

SafetyPass

Scientifically documented.



Introduction.

[An implant system is worthless without safety and reliability – safety and reliability are worthless without scientific documentation.]

This expresses very concisely what is important for Dentaaurum Implants:

safety and reliability validated by scientific documentation – these are essential features of a modern implant system.

The user must be able to rely on a sophisticated, clinically proven implant system that guarantees a reliable, efficient technique. The user must also have the assurance that important aspects relating to safety and reliability have been scientifically documented.

Comprehensive, informative scientific documentation on safety and reliability is required along with precise instructions for use, product catalogues and patient leaflets.

The information in this booklet provides an overview of the safety features and scientific documentation of the tioLogic® implant system. Please contact us if you have any questions about the system.

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The tioLogic® Implant system

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Thread geometry.^{1,2}

Description.



Integrated platform switching.

The cervical chamfer (0.3 mm) of the implant shoulder in a tioLogic® implant takes into account the biological width. The combination of cervical chamfer (Pos. 1), crestal fine thread (Pos. 2) and CBS surface (Pos. 6), which extends right to the cervical chamfer, promotes the apposition of bone tissue, reduces bone collapse and gingival recession. This provides the basis for excellent, durable aesthetics.

Crestal fine thread.

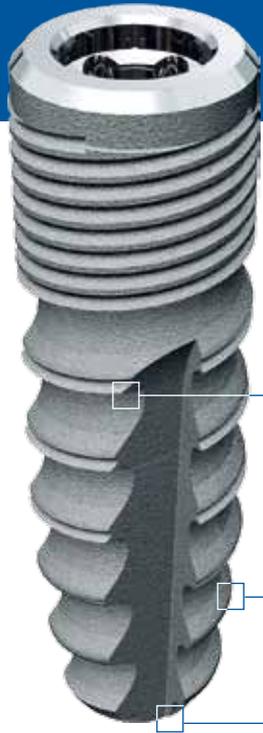
The crestal fine thread (Pos. 2) of the tioLogic® implant is ideally tailored to the density of the cortical bone and ensures high primary stability, even with poor horizontal bone availability.

Progressive coarse thread.

The progressive coarse thread (Pos. 3), which follows on seamlessly from the fine thread (Pos. 2), is tailored to the density of the spongiosa bone and provides high primary stability, even with unfavourable bone conditions. It also guarantees perfect placement of the tioLogic® implant.

Thread geometry.^{1,2}

Description.



¹ A. Rahimi, F. Heinemann, A. Jäger, C. Bourauel: Biomechanische Untersuchungen des Einflusses von Geometrievarianten des tioLogic® Implantats (Biomechanical tests on the effects of different types of tioLogic® implant geometry); Universität Bonn 2006.

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

Optimal thread geometry (Pos. 4).

CBS technology (Pos. 5).

Rounded apex (Pos. 6).

Optimal thread geometry.

The design detail of the thread flanks and the contour of the thread depth and pitch of the tioLogic® implant have been developed to provide optimal load distribution. The thread design (Pos. 4) prevents strain or stress peaks in the bone. It also ensures excellent primary and secondary stability.

Conical-cylindrical design.

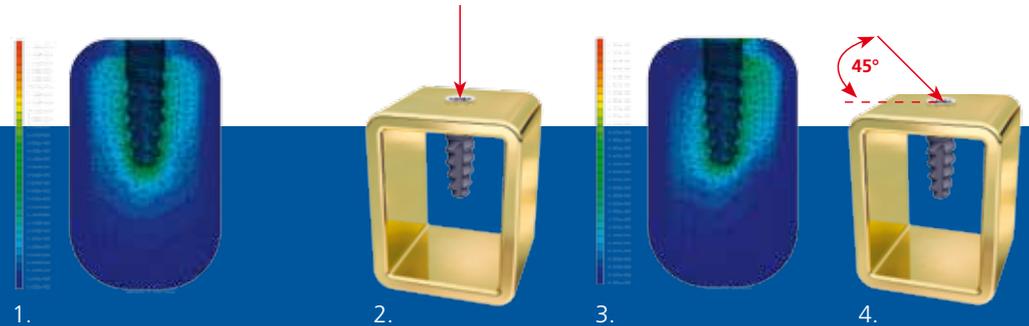
The clinically proven external geometry of the tioLogic® implant, which is similar to the shape of a root, ensures physiological load distribution that produces minimum stress on the bone and also contributes to improved primary and secondary stability. The rounded apex (Pos. 6) prevents damage to anatomical structures (e.g. sinus floor) during insertion.

