synergy potential this creates leads to groundbreaking innovations und results in solutions that are convincing – Made in Germany. Similarly, long-term scientific cooperations with experts at universities and clinics and ongoing discourse with dentists and dental technicians have been equally successful.

1995

TIOLOX® implant system – the perfect fusion of function, safety and user friendliness.

2007

tiologic Implant system

tioLogic®, the patented implant system – developed from the sum of our experience. For maximum safety, perfect aesthetics and easy handling.

2007

2009

2010

2011

tioLogic® digital. Complete solution for your CAD/CAM workflow with tioLogic® implants.

tioLogic® ST implant system and tioLogic® ADVANCED. For quick and atraumatic implant insertion and high primary stability.

2013

2013

2015

CITO mini® implant system – one-piece implants, reduced in diameter with ball abutment.

tioLogic® TWINFIT, the patented implant system. The unique Abutment Switch on one implant offers maximum flexibility in prosthetic restorations.

2018

2018

tiologic Implant system

After more than 11 successful years, the brand tioLogic® makes a new appearance in a modern design.

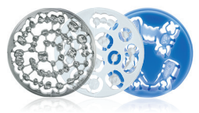
to be continued ...

Dentaurum.
Dental competence spanning more than 130 years.

Orthodontics

Implantology

Prosthetics



Ceramics

Foto: © Christian Ferrario

Quality is your demand and our expertise.

Dental technologies set standards.

Dentaurum develops, produces and sells products for dentists and dental technicians worldwide. The variety of products for dental technology, orthodontics and implantology is unique in the dental world.

Quality inspires confidence.

As the oldest independent dental company in the world, we have worldwide experience with high-quality dental products. We owe our success on the market to the fact that we consistently fulfill customer and market requirements. This is why we are committed to the constant further development of the company and continuous improvement of the quality of our processes and products.

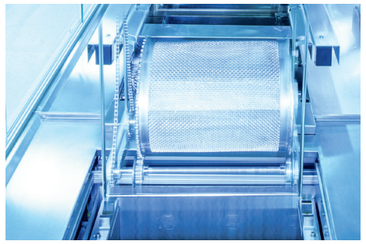
Service as added value.

There are many reasons for using Dentaurum products both in the dental practice and in the laboratory. Quality is the decisive factor. Our company philosophy is to not only offer high quality products, but to provide additional services for the products as well. For example, we have an extensive training program for new and advanced users with an internationally experienced team of course instructors. We're happy to provide you with more information.

High-tech in-house.

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

A further result of these efforts: a comprehensive product portfolio which is one of Dentaurum's strengths. No other dental company has such an extensive range of products offering a total of more than 8,500 articles.



Safety information.

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

Brief description.

tioLogic® ST and tioLogic® TWINFIT implant types 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® ST and tioLogic® TWINFIT implant systems contain specially coordinated instruments, abutments and accessories for insertion of the implant and fabrication of the prosthetic restoration. Only original components of the tioLogic® ST and tioLogic® TWINFIT implant systems 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 implantologist should note and document any problematic cases and inform the manufacturer Dentaurum.

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

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

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

tioLogic® ST and tioLogic® TWINFIT implant types are not known to have any side effects or produce any interaction. It cannot, however, be ruled out that in rare cases allergies to components used in the materials of the tioLogic® ST and tioLogic® TWINFIT implant systems may occur or that there may be electrochemically-induced discomfort.

Use, availability, precautions, documentation.

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

Before use, operators should ensure that they have carefully read and understood the Instructions for use / manuals of all tioLogic® ST and tioLogic® TWINFIT implant systems. As the instructions and manuals cannot cover all aspects for immediate use, we strongly recommend that, before using the systems, clinicians attend a tioLogic® ST and tioLogic® TWINFIT implant system training course offered by Dentaurum to learn the correct techniques. **Note: Instructions for use / manuals cannot describe every eventuality and possible application.**

- Refer to the product catalogs and the surgery manuals for further information on precautions and the selection of components for the surgical procedure.
- Refer to the product catalogs and the prosthetic manuals for information on precautions and the selection of components for the prosthetic procedure.

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

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

Note: Not all components are available in every country.

Quality, warranty and liability.

