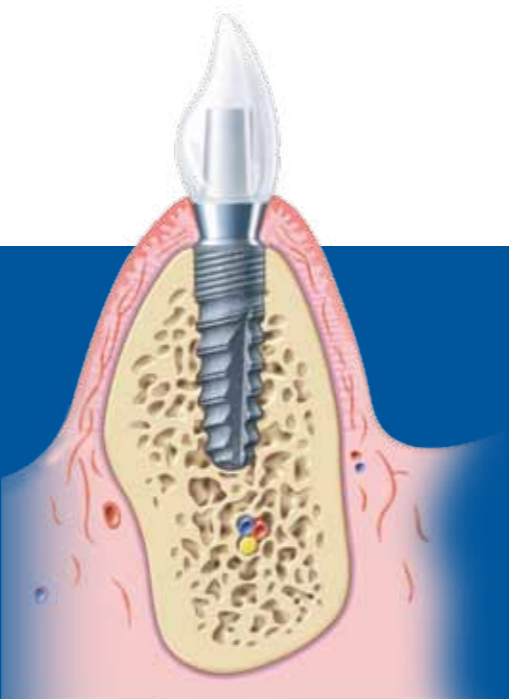


Manual Prosthetic AngleFix.



Content.

We would like to thank:
Prosthetic restorations and photos:
Dr. Sigmar Schnutenhaus
Dirk Bachmann (Master Dental Technician)



| | |
|--|----|
| tioLogic® implant system | |
| External geometry | 4 |
| Internal geometry | 5 |
| S - M - L concept | 6 |
| tioLogic® AngleFix overview | 8 |
| Diagnosis and planning | |
| Indications | 10 |
| Contraindications | 11 |
| Standard planning/planning for template-guided implant insertion | 12 |
| Diagnostic model | 13 |
| Set-Up/Wax-Up, planning stent | 13 |
| X-ray stent, surgical stent | 14 |
| Template-guided implant insertion | 16 |
| Preparation for surgery | 17 |
| Working procedures | |
| Implant position | 18 |
| Healing | 23 |
| Gingiva forming and open healing | 23 |
| Impression taking | 24 |
| Open impression technique | 25 |
| Closed impression technique | 25 |
| Model fabrication open impression technique | 26 |
| Model fabrication closed impression technique | 27 |
| AngleFix restoration | 28 |
| Fitting the AngleFix abutments | 28 |
| Fabricating the restoration | 29 |

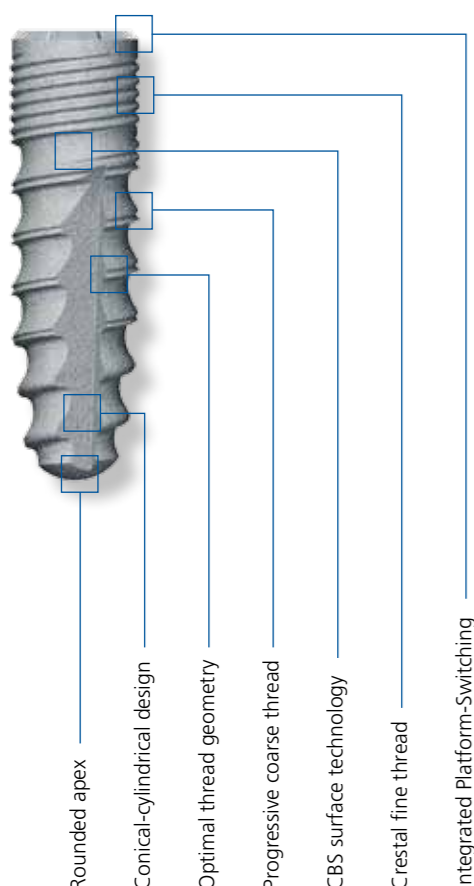
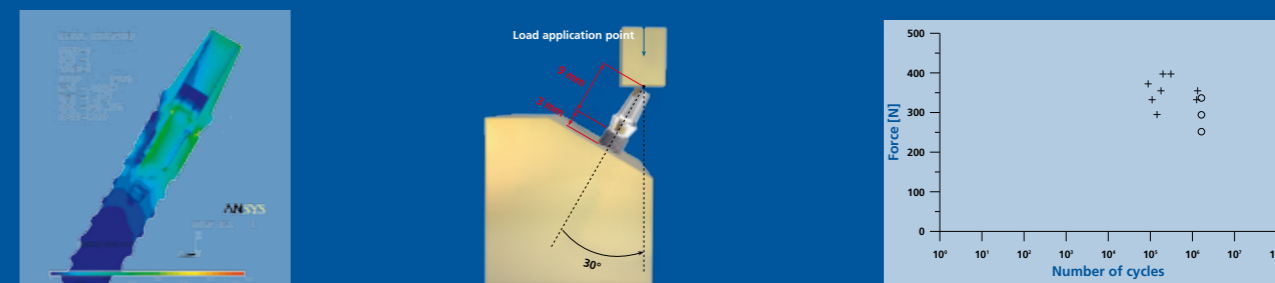
| | |
|---|----|
| Torque ratchet | |
| Description | 34 |
| Application | 35 |
| Overview – Inserts for the torque ratchet | 36 |
| Table – Starting torques for implants | 37 |
| Reusability of surgical instruments | |
| Torque ratchet | 38 |
| Safety notes | |
| Manufacturer | 40 |
| Brief description | 40 |
| Further information | 40 |
| Packaging and sterility | 41 |
| Storage | 41 |
| Application, availability, precautions, documentation | 42 |
| Quality, warranty and liability | 43 |

The tioLogic® implant system.

FEM-optimized implant shape and thread geometry.^{1,2}



FEM-optimized internal geometry³ and ISO-compliant fatigue strength.⁴



External geometry.

The design of the tioLogic® implant shape and thread geometry were calculated and recorded based on FEM analyses¹. These tests indicated uniform, gentle loading of the bone, which avoided stress peaks that could damage the bone and localized overloading.

tiologic® implants have a cylindrical-conical external geometry and a rounded apex. The non-sandblasted cervical chamfer (integrated platform switching) of the implant shoulder is 0.3 mm and takes into account the biological width. In the crestal region the implant has a fine thread that is tailored to the bone density of the cortical bone. The progressive coarse thread, which follows on seamlessly, is tailored to the density of the spongiosa bone and has three radial vertical grooves. The design of the thread flanks and the contour of the thread depth and pitch of the implant have been developed to provide optimum load distribution in the bone. The surgical area of the implant has a Ceramic Blasted Surface (CBS) in the endosseous region.