CBS technology.

The implant surface has been conditioned in the endosseous region using CBS (ceramic blasted surface) technology (Pos. 5) so that it optimally resembles the cellular bone structure. This enables rapid, direct apposition of bone tissue and ensures optimal osseointegration of the tioLogic® implant.

Thread geometry.^{1,3}

Scientific documentation.



Biomechanical tests.¹

The design of the thread (fine/coarse thread), thread geometry¹, conical-cylindrical implant shape and rounded apex were calculated and documented using FEM analyses.

FE-Modell¹ – Finite element (FE) models were generated based on CAD data of tioLogic® dental implants. The implants were given a fine thread (cervical area) and a coarse thread. Implants in lengths of 11 mm and 13 mm with diameters of 3.3 mm, 3.7 mm, 4.2 mm, 4.8 mm and 5.5 mm were tested. The alveolar bone was contoured as an ideal bone segment with a 2 mm or 3 mm thick cortical bone layer and internal spongiosa. The modulus of elasticity for the cortical bone and spongiosa was 20 GPa and 300 Mpa respectively; 110 GPa was assumed for the implant. The implants were initially loaded with a vertical force of up to 300 N (Fig. 1 + 2) and with a transversal force (Fig. 3 + 4).

The deflection of the implants was between 4 µm and 17 µm in the direction of the force depending on the implant diameter and thickness of the cortical bone. There was a maximum strain of 2100 µstrain in the spongiosa with vertical loading of 100 N. The maximum stress in the cortical bone was increased by max. 3% due to the fine thread in the cervical area; the fine thread had no effect on strain distribution.

The fine thread was effective in transmitting the load to the cortical bone. It also did not produce any additional stress or strain peaks compared with implants with a conventional thread design. All strains in the bone remained in the physiological range defined by Frost³.

¹ A. Rahimi, F. Heinemann, A. Jäger, C. Bouraue: Biomechanische Untersuchungen des Einflusses von Geometrievarianten des tioLogic® Implantats (Biomechanical tests on the effects of different types of tioLogic® implant geometry); Universität Bonn 2006.

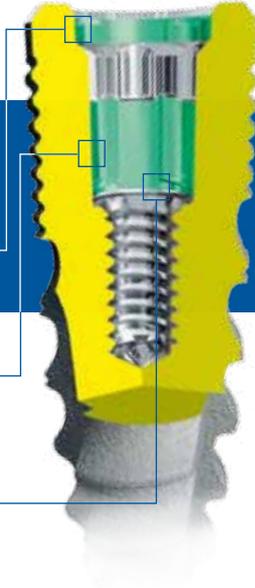
³ H.M. Frost, Vital Biomechanics: Proposed General Concepts for Skeletal Adaptions to Mechanical Usage. *Calcif Tissue* 42 (1988) 145-156.

Inner geometry.

Cylinder interface (Pos. 1).

Long lower inner cylinder (Pos. 2).

Micro-round junctions (Pos. 3).



Internal interface with dual contact.

The dual contact of the system components in the tioLogic® implant guarantees high positional stability as well as excellent torsional and flexural stability. This significantly reduces material fatigue in this generally critical area. The position and dimensions of the two interfaces were calculated based on FEM⁴ analyses.

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

Dual contact – Short cervical inner cylinder.

The top cylinder interface (Pos. 1) is positioned directly above the rotational security and is short. This precisely fitting cylindrical connection guarantees optimum centring of the system components and directs any transversal forces to the inner geometry.

Long lower inner cylinder.

The lower cylinder interface (Pos. 2) is positioned directly below the rotational security and is longer. Any bending moments that occur are transmitted smoothly via this interface. This interacts with the upper cylindrical interface to produce a connection with maximum stability. The cylinder also provides precise guidance and ensures quick, reliable positioning of the longitudinal axis of the implant before the horizontal PentaStop® rotational security engages.

Micro-round junctions.

Micro-round junctions (Pos. 3) have been incorporated in several sections of the inner connection of the tioLogic® implant and in the abutment components. These ensure on the one hand that the load distribution produces less stress on the material and on the other hand that the fit is optimized to provide increased stability.

Inner geometry.



