ZIRKONUS
Implantatsysteme

SURGICAL MANUAL

ZIRKONUS

IMPLANTATSYSTEME

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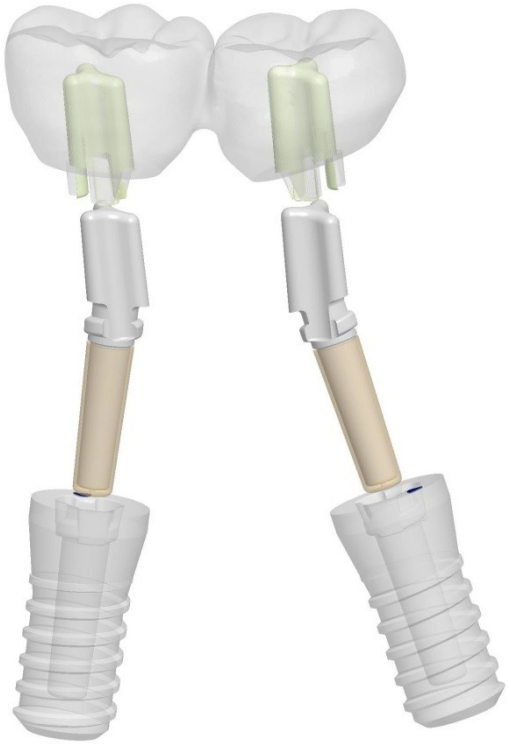

*This **Surgical Manual** is an **Instruction for use and handling** of the ZIRKONUS implant system*

Content

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1. Fundamental Principles of the System

1.1. Geometric structure

The dental ZIRKONUS implant system is a metal-free, one- and multi-part implant system. The coupling geometry between implant, abutment and crown is patented in the multi-part system. It is a ceramic-friendly design in which the dimensioning of the component geometries is optimally adapted to the material properties of the ceramic.

The one-piece and multi-part system differs in that in the one-piece system, the abutment is fused with the implant body to form a complex.

The surgeon who is dealing with the ZIRKONUS implant system for the first time must therefore be aware that there are fundamentally different principles or procedures due to the completely different geometric structure compared to a metal construction.

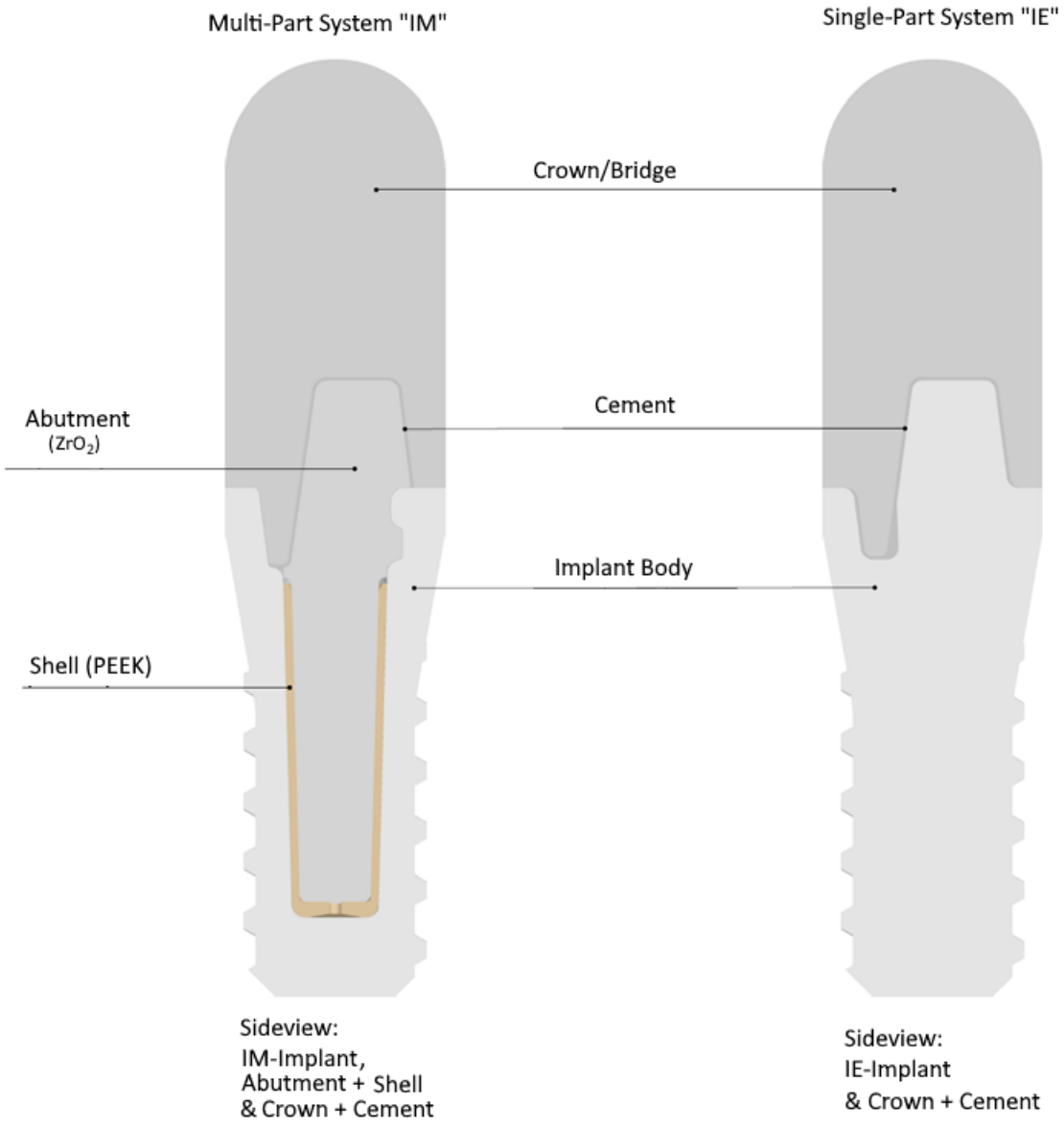


Fig. 1.1-01

1.1.1. System components of the multi-part system

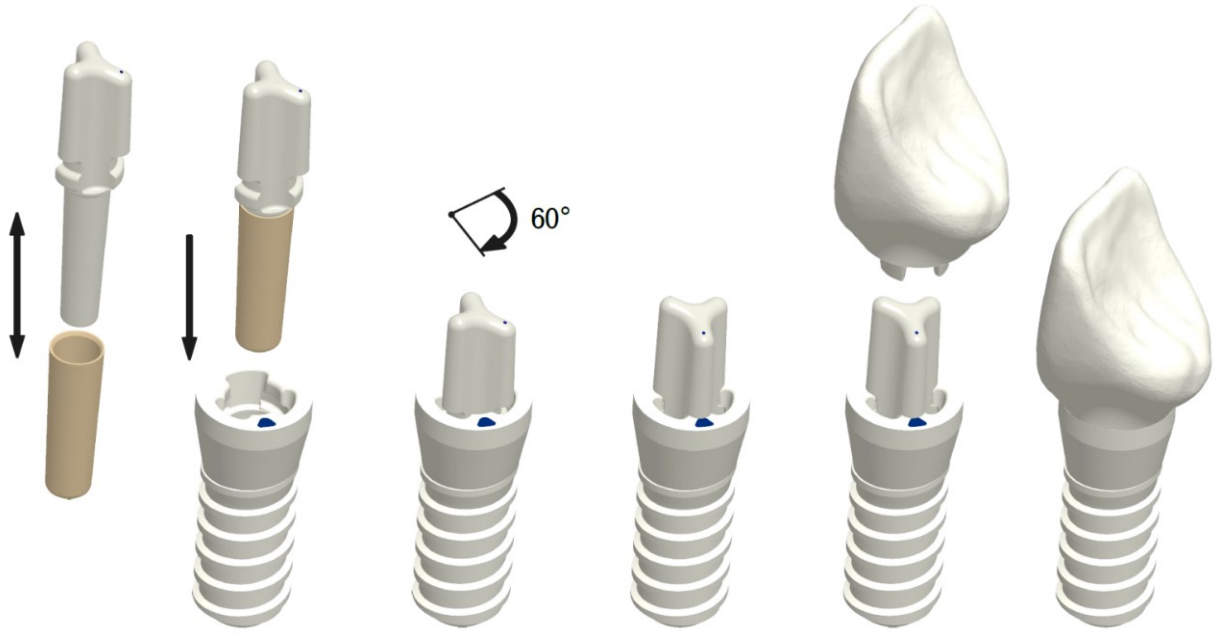


Fig. 1.1-02

According to EU/US patent (EU No. 1992304/US No. 7,726,969 B2), the implant body and the abutment are coupled by a Renk connection (rotation of the abutment by 60 degrees when rotated to the right).

When screwed in, the abutment lowers to the end position at 5°. The rotation is then secured by placing the tooth crown.

The abutment is made of zirconium dioxide, and a PEEK sleeve is required to transmit force from the cone to the inner wall of the implant.

No screw channels are necessary for the superstructure, not even for the abutment. This allows much more delicate abutments and scaffolding constructions to be realized. Cavities in the implant-abutment-crown complex are also minimized (similar to a 3D puzzle), so that there is no exciter reservoir as in metal constructions.

All secondary parts or abutments can be changed as often as desired in the ZIRKONUS implant system. The crowns are cemented onto the implant/abutment complex. Only after the tooth crown has been removed can a reverse rotation with removal of the abutment take place.

There is a color marking on the shoulder of the implant. It enables the precise insertion and replacement of secondary parts. The colour indicates the diameter of the implant (see 2.4.). All instruments for the same implant diameter are equally color-coded.

The instruments are designed in such a way that ceramic surfaces cannot come into contact with metal. This ensures that they are not contaminated by metal abrasion.

The implant diameters ø 4mm (REGULAR) and ø 5mm (WIDE) as well as ø 6mm (LARGE) are pre-cut in the jawbone, while the implant diameters (core cylinders) ø3.2mm (SMALL), ø7mm (OVERSIZE), ø8mm (OVERSIZE X), ø9mm (OVERSIZE 2X) and ø10mm (OVERSIZE 3X) are self-tapping implants.

Ceramic caps and ceramic gingival abuters are fixed exclusively with zirconium oxide screws.