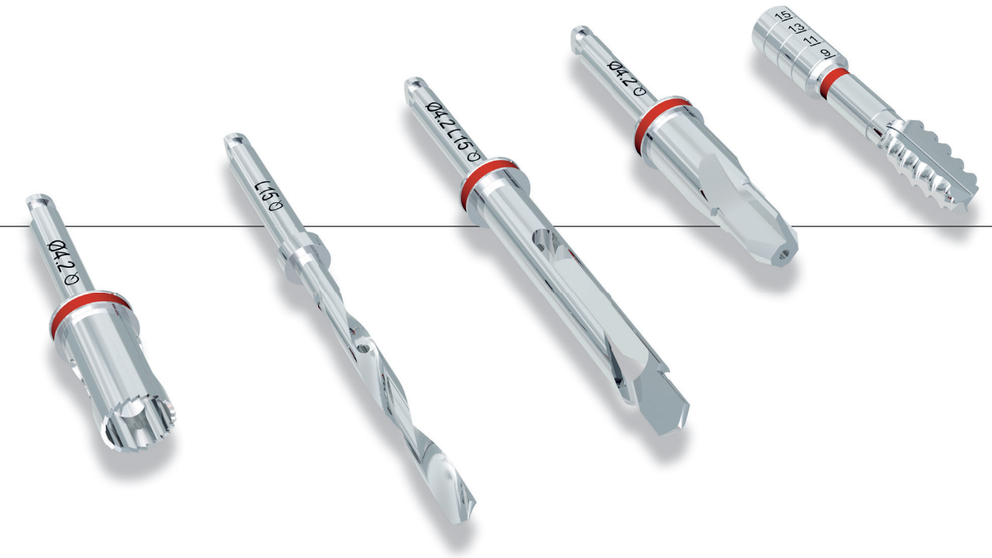
Development, clinical testing, production and quality control of the tioLogic® ST and tioLogic® TWINFIT product ranges are completed in accordance with the Medical Device Directive 93/42/EEC. Sections 9 and 10 of our General Terms of Delivery and Payment apply with regard to warranty or liability – unless 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® ST and tioLogic® TWINFIT product ranges are used in combination with products from other manufacturers, which have not been specifically recommended for use by Dentaurum.

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

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

Surgical instruments pOsition for tioLogic®.



The pOsition for tioLogic® system contains specially coordinated instruments and accessories for bone site preparation and implant insertion. All rotary instrument procedures as well as implant insertion can be completed using the surgical stent. Only original components of the pOsition for tioLogic® implant system should be combined in accordance with the Instructions for use / manuals.

Preparation of the implant site.

- The internally cooled gingiva cutter removes mucosa to the diameter of the implant and is used for all lengths of implants with the same diameter (optional). An integrated depth stop ensures that it does not exceed the predefined insertion depth. The gingiva cutter is color-coded to indicate the diameter as well as laser-marked with the implant diameter.
- The internally cooled depth drill prepares the final depth and alignment of the implant site. An integrated depth stop ensures that it does not exceed the planned insertion depth. It is laser-marked with the respective length and 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, planning and preparation.
- The internally cooled stepped countersink contours the implant site to the implant diameter. It has an integrated depth stop and is available for each diameter and length. An integrated depth stop ensures that it does not exceed the planned insertion depth. The design of the cutter geometry allows bone chips to be collected in the corresponding cavities. The stepped countersink is color-coded to indicate the diameter and laser-marked with the implant diameter and length.
- The internally cooled expander prepares the fine thread section of the implant site to the diameter of the implant. The integrated depth stop ensures that it does not exceed the planned insertion depth. The expander is color-coded to indicate the diameter and laser-marked with the implant diameter and length.
- The thread tap is used manually with high-density bone (torque ratchet). It is used for the final preparation stage and has the same diameter as the implant. The depth markings allow alignment at the relevant implant length. The thread tap is color-coded to indicate the diameter and is also laser-marked.

CAUTION:

- **Use thread tap pOsition only for tioLogic® implants.**
- **Use thread tap ADVANCED only for tioLogic® ST and tioLogic® TWINFIT implants.**

Instruments

All rotating 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. All reusable rotary instruments are supplied non-sterile and should be sterilized before use.

They should be thoroughly cleaned, disinfected and conditioned before being used 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 clearly marked should be used (refer to chapter General Information).

Rotary instruments – used with proper care and provided that they are not damaged or contaminated – can be reused in dense bone 15 to 20 times; it is the implantologist's responsibility to ensure that they are not used beyond this and that no damaged and / or contaminated instruments are used. No liability is accepted if these instructions are disregarded. To record the number of drilling applications, you can download and print the form Frequency of drilling applications tioLogic® pOsition at www.dentaurum.de.

Various extensions for mechanical and manual instruments are available for working in limited space conditions.

Diagnosis and planning.

This section provides a general overview of diagnosis and planning.

For more detailed information on these aspects, please refer to current literature.

Implantologists and dental technicians with many years of experience are available to answer any questions that you may have.

Indications.

All tioLogic® ST and tioLogic® TWINFIT implant types can be used in both 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 all tioLogic® ST and tioLogic® TWINFIT implant types should be in proportion to the prosthetic restoration.

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

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

The Dentaurum training program ensures that all dentists, dental technicians and dental assistants involved in the implant procedure are optimally prepared by experienced lecturers.

Dentaurum provides numerous training courses at different levels tailored to suit the target group, the level of knowledge and individual interests.

