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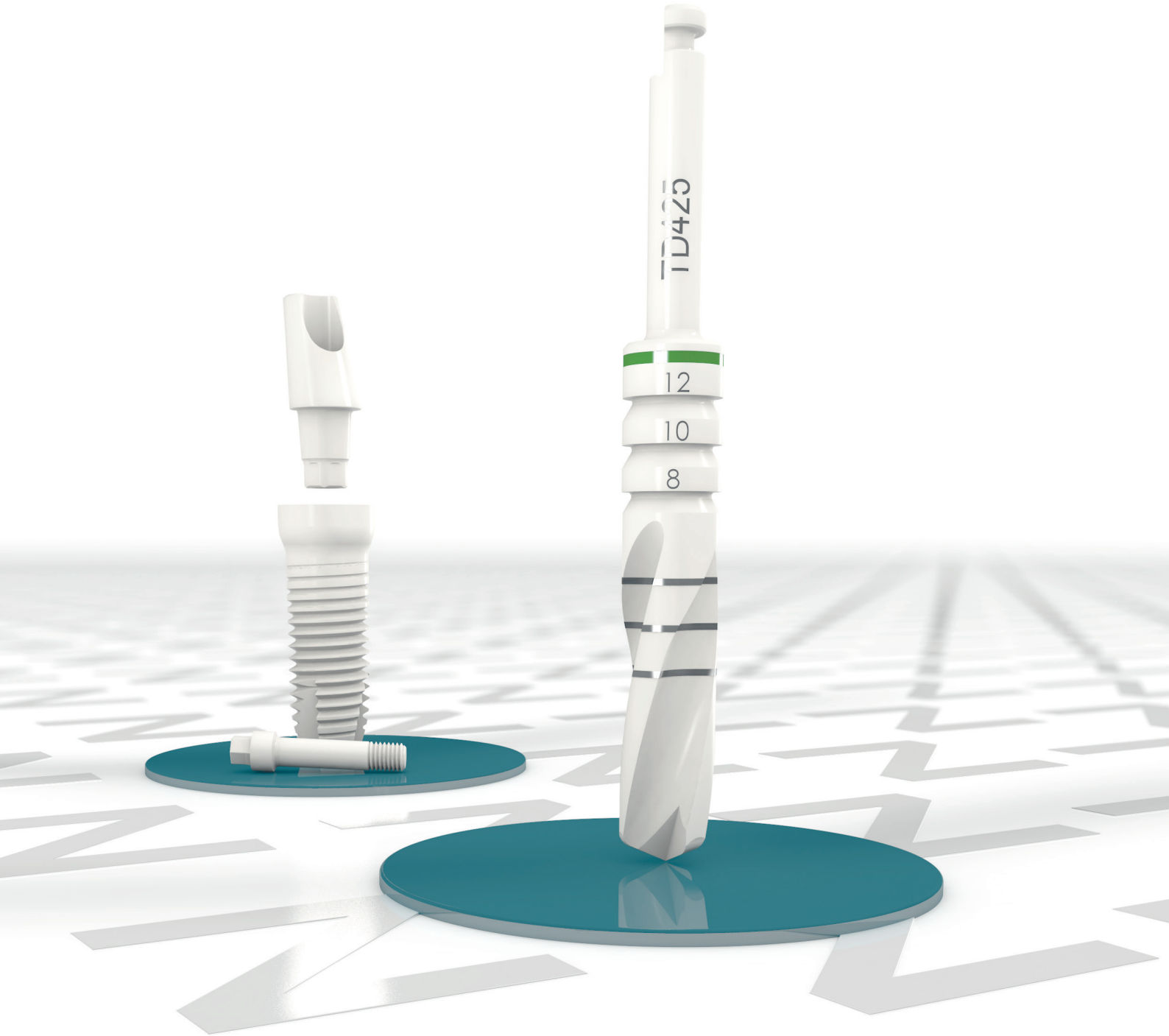
Surgical and Prosthetic Concepts



Z-SYSTEMS
ceramic implants

Welcome to the world of ceramic implants

Established in 2004, the innovative Z-SYSTEMS dental implant systems are the result of extensive laboratory testing and practical experience. Z-SYSTEMS implant systems were designed with safety as the utmost priority.

This manual has the essential surgical and prosthetic guidelines for dentists and dental lab technicians to best place and restore Z-SYSTEMS dental implants, as well as implement an overall treatment plan, This manual does not replace the proper training needed for dental implant placement or the restoration of existing dental implants. It is assumed that the dentist or lab technician has been well trained in dental implant and prosthetic procedures.

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1 General information

General features and important information

General features

Z-SYSTEMS implants are unique in their combination of design and material. We kindly ask you to thoroughly read this manual before starting any treatment planning, surgery or prosthetic procedures.

To ensure successful implantation with Z-SYSTEMS, one must follow these specific instructions and surgical and prosthetic protocols.

Because the health of your patients is our top priority, we have compiled a technical guide that will help ensure your Z5 implant long term success. The surgical and prosthetic phase should be preceded by extensive preoperative assessment, diagnosis and planning. This careful planning and adherence to the protocols set forth, will deliver optimum Z5 implant results and help prevent potential issues.

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

Important information

Disclaimer: The Z5 implant system is part of a comprehensive plan and may only be used in conjunction with the corresponding materials, tools and instruments and in accordance with Z-SYSTEMS instructions and recommendations. Instructions regarding the application of our products represent the latest thinking and processes. They are offered verbally, in writing, electronically or through practical training, Dentists and lab technicians must decide whether or not a Z5 product is suitable for a patient and a specific situation. Z- SYSTEMS will not accept any liability for damages resulting from the improper use or implantation of Z5 products or in connection with, errors in professional assessment or application/indication, in particular. This includes claims due where general implantology and prosthetic guidelines pertaining to implants were disregarded. The user is also obliged to stay abreast of the latest Z5 implant system developments and applications.

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

Validity: As of publication, this manual replaces all previous versions which reference Z-SYSTEMS implants.

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1.1

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 respective country.

Precautions: When using our products, patients must be protected from aspiration duringintra-oral 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 item.

Documentation: Detailed instructions regarding the Z5 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

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

Colour coding of the surgical and prosthetic products:

Yellow: 3.6 mm diameter
Red: 4.0 mm diameter
Green: 5.0 mm diameter

Explanation of the symbols on labels and package inserts

LOT	Batch number
REF	Item number
STERILE | PLASMA	Plasma sterilised
NON STERILE	Non-sterile
	Do not use if packaging is damaged
	Single use, not reusable
	Consult the instructions for use
	Use before expiration date
	Date of manufacture
	Manufacturer
CE xxxx	Z5 products are CE marked and meet the requirements of the Medical Devices Directive 93/42 EEC.
Rx only	CAUTION: United States Federal Law restricts this device to sale to, or on the order of, a licensed dentist or physician.

Review the package insert.
Do not expose the products to direct sunlight.

Material, biocompatibility and osseointegration

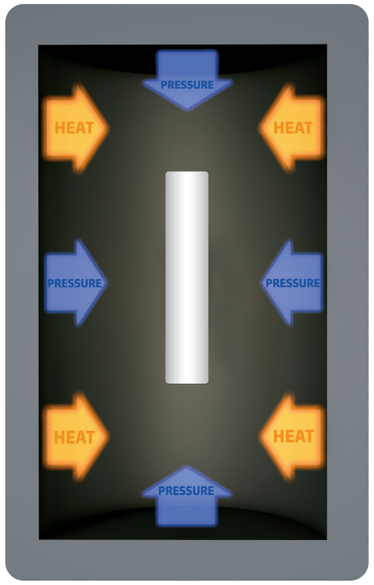
Material

All Z5 implants are manufactured according to the unique «Zirkolith®» process from zirconium dioxide Y-TZP bio-ceramics, and comply with the ISO 13356 standard. It reflects our extensive experience in the development, material processing, quality assurance and finishing of zirconium dioxide. The composition and production processes for zirconium dioxide vary according to the requirements for the system components. For example, whether it is an implant, a cutting instrument or some other surgical instrument.

The "Hot Isostatic Pressing" process gives the material its flexural strength, which is many times greater than conventionally used titanium. In this process, the material is re-compressed in a tunnel kiln for three days at 2000 bar after the sintering process. This significantly improves the physical properties of the base material, breaking strength and age resistance.

The material used by Z-SYSTEMS is one of the safest and most stable zirconium dioxide ceramics on the market and significantly more stable than the zirconium dioxide used in conventional dental technology.