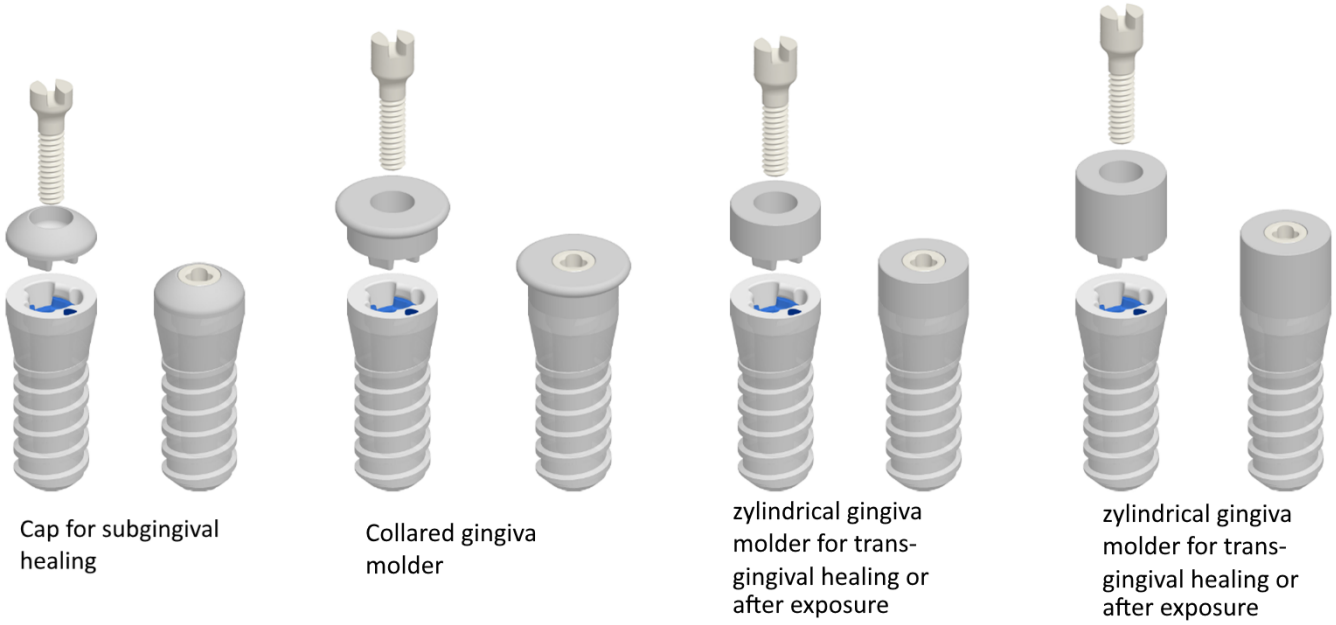


Fig. 1.1-03

The implant is delivered with a pre-assembled anchor part. The anchor part remains in the implant during the healing phase and allows the fixation of secondary parts (closure cap, gingival former, impression posts, planning base elements, etc.).

Fig. 1.1-04

During the healing phase, the anchor part initially remains in the implant body for the fixation of secondary parts. Only at the definitive restoration is the anchor part replaced by the ceramic abutment including PEEK sleeve. (see Fig. 1.1-5)

Figure 1.1-05 to Fig. -07 shows the 3D planning in the ZIRKONUS application for a bridge construction in the posterior region. Here, the abutments are designed in height and angle after determining the insertion direction, taking into account the minimum wall thicknesses of the implant crowns.

Fig. 1.1-05

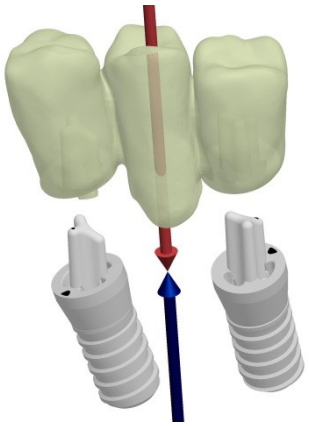


Fig. 1.1-06

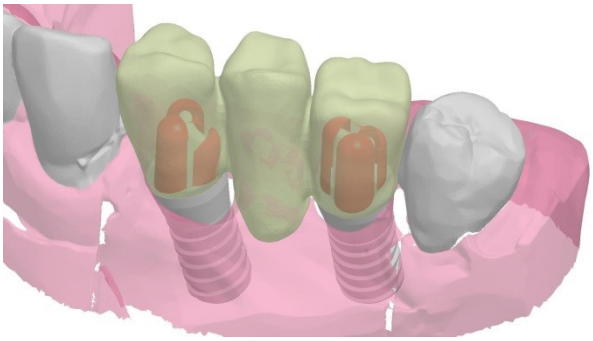


Fig. 1.1-07

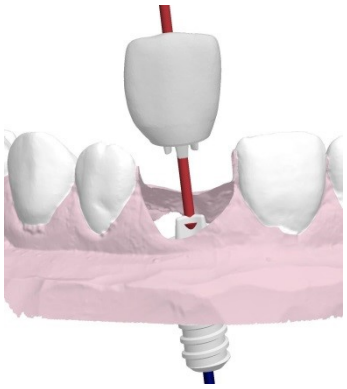


Fig. 1.1-08

Fig. 1.1-09

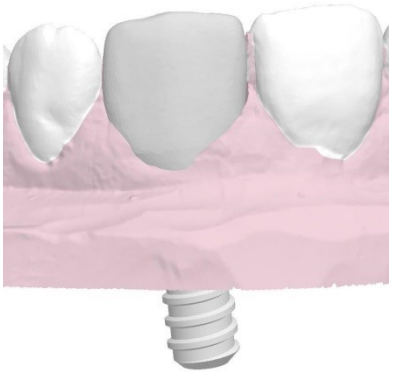


Fig. 1.1-10

Figures Figs. 1.1.08 to Figs. 1.1-10 show the situation of a single crown restoration. Here, too, the insertion direction is important so that the geometry of the adjacent teeth and the antagonists can be taken into account.

The ZIRKONUS implant system is designed in such a way that implant bodies, abutments and scaffold constructions can only be manufactured using the ZIRKONUS CAD/CAM process. Production in any other way is not envisaged and also not possible.

1.1.2. System components of the one-piece system

In the case of a single tooth gap, where it is ensured that a secure splint can be attached between the adjacent teeth to prevent unwanted chewing forces during the healing phase, where there has also been no significant vertical bone resorption, so that the intermaxiliary distance to the opposing jaw is not too large (<=2mm HDK applied from the upper edge), there are no undercuts due to a problematic insertion direction during the subsequent crown restoration , the practitioner can certainly think about whether to place a one-piece implant instead of a multi-part single implant. In cases that cannot be clearly assessed, however, preference should always be given to the IM system.

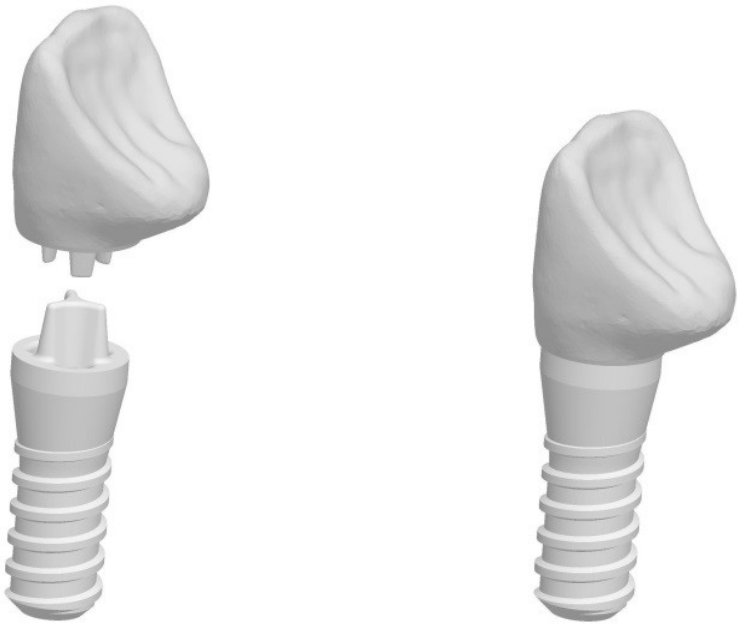
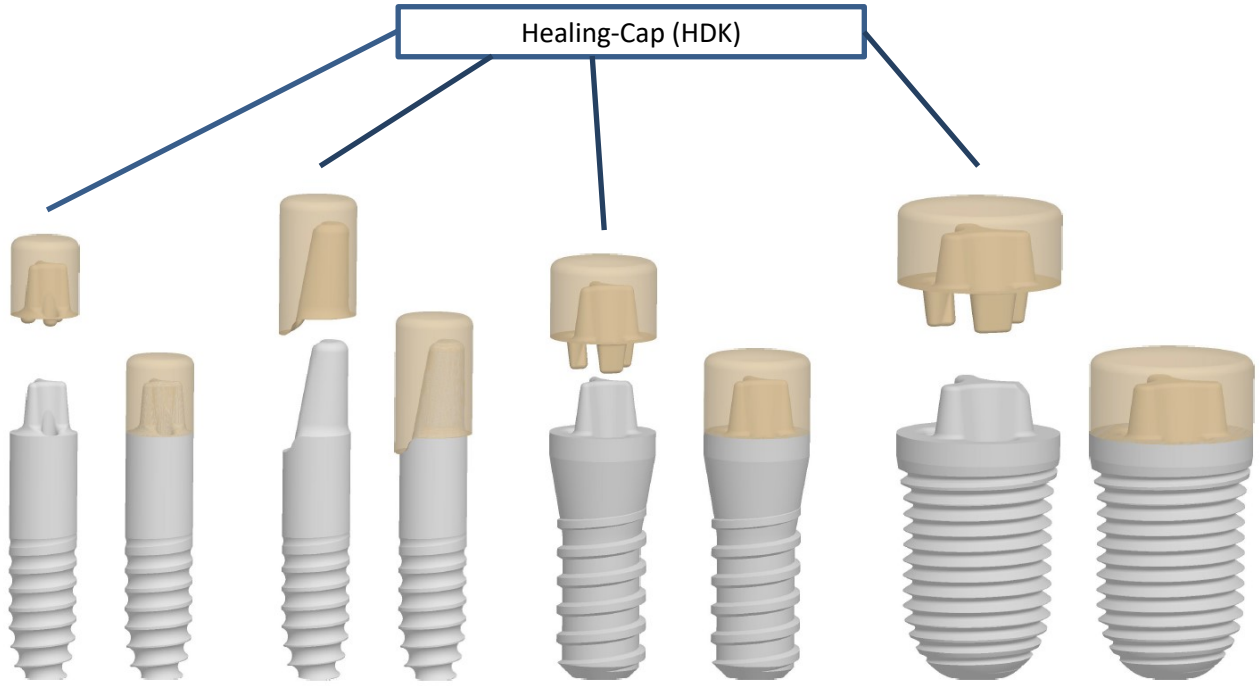


Fig. 1.1-11 Single tooth crown on IE implant

The abutment geometry of the IE implant is fused with the implant body, the crown only needs to be cemented. This is a comparatively inexpensive design for single dentures.

The healing cap is placed on the IE implant immediately after insertion into the bone to prevent the gingiva from growing onto the implant shoulder area.



Self-Tapping SMALL Implants		cylindrical Implant	Self-Tapping Oversize Implants
Type IE-SBE Fig. 1.1-12	Typ IE-SST Fig. 1.1-13	Typ IE-R (-W/-L) Fig. 1.1-14	Typ IE-O (-OX, -2OX, -3OX) Fig. 1.1-15

The one-piece system has essentially the same external geometry as the multi-part system.

If stress-free healing is not ensured during the healing phase of the implant due to the situation in the patient's jaw, one-piece implants may not be used.

SMALL implants are available in two different abutment designs (each in two different lengths: L11 (mm) and L14 (mm)).

On the one hand, there is the IE-SBE type (see Fig. 1.1-12), and on the other hand, the IE-SST type (see Figs. 1.1-13).

The IE-SBE type is intended for bridge extension, only in rare individual cases it makes sense as a single tooth prosthesis for a narrow gap in the molar area.

The IE-SST type is used for single tooth restoration in the upper and lower jaw anterior region in narrow gaps, ideally in the case of tooth replacement 12/22, e.g. in the case of aplasia or in the case of replacement of the lower jaw incisions 31/32/41/42.

With this type, it is essential to ensure that the one-sided throat is always directed towards the buccal. It is designed in such a way that the acting chewing force always acts from the back, which has a cylindrical contour parallel to the axis.

The impression taken after the implants have healed is carried out by the dentist in a conventional way using an individual spoon and plastic impression material using ZIRKONUS impression posts. Unfortunately, enoral scanners are not suitable in terms of accuracy at the moment.

After a plaster model has been produced, it is scanned in the laboratory by a suitable scanner, preferably from the manufacturers: Imetric, 3Shape (900 series), ZfX Evolution. Suitable planning software is Exocad.