Contraindications.

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

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

General contraindications for dental surgery procedures apply. These include:

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

Local / personal contraindications.

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

Diagnosis and planning.

Planning for template-guided implant insertion.

pOsition for tioLogic® is a sleeve and drill system from Dentaurum that ensures reliable, minimally invasive and precise template-guided implant insertion using coordinated planning software for accurate diagnosis and 3D planning.

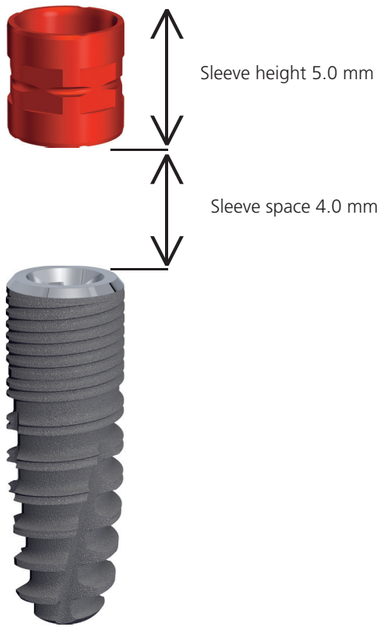
Precise fabrication of the surgical stent and exact transfer from the planning software to the surgical stent are basic requirements for the application of pOsition for tioLogic®.

During planning, the minimum distance to critical structures must be maintained and the corresponding instructions of the planning software used must be followed.

This applies, inter alia, to:

- Distance to the mandibular nerve and inferior alveolar nerve.
- Distance to an adjacent natural tooth.
- Distance to an adjacent implant.
- Implant diameter and length should be determined so that there is adequate bone availability around the implant.
- Sleeve height and space between the sleeve and implant shoulder.

Sleeve height and space between the sleeve and implant shoulder



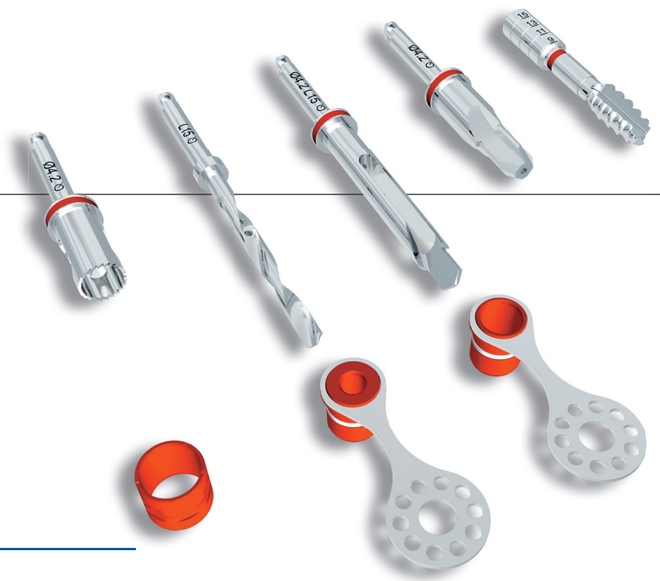
Supported software systems.

You can find an overview of the supported software systems on Guided Surgery here:
www.dentaurum.de/deu/position-for-tiologic-33490.aspx

The overview shows the allocation of the implant diameters to the corresponding sleeves (basic sleeves / inner sleeves):

	S	M		L	
Implant diameter	ø 3.3 mm	ø 3.7 mm	ø 4.2 mm	ø 4.8 mm	ø 5.5 mm
Basic sleeve					
Inner diameter Outer diameter	4.3 mm 5.1 mm	4.3 mm 5.1 mm	4.8 mm 5.6 mm	5.4 mm 6.2 mm	6.1 mm 6.9 mm
Inner sleeve Depth drill					
Inner diameter Outer diameter	2.05 mm 4.3 mm	2.05 mm 4.3 mm	2.05 mm 4.8 mm	2.05 mm 5.4 mm	2.05 mm 6.1 mm
Inner sleeve Stepped countersink					
Inner diameter Outer diameter	2.85 mm 4.3 mm	3.15 mm 4.3 mm	3.65 mm 4.8 mm	4.25 mm 5.4 mm	4.95 mm 6.1 mm

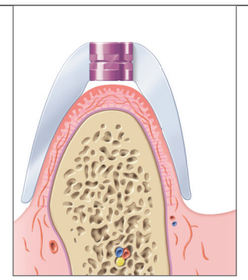
Treatment procedure.



Description implant insertion.

The sleeves for the pOsition for tioLogic® system are manufactured from titanium grade 5 and guarantee exact guidance of the corresponding drills. All sleeves are designed as single-patient components to ensure this exact guidance with each drilling procedure. Any additional use can result in inexact drill guidance and associated inaccurate positioning of the implant.

