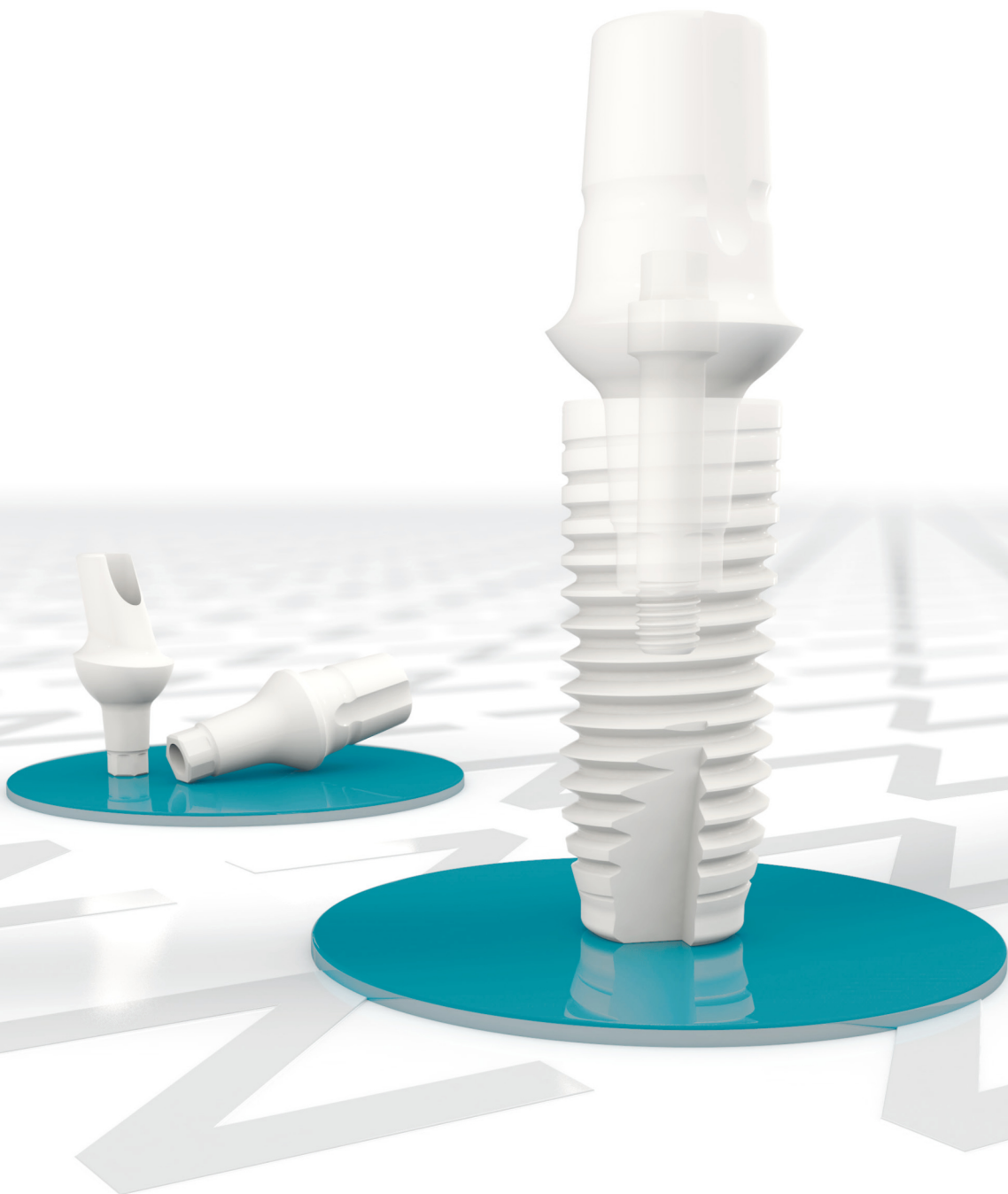


Surgical and Prosthetic Concept Bone Level Implant Z5-BL



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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General aspects and important information

General features

Z-SYSTEMS implants are unique in their combination of design and material. We expressly ask you to read this manual before starting 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 will 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-BL 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-BL implants reduces/avoids problems/errors during implantation and especially during prosthetic restoration.

We recommend the use of Z5-BL 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-BL 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-BL

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-BL 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-BL 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/CE/ISO13485/MDD93/42 EWG

Z-SYSTEMS have complied fully since 2004 with the current normative and legal requirements for medical products through European certification according to ISO 13485, as well as the guideline 93/42/EEC for medical devices. Z-SYSTEMS have been registered with the FDA (US Food and Drug Administration) since 2007.















Colour coding of the surgical and prosthetic products:

Yellow: 3.6mm diameter

Red: 4.0mm diameter

Green: 5.0mm diameter

Explanation of the symbols on labels and package inserts

	Medical Device
	Batch number
	Catalogue number
	Plasma sterilised
	Non-sterile
	Do not use if packaging is damaged
	Do not re-use, one time use
	Caution: Observe Warnings and precautions
	Consult the instructions for use
	Use before expiration date
	Date of manufacture
	Manufacturer
	CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC legislation. Where applicable: The identification number of the Notified Body shall follow this symbol.
	CAUTION! United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.

Do not expose the products to direct sunlight.

Material, biocompatibility and osseointegration

Material

All Z5-BL implants are manufactured according to the unique «Zirkolith®» process from zirconium oxide Y-TZP bioceramics in compliance with the ISO13356 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.

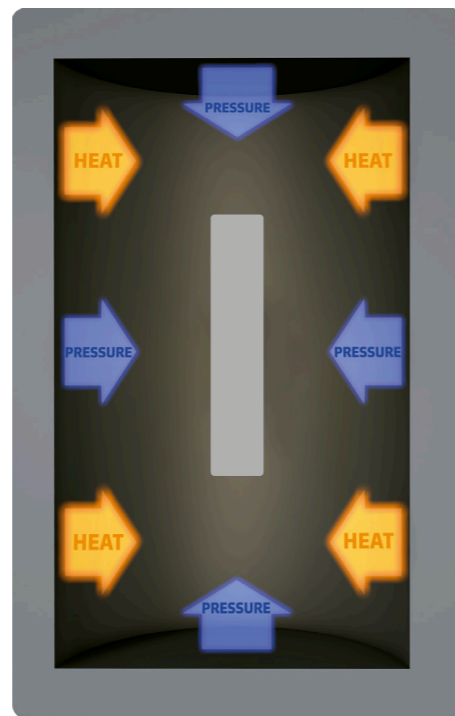
Not only the implants, but also the instruments that come into direct contact with the bony surgical area are made of zirconium oxide. The cutting instruments are made of high-strength ATZ high-performance ceramics (Alumina Toughened Zirconia).

Biocompatibility

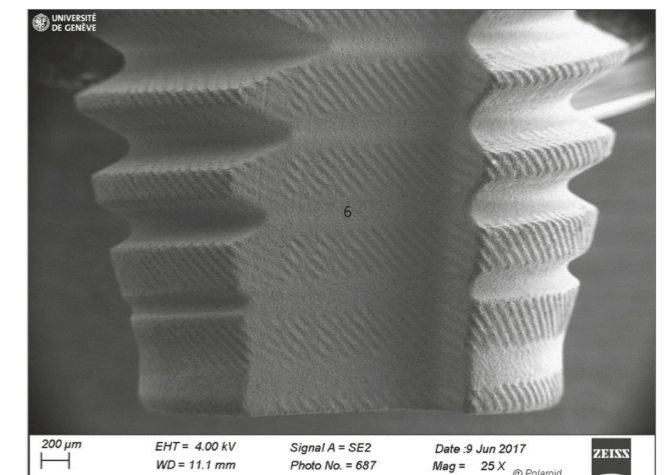
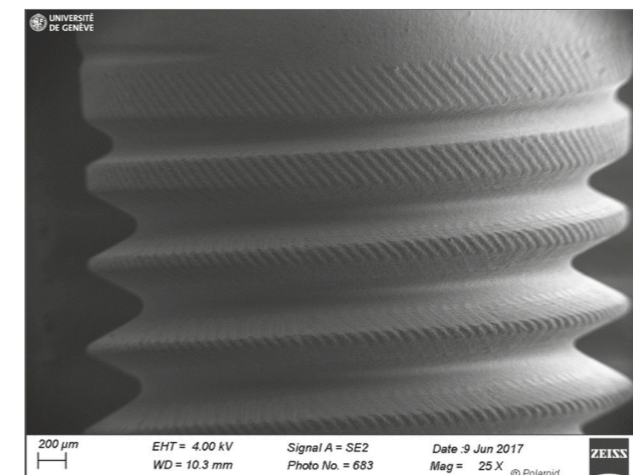
Numerous studies since the 1960s have confirmed the biocompatibility of zirconium oxide ceramics.