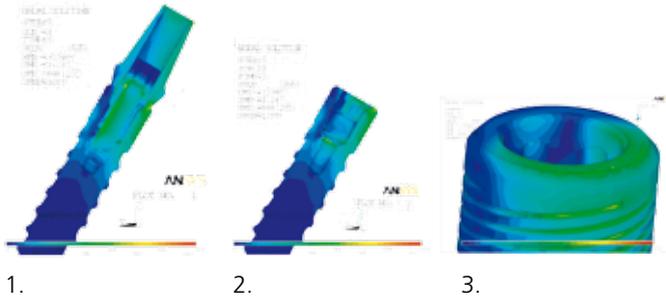
Round PentaStop® rotational security.

The five internal PentaStop® rotational security stops (Pos. 4) provide an optimum combination of maximum rotational security and outstanding flexibility when positioning the system components. The round, precision-milled rotational security ensures reliable transmission of the insertion forces when screwing in the implant and minimizes any stresses.

The 5 positioning options for the prosthetic components ensure that they can be optimally aligned; incorrect positioning of the implant is immediately apparent. These are optimal features for ensuring customized, durable and aesthetically perfect superstructures.

Inner geometry.

Scientific documentation.



FEM-optimized inner geometry.⁴

The design of the internal cylinders and rotationally secure internal geometry (PentaStop®) was calculated and documented on the basis of FEM analyses (Fig. 1).

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

FEM simulation.

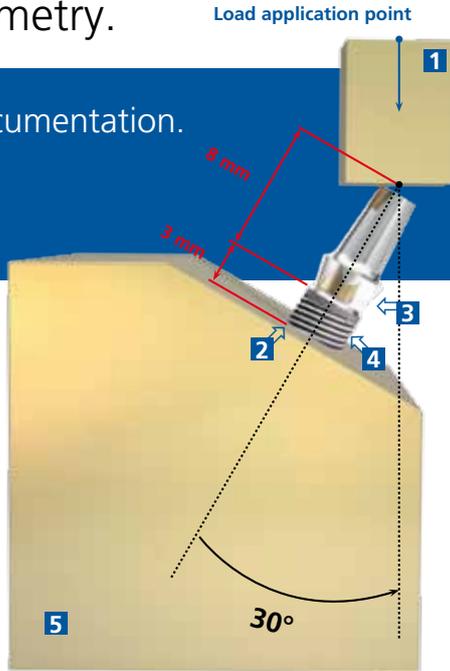
Finite element models were generated based on CAD data of tioLogic® dental implants, abutments and prosthetic screws. In the model an abutment was secured onto the implant with a prosthetic screw using a defined initial torque of 20 Ncm (Fig. 2 p. 18). Four loads were simulated with different implant diameters (3.3 mm, 3.7 mm and 4.2 mm) and loading angles (10°, 20° and 30°) with a transversal force of 300 N (Fig. 2). A simulated bone collapse of 3.0 mm was initially calculated for each implant diameter. A case without bone collapse, in which there was fixed loading along the entire endosteal length of the implant, was also calculated for the 3.7 mm ø implant to check for any other stresses occurring in the area of the internal connection (Fig. 3). The implant with a reduced diameter of 3.3 mm was simulated at a loading angle of 10° and 20° due to its limited approved application.

The internal geometry, which was designed on the basis of the results of the FEM analysis, demonstrated outstanding torsional and flexural stability in the simulations performed.

Inner geometry.

Scientific documentation.

- 1 Loading machine
- 2 Nominal bone margin
- 3 Abutment
- 4 Implant
- 5 Specimen holder



ISO-compliant fatigue strength⁵ – Test design.

A dental implant has to withstand high, long-term functional loading in situ, i.e. it must have a high fatigue strength. The fatigue strength was therefore tested very thoroughly during development of the tioLogic® implant.

The renowned Fraunhofer Institute for Material Mechanics in Freiburg, a neutral, independent test centre, was commissioned to complete the tests.

Tests complied with the international standard DIN EN ISO 14801 (Fatigue test for endosseous dental implants).

The implant, comprising an endosteal section and screw-retained abutment, was fitted with a conventional crown and subjected to a loading test with cyclic forces. Testing was completed at an angle of 30° and with a simulated bone collapse of 3 mm. The aim was to record the force at which there was no system failure due to fracture even after 2 million load cycles.

The test was carried out on endosseous tioLogic® implants, 3.7 mm in diameter and 13 mm in length, fitted with M abutments. A defined initial torque of 20 Ncm was used for insertion.

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

Inner geometry.

Scientific documentation.