Not only the implants, but also the instruments that come into direct contact with the bony surgical area are made of zirconium dioxide. 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 excellent biocompatibility of zirconium dioxide ceramics.

Osseointegration

Zirconium dioxide has similar osseointegration behavior to commercially pure titanium, and has been proven in a large number of studies.

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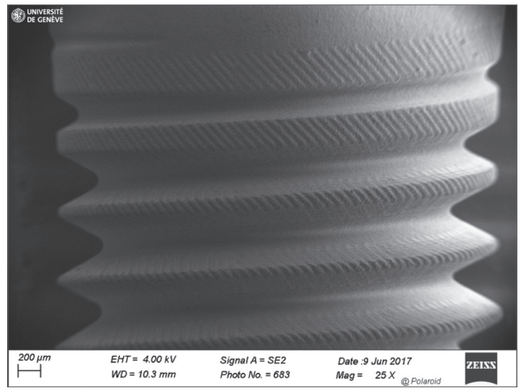
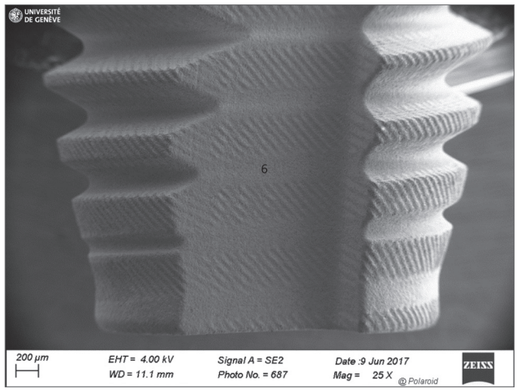
1.2





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 a corresponding increase in macro and micro roughness. Together with our plasma sterilization process, this gives increased hydrophilicity and therefore, rapid and producible osseointegration.

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, with temporaries or prepped 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.

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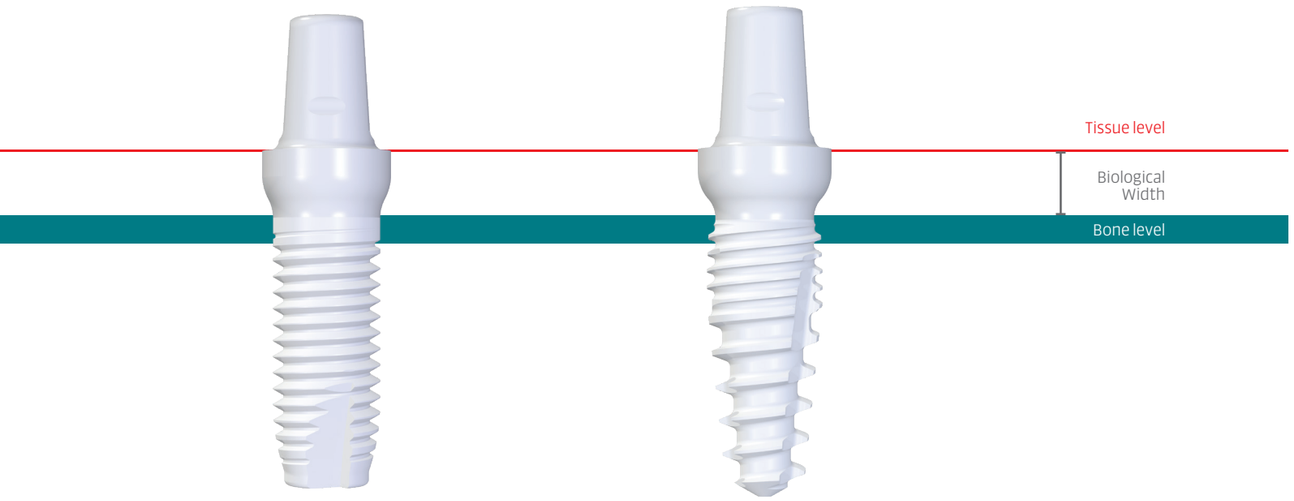
2 System overview

System overview

The Z-SYSTEMS implant system offers five different product lines, both one-piece and two-piece tissue and bone level implants. All of the implants are available in different diameters and lengths



Z5m

The implant for a variety of indications

Z5m(t)

The implant for immediate implantation and soft bone classes

Z-SYSTEMS implants are suitable for almost all indications in the upper and lower jaw for the functional and aesthetic oral rehabilitation of edentulous or partially edentulous patients. Z-SYSTEMS implants are restored either with fixed cement-retained crowns and bridges or with removable prosthetic work.

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2.1

Implant size	Thread diameter	Shoulder diameter	Minimum space requirements orovestibular (surgery)	Minimum space requirements mesio-distal (prosthetics)	Optimum indication odontogram	Further possible indication odontogram	Single tooth	Blocking	Bridge in premolar width (max. span 1 pontic)	Extension bridge	Bar	Telescope
3.6	3.6 mm	4.6 mm	5.6 mm	5.6 mm	UPPER RIGHT | 1. Quadrant / UPPER LEFT | 2. Quadrant USA: 7 / 10 FDI: 12 / 22 FDI: 42 41 / 31 32 USA: 26 25 / 24 23 LOWER RIGHT | 4. Quadrant / LOWER LEFT | 3. Quadrant		+	+	–	–	–	–
4.0	4.0 mm	4.8 mm	6.0 mm	5.8 mm	UPPER RIGHT | 1. Quadrant / UPPER LEFT | 2. Quadrant USA: 2 3 4 5 7 8 / 9 10 12 13 14 15 FDI: 17 16 15 14 12 11 / 21 22 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 | 4. Quadrant / LOWER LEFT | 3. Quadrant	6/11 13/23	+	+	+	–	+	(+)
5.0	5.0 mm	6.0 mm	7.0 mm	7.0 mm	UPPER RIGHT | 1. Quadrant / UPPER LEFT | 2. Quadrant USA: 2 3 4 5 6 8 / 9 11 12 13 14 15 FDI: 17 16 15 14 13 11 / 21 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 | 4. Quadrant / LOWER LEFT | 3. Quadrant		+	+	+	–	+	(+)

\+ recommended | (+) not recommended | – not possible

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 proportionately with the increased diameter of the implant.

Applications for 3.6 mm

Ø 3.6 mm implants are only approved for use in the lateral incisor region (tooth 12/22) of the upper jaw and in the incisor region (tooth 32/31/41/42) 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 11/21, molars, premolars, extended crowns, extension bridges, bridges, bar work, telescopic work).

Applications for 4.0 mm

A universal implant that is suitable for most indications. It is not suitable for indications where there is a risk of cantilever like movement (e.g., extended crowns, extension bridges, bridges with more than one pontic). There is limited suitability for telescopic restorations. Use for telescopic restorations is only recommended for one-piece implants and requires special planning. Telescopic restoration on at least 4 implants in the mandibular and 6 implants in the maxilla is recommended.

Applications for 5.0 mm

A universal implant, suitable for most indications where there is sufficient bone. Implants with Ø 5.0 mm are recommended for canines, central upper incisors and upper jaw/lower jaw molars. There is limited suitability for telescopic restorations. Use for telescopic restorations is only recommended for one-piece implants and requires special planning. Telescopic restoration on at least 4 implants in the mandibular and 6 implants in the maxilla is recommended.

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3 Treatment planning

Fundamentals of treatment planning

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

The Implant prosthetic restoration involves teamwork between the dentist/surgeon and dental technician and also requires a high degree of clinical experience and detailed knowledge from all involved.

The following are important planning points:

Z-SYSTEMS recommends the selection of the appropriate implant and its restoration based on the following criteria:

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

Aesthetically optimum result

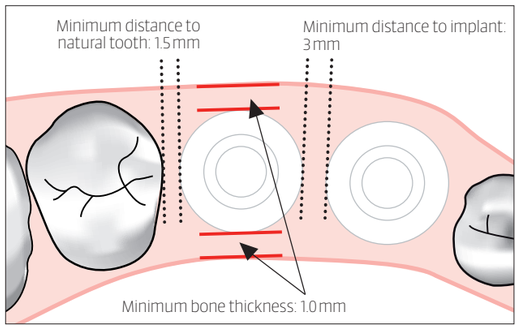
The following conditions are necessary for an aesthetically optimum result:

- the harmonious course of the gingiva
- the best implant position (vertical, buccal-linguall and mesiodistal)
- the shape of the crown and
- the presence of interdental papilla

Planning the positionofthe implant

During planning, the instructions for the hard tissue configurations should be calculated and soft tissue management protocols followed.