After 3D planning, the scan and the desired external geometry are transmitted to ZIRKONUS implant systems via the Internet. There, the abutment and superstructure are produced without intermediate impressions.

1.1.3. Replacement of multi-root molars with OVERSIZE implants

In the shoulder area, the largest ZIRKONUS implant (OVERSIZE 3X) measures 11.5 mm in diameter on the shoulder platform

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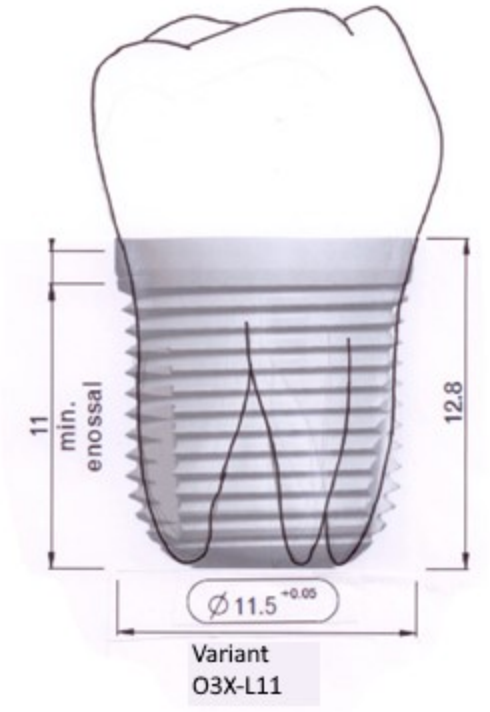


Fig. 1.4-01

In addition to the most commonly available implant diameters of approx. 3.5 to 6.5 mm, ZIRKONUS Implantatsysteme offers ceramic implants with a shoulder diameter of up to 11.5 mm. The corresponding core hole diameter here is a maximum of 9.9mm.

The reason for this is that the anatomical relationships between large and small individuals, men and women, old and young people, and finally also large differences between alveolar processes in the front, premolar and molar regions. In this respect, it is generally surprising that the diameters available on the market since then are usually only between 3.5 and 6 mm.

The so-called oversize implants, available in 4 diameter variants, are specially configured for very cancellous bone, especially for the maxillary molar area. In this case, the bone is very cancellous, i.e. it has large parts of bone marrow and little spongiosa, especially in edentulous areas with reduced height. If implants are placed here, they should have a platform at bone level from the outset that corresponds to the lost tooth with a large diameter, so that a harmonious transition from the implant platform to the attached crown is achieved.

Much more important, however, is that the threads are supported by the lateral compacta layer and not like a screw with a smaller diameter in the soft, flexible cancellous layer, and thus only an often unsatisfactory primary stability can be achieved. In addition, with the reduced bone height often found there with the much larger bone contact area, enormous primary stability can still be achieved with a larger circumference.

During the definite chewing load in the healed state of the implant, the surface pressure on the bone is reduced and thus reaches values in the order of a multi-root tooth.

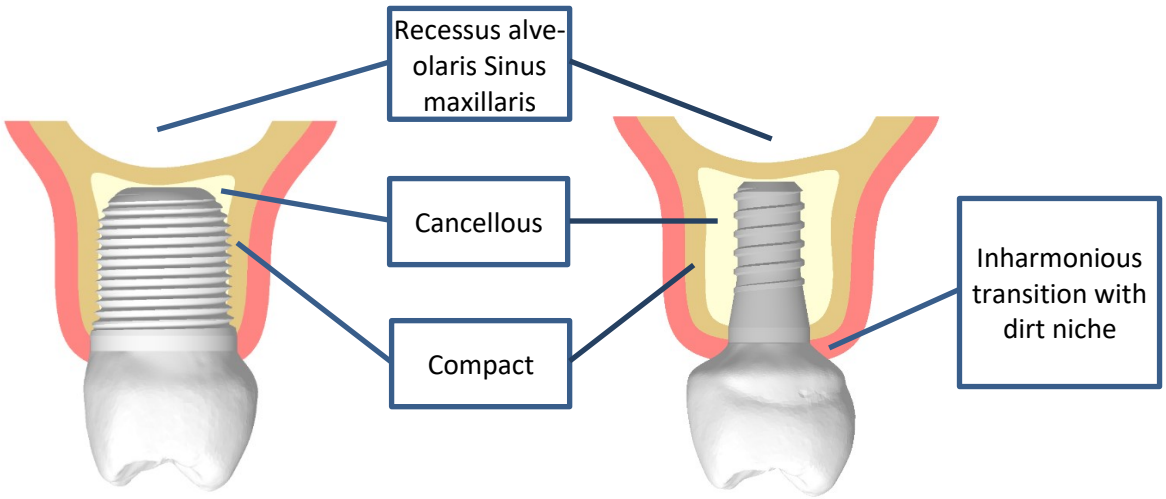


Fig. 1.4-02:Cross-sectional images in the upper chival area with inserted oversize implant and oversize implant conventional screw with D=6mm implant

The threads can be supported from the inside on the compacta layer. The shoulder plateau ensures a harmonious transition to the dental crown.

In addition, it must be noted that the highest chewing force is present in the molar area, and therefore there is the highest risk of breakage for implant bodies and implant abutments. However, the more massive the implants are there, the better the forces are distributed over the larger surfaces (shoulder surface and sheath surface), resulting in a reduction in surface pressure and an overall reduction in compressive stresses, making them enormously resilient. A fracture of the implant bodies can be almost ruled out.

1.2. Supraosseous principle – placement of the implants in the bone – comparison of the systems

The white implant material can be located directly under the mucous membrane and you don't have to worry that it will shine through the mucous membrane gray-blue, as is the case with titanium.

Therefore, you don't have to hide the material in the bone as with the bone level principle. As a rule, the alveolar process bone should be fully preserved, regardless of its height, without having to mill it down to the wide plateau required for bone-level implants.

Nevertheless, the surgeon must always pay strict attention to the fact that the bone reaches the level of the implant shoulder everywhere just below it and that it is only exposed in places on the side of the alveolar process (see also Fig. 1.2-03). Either he places the implants deep enough, or he performs augmentative measures on a narrow alveolar process to ensure this. At the highest point of the alveolar insertion, the bone protruding above the implant shoulder level should be left to support the mucosa.

Due to the support of the abutment/crown complex on the implant shoulder, the ZIRKONUS implant system does not cause expansion and splitting between the abutment and the implant body as is the case with thin-walled bone-level implants.

With ZIRKONUS implants, the bone can therefore easily be designed to run pointedly to the implant shoulder; there is no need to fear that the implant wall of ZIRKONUS implants will be stretched and damage the bone.

In reality, it can often be observed that in the first few months after the implants are placed, there is a vertical bone loss of 0.5 – 1 mm. This is irrelevant in the case of the tissue-friendly and white zirconium dioxide (ZrO2), as it is often observed that the mucous membrane adheres directly to the ceramic and there is no discoloration of the marginal gingiva. Bone resorption of up to 3 mm in relation to the implant shoulder level is also not a problem for the stability of the implant system. This has been proven with dynamic load tests in accordance with DIN EN ISO 14801. There are no undercuts as with bone-level implants with dirt niches with ZIRKONUS implants, but the platform switching principle is still practiced because the manufacturing tolerances of the implant diameters are in the plus and the contact surfaces of the implant crowns are in the negative.

The ZIRKONUS implant system thus takes an extreme opposite position to the bone level principle. Nevertheless, the surgeon must of course keep in mind that the implant is ALWAYS marginally covered by mucous membrane at the lowest point of the bone level and will remain so later! The implant shoulder should be just above bone level if the bone is level. This ensures that there is no separation between the implant body and the implant crown at bone level, and that the cylindrical part of the zirconium implant body should only end above bone level.

In some cases, however, the bone can remain standing above the shoulder level of the implants without any problems. This is advantageous for supporting the inter-implant mucosal papillae.

For orientation during the milling process, the upper edge of the depth marking (black marking, see Fig. 2.3-11) on the cone-shaped moulding cutter shows the practitioner a level above the bone surface of 0.5mm, so that the implant is then placed with the shoulder just above the flat bone level.

In the case of bone-level implants, the author has never made the observation that bone apposition has occurred after the storage of bone substitute material above the gap between the implant shoulder and the abutment.

The following diagram is intended to show the situation with flat bones as well as with a pointed alveolar process.

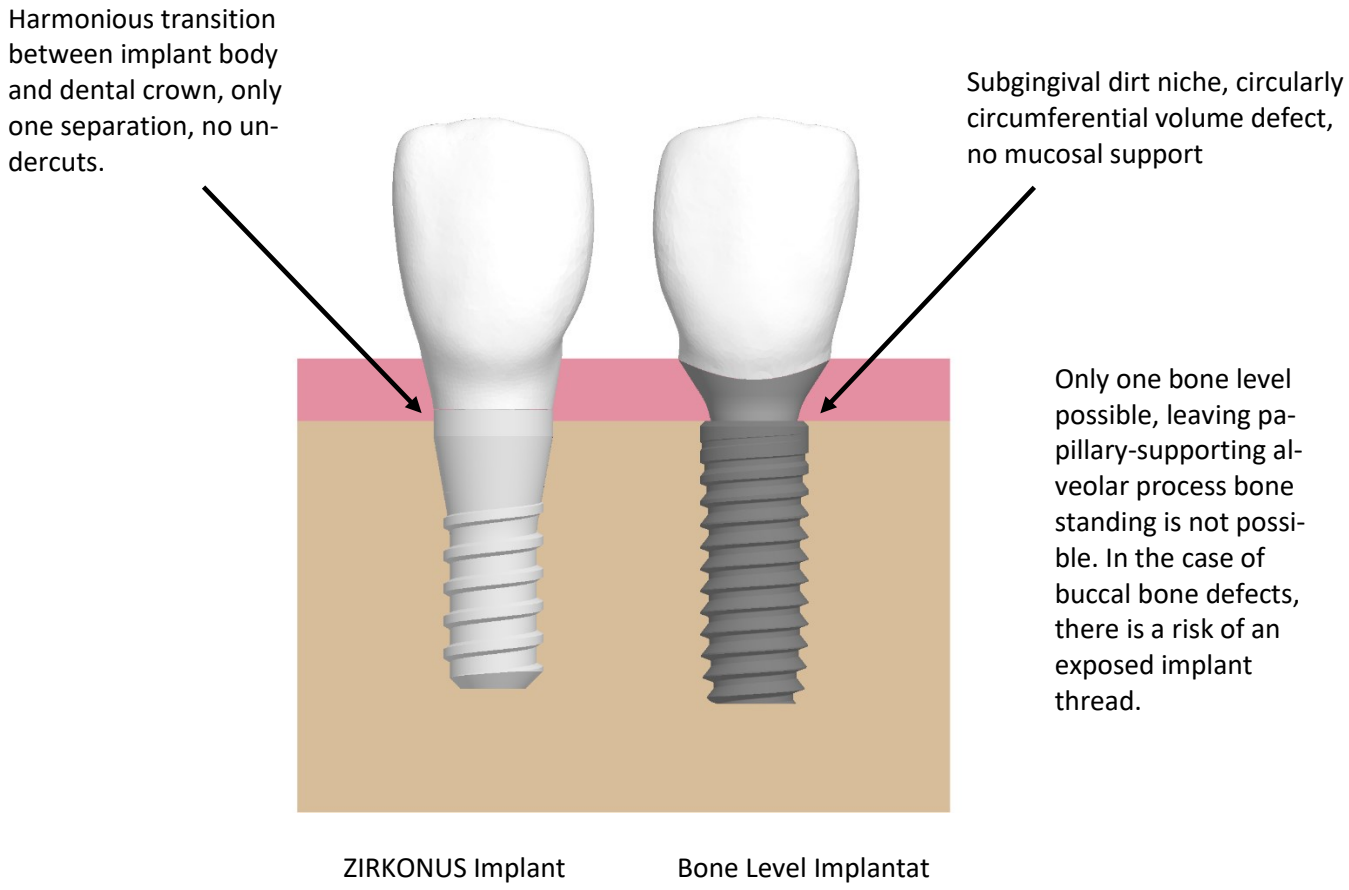


Fig. 1.2-01 Schematic comparison of mucosal and bone conditions in flat bone

In anatomical situations with flat bone, where total reabsorption of the alveolar proposition has occurred, as is often the case in the mandibular posterior region, there are no serious differences in the placement between ZIRKONUS implants and BoneLevel implants, here the difference is only that the bone is flush with the upper edge of the bone level implant, with ZIRKONUS implants the shoulder surface is just above the bone level.
This has the advantage of avoiding irritation of the tissue at the point of passage of the implants on the bone surface, which is present due to material fatigue in the bone level implant principle due to a leaky gap that is often observed.