The basic sleeves guide the gingiva cutter and expander. The corresponding inner sleeves guide the depth drill and stepped countersink. The inner sleeves are inserted in the respective basic sleeves (color-coded) and secured with a silicone ring to ensure positional stability during use. They have a grip section which, due to its special bending zone, can be adapted three-dimensionally according to the amount of space available orally. The inner sleeves can also be screw retained on the holder for inner sleeve using their grip section. This ensures optimal application of the inner sleeves particularly in the distal region, as the entire grip section is extended and there is also the above-mentioned three-dimensional adaptability.

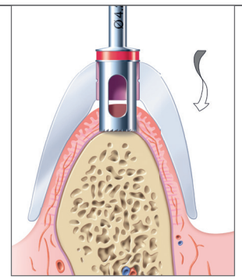


Fitted surgical stent.

Fitting the surgical stent.

Before surgery starts, check that the diagnostic information is complete, including the surgical stent that was fabricated and disinfected beforehand.

When fitting the disinfected surgical stent check that it is correctly positioned, e.g. on the residual dentition of a partially edentulous jaw. Positioning of the surgical stent in the patient's mouth must correspond exactly with planned positioning of the surgical stent in the planning software. The gingiva or other structures should not interfere with the correct fit of the stent. If this is the case, the gingiva must be mobilized or the structure adapted so that it is possible to fit the stent without any interference. Raising a gingival flap also makes it easier to view the operation site.

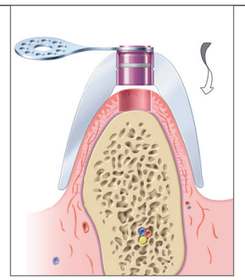


Gingival incision pOsition.

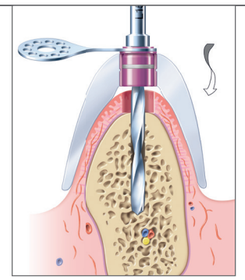
Gingival incision pOsition.

As an alternative to the method for opening the mucosa described above, the gingiva can be removed minimally invasively using the gingiva cutter pOsition. The gingiva cutter has a color-code, which is marked with the planned final implant diameter(here: red for ø 4.2 mm). The internally cooled gingiva cutter is inserted in the basic sleeve (here: red for ø 4.2 mm) and cuts through the mucosa to the bone. The stent must be removed to allow excision of the separated mucosa.

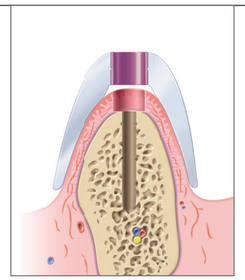
Depth drilling is completed using a green contra-angle handpiece (500 – 800 min^{-1}) and sufficient cooling using a sterile cooled physiological saline solution (5 °C / 41 °F). Drilling should be completed intermittently without pressure, to allow the tip of the gingiva cutter to cool.



Inserted inner sleeve for depth drilling.



Depth drilling pOsition.



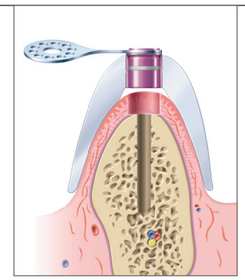
Result of depth drilling.

Depth drilling pOsition.

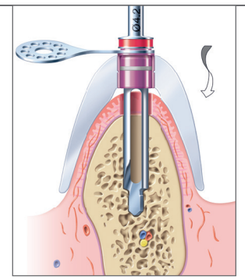
The correct color-coded inner sleeves should be used for application of the depth drill (refer to p. 19).

The internally cooled depth drill prepares the final depth and alignment of the implant site independent of the implant diameter. The respective inner sleeve for depth drilling should be used for application of the depth drill pOsition (here: red for ø 4.2 mm). The inner sleeve is inserted in the corresponding basic sleeve (here: red for ø 4.2 mm) and accurately guides the depth drill with the diameter 2.0 mm. The respective depth drill is selected according to the planned length of the implant (here: length 15.0 mm) and inserted through the corresponding inner sleeve as far as the integrated depth stop. This ensures that the planned insertion length is not exceeded, even when the site is difficult to see. All depth drills have internal cooling and a diameter of 2.0 mm. They are laser-marked with the respective length. For technical reasons, the depth drill is 1.0 mm longer than the given preparation length. This should be taken into account during planning and preparation.

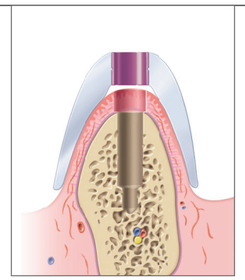
Depth drilling is completed using a green contra-angle handpiece (500 – 800 min^{-1}) and sufficient cooling using a sterile cooled physiological saline solution (5 °C / 41 °F). Drilling should be intermittent without applying pressure to ensure that the tip of the drill can cool.