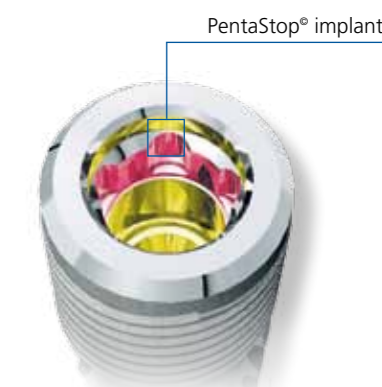
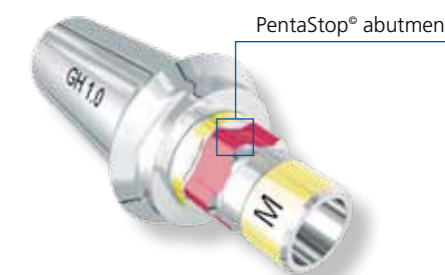
- ¹ A. Rahimi, F. Heinemann, A. Jäger, C. Bourauel: Biomechanische Untersuchungen des Einflusses von Geometrievarianten des tioLogic® Implantats (Biomechanical tests on the effects of different types of tioLogic® implant geometry); Universität Bonn 2006.
- ² Bibliography (Studies and Publications) Dentaaurum Implants, REF 989-767-10, 2011.
- ³ F. O. Kumala: Analyse des tioLogic® Implantats mittels FEM (Analysis of the tioLogic® implant using FEM); CADFEM Stuttgart 2006..
- ⁴ R. Schäfer, R. Jaeger, D. Ulrich, U. Köster: Bestimmung der Ermüdungsfestigkeit eines Dentalimplantats (Determination of the fatigue strength of a dental implant); Fraunhofer Institut Werkstoffmechanik Freiburg 2006
DIN EN ISO 14801: 2003, Ermüdungsprüfung für endossale dentale Implantate (Fatigue test for endosseous dental implants), DIN – Deutsches Institut für Normung, Berlin.

Internal geometry.

The design of the internal cylinders and of the rotationally secure internal geometry (PentaStop®) of tioLogic® implants was calculated and verified in FEM analyses³ and physical tests by the Fraunhofer Institute for Material Mechanics using an ISO 14801-compliant fatigue test⁴. In each of the FEM simulations the internal geometry, which was based on the results of the FEM analyses, shows a high distortional and flexural strength and a high flexural strength in the physical studies of the fatigue test under continuous load.

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

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



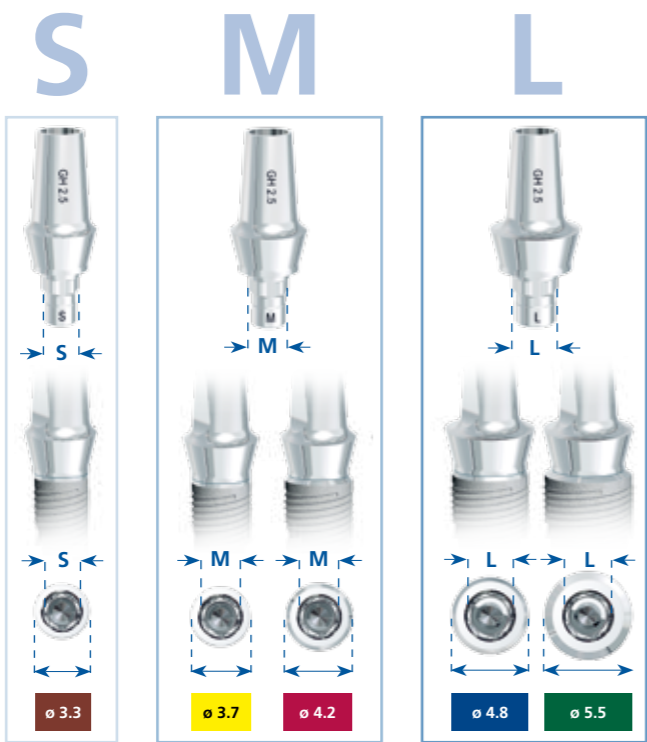
The tioLogic® implant system.

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), zirconia, titanium and precious metal and include CAD/CAM, bars, ball abutment, AngleFix, SFI-Bar®, LOCATOR® and magnets. The construction components S are used for the implant diameter 3.3 mm, the construction components M for the implant diameters 3.7 mm and 4.2 mm and the construction components L for the implant diameters 4.8 mm and 5.5 mm. For exact identification all components are marked with S, M or L by laser.



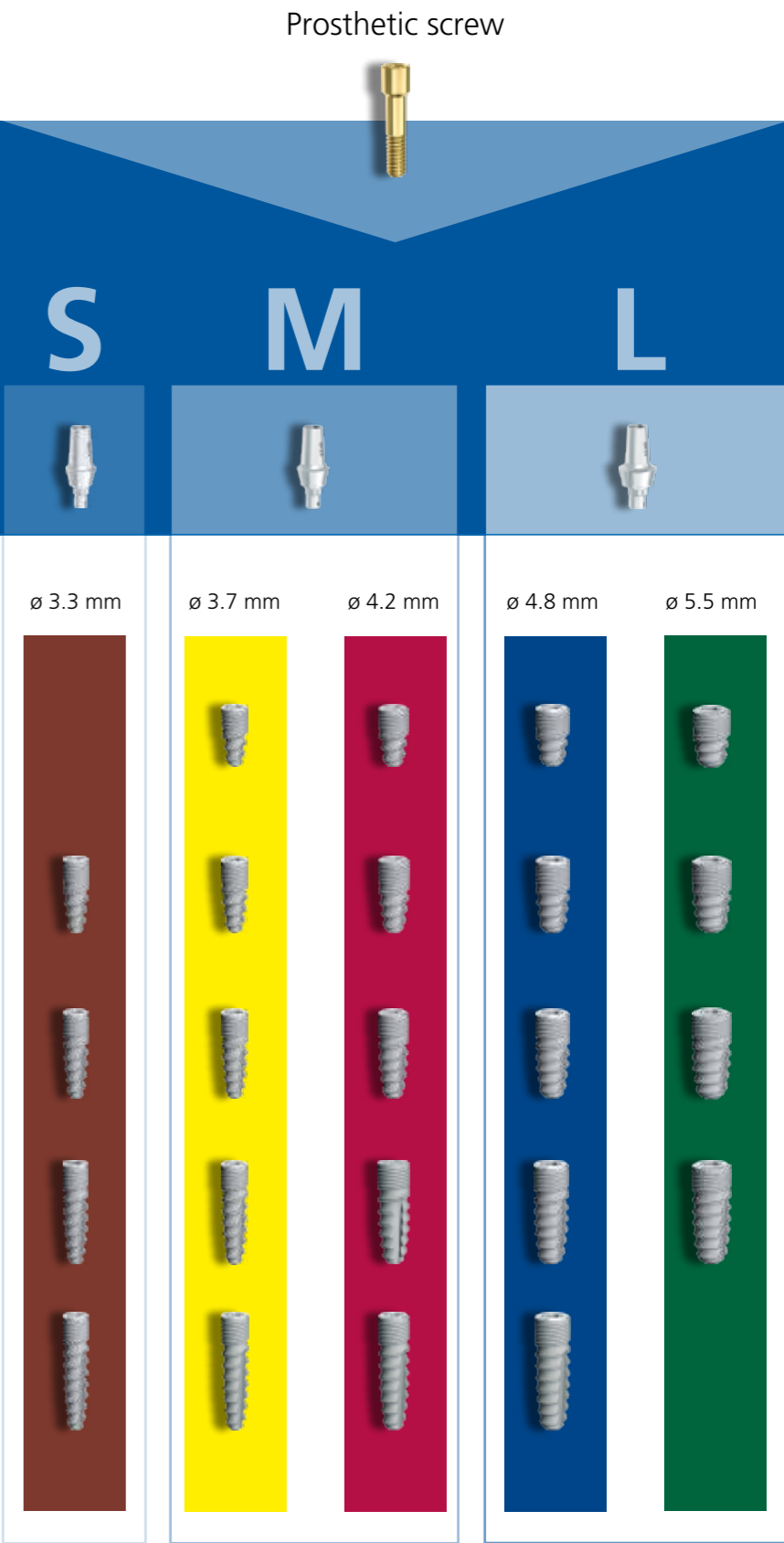
3 series of abutments.