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

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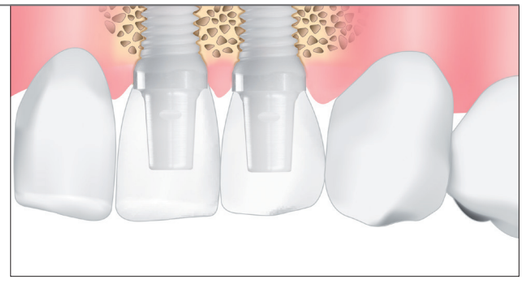
3.1

Restorations

Single-tooth crowns

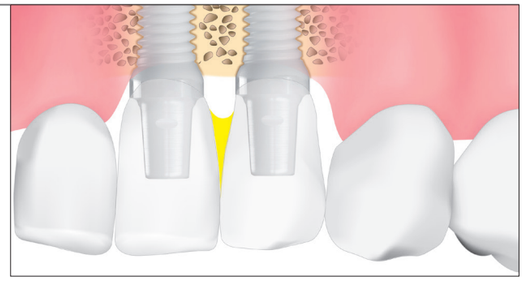
Restoration with single crowns is possible under the rules of "restitutio ad integrum", meaning 'restore to its natural state'. All of this is achievable during periprosthetic rehabilitation.

Meeting these requirements prevents further atrophy to the hard and soft tissues.



Blocked crowns

Attaching the crowns may be necessary for static reasons (such as unfavorable lever ratios). When attaching the crowns is advisable, it is important to maintain good hygiene. A common crown block insertion direction must be achieved by preparation of the abutment.



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.

3.2

Protective measures

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

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

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4 Surgery

Set/Surgery cassette

A Z-SYSTEMS surgery kit is to be used.

The surgical kit contains all the instruments required for implantation and has been designed to be user-friendly. The rotating instruments are sorted according to the treatment process and marked with a color code throughout. To avoid any risk of confusion, both the instruments and their respective spaces have been identified by item code.

For additional convenience, the drills are arranged in the kit according to the treatment sequence.

Material properties

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

This alumina-reinforced zirconium dioxide 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.

Driver

ZT-MD
Mandrel

ZT-HA-8
Contra-angle adapter

ZT-RA10-8
Ratchet adapter 10 mm

ZT-RA20-8
Ratchet adapter 20 mm

HA12
Z5m contra-angle adapter

RA16
Z5m Ratchet adapter 16 mm

RA24
Z5m Ratchet adapter 24 mm

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4.1

Drills

RD230
Round burr
2.3×16 mm

TD170
Twist drill
1.7×16 mm
Z5m(t)

TD230
Twist drill
2.3×16 mm

TD285
Twist drill
2.85×16 mm

TD325
Twist drill
3.25×16 mm

TD375
Twist drill
3.75×16 mm

TD425
Twist drill
4.25×16 mm

CD355-1
Cortical drill
3.55×12 mm
Z5m(t)

CD455-1
Cortical drill
4.55×12 mm
Z5m(t)

Counter-Sinks

CS360-1
Counter sink
3.6 mm

CS400-1
Counter sink
4 mm

CS500-1
Counter sink
5 mm

Taps

T360-1
Tap
3.6 mm

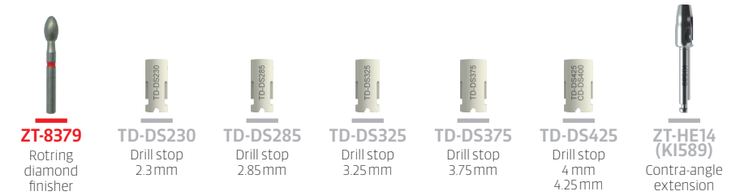
T400-1
Tap
4 mm

T500-1
Tap
5 mm

Ratchet

TR-70
Ratchet torque

Accessories



ZT-8379
Rotring diamond finisher

TD-DS230
Drill stop
2.3 mm

TD-DS285
Drill stop
2.85 mm

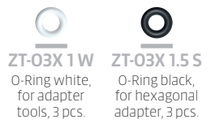
TD-DS325
Drill stop
3.25 mm

TD-DS375
Drill stop
3.75 mm

TD-DS425
Drill stop
4 mm
4.25 mm

ZT-HE14 (KI589)
Contra-angle extension

Accessories



ZT-03X 1 W
O-Ring white, for adapter tools, 3 pcs.

ZT-03X 1.5 S
O-Ring black, for hexagonal adapter, 3 pcs.

Gauges

DP230
Depth gauge
2.3 mm

DP285
Depth gauge
2.85 mm

DP325
Depth gauge
3.25 mm

DP375
Depth gauge
3.75 mm

DP425
Depth gauge
4.25 mm

Colour designation:

yellow = Ø 3.6 mm, **red** = Ø 4 mm,
green = Ø 5 mm, **blue** = Z5m(t)

Preparation instructions for the surgical kit

Detailed instructions are included for cleaning, disinfecting and sterilizing the Z5 Implant System instruments and surgical kit.

Sterilizing and Disinfecting

Please note that sterility of the instruments during use is critical and your responsibility.

- The steam sterilisers used must comply with EN 13060 or EN 285
- Only specifically validated processes are used for the cleaning/disinfection and sterilization of the devices and product
- The equipment used is regularly serviced and checked
- The validated parameters are maintained at each cycle

The dentist's or doctor's practice or hospital must comply with national legal and hygiene regulations, especially as it appies to effective prion inactivation requirements.

Important notes

Unless otherwise specified in the instructions, reusable Z5 products (e.g., drills) may be used and sterilized until they have reached their expiration. Instrument parts must be disassembled for effective cleaning. The silicone O-rings of the insertion adapters must be replaced after 20 sterilization cycles. The number of sterilization cycles must be documented. Z5 products intended for single use may not be reused, as safe preparation and/or functional safety cannot be guaranteed.

Instruments

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

General remark

Instruments made of zirconium dioxide 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 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 fusing blood, secretions, tissue residues, etc.).

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4.1

Disassembly

Completely disassemble all instruments parts (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 is for your own safety and prevents contaminants from drying out. Be certain to follow manufacturer instructions for the specified concentration and application time of the combined cleaning and disinfectant agents. This initial disinfection does not replace the subsequent 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. Use a cannula and a syringe (min. 10 ml).

Combined cleaning and disinfection

The instruments must be completely submerged in a freshly combined cleaning and disinfectant bath 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 residue. Ratchet adapters, contra-angle extensions, mandrels and parts of the torque ratchet, have places that are difficult to access. Remove residue that has collected in these areas.

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 10 ml).

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

Inspection

Regularly inspect the instruments for corrosion, surface damage, chipping and soiling. Damaged instruments must be removed. Instruments that remain soiled must be cleaned and disinfected again. Comply with the maximum permissible number of drilling applications – as specified in the instructions.

Assembly

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

Packaging

Pack the instruments for sterilization as soon as possible. We recommend that the instruments are sorted into the Z-SYSTEMS surgical kit and the kit packed in a disposable sterilization package according to ISO 11607. The instruments can also be packed individually in disposable sterilization packaging according to ISO 11607. Ensure that the packaging is suitable for steam sterilization (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 sterilizer/autoclave

Use steam sterilization processes with a fractionated vacuum process (and sufficient product drying). Other sterilization methods (including gravitational steam sterilization) are not permitted. Care must be taken that:

- the sterilization temperature does not exceed 138°C/280°F
- EU: the sterilization holding time (exposure time at sterilization temperature) is at least 4 minutes at a minimum temperature of 134°C/273°F.
- USA: the sterilization holding time (exposure time at sterilization 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 kit, make sure that it does not touch the walls of the steam sterilizer, as high local temperatures could deform the plastic.

ATTENTION: Z5 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 ratchet (TR70)**
  The disassembly, care and assembly of the torque ratchet is described in the torque ratchet instruction leaflet.

- **All contra-angle and ratchet adapters with an O-ring**
  The O-ring on the adapter must be removed before cleaning/disinfection. Refit the O-ring before sterilisation. Replace the O-rings after using 20 times.

