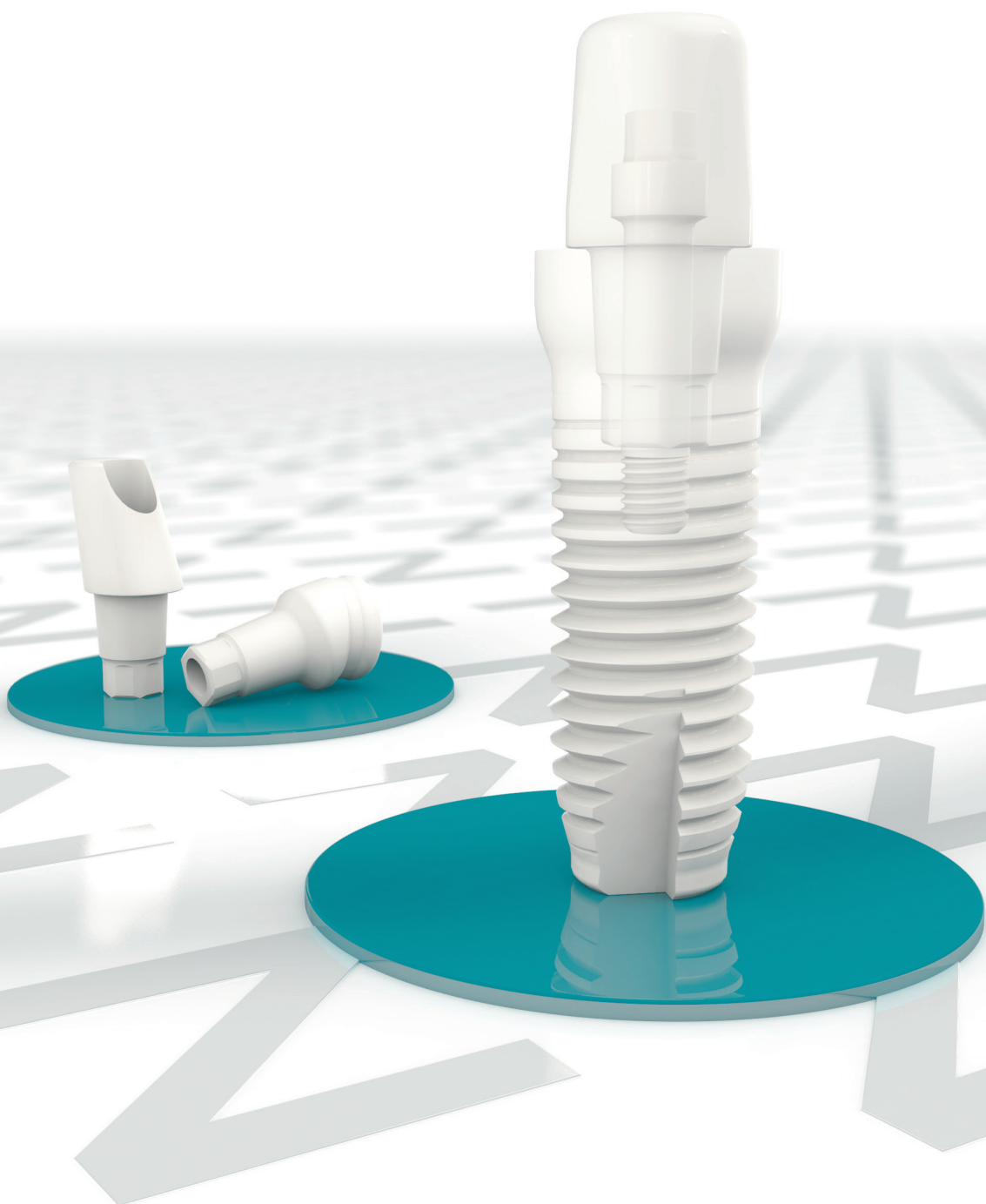


Surgical and Prosthetic Concept Tissue-Level Implant Z5-TL





Welcome to the world of ceramic implants

The Z-SYSTEMS implant system is the result of many years of clinical and laboratory experience since 2004. Safety is our foremost priority.

This basic information on the surgical and prosthetic procedure of the Z-SYSTEMS Implant System is intended to provide dentists, physicians, surgeons and dental technicians with a description of the most important surgical and prosthetic steps for the planning, treatment and procedure of the Z-SYSTEMS System. This manual cannot replace implantological and prosthetic training. It is assumed that the user is familiar with the implant procedure.



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1.1

General aspects and important information

General aspects

Z-SYSTEMS implants are unique in their combination of design and material. We expressly ask you to read this manual thoroughly before starting planning and to exactly follow our specific instructions on preparation as well as surgical and prosthetic procedures.

Observing these specific instructions and following the general implantological and prosthetic principles may help ensure successful implantation with Z-SYSTEMS implants.

The health of your patients is our top priority. For this reason we have compiled a technical guide that will contribute to the success of treatment with Z5-TL implants. The surgical and prosthetic phase should be preceded by extensive preoperative assessment, diagnosis and planning. Careful planning and adherence to the protocols for implantation and prosthetic restoration of Z5-TL implants reduces/avoids problems/errors during implantation and especially during prosthetic restoration.

We recommend the use of Z5-TL implants only for dentists with thorough, practical and surgical training and with expertise and experience in implantology. Instruction/training by an implantologist or Z-SYSTEMS representative familiar with the use of the instruments is strongly recommended.

Important information

Disclaimer: The Z5-TL implant system is part of an overall concept and may only be used in conjunction with the corresponding original components and instruments and according to the Z-SYSTEMS instructions and recommendations. Instructions regarding the application of our products are given verbally, in writing, electronically or through practical training, in accordance with the state of the art at the time of product launch. The user of Z5-TL products must decide whether or not a product is suitable for a patient and a specific situation according to their indication. Z-SYSTEMS excludes any liability for damages resulting from the use or implantation of Z5-TL products as a result of, or in connection with, errors in professional assessment or application/indication, in particular also claims due to the disregard of general implantological and prosthetic principles in connection with implants. The user is also obliged to inform themselves regularly about the latest developments of our system and its applications.

Send us an e-mail to support@zsystems.com and we will be happy to send you the latest information.

Availability: Not all of the products described in this manual are available in all countries. For further information, please contact our subsidiary or sales company in your country.

Precautions: Our products must be protected from aspiration during intraoral use.

Delivery: The sale of these products is limited to dentists, doctors or licensed dental technicians or orders made on their behalf.

Units per package: Unless otherwise stated, the package unit is 1 piece.

Documentation: Detailed instructions regarding the Z5-TL implant system are available from your account manager or customer service department in our headquarters.

Qualified users: Z-SYSTEMS implants should only be used by dentists, doctors, surgeons and dental technicians that are trained to use the system.

Certification:

FDA / ISO 13485 / CE (MDD 93/42/EEC)







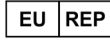
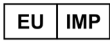












Z-SYSTEMS has been certified to ISO 13485 since 2004. Our medical devices are CE marked in accordance with the EU Medical Devices Directive 93/42/EEC (MDD). Z-SYSTEMS has been registered with the FDA since 2007, and relevant products are cleared via the 510(k) pathway.

Colour coding of the surgical and prosthetic products:

Red: 4.0mm diameter

Green: 5.0mm diameter

Explanation of the symbols on labels and package inserts

 ifu.zsystems.com	Consult instructions for use. Please follow the link to the e-IFU: ifu.zsystems.com
	Caution
	Manufacturer
	Manufacturing date
	Products are CE marked and comply with the requirements of the Medical Device Regulation (EU) 2017/745.
	Medical Device
	European representative (Indicates the authorized representative in the European Community)
	European importer (Indicates the entity importing the medical device into the European Community)
	Article number
	Lot/batch number
	Plasma sterilized
	Single sterile barrier system
	Double sterile barrier system
	Single use, do not re-use.
	Do not re-sterilize
	Non-sterile
	Use before expiration date
	Do not use if packaging is damaged
	Keep away from sunlight
	Keep dry
Rx only	CAUTION! United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician
Qty.:	Quantity

1.2

Material, biocompatibility and osseointegration

Material

All Z5-TL implants are manufactured according to the unique "Zirkolith®" process from zirconium oxide Y-TZP bioceramics in compliance with the ISO 13356 standard - it encompasses our experience in the development, material processing, quality assurance and finishing of zirconium oxide. The composition and production processes for zirconium oxide vary according to the requirements for the system component, for example whether it is an implant, a cutting instrument or some other surgical instrument.

The material achieves its properties through the "Hot Isostatic Pressing" process. In this process, the material is recompressed in a tunnel kiln for three days at 2000 bar after the sintering process, which improves the physical properties of the base material.

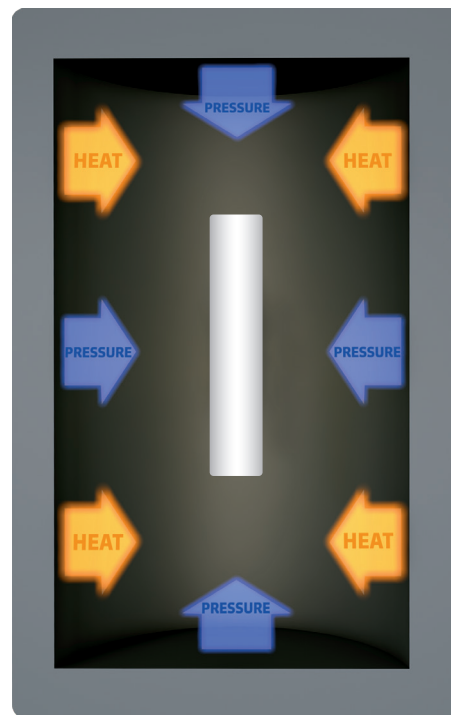
Not only the implants, but also the instruments that come into direct contact with the bony surgical area are made of zirconium oxide. The cutting instruments are made of high-strength ATZ high-performance ceramics (Alumina Toughened Zirconia).

Biocompatibility

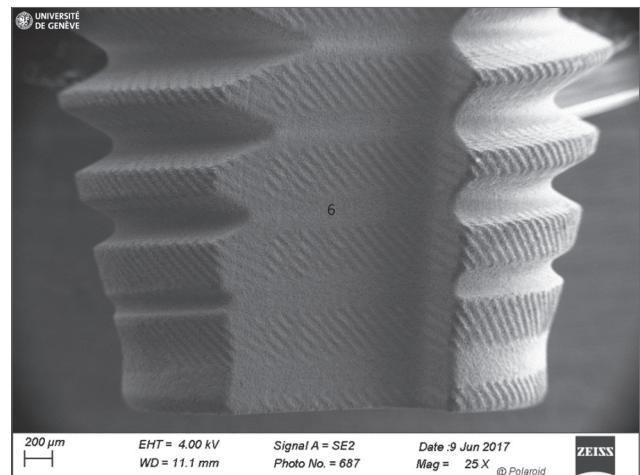
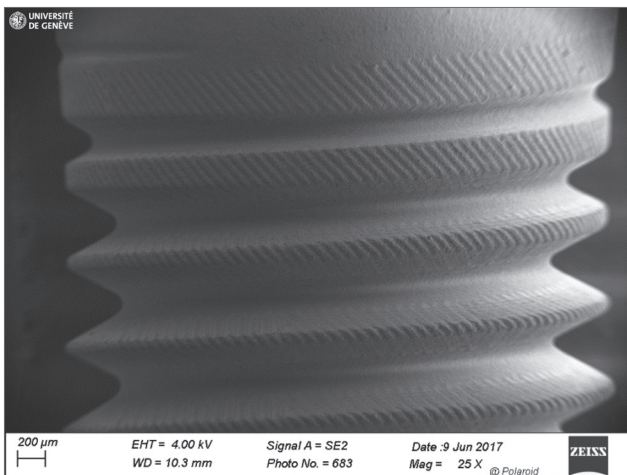
Numerous studies since the 1960s have confirmed the excellent biocompatibility of zirconium oxide ceramics.