Inserted inner sleeve for stepped countersinking.



Stepped countersinking pOsition.



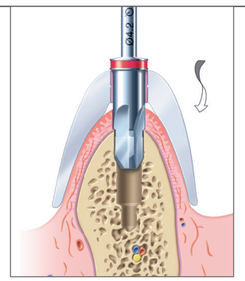
Result stepped countersinking.

Stepped countersinking pOsition.

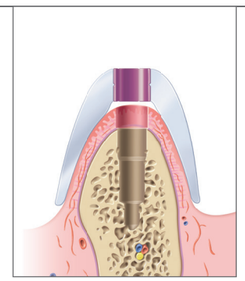
The correct color-coded inner sleeves should be used for application of the stepped countersink (refer to p. 19).

The internally cooled stepped countersink widens the implant site to correspond to the implant contour. The respective inner sleeve for stepped countersinking should be used for application of the stepped countersink pOsition (here: red for ø 4.2 mm). The inner sleeve is inserted in the corresponding basic sleeve (here: red for ø 4.2 mm) and accurately guides the stepped countersink. The respective stepped countersink is selected according to the planned length and diameter of the implant (here: red for ø 4.2 mm, length 15.0 mm) and inserted through the corresponding inner sleeve as far as the integrated depth stop. This ensures that the planned insertion depth is not exceeded, even when the site is difficult to see. All stepped countersinks have internal cooling and a special cavity for collecting bone chips. They are laser-marked with the respective diameter and length and color-coded to indicate the diameter. For technical reasons the stepped countersink is 1.0 mm longer than the given preparation length. This should be taken into account during planning and preparation.

Depth drilling is completed using a green contra-angle handpiece (500 – 800 min^{-1}) and sufficient 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 stepped countersink can cool.



Expanding pOsition.



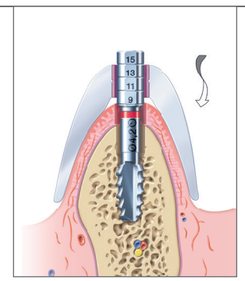
Result, expanding.

Expanding pOsition.

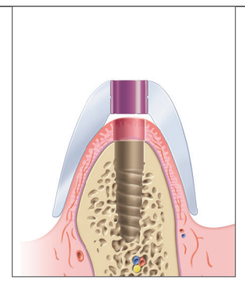
After use of the stepped countersink, the fine thread section of the implant site is prepared to the diameter of the implant using the internally cooled expander. The internally cooled expander (here: red for ø 4.2 mm) is inserted through the basic sleeve (here: red for ø 4.2 mm) as far as the integrated depth stop.

The expander is laser-marked with the respective diameter and color-coded to indicate the diameter.

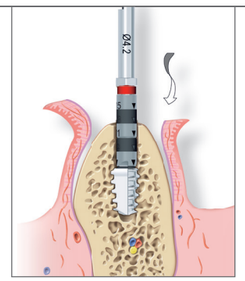
Depth drilling is completed using a green contra-angle handpiece (500 – 800 min^{-1}) and sufficient cooling using a sterile cooled physiological saline solution (5 °C / 41 °F). Drilling should be completed intermittently without pressure, to allow the tip of the expander to cool.



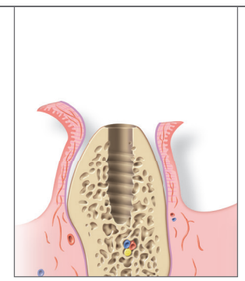
Thread tapping pOsition.



Result, thread tapping.



Thread tapping ADVANCED.



Result, thread tapping.

Thread tapping.

CAUTION:
Use thread tap pOsition only for tioLogic® implants.
Use thread tap ADVANCED only for tioLogic® ST and tioLogic® TWINFIT implants.

Depending on the quality of the bone, a recommended option is to complete preparation of the implant site using the thread tap through the basic sleeve. The thread tap is the same diameter as the available implant diameters and has the corresponding color-coded groove (here: red ø 4.2 mm) and a laser marking on the shank. The thread tap does not have an integrated depth stop and is not guided using the basic sleeve. The depth reached can be read at the upper edge of the basic sleeve using the depth markings on the thread tap pOsition. When using thread taps ADVANCED, the depth reached can be read at bone level. Corresponding depth markings on the thread tap indicate when the planned implant length is attained (here: L 15.0 mm).

The thread should be tapped gradually in several preparation stages using light axial finger pressure until the relevant depth mark is level with the upper edge of the basic sleeve. Two to four preparation stages may be required depending on the bone density to ensure that the threads are clearly defined and the correct depth is attained.

Alternatively thread tapping can be completed using a green contra-angle handpiece (max. 10 min^{-1}) and sufficient external cooling using sterile cooled physiological saline solution (5 °C / 41 °F).