Surgical procedure / Drilling protocol

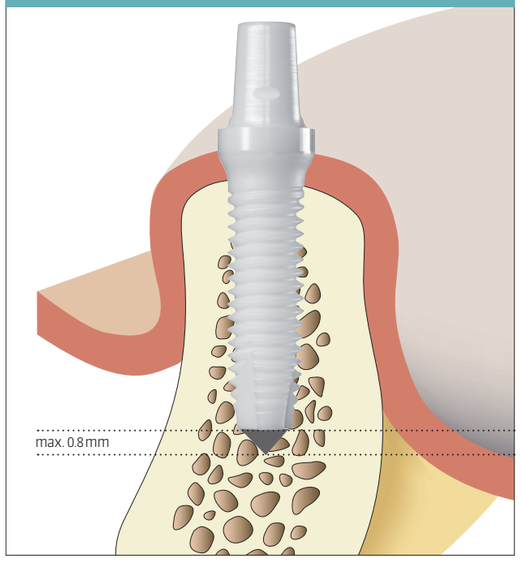
General drilling protocol

General note:

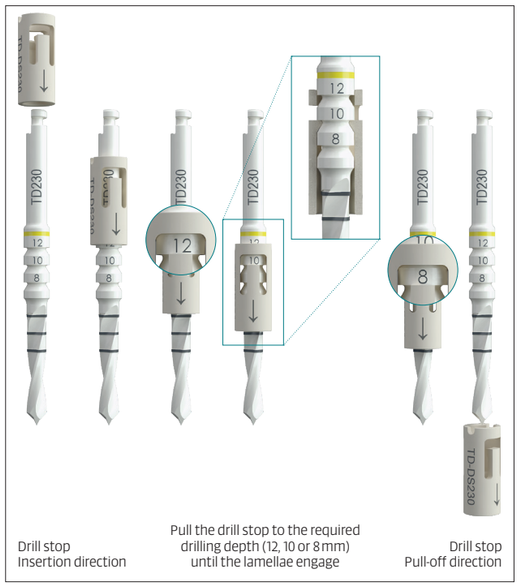
Round burr
To predrill the cortical bone, index the implant position.

Twist drill
The implant site 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.

NOTE: 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.



Tap
In principle all Z5 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: Tap the entire length
Bone class D2: Tap the cortical bone
Bone class D3+D4: Do not tap

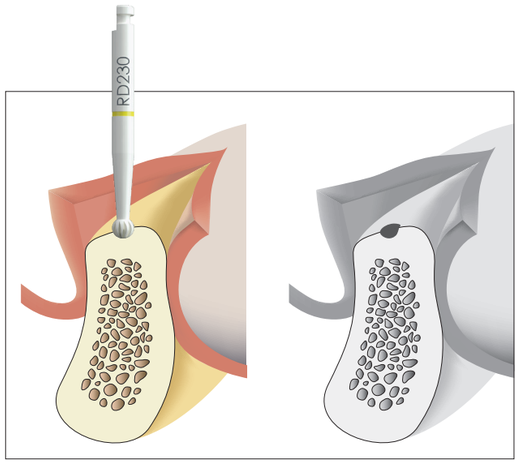
An ideal procedure: Preparing the implant site

The following shows how to prepare the implant site using the example of a Z5m 4.0 mm implant / 10 mm in very dense bone (D1).

The initial preparation of the implant site begins after laying a tissue flap. The implant site is indexed by using the round burr (RD230). Next, based on the implant diameter, further preparation is made using the pilot and twist drills.

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

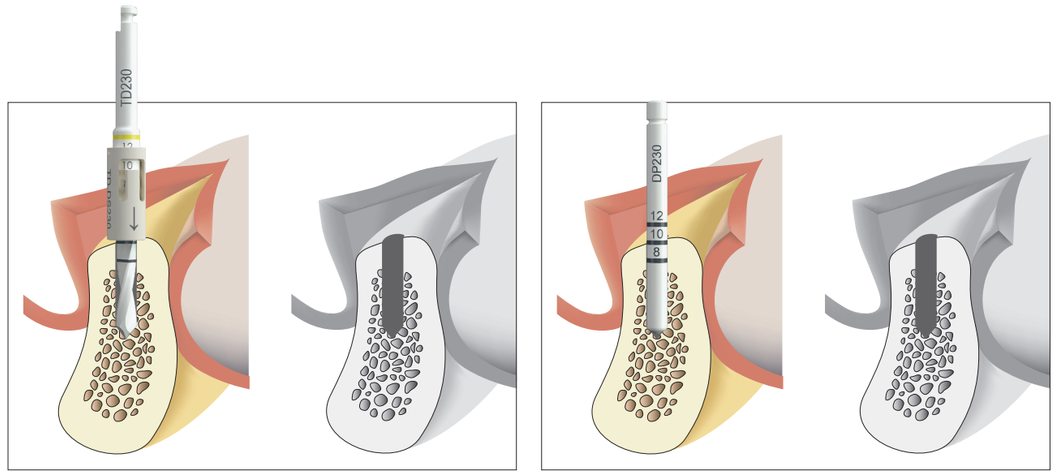
1. Preparation of the alveolar ridge and marking of the implantation site



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

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

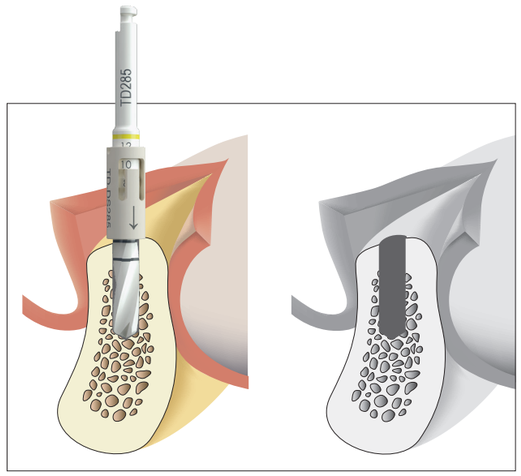
2. Implant axis and depth



Use the twist drill TD230 to mark the implant axis by drilling to a depth of about 6 mm. Use the depth gauge DP230 to check the correct orientation of the implant axis. Drill the implant site to the final preparation depth with the twist drill TD230. If necessary, correct the orientation of the implant axis.

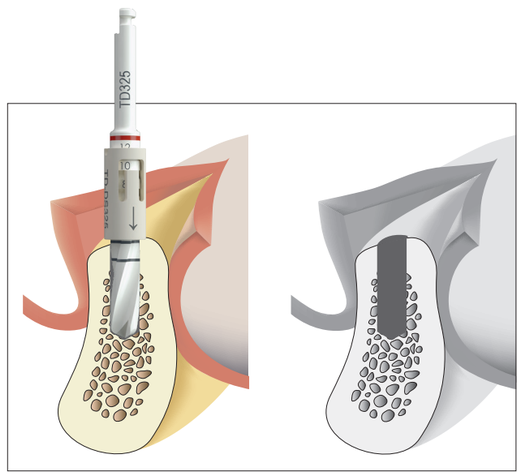
Use the depth gauge DP230 to check the implant axis and preparation depth. Take an x-ray at this time, especially if the vertical bone volume is reduced. The depth gauge is inserted into the prepared site and allows a visual assessment of the placement in relation to the anatomical structures.

3. Widening the implant site to ø 2.85 mm



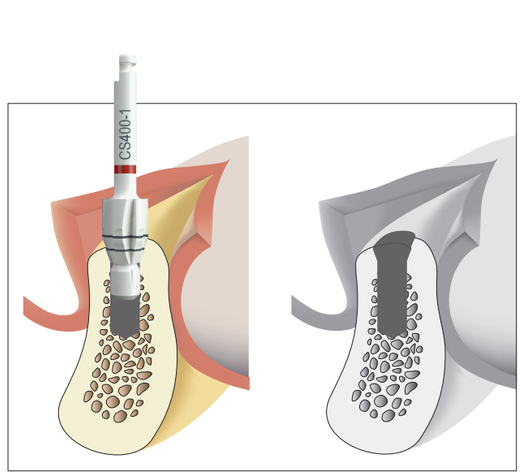
Widen the implant bed with twist drill TD285.

4. Widening the implant site to ø 3.25 mm



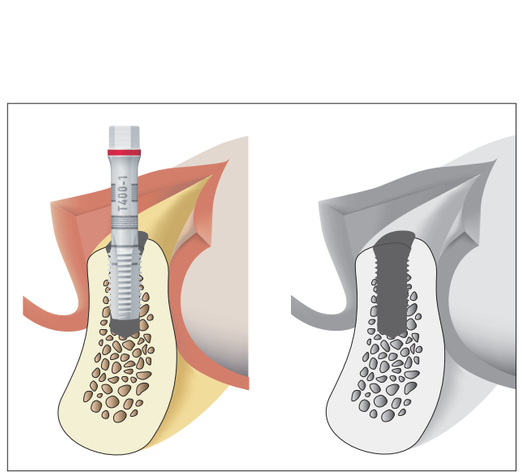
Widen the implant bed with twist drill TD325.