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 2.000 bar, temperatures up to 2.000°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.

Indications for Use

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

implants are suitable for patients with metal allergies and the chronic diseases resulting from them. Z5-BL 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.

Applications for 3.6mm

Ø3.6mm implants are only approved for use in the lateral incisor region (tooth 7/10) of the upper jaw and in the incisor region (tooth 23/24/25/26) of the lower jaw. Their inclusion in bridge constructions are only permitted if each tooth to be replaced is with an implant and is located in the regions mentioned above.

The inserts are not suitable for applications where there is a risk of excessive cantilever like movement (e.g., single-tooth replacement for 8/9, molars, premolars, extended crowns, extension bridges, bridges, bar work, telescopic work).

Applications for 4.0mm

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. Telescopic or Locator-type abutment restoration on at least 4 implants in the mandibular and 6 implants in the maxilla is recommended.

Applications for 5.0mm

Universal implant, suitable for most indications where there is insufficient 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 Ø5.0mm are recommended for the indication canines, central upper incisors and upper jaw/lower jaw molars. Limited suitability for telescopic restorations. 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 over 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		
3.6	3.6mm	3.6mm	5.6mm	5.6mm	UPPERRIGHT 1st Quadrant	+	+	-	-	-	-		
					USA							7	10
					FDI							12	22
					USA							42 41	31 32
USA	26 25	24 23											
4.0	4.0mm	4.0mm	6.0mm	7.0mm	UPPERRIGHT 1st 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
					USA							47 46 45 44 43	33 34 35 36 37
USA	31 30 29 28 27	22 21 20 19 18											
5.0	5.0mm	5.0mm	7.0mm	8.0mm	UPPERRIGHT 1st 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
					USA							47 46 45 44 43	33 34 35 36 37
USA	31 30 29 28 27	22 21 20 19 18											

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

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

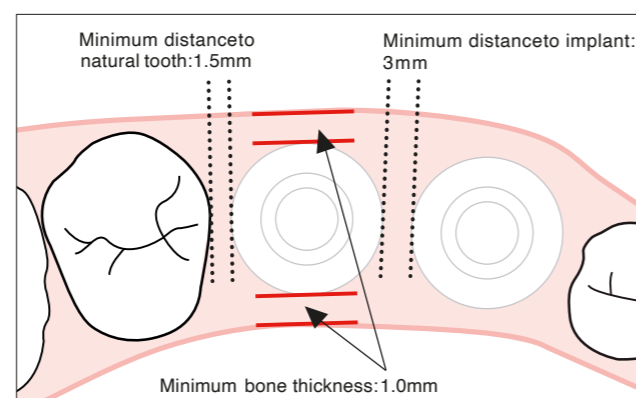
Many conditions are decisive for an aesthetically optimum result:

- the harmonious course (contour) 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

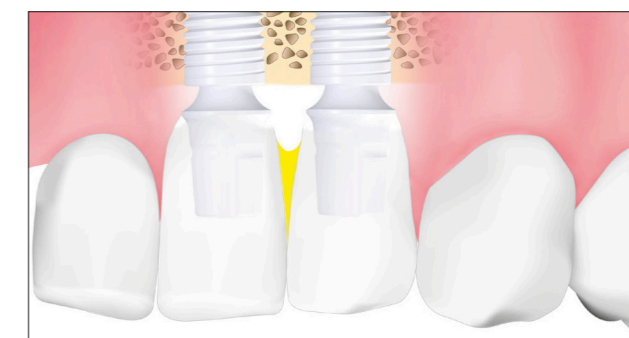
Restoration with single crowns is a possible restoration under the aspect of "restitutio ad integrum" ("restoration to original condition"). It includes all the advantages that are possible in periosteal rehabilitation.

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



Splinted crowns

Splinting of the crowns may be necessary for static reasons (such as unfavourable lever ratios). When selecting splinting, maintenance of good hygiene must be considered.



Implant-supported bridges

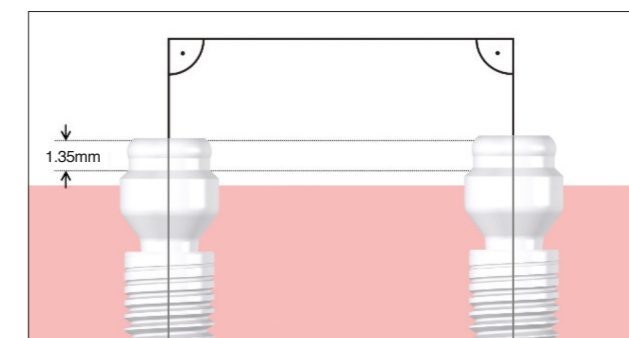
Implant-supported bridges can be inserted in positions that do not permit implant placement. The implant distribution must be selected so that small span segments are created.



Locator-type abutment restoration

Locator-type abutments are for attachment of overdenture prostheses into the edentulous upper and lower jaw.

- The principle of 4-point-support is recommended
- Avoidance of axis divergence



Planning and specific features of applications with locator-type abutments

This page must be followed for the treatment of patients with locator-type restorations.

NOTE: To ensure optimal performance of the retentions and avoid loading the implants beyond their stability, strive for an axial transfer of force to the implants. For this purpose, the implants should be positioned as parallel to each other and perpendicular to the occlusal plane as possible. If practical, the implants should be placed in the same horizontal plane to allow easy handling when removing or inserting the prosthesis.

Guided surgery

When case planning, Z-SYSTEMS recommends using 3-dimensional x-ray images (CBCT) and referencing the drill guide. Planning in this way will allow for a more axial alignment and assist with parallelism.

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 anesthesia).

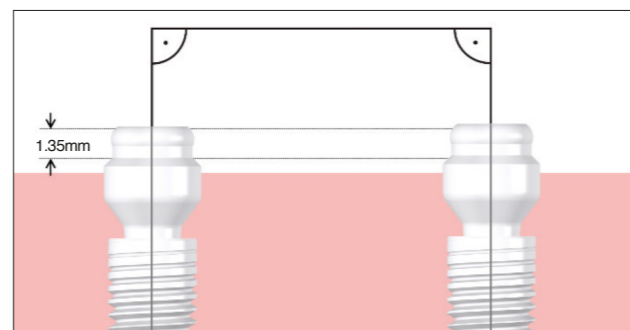
Implant divergence

After pilot drilling with the DP230 depth gauge, Z-SYSTEMS recommends a visual check of the axis alignment for parallelism.

The maximum divergence between multiple implants is 40° and the maximum angulation per implant body is 20° . For implants angulated or near the maximum recommended angulation, we recommend the use of the Angle LC abutments which have an angulation of 15° . If there is a divergence of more than 20° per implant to the occlusal plane,

or more than 40° between several implants, the axial alignment must be corrected.

To ensure optimal performance of the Novaloc®-matrix, the working area is 1.35mm above the surrounding gingiva (1.85mm if the overdenture is to be made with 0.5mm gingival clearance).



Avoidance of axis divergence

There are straight and angled locator-type abutments in two different gingival heights (GH).



Protective measures

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

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

2 Surgery

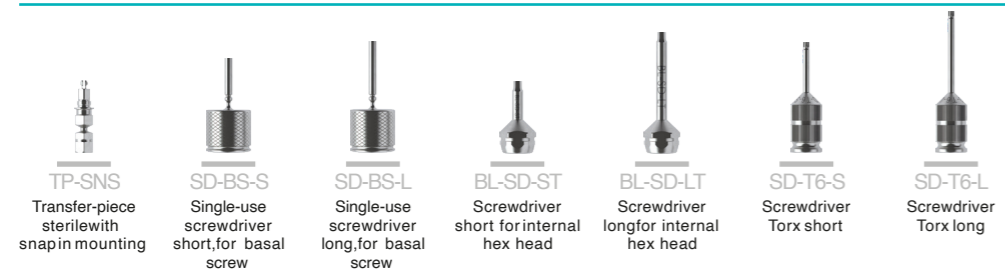
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Instruments

The Z5-BL surgical instruments from Z-SYSTEMS are to be used.