Osseointegration

Zirconium oxide has similar osseointegration behaviour to commercially pure titanium, which has also been proven in a large number of studies.



Hot Isostatic Pressing in a tunnel kiln:
Pressure up to 2000 bar, temperatures up to 2000 °C



Surface

Surface modification is made in the SLM® process developed by Z-SYSTEMS using laser technology and results in an increase in surface area and therefore to increased macro and micro roughness.

Healing time

We recommend a healing time of 3 months in the lower jaw and 6 months in the upper jaw* for healthy patients with good bone density and sufficient bone quality.

We strongly recommend that each implant is protected during the healing phase, for example through provisional arrangements or ground prostheses.

* Please note that all references to bone classification in this manual refer to the classification as described by Lekholm and Zarb: Lekholm U.R. & Zarb G.A.: Patient selection and preparation, in Brånemark P.-I., Zarb G.A., Albrektsson T. (eds): Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago IL, Quintessence, 1985, PP 199–209.

1.3

Indications

Z5-TL implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5-TL

implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-TL implants are intended for delayed loading.

General areas of application

As a rule of thumb, the implant with the largest possible diameter should always be used, because the mechanical strength increases disproportionately with increasing diameter of the implant.

4.0 mm application

Universal implant that is suitable for most indications. Not suitable for applications where there is a risk of excessive bending moments (e.g. extended crowns, extension bridges, bridges with more than one pontic). Limited suitability for telescopic restorations. Use for telescopic restorations is only recommended for one-piece implants and require special planning. Telescopic or Locator-type abutment restoration on at least 4 implants in the mandibular and 6 implants in the maxilla is recommended.

5.0 mm application

Universal implant, suitable for most indications where there is sufficient bone. Not suitable for applications where there is a risk of excessive bending moments (e.g. extended crowns, extension bridges, bridges with more than one pontic). Implants with Ø 5.0 mm are recommended for the indication canines, central upper incisors and upper jaw/lower jaw molars. Limited suitability for telescopic restorations. Use for telescopic restorations is only recommended for one-piece implants and require special planning. Telescopic or Locator-type abutment restoration on at least 4 implants in the mandibular and 6 implants in the maxilla is recommended.

Implant size	Thread diameter	Shoulder diameter	Minimum space requirements oro-vestibular (surgery)	Minimum space requirements mesio-distal (surgery)	Optimum indication odontogram	Single-tooth	Blocking	Bridge in premolar width (max. span 1 pontic)	Extension bridge	Bar	Telescope	
4.0	4.0mm	4.8mm	6.0mm	7.0mm	UPPER RIGHT 1st Quadrant	UPPER LEFT 2nd Quadrant	+	+	+	-	+	(+)
					USA 2 3 4 5 6 7 8	9 10 11 12 13 14 15						
					FDI 17 16 15 14 13 12 11	21 22 23 24 25 26 27						
					FDI 47 46 45 44 43	33 34 35 36 37						
USA 31 30 29 28 27	22 21 20 19 18											
					LOWER RIGHT 4th Quadrant	LOWER LEFT 3rd Quadrant						
5.0	5.0mm	6.0mm	7.0mm	8.0mm	UPPER RIGHT 1st Quadrant	UPPER LEFT 2nd Quadrant	+	+	+	-	+	(+)
					USA 2 3 4 5 6 7 8	9 10 11 12 13 14 15						
					FDI 17 16 15 14 13 12 11	21 22 23 24 25 26 27						
					FDI 47 46 45 44 43	33 34 35 36 37						
USA 31 30 29 28 27	22 21 20 19 18											
					LOWER RIGHT 4th Quadrant	LOWER LEFT 3rd Quadrant						

+ recommended | (+) not recommended | - not possible

1.4

Fundamentals of treatment planning

The patient must meet the generally valid implant surgery and prosthetic criteria for an implant restoration.

Implant prosthetic restoration is a collaboration involving the dentist/surgeon and dental technology and requires a high degree of clinical experience and detailed knowledge from all involved.

The following are important planning points:

Z-SYSTEMS recommend the selection of the appropriate implant and its restoration according to the following criteria:

- Endosseous diameter of the implant
- Shoulder diameter of the implant
- Length of the implant
- Vertical implant position

Aesthetically optimum result

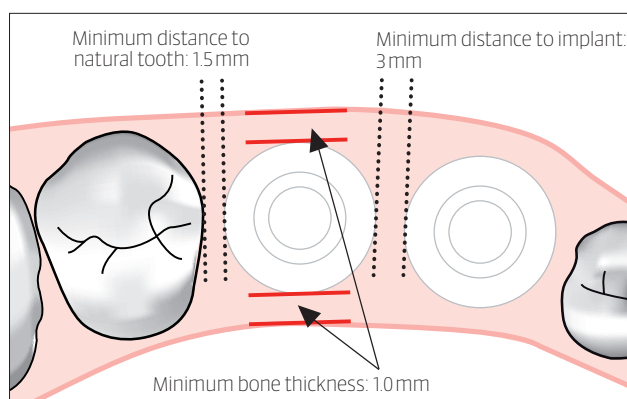
Many conditions are decisive for an aesthetically optimum result:

- the harmonious course of the gingiva
- the best implant position (vertical, orofacial and mesio-distal)
- the shape of the crown and
- the presence of interdental papillae

Planning the position of the implant

During planning, the instructions for the hard tissue configurations are to be complied with and soft tissue management must be observed.

The implant diameter and implant length must be determined so that there is sufficient bone (at least 1mm) around the implant. A minimum distance of 1.5mm to an adjacent natural tooth and 3mm to an adjacent implant must be maintained.



Structure-preserving and structure-protecting procedures are to be used for flap design and implant placement. The oral hygiene requirements must be taken into account as early as the planning stage.

Restorations

Single-tooth crowns

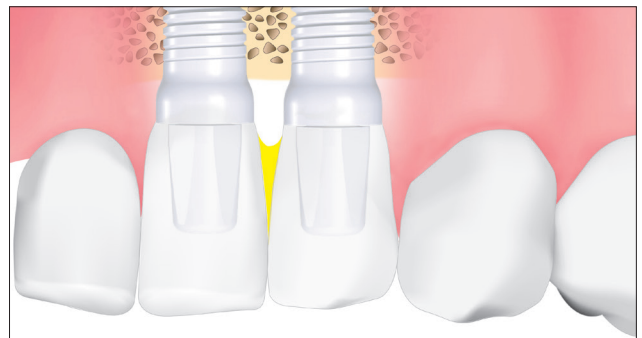
Restoration with single crowns is a possible restoration under the aspect of "restitutio ad integrum". It includes all the advantages that are possible in periprosthetic rehabilitation.

The physiologically adequate biomechanical load prevents further atrophy of the hard and soft tissue.



Blocked crowns

Blocking of the crowns may be necessary for static reasons (such as unfavourable lever ratios). When selecting blocking, the possibility to maintain good hygiene must be considered.



Implant-supported bridges

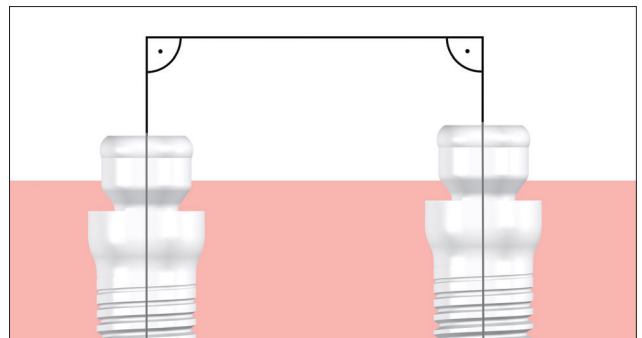
Implant-supported bridges can be inserted in positions that do not permit implant placement. The implant distribution must be selected so that small span segments are created.



Zloc prosthetic restoration

Zloc abutments are used to attach prostheses in the restoration of the edentulous upper or lower jaw.

- The all-on-four treatment concept is to be observed
- Avoidance of axis divergence



1.4

Planning the implant position for Zloc restorations

CAVE: To ensure trouble-free function of the retentions and avoid loading the implants beyond their stability, an axial transfer of force to the implants should be ensured as far as possible. For this purpose, the implants should be positioned as parallel to each other and perpendicular to the occlusal plane as possible. The implants should be placed on the same horizontal plane if possible to allow easy handling when removing or inserting the prosthesis.

Guided surgery

Z-SYSTEMS recommends case planning using three dimensional X-ray images (DVT/CT) and the use of a drilling template produced on the basis of this planning in the sense of "guided surgery" to ensure that the axial alignment of the Z5-TL implants is as parallel as possible.

Gingiva height

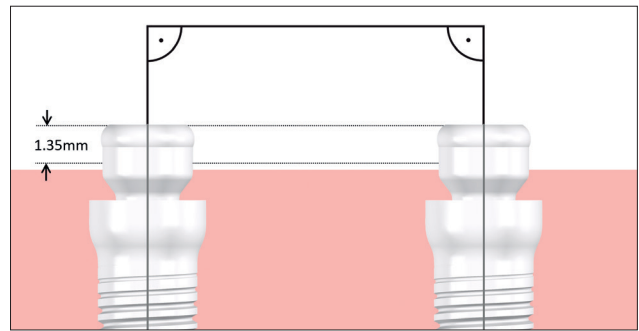
Before surgery measure the maximum tissue thickness at the planned implantation site (e.g. using a probe and attached measuring stop root canal instrument, local anaesthesia).

Implant divergence

Z-SYSTEMS recommends an optical check of the axis alignment for parallelism after pilot drilling using the DP230 depth gauge.

With straight or angled Zloc abutments, the maximum divergence between several implants is 30°. If there is a divergence between the load (perpendicular to the occlusal plane) and implant axis of more than 15° per implant, or more than 30° between several implants, the axial alignment of the implant must be corrected.