5 implant diameters.

3 series of abutments.

5 implant diameters.

5 implant lengths.



Prosthetic screw








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

tioLogic® AngleFix overview.

The prosthetic restoration is an essential factor for long-term implant success. Intensive communication between the attending dentist and dental technician, careful pre-prosthetic planning and the inclusion of patient expectations are important prerequisites for a successful implant-borne restoration.












The healing period of implants is generally between three and six months. This period may be shorter or longer depending on bone quality, healing process and anatomy. Prosthetic treatment can begin after healing of the implant and contouring of the gingiva. The tioLogic® AngleFix prosthetic manual provides a guide for treating difficult implant positions in the edentulous jaw and jaws with reduced bone using occlusally screw-retained abutments and describes the procedure using several selected cases.

The Dentaureum Implants hotline is available with experienced implantologists and dental technicians to answer any questions. They provide assurance in all areas of surgery, implantology and dental technology.

| ■ AngleFix components | | | |
|-----------------------|---|--|----------------|
| REF 386-144-00 |  | AngleFix abutment S | GH 1.0 mm, 0° |
| REF 386-244-00 | | AngleFix abutment M | GH 1.0 mm, 0° |
| REF 386-344-00 | | AngleFix abutment L | GH 1.0 mm, 0° |
| REF 386-146-00 |  | AngleFix abutment S, incl. AnoTite screw | GH 2.5 mm, 18° |
| REF 386-246-00 | | AngleFix abutment M, incl. AnoTite screw | GH 2.5 mm, 18° |
| REF 386-346-00 | | AngleFix abutment L, incl. AnoTite screw | GH 2.5 mm, 18° |
| REF 386-148-00 |  | AngleFix abutment S, incl. AnoTite screw | GH 2.5 mm, 32° |
| REF 386-248-00 | | AngleFix abutment M, incl. AnoTite screw | GH 2.5 mm, 32° |
| REF 386-348-00 | | AngleFix abutment L, incl. AnoTite screw | GH 2.5 mm, 32° |
| REF 386-466-18 |  | AngleFix angle aid | 18° |
| REF 386-466-32 |  | AngleFix angle aid | 32° |

All tioLogic® AngleFix components should be handled safely to avoid the risk of aspiration by the patient. AngleFix abutments should not be modified (e.g. trimming, sandblasting of the connector geometry to the implant).

The cone of the AngleFix abutments is always the same (12°), so that only one size of impression posts, closure caps etc. is required.

| ■ Conical S | | | |
|----------------|---|--|-----------------|
| REF 386-452-00 |  | AngleFix impression post, open incl. screw | |
| REF 386-454-00 |  | AngleFix impression post, closed, incl. impression cap, bite registration cap, screw | |
| REF 386-462-00 |  | AngleFix AngleFix impression cap, closed, 5 caps | |
| REF 386-464-00 |  | AngleFix bite registration cap, closed, 5 caps | |
| REF 386-450-00 |  | AngleFix closure screw | |
| REF 386-456-00 |  | AngleFix laboratory implant | |
| REF 386-468-00 |  | AngleFix cylinder pin for the screw channel | |
| REF 386-458-00 |  | AngleFix plastic cap incl. AnoTite screw | |
| REF 386-460-00 |  | AngleFix titanium cap incl. AnoTite screw | |
| REF 386-910-00 |  | AnoTite screw AngleFix abutment | M 1.6, L 9.0 mm |
| REF 386-912-00 |  | AnoTite screw AngleFix cap | M 1.6, L 6.0 mm |

Diagnosis and planning.

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

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

Indications.

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

In any implantological case the implant diameter and length of the tioLogic® implants 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.

tioLogic® implants S ø 3.3 mm are available for indications with a reduced buccolingual bone width. They have limited application due to their smaller diameter and lower loading capacity (compared with e.g. tioLogic® implants M ø 4.2 mm). In an edentulous jaw a minimum of four tioLogic® implants S ø 3.3 mm should be placed and fitted with a splinted bar restoration. With implant-borne restorations in a partially edentulous jaw ø 3.3 mm implants should be used in conjunction with tioLogic® M ø 4.2 mm implants and fitted with a fixed, splinted prosthetic restoration. With single-tooth restorations ø 3.3 mm implants should only be used for lower incisors or upper lateral incisors.

Contraindications.

General contraindications for dental surgery apply. These include:

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

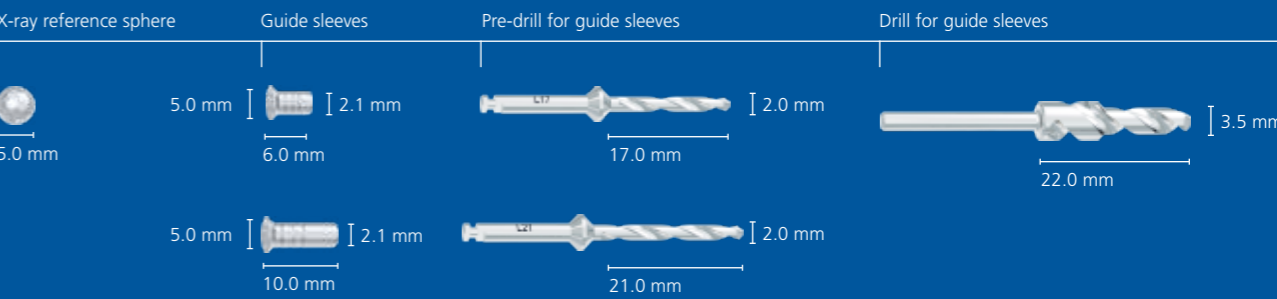
Local contraindications / personal contraindications.

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

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

Diagnosis and planning.

Components used in planning Standard.



Standard planning/
planning for template-guided
implant insertion.

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

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

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

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

Diagnostic model.