The instruments required for implantation and have been designed to be user-friendly. The rotating instruments are marked with a colour code. The instruments are labelled with the respective instrument designation to avoid any risk of confusion.

Driver



Gauge



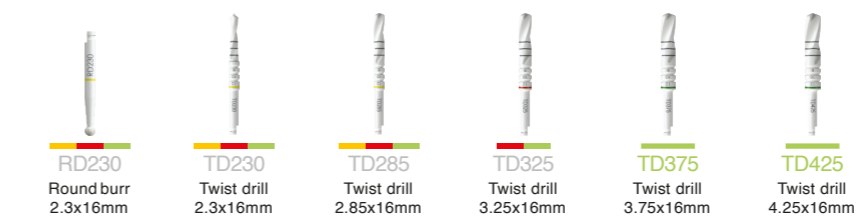
Meaning of the colours:
yellow = ø 3.6mm, red = ø 4mm, green = ø 5mm

Material properties

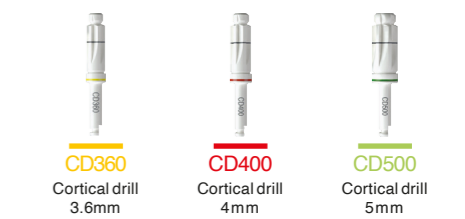
All instruments that come into direct contact with the surgical field are made of zirconium oxide. The cutting instruments are made of high-strength ATZ high-performance ceramic (Alumina Toughened Zirconia).

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



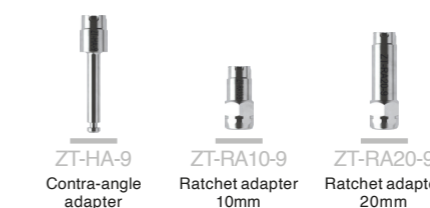
Cortical drill



Tap



Adapter for tap



Ratchet



Accessories



Preparation instructions for the surgical cassette

These descriptions contain detailed instructions for cleaning, disinfecting and sterilising the Z5-BL implant system instruments and surgical cassette.

Steriliser and disinfectant

Please note that as part of your responsibility for the sterility of the products during use,

- the steam steriliser used must comply with EN 13060/ EN285 or ANSI AAMI ST79,
- only specifically validated processes are used for the cleaning/disinfection and sterilisation of the devices and product,
- the equipment used is regularly serviced and checked and
- the validated parameters are maintained at each cycle.

The national legal regulations and the hygiene regulations of the dentist's or doctor's practice or hospital must be observed. This applies in particular to the requirements for effective prion inactivation.

Important notes

Unless otherwise specified in the instructions for use, reusable Z5-BL products may be prepared as often as the inspection stipulated in the instructions for use or preparation instructions is successfully passed. Removable instruments must be disassembled for effective cleaning. Z5-BL products intended for single use may not be reused, as safe preparation and/or functional safety cannot be guaranteed.

Instruments

The Z5-BL implant system instruments are not supplied sterile unless expressly marked as sterile. They must be cleaned, disinfected and sterilised before the first and every subsequent use on a patient. Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation. During use, care must be taken to ensure that contaminated instruments are collected separately and not returned to the surgical cassette to avoid contamination of the occupied instrument tray. After cleaning and disinfection, the instruments must be sorted and placed back in the surgical cassette. The fully loaded surgical cassette must then be sterilised.

General remark

Instruments made of zirconium oxide must always be prepared and stored separately from metal instruments, otherwise metallic abrasion could occur on the instrument surface.

Manual cleaning and disinfection

The following information refers to a manual preparation process with a combined cleaning and disinfecting agent. When selecting the combined cleaning and disinfecting agent, ensure that it:

- is suitable for cleaning and disinfection of dental instruments,
- is suitable for ultrasound cleaning (no foaming),
- has tested effectiveness in disinfection (VAH/DGHM or FDA approval or CE marking),
- is compatible with the materials of the products to be cleaned and disinfected and is aldehyde-free (otherwise there is a risk of the fusing of blood, secretions, tissue residues, etc.).

Disassembly

Completely disassemble all removable instruments (see instrument disassembly and assembly).

Initial disinfection

Immediately after use, place all instruments in a bath with combined cleaning and disinfectant agent (e.g. freshly prepared Comet DC1 (Brasseler GmbH & Co. KG, Lemgo, Germany), 2% solution at room temperature +15/+25°C, application time 5 minutes). This serves for your own safety and prevents contaminants from drying out. The concentration and application time of the combined cleaning and disinfectant specified by the manufacturer must be observed. This initial disinfection does not replace the later disinfection step after cleaning.

Preliminary cleaning

Coarse contamination on the instruments must be removed within a maximum of 2 hours after use. Use running water and a soft plastic brush (no metal bristles or steel wool) for this purpose. In areas difficult to access remove contaminants using suitable instruments and rinse at least three times with water using a cannula and a syringe (min. 10ml).

Combined cleaning and disinfection

The instruments must be placed completely covered in a combined cleaning and disinfectant bath freshly prepared for cleaning and disinfection within the prescribed exposure time.

The instruments must not touch each other. Exposure to a 10-minute ultrasonic bath is recommended before brushing. The instruments must be brushed off with a soft plastic brush to completely remove residues. Ratchet adapters and contra-angle adapters, contra-angle extensions, mandrels and parts of the torque ratchet have places that are difficult to access; remove residues in these difficult to access places with a soft plastic brush and rinse with at least 2x 25ml cleaning and disinfecting agent with the help of a syringe.

Rinsing and drying

Remove the instruments and rinse completely for at least one minute with deionised, low-germ (maximum 10 germ/ml) and low-endotoxin (maximum 0.25 endotoxin units/ml) water (e.g. Aqua purificata [valde]). Even areas that are difficult to access must be flushed at least five times with the aid of a cannula and a syringe (at least 10ml).

Use lint-free disposable cloths and oil-free, dry and low-germ compressed air. We also recommend the use of a sterile filter.

Inspection

Inspect the instruments for corrosion, surface damage, chipping and soiling. Damaged instruments must be sorted out. Instruments that remain soiled must be cleaned and disinfected again. The maximum permissible number of drilling applications - as specified in the instructions for use - must be observed.

Assembly

Reassemble all disassembled instruments (see disassembly and assembly instructions).

Packaging

Pack the instruments for sterilisation as soon as possible. We recommend that the instruments are sorted into the Z-SYSTEMS surgical cassette and the cassette packed in a disposable sterilisation package according to ISO 11607. The instruments can also be packed individually in disposable sterilisation packaging according to ISO 11607. It must be ensured that the packaging is suitable for steam sterilisation (temperature resistant up to at least 141°C/286°F with sufficient steam permeability) and that the products are adequately protected against mechanical damage.

Sterilisation in a steam steriliser/autoclave

Use steam sterilisation processes with a fractionated vacuum process (and sufficient product drying). Other sterilisation methods (including gravitational steam sterilisation) are not permitted. Pay attention that:

- the sterilisation temperature does not exceed 138°C/280°F (plus tolerance according to EN ISO 17665-1).
- EU: the sterilisation holding time (exposure time at sterilisation temperature) is at least 4 minutes at a minimum temperature of 134°C/273°F.
- USA: the sterilisation holding time (exposure time at sterilisation temperature) is at least 4 minutes at a minimum temperature of 132°C/270°F.

We recommend a drying time of at least 30 minutes for each of the cycles described above.

When using the surgical cassette, make sure that it does not touch the walls of the steam steriliser, as high local temperatures could deform the plastic.

ATTENTION: Z5-BL products that are not sterile packed must not be sterilised in their original Z5 packaging!

Instrument disassembly and assembly

The following instruments must be cleaned and disinfected when dismantled:

- Torque Wrench (TR70)
The disassembly, care and assembly of the torque ratchet is described in the torque ratchet instruction leaflet.