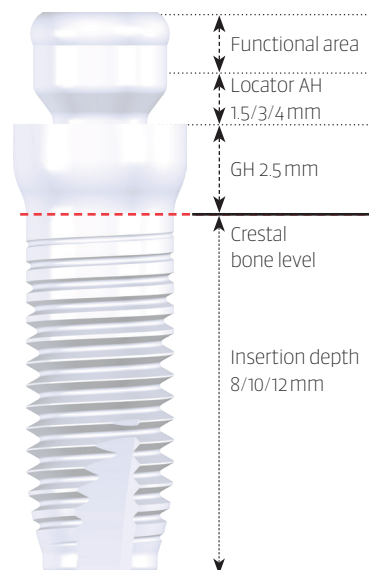
The functional area of the Novaloc™ matrix is 1.35mm (1.85mm if the overdenture is to be made with 0.5mm gingiva clearance) above the surrounding gingiva to ensure the trouble-free function of the Novaloc™ matrix.



Avoidance of axis divergence

Zloc gingiva height

Zloc abutments have different abutment heights (AH). The implant has a gingiva height (GH) of 2.5 mm. Therefore, the total gingiva height consists of the implant GH and Zloc AH.



Protective measures

For successful osseointegration, the implants must be protected from macro movements during the healing phase. Depending on bone quality, insertion torque, periotest measurement and general patient compliance, the dentist decides whether and which additional protective measures are necessary. Possible protective measures are: protective splints, blocked temporary restorations or protective prostheses.

Examples of protective measures are available on request from support at support@zsystems.com.



2 Surgery

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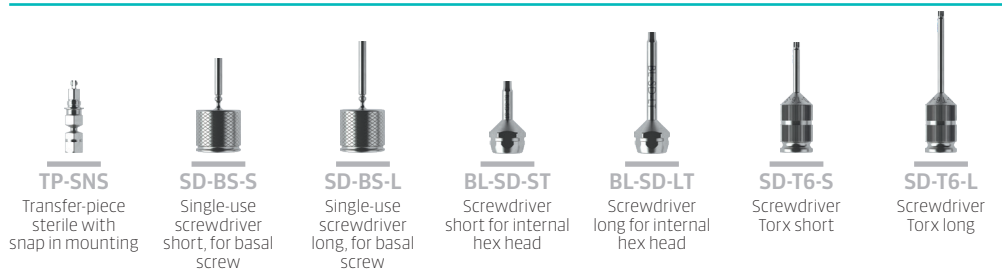
2.1

Instruments

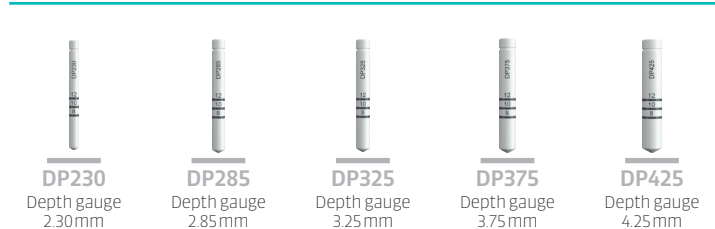
The Z5-TL surgery cassette from Z-SYSTEMS is to be used.

The instruments required for implantation have been designed to be user-friendly. The rotating instruments are marked with a colour code throughout. The instruments are labelled with the respective instrument designation to avoid any risk of confusion. The drills are arranged in the cassette according to the treatment sequence.

Driver



Gauges



Meaning of the colours:

red = ø 4 mm, green = ø 5 mm

Material properties

All instruments that come into direct contact with the surgical field are made of zirconium oxide. The cutting instruments are made of high-strength ATZ high-performance ceramic (Alumina Toughened Zirconia).

This alumina-reinforced zirconium oxide is ideal for the manufacture of drills and taps. The ATZ drills cut excellently with very little wear. Note: The drills must be examined after every use for blunt cutting edges or damage and if necessary, exchanged.

Drills



RD230
Round burr
2.3x16mm



TD230
Twist drill
2.3x16mm



TD285
Twist drill
2.85x16mm



TD325
Twist drill
3.25x16mm



TD375
Twist drill
3.75x16mm



TD425
Twist drill
4.25x16mm



CD400
Cortical drill
4mm



CD500
Cortical drill
5mm

Cortical drill

Counter-sinks



CS400-1
Counter sink
4mm



CS500-1
Counter sink
5mm



T400-3
Bone tap
4mm



T500-3
Bone tap
5mm

Tap

Adapter for tap



ZT-HA-9
Contra-angle
adapter



ZT-RA10-9
Ratchet adapter
10mm



ZT-RA20-9
Ratchet adapter
20mm

Ratchet



TR-70
Torque
Wrench

Accessories



TD-DS230
Drill stop
2.3mm



TD-DS285
Drill stop
2.85mm



TD-DS325
Drill stop
3.25mm



TD-DS375
Drill stop
3.60mm
3.75mm



TD-DS425
Drill stop
4mm
4.25mm



CD-DS500
Drill stop
5mm



KI589
Drill extension



BL-CD
Abutment-
Removal
Instrument

2.1

Combined Cleaning and Disinfection Instructions for the Surgical Cassette of the of the Z5-BL/TL Sterilizer and Disinfectant

Within the scope of your responsibility for maintaining product sterility during use, ensure that:

- The steam sterilizers used comply with EN 13060 / EN 285 or ANSI AAMI ST79.
- Only device- and product-specific validated procedures for cleaning, disinfection, and sterilization are used.
- the equipment used is regularly maintained and inspected
- The validated parameters are observed during each cycle.

Observe the national legal requirements and hygiene regulations of the respective medical facility, particularly with regard to measures to minimize the risk of prion transmission.

Important Notes

- Reusable Z5-TL products may be reprocessed as often as the inspection specified in the instructions for use or reprocessing instructions has been successfully completed.
- Instruments that can be disassembled must be disassembled for effective cleaning.
- • Z5-TL products intended for single use must not be reused, as safe reprocessing and functional reliability cannot be ensured.

Instruments

The instruments of the Z5-TL implant system are supplied non-sterile unless explicitly labeled as sterile.

They must be cleaned, disinfected, and sterilized before the first use and before each subsequent use on a patient.

- Cleaning and disinfection are a prerequisite for effective sterilization.
- During use, contaminated instruments must be collected separately and must not be returned to the surgical cassette to prevent contamination.

After cleaning and disinfection, the instruments must be placed back into the surgical cassette.

The fully assembled surgical cassette is then sterilized.

General Note

Zirconia instruments must be reprocessed and stored separately from metal instruments to prevent metallic abrasion on the instrument surface.

Important Notes for Reprocessing Zirconia Instruments

Zirconia instruments must always be reprocessed and stored separately from metal instruments to avoid metallic abrasion.

Cleaning and Disinfection

1. Manual Cleaning and Disinfection

Initial disinfection:

After the surgical procedure, the instruments must be immediately placed in a bath containing a combined cleaning and disinfecting agent.

Example:

Komet DC1

2% solution at room temperature

Exposure time minimum 5 minutes

This initial disinfection prevents contamination from drying and serves as a preparatory step for subsequent cleaning.

Preparation for cleaning:

- Avoid drying of blood, tissue, or other biological residues.
- Contaminated instruments should therefore not be allowed to dry prior to reprocessing.
- For instruments with difficult-to-access areas (e.g., drill holes or channels), ensure that all internal surfaces come fully into contact with the cleaning solution.
- Disassemble all instruments according to the corresponding instructions.

Manual cleaning procedure:

1. Rinse the instruments with cold water for at least 5 minutes. Use a soft brush if necessary.
2. Immerse the instruments for at least 10 minutes in an enzymatic cleaner or a suitable detergent with a pH value of 7-9. Ensure that all surfaces are completely wetted.
3. Rinse the instrument with cold water for 5 minutes (or less) and clean hard-to-reach areas with a syringe or pipette.
4. Repeat the cleaning process by immersing the instruments for at least 10 minutes in an enzymatic cleaner or detergent (pH 7-9) and rinse again with cold water.

Post-Treatment

- Rinse the instruments finally with cold water for at least 3 minutes and clean drill holes or difficult-to-reach areas using a pipette or syringe if necessary.
- Dry the instruments with clean compressed air or a lint-free cloth. Allow the instruments to dry completely in a clean environment.

2. Automated Cleaning and Disinfection

Cleaning and disinfection may be performed manually or using automated equipment. For automated cleaning, suitable cleaning and disinfection devices may be used. The following process parameters must be observed at minimum:

- **Pre-wash** minimum 4 minutes
- **Cleaning with detergent** minimum 5 minutes at 50 °C
- **Intermediate rinse with mildly alkaline detergent** minimum 2 minutes at temperatures above 30 °C
- **Final rinse** minimum 2 minutes
- **Thermal disinfection** minimum 5 minutes at 90 °C
- **Drying** minimum 25 minutes

Rinsing and Drying

- Rinse the instruments for at least one minute with deionized or appropriately treated water. Ensure that difficult-to-reach areas are thoroughly rinsed.
- For drying, lint-free disposable cloths or oil-free dry compressed air may be used.

2.1

Inspection of Instruments

Inspect the instruments for:

- corrosion
- surface damage
- residual contamination

Damaged or still contaminated instruments must be discarded and reprocessed again.

Observe the maximum permitted number of drill uses according to the respective instructions for use.

Assembly and Packaging

- After cleaning and disinfection, all disassembled instruments must be reassembled according to the corresponding instructions.
- Package the instruments for sterilization in a suitable sterilization packaging in accordance with ISO 11607.
- The Z-SYSTEMS surgical cassette is suitable for sterilization in a steam sterilization process.
- Ensure that the packaging is suitable for steam sterilization and that the products are protected from mechanical damage.

Sterilization

Sterilization is performed using steam sterilization with a fractionated vacuum process and adequate product drying.

- The sterilization temperature must not exceed 138 °C.
- **EU:** Sterilization at minimum 134 °C with a holding time of at least 5 minutes.
- **USA:** Sterilization at minimum 132 °C with a holding time of at least 5 minutes.
- A drying time of at least 30 minutes is recommended.

Special Notes

- Ensure that the surgical cassette does not come into contact with the walls of the steam sterilizer, as this may cause deformation of the plastic due to locally elevated temperatures.

Surgical procedure / Drilling protocol

General drilling protocol

General note:

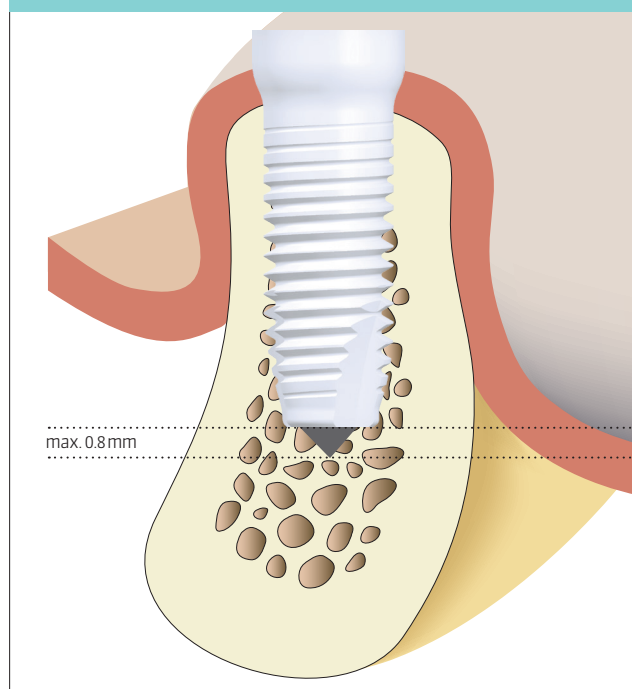
Round burr

To predrill the cortical bone fix the implant position.