In the case of narrow alveolar processes, there are fundamental differences between the implant systems when placing the implant bodies. This is shown schematically in the following figure.

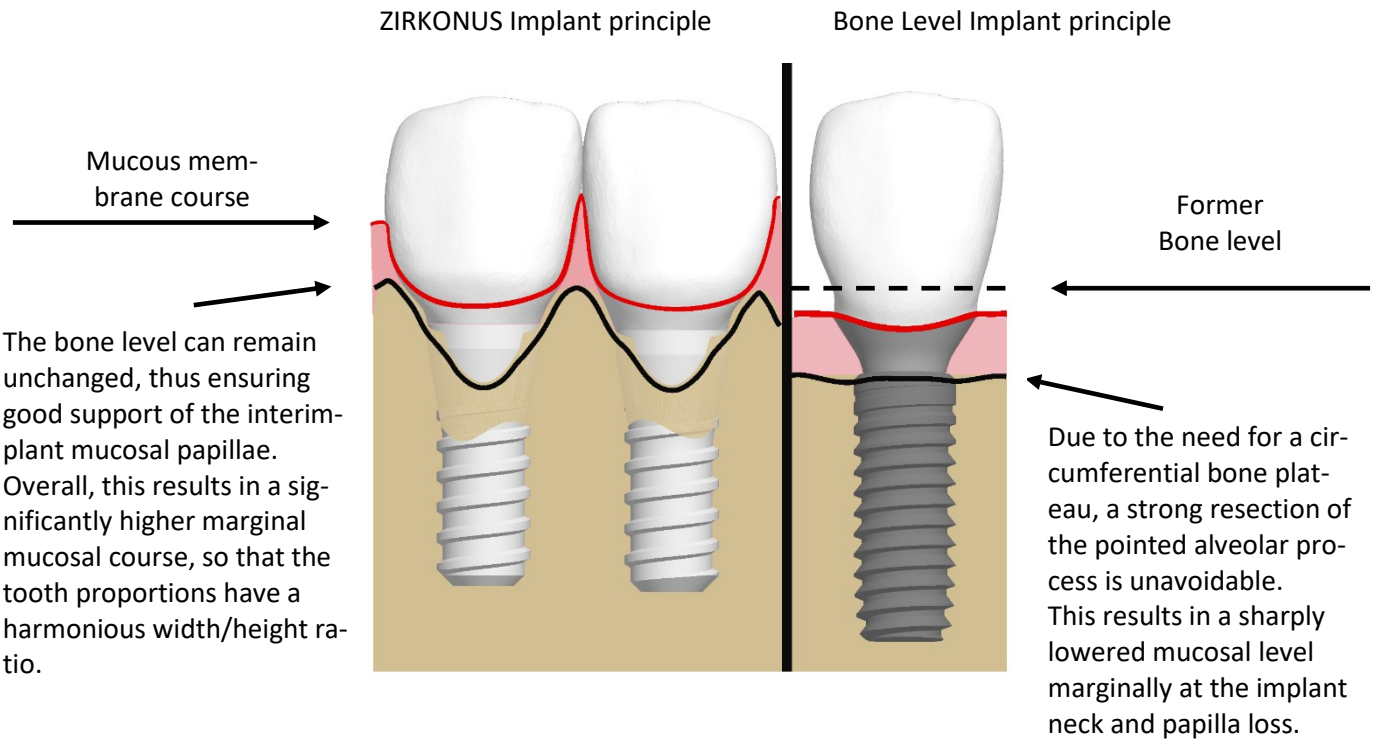


Fig. 1.2-02 Comparison of bone level ZIRKONUS and bone level implant in narrow alveolar process

With the ZIRKONUS implant system, there is no need to mill a plateau on the alveolar process, as is the case with the bone level, in order to ensure that at least 1 mm of bone is still present horizontally around both buccal and orally.

The figure also shows that the bony supporting structures in the bone level implant have been lost as a result, consequently the mucous membrane also sinks, there are no sufficient mucosal papillae, the tooth crown has a significantly longer tooth neck with an unfavorable height-width ratio, which has a cosmetically unfavorable effect. The typical garland-like course of the mucosal papillae can only be realized with the ZIRKONUS implant system. The so-called emergence profile formation in the bone level principle of mucous membrane not supported by the bone can never compensate for this deficiency.

In the case of the bone level implant, two separations are required due to the system: implant / abutment and abutment / crown.

The separation at bone level is, as is well known, extremely problematic because of the gap at bone level, which acts as a bacterial pump. The patient also has no chance of cleaning the circumferential groove at bone level. The second separation in the bone level principle just below the mucosal level inevitably results in an unsatisfactory wide gap, since a cove is not suitable for a ceramic/ceramic connection in terms of manufacturing technology.

Compared to these two weak points of the bone level principle, the ZIRKONUS implant system offers the significant advantage of separation just below gingival level, between implant and crown. Technically, this allows for an almost gap-free transition, because the geometries of the circular radius and shoulder plane are clearly defined, collide at right angles and can therefore be easily implemented in terms of production technology.

In the ZIRKONUS implant system, the mucous membrane has grown marginally at bone level due to the tissue-friendliness of the material. In the area of the dividing line (implant/crown), which is only just subgingival, it is possible to clean it with dental floss without any problems.

1.3. Placement of implants in the jaw

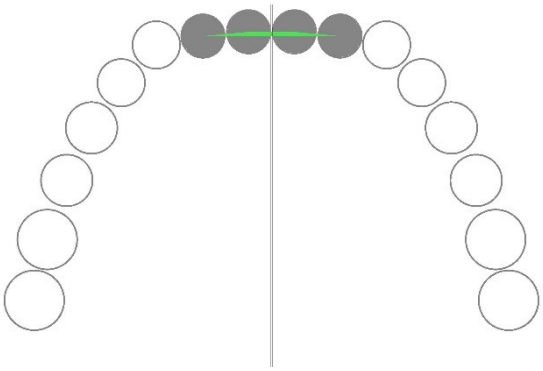
A maximum of one intermediate link should be suspended between 2 implants (distances between the drilled core hole walls may be max. 8mm apart, pendants in bridge constructions may overhang max. 4mm); larger spans are not permitted and are risky due to the risk of fractures or overloading of the implants in the bone. If all teeth are missing in one half of the jaw, it is strongly recommended to place at least 4 implants, preferably 5 or more. In case of reduced bone supply, each tooth should be replaced by an implant, this is especially true in the case of large intermaxillary distance due to the leverage effect. As a general rule, it is important to lock all implant crowns together, this also applies to single crowns of two implants standing directly next to each other.

Blockages with prepared neighboring teeth are possible and useful, especially if bruxism is suspected and unfavorable leverage conditions in the case of long implant crowns.

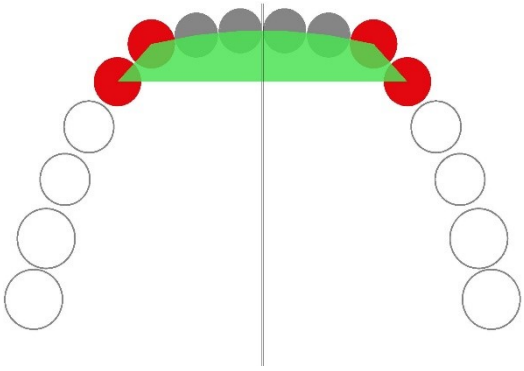
Only in exceptional situations should larger jaw sections be treated in combination with IE and IM implants, in which case the IM system should always be preferred in cases of doubt. If several IE implants are placed, it is essential to pay attention to parallelism (maximum angular deviation from each other of 15°), especially if a connecting superstructure is provided.

In general, the largest possible implant diameter of the available implants should be chosen for the present alveolar process.

It is important that implants to be treated with blocked crowns are not in a line, but that care is always taken to ensure that a surface is stretched. This is very important in the OC/UK front.



If the implants are in line in the front of the upper or lower jaw. In the case of protrusion, there is a lot of stress on the abutments, which poses a risk of fracture



In these cases, it must be urgently advised to include the neighboring pillars in the construction and to block with them.

1.4. Intended use

1.4.1. Purpose

1.4.1.1. Implantatsystem

The Zirkonus implant system is used for the permanent replacement of the tooth root as well as for the fixation of individual dentures or complete bridge constructions in the event of partial or complete tooth loss.

1.4.1.2. Abutments

ZIRKONUS abutments are components of the IM system (multi-part implants), they serve to ensure that the superconstructions (single crowns, bridges) can be attached to the implants after undisturbed osteointegration. Thus, they are part of the definitive supply.

1.4.1.3. Cap

The closure caps are parts of the IM system, they are suitable for subgingival healing of the implants, if necessary in conjunction with augmentative measures. They are fastened by ceramic screws, which are held in the in situ armature part by the internal thread of the armature.

1.4.1.4. Gingival abutments and healing caps

ZIRKONUS gingival abutments / healing caps are used by temporary fixation on implants surgically inserted into the patient's jawbone to promote a controlled restoration of the soft tissue (gingiva) for later permanent prosthetic restoration by means of a dental crown or bridge.

1.4.1.5. Planungsbasiselements

ZIRKONUS planning base elements are used to support a fixed temporary restoration by means of temporary fixation on implants surgically inserted into the jawbone. The basic prerequisite is resilient and osteointegrated implants of the one-piece IE system and multi-part IM system.

1.4.2. Expected clinical benefit

The expected clinical benefit of the ZIRKONUS Dental Implant System lies in the restoration of chewing function as well as natural oral aesthetics in the case of partial or complete tooth loss.

1.4.3. Indication

The ZIRKONUS Dental Implant System is indicated for fixed dentures (single tooth restoration and bridges of unlimited size), also for immediate implantation.

OVERSIZE implants are primarily suitable for the OK posterior region, in the case of height-reduced and strongly flattened alveolar processes, provided that there is predominantly cancellous bone (type 3 and type 4).

The self-tapping SMALL implants IE-SST and IE-SBE are suitable for narrow tooth gaps with usually narrow alveolar processes.

The IE-SBE type is intended for bridge extension, only in rare individual cases it makes sense as a single tooth prosthesis for a narrow gap in the molars area.

The IE-SST type is used for single tooth restoration in the upper and lower jaw anterior region in narrow gaps, ideally in the case of tooth replacement 12/22, e.g. in the case of aplasia or in the case of replacement of the lower jaw incisions 31/32/41/42.

Depending on the bone supply (class A and B) and the bone quality (types 1,2,3,4) with different hardness of the bone, the selection of the different types of implants offered must be made by the practitioner. Assistance for the selection of suitable implants for the bone classes and bone quality types can be found in the following table.