Surgical procedure/Drilling protocol

General drilling protocol

General note:

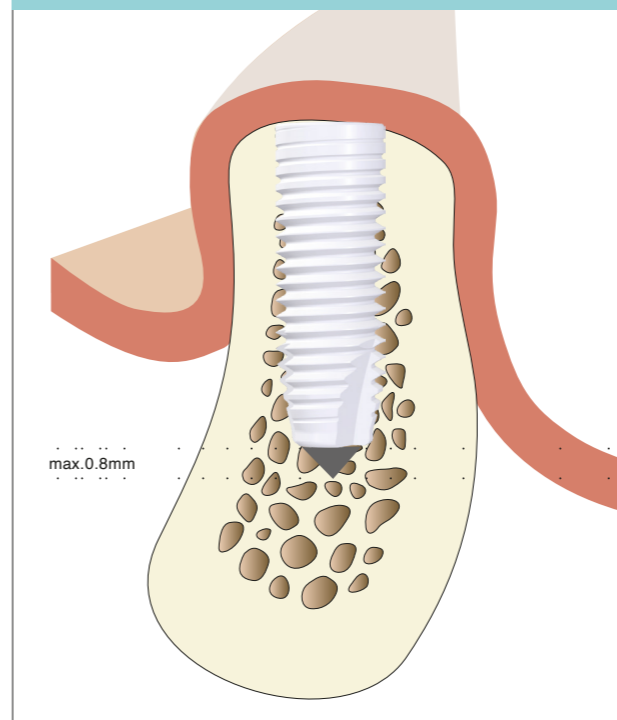
Round burr

To predrill the cortical bone and fix the implant position.

Twist drill

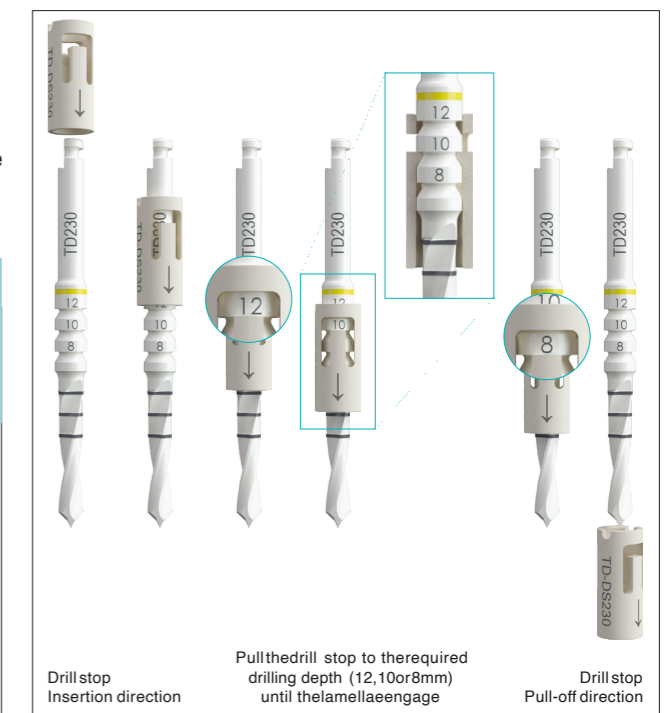
The implant bed is prepared with the twist drills in ascending order. The last drill used depends on the diameter of the implant to be inserted. Please follow the detailed instructions. The depth markings on the drill are easy to read. The first depth mark is 8mm.

CAVE: The apical excess length of the drill tip is maximum 0.8mm 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 recommended for cases with hard bone or hard cortical bone.

Tap

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

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

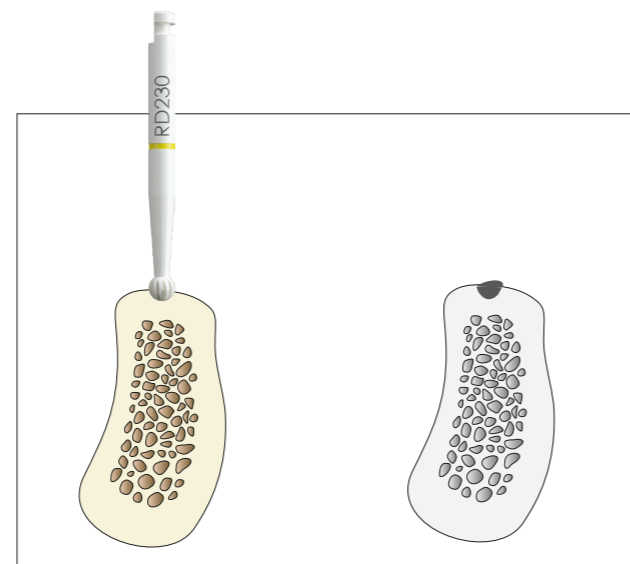
Exemplary procedure: Preparing the implant bed

The following shows how to prepare the implant bed using the example of a Z5-BL implant \varnothing 4.0mm/10mm 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 twist drill (TD230) and the further preparation of the implant bed using the twist 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.

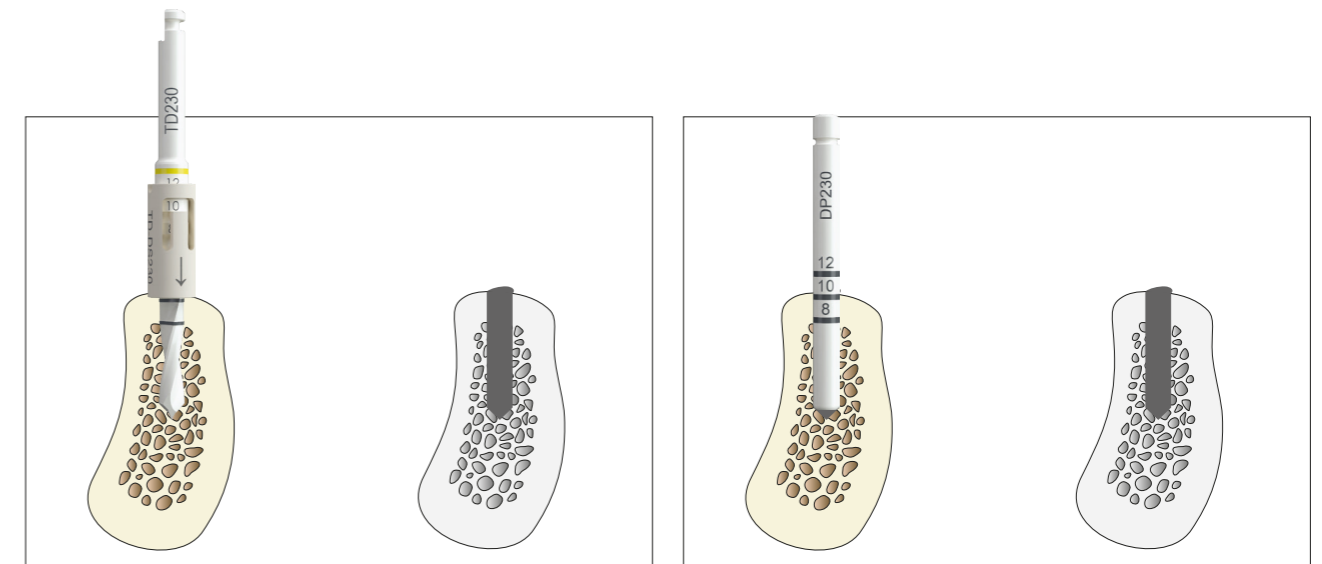
1. Preparation of the alveolar ridge and marking of the implantation site



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 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).

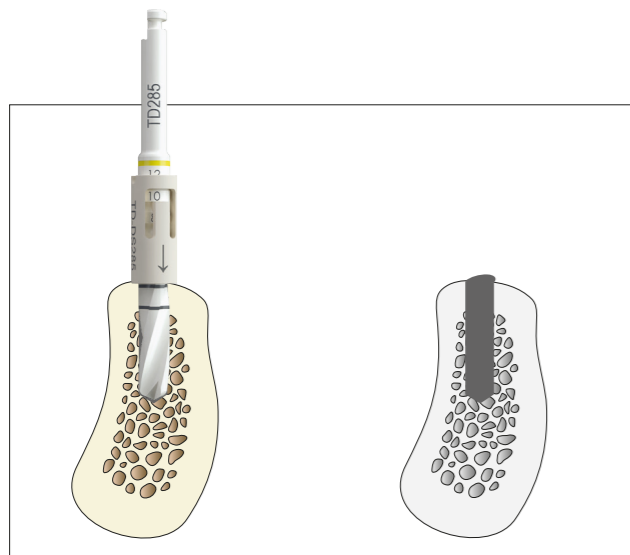
2. Implant axis and depth



Use the twist drill TD230 to mark the implant axis by drilling to a depth of about 5mm. 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.