Twist drill

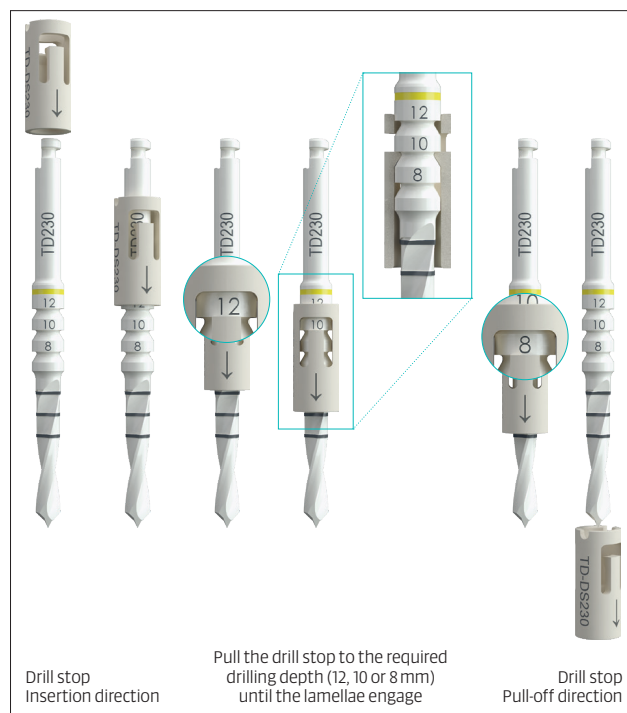
The implant bed is prepared with the twist drills in ascending order. The last drill used depends on the diameter of the implant to be inserted. Please follow the detailed instructions. The depth markings on the drill are easy to read. The first depth mark is 8 mm.

CAVE: The apical excess length of the drill tip is maximum 0.8 mm longer than the insertion depth of the implant. Please take this into account during the drilling process.



Drill stops

Drill stops are available for twist drills and cortical drills in the respective diameters. These are attached to the corresponding drills from the contra-angle handpiece connection side in the direction of the arrow and fixed at the required drilling depth. To remove, simply pull off in the direction of the arrow.



Cortical drill

Cortical drills are available to expand the cortical area according to the implant diameter. The use of a cortical drill is expressly recommended for cases with hard bone or cortical bone.

Tap

In principle, all Z5-TL implants are self-tapping. The use of a tap is recommended for cases with hard bone or hard cortical bone.

2.2

The general recommendations are:

Bone class D1+D2:

- Cortical area expansion with the cortical drill up to the depth marking
- Tap the entire length

Bone class D3+D4: do not tap

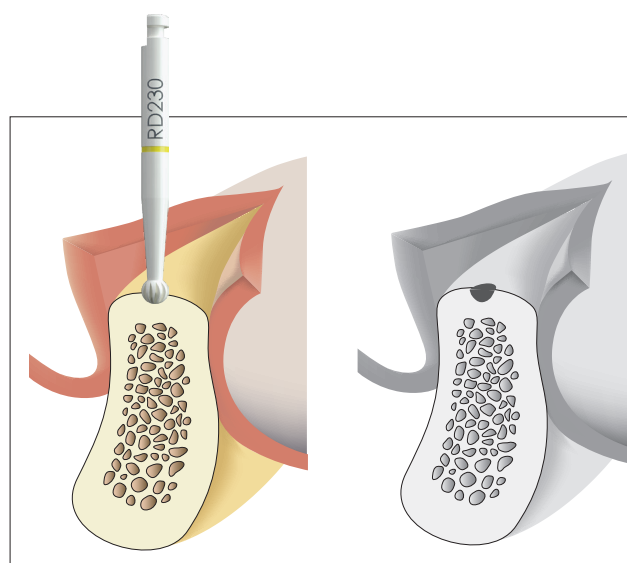
Exemplary procedure: Preparing the implant bed

The following shows how to prepare the implant bed using the example of a \varnothing 4.0mm/10mm Z5-TL implant in hard bone (D1).

After unfolding the gingiva, the basic preparation of the implant bed begins with preparation of the alveolar ridge and marking the implantation site with a round burr (RD230). This is followed by the pilot drill with the spiral drill (TD230) and the further preparation of the implant bed using the spiral drills in accordance with the endosteal implant diameter.

The threads are pre-cut with the tap; please refer to the notes on the previous page.

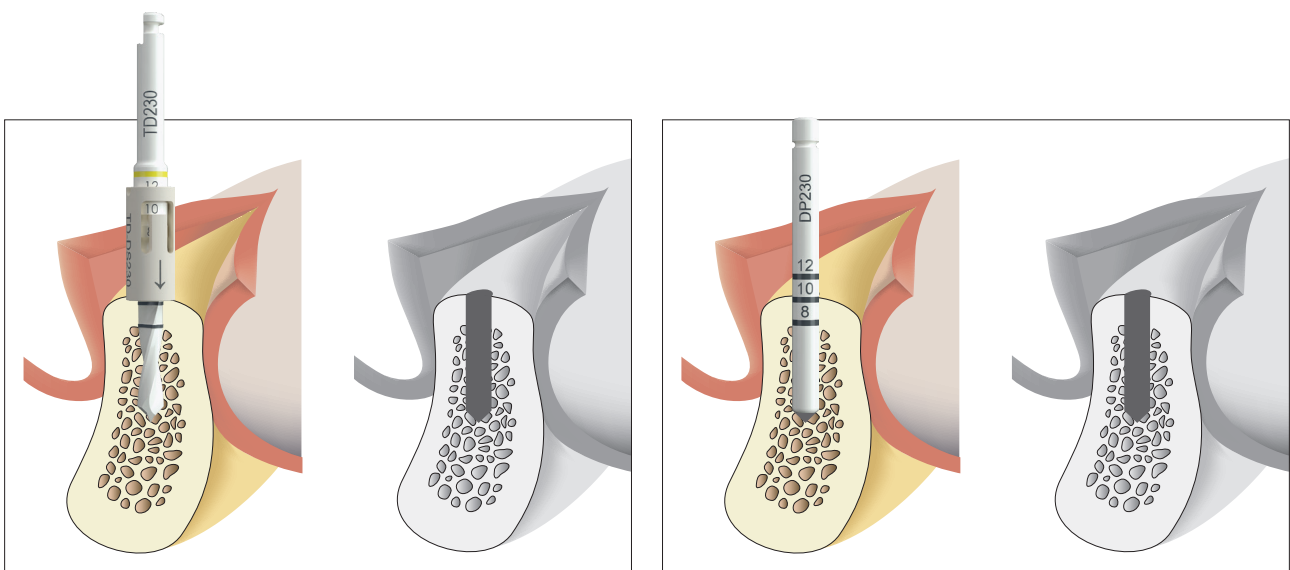
1. Preparation of the alveolar ridge and marking of the implantation site



Carefully reduce and smooth a narrow and tapered alveolar ridge with the RD230 round burr. This results in obtaining a flat and sufficiently wide bone surface. Mark the implantation site determined during the planning of the implant position with the RD230 round burr.

Note: Depending on the clinical situation, this step may be omitted or applied in a modified form (e.g. for fresh extraction sockets).

2. Implant axis and depth

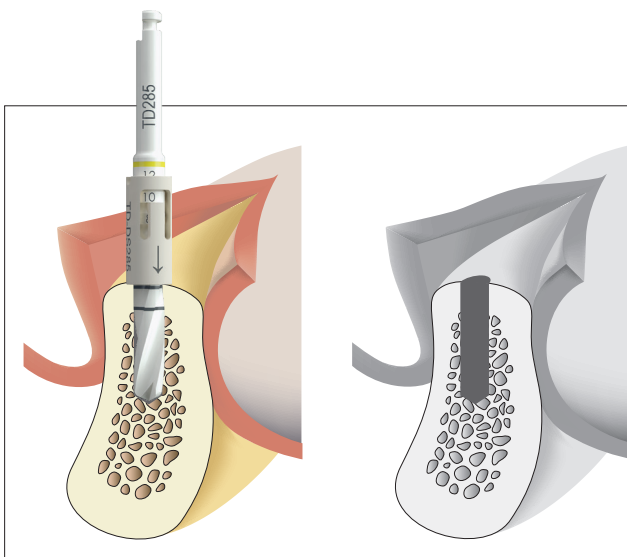


Use the twist drill TD230 to mark the implant axis by drilling to a depth of approximately 5 mm. Use the depth gauge DP230 to check the correct orientation of the implant axis. Drill the implant bed to the final preparation depth with the twist drill TD230. If necessary, correct the orientation of the implant axis.

Use depth gauge DP230 to check the implant axis and preparation depth. Take an x-ray at this time, especially if the vertical bone volume is reduced. The depth gauge is inserted into the drilled hole and allows a visual assessment of the hole in relation to the anatomical structures.

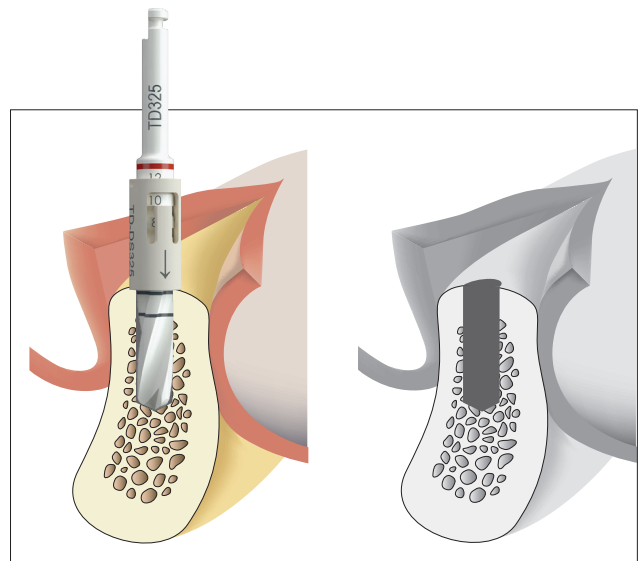
2.2

3. Widening the implant bed to \varnothing 2.85 mm



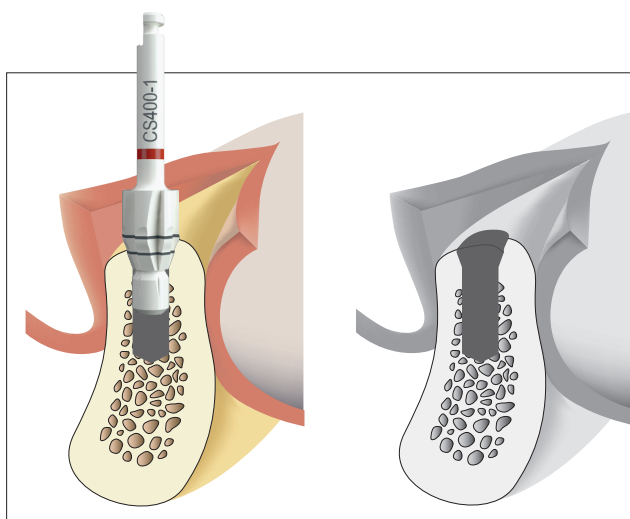
Widen the implant bed with twist drill TD285.

