

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.

Contents

1	General information	
1.1 1.2 1.2 1.4 1.5	General aspects and important information Material, biocompatibility and osseointegration Indications Fundamentals of treatment planning Protective measures	1 1 1
2	Surgery	
2.1	Instruments	1
2.2	Surgical procedure/Drilling protocol	2
2.3	Specific features of Z5-BL	3
2.4 2.5	Implant removal Post-operative Care	3
2.3	rost-operative care	ر
3	Prosthetic concept	
3.1	Fixing the abutment with Z5-BL implants	3
3.2	Impression with Z5-BL implants	3
3.3	Healing abutments	4
3.4	Model fabrication	4
3.5 3.6	Temporary care of Z5-BL implants Restoration with a laboratory-fabricated long-term temporary restoration after osseointegration	4
3.7	Final restorations on Z5-BL implants	4
3.8	Prosthetic restoration of Z5-BL implants	4
3.9	Prosthetic restoration of Z5-BL implants in the edentulous jaw	4
3.10	Prosthetic aftercare of the Z5-BL implants	4
3.11	Cementing of restorations on Z5-BL implants	5
3.12	Prophylaxis for Z5-BL implants	5

General aspects and important information

General features

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...

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 Availability: Not all of the products described in this 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 corresponding original components and instruments or customer service department in our headquarters. and according to the Z-SYSTEMS instructions and recomthrough practical training, in accordance with the state are trained to use the system. of the art at the time of product launch. The user of Z5-BL

products must decide whether or not a product is suitable **Z-SYSTEMS** implants are unique in their combination of 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 Observing these specific instructions and following the 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.

> 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 concept and may only be used in conjunction with the implant system are available from your account manager

mendations. Instructions regarding the application of our **Qualified users:** Z-SYSTEMS implants should only be used products are given verbally, in writing, electronically or by dentists, doctors, surgeons and dental technicians that

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: 3.6 mm diameterr **Red:** 4.0 mm diameter **Green:** 5.0 mm diameter

Explanation of the symbols on labels and package inserts

[NAD]			
MD	Medical Device		
LOT	Batch number		
REF	Catalogue number		
STERILE PLASMA	Plasma sterilised		
NON	Non-sterile		
	Do not use if packaging is damaged		
	Do not re-use, onetime use		
\triangle	Caution: Observe Warnings and precautions		
[]i	Consult the instructions for use		
	Use before expiration date		
M	Date of manufacture		
	Manufacturer		
C€xxxx	CE marking is the manufacturer 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.		
Rx only	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.

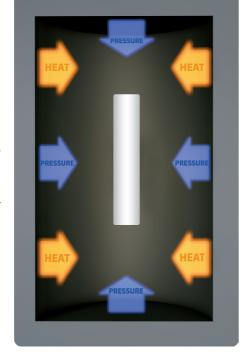
Material, biocompatibility and osseointegration

Material

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



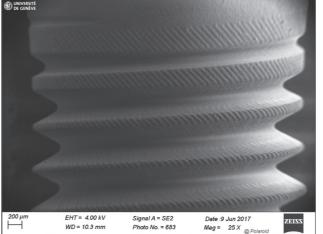
Hot Isostatic Pressing in a tunnel kiln: Pressure up to 2.000 bar, temperatures up to 2.000°C

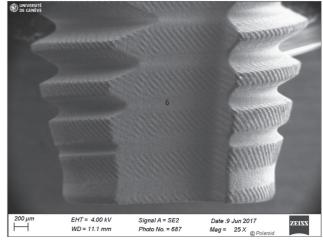
Biocompatibility

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.





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 with good bone density and sufficient bone quality. 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

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-J, Zarb G.A., Albrektsson T. (eds): Tissue-Integrated Prostheses: Osseointegration in Clinical Dentistry. Chicago IL, Quintessence, 1985, PP 199-209.

Indications for Use

into the upper and lower jaw for the attachment of the chronic diseases resulting from them. Z5-BL implants prosthodontic appliances to replace missing teeth. Z5-BL are intended for delayed loading.

Z5-BL implants are designed for surgical implantation implants are suitable for patients with metal allergies and

General areas of application

diameter should always be used, because the mechanical ameter of the implant.