Impressions are taken of the upper and lower jaw for fabricating the diagnostic models, which are mounted in an articulator after bite registration. The impression should optimally reproduce the hard and soft tissue situation. Any hard or soft tissue defects give an indication of the implant inclination or augmentation measures required. These factors will already have been considered at the planning stage.

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

Set-Up/Wax-Up, planning stent.

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

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

Diagnosis and planning.

X-ray stent, surgical stent.

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

Orthopantomograph (OPG).

Model analysis for measuring the ridge height and width after initial examination can also be used for integrating the guide sleeves in the plastic template. During model analysis the relationship to the adjacent teeth and opposing dentition is assessed and transferred to a special sectioned model. The surgical stent is placed on the sectioned model and the implant alignment checked. If the checks on the sectioned model are correct, an OPG can be taken with the X-ray foil. The position, diameter, length of the implants and their alignment in relation to the adjacent teeth can be checked two-dimensionally.

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

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

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

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

Known data:

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

Data to be calculated:

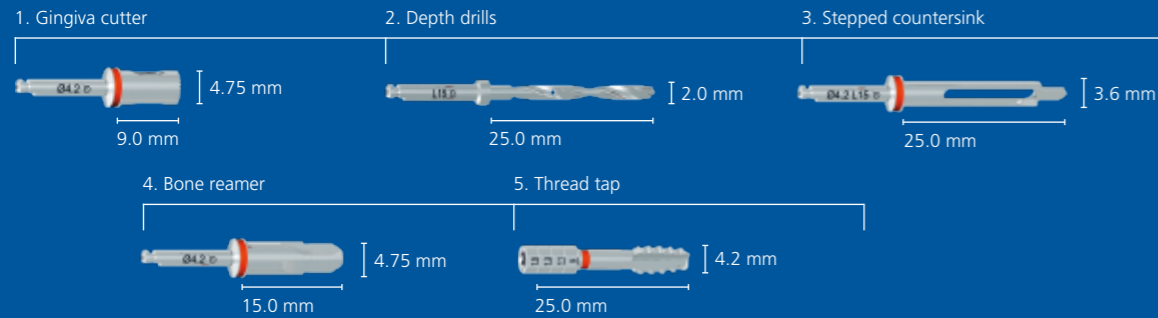
- Actual alveolar bone height (Kr)

Formula:

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

Diagnosis and planning.

Template-guided implant insertion – tioLogic® pOPosition.



Template-guided implant insertion.

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

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

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

tioLogic® pOPosition is a sleeve and drill system from Dentaaurum 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 pOPosition REF 989-999-20).

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

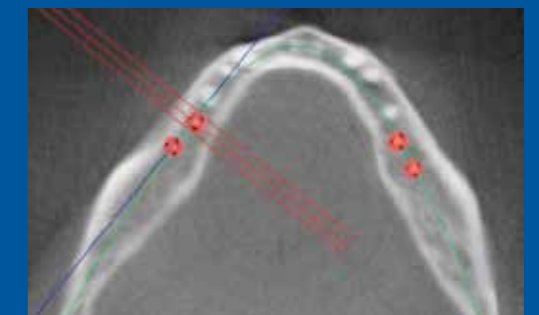
The planned implant restoration is discussed with the patient with regard to the patient's expectations (extent and cost of treatment) and a decision reached. The surgical stent is modified according to any adjustments made to the planned restoration.

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

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



3D implant positioning.



Implant positioning.

Preparation for surgery.

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

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

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

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

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

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



Working procedures.

Implant position.

Before beginning treatment adequate vertical and horizontal bone, both in terms of quantity and quality, must be exposed, while paying particular attention to the position of the inferior alveolar canal and the mental foramen in the mandible and the maxillary sinus in the maxilla. A minimum clearance of 3.0 mm should be maintained to these critical anatomical structures.

To ensure adequate stability only tioLogic® implants with the following dimensions should be used for the AngleFix system:


Angular position implant
angled



13.0 mm

15.0 mm

Angular position implant
straight












11.0 mm

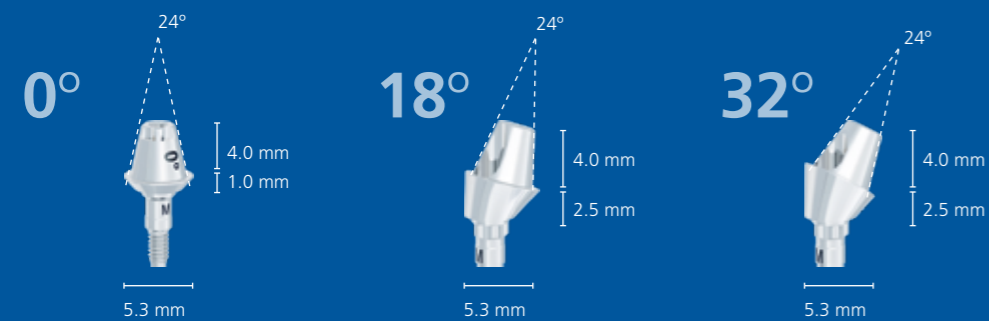
13.0 mm

15.0 mm

17.0 mm

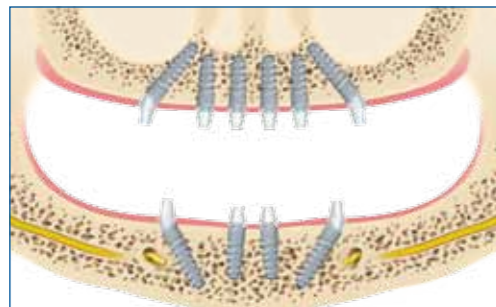
| | S | M | | L | |
|-----------------------------------|---|---|---|---|---|
| | ø 3.3 mm | ø 3.7 mm | ø 4.2 mm | ø 4.8 mm | ø 5.5 mm |
| Angular position implant angled | |  |  |  |  |
| Angular position implant straight |  |  |  |  |  |

Working procedures.



AngleFix abutments 0°, 18° and 32°.

Implant position in the mouth.