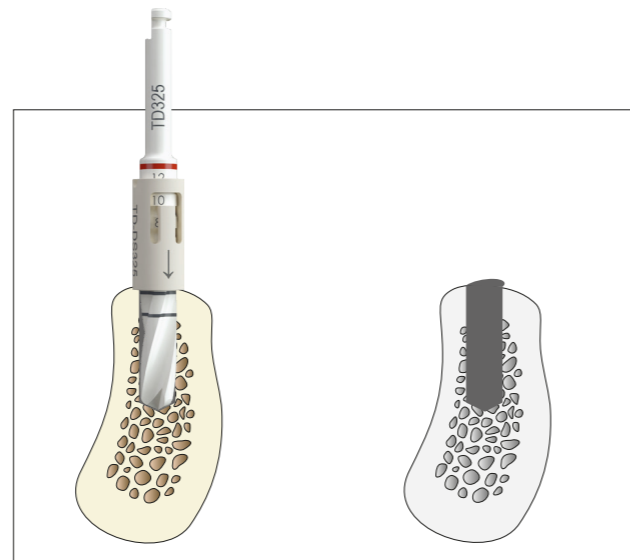
Use depth gauge DP230 to check the implant axis and preparation depth. Take an x-ray at this time, especially if the vertical bone volume is reduced. The depth gauge is inserted into the drilled hole and allows a visual assessment of the hole in relation to the anatomical structures.

3. Widening the implant bed to $\varnothing 2.85\text{mm}$



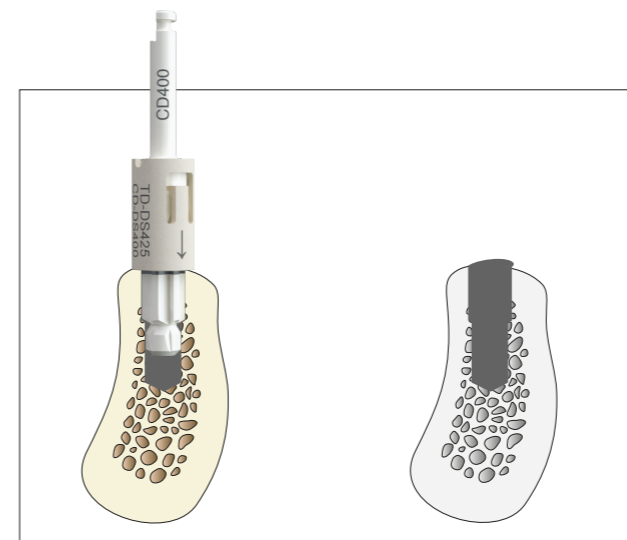
Widen the implant bed with twist drill TD285.

4. Widening the implant bed to $\varnothing 3.25\text{mm}$



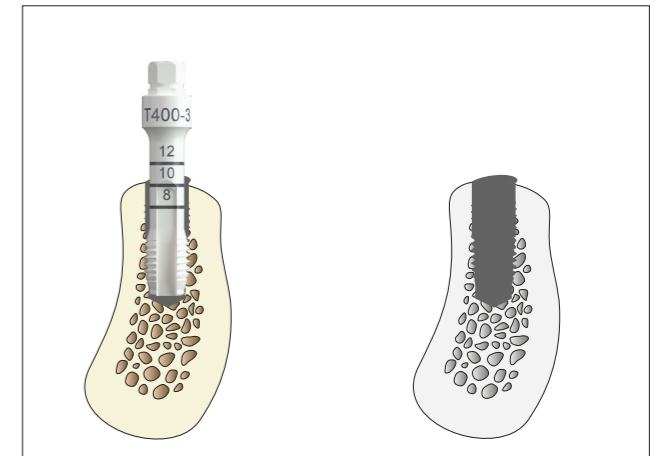
Widen the implant bed with twist drill TD325.

5. Profile drilling



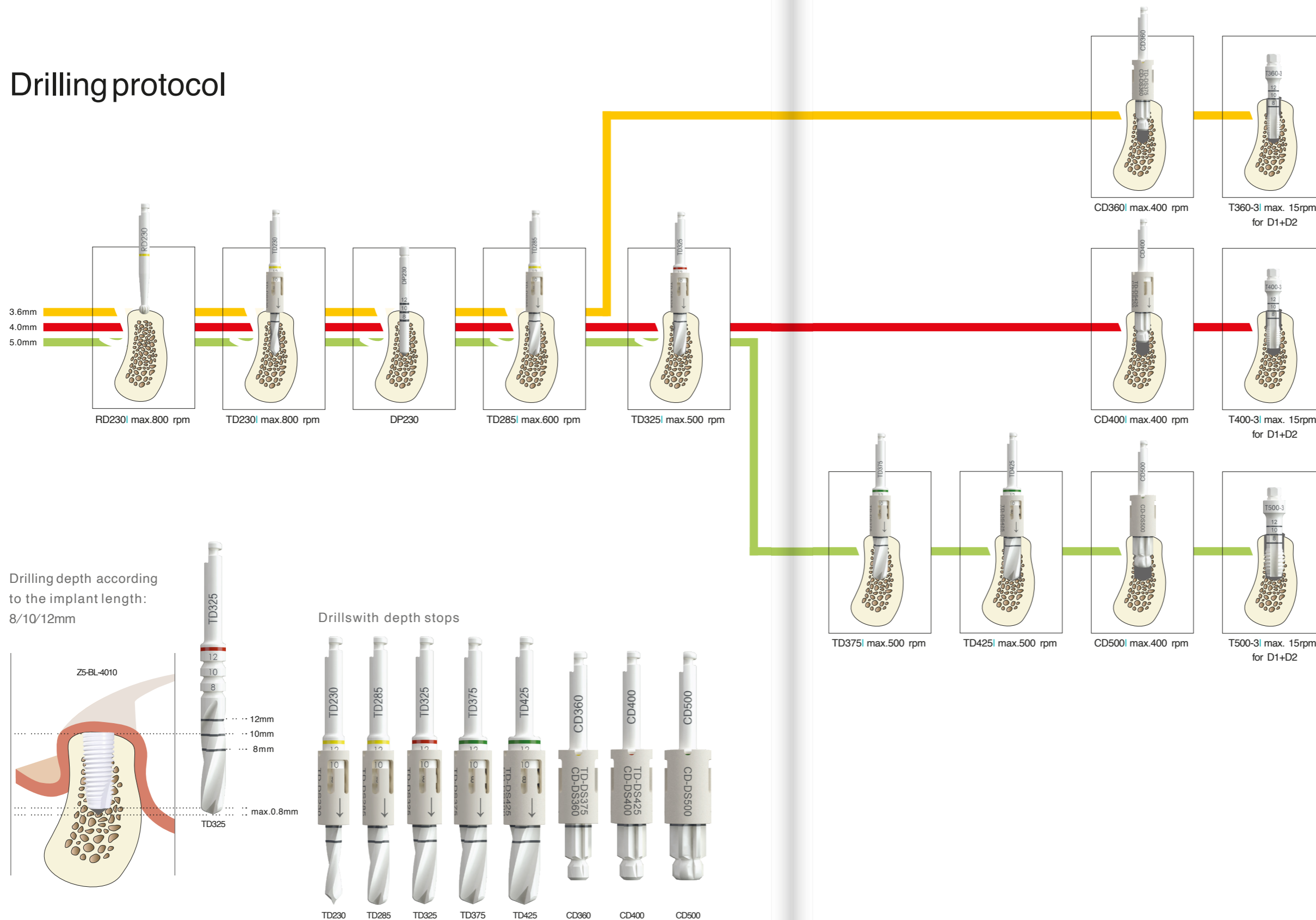
The cortex is widened to the diameter of the implant with the CD400cortical drill.

6. Tap



Pre-tap the thread with the T400-3tap over the entire length of the implant bed preparation for bone classD1+D2.

Drilling protocol



Specific features of Z5-BL

Concept

The threaded Z5-BL implant is a self-tapping bone level implant. The Z5-BL implant has no transgingival portion (shoulder) and is surgically placed at bone level. Inside the implant there is a thread in which components such as healing caps, healing abutments and abutments are fixed with the aid of a basal screw. After implantation, the inner lumen of the Z5-BL implant is closed with the supplied healing cap (BL-HC) made of radiopaque PEEK (polyether ether ketone) by simply screwing in the healing cap for submerged healing. A selection of standard healing abutments is available 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 and angled standard abutments, the Z-abutment, crown and bridge abutments as well as Locator-type abutments are available for the final prosthetic restoration.

During surgery the clinician decides the dimensions of the preparation, depending on the bone quality. The recommended drilling protocol must be observed.