Bone quality → / **Bone quantity ↓**	**TYPE 1** Mainly Compacta, less than 10% cancellous, little elasticity e.g. age-related atrophy or atrophy in the case of non-tooth attachments, problematic when preparing the bone storage due to high hardness	**TYPE 2** Balanced ratio of Spongiosa to Compacta 30% - maximum 60% Spongiosa good elasticity	**TYPE 3** Spongiosa predominates 60% - 90%, but still so much compacta that bone can be easily impressed, still elasticity present	**TYPE 4** Compacta layer is less than 10% in favor of cancellous, compressible, hardly any elasticity no regression after impressing, mostly maxillary posterior region
A Slight to moderate loss of height of the alveolar process, almost complete width of the alveolar process preserved	Preferably Cylindrical Small/ Regular/ Wide/ Large implants possible Rare anatomical conditions	All implant geometries and diameters are possible without restrictions. This type often occurs with recent traumatic tooth loss.	Preferably self-tapping bone-tightening implants of the sizes Oversize, Oversize X, Oversize 2X or Oversize 3X possible, cylindrical implants possible but severely limited indication for small implants	Self-tapping implants of size Oversize, Oversize X, Oversize 2X and Oversize 3X preferred Limited indication for cylindrical implants Contraindication for small implants
B Strong resorption of the alveolar process, at most rudimentary, defects in the jawbone also possible	Prefers cylindrical implants Limited indication for small implants due to risk of fracture during insertion Only for large bone defects Oversize (O, OX, O2X, O3X) implants, otherwise contraindication for OVERSIZE implants	All implant geometries, depending on the desired diameter Good indication for small implants. Only use large bone defects Oversize, Oversize X, Oversize 2X or Oversize 3X implants.	Main indication for self-tapping oversize implants Severely limited indication for cylindrical implants, severely limited indication for small implants due to insufficient primary stability.	Main indication for self-tapping oversize implants Severely limited indication for cylindrical implants, Contraindication for small implants

1.4.4. Contraindication

1.4.4.1. Absolute contraindication

- Infected extraction sockets, larger apical ostitis (bone inflammation) and bone inflammation in the jaw area.
- Serious diseases of the bone, metabolism, blood clotting, circulation, heart and immune system, etc.
- Immunsuppression
- Alcohol or drug abuse

1.4.4.2. Relative contraindication

- Radiotherapie
- Schwere Diabetes, speziell juvenile Diabetes
- Hemorrhagic diathesis or anticoagulation
- Nicotinabusus
- OVERSIZE implants: Average compacts in the mandibular posterior region

1.4.4.3. Local risk factors (= relative local contraindications)

- Erosive or bullous diseases of the mucous membrane of the alveolar process
- Bruxism, Parafunctional Habits
- Severe bone resorption

1.4.4.4. Temporary contraindication

- Untreated periodontitis
- Root residues at the implantation site (possibly immediate implantation after extraction)
- Premises Infekt

* The use of the products must be weighed against the risks on a case-by-case basis and carefully considering the expected clinical benefits

1.4.4.5. Implant-dependent contraindications

Due to the usually narrow alveolar process, OVERSIZE implants are not suitable in the anterior and premolar area.

SMALL implants IE-SST and IE-SBE are contraindicated if there is a large tooth gap with a wide alveolar process. The general principle here is that the entire width of the alveolar process should always be used, i.e. that the largest possible implant diameter should always be chosen.

One-piece implants are not suitable for use in conjunction with bone-building measures and are contraindicated for such procedures.

If load-free healing is not ensured during the healing phase of the implant due to the situation in the patient's jaw, one-piece implants may not be used.

1.4.4.6. Product-specific contraindication ZIRKONUS abutments

ZIRKONUS abutments may only be used for permanent restoration in conjunction with multi-part implants provided for this purpose by ZIRKONUS Implant Systems and are contraindicated for any use with third-party systems.

1.4.4.7. Product-specific contraindication caps

ZIRKONUS caps are not intended for transgingival healing, gingival abuters and healing caps are available for this purpose, see the following chapter.

1.4.4.8. Product-specific contraindication gingival abutments and healing caps

Gingival abutments and healing caps may only be used in preparation for permanent restoration in conjunction with implants provided for this purpose by ZIRKONUS Implant Systems and are contraindicated for any application with third-party systems.

1.4.4.9. Product-specific contraindication of planning basic elements

ZIRKONUS planning base elements may only be used as a support for a temporary restoration on implants from ZIRKONUS Implant Systems and are contraindicated for any application with third-party systems.

1.4.5. Risk Factors / Warnings

1.4.5.1. The risk factor

- Previous or existing therapy with bisphosphonates (intravenous or oral) for the treatment of metastatic disease, osteoporosis, or osteopenia

1.4.6. Possible complications

1.4.6.1. Possible procedural complications

- Post-operative bleeding
- Trauma to the surrounding anatomical structures
- (Persistent) Ache
- Neuropathies or paresthesia
- Inflammation and/or infection (acute or chronic)
- Fistulas (nasal or maxillary sinus)
- Fracture of the jaw
- Reactive hyperplasia of the gingiva
- Keloid
- Untreated implant, unstable implant, implant loss
- Loss of function
- Progressive bone loss
- Increased exploratory depth
- Persistent peri-implant radiolucency

1.4.6.2. Implant-related complications

- Implantatfracture
- Fracture of occlusal materials
- Broken or loosened prosthetic components
- Loss of abutments or screws

1.4.7. Implant-dependent warnings

Classes A3, A4, B1, B3, B4 are critical for self-tapping small implants, and caution is also advised with type 1 bone when inserting bone-densifying conical oversize implants, because a situation could arise whereby the implant cannot be placed in the final position, on the other hand, there are also great difficulties in removing it from the bone because it has seized.

With the implant type IE-SST, it is essential to ensure that the one-sided groove is always directed towards the buccal. It is designed in such a way that the acting chewing force always acts from the back, which has a cylindrical contour parallel to the axis.

1.5. Application, availability, precautions and documentation

The denatle ZIRKONUS implant system is intended exclusively for dentists who are familiar with dental implantology, including diagnosis, preoperative planning, surgical procedure and prosthetic care. Before use, the user must ensure that he has developed and understood the instructions for use, manuals and other product-related information provided by ZIRKONUS. In addition, it is mandatory to attend a training course for the application of the ZIRKONUS dental implant system offered by ZIRKONUS in order to learn the safest technique for the system, since the instructions for use and manuals cannot possibly cover all eventualities in the safe application and replace the personal experience of the tutors.

A product catalogue (attached) is available for the selection of components.

It is the sole responsibility of the user to examine and inform his patients in detail before using ZIRKONUS implants – as usual. In order to reduce liability and ensure optimal implantation success, ZIRKONUS recommends complete clinical, radiological, photographic and statistical documentation of the anamnesis.

1.6. Quality, Warranty and Liability and Development

Development, clinical trials, manufacturing, quality assurance, risk management and market observation are carried out in accordance with Directive 93/42/EEC - Medical Devices Directive and national medical device law.

In principle, there is an exclusion of warranty and liability in the event of improper use of the system components by the user or third parties; this applies in particular to a combination of system components of the ZIRKONUS implant system with third-party products, unless ZIRKONUS has expressly recommended their compatibility. The use of implants and system components of the ZIRKONUS implant system is outside the control of the manufacturer and is the sole responsibility of the user.

The technical advice (oral and written) is carried out in accordance with the state of the art in science and technology when placing the dental ZIRKONUS implant system and its components on the market. It does not relieve the user of the obligation to carefully check their suitability for the intended indications and applications. The procedures for implantation described here are only recommendations, but they are based on many years of experience of the experts of the company ZIRKONUS, from which, however, no assurances or warranty commitments can be derived.

All system components are subject to continuous further development, taking into account the latest progress in the state of the art and new scientific findings. **Changes in construction, design and material are therefore subject to change.**

2. The ZIRKONUS Implant System/System Components/System Description

2.1. Materials used

Only biocompatible materials are used for the system components of the implant system from ZIRKONUS.

For the definitive restoration, zirconium oxide ceramic (ZrO2), which is approved for surgical implants, and the high-performance plastic PEEK (polyetheretherketone) are used.

In addition to zirconium oxide ceramics, ZIRKONUS instruments are also made of the high-performance plastic PPSU (polyphenylsulfone), surgical, stainless steels and titanium.

(e.g. ratchet / ratchet adapter / elbow shanks / coupling bolts / RA shanks)

2.2. Structure of the implant/abutment/dental crown/bridge construction

In the case of implants placed in such a divergent manner, a blocked superstructure can only be realized with the IM system, where the abutments are parallelized for a common insertion direction.

With the IE system, this situation would have to be solved with two single crowns that are not blocked with each other. Blocking of the IE system is only possible up to a total of 15° deviation of the implant axes from each other.

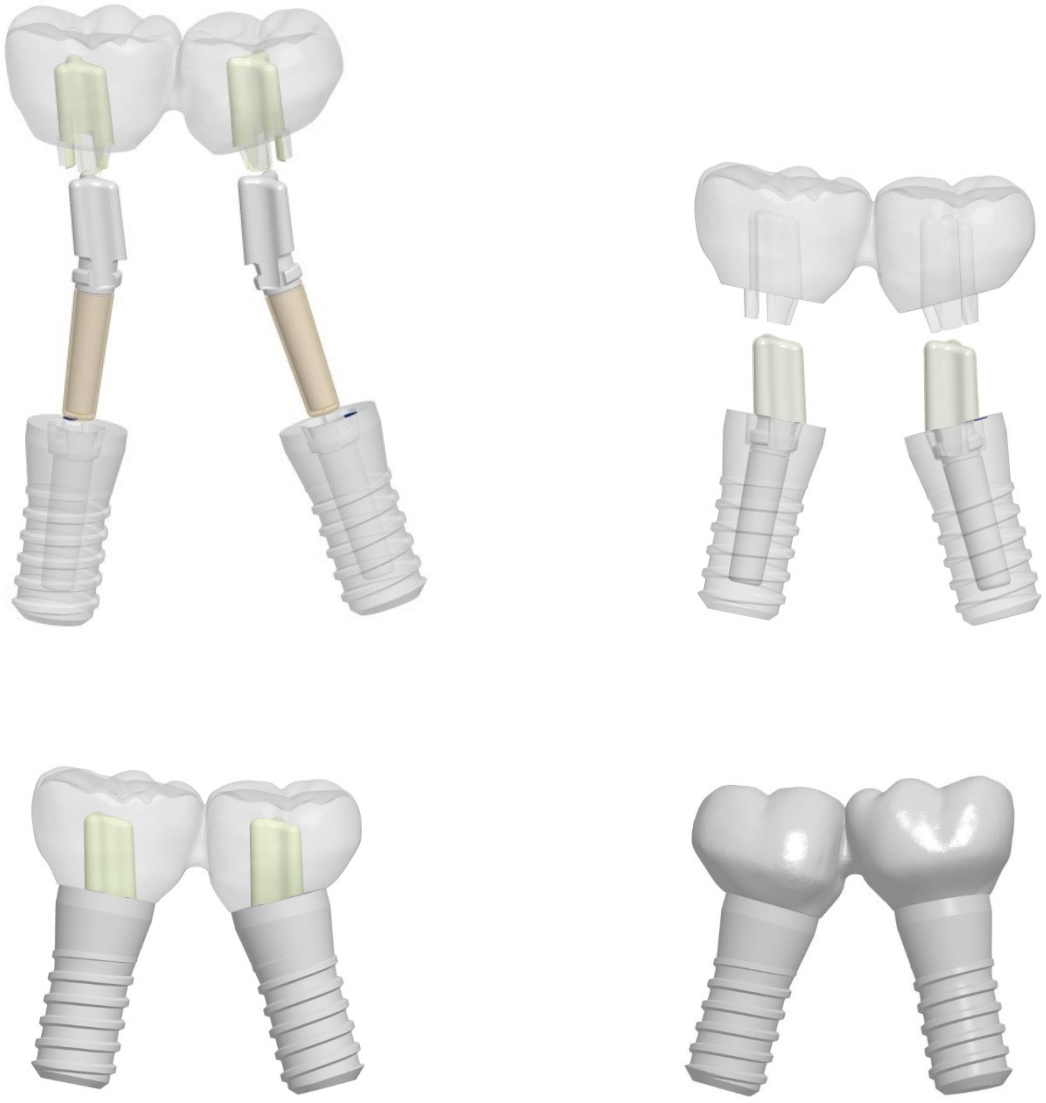


Fig. 2.2-01 Implant, individual abutments, bridge on non-axially parallel implants

A prosthetic restoration with a blocked superstructure is still possible with the IM system up to a divergence of the implant axes to each other of 60°, because the individual abutments can be angled up to 30° in extreme cases, normally axial divergences of 15° per implant should not be exceeded. The height of the abutments can also be individually adjusted according to the situation.