Applications for 3.6 mm

incisor region (tooth 7/10) of the upper jaw and in the incisor region (tooth 23/24/25/26) of the lower jaw. Their in- Applications for 5.0 mm clusion in bridge constructions are only permitted if each regions mentioned above.

work).

Applications for 4.0 mm

As a rule of thumb, the implant with the largest possible Universal implant that is suitable for most indications. Not suitable for applications where there is a risk of excesstrength increases disproportionately with increasing discretized increases disproportionately disproportionately with increasing discretized increases disproportionately disproportion bridges, bridges with more than one pontic). Limited suitability for telescopic restorations. Telescopic or Locatortype abutment restoration on at least 4 implants in the Ø 3.6 mm implants are only approved for use in the lateral mandibular and 6 implants in the maxilla is recommended.

Universal implant, suitable for most indications where there tooth to be replaced is with an implant and is located in the 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). Im-The inserts are not suitable for applications where there plants with Ø 5.0 mm are recommended for the indication is a risk of excessive cantilever like movement (e.g., single-canines, central upper incisors and upper jaw/lower jaw tooth replacement for 8/9, molars, premolars, extended molars. Limited suitability for telescopic restorations. Telecrowns, extension bridges, bridges, bar work, telescopic scopic 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 orovestibular (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	3.6 mm	3.6 mm	5.6 mm	5.6 mm	UPPER RIGHT 1st Quadrant USA 7 10 FDI 12 22 FDI 42 41 31 32 USA LOWER RIGHT 4th Quadrant LOWER LEFT 3rd Quadrant LOWER LEFT 3rd Quadrant LOWER LEFT 3rd Quadrant	+	+	-	_	-	-
4.0	4.0 mm	4.0 mm	6.0 mm	7.0 mm	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	+	+	+	_	+	(+)
5.0	5.0 mm	5.0 mm	7.0 mm	8.0 mm	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

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 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

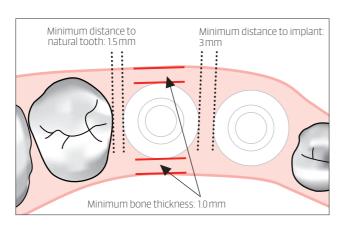
Many conditions are decisive for an aesthetically optimum

- 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 conhigh degree of clinical experience and detailed knowledge figurations 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 1.5 mm 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 Splinting of the crowns may be necessary for static under the aspect of "restitutio ad integrum" ("restoration" reasons (such as unfavourable lever ratios). When selecting to original condition"). It includes all the advantages that splinting, maintainence of good hygiene must be considered are possible in periprosthetic rehabilitation.

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



Implant-supported bridges

Implant-supported bridges can be inserted in positions Locator-type abutments are for attachment of overdenture that do not permit implant placement. The implant distribution must be selected so that small span segments are

The principle of 4-point-support is recommended created.



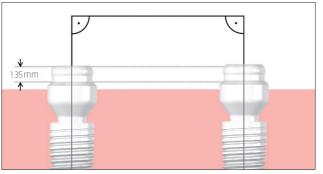
Splinted crowns



Locator-type abutment restoration

prostheses into the edentulous upper and lower jaw.

- Avoidance of axis divergence



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, zontal plane to allow easy handling when removing

Guided surgery

When case planning, Z-SYSTEMS recommends using 3-dimensional x-ray images (CB/CT) 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).

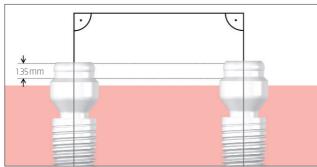
Implant divergence

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,

Planning and specific features of applications with 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 1.35 mm above the surrounding gingiva (1.85 mm if the overdenture is to be made with 0.5 mm 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, periotest 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.

Contents

17

2 Surgery

2.1	Instruments	18
2.2	Surgical procedure/Drilling protocol	21
2.3	Specific features of Z5-BL	30
2.4	Implant removal	32
2.5	Post-operative Care	34

Instruments

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

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

Driver



Gauge



Meaning of the colours:

Material properties

All instruments that come into direct contact with the surgical field are made of zirconium oxide. The cutting instrumanufacture of drills and taps. The ATZ drills cut excellently ments are made of high-strength ATZ high-performance with very little wear. Note: The drills must be examined ceramic (Alumina Toughened Zirconia).

after every use for blunt cutting edges or damage and if necessary, exchanged.