After thread tapping is completed, the alveolus should be thoroughly rinsed with sterile, cooled physiological saline solution (5 °C / 41 °F).

*Thread tap pOsition (use only for tioLogic® implants)	
REF 382-833-00	Thread tap pOsition, ø 3.3 mm
REF 382-837-00	Thread tap pOsition, ø 3.7 mm
REF 382-842-00	Thread tap pOsition, ø 4.2 mm
REF 382-848-00	Thread tap pOsition, ø 4.8 mm
REF 382-855-00	Thread tap pOsition, ø 5.5 mm

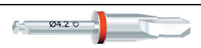
**Thread tap ADVANCED (use only for tioLogic® ST and tioLogic® TWINFIT implants)	
REF 382-933-00	Thread tap ADVANCED, ø 3.3 mm
REF 382-937-00	Thread tap ADVANCED, ø 3.7 mm
REF 382-942-00	Thread tap ADVANCED, ø 4.2 mm
REF 382-948-00	Thread tap ADVANCED, ø 4.8 mm
REF 382-955-00	Thread tap ADVANCED, ø 5.5 mm

Preparation protocol – pOsition for tioLogic®.

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

X Preparation depth in accordance with implant length

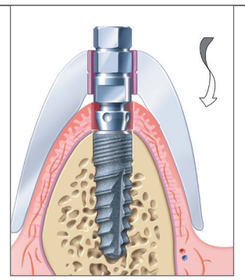
( ) Optional application
(taking into account the respective bone quality)

		Soft bone quality				
		ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
Gingiva cutter pOsition[1]		(X)	(X)	(X)	(X)	(X)
Depth drill pOsition[2]		X	X	X	X	X
Stepped countersink pOsition[1]		X	X	X	X	X
Expander pOsition[1]		X	X	X	X	X
Thread tap ADVANCED[1/3]						
Thread tap pOsition[1/4]						

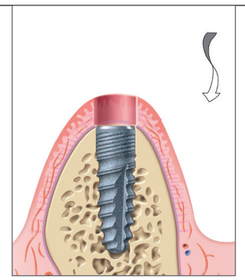
	Medium bone quality				
	ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
Gingiva cutter pOsition[1]	(X)	(X)	(X)	(X)	(X)
Depth drill pOsition[2]	X	X	X	X	X
Stepped countersink pOsition[1]	X	X	X	X	X
Expander pOsition[1]	X	X	X	X	X
Thread tap ADVANCED[1/3]					
Thread tap pOsition[1/4]					

	Hard bone quality				
	ø 3.3	ø 3.7	ø 4.2	ø 4.8	ø 5.5
Gingiva cutter pOsition[1]	(X)	(X)	(X)	(X)	(X)
Depth drill pOsition[2]	X	X	X	X	X
Stepped countersink pOsition[1]	X	X	X	X	X
Expander pOsition[1]	X	X	X	X	X
Thread tap ADVANCED[1/3]	(X)	(X)	(X)	(X)	(X)
Thread tap pOsition[1/4]	(X)	(X)	(X)	(X)	(X)

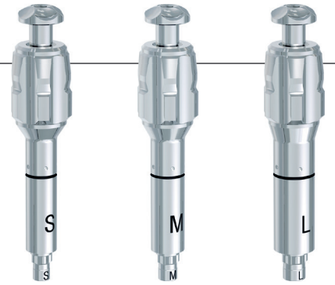
[1] Exemplary illustration of rotary instruments ø 4.2 mm (red).
[2] The insertion depth / length of the depth drill depends on the implant length.
[3] Use thread tap ADVANCED only for tioLogic® ST and tioLogic® TWINFIT implants. Thread taps must be used if implant insertion torque exceeds 40 N cm. The depth scales must be observed.
[4] Use thread tap pOsition only for tioLogic® implants. Thread taps must be used if implant insertion torque exceeds 40 N cm. The depth scales must be observed.



Implant insertion.



Result, implant insertion.



Manual insertion keys S-M-L tioLogic®.

Implant insertion – tioLogic® ST.

tioLogic® ST implant types.

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

Manual insertion.

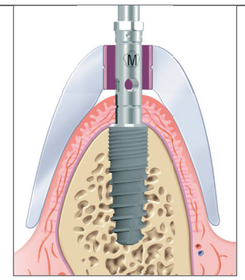
The hex key 2.5 mm (available in three different lengths) is inserted into the insertion aid, the implant is released from the implant holder by a ¼ turn and manually inserted into the prepared implant site through the basic sleeve. The planned implant position is attained when the groove on the placement aid is level with the upper edge of the basic sleeve.

Handpiece insertion.