2.3. System Components

2.3.1. Components for sterilization

2.3.1.1. Tray with inserts (in planning)

A flat base cassette made of zirconia is provided for steam sterilization of small parts with various removable dividers.

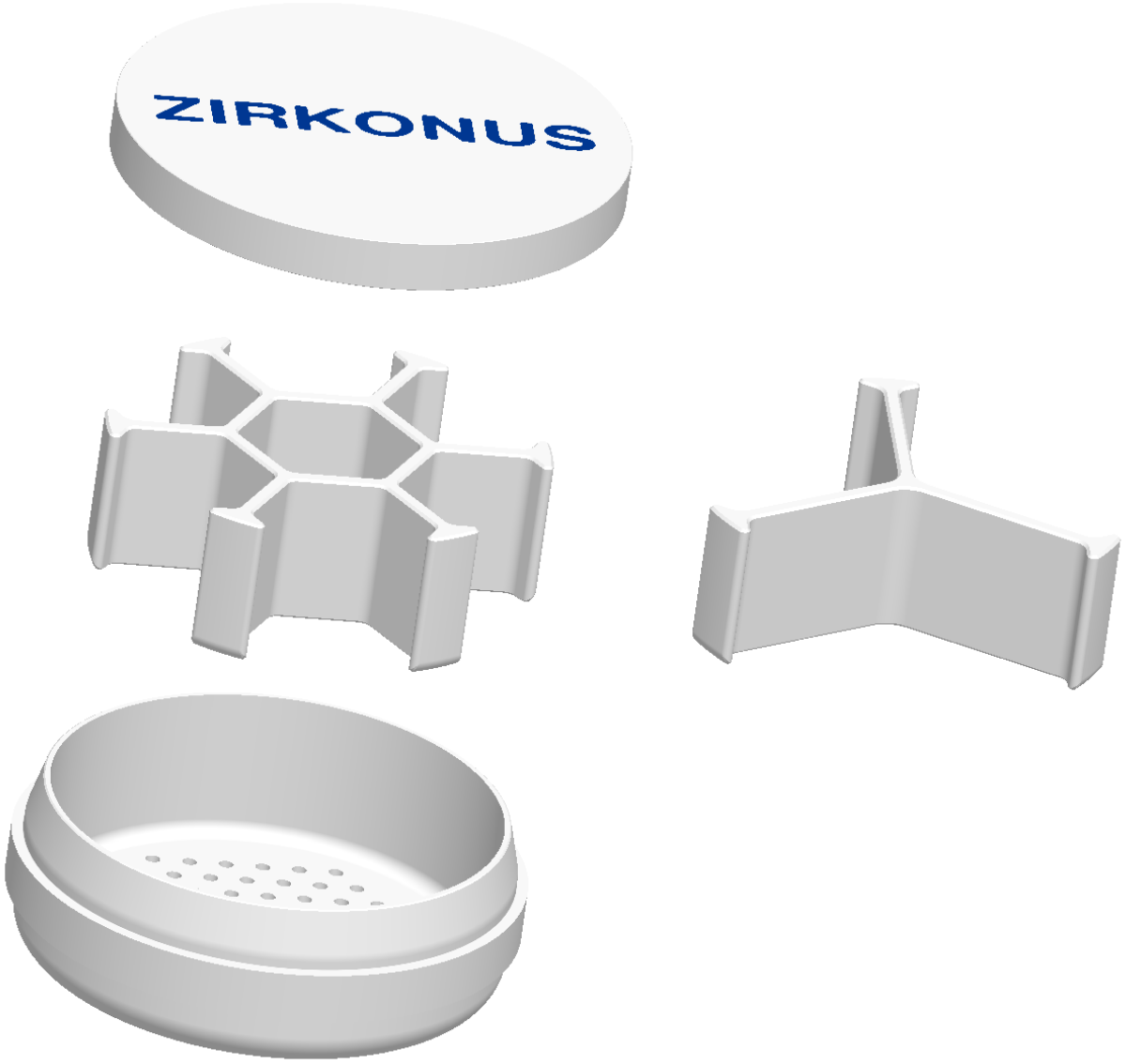


Fig. 2.3-01 Basic cassette made of zirconium oxide with an outer diameter of 80mm, Height 39 mm and inserts

We also provide a cassette with a high lid for instrument carriers. The instrument trays are divided for instruments for small implant diameters: small, regular, wide, large and for large oversize implant diameters.

Fig. 2.3-02 Basic cassette made of zirconium oxide with an outer diameter of 80mm and a high lid (total height 48mm) and for instrument carriers:
Left Fig.: Small Implant Diameter Right Fig.: Large Implant Diameter

Fig. 2.3-05 2 round ceramic containers (basic cassettes) can be placed next to each other in a sterilization box

The sterilization box should have a minimum interior space of length L = 165 mm, width W = 85 mm and height H = 40 mm. Alternatively, the ceramic containers with their contents can also be shrink-wrapped in sterilization foil.

The inserts in the ceramic basic cassettes are used for the orderly storage, cleaning and sterilization of the ZIRKONUS system components. The colour coding on the insert makes it easier to assign them to the implant variants.

2.3.1.2. Film shrink-wrapping method

We generally recommend shrink-wrapping and sterilizing instruments separately according to materials for the respective operation in sensible combinations.

In the case of drills, care must be taken to ensure that the titanium shanks do not come into contact with the ceramic drill bodies in order to avoid metal abrasion on the ceramic (see Fig. 2.3-06 and Fig. 2.3-07)

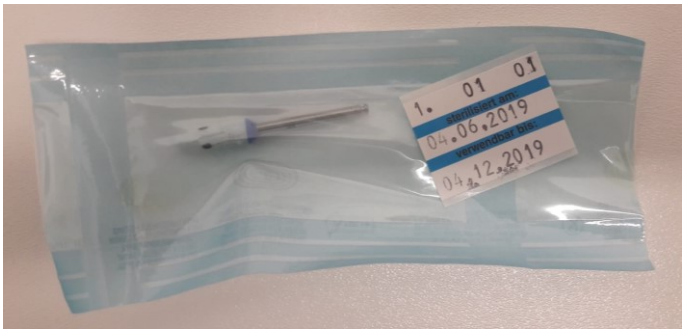


Fig. 2.3-06

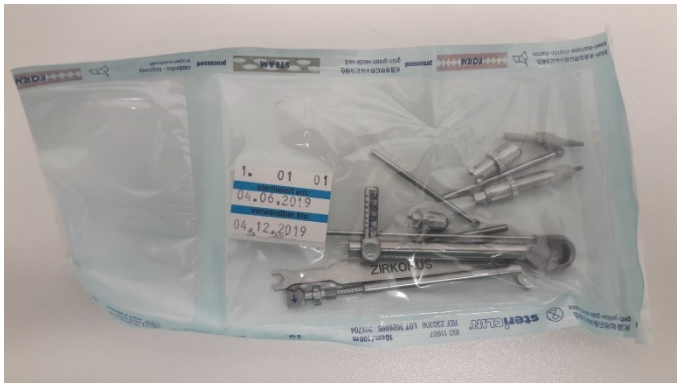


Fig. 2.3-07

When cleaning in the thermal disinfector , it is also important to ensure that the instruments do not have any contact between the ceramic and the metal. The drills are clamped into the grid of the bracket on the titanium shaft.

Assembled instruments such as thread cutters are dismantled for cleaning and sterilization and only put together before use.

Fig. 2.3-08 Instrument holder for thermal disinfector

This is ideal for clamping instruments with titanium shafts. This ensures that the ceramic drill bodies have no contact with the metal during processing.

2.3.2. Instruments for dissection

The system components are supplied non-sterile and can be steam sterilized.

The bone drills for cavity preparation are available in the diameter range from 2.5 to 10 mm.

The depth coding allows an orientation with regard to the depth of the bore and an estimation of the bone level in relation to the later location of the implant.

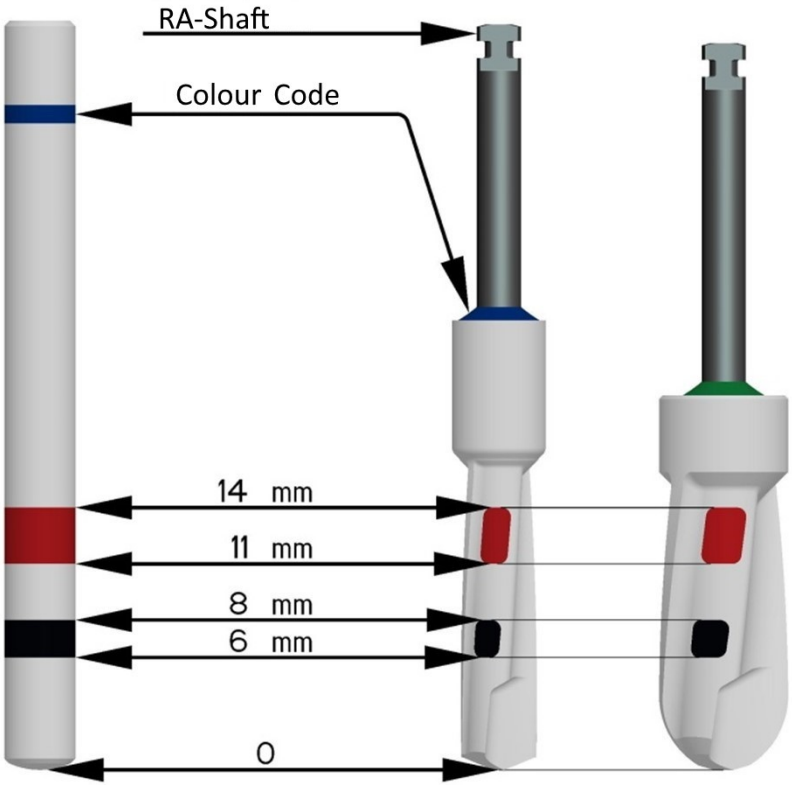


Fig. 2.3-10 Depth gauge, Bone drill, Final drill

For each desired implant diameter, the pre-drilled hole is then shaped with the moulding cutter. The black marking allows an estimate of the later fit of the implant when milling out with the shape cutter.

Sink the cutter until the bone reaches the lower edge of the mark at its lowest point. The general bone level should reach at least to the top of the mark.