Accessories



Preparation instructions for the surgical cassette

system instruments and surgical cassette.

Steriliser and disinfector

rility of the products during use,

- the steam sterilisers 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 surface. observed. This applies in particular to the requirements for effective prion inactivation.

Important notes

reusable Z5-BL products may be prepared as often as the inspection stipulated in the instructions for use or prep- is suitable for cleaning and disinfection of aration instructions is successfully passed. Removable instruments must be disassembled for effective cleaning. • is suitable for ultrasound cleaning (no foaming), Z5-BL products intended for single use may not be reused. • has tested effectiveness in disinfection (VAH/DGHM as safe preparation and/or functional safety cannot be guaranteed.

Instruments

These descriptions contain detailed instructions for The Z5-BL implant system instruments are not supplied cleaning, disinfecting and sterilising the Z5-BL implant 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 Please note that as part of your responsibility for the ste-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

Manual cleaning and disinfection

The following information refers to a manual preparation process with a combined cleaning and disinfecting agent. Unless otherwise specified in the instructions for use, When selecting the combined cleaning and disinfecting agent, ensure that it:

- dental instruments,
- 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, with at least 2 x 25 ml cleaning and disinfecting agent with application time 5 minutes). This serves for your own the help of a syringe. 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 the aid of a cannula and a syringe (at least 10 ml). removed within a maximum of 2 hours after use. Use running water and a soft plastic brush (no metal bristles Use lint-free disposable cloths and oil-free, dry and lowor 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. 10 ml).

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

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. Agua purificata [valde]). Even areas that are difficult to access must be flushed at least five times with

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).

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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 • Torque Wrench (TR70) 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

Instrument disassembly and assembly

The following instruments must be cleaned and disinfected when dismantled:

The disassembly, care and assembly of the torque ratchet is described in the torque ratchet instruction leaflet.

Surgical procedure/Drilling protocol

General drilling protocol

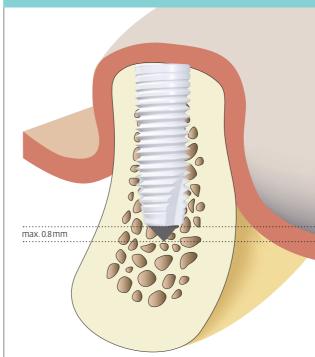
General note:

Round burr

To predrill the cortical bone and fix the implant position.

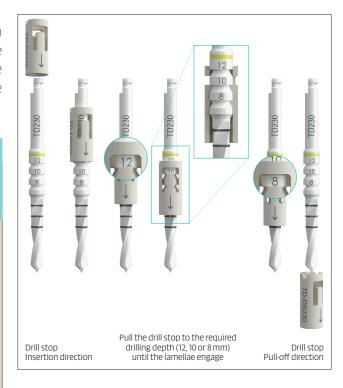
The implant bed is prepared with the twist drills in ascending order. The last drill used depends on the diameter of the implant to be inserted. Please follow the detailed instructions. The depth markings on the drill are easy to read. The first depth mark is 8 mm.

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 recommended for cases with hard bone or hard cortical bone.

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

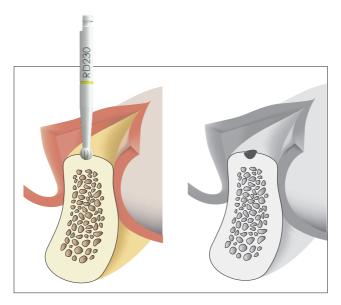
Exemplary procedure: Preparing the implant bed

The following shows how to prepare the implant bed using the example of a Z5-BL implant ø 4.0 mm/10 mm 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 with the endosteal implant diameter.

The threads are pre-cut with the tap; please refer to the position with the RD230 round burr. notes on the previous page.