4. Widening the implant bed to \varnothing 3.25 mm



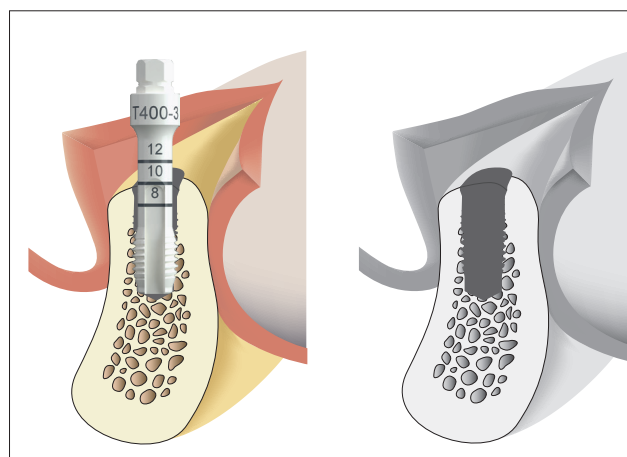
Widen the implant bed with twist drill TD325.

5. Profile drilling uneven alveolar ridge



Form the coronal part of the implant bed with the countersink CS400-1 up to the marking on the buccal bone lamella for countersinking the implant shoulder.

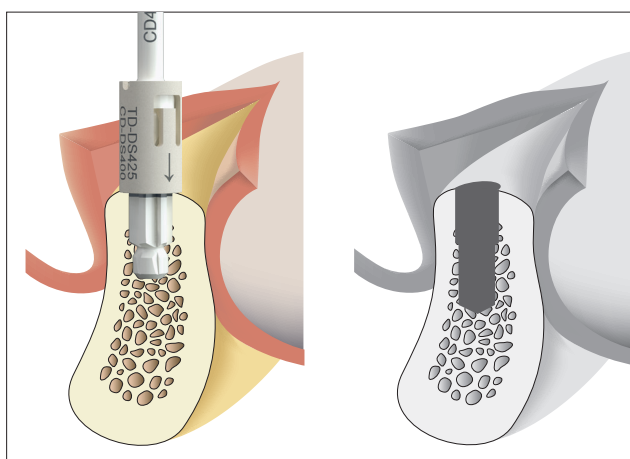
7. Tap



Pre-tap the thread with the T400-3 tap over the entire length of the implant bed preparation for bone class D1+D2.

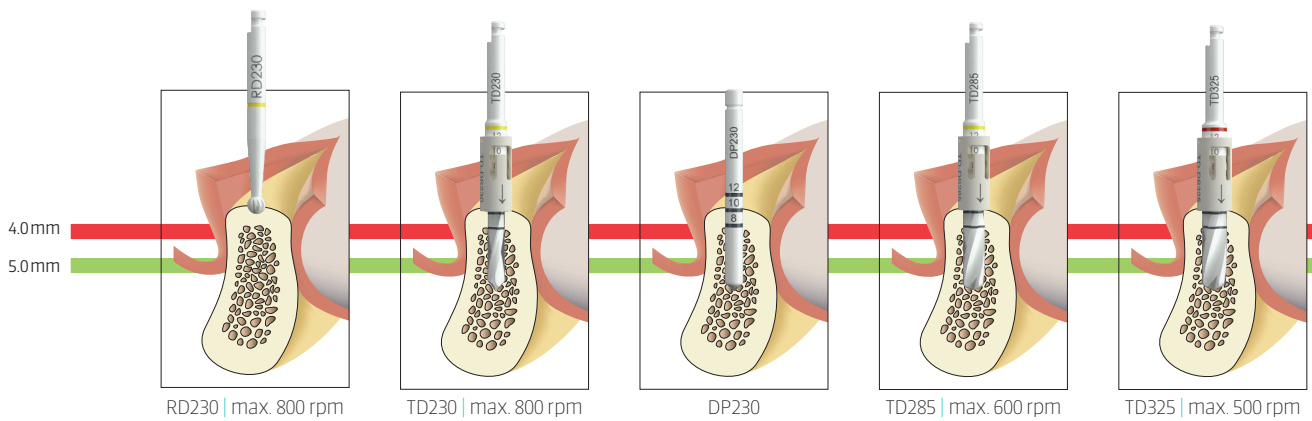
6. Profile drilling

The cortex is widened to the diameter of the implant with the CD400 cortical drill.

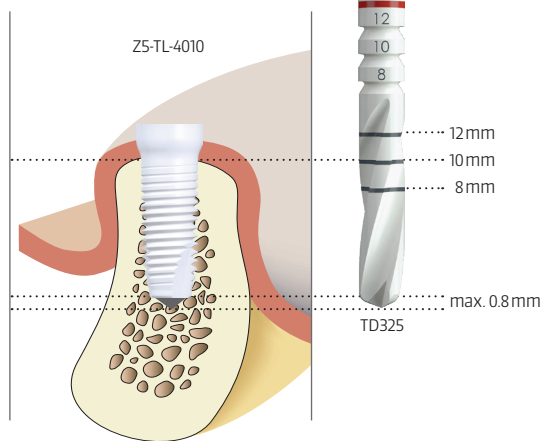


2.3

Drilling protocol

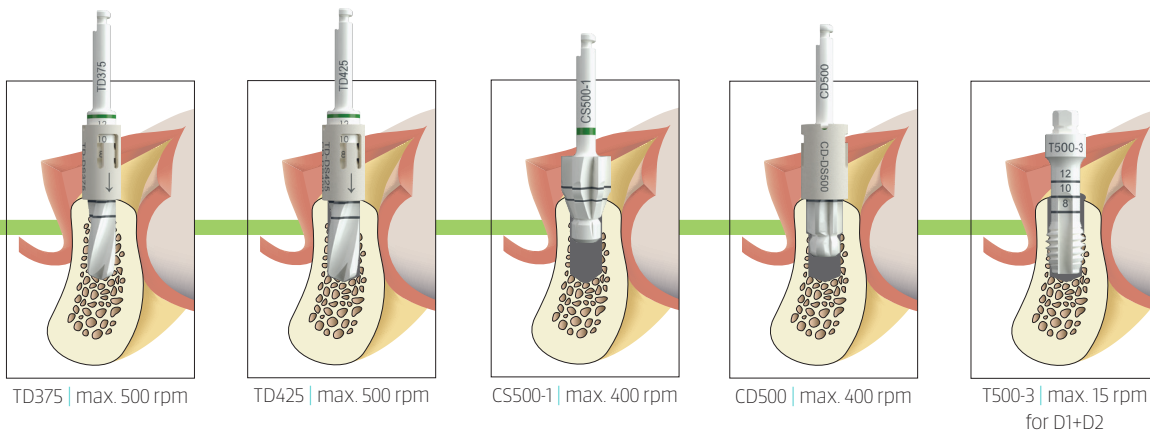
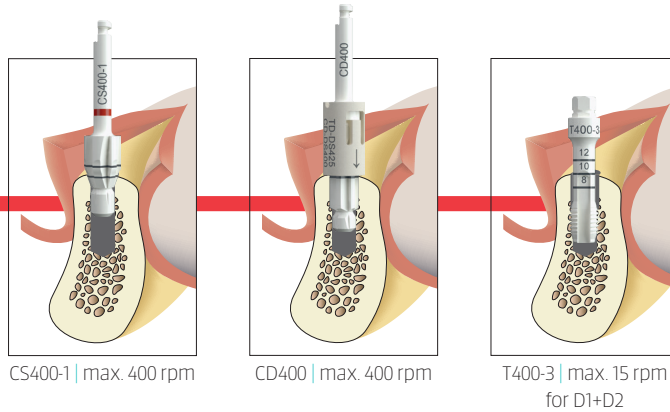


Drilling depth according to the implant length:
8/10/12 mm



Drills with depth stops





2.4

Specific features of Z5-TL

Concept

The two-piece, threaded Z5-TL implant is a self-tapping tissue-level implant. The Z5-TL implant has a transgingival portion (shoulder). There is a thread inside the implant in which abutment components such as healing caps, healing abutments and abutments are fixed with the aid of an occlusal screw. After implantation, the inner lumen of the Z5-TL implant is closed with the supplied healing cap (BL-HC) made of radiopaque PEEK (polyether ether ketone) by simply screwing and open healing is aimed for. A selection of standard healing abutments is available for each implant diameter for shaping the soft tissue before the prosthetic restoration. An individual design of the emergence profile can be achieved with the help of the temporary abutment and a temporary crown. Straight, angled and locator abutments are available for the final prosthetic restoration.

During the operation the surgeon decides to which dimension is to be prepared, depending on the bone quality. The drilling protocol must be observed and adhered to.

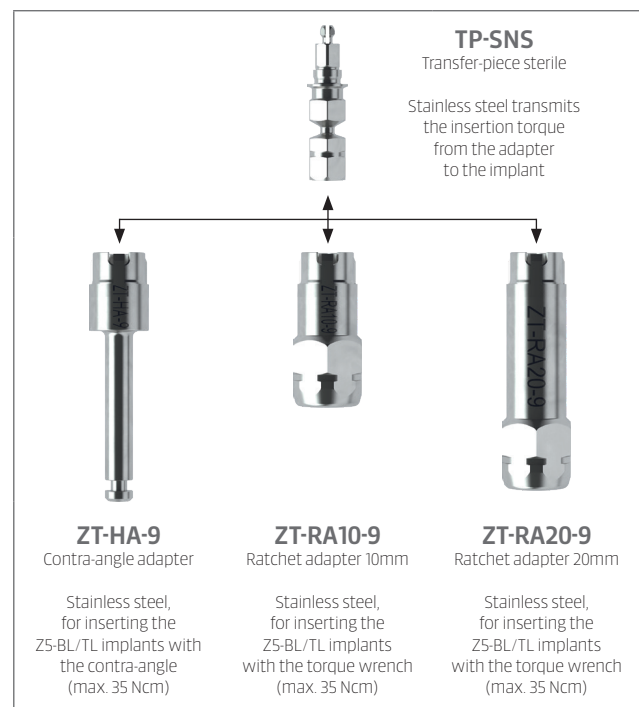
The optimum insertion torque is in the range of 25–35 Ncm. In the case of uneven alveolar ridges the countersink drill is to be used. For harder bone, a tap should be used to avoid torques of over 35 Ncm when inserting. The twist drills have a depth stop to ensure safe and precise preparation of the implant tunnel.