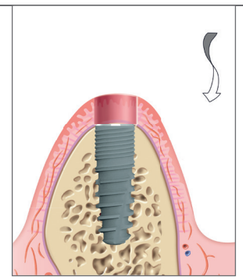
The hex key 2.5 mm (available in two different lengths) is inserted into the insertion aid, the implant released from the implant holder by a ¼ turn and inserted into the prepared implant site through the basic sleeve using a handpiece. The planned implant position is attained when the groove on the placement aid is level with the upper edge of the basic sleeve.

If the placement aid does not have a groove, it should be removed as follows:
After implant insertion through the basic sleeve (not to the full insertion depth), the screw in the placement aid should be loosened using the hex key 1.3 and the placement aid removed. If the implant turns when loosening the screw, the holding key for placement aid should be used to provide rotational security.

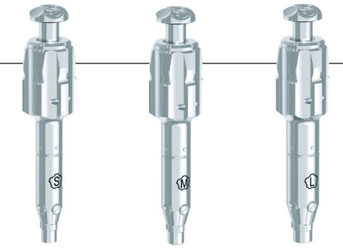
The suitable insertion key (S, M, L) is fitted, secured on the implant using the counter screw and the implant screwed into position. The planned implant position is attained when the groove on the insertion key is level with the upper edge of the basic sleeve.



Implant insertion.



Result, implant insertion.



Manual insertion keys S-M-L tioLogic® TWINFIT.

Implant insertion – tioLogic® TWINFIT.

tioLogic® TWINFIT implant types.

The silicone seal with the closure screw is removed.
Note:
Do not tilt as the implant lies loose in the inner container.

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

Manual insertion.

The adapter ISO shank/ratchet is placed on the insertion key. After making a slight turn, the insertion key snaps into place in the implant and can be inserted manually through the basic sleeve into the prepared implant site.

Handpiece insertion.

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

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

The additional 5 marks on the insertion key correspond to the 5 rotational security stops in the implant and allow alignment of the rotational security stops with regard to the subsequent prosthetic restoration. The implant position can be finely adjusted if a point in the final position is not aligned exactly towards the buccal or in the direction of the alignment mark placed on the basic sleeve by the dental technician. Special insertion keys are available for tioLogic® ST and tioLogic® TWINFIT for the series of abutments S, M and L.

Treatment procedure.

Transgingival healing.

For optimal gingiva management in transgingival healing, there is the choice of conical and cylindrical gingiva formers for the tioLogic® ST and anatomical and cylindrical gingiva formers for the tioLogic® TWINFIT system. The conical and anatomical gingiva formers are designed to form a wide gingival contour. Depending on the type of prosthetic restoration, this can make it easier for the implantologist to fit the restoration. The gingiva formers are selected according to the series of abutments, gingival height and insertion depth of the implant. They are available for the series of abutments S, M or L and the different gingival heights. As particularly gentle on the tissue, there is the option of using 4Base abutments directly with the tioLogic® TWINFIT system and bridges, bars, as well as AngleFix abutments with the tioLogic® ST system.

Tightening torque:

- Gingiva former: manually or 15 Ncm

  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.

Important:
The gingiva formers, 4Base abutments and bridge, bar and AngleFix abutments should be sterilized before insertion in the implant.

Immediate restoration (temporary abutment).

It is possible to fit a long-term, non-functional immediate temporary restoration on implants if there is adequate primary stability and no recession of the implant site. In aesthetically relevant areas the peri-implant structures are preserved and formed with a temporary abutment.

An optimal impression can then be taken. The temporary abutment is 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. The crown should only be retained temporarily.

Tightening torque:

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

Subgingival healing.

If the mucosa has not been removed minimally invasive using the gingiva cutter but was exposed using an alveolar incision, the implant is sealed using the closure screw and healing is completed sub gingivally.

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

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

Tightening torque:

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

Documentation.

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

Surgical protocol.

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

Treatment procedure.

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

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

Post-operative treatment.

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

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

Healing stage.

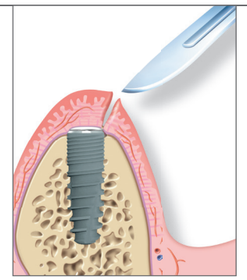
The healing stage in the mandible is normally 3 months and in the maxilla 6 months. It can vary depending on the bone quality, the surgical procedure used and the patient's anatomy.

If examinations after the healing stage indicate osseo-integration of the implant, the prosthetic restoration can be fabricated. Detailed information on this is contained in the Prosthetic Manual tioLogic® ST (REF 989-960-20) and tioLogic® TWINFIT (REF 989-913-20).

Follow-up.

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

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



Implant exposure.

Safety information.

- Only use tioLogic® ST prosthetic components in combination with tioLogic® ST implants.
- Only use tioLogic® TWINFIT prosthetic components in combination with tioLogic® TWINFIT implants.
- Temporary restoration in situ up to 180 days
- No primary bracing of abutments
- No single restoration with cantilever bridge unit
- Restoration with a maximum length ratio to the length of the implant 1:1.25
- The implant should not be subjected to mechanical stress

Implant exposure.