5. Profile drilling



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

6. Tap



Pre-cut the threads with the tap T400-1 over the entire length of the implant site preparation, please refer to the notes in this manual for bone density.

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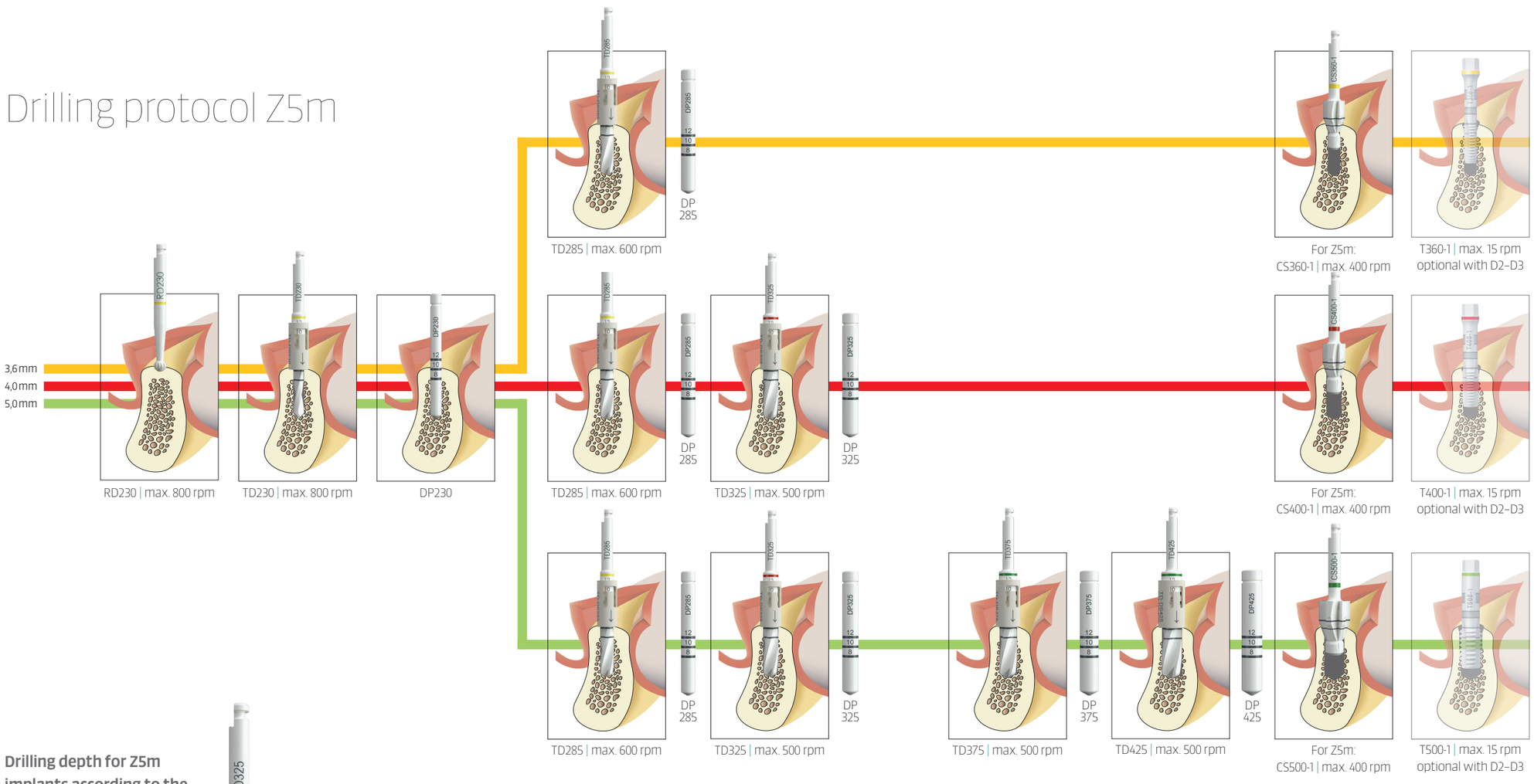
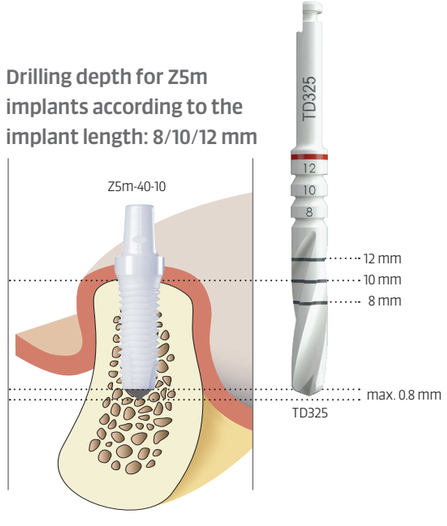
4.2

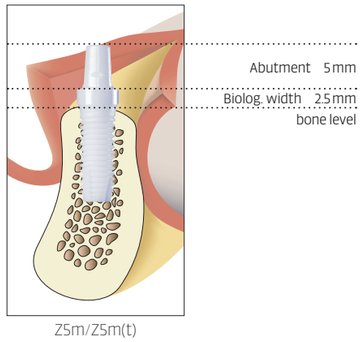
Drilling protocol Z5m



Drilling depth for Z5m implants according to the implant length: 8/10/12 mm



Insertion Depth



Z5m/Z5m(t)

Specific features of Z5m(t)

Z5m(t) implants are only suitable for softer bone classes D3/D4.

General remark

The instructions below must also be followed for the treatment of patients with Z5m(t) implants. The subsequent pages show both the specific features of the Z5m(t) implants and deviations from the standard procedure.

Concept

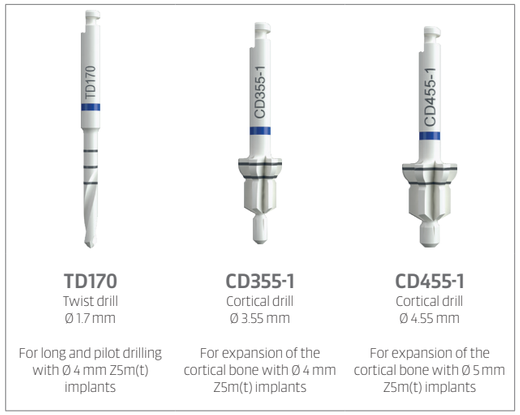
The Z5m(t) implant combines a basic conical shape with a dynamic self-tapping thread. The supracrestal area of the implant (abutment/tulip) is identical to the Z5m.

In the soft, predominately cancellous bone of class D3/D4, the standard under-preparation for the Z5m(t) implant site allows more bone condensation, resulting in a higher primary stability.

Special instruments for Z5m(t) implants

The Z5m(t) implant has a special fine thread in the cortical area to relieve the cortical bone. The compatible cortical drills expand the osteotomy in the cortical bone area. In most cases (depending on the bone quality – see drilling protocol), the cortical drill must be countersunk up to the first laser marking to the crestal bone level; The maximum speed is 400 rpm.

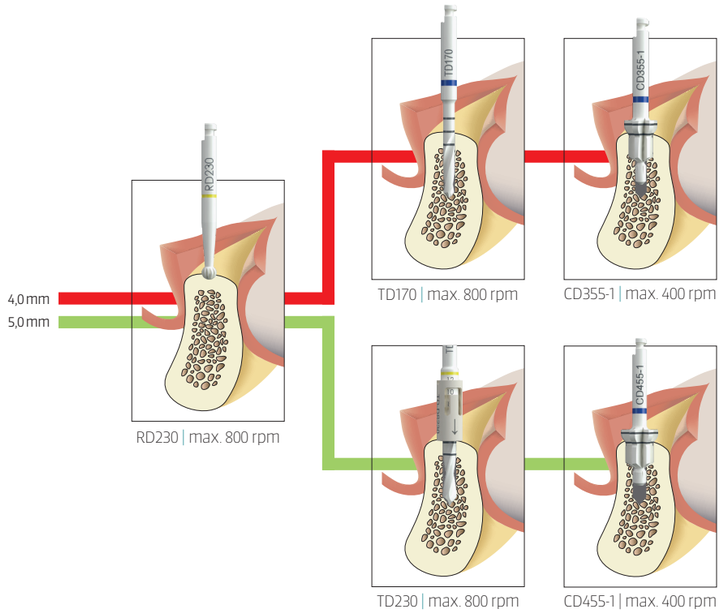
Drills



TD170	CD355-1	CD455-1
Twist drill Ø 1.7 mm	Cortical drill Ø 3.55 mm	Cortical drill Ø 4.55 mm
For long and pilot drilling with Ø 4 mm Z5m(t) implants	For expansion of the cortical bone with Ø 4 mm Z5m(t) implants	For expansion of the cortical bone with Ø 5 mm Z5m(t) implants

The drilling protocol for tapered Z5m(t) implants differs from that of cylindrical Z5m implants.