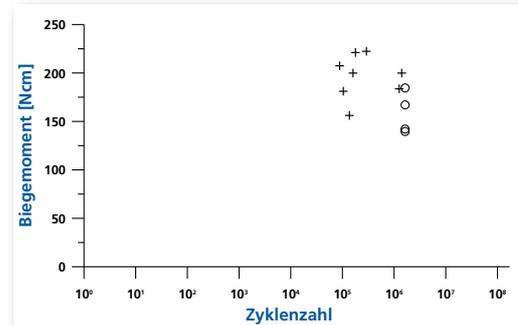
ISO-compliant fatigue strength⁵ – Test result.

The result conclusively confirmed that the tiologic® implant concept had achieved its aim, which was to create a synthesis incorporating proven components, the latest developments in dental implantology and current requirements of implantologists, dental technicians and patients for functionality and aesthetics.

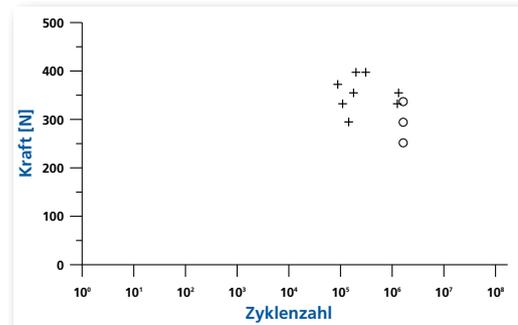
A flexural loading of 138 Ncm (Fig. 1) was attained at 2 million load cycles with an applied force of 250 N (Fig. 2).

In testing technology these tests are classified as fatigue strength tests. The result is illustrated using a Wöhler diagram.

1.



2.



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

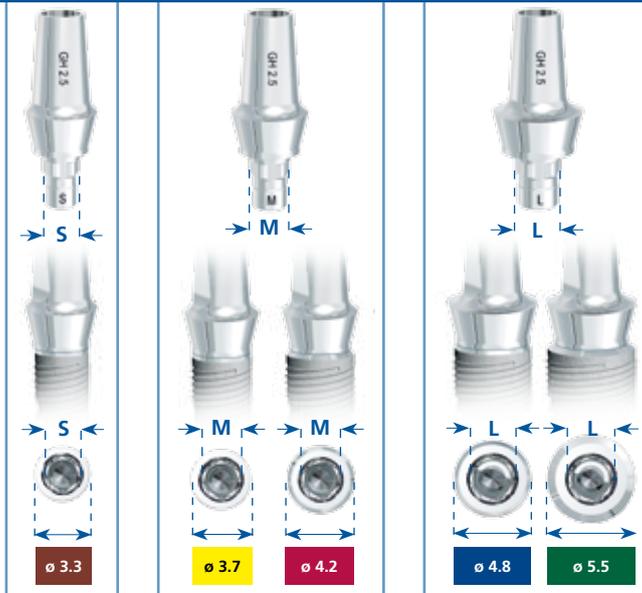
S-M-L concept.

Three different internal connections.

S

M

L



The S-M-L concept includes aspects such as integrated platform switching and offers new options for an individual, easy, cost-efficient technique with high reliability. The user has a choice of 5 implant diameters, 5 implant lengths and 3 series of prosthetic abutment.

The optimal grading of implant diameters and lengths ensures that the appropriate implant is used for the indication. Components of the 3 series of abutments are made of plastic (temporaries), zirconia, titanium and precious metal and include CAD/CAM, bars, ball abutment, AngleFix and LOCATOR®.

The construction components S are used for the implant diameter 3.3 mm, the construction components M for the implant diameters 3.7 mm and 4.2 mm and the construction components L for the implant diameters 4.8 mm and 5.5 mm. For exact identification all components are marked with S, M or L by laser.