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

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.

Use.

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

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

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

Preconditioning.

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

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

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

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

Mechanical cleaning / disinfection (disinfector or washer disinfector).

When choosing and using a disinfector, ensure that

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

Cleaning agents.

When choosing a cleaning agent system, ensure that

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

Procedure.

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

Manual cleaning and disinfection.

When choosing a cleaning agent and disinfectant, ensure that

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

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

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

Procedure - cleaning.

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

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

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

Procedure - disinfecting.

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

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

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

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

Care, monitoring.

Instruments should be checked after cleaning or cleaning/disinfection for corrosion, damaged surfaces, chipped edges and contamination. Damaged instruments should be discarded (limited reuse see p. 15). Instruments that are still contaminated should be cleaned and disinfected again.

Maintenance.

Reassembly of instruments (see chapter Reusability of surgical instruments).

Instrument oils should not be used if possible. If oil is to be used, ensure that only oils for contra angles are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and are certified to be biocompatible.

Packaging.

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

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

- DIN EN ISO/ANSI AAMI ISO 11607-1/2 (formerly: DIN EN 868/ANSI AAMI ISO 11607)
- suitable for steam sterilization (temperature resistant to min. 134 °C / 273 °F adequate steam permeability) 134 °C / 273 °F, adequate steam permeability)
- adequate protection of the instruments and sterilization packaging against mechanical damage
- regularly maintained according to the manufacturer's instructions (sterilization containers)

Sterilization procedure.

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

Steam sterilization.

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

Flash sterilization or gravitational method should never be used.

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

Correct storage.

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

Material resistance.

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

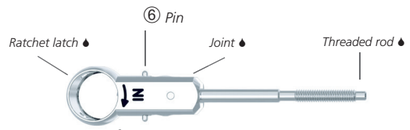
- organic, mineral or oxidizing acids (maximum permitted pH 9.5, a neutral / enzymatic cleaner is recommended)
- strong alkali
- organic solvents (e.g. alcohol, ether, ketones, benzene)
- oxidation agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/ halogenated hydrocarbons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

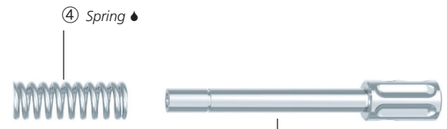
Never clean instruments and sterilization trays with metal brushes or steel wool.

Torque ratchet.

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

① *Ratchet wheel*

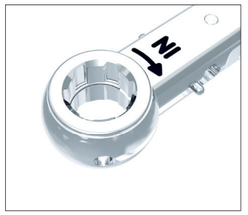




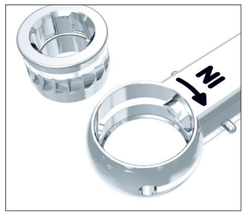
Disassembly.

Before cleaning (regardless of the selected cleaning method), the torque ratchet must be dismantled into the individual parts. This can be done without tools. Completely unscrew the torque adjustment screw ⑤, and remove the spring ④ and the ratchet head ② with threaded rod. Take care not to lose the plastic washer ⑧ as this would have a negative impact on the instrument's precision. (The plastic washer needs only to be removed if there is visible contamination. It can be pulled off if necessary and replaced after cleaning).

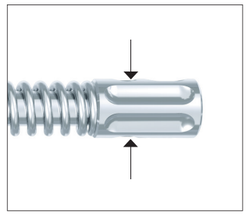
Blocking function – „∞" mark.



Ratchet head, assembled.



Ratchet head, disassembled.



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

Maintenance.

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

Lubricating point (♦)

Lubricate the areas marked with the "drop" symbol lightly with maintenance oil for instruments. Ensure that only instrument oils (paraffinic white oil without corrosion inhibitor or other additives) are used, which – depending on the maximum sterilization temperature used – are approved for steam sterilization and are certified as biocompatible. The oil should be used sparingly. Reassemble the ratchet and perform a function test.

Assembly.

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

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

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

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

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

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

Material composition.

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

■ Titanium Grade 4 DIN EN ISO 5832-2

Chemical composition (% by mass)	
O	0.4 % max.
Fe	0.5 % max.
C	0.1 % max.
N	0.05 % max.
H	0.0125 % max.
Ti	Rest
Physical and mechanical properties	
0.2% yield strength	520 MPa min.
Tensile strength	680 MPa min.
Elongation at rupture	10 % min.

■ Titanium Grade 5 DIN EN ISO 5832-3

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

■ PEEK

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

The SSCP is available at https://ec.europa.eu/tools/eudamed.

Dentaurum

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Date of information: 2023-10
Subject to modifications

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989-999-20 Printed by Dentaurum Germany 2023-10/C/R1-4