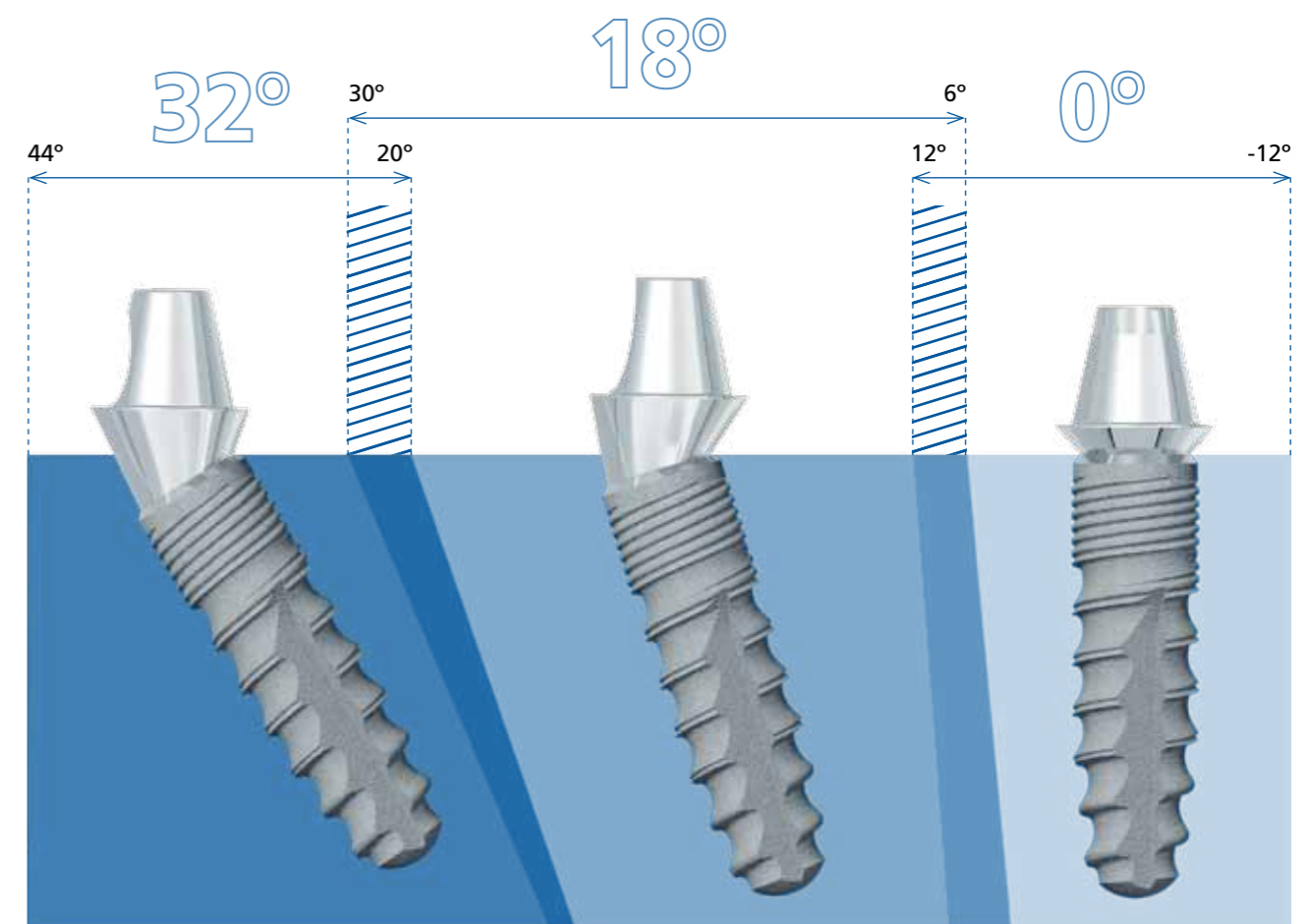
A prerequisite for successful use of the AngleFix system is the most accurate angular position of the implant possible. The more accurate this angle can be maintained, the easier the prosthetic treatment, as the abutments are then positioned parallel to one another.

To ensure that the implants are reliably placed in this angle we recommend the use of navigated implant placement with the tioLogic® pOosition system (see Surgery Manual tioLogic® pOosition REF 989-999-20).

Alternatively or as a control instrument there are angle aids available with 18° and 32°, which are used as orientation for implants in situ.

The AngleFix abutments are provided in 3 angulations: 0°, 18° and 32°. The cone of the AngleFix abutments is always identical (24°), so that only one size of impression posts, closure caps etc. is required. For biomechanical reasons we recommend that the following angulations are not exceeded:

- Abutments with 0°: 0° – 12°
- Abutments with 18°: 6° – 30°
- Abutments with 32°: 20 – 44°

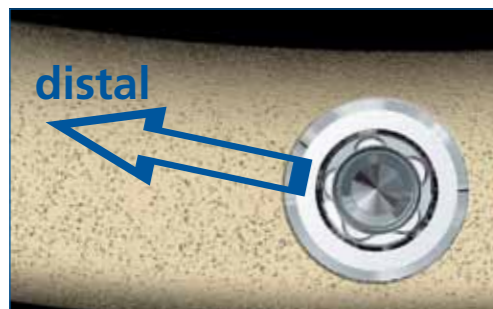


Working procedures.



AngleFix angle aid for 18° and 32°.

Implant aligned distally in the posterior region.



In order to achieve an accurate alignment of the angulated cone of the angled abutments the implants should be aligned so that when viewed distally the marking can be seen symmetrically on the placement aid and insertion aid.

First, the two anterior implants are inserted, whereby the paralleling posts can be used to aid parallel alignment.

When handling the AngleFix abutments, ensure that the occlusal screw is not damaged by tweezers etc.

The angulated AngleFix abutments have a larger diameter than the implants. As part of the abutments may be below the bone line, the bone must be removed in this region, if required, so that the abutment sits correctly on the implant.

After fixing the AngleFix abutments in position on the anterior implants, the corresponding angle gauge 18° or 32° is secured on the abutments according to the angular position given from the planning. The pin on the angle gauge functions as a parallel guidance aid for the pilot drill.

Healing.

Depending on the indication, immediate loading is possible with the AngleFix prosthetic concept. If immediate loading is not indicated, closure screws and gingiva formers are available for preparing the prosthetic restoration.

Submerged healing.

Implants (in the anterior region) can conventionally heal submerged when fitted with a closure screw. The closure screw is removed from the implant holder using the hex key SW 1.3 and inserted in the implant. Closure screws must fit flush on the implant, so that no bone tissue can grow in and the inside of the implant is sealed. They are marked with S, M or L according to the series of abutments and are intended for single use only.

Tightening torque

- Closure screw: manually or 15 Ncm

Gingiva forming and open healing.

Gingiva formers or AngleFix abutments, a version that is particularly gentle on the soft tissue, are available for the operator to ensure optimal management of the gingiva. The gingiva formers are selected according to the series of abutments, gingival height and the insertion depth of the implant. The gingival formers and AngleFix abutments are available for the series of abutments S, M and L (laser marked). During the healing period the AngleFix abutments are covered with the AngleFix closure screw.