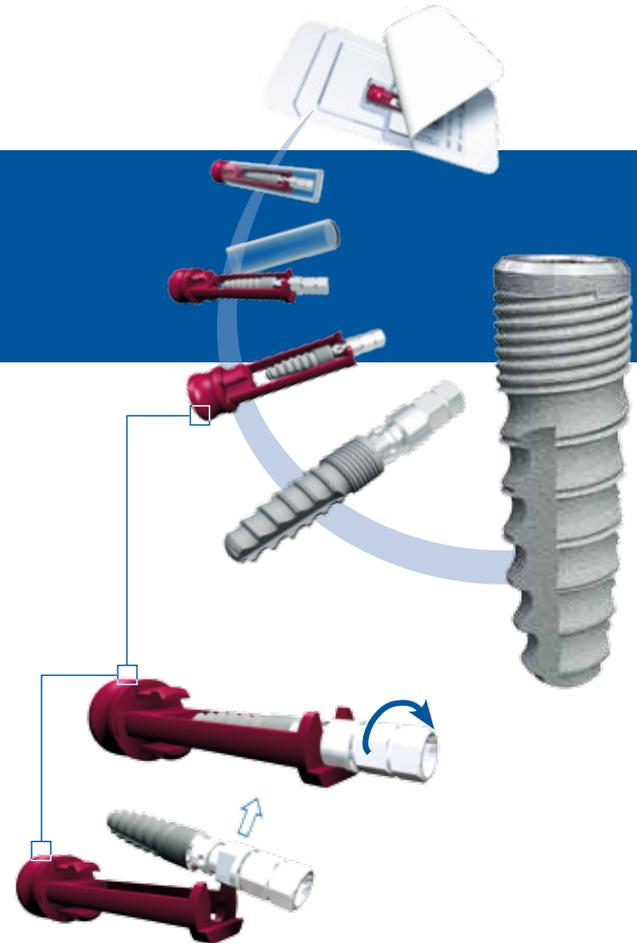
Handling concept.

Implants.

Universal handling technique ensures maximum safety.

The packaging concept, which was developed in close collaboration with experienced implantologists, ensures an optimal handling technique when placing the tiologic® implant. The innovative combination of implant holder and placement aid in the tiologic® implant packaging not only guarantees quick, safe, contact-free placement, but also ensures that the implant is inserted absolutely sterile directly from the packaging.

- Double packaging concept
- Colour-coded diameters
- Clear identification
- Contact-free removal
- Contact-free handling for all indications
- Direct removal without an intermediate adaptor
- Manual insertion: direct or with an adaptor
- Handpiece insertion: with an adaptor



Handling concept.

Surgical tray – standard.



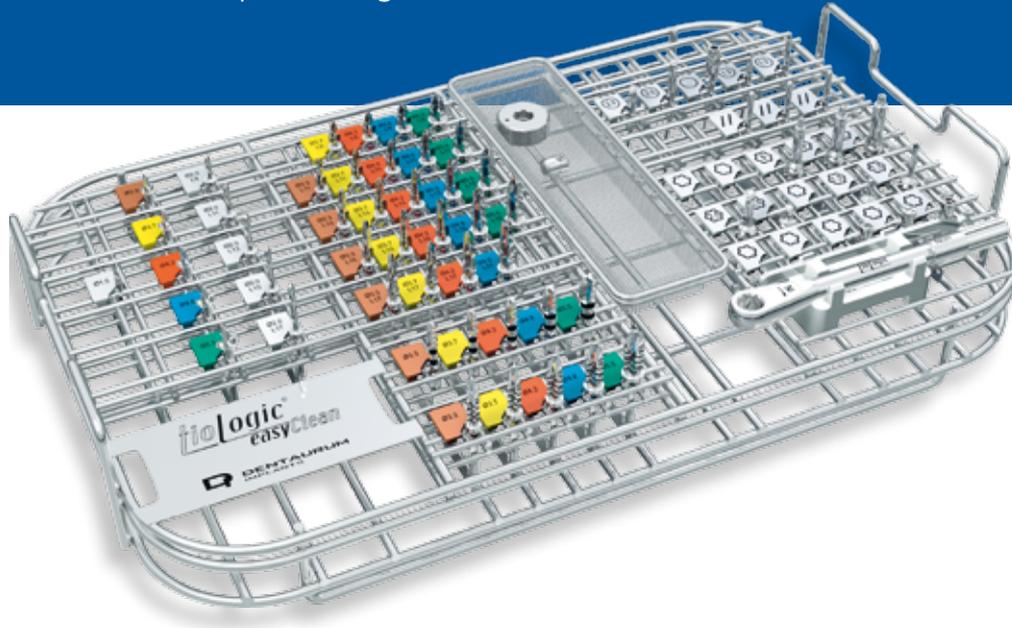
Layout tested in the practice.

The tiologic® surgical tray contains all surgical instruments and accessories required for implant placement. The layout of the tray is structured to provide an efficient procedure and ensures a reliable, systematic technique.

The standard aluminium container and stainless steel insert have been designed to comply with sterilization and cleaning guidelines. The standard aluminium container has integrated hydrophobic permanent PTFE filters.