Implant removal from the sterile packaging

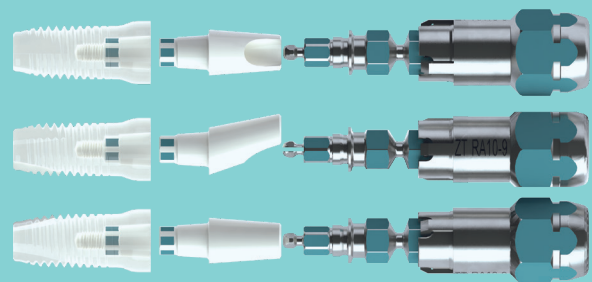
After opening the secondary packaging, removing the sterile inner blister and open the sealed lid. The white implant holder is rotated clockwise, and the implant is now easily accessible.

The implant driver is a two-piece component. The transfer-piece (TP-SNS) is inserted into the preferred adapter (ZT-HA-9, ZT-RA10-9, ZT-RA20-9) until it clicks into place.

Firmly press the corresponding adapter with the TP-SNS into the implant, taking into account the hexagon. Now the implant can be removed and inserted into the prepared osteotomy. After insertion, the implant driver must be removed again.

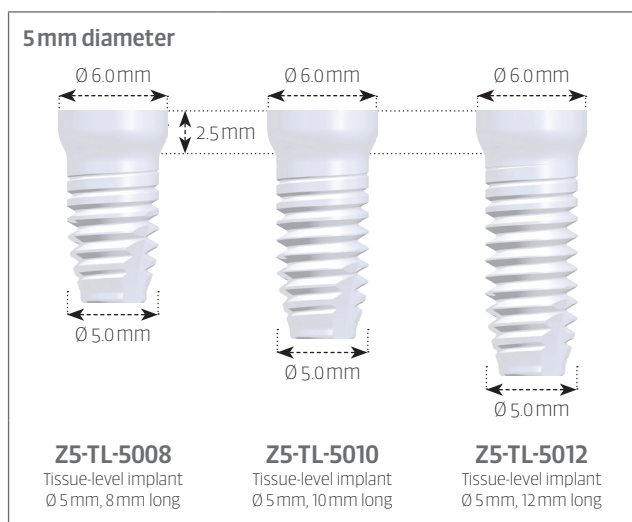
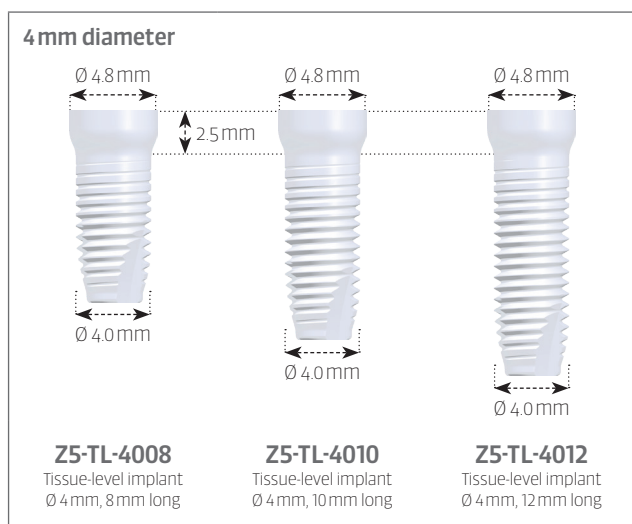


The alignment of the angled abutment can be defined with the transfer-piece. The hexagon on the ratchet adapter and transfer-piece correspond to the six sides of the internal geometry, as highlighted. The angled abutments overlap the hexagonal surface.



Implants

A total of six different Z5-TL implants are available. Two diameters, 4.0 and 5.0 mm, each in lengths of 8, 10 and 12 mm.



Healing phase

After implantation, the inner lumen of the Z5-TL implant is closed with the supplied healing cap (BL-HC) made of PEEK (polyether ether ketone) with simple, manual screwing using the screwdriver SD-T6-S or SD-T6-L. Whenever possible, open/transgingival healing should be sought. A good wound closure with tightly fitting gingiva is important.

Protective measures during the healing phase

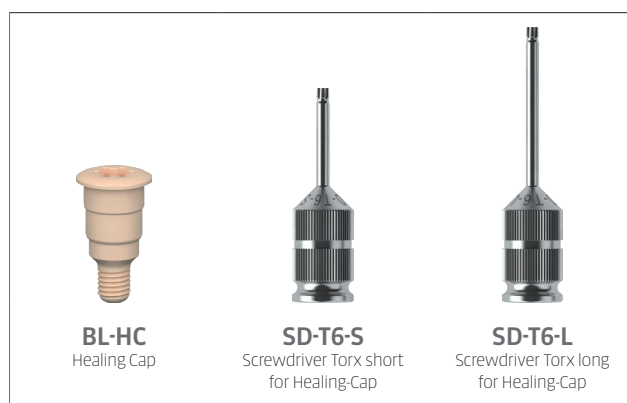
No forces may be exerted on the transgingival healing Z5-TL implants.

For protective devices:

- if the tooth gap will be closed during the healing phase
e.g. with a Maryland Bridge, thermoplastic clasp denture
- or a protective splint

keep a space of 1.5–2.0 mm between protective device and the Z5-TL implant in order to ensure a load-free healing of the implant.

Please note that the (TL-TA0060) temporary abutment is only intended for use after the healing phase.



TORX SCREWDRIVER FOR HEALING CAP

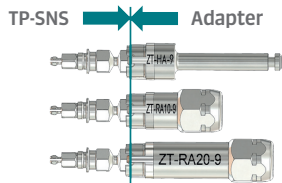
To prevent accidental swallowing of the screwdriver or the Healing Cap, the screwdriver should be secured with a dental floss loop and the Healing Cap socket must be firmly pressed on the screwdriver.

2.5

Removing the implant from the packaging

All Z-SYSTEMS implants are delivered in a sturdy cardboard box well as the package insert and three removable label strips for documentation. Inside is an outer blister (secondary packaging), with the inner blister (primary packaging) and the implant, as

1



Connect the TP-SNS to the preferred adapter. Before pushing down the adapter on the transfer piece, assure correct alignment of the hexagon. A click is heard when the adapter is attached correctly.

2



Carefully apply light pressure to stabilize the white insert.

3



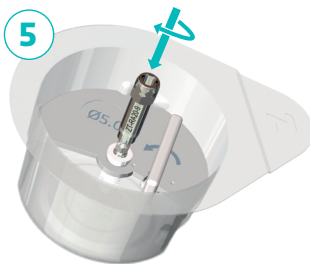
Open the sealed lid

4



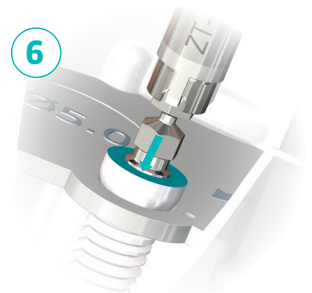
Turn the implant holder anticlockwise

5



Slide the transfer piece into the implant with a slight rotational movement. A click will be heard when the transfer piece is properly attached.

6



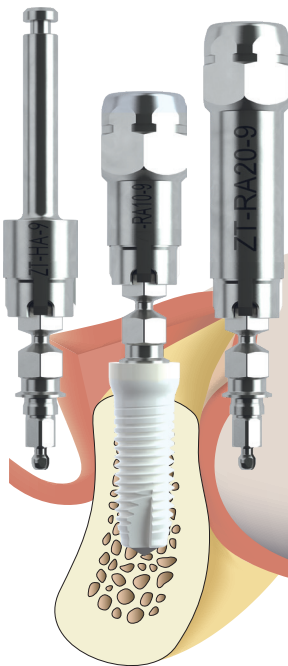
For safe removal, ensure that there is no gap between the TP-SNS and the implant shoulder

7



Remove the implant from the insert by hand or by attaching the ratchet or handpiece

Implant placement



Transfer-piece TP-SNS driven by:
ZT-HA-9 | ZT-RA10-9 | ZT-RA20-9

Insertion speed (rpm)	15
max. torque	25–35

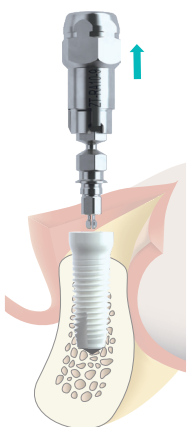
USER TIP:

Turn the implant slightly to the left before insertion. The thread noticeably engages in the osteotomy and then follows the threads in a clockwise direction as it is inserted.

Transfer-piece for Z5-BL/-TL Implants

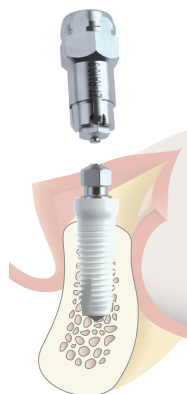
- Retentive notch**
 - to ensure secure retention to adapter i.e. handpiece or ratchet
- Predefined breaking point**
 - to ensure excess torque is not applied to the implant.
- Abutment alignment indicator**
 - Alignment aid for ideal prosthetic abutment orientation
Congruent hexagon (Implant – TP-SNS – Abutment)
- Retentive notch**
 - to ensure secure retention to adapter i.e. handpiece or ratchet after failure of the predefined breaking point
- Snap feature/Retention**
 - to ensure secure retention of the implant
 - Detaches with Adapter after implant insertion.

Implant Driver Removal



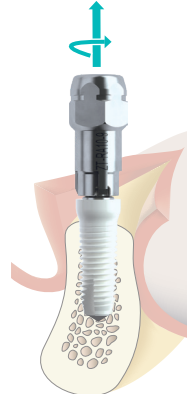
After the implant placement, remove the transfer piece from the implant with the adapter still mounted completely.

Removal of a broken Transfer-piece



The transfer-piece is provided with a predetermined breaking point to prevent excessive tightening torque. If the transfer-piece breaks during insertion, one fragment remains in the implant and one in the adapter. To extract the implant, simply take out the broken transfer-piece part from the adapter with tweezers, re-insert the adaptor on the transfer-piece part in the implant. Anticlockwise turns will remove the implant. To ensure an insertion torque of 35 Ncm, the implant bed preparation must be checked and re-prepared, to avoid bone overcompression.

Implant extraction after breaking the pre-defined breaking point to check the implant bed preparation



2.6

Postoperative recall protocol

Postoperative recall protocol

The following postoperative checks should be carried out at the intervals indicated:

Regular hygiene examinations (depending on the oral hygiene of the patient) up to the beginning of the prosthetic restoration.

Consultation with the surgeon to determine the recall during the first 6–8 weeks of the healing phase. Depending on the case, further conditioning of the soft tissue can be performed with the aid of a healing abutment before the final impression is taken.

The patient should be instructed to contact the practice immediately in the event of any complaints. A prophylactic check should be carried out 14 days and 6 weeks after implantation, at the latest however after three months.