Important:

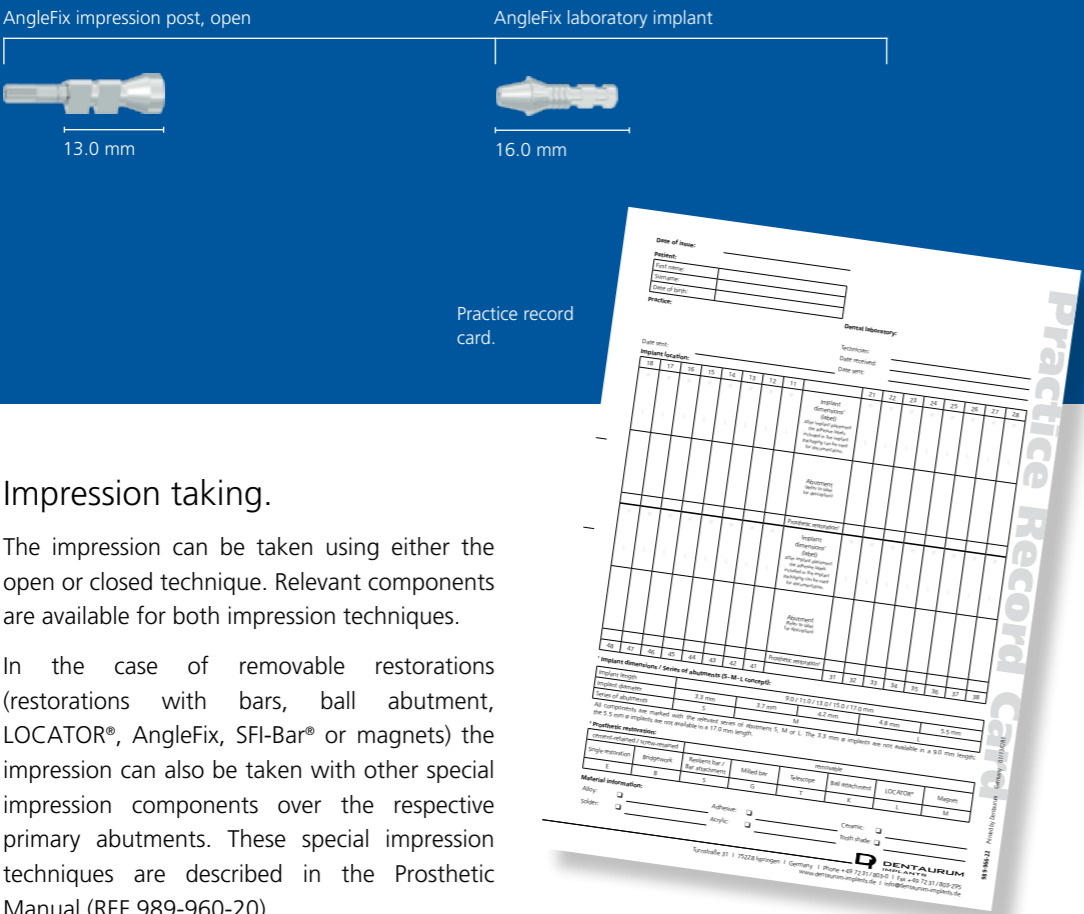
The gingiva formers and AngleFix abutments should be sterilised before insertion in the implant.

If a temporary restoration is to be fitted during gingiva forming, the denture should be relieved to avoid loading the gingiva formers or the AngleFix abutments. The impression should only be taken when the conditions are completely non-irritant.

Tightening torque

- Gingiva former: manually or 15 Ncm
- AngleFix abutment: 35 Ncm
- AngleFix closure screw: 15 Ncm

Working procedures.



Impression taking.

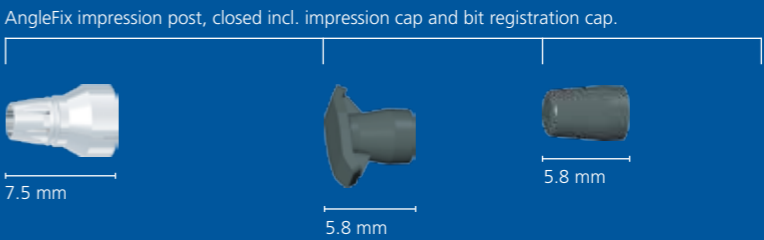
The impression can be taken using either the open or closed technique. Relevant components are available for both impression techniques.

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

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



Open impression technique.

Impression posts are available for the series of abutments S, M and L in lengths of 10.0 mm and 14.0 mm with the corresponding screws to cater for different occlusal spaces. The impression posts are laser printed with S, M or L on the retention surface and at the interface.

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

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

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

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

Closed impression technique.

Impression posts including screws and impression caps are available for taking the closed impression.

When taking the closed impression the AngleFix abutment is fixed in position in the implant and the AngleFix impression post for the closed impression is screw retained on the abutment. The AngleFix impression cap is fitted taking into account the vertical retention grooves until it can be clearly felt and heard snapping into position. The retention grooves are designed so that it is possible to position a groove contact free opposite adjacent teeth.

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

- Tightening torque**
- Impression post sure-grip screw: 15 Ncm
 - Closure screw on AngleFix abutment intraorally: 15 Ncm

Working procedures.

Model fabrication open impression technique.

The impression material is removed from the occlusal to the upper edge of the impression posts to check the exact fit of the impression posts. The screw is inserted into the impression post before fitting the respective AngleFix laboratory analogue. This provides additional guidance when fitting.

Tightening torque

- Impression post sure-grip screw:
in the laboratory analogue manually or 15 Ncm

Fabricating the gingival mask.

A flexible gingival mask is recommended for implant work. This ensures an optimal design of the superstructure and provides a clear view of the implant neck when it is removed, which allows the exact fit of the implant abutments to be checked. The flexible gingival mask is applied directly into the implant region in the impression.

Warning: The silicones used can form an inseparable bond. It is therefore absolutely essential to apply separating agent beforehand.

Fabricating the stone model.

After the gingival mask material has cured, the dental arch is poured as usual and based. The AngleFix laboratory analogues must sit in the model without any free play. The screws must be removed before lifting off the impression tray.

Model fabrication closed impression technique.

The impression post is fixed in position together with the respective AngleFix laboratory analogue using a screw. The impression post is fitted taking into account the vertical retention grooves until it can be clearly felt and heard snapping into position. The laboratory analogue screw retained in the impression must be securely anchored and the impression cap in turn must also be securely anchored in the impression material.

Tightening torque

- AnoTite screw impression post in the laboratory analogue: manually or 15 Ncm

Fabricating the gingival mask.

The gingival mask and model are fabricated using the same procedure as described at model fabrication open impression technique. Only loosening and removal of the sure-grip screws is no longer required with the closed impression. The impression tray can be removed directly from the model.

Impression caps and bite registration caps are single-use components. They are unsuitable for sterilisation. Multiple use results in transfer inaccuracies. Both components can be reordered separately.

Working procedures.



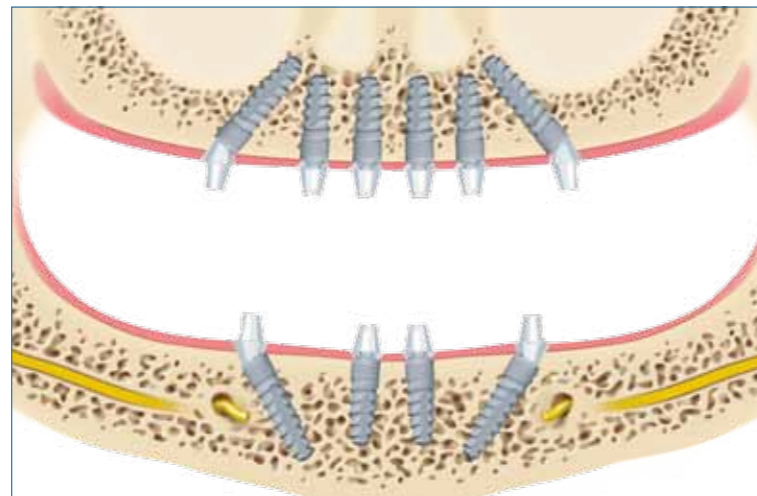
AngleFix restoration.