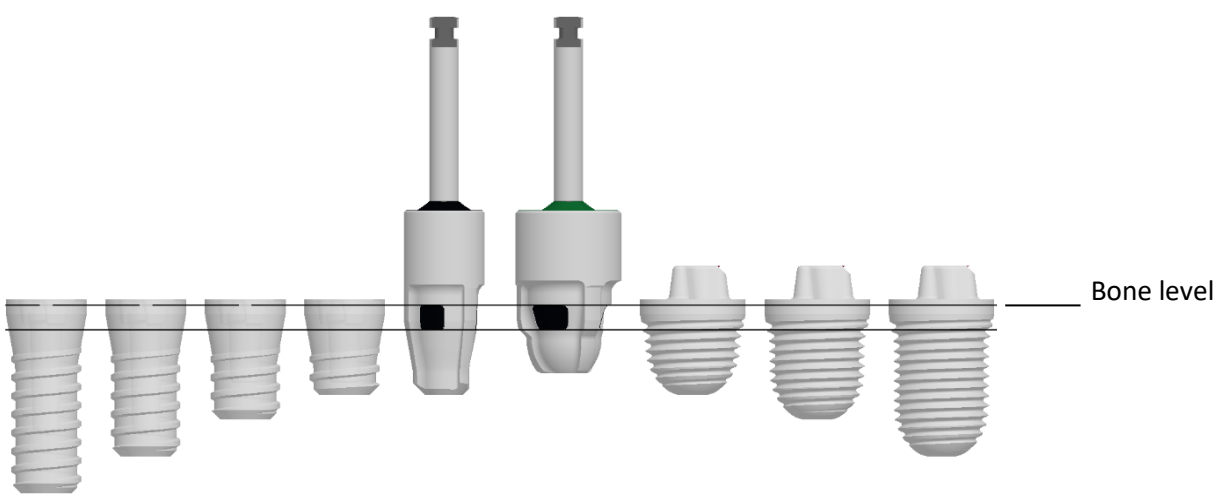


Fig. 2.3.-11: IM-System Moulding cutters IE-System

The instruments for bone preparation are identical for the implant systems.

There are no differences in the external geometry of the implants between the IE and the IM system. In the figure, the IM system is shown on the left as an example for cylindrical implants, on the right the IE system for oversize implants as an example.

Thread Cutter Components

For the implant variants "Regular, Wide, Large", a thread must be pre-cut in the bone.

The tapping instrument consists of three components.

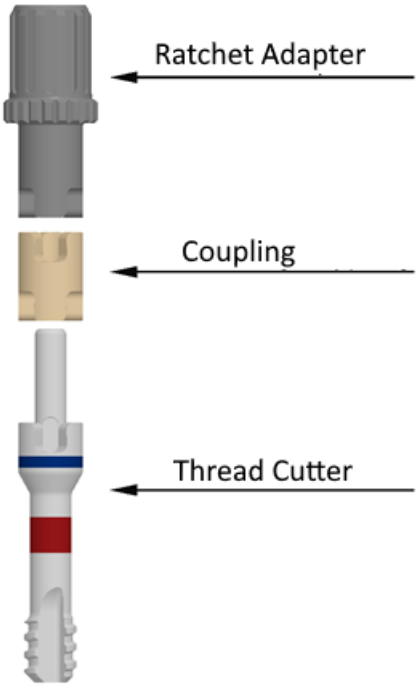


Fig. 2.3-12

The thread cutter (ZrO2) is connected to the ratchet adapter by means of PEEK connection coupling.
It can be steam sterilized, and components can be disassembled!

Gewindeschneider						
GS-R	GS-W	GS-L	GS-R with coupling	GS-R with turning tool 03 for ratchet	with turning tool 08	with turning tool 11
						

Fig.2.3-12a

2.3.3. Instruments for insertion

After removing the implant holder from the blister primary packaging, the implant is coupled into the insertion tool.

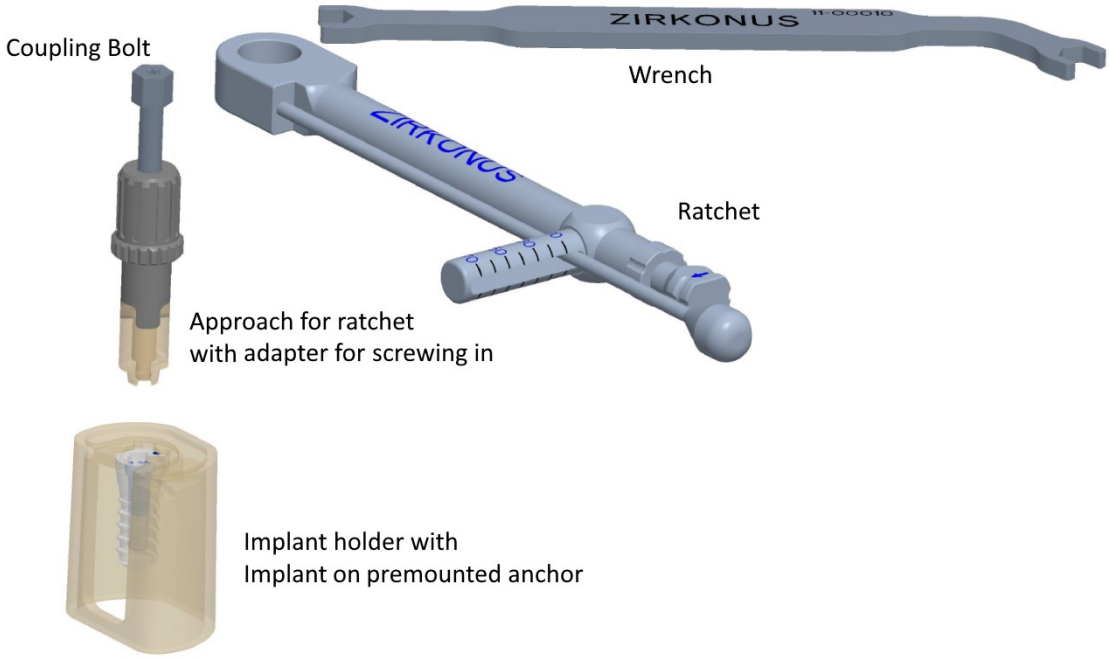


Fig. 2.3-13 multi-part system

Representation of the system components:Screw-in tool consisting of ratchet attachment/screw-in adapter/ratchet/coupling bolt/open-end wrenchImplant in implant holder with pre-assembled anchor part

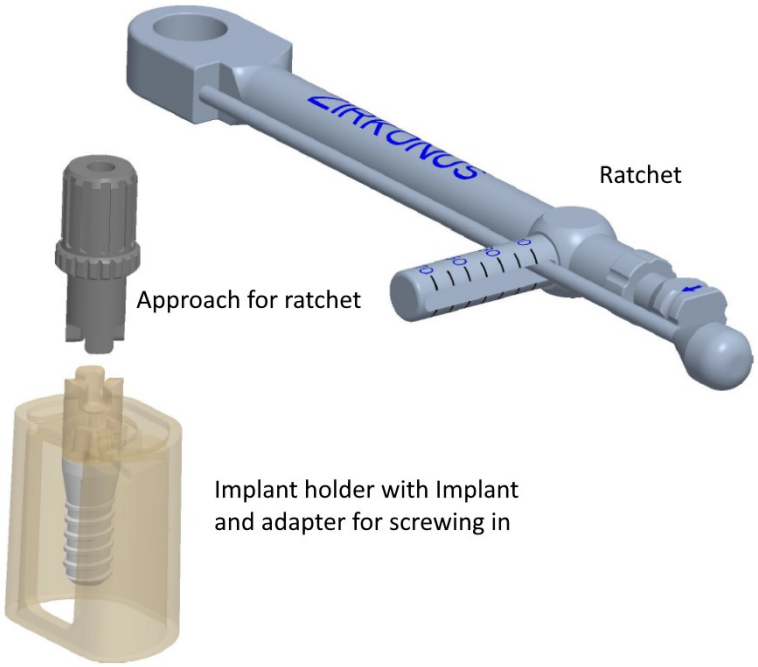


Fig. 2.3-14 one-piece system

2.3.4. Instruments / Parts for Prosthetics

2.3.4.1. Caps / Healing caps

After the implant has been placed or has been exposed, the following geometries are available for each diameter to close the implant and/or shape the gingiva.

Fig. 2.3-15

Cap for subgingival healing

Fig. 2.3-16

Extended Gingiva Shapes

Fig. 2.3-17

Cylindrical gingival former for transgingival healing or after exposure

Fig. 2.3-18

cylindrical gingival former for transginal healing or after exposure

2.3.4.2. Screwdriver for ceramic screw

Interchangeable bits made of PEEK are available for the ratchet adapter or the handpiece drive with shank adapter typ 1 (DIN EN ISO 1797-1), screwdriver Bits S06 in different lengths, suitable only for our ceramic screws.

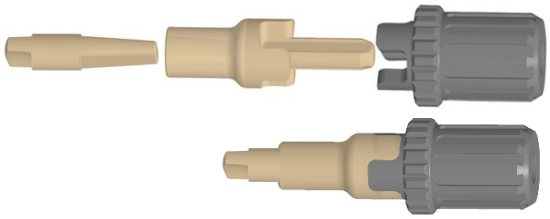


Fig. 2.3-19 a

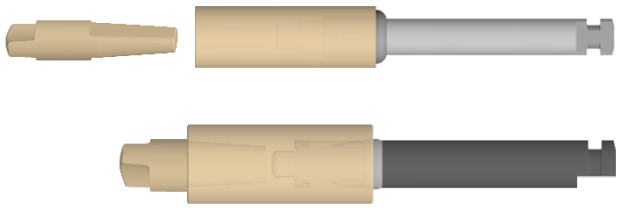


Fig. 2.3-19 b

Screwdriver Bit S06 in different lengths

2,35 x 11mm | 2,35 x 15mm | 2,35 x 20mm | 2,35 x 25mm

Fig. 2.3-19 a

Ratchet attachment with swivel wrench adapter for PEEK bits for ceramic screws, Standard screw-driver for ceramic screws.

Fig. 2.3-19 b

Adapter Twist Wrench for PEEK screwdriver Bits with shank adapter typ 1 (DIN EN ISO 1797-1) for coupling to the angle turner tool

Only use PEEK screwdriver for ceramic screw

Fig. 2.3-20 Flat head

Fig. 2.3-21 High head

2.3.4.3. Rotary wrenches for steel screws

For steel screws, the rotary wrench is provided with a hexagonal and connection for the torque ratchet. It is also used for screwing in SMALL implants, see also Fig. 2.2-23.

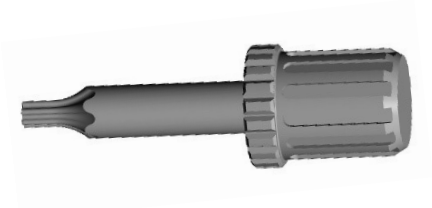


Fig. 2.3-22 Rotary wrench T6

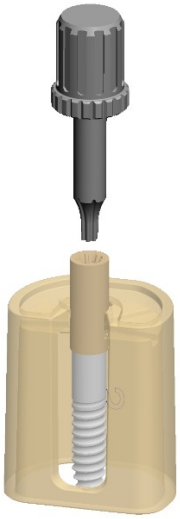


Fig. 2.3-23 Rotary wrench T6 with screw-in cou pling part for SMALL implants

Fig. 2.3-24 Contra-angle wrench

The steel wrenches must never be used for ceramic screws.

2.3.4.4. Screw

Fig. 2.3-25 Screw impression post

Fig. 2.3-26 Screw Scanbody

The screw impression post is described in Figure 3.6-01, screw scanbody see Fig. 3.6-02.