Cleaning – so easy.

tioLogic® easyClean – the tray for machine processing.¹



tioLogic®
easyClean

The tioLogic® easyClean 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 colour-coded and laser-labelled 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 the intended place. After implantation, the completely packed tioLogic® easyClean is transferred to the machine treatment cycle. Small parts and accessory components to be disassembled are placed in the mesh tray.

¹ Cleaning investigation tioLogic® easyClean, AFIP, 2012.

Safety features.

Range of safety features.

It is essential that a modern implant system provides the operator with an optimal combination of high flexibility, easy handling, an efficient technique and maximum safety and reliability. Particularly with regard to surgical instruments, it is essential that the operator can rely fully on the system during the surgical procedure, even in difficult situations, e.g. with a poor view of the operating site.

The design of the instrument range and individual instruments is based on many years of experience and on close collaboration with experts.

Planning and diagnosis.

In planning, guide sleeves are important components for determining the number, position, diameter, length and direction of the implant. They are integrated into the plastic splint at the ideal prosthetic implant position and alignment for

fabricating an X-ray stent or surgical stent. The parameters determined using the X-ray stent can be checked by means of a computer tomograph (CT), digital volume tomography (DVT) or orthopantomograph (OPTG).

Modern 3D imaging techniques such as CT and DVT enable the operator to identify existing structures three-dimensionally in the jaw prior to surgery and coordinate the course of treatment accordingly. Implants can be positioned virtually with this imaging technique using 3D implant planning software, so that reliable template-guided surgery as well as functional and aesthetic prosthetic treatment is then possible.

tioLogic® pOosition is a template-guided surgical system, used for positioning tioLogic® implants in the jaw with the aid of coordinated 3D implant planning software and a surgical stent.



Safety features.

Range of safety features.

* For technical reasons the instruments are 1.0 mm longer than the given preparation length.



Pilot drill.*

This drill with a small diameter of only 1.4 mm is ideal for pilot drilling.

With difficult or very compact bone conditions the pilot drill ensures careful and minimally invasive depth drilling. Gradual, careful preparation of the implant site is also possible with narrow bone availability.



Surface cutter (optional).

The surface cutter with four blades has an excellent cutting capacity, which ensures reliable preparation without applying a lot of pressure. The flat bone surface produced by the surface cutter forms an optimal support area for the depth stop. Even before implant placement, the circular area on the bone also indicates that the cervical of the implant will be fully surrounded by bone.

For easy identification the diameter of all surface cutters is laser printed as well as colour coded.

Safety features.

Range of safety features.

* For technical reasons the instruments are 1.0 mm longer than the given preparation length.



Depth drill.*

The depth drills have an integrated depth stop. This ensures that the planned insertion length is not exceeded. The integrated depth stop eliminates the possibility of a mix-up when attaching a depth stop to the drill. This type of depth stop is also safer from a hygienic point of view because it is much easier to clean.

The length is permanently legible as it is laser marked on the shank.



Conical former.*

The special geometry and number of cutting flanks are particular features of the tioLogic® system conical formers. Their cutting capacity guarantees optimal guidance and perfect excavation of the implant site without the operator having to apply great pressure. The cutting flanks also enable the effective harvesting of bone chips for possible grafting. Combined with the integrated depth stop, this ensures easy, reliable preparation.

Conical formers (dense bone) are also available for use with high-density bone.

For easy identification the diameter of all conical formers is laser printed as well as colour coded.

Safety features.

Range of safety features.



Thread tap.

The thread taps are designed to ensure minimum stress on the bone during manual preparation. Manual preparation and broad laser markings ensure that the thread depth to be cut is clearly visible. The special geometry of the thread tap produces a very precise thread cut for optimum fit and primary stability.

For easy identification the diameter of all thread taps is laser printed as well as colour coded.