Successful integration:

- No peri-implantitis
- No clinically noticeable loosening of the implant
- No pain in the vicinity of the implant
- No radiographic visible peri-implant gap

3 Prosthetic concept

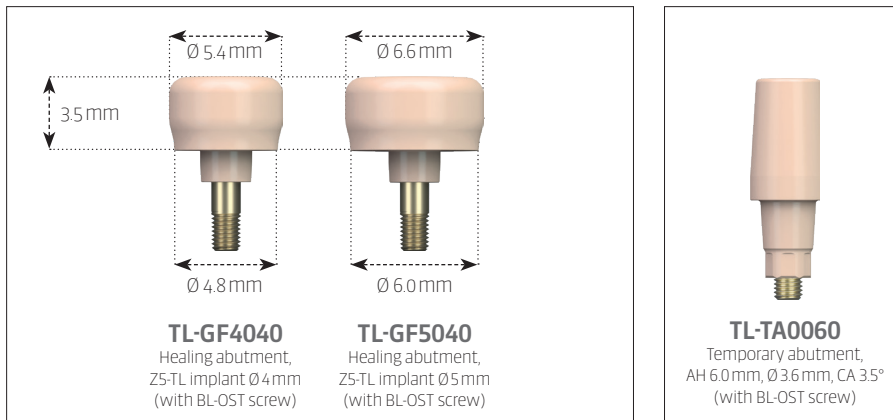
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3.1

Healing Abutments

A healing abutment is available for each implant diameter for shaping the soft tissue before the prosthetic restoration. These are screwed into the implant using a screwdriver and the BL-OST basal screw. An individual design of the emergence profile can be achieved with the help of

the temporary abutment and a temporary single-tooth restoration. The healing abutments and the temporary abutment are supplied non-sterile and must be sterilised before use on the patient.



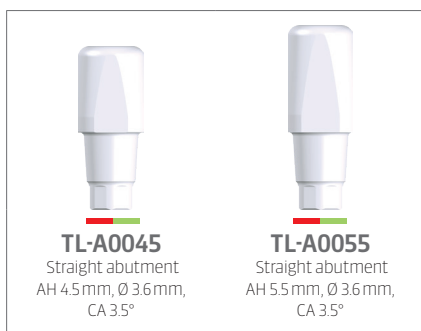
Fixing the abutment with Z5-TL implants

The abutments should be selected between the dentist and dental technician, taking into account the previous prosthetic planning. The implant axis, the abutment height and the occlusion concept must be taken into account.

All abutments are supplied non-sterile and must be sterilised before use by the patient.

The following abutments are available:

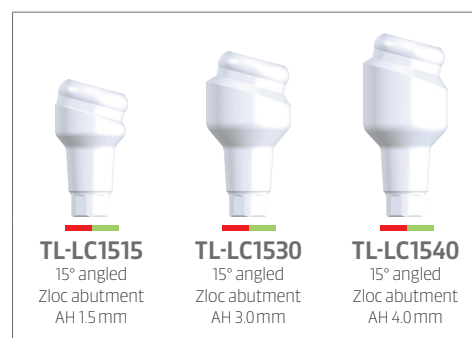
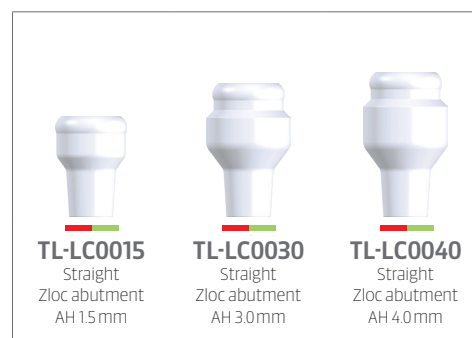
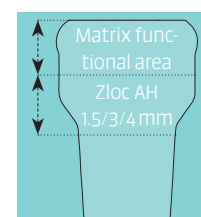
- Straight standard abutments in two different abutment heights for cementable single-tooth crown and bridge restorations.



- 15° angled abutments in two different abutment heights for cementable single-tooth crown and bridge restorations.

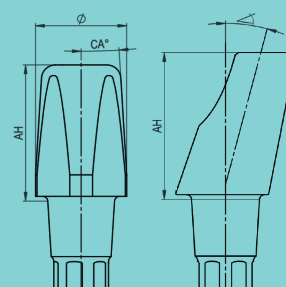


- Straight and angled Zloc abutments in three different abutment heights for removable anchoring of implant-supported full dentures in the edentulous jaw.



Explanation of abbreviations:

- ∠ Angle dimension
- ∅ Platform diameter
- GH Gingiva height
- AH Abutment height
- CA Cone angle



Meaning of the colours: red = Ø 4 mm, green = Ø 5 mm

3.2

Fixing the abutments

Firmly press the abutment into the implant body by hand. Make sure that the abutment engages in the hexagon.

The connection between abutment and implant is secured by screwing a basal screw into the internal thread of the implant body. A short as well as a long screwdriver are available for the basal screws (SD-BS-S and SD-BS-L). The maximum permissible tightening torque value is reached when the handle of the screwdriver is turned off.

The thread is reversible and can be loosened again. In addition, if necessary, the cone disconnect instrument (BL-CD) may also be used to remove the abutment from the implant.



To prevent accidental swallowing of the screwdriver pin or its handle, both parts should be secured with a dental floss loop.

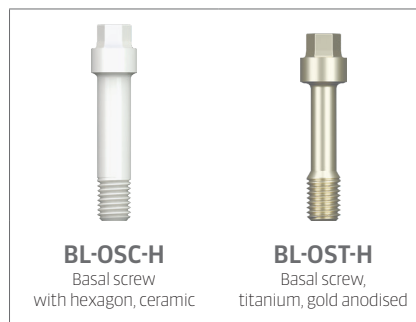
Loosening the abutment

Since the conical implant-abutment connection has a very high fitting accuracy, there is a positive fit between implant and abutment. To be able to loosen the abutment safely again, the removal instrument (BL-CD) must be used.



Basal screw

Two different types of screws are available. A ceramic basal screw (BL-OSC-H) or a gold anodized titanium basal screw (BL-OST) is available. In order to reach the correct torque value, both screw types, ceramic and titanium, must be tightened until the handle of the disposable screwdriver turns off.



The provisional abutment TL-TA0060 can be used until final restoration, by using the Basal screw BL-OST and the screwdriver BL-SD-ST or BL-SD-LT - with a maximum tightening torque of 10-15 Ncm.

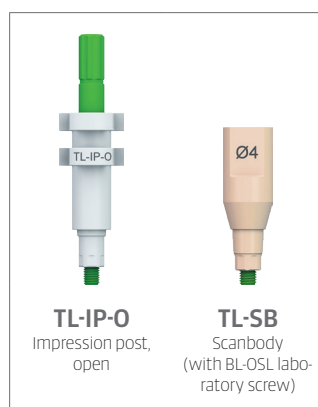


Impressions with the Z5-TL implant

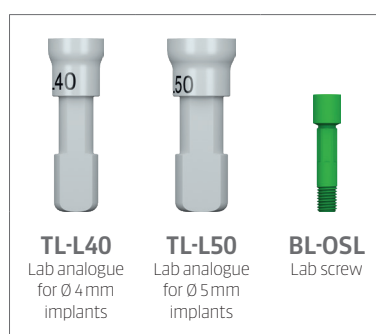
Precise and rotationally stable transfer parts are available for impression taking at implant level. An impression post for the open impression (TL-IP-O), and a scan body for the digital impression (TL-SB).

Note regarding TL-SB

Z-SYSTEMS cannot currently guarantee the provision of individual abutments. Z-SYSTEMS does not assume any guarantee for externally manufactured parts on original Z-SYSTEMS parts.



The laboratory analogues TL-L40/50 is available for a conventional reconstruction on the gypsum model.



3.4

Model fabrication

Fabrication of the master model

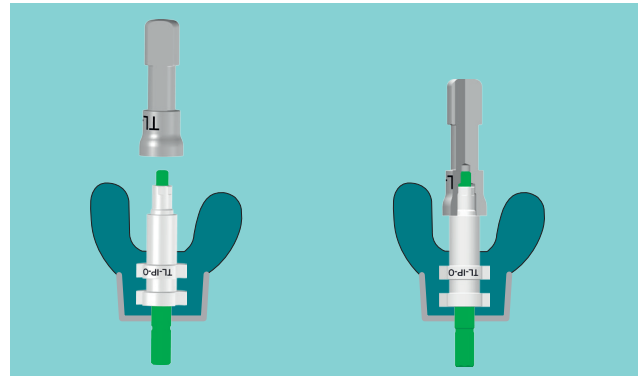
Position and fix the matching Lab Analog (TL-L40/TL-L50) to the impression using the guide screw. Hand-tighten the guide screw or by screwdriver (BL-SD-ST/LT).

A gingival mask should always be used to ensure that the emergence profile is optimally contoured. Fabricate the master cast.

Note:

- Open-tray impression procedure requires a custom-made tray with perforations.
- Impression posts and laboratory analogues are intended for single use to ensure optimal fit and precise impression taking for each patient.

CAVE: Prior to the fabrication of the master model it must be established which lab analogue is to be used – TL-L40 or TL-L50.



Temporary care of Z5-TL implants

General note

The general information on implant-supported restoration applies to the temporary restoration of Z5-TL implants after the healing phase.

Occlusion contacts must always be set so that a simple shim-stock foil can be pulled through interocclusally with slight resistance in the final bite position with maximum intercuspitation. Occlusion contacts should be point-shaped. Flat contacts must be avoided. A group function must be aimed for to relieve a single implant in the canine position.

If temporary restorations are to remain in place for a longer period of time, a close inspection of the firm hold and the static and dynamic occlusion and the periodontal conditions with any appropriate corrections and prophylactic sessions must be ensured. Temporary restorations on Z5-TL implants must have a passive fit.

Direct temporary restoration

Two different procedures are recommended for the fabrication of direct temporary restorations on Z5-TL implants in the mouth:

- Fabrication of a temporary restoration using an anatomic impression taken directly in the mouth
- Restoration with egg shell temporary

3.6

Restoration with a laboratory-fabricated long-term temporary restoration after osseointegration

If a temporary restoration on Z5-TL implants is intended to stay in place for a longer period (several months), it is recommended to use laboratory-fabricated, framework-reinforced, long-term temporary restorations for stability reasons. The laboratory requires precise impressions for their fabrication.

The long-term temporary restoration must be completely stress-free and must have sufficient space for the placement of cement. Occlusion and dynamic occlusion must be precisely adjusted.

Procedure

- Check the passive fit of the long-term temporary restoration
- Check the aesthetics, form, phonetics
- Check the occlusion and dynamic occlusion
- Cement

Final restorations on Z5-TL implants

General note

Z5-TL implants can be restored with all restorative materials used in modern dentistry.

In addition to all-ceramic restorations, composites, metal restorations and combinations (VMK) are also conceivable. All restoration types are permanently cemented in the conventional manner.

Adhesive extraoral cementation of the restoration to Z5-TL abutment/s is not allowed, to avoid inadequate friction fit connection between the abutment and implant. When restoring Z5-TL implants, the generally applicable guidelines for the planning and fabrication of implant-supported prosthetics must be observed. Particular care must be taken to ensure that the restoration is free of tension.

The static, occlusal contact of the restoration must be kept weak in relation to the contacts of permanent teeth. The movement of permanent teeth must be taken into account, particularly with single-tooth restorations. Dynamic occlusal contacts on the restoration must be avoided. A group function must be aimed for to relieve a single implant in the canine position. A sufficient number of the supporting abutments and a statically favourable distribution must be ensured, as well as good cleaning possibilities.