The thread of the Z5m(t) implants is self-tapping and has the ability to condense soft bone when the site diameter is under-prepared. This advantage allows high primary stability (≥ 35 Ncm) even in soft, predominantly cancellous bone. The special thread design relieves the bone in the area of the cortical bone.



Drilling depth for bone class D3/D4

	Ø 4 mm			Ø 5 mm		
Implant length (in mm)	8	10	12	8	10	12
TD170	8	10	12			
TD230				8	10	12

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4.4

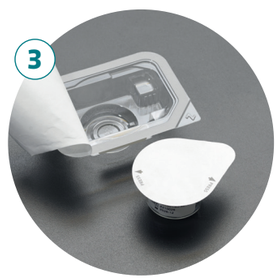
Removing the implant from the packaging

All Z-SYSTEMS implants are delivered in a sturdy cardboard box. Inside is an outer blister with the inner blister that contains the implant.

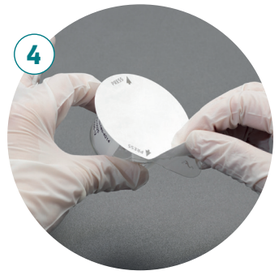
The two-piece implants will include a healing cap. Also enclosed are package leaflet and three removable label stickers for documentation purposes.

Tear open the lateral perforation

Remove the outer blister and open the sealed lid



Remove the sterile inner blister



Grip the inner blister in the **vicinity of the arrows** using light pressure

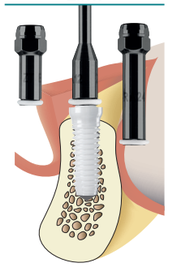
Open the sealed lid

Carefully apply light pressure to stabilise the white insert. For Z5m(t) turn the white implant holder to gain access to the implant.

Attaching the contra-angle adapter or ratchet adapter by applying pressure

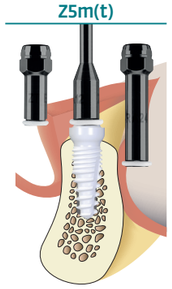
For one-piece implants remove the implant using a sideways movement.
The removal of two-piece implants can be seen on the next page.

Z5m



RA16 | HA12 | RA24

Z5m(t)



RA16 | HA12 | RA24

	Z5m/Z5m(t)
Insertion speed (rpm)	15
Recommended torque	35–70
min. torque for sufficient primary stability	20
max. torque	70

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

Follow up care

Postoperative recall protocol

The following postoperative checks should be carried out as indicated below:

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

Schedule a consultation with the surgeon to determine the follow up care during the first 6–8 weeks of the healing phase. Depending on the situation, further conditioning of the soft tissue can be performed with the aid of a gingival former before the final impression is taken.

The patient should be instructed to contact the practice immediately in the event of any concern or issues. A prophylactic check should be carried out 14 days and 6 weeks after implantation; at the very latest,three months. These consultations must ensure the safe healing and health of the patient.

Successful integration:

- No peri-implantitis
- No clinically noticeable loosening of the implant
- Periotest® values of < 0 (minus values)
- No pain in the vicinity of the implant
- No radiographic visible peri-implant gap

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5 Prosthetic concept

Exposing the Z5 implants

The zirconium dioxide used for the Z5 implants is distinguished by its outstanding tissue response. To accurately expose the prepared margin for an impression, it is often necessary to remove excess gingiva in the area of the abutment after the implant healing time. Reducing the tissue may also be necessary to provide the abutment with scalloped margins or to shape the abutment with prepping.*

Exposing the Z5 implants with the electocautery device

As Z5 implants are made of zirconium dioxide, they are not electrically conductive.

After appropriate local anaesthesia, the exposure can be performed easily and without risk to the peri-implant tissue with an HF electrotomy device.

Exposure with a retraction cord

As with a natural tooth, the sulcus tissue can be displaced by means of a retraction cord if the peri-implant gum tissue protrudes only slightly above the abutment margin. We also recommend appropriate pain management using topical or infiltration anaesthesia.

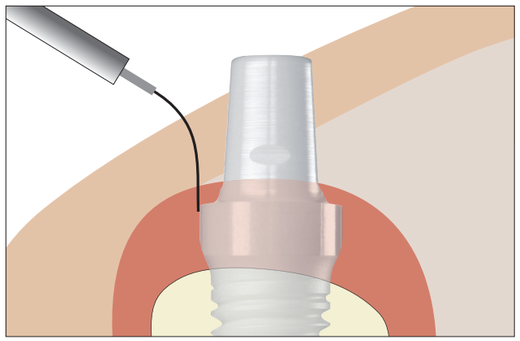
Exposure using a laser

It is possible to use laser devices to expose the Z5 implant.

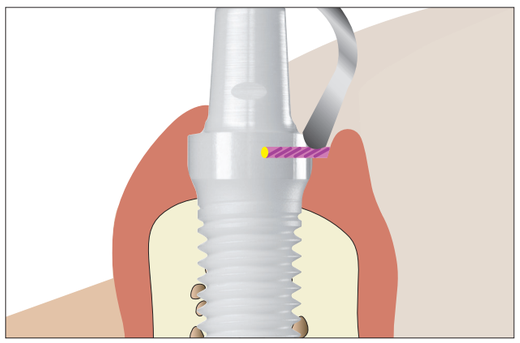
Z-SYSTEMS strongly recommends that the manufacturer of the respective laser device is contacted before use to verify the settings and apprise of any necessary precautions.

Exposure with scalpel

The gingivectomy can be performed in the customary way using a scalpel.



Electrocautery device probe guided along the abutment



Implant abutment with retraction thread and Heidemann spatula.

* Applies only to Z5m/m(t)

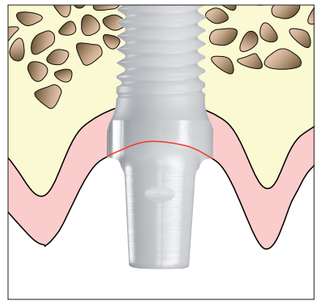
Prepability of implants and abutments

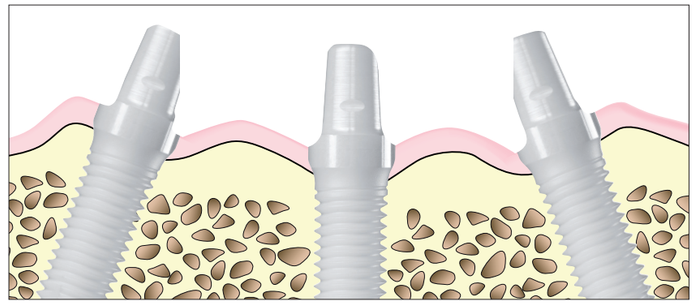
Prepability of implants

Given the high degree of stability and outstanding quality of the Zirkolith® material,it is possible to prepare certain implants to specified preparation margins. This unique capability in implantology gives the user a great deal of freedom for custom adaptation to the existing anatomical conditions.

A natural-looking implant can produce an outstanding aesthetic and functional result. The crown margin should be slightly sub-gingival.

The Prepability of the implant shoulder allows an optimal adaptation to the bone level with angulated implants.



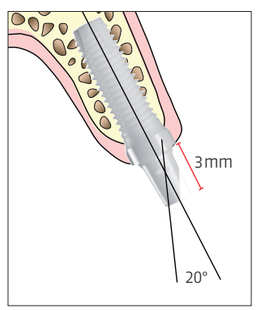


Prepability of the abutments

A major advantage of Z-SYSTEMS products is that the material can be prepped and has been tested by the Fraunhofer Institute. Customizing the abutment may be necessary and useful for various reasons:

- Individual adaptation to the gingival contour after healing
- Corrections to create a common insertion direction
- Angling the abutment in the anterior region
- Shorten the abutment height by up to 2 mm

The abutment can be prepped directly in the mouth. This makes individual, fast and cost-effective treatment possible. Generally, preparation is the same as that for conventional crowns and bridges. The implant abutment must be prepped so that there is sufficient occlusal space for the final restoration. It is recommended that a red stripe fine diamond burr be used.