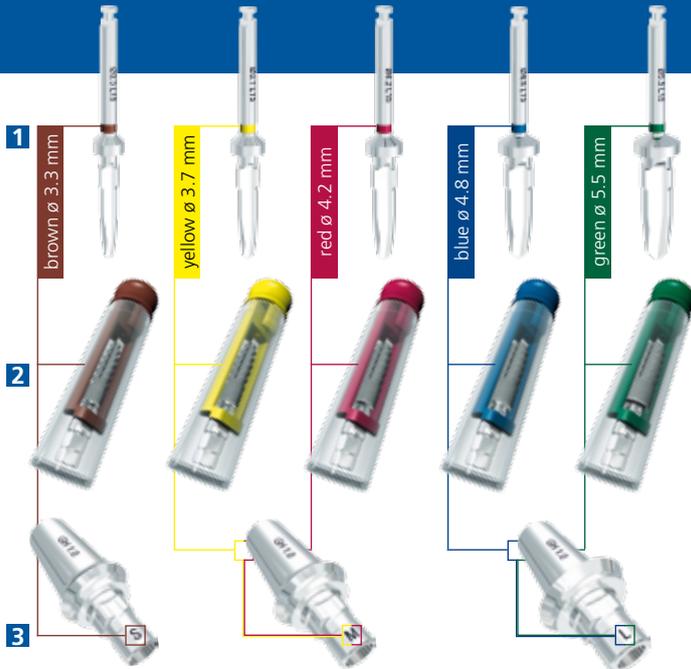


Torque ratchet.

The torque ratchet ensures that a defined, safe torque is not exceeded. This prevents overloading and possible damage to the components.

Component concept.

System components –
quick, clear identification.



The identification concept of the tioLogic® implant system features an easy, intuitive identification system that provides the operator with maximum reliability. The system uses permanent colour coding and clearly legible laser printing.

1 Instrument colour coding.

All surgical instruments have a different coloured ring on the shank for clear identification of the diameter. The colour code for the diameter corresponds to that of the implant.

2 Implant colour coding.

The plastic implant holders are colour coded to indicate the relevant diameter.

3 S-M-L component laser marking.

All components from closure screws and gingiva formers to the impression and prosthetic components are laser marked with S, M or L to correspond clearly with the respective implant platform.

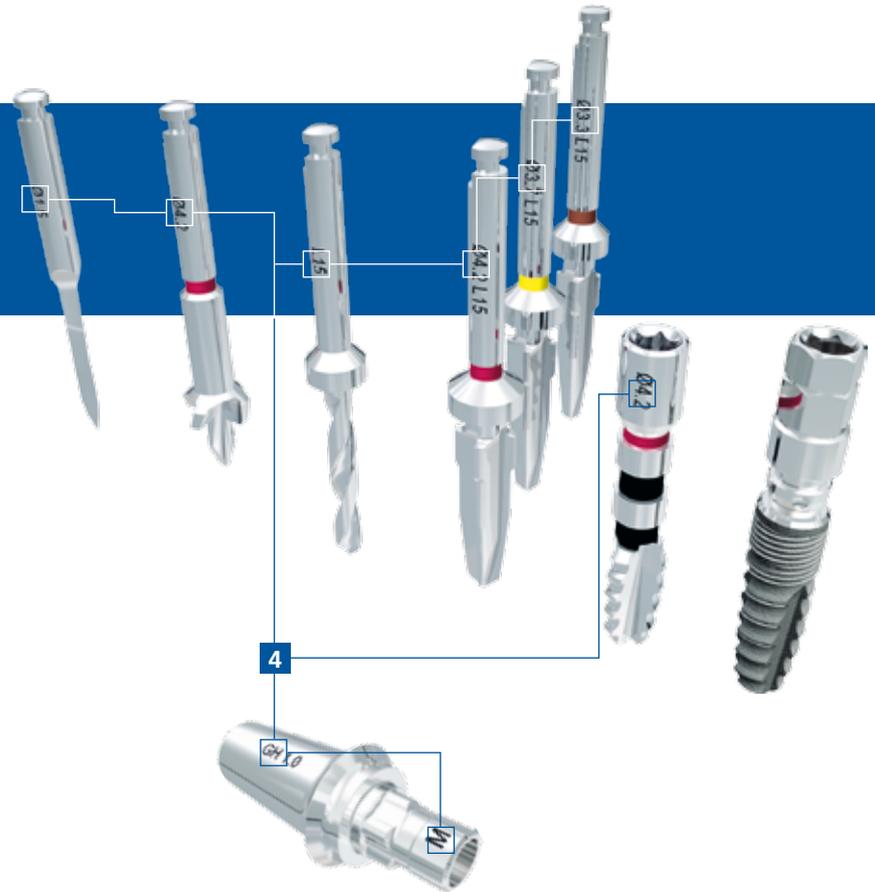
Component concept.

System components.

4 Instrument / Prosthetic component laser marking.

The instruments have laser marking on the shank for easier, clearer identification. They are marked with the diameter or length or both depending on the type of instrument. With gingival formers and titanium abutments the gingival height is also clearly laser marked for identification of the abutment level.