Indication for the final prosthetic restoration of Z5-TL implants

The following clinical or radiographic findings indicate that the final prosthetic restorations can be fitted:

- No peri-implantitis
- No clinically noticeable loosening of the implant
- No loosening when attempting to unscrew (max. 15 Ncm/ anaesthesia)
- No pain in the vicinity of the implant
- No radiographic visible peri-implant gap

3.8

Prosthetic restoration of Z5-TL implants

The valid general guidelines for the fabrication of fixed restorations on implants must be observed on Z5-TL implants. This applies in particular to the static and dynamic occlusion and the periodontium-prophylactic design of the restoration.

Indication of single-tooth restoration on Z5-TL implants

Z5-TL implants allow a restoration with fixed single-tooth crowns in the anterior and posterior regions.

The indication guidelines for implant selection must be observed. Furthermore, the instructions for restorations on Z5-TL implants with regard to static and dynamic occlusion, the periodontium-prophylactic design of the restoration, as well as the valid general guidelines for the fabrication of fixed restorations on implants must be observed.

Restoration of interdental gaps on Z5-TL implants

Fixed restorations can be placed on Z5-TL implants to close interdental gaps. Please note the preoperative selection of Z5-TL implants according to the Z-SYSTEMS indication guidelines and the sufficient number of abutments according to generally applicable prosthetic guidelines.

The mesial and / or distal extension of the restoration is not permitted under any circumstances. The integration of Z5-TL implants in composite bridges requires the exact observance of the corresponding recommendations of the implantological societies.



Single-tooth restoration of a front tooth with a Z5-TL implant

Prosthetic restoration of Z5-TL implants in the edentulous jaw

Restoration of Z5-TL implants with a bar construction

When planning a prosthetic restoration of Z5-TL implants using bar construction and removable prosthesis, the indication guidelines for implant selection must be observed. Number and location of implants (Z-SYSTEMS recommends 6 implants in the upper jaw, 4 implants in the lower jaw, min. 5 mm diameter) and the design of the prosthesis body and occlusion should depend on anatomical, functional and hygienic aspects.

The task of a bar restoration

- Stabilisation and primary blocking of the implants
- Securing the prosthesis against pulling and levering forces
- Thrust distribution
- Resilience compensation through degrees of freedom

The relining of an implant-supported bar prosthesis

Hybrid prostheses with resilient anchoring elements must be checked in a recall examination approximately every three months, to remedy any damaging movement of the prosthesis at an early stage using appropriate measures (such as relining).

Restoration of Z5-TL implants with a telescopic construction

In principle, the Z5-TL implants can be restored with telescopic constructions in combination with removable prostheses and bridges. However, there is an increased risk of forces not applied through the axis (especially high shear forces) acting on the implants. The abutments must be distributed so that at least one telescope is located at the distal end of the prosthesis (masticatory centre) so that no resiliencies act on the implants. A minimum implant diameter of 4 mm and a minimum number of 4 implants in the mandibular and 6 implants in the maxilla must be complied with. The integration of Z5-TL implants in telescopic construction requires the exact observance of the corresponding recommendations of the implantological societies.



Schematic diagram: No inclined arrangement of the bar link



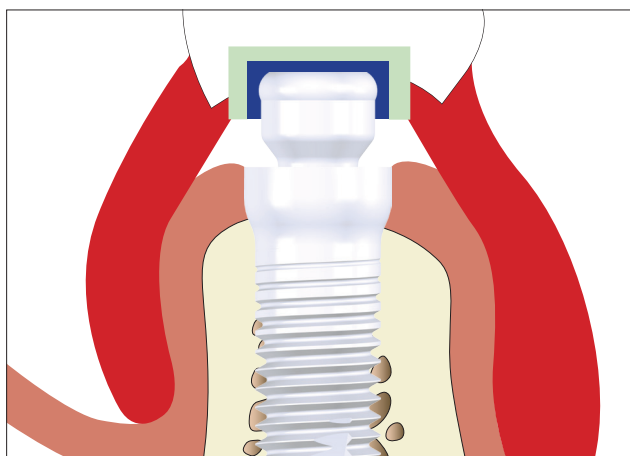
Schematic diagram

3.9

Prosthetic restoration of Z5-TL implants with Zloc abutments

The new fabrication of the prosthesis is always recommended as part of the overall planning or after implant restoration.

When fabricating the overdenture, please observe the detailed working instructions of the manufacturer Valoc (www.valoc.ch) for the assembly of Novaloc™ matrices.



Schematic diagram: Z5-TL implant, Zloc abutment TL-LC0015, Novaloc™ matrix and prosthesis cross-section.



Novaloc™ PEEK matrix, manufacturer: Valoc (www.valoc.ch)

Matrices

For prosthetic restoration of Z5-TL implants with locator-type abutments only original Novaloc™ matrices of the manufacturer Valoc (www.valoc.ch) are recommended.

Matrix housings are available from PEEK or titanium. Colour-coded retention inserts are available with different retention values (red extra light/white light/yellow medium/green strong/blue extra-strong). The retention value (pull-off strength) can be varied easily by simple exchange of the retention insert. Please follow Valoc's (www.valoc.ch) manufacturer's instructions.

When gluing the Novaloc™ matrix into the prosthesis chairside, under no circumstances may plastic flow between the matrix and the implant abutment. This can be ensured by placing a thin foil or a rubber dam between the abutment and the matrix. Sufficient space must be available for both the matrix and the plastic (preoperative prosthetic planning!).

Try-in of the overdenture

The try-in should first take place without the retention elements built into the Novaloc™ matrix. In the first step, check the fit of the prosthesis on the gingiva and the occlusion. In the second step, the prosthesis is tried on with built-in retention elements and the retentive force is adjusted.

Impression taking

The impression can be taken with the Z5-TL impression components or with the Novaloc™ impression cap. A Novaloc™ forming/fixing matrix (impression cap) is available for impression taking. Please follow the relevant instructions of the manufacturer Valoc (www.valoc.ch).

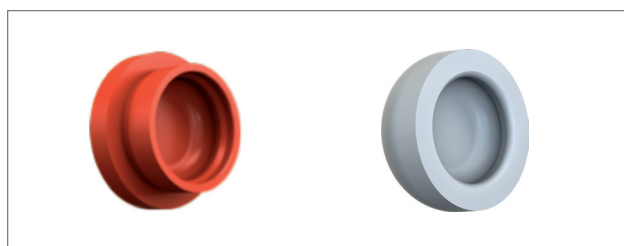
Impression taking by Z5-TL impression components

- Impression with tissue level impression components
- Master model production with the lab analog (TL-L40/TL-L50)
- Fix the locator-type abutment with the laboratory screw into the lab analog (TL-L40/TL-L50)
- place the Novaloc™ processing spacer* on the locator-type abutment
- fabrication of the prosthetic restoration

Impression taking by Novaloc™ forming/fixing matrix*

- Fix the locator-type abutment with occlusal screw in the implant
- Put on the Novaloc™ forming/fixing matrix*
- take impression
- Master model production with straight or angled Novaloc™ model analogue*
- place the Novaloc™ processing spacer* on the locator-type abutment
- fabrication of the prosthetic restoration

* Please follow the relevant instructions of the manufacturer Valoc (www.valoc.ch).



Left: Novaloc™ forming/fixing-matrix, right: Novaloc™ processing spacer
Manufacturer: Valoc ([wwwvaloc.ch](http://www.valoc.ch))



Left: Novaloc™ model analogue blue, right: Novaloc™ Model analogue angled 15°
Manufacturer: Valoc ([wwwvaloc.ch](http://www.valoc.ch))

3.10

Prosthetic aftercare of the Z5-TL implants

Regular prosthetic aftercare of Z5-TL implants is necessary as with all implant systems. As individual factors such as the patient's oral hygiene, cooperation, etc. play a major role in determining regular prosthetic aftercare, the interval proposed here can only be regarded as a guideline.

On the day of final placement of the restoration

- Repeat check for impression material residues
- Check the cement in the sulcus area
- Static and dynamic occlusion check
- Oral hygiene instruction
- X-ray examination

1 day after placement of the restoration

- Check the cement in the sulcus area
- Static and dynamic occlusion check
- Oral hygiene instruction

3 months after placement of the restoration

- Check for plaque
- Static and dynamic occlusion check
- Hygiene check; if necessary
reinstruction and motivation
- Performance of a prophylaxis
- For removable prosthetic restorations, check resilience and perform relining if necessary

6 months after placement of the restoration

- Check for plaque
- Static and dynamic occlusion check
- Hygiene check; if necessary
reinstruction and motivation
- X-ray examination
- Performance of a prophylaxis
- For removable prosthetic restorations, check resilience and perform relining if necessary

> Check-up every 6 months

> Regular prophylaxis

Cementing of restorations on Z5-TL implants

General note

The following points must be observed when fixing temporary or final restorations on Z5-TL implants:

- Relative drainage of the working area
- Completely remove blood and/or saliva
- Cement residues must be completely removed
- Clean the peri-implant sulcus completely of cement residues (probe, superfloss)
- Temporary cementation of final bridge constructions carries the risk of a one-sided loosening of a bridge anchor with an increased risk of a possible fracture of the bridge or abutment ceramic.

Final cementing on Z5-TL implants

Z-SYSTEMS recommends the use of cements for final cementation that are suitable for zirconium oxide cementation. Zirconium oxide cannot be roughened intraorally by known adhesive systems.

NOTE: The temporary cementing of final restorations is not recommended.

Z-SYSTEMS accepts no liability for incorrect use of fastening systems or damage to the prosthetic restoration and/or to the implant itself resulting therefrom.

3.12

Prophylaxis for Z5-TL implants

Zirconium oxide has a very low affinity for plaque. Therefore, compared to other materials used in dentistry, there is very little plaque on Z5-TL implants. Nevertheless, regular and adequate prophylaxis is also indispensable for Z5-TL implants.

Due to their special material and design, some points deviating from the usual prophylaxis guidelines for implants must be observed with Z5-TL implants.

CAVE: Use only Teflon-based hand scalers and curettes for cleaning Z5-TL implants.

Rinsing solutions based on chlorhexidine and/or alcohol can be used in the short-term without concern. These solutions are not recommended for long-term use due to possible discolouration of the tooth structure and cement gaps.

Do not use ultrasound-operated, metallic cleaning aids to clean Z5-TL implants. Always avoid the application of ultrasound to Z5-TL implants through metallic carriers. Improper use and application of ultrasound can cause lasting damage to the surface of the Z5-TL implant.

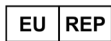
When working with metallic cleaning aids (ultrasound-operated scalers or hand-curettes or scalers) there is the possibility of metallic abrasion on the implant surface. This abrasion is difficult or impossible to remove.

Do not use abrasive prophylaxis pastes to clean Z5-TL implants. A powder/water jet cleaner (Air-Flow®) is not suitable for cleaning Z5-TL implants.

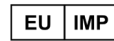




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