Minimum
Upper structure height:
3mm

Maximum
angle: 20°

When prepping the upper structure of the implant and abutment, comply with the following guidelines:

- Maximum speed (160.000 rpm)
- Maximum water cooling (50 ml/min)
- Exert a minimum of lateral pressure

Chap5_P.3

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5.3

Impression taking with Z5 implants

One-piece implants

General note

If existing implant or dental-supported bridge restorations are present, they must always be adequately protected using a suitable means (e.g. block-out wax) before an impression is taken to prevent underflow by the impression material.

Recommended impression material

To take impressions of Z5 implants, Z-SYSTEMS recommends the use of (irreversible) elastic impression materials such as elastomers (polyethers, silicones).

Do not use rigid impression materials such as impression plaster, zinc oxide eugenol pastes and plastics, or thermoplastic impression materials. Impressions with reversible, elastic impression materials are not recommended.

Impression taking procedures for Z5m/Z5m(t)

Ready-to-use impression caps made of radiopaque PEEK and compatible laboratory analogs made of titanium are available for the impression taking of one-piece Z5m and Z5m(t) implants where the abutment has not been modified/prepped.

The impression cap enables fast, simple and precise transfer to the master model of both the exact implant position and the surrounding soft tissue when used with the appropriate laboratory analog, The optimized design of the impression caps facilitates the correct transfer of the soft tissue profile and a go o d hold of the im p ression material. The easily reproducible coded positioning on the abutment is guaranteed, as are the exact positioning and secure hold of the laboratory analog in the impression cap.

The abutments of the one-piece Z5m implants differ only in their shoulder width. Consequently, 3 differently coded impression caps (I36, I40, I50) and the matching colored laboratory analogs (L36, L40, L50) are available.

Practical procedure for impression taking of unexposed one-piece Z5m implants using impression caps

After exposing the one-piece Z5m implant, the impression cap is fixed to the abutment with correct placement. The impression cap is inserted over the two phases of the abutment and then snapped into the retention abutment's groove. The noticeable click when snapping into the retention groove indicates that the impression cap is definitely in the correct position. Verifying the correct fit with X-rays, which are often stressful to patients,is no longer necessary.

The retention structure on the outside of the impression cap ensures a secure hold with the impression material. However, depending on the impression material used, it may be advisable to also coat the outer surface of the impression cap with adhesive before taking the impression.

In the next step, the impression cap is covered with the thinnest layer of impression material possible. Then, the individual impression tray (already filled with viscous impression material) is positioned.

NOTE: An impression of multiple implants using impression caps can only be taken if the implants are as parallel as possible to each other. Impression caps are only suitable for unprepped one-piece Z5m abutments. When taking an impression using pre-formed impression caps, there is the general risk of aspiration/swallowing. One possible safeguard is the use of a safety thread.

Impression cap I40

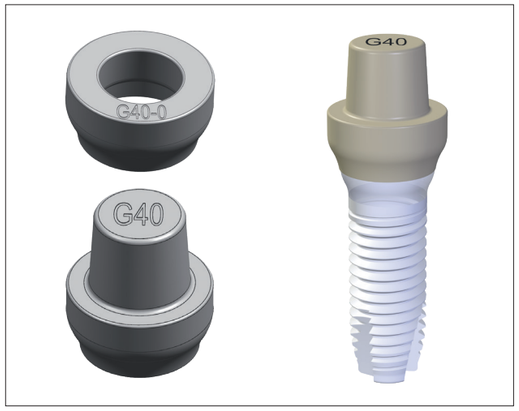
Lab analog L40

Gingiva formers

After exposing the implant, the gingival former (made of biocompatible radiopaque PEEK) allows the anatomical shaping of the gingiva to give a natural emergence profile. The common occurrence of tissue growth over the implant shoulder, is also effectively prevented by the use of the gingival former. Please note that the gingival former is only approved for use after exposure of the implant and may remain in the mouth for a maximum of 180 days. Four gingiva formers of different widths are available, corresponding to the shoulder diameter in both open and closed surgeries.

Gingiva formers can also be used for the fabrication of single-toothe temporaries or as a base perfectly matching the abutment. Z-SYSTEMS recommends placing retention grooves into the outer surface of the gingival former to ensure mechanical retention of the temporary resin with the gingival former. PEEK does not enable chemical bonding to the temporary material.

When using a gingival former as a base for single-tooth temporaries the maximum period that they can remain in the mouth is also 180 days.



Gingiva formers

Fabrication

The general rules for temporary restorations on natural teeth using the crown and bridge technique, apply to the fabrication of chairside prostheses on implants with or without gingiva formers, taking into consideration the implant's lack of resiliency.

Special attention must be paid to the parallel direction of insertion and overhangs. In particular, uncontrolled and excessive forces – especially shear forces – must not be applied to the implants. Otherwise, fractures or loss of osseointegration can occur.

After completing fabrication, fasten the temporary restoration according to the gingival former procedure described earlier.

After delivering the temporary restoration, the static and dynamic articulation points must be checked in the same way as with the final restoration.

Make certain that the occlusion on implants do not allow excessive forces to occur at any time, particularly in dynamic articulation, and that no excessive shear forces stress the implants. The resilience of the adjacent teeth must be taken into account. Please also refer to our instructions for temporary restorations on Z5 implants in our manual.

NOTE: Temporary fabrication using a gingival former is only useful for unprepped Z5 implants. Multiple implants may only be treated with a common temporary restoration if the implants are precisely parallel to each other.

Model fabrication

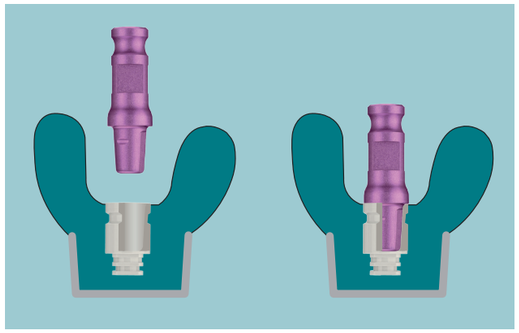
Fabrication of the master model

When using impression copings (only available for non-prepped one-piece Z5m/Z5m(t) and two-piece Z5s implants): The matching laboratory analog is inserted into the impression coping so that the laboratory analog perceptively clicks into the impression cap. This is the only way to ensure that the condition in the mouth is correctly represented in the master model.

The impression can then be cast with plaster and the master cast can be completed.

For prepped implants/abutments, the impression is taken in the same way as for a natural tooth with model fabrication. The prepared margin shows like that for natural dentition models. Generally, this type of crown and bridge impression is always recommended.

Please note that narrow post requires suitable materials.


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

Temporary restoration of Z5 implants in the osseointegration phase

General note

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

Occlusal 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 intercuspation. Occlusal contacts should be point-shaped. Flat contacts must be avoided. Strive for group function to relieve a single implant in the canine position.

If temporary restorations are to remain in place for a longer period of time, closely inspect the static and dynamic occlusion and the periodontal conditions and make any appropriate adjustments/dental hygiene recall. Temporary restorations on Z5 implants must have a passive fit.

The gingival former can be used as a perfectly fitting temporary base on unprepped Z5 abutments.

Direct temporary restoration

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

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

In the laboratory, an anatomic impression is made of silicone using a wax-up model and prepared accordingly (margins are trimmed, the cervical area is developed). This variant is only recommended for small restorations, as the "risk of distortion" of the silicone impresson is too great for larger restorations.

Procedure

- Produce the silicone impression using Wax-Up
- Cut-out the cervical area in the silicone impression ("spoon effect")
- Check the fit of the silicone index in the mouth (if necessary, the parallelism of the abutments where there are multiple implants)
- If necessary, slightly isolate the abutment with Vaseline
- Apply a sufficient amount of plastic to the silicone impression
- Insert the silicone impression into the mouth
- Remove the silicone impression once the plastic has cured
- If necessary, line the temporary restoration and finish in accordance with periodontal health practices as well as occlusion and articulation considerations.
- Cement (permanent cement must be used, for example GIZ)

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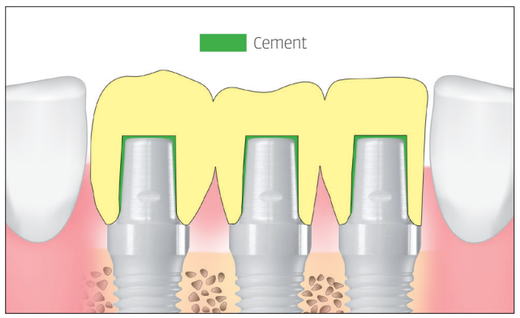
Procedure

- Create a thermoforming material on the model
- Check the fit in the mouth
- In the case of multiple-unit temporary restorations or in the anterior region, a vestibular reinforcement with tooth-colored, light curing composite is recommended before introducing the temporary restoration plastic.
- Introduction of a surplus of plastic (creamy consistency)
- Insert the thermoforming material in mouth
- If necessary, light-cure the tooth-colored composite
- Before the plastic of the temporary restoration is fully cured, remove the thermoforming material with the temporary restoration from the mouth
- Take the temporary restoration out of the thermoforming material, remove any coarse excess and reinsert provisionally
- Leave the temporary restoration in the mouth until completely cured, during this process periodically remove from the abutments
- After curing, finish the temporary restoration for the health of the tissue and for occlusal considerations
- Cement (permanent cement must be used, for example GIZ)

Restoration with egg shell temporary

The preoperative laboratory-fabricated egg shell temporary enables an attractive aesthetic appearance in the anterior region. For immediate treatment it is imperative that the temporary restoration has no proximal contact and is free of any occlusal contact and dynamic occlusion. A protective splint must also be worn over the temporary restoration. In this case, the corresponding instructions for fabricating a protective splint and direct restoration with a temporary veneer must be followed.