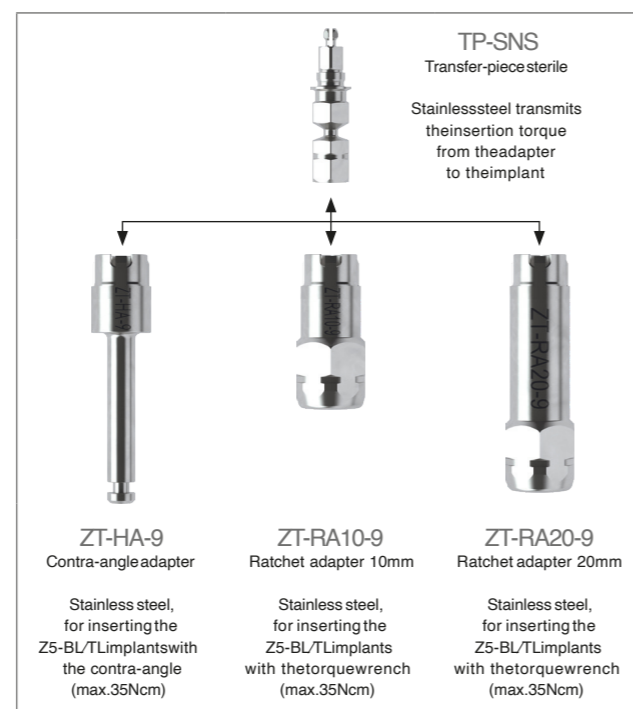
The optimum insertion torque is in the range of 25–35Ncm. For harder bone, a tap should be used to avoid torques of over 35Ncm when inserting. The twist drills have a depth stop to ensure safe and precise preparation of the implant osteotomy.

Implant removal from the sterile packaging

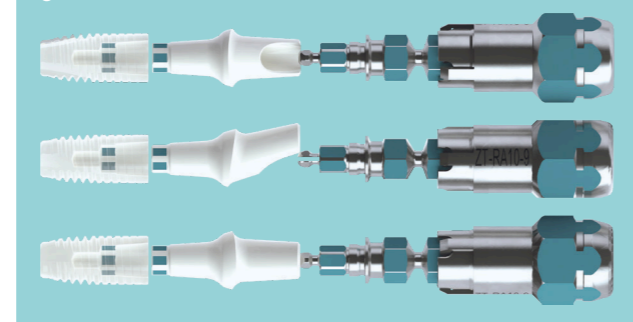
After opening the secondary packaging, removing the sterile inner blister and open the sealed lid. The white implant holder is rotated clockwise, and the implant is now easily accessible.

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.

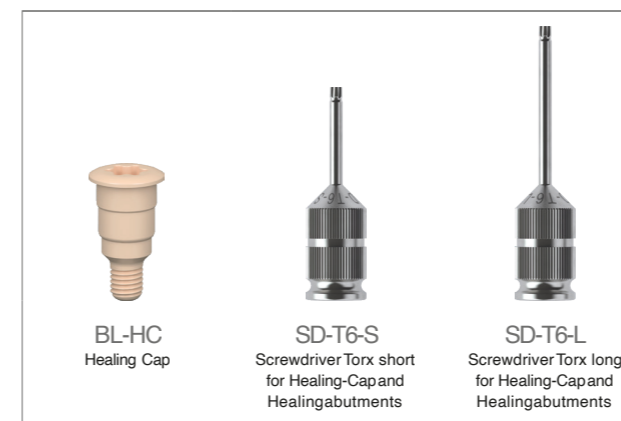


The alignment of the angled abutment can be defined with the transfer-piece. The hexagon on the ratchet adapter and transfer-piece correspond to the six sides of the internal geometry, as highlighted. The angled abutments overlap the hexagonal surface.

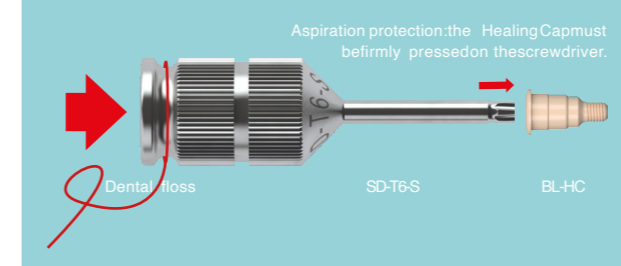


Healing phase

After implantation, the inner lumen of the Z5-BL implant is closed with the supplied healing cap (BL-HC) made of PEEK (polyether ether ketone) with a simple, hand-tight screw in using the screwdriver SD-T6-S or SD-T6-L. Whenever possible, a submerged healing is desired. A good wound closure with tightly fitting gingiva is important. No forces should be exerted on the Z5-BL implants during the submerged healing phase. No other special protective measures are necessary. After the healing phase, the implants are exposed and the healing cap removed.



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.



Implants

A total of nine different Z5-BL implants are available. Three diameters, 3.6, 4.0 and 5.0mm, each in lengths of 8, 10 and 12mm.



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 TP-SNS Adapter
ZT-HA-9 ZT-RA10-9 ZT-RA20-9

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

USERTIP:
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.

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 adapter 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.

Transfer-piece for Z5-BL/-TL Implants

Retentive notch
• to ensure secure retention to adapter i.e. handpiece or ratchet

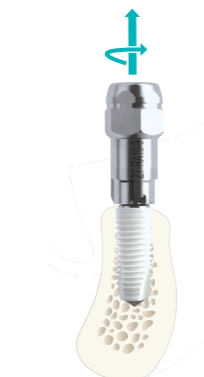
Predefined breaking point
• to ensure excess torque is not applied to the implant.

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



Post-operative Care

Postoperative care 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 return visit schedule 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, and at 3 months at the latest.

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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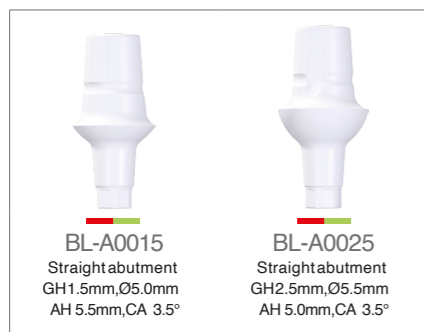
Fixing the abutment with Z5-BL implants

Abutments

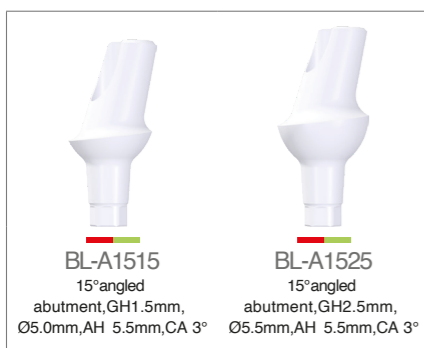
The abutments should be selected by the dentist, taking into account the previous prosthetic planning. The implant axis, the gingival height and the occlusion concept must be taken into account.

The following abutments are available:

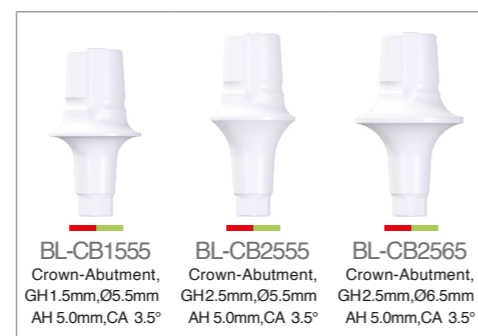
- Straight standard abutments in two different gingiva heights for cementable single-tooth crown and multiunit bridge restorations.



- 15° angled abutments in two different gingiva heights and an anatomically adapted shape for cementable single-tooth crown and multi-unit bridge restorations.



- Crown and Z abutments in three different widths and two different gingival heights for cementable single crown and bridge restorations. The scanbody (BL-SB-36) can be visually detected with suitable dental scanners and subsequently used in the modelling and fabrication of final prostheses (direct crowns) using CAD/CAM techniques.



Explanation of abbreviations:

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

Meaning of the colours:
 yellow = ∅ 3.6mm, red = ∅ 4mm, green = ∅ 5mm

- Bridge abutments in two different gingiva heights without indexing (anti-rotation) in the implant-abutment connection for cementing bridges.



- Straight and angled Locator-type abutments in two different gingiva heights for anchoring of removable implant-supported full dentures in the edentulous jaw.



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.