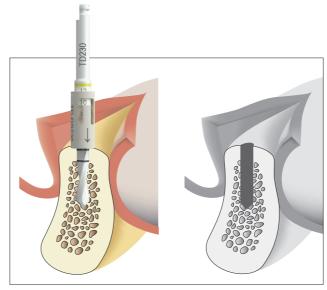
1. Preparation of the alveolar ridge and marking of the implantation site



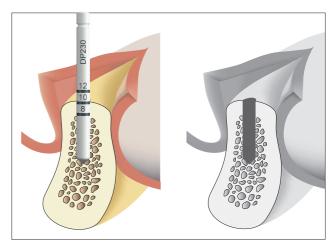
the twist drill (TD230) and the further preparation of Carefully reduce and smooth a narrow and tapered alveolar the implant bed using the twist drills in accordance ridge with the RD230 round burr. This results in obtaining a flat and sufficiently wide bone surface. Mark the implantation site determined during planning of the implant

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

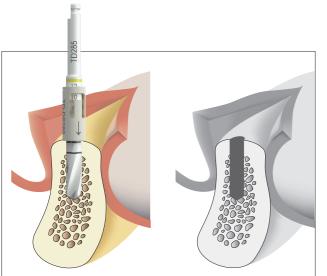
2. Implant axis and depth



Use the twist drill TD230 to mark the implant axis by Use depth gauge DP230 to check the implant axis and drilling to a depth of about 5 mm. Use the depth gauge preparation depth. Take an x-ray at this time, espe-DP230 to check the correct orientation of the implant axis. cially if the vertical bone volume is reduced. The depth Drill the implant bed to the final preparation depth with gauge is inserted into the drilled hole and allows a visual the twist drill TD230. If necessary, correct the orientation of assessment of the hole in relation to the anatomical structhe implant axis.

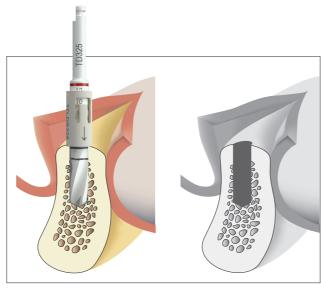


3. Widening the implant bed to Ø 2.85 mm



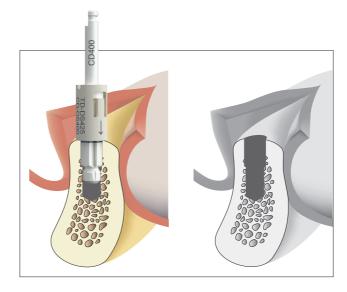
Widen the implant bed with twist drill TD285.

4. Widening the implant bed to \emptyset 3.25 mm



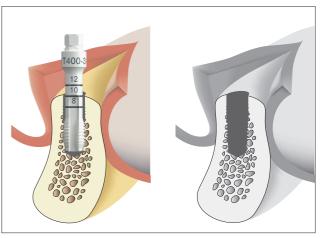
Widen the implant bed with twist drill TD325.