This ensures that all the components can be quickly and easily identified, even after they have been removed from the packaging. This provides increased safety and reliability.



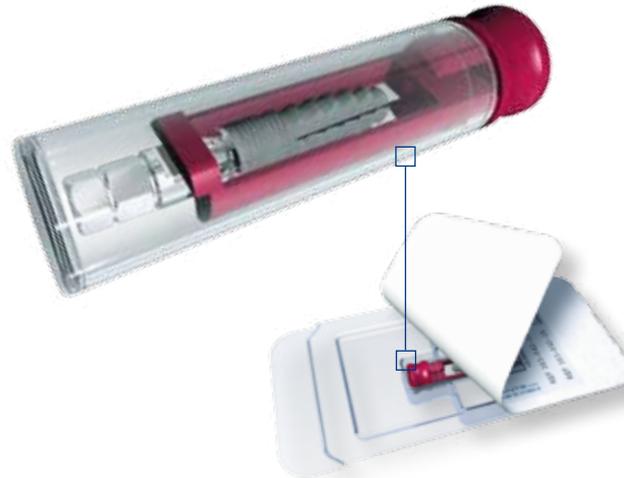
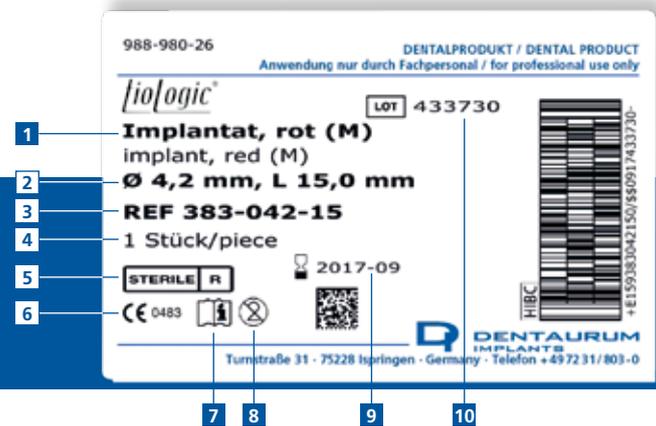
Component concept.

Multifunctional label:
All the information at a glance.

The label contains all the basic information required by the operator and assistant. The sandwich labels also allow the information to be quickly and reliably documented in the patient file and patient ID card.

The pictographs, which are intuitively identifiable, comply with international guidelines and provide a quick, clear means of conveying information.

Additional labels are included for the patient file and patient ID card.



- 1 Contents
- 2 Diameter and length
- 3 Order number (REF)
- 4 Quantity
- 5 Symbol for gamma-sterilisation
- 6 Identification number of the notified body in accordance with Directive 93/42 EEC
- 7 Refer to the instructions for use
- 8 For single use only
- 9 Sterility expiry date
- 10 LOT number on a self-adhesive label

The Dentaurem-Group.

Worldwide dental competence for more than 125 years.



*Quality is
your demand
and our expertise.*



Dental technology setting standards.

The Dentaurem Group 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. Dentaurem Implants, a manufacturer of implants, is a subsidiary of Dentaurem.

Quality inspires confidence.

As the oldest dental company in the world, we have worldwide experience with high-quality dental products. Our market success is based on consistent implementation of customer and market demands.

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 many reasons for using Dentaurem Group products in the practice and laboratory. Quality is the decisive factor. Our company philosophy is to perfect the quality by providing additional performance and service for our products. We offer a wide-ranging training programme for new and advanced users with an internationally experienced team of course instructors. Contact us for further information.

Customer support.

We take care.



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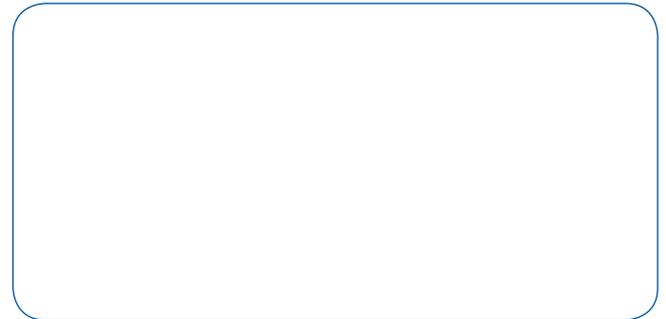
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