Due to the steep inclination of the implants a splinted denture is absolutely essential.

Fitting the AngleFix abutments.

When fitting the angulated AngleFix abutments ensure that the abutments have a larger diameter than the implants. As part of the abutments may be below the bone line, the bone must be removed in this region, if required, so that the abutment sits flush on the implant.

Implant position in the mouth.



Fabricating the restoration.

The AngleFix abutments are available for the series of abutments S, M and L in the straight and angulated (18° and 32°) versions. They are available for the straight abutments in a gingival height of 1.0 mm and in a gingival height of 2.5 mm for the angulated abutments.

The anterior implants are fitted with straight abutments and the posterior region with AngleFix abutments in an angulation of 18° or 32° according to the implant positioning.

Titanium copings or plastic copings can be used for fabricating a restoration on AngleFix abutments. The AngleFix copings fit on all three AngleFix series of abutments (S-M-L), as the fitting surface of all AngleFix abutments and the cone (24°) are identical (ø 5.3 mm). They are secured in position on the AngleFix abutments using the AnoTite screw L 6.0 mm supplied.

Tightening torque

- AnoTite screw AngleFix abutment on the model: manually
- AnoTite screw AngleFix abutment intraorally: 30 Ncm

In the cases described the straight AngleFix abutment M 0° in the anterior and the angulated AngleFix abutments with 32° angulation are used.

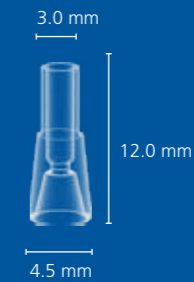
Tightening torque

- Cap on AngleFix abutment on the model: manually
- Cap on AngleFix abutment intraorally: 25 Ncm

Working procedures.



AngleFix titanium cap



AngleFix plastic cap

Case 1: Temporary restoration.

The AngleFix titanium copings are secured in position on the AngleFix abutments using the AnoTite screw L 6.0 mm for fabricating a temporary restoration.

The available space is checked using buccal and lingual indexes.

If there is insufficient space available, the AngleFix titanium copings can be lightly and easily trimmed.

The titanium should not be overheated during preparation, as this can result in different surface hardening (alpha case layer). This can make the working stages more difficult or prevent them.

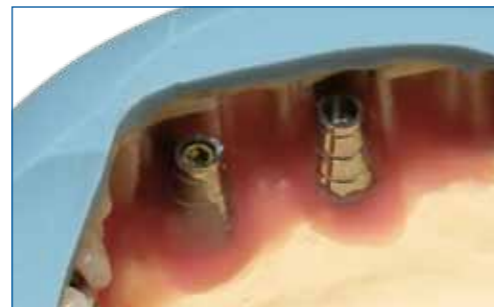
A wax set-up is then fabricated, which can be checked using the buccal and lingual indexes.

Before waxing up the temporary restoration, ensure that there is an adequate, uniform cement gap between the AngleFix titanium copings and the temporary restoration by blocking out using preparation and casting wax (e.g.: Dentaurem REF 120-025-00). This guarantees a stress-free fixation.

Finishing, trimming and polishing should be completed according to the instructions of the acrylic manufacturer.

PTFE cylinder pins are available for restorations which are bonded in the laboratory. The pins do not bond with the adhesive and prevent it getting into the screw canal.

Lingual view of the model with shortened titanium copings on AngleFix abutments.



Model with blocked out titanium copings.



Poured temporary restoration with the index.



Case 2: AngleFix long-term restoration

The AngleFix plastic copings are secured in position on the AngleFix abutments using the AnoTite screw L 6.0 mm.

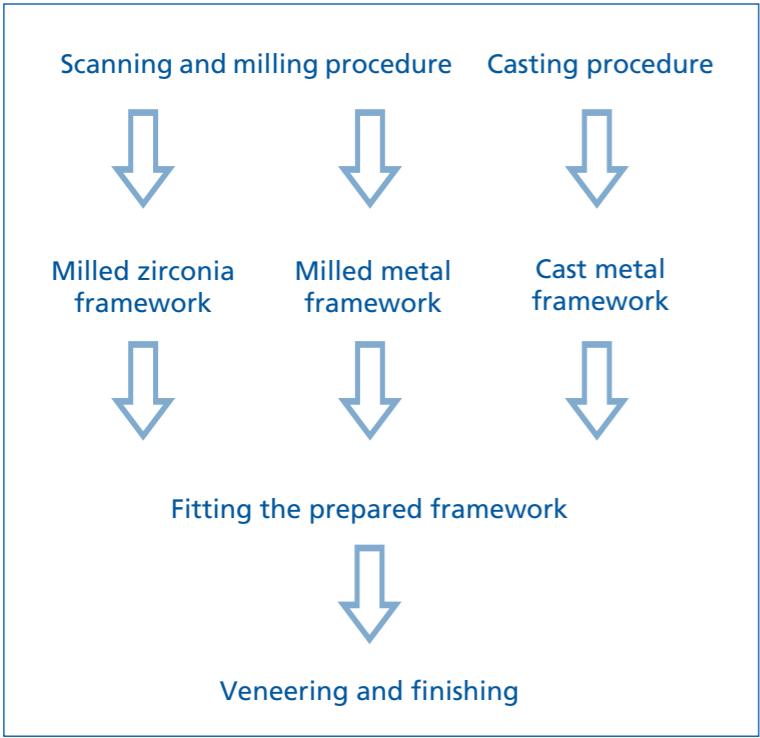
The available space is checked using buccal and lingual indexes.

If there is insufficient space available, the AngleFix plastic copings can be lightly and easily trimmed.

A base structure is then fabricated as a strengthener for a long-term restoration. The wax-up is fabricated taking into consideration the buccal and lingual indexes. This procedure guarantees that there is still sufficient space for subsequent working stages and the preprosthetic planning can be maintained.

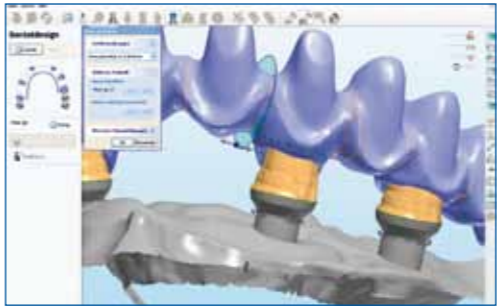
Working procedures.