5. Profile drilling

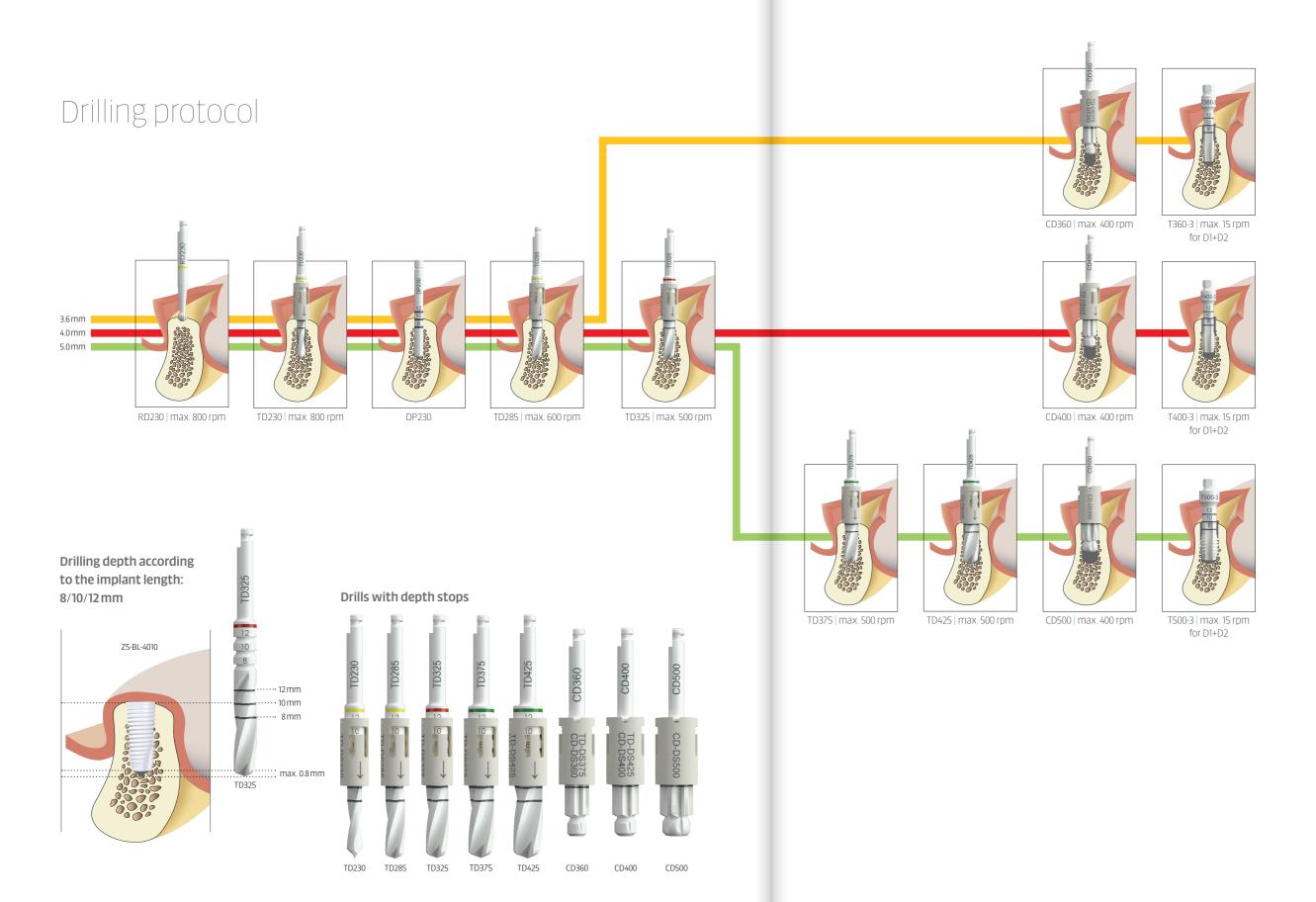


the CD400 cortical drill.

6. Tap



The cortex is widened to the diameter of the implant with Pre-tap the thread with the T400-3 tap over the entire length of the implant bed preparation for bone class D1+D2.



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 an 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.

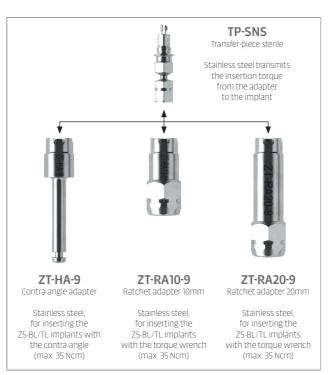
The optimum insertion torque is in the range of 25–35 Ncm. For harder bone, a tap should be used to avoid torques of over 35 Ncm when inserting. The twist drills have a depth stop to ensure safe and precise preparation of the implant osteotomy.

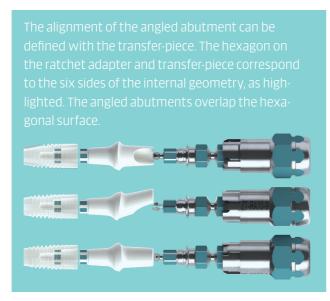
Implant removal from the sterile packaging

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 transferpiece (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.





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.