All zirconia abutments and basal (abutment) screws are supplied non-sterile and must be sterilised before use in the patient.

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



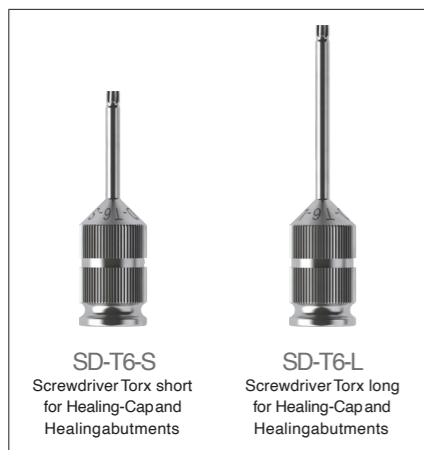
Indication restriction:
 The abutments BL-ZB1538 and BL-AN1515 are exclusively for the ∅ 3.6mm bone level implant.

Loosening the abutment

Since the conical implant-abutment connection has a very high accuracy of fit, 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.



The Healing Cap and Healing abutments are monolithic and can only be tightened by hand with the screwdrivers SD-T6-S or SD-T6-L.



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-H) 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 BL-TA0030 or the diameter reduced BL-TA1538 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.

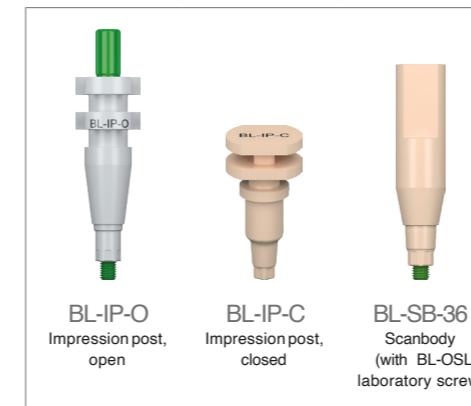
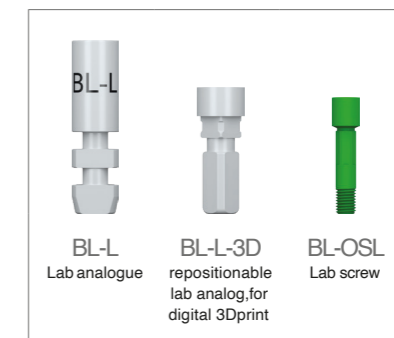


Impression with the Z5-BL implant

Precise and rotationally stable transfer parts are available for impression taking at implant level. An impression post for the closed impression (BL-IP-C), one for the open impression (BL-IP-O), and a scan body for the digital impression (BL-SB-36).

Note BL-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.

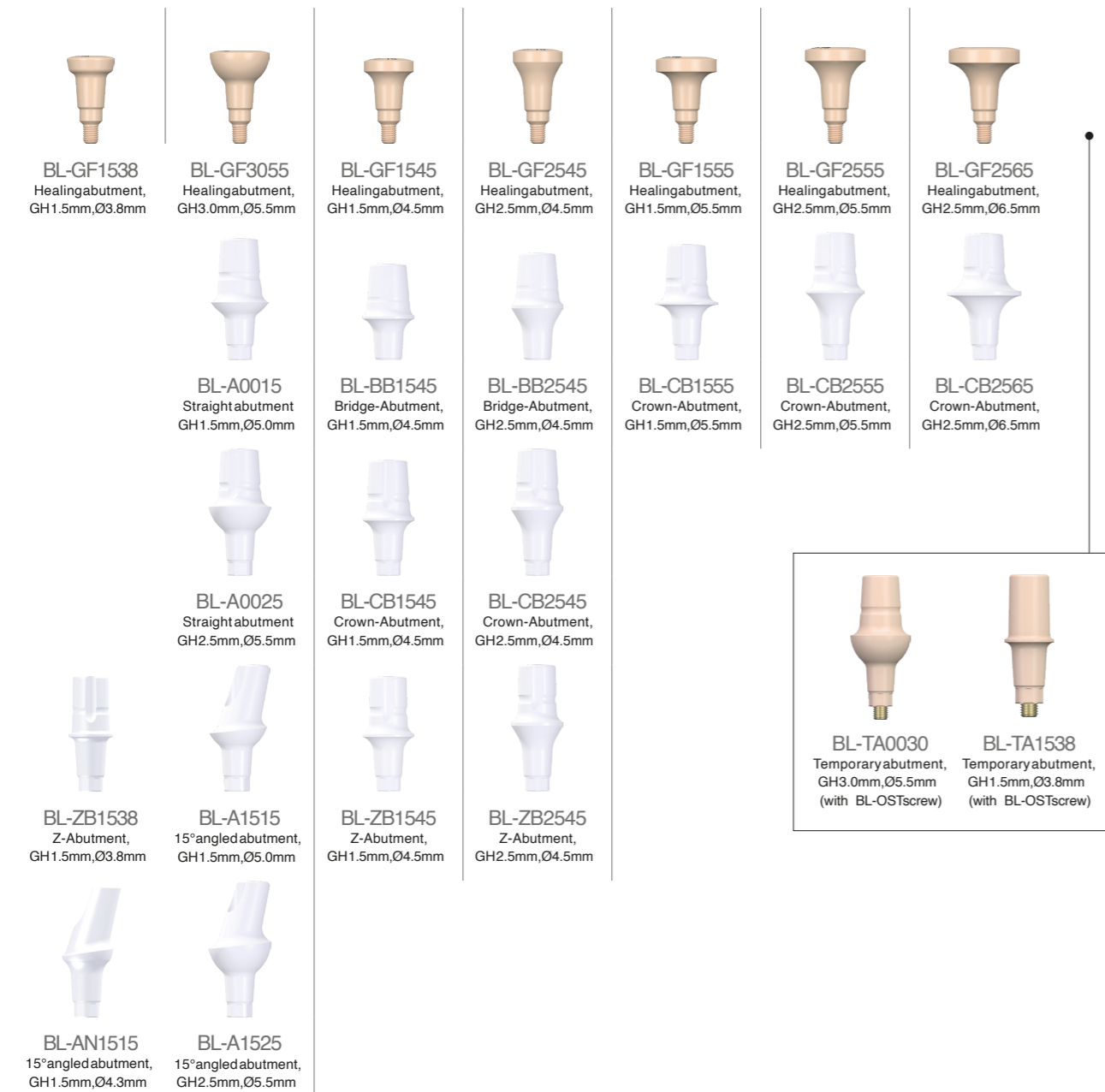
The laboratory analogue BL-L is available for a conventional reconstruction on the stone model and a repositionable analog BL-L-3D for the digital work flow and 3D print.



Healingabutments

A selection of healing abutments with different gingiva heights and widths is available for shaping the soft tissue before prosthetic restoration. These are screwed into the implant hand-tight using a screwdriver. An individual design of the emergence profile can be achieved with the help of the temporary abutment and a temporary single-tooth restoration. All healing abutments are supplied non-sterile and must be sterilised before use in the patient.

Healingabutment-assortment

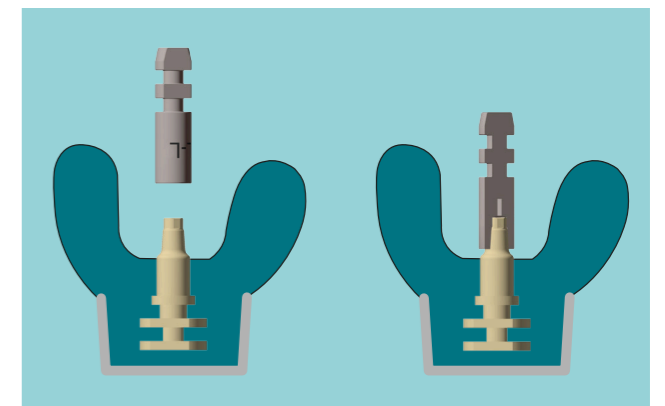


Model fabrication

Fabrication of the master model

Closed Impression:

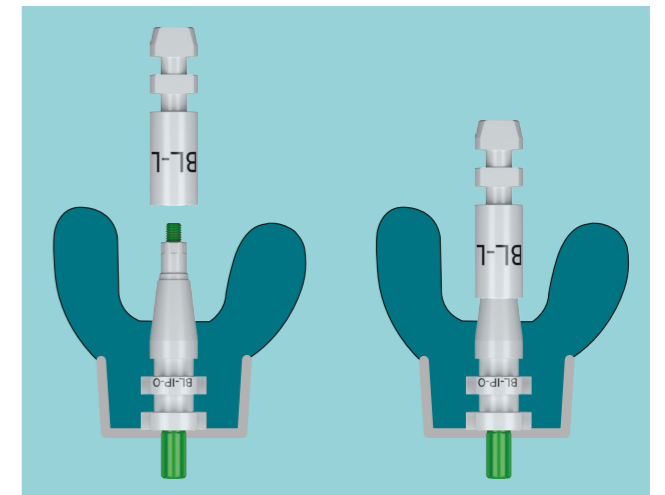
The matching laboratory analogue is inserted into the impression cap so that the lab analogue clicks into the impression cap with a perceptible click. This is the only way to ensure that the situation in the mouth is correctly represented in the master model.