After waxing up, the base structure can be produced using different fabrication techniques. Both the CAD/CAM fabrication and the classic casting technique can be used:



CAD/CAM fabrication, casting, finishing and polishing should be completed according to the CAD/CAM and alloy manufacturers' instructions.

Framework design in CAD/CAM software.



Milled zirconia framework.



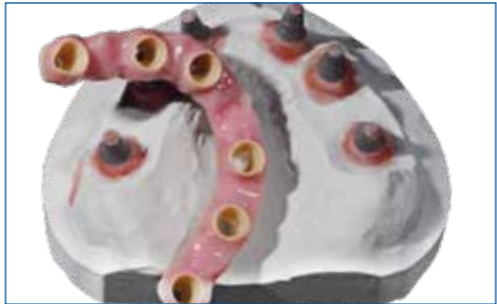
Firing the gingiva section in porcelain.



Firing the gingiva section in porcelain crowns.



Bonding of the zirconia framework on the AngleFix copings.



Finished porcelain restoration on the AngleFix abutments.





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. 38 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 ± 3 Ncm.



Application.

The torque ratchet can be used for the surgical procedure, implant insertion, securing the closure screws, gingiva formers and impression posts and for temporary and permanent prosthetic restorations. Different inserts are available depending on the application (p. 36).

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

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

The graduations are from 15 to 50 Ncm. As soon as the required torque is reached, the lock in the ratchet head disengages and the torque ratchet rotates freely. The recommended torques for inserting different components should not be exceeded (p. 37, table for starting torques).

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

When fitting the permanent prosthetic restoration, all prosthetic screws should be tightened with the torque ratchet set at the relevant torque (p. 37 table for torque ratchet settings) and then retightened after approx. 5 minutes using the same torque. It is important that the insertion key fits flush in the prosthetic screw. We recommend using AniTite new prosthetic screws for the final fitting.



Torque ratchet.




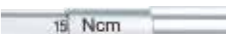

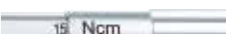

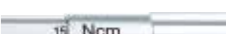

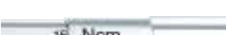

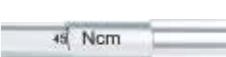













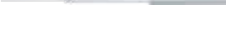






Overview – Inserts for the torque ratchet.

Depending on the application there are different inserts available.



Table – Starting torques for implants.*

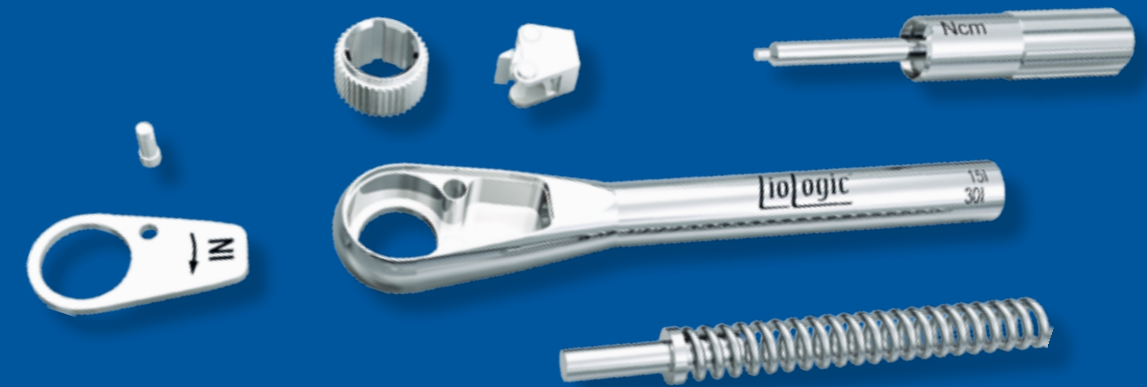
The torque ratchet is only intended for clinical use. Prosthetic screws should be tightened manually in the laboratory.

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

* primary stable and osseointegrated

Reusability of surgical instruments.

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



Torque ratchet.

Disassembly.

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

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

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

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

Removing the adjusting screw.



Opening the ratchet head.



Cover removed.



Ratchet wheel.



Ratchet wheel and ratchet core.



Assembly.

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

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

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

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

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

Check the function after assembly.

Sterilization.

The torque ratchet should be fully assembled for sterilization.

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

Safety instructions.

Manufacturer.

Dentaurum Implants GmbH | Turnstraße 31
75228 Ispringen | Germany

SAFETY



Brief description.

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

The tioLogic® implant system contains specially coordinated instruments, abutments and accessories for insertion of the implant and fabrication of the prosthetic restoration. Only original components of the tioLogic® implant system should be used in combination according to the instructions for use/manuals.

Further information.

Though insertion of dental implants has a high rate of success and implants have a high survival rate, successful treatment cannot be guaranteed. The operator should note and document any problem cases and inform Dentaurum Implants.

An inadequate number of implants, implants with an insufficient length or diameter, unfavourable positioning of the implants or an unstable prosthetic restoration can cause fatigue fracture in implants, abutments and prosthetic screws under biomechanical loading. The particular oral situation should be taken into account during implant insertion and fabrication of the prosthetic restoration to avoid overloading the components.

The use of tioLogic® implant system components not clearly defined as combinable within the terms specified in the instruction manual can also lead to mechanical failure, tissue damage or unsatisfactory aesthetics.

Adverse effects and interactions of tioLogic® implants are unknown. It still cannot be ruled out that in rare cases allergic reactions to certain elements in the material used within the tioLogic® implant system or electrochemical induced paraesthesia may occur.

Packaging and sterility.

All tioLogic® implants are supplied individually with the correct closure screw in a gamma-sterilised double-skinned package. They are for single-use only. The double-skinned package (foil and blister package) protects the inner container with its sterile implant and screw from contamination. The contents are only sterile when the packaging is undamaged. If the double-skinned packaging is damaged, the product may not be used. The double-skinned packaging is protected again by another outer packaging.

All instruments must be cleaned, disinfected, and sterilised every time before use. This applies especially to first-time use, as all instruments (apart from single-patient instruments) are supplied non-sterile. Further advice is available in the surgical manual.

Storage.

tioLogic® implants are to be stored only in the original packaging in a dry, dark area at room temperature. The implant may not be used after the use-by date (see label), has expired.

Safety instructions.

SAFETY



Application, availability, precautions, documentation.

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

Before using the system, operators should ensure that they have carefully read and understood all the information in the tioLogic® instructions for use/manuals. Operators are also strongly advised to attend one of the training courses on the tioLogic® system offered by Dentaaurum Implants to learn the correct techniques because the instructions for use/user manuals cannot cover all possible clinical situations to allow immediate use.

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

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

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

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

Several components are not available in all countries.

Quality, warranty and liability.

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

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

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

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

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

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

Dentaurum Group

Germany | Benelux | España | France | Italia | Switzerland | Australia | Canada | USA
and in more than 130 countries of the world.



➔ For more information on our products and services, please visit www.dentaurum.de

Date of information: 01/13

Subject to modifications