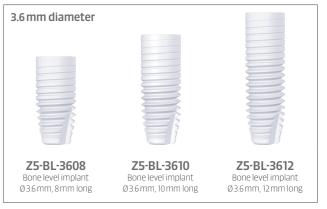
TORX SCREWDRIVER FOR HEALING CAP

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 5.0 mm, each in lengths of 8, 10 and 12 mm





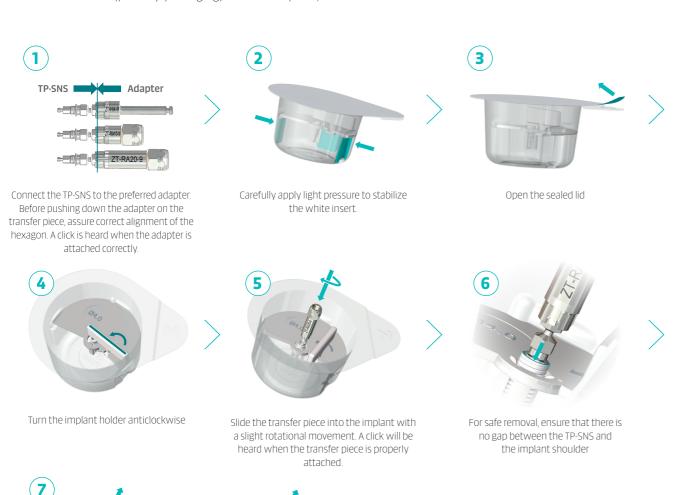


Removing the implant from the packaging

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

Remove the implant from the insert by hand

or by attaching the ratchet or handpiece



Implant placement



Transfer-piece TP-SNS driven by:

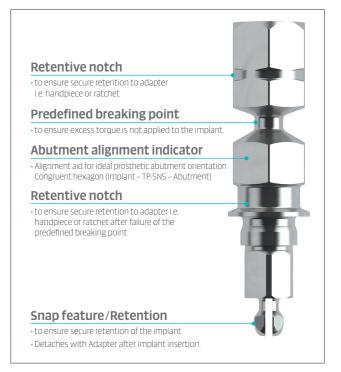


ZT-HA-9 | ZT-RA10-9 | ZT-RA20-9

Insertion speed (rpm) 15

max. torque 25-35

Transfer-piece for Z5-BL/-TL Implants



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



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



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 adaptoron 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.

Contents

Post-operative Care

Postoperative care protocol

The following postoperative checks should be carried out

No peri-implantitis at the intervals indicated:

Regular hygiene examinations (depending on the oral • No radiographic visible peri-implant gap 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 clinically noticeable loosening of the implant
- No pain in the vicinity of the implant

Prosthetic concept

3.1	Fixing the abutment with 25-BL implants	36
3.2	Impression with Z5-BL implants	39
3.3	Healing abutments	40
3.4	Model fabrication	41
3.5	Temporary care of Z5-BL implants	42
3.6	Restoration with a laboratory-fabricated long-term temporary restoration after osseointegration	43
3.7	Final restorations on Z5-BL implants	44
3.8	Prosthetic restoration of Z5-BL implants	45
3.9	Prosthetic restoration of Z5-BL implants in the edentulous jaw	46
3.10	Prosthetic aftercare of the Z5-BL implants	49
3.11	Cementing of restorations on Z5-BL implants	50
3.12	Prophylaxis for Z5-BL implants	51

Z-SYSTEMS | Z5-BL | Surgical and Prosthetic Concept | 03/2024

3.1

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.



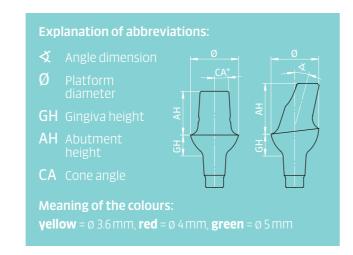
 15° angled abutments in two different gingiva heights and an anatomically adapted shape for cementable single-tooth crown and multi-unit bridge restorations.



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.







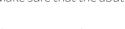
 Bridge abutments in two different gingiva heights without indexing (anti-rotation) in the implantabutment connection for cementing bridges.



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



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



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.



Indication restriction:

The abutments BL-ZB1538 and BL-AN1515 are exclusively for the Ø 3.6 mm 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 screw (BL-OSC-H) or a gold anodized titanium basal screw and abutment. To be able to loosen the abutment safely again, the removal instrument (BL-CD) must be used.



SD-T6-S or SD-T6-L.