Inserting the laboratory analogue into the impression before casting with plaster.

Open Impression:

Assemble the corresponding laboratory analog in the impression. Fix the laboratory analog in the impression using the guide screw. Hand-tighten the guide screw or by screwdriver (BL-SD-ST/LT).



Open Impression: Inserting the laboratory analogue into the impression before casting with plaster.

A gingival mask should always be used to ensure that the emergence profile of the crown is optimally contoured. Then the master cast using standard methods and type-4 dental stone can be produced.

Note:

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

Temporary care of Z5-BL implants

General note

The general information on implant-supported restoration applies to the temporary restoration of Z5-BL implants.

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-BL implants must have a passive fit.

Direct temporary restoration

Two different procedures are recommended for the fabrication of direct temporaries on Z5-BL implants in the mouth:

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

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

If a temporary restoration on Z5-BL implants is intended to stay in place for a longer period (several months), it is recommended to use laboratory-fabricated, framework-reinforced long-term temporaries 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-BL implants

General note

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

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

Adhesive cementation of restorations to Z5-BL abutments are only possible for single-tooth reconstructions. In general, intraoral cementing of the reconstructions is recommended and must be strictly observed for bridges such as splited crowns, to avoid inadequate friction fit connection between the abutment and implant. When restoring Z5-BL implants, the generally applicable guidelines for the planning and fabrication of implant-supported prosthetics must be observed.

The static, occlusal contact of the restoration must be considered 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-BL 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

Prosthetic restoration of Z5-BL implants

The valid general guidelines for the fabrication of fixed restorations on implants must be observed on Z5-BL 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-BL implants

Z5-BL 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-BL 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-BL implants

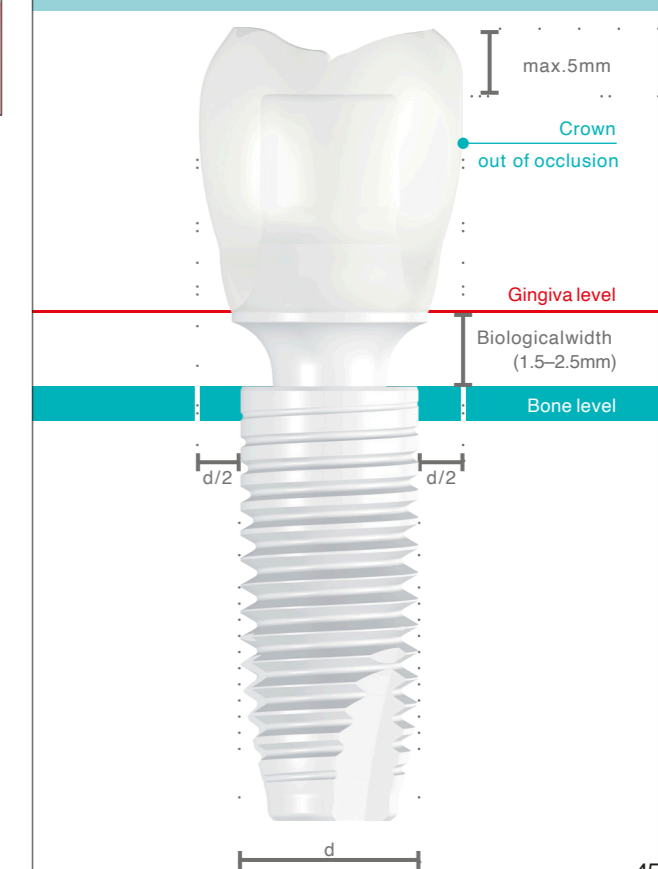
Fixed restorations can be placed on Z5-BL implants to close interdental gaps. Please note the preoperative selection of Z5-BL implants according to the Z-SYSTEMS indication guidelines and the sufficient number of abutments according to generally applicable prosthetic guidelines.

The mesial and/or distal extension of the restoration is not permitted under any circumstances. The integration of Z5-BL implants in composite bridges requires the exact observance of current dental implant clinical practice recommendations.



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

NOTE: To prevent excessive bending moments, the crown should be max. 5mm longer than the abutment occlusal or incisal. Recommendation: The horizontal crown width should overlap the implant diameter d by a maximum of $d/2$.



Prosthetic restoration of Z5-BLimplants in the edentulous jaw

Restoration of Z5-BLimplants with a bar construction

When planning a prosthetic restoration of Z5-BLimplants 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. 5mm 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
- Forced 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-BLimplants with a telescopic construction

In principle, the Z5-BLimplants 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-BLimplants in telescopic construction requires the exact observance of the corresponding recommendations of the implantological societies.



Schematic diagram: No inclined arrangement of the bar link

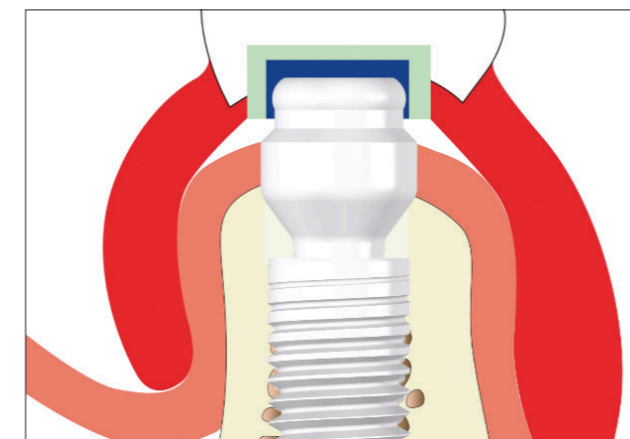


Schematic diagram

Prosthetic restoration of Z5-BLimplants with locator-type abutments

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

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



Schematic diagram: Z5-BLimplant with BL-LC0030 abutment, Novaloc™ Section through matrix and prosthesis

For chair-side matrix fixation into the denture, prevent any resin from entering in between the matrix and the implant abutment. This can be accomplished by placing thin foil or a rubber dam between abutment and matrix. Make sure to provide sufficient space for the matrix and the resin in the overdenture.

Try-in of the overdenture

The try-in should take place at first without the retention inserts installed in the Novaloc™ matrices. In the first step you should check the fit of the overdenture on the gingiva and in occlusion. In the second step the denture is tried in with built-in retention inserts and the retention force is adjusted.

Matrix

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



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

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.

Impression taking

The impression can be taken with the Z5-BL 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).

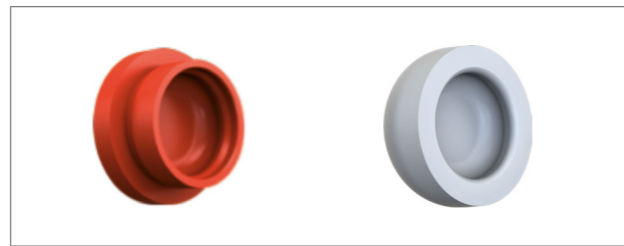
Impression taking by Z5-BL impression components

- Impression with bone level impression components
- Master model production with the lab analog (BL-L)
- Fix the locator-type abutment with the laboratory screw into the lab analog (BL-L)
- 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(www.valoc.ch)



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

Prosthetic aftercare of the Z5-BL implants

Regular prosthetic aftercare of Z5-BL 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

3.11

Cementing of restorations on Z5-BLimplants

Generalnote

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

- 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-BLimplants

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-BLimplants

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

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

NOTE: Use only Teflon-based hand scalers and curettes for cleaning Z5-BLimplants.

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 discoloration of the tooth structure and cement gaps.

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

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-BL implants. A powder/water jet cleaner (Air-Flow®) is not suitable for cleaning Z5-BLimplants.



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