When the egg shell temporary restoration is to be used as a temporary restoration after a successful healing phase, only follow the general instructions for the fabrication of temporary restorations on Z5 implants need to be observed. The wearing of a protective splint can be omitted in this case.



Egg shell temporary

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

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

Long term temporary restorations must be completely stress-free and 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 implants

General note

Valid for all one-piece and two-piece implants

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

In addition to all-ceramic restorations, metal restorations and combinations are also acceptable. Regardless of restoration type, all are permanently cemented in the conventional manner.

Adhesive cementation of restorations to Z5 abutments is not possible. When restoring Z5 implants, the general guidelines for the planning and fabrication of implant-supported prosthetics must be followed.

The static, occlusal contact of the restoration must be kept weak in relation to the contacts of permanent teeth. The movement of permanent teeth must be taken into account, particularly with single-tooth restorations. Dynamic and excursive occlusal contacts on the restoration must be avoided. In order to relieve a single implant in the canine position, group function must be taken into account. A sufficient number of the supporting abutments and a statically favorable distribution must be achieved, as well as a periodontally healthy and cleanable restoration design.

Indication for the final prosthetic restoration of Z5 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 Periotest®: Values of < 0 (minus values) mean that the implant is osseointegrated and may be restored
- No loosening when attempting to unscrew (max. 15 Ncm/anaesthesia)
- No pain in the vicinity of the implant
- No radiographically visible peri-implant space

Prosthetic restoration of Z5 implants

For the fabrication of fixed restorations on Z5 implants, the general guidelines must be followed. In particular, this applies to the static and dynamic/excursive occlusion and the periodontally healthy and cleanable restorative design.

Indications for single-tooth restorations on Z5 implants

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

The indication guidelines for implant selection must be followed. It is also important to follow instructions for restorations on Z5 implants with regard to static and dynamic/excursive occlusion, periodontally healthy design and for the fabrication of fixed restorations on implants.

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

Restoration of interdental spaces on Z5 implants

Fixed restorations can be placed on Z5 implants to close interdental spaces. Please note the preoperative selection of Z5 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. When bridges are involved in the integration of Z5 implants, follow the specific recommendations of the implantology societies.

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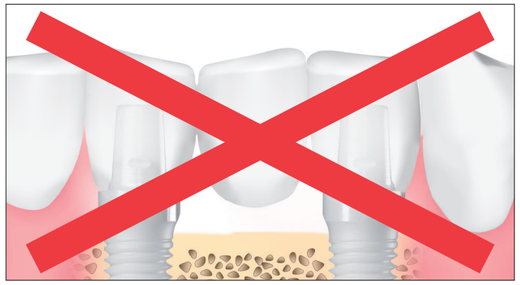
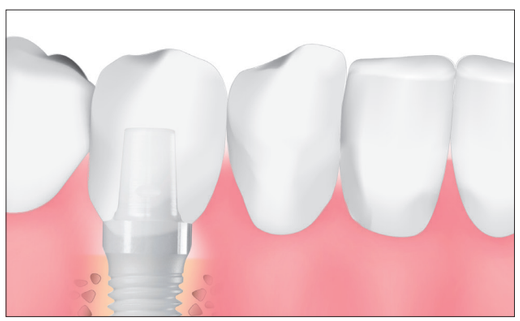
Z5 implants with a diameter of 3.6 mm in an interdental gap. Every tooth is replaced with an implant, blocking is recommended.



Z5 implants with a diameter of 3.6 mm may not be used in bridge constructions



Single-tooth restoration with a Z5 implant

Restoration of an interdental space on Z5 implants with a diameter of 3.6 mm

It is possible to close interdental spaces with a fixed restoration on Z5 implants that have a diameter of 3.6 mm when following strict protocols:

- Correct preoperative selection of Z5 implants according to Z-SYSTEMS' indication guidelines.
- All missing teeth must be replaced by Z5 implants. Z- SYSTEMS recommends connecting the individual implants.
- With regard to static and dynamic occlusion (see beginning of chapter) and the periodontal design of the restoration, it is important to follow instructions and general guidelines for the fabrication of fixed restorations on Z5 implants.

NOTE: Z5 implants with a diameter of 3.6 mm may not be used in bridge constructions

Prosthetic restoration of Z5 implants in the edentulous jaw

Restoration of Z5 implants with a bar construction

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

The task of a bar restoration

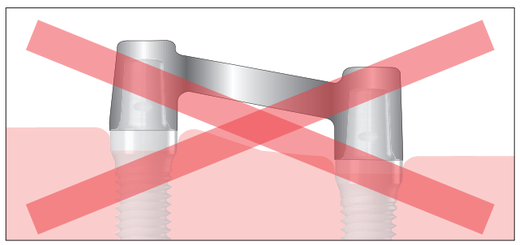
- Stabilization and primary connection of the implants
- Securing the prosthesis against pulling and shear forces
- Thrust distribution
- Resilience compensation through degrees of freedom

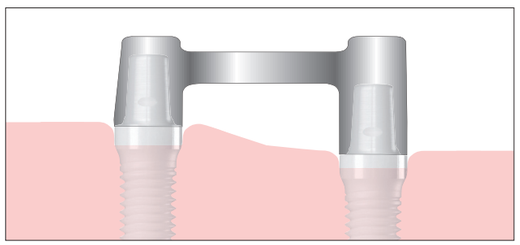
The relining of an implant-supported bar prosthesis

To prevent any harmful movement of the prosthesis at an early stage, hybrid prostheses with resilient anchoring elements must be examined in follow-up patient visits approximately every three months, using appropriate measures (such as relining).

Restoration of Z5 implants with a telescopic construction

Generally, the Z5 implants can be restored with tele- scopic 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) impact on the implants. So that no forces adversely affect the implants, the abutments must be distributed so that at least one telescope is located at the distal end of the prosthesis (masticatory center). A minimum implant diameter of 4 mm and a minimum number of 4 implants must be used. The integration of Z5 implants in telescopic construction should comply with implantology societies recommendations.





No inclined arrangement of the bar link

Prosthetic follow-up for the Z5 implants

As with all implant systems, regular prosthetic follow up care of Z5 implants is necessary. The protocol proposed here can only be regarded as a guideline, as individual factors such as the patient's oral hygiene, cooperation, etc., play a major role in determining a care regimen.

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/excursive 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/excursive check
- Check occlusion and review oral hygiene instructions

3 months after placement of the restoration

- Check for plaque
- Static and dynamic/excursive occlusion check
- Hygiene check; if necessary, reinstruction and motivation
- Scheduled 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/excursive check
- Check occlusion and hygiene; if necessary, reinstruction
- X-ray examination
- Scheduled prophylaxis
- For removable prosthetic restorations, check resilience and perform relining if necessary

> **Check-up every 6 months**
> **Regular prophylaxis**

Cementing of restorations on Z5 implants

General note

The following points must be observed when repairing temporary or final restorations on Z5 implants:

- Dry 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)
- There is a risk of a one-sided loosening of a bridge anchor and a possible fracture of the bridge or abutment ceramic with temporary cementation of final bridge constructions.

Final cementing on Z5 implants

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

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

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

Prophylaxis for Z5 implants

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

Please note that due to the special material and design of Z5 implants, there are some discrepancies with the usual prophylaxis guidelines for implants.

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

Rinsing solutions with 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 spaces.

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

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

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

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ceramic implants

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