Basal screw

Two different types of screws are available. A ceramic basal (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 Healing Cap and Healing abutments are monolithic The provisional abutment BL-TA0030 or the diameter reduced and can only be tightened by hand with the screwdrivers 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

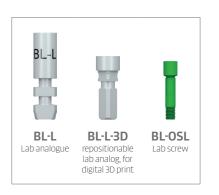
for impression taking at implant level. An impression post for the closed impression (BL-IP-C), one for the open analog BL-L-3D for the digital work flow and 3D print. impression (BL-IP-O), and a scan body for the digital impression (BL-SB-36).

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.



Precise and rotationally stable transfer parts are available The laboratory analogue BL-L is available for a conventional reconstruction on the stone model and a repositionable



Healing abutments

heights and widths is available for shaping the soft tissue help of the temporary abutment and a temporary sinbefore prosthetic restoration. These are screwed into gle-tooth restoration. All healing abutments are supplied the implant hand-tight using a screwdriver. An individual non-sterile and must be sterilised before use in the patient.

A selection of healing abutments with different gingiva design of the emergence profile can be achieved with the

Healing abutment-assortment



BL-GF1538 GH15mm Ø38mm



BL-A0015 GH 1.5 mm, Ø 5.0 mm



BL-A0025 Straight abutment GH 2.5 mm, Ø 5.5 mn

BL-A1515 GH 1.5 mm, Ø 5.0 mm

BL-A1525



BL-ZB1538



BL-AN1515 15° angled abutment, 15° angled abutment GH 1.5mm, Ø 4.3mm GH 2.5mm, Ø 5.5mm



BL-GF3055



GH15mm Ø45mm

BL-BB1545 Bridge-Abutment, GH 1.5 mm, Ø 4.5 mm



BL-CB1545



BL-ZB1545 GH 1.5 mm, Ø 4.5 mm



BL-GF2545 GH 2.5 mm, Ø 4.5 mm



BL-BB2545



BL-CB2545



BL-ZB2545



BL-GF1555 GH 1.5 mm, Ø 5.5 mm



BL-CB1555 Crown-Abutment GH 1.5 mm, Ø 5.5 mm



BL-CB2555 Crown-Abutment GH 2.5 mm. Ø 5.5 mm



BL-GF2565 GH25mm Ø65mm







BL-TA0030 Temporary abutment. Temporary abutment GH 3.0 mm, Ø 5.5 mm GH 1.5 mm, Ø 3.8 mm (with BL-OST screw)

BL-TA1538 (with BL-OST screw)

Model fabrication

Fabrication of the master model

Closed Impression:

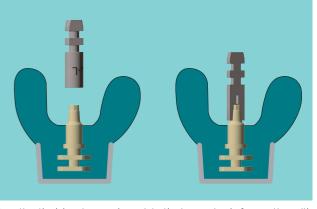
The matching laboratory analogue is inserted into the impression cap so that the lab analogue clicks into the impression cap with a perceptible click. This is the only way to ensure that the situation in the mouth is correctly represented in the master model.

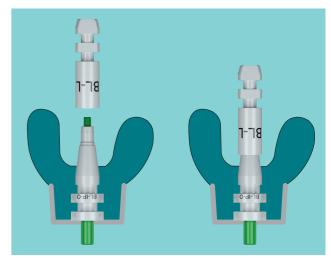
Open Impression:

Assemble the corresponding laboratory analog in the impression. Fix the laboratory analog in the impression inserting the laboratory analogue into the impression before casting with 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 of the crown is optimally contoured. Then the master cast using standard methods and type-4 dental stone can be produced.

- 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.





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

Temporary care of Z5-BL implants

General note

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

shim-stock foil can be pulled through interocclusally with slight resistance in the final bite position with maximum • Restoration with egg shell temporary intercuspidation. Occlusion contacts should be pointshaped. 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:

- Occlusion contacts must always be set so that a simple

 Fabrication of a temporary restoration using an anatomic impression taken directly in the mouth

Restoration with a laboratory-fabricated longterm temporary restoration after osseointegration

If a temporary restoration on Z5-BL implants is intended to **Procedure** stay in place for a longer period (several months), it is rec- • Check the passive fit of the ommended to use laboratory-fabricated, framework-reinlong-term temporary restoration forced long-term temporaries for stability reasons. The lab- • Check the aesthetics, form, phonetics oratory requires precise impressions for their fabrication. • Check the occlusion and dynamic occlusion

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.

- 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. • No clinically noticeable loosening of the implant All restoration types are permanently cemented in the conventional manner.

Adhesive cementation of restorations to Z5-BL abutments • No radiographic visible peri-implant gap are only possible for single-tooth reconstructions. In general, itraoral 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
- (max. 15 Ncm/anaesthesia)
- No pain in the vicinity of the implant

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 according to generally applicable prosthetic guidelines. observed. Furthermore, the instructions for restorations on Z5-BL implants with regard to static and dynamic The mesial and/or distal extension of the restoration is not 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.

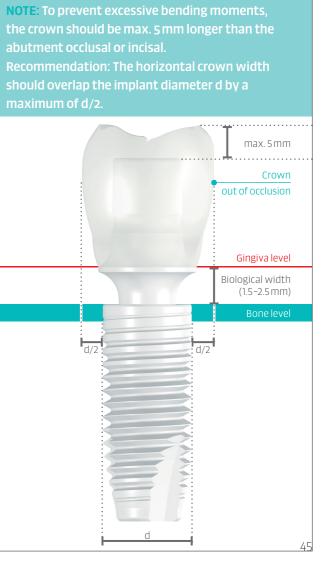


Single-tooth restoration of a front tooth with a Z5-BL implant

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

permitted under any circumstances. The integration of Z5-BL implants in composite bridges requires the exact observance of current dental implant clinical practice recommendations.



Prosthetic restoration of Z5-BL implants in the edentulous jaw

Restoration of Z5-BL implants with a bar construction

When planning a prosthetic restoration of Z5-BL implants cation guidelines for implant selection must be observed. mends 6 implants in the upper jaw, 4 implants in the lower (such as relining). 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

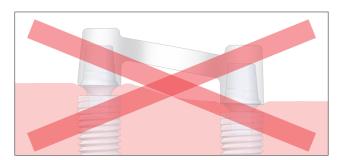
- Stabilisation and primary blocking of the implants
- Securing the prosthesis against pulling and levering forces
- Force distribution
- Resilience compensation through degrees of freedom

The relining of an implant-supported bar prosthesis

Hybrid prostheses with resilient anchoring elements must using bar construction and removable prosthesis, the indibe checked in a recall examination approximately every three months, to remedy any damaging movement of the Number and location of implants (Z-SYSTEMS recomprosthesis at an early stage using appropriate measures

with a telescopic construction

In principle, the Z5-BL 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-BL 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

Prosthetic restoration of Z5-BL implants 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-BL implant 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

Matrix

For prosthetic restoration of Z5-BL implants with locatortype 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.



3.9 3.10

Impression taking

The impression can be taken with the Z5-BL impression components or with the Novaloc™ impression cap. A Novaloc[™] forming/fxing 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



Left:Novaloc™ forming/fxing-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 **3 months after placement of the restoration** as with all implant systems. As individual factors such as • Check for plaque the patient's oral hygiene, cooperation, etc. play a major

Static and dynamic occlusion check role in determining regular prosthetic aftercare, the interval • Hygiene check; if necessary 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

- 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

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

3.11 3.12

Cementing of restorations on Z5-BL implants

General note

porary or final restorations on Z5-BL 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-BL implants

The following points must be observed when fixing tem- 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

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.

Prophylaxis for Z5-BL implants

Z5-BL implants.

ating from the usual prophylaxis guidelines for implants must be observed with Z5-BL implants.

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

Zirconium oxide has a very low affinity for plaque. Do not use ultrasound-operated, metallic cleaning aids Therefore, compared to other materials used in dentistry, to clean Z5-BL implants. Always avoid the application of there is very little plaque on Z5-BL implants. Nevertheless, ultrasound to Z5-BL implants through metallic carriers. regular and adequate prophylaxis is also indispensable for Improper use and application of ultrasound can cause lasting damage to the surface of the Z5-BL implant.

Due to their special material and design, some points devi- When working with metallic cleaning aids (ultrasoundoperated 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-BL implants.



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