Fig. 2.3-27 Screw anchor

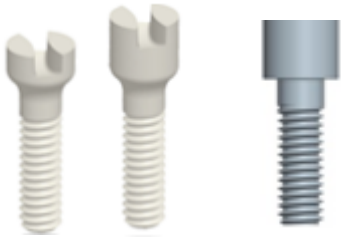


Fig. 2.3-28 Screw PBE (ceramic and steel)

The screw anchor is used in conjunction with the anchor screw-out and screw-in pull-in, see Fig. 3.7-01.

It is also used for the screw pull for the IM system, see Figs. 3.2-02 and Figs. 3.3-02.

The Planning Base Element (PBE) screw is used to fix the planning base elements, which are available in different diameters, see Fig. 2.3-30.

Fig. 2.3-29 sleeve remover tool with sleeve short and long

In the event that a definitive abutment inserted with a sleeve has to be removed again, for example in the event of a fracture or during the try-in, and the sleeve does not stick to the cone of the abutment, but is still stuck to the inner wall of the implant, this ceramic instrument (sleeve remover tool) is very helpful to remove the sleeve from the implant, a few turns of the instrument are sufficient, so that the fine thread builds up adhesion in the malleable PEEK sleeve and so that the sleeve can usually be removed easily and quickly.

2.3.4.5. Planungsbasiselemente (PBE)

After the implants have healed, it is possible to support a fixed, temporary restoration on the implants. For this purpose, planning base elements made of PEEK are available, which can be fixed with steel or ceramic screws. It is advisable to place the flattened phase on the side of the strongest tilt in order to achieve an insertion direction without undercuts.

Ceramic screws are available in case there are concerns about metal in the patient concerned. If necessary, metal can also be completely dispensed with during the provisional supply.

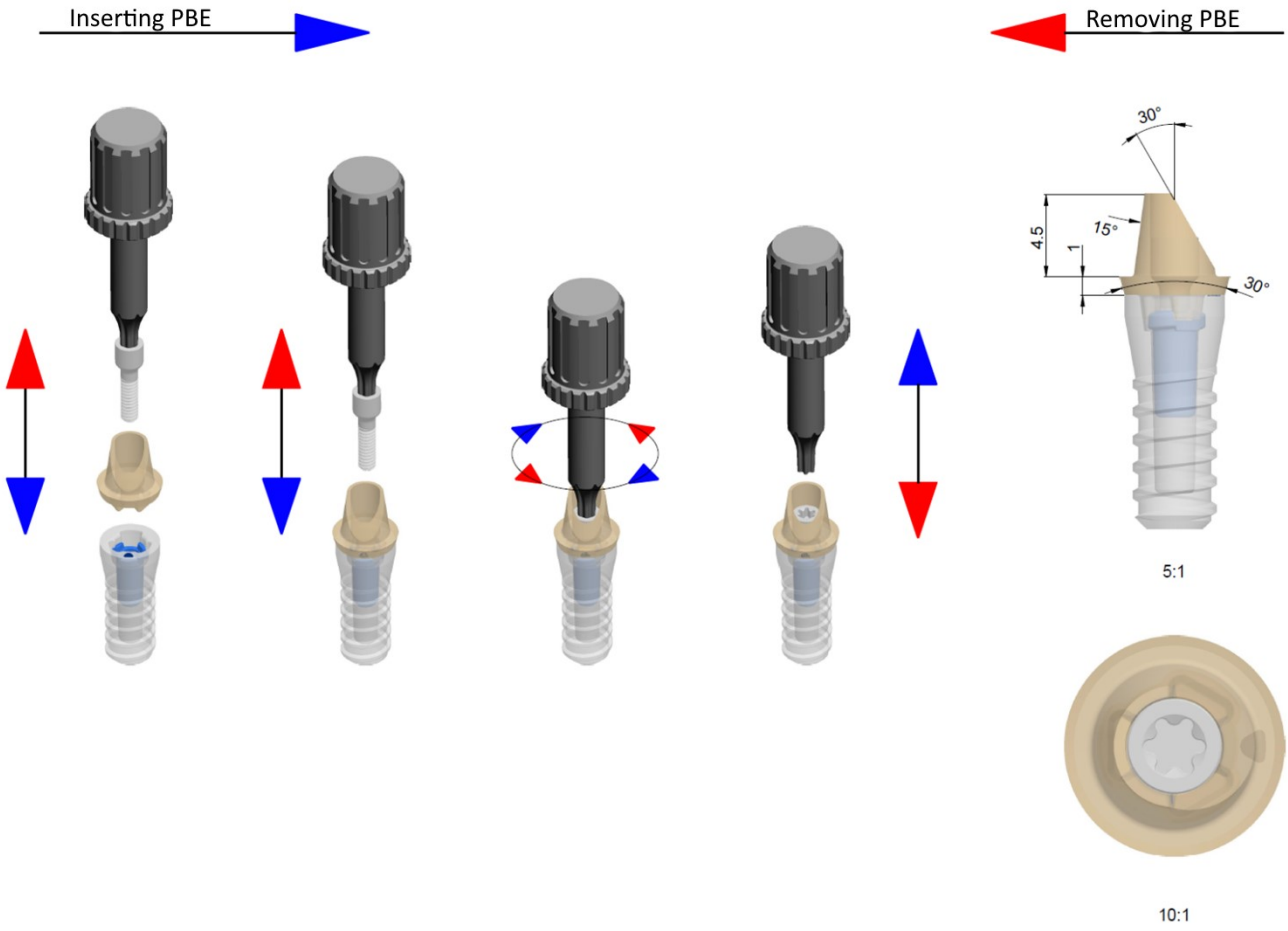


Fig. 2.3-30

The plastic anchor ensures that the steel screw cannot come into contact with the ceramic implant.

2.3.4.6. Anchor Screw-in and Screw-Out Tool

Once all phases of the treatment have been completed, including the impression in the jaw, and the final work on the IM system has been completed with the delivery of the individual abutments and the superstructure but the dental laboratory, the anchor parts must be removed from the implants.

A special instrument, the anchor insertion and removal tool, is available for this purpose.

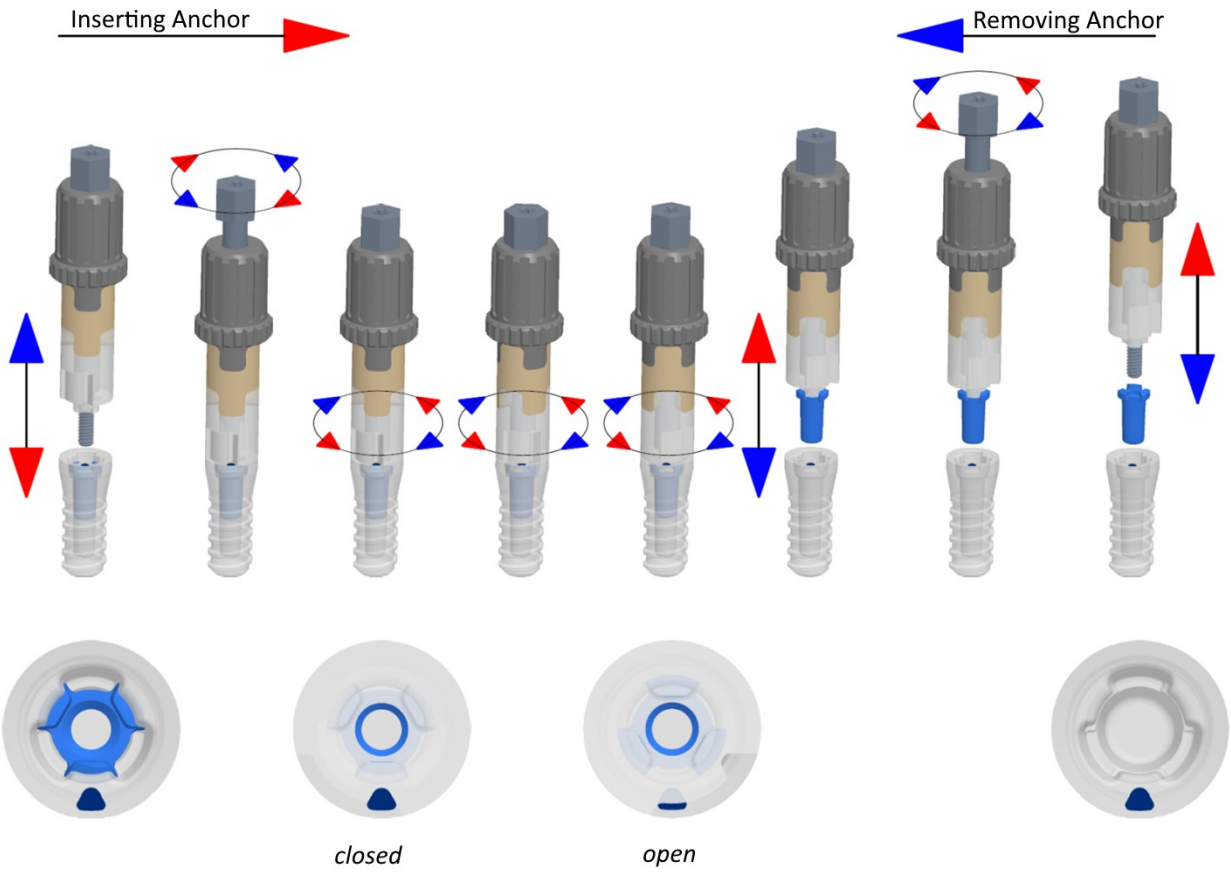


Fig. 2.3-31

Here is an example of how an anchor part can be is removed with the instrument components shown. The dot on the implant is right-aligned in the viewing window, and after turning it to the left, the marking moves to the left edge of the viewing window. In this position, the coupled anchor part can be pulled out of the implant.

Anchor part in implant (as supplied)
Only after the impression has been taken and the scaffolding construction has been completed is the pre-assembled anchor part removed from the implant.

With Same Instrument can be an anchor part can be reinserted into the implant if this should become necessary in exceptional cases, e.g. to attach secondary parts.

2.3.4.7. Planning template

Fig. 2.3-32

Often, an experienced surgeon does not need 3D X-ray diagnostics for surgical planning with the production of drilling templates. If possible, the patient should be spared the considerable radiation exposure caused by CT/CBCT images. In particular, the resolution of dental CBCT images is worse than CT images, and in addition, there is also a transcription error when fixing the drilling templates in the jaw, especially if they are supported by mucous membranes, so that for this reason alone it is not possible to place them with millimeter precision.

In general, however, the planning template we developed for drawing through on printed OPG is very helpful, it is designed for the commonly used magnification factor 1:1.2.

The templates contain a safety area of approx. 2mm on all sides, as distortions and insufficiently accurate magnification ratios must be expected during X-ray diagnostics. In addition, it can be assumed that a height offset error can occur in the case of implantation. In general, an overestimation of the bone supply of up to 6% must be taken into account.

However, it should also be taken into account that, depending on the location, distortions of 30% to 70% in the horizontal direction of some devices can amount to 20% to 30% in the vertical direction, and it must also be taken into account that the magnification factor within an image can fluctuate between a factor of 1.1 and 1.3. In this respect, it is still unavoidable to fix reference bodies of known geometry enorally in the area of desired implant positions and to produce X-ray images, so that a conclusion can be drawn about the distortion factor at the desired implant position from the representation of the reference bodies.

In this context, it is helpful if the planning template is placed over the printed OPG image for each X-ray patient after the implant has been placed, in order to determine how the magnification and distortion factor of the patient's own device is in different locations in order to take these important findings into account for further surgical planning for other patients.

2.4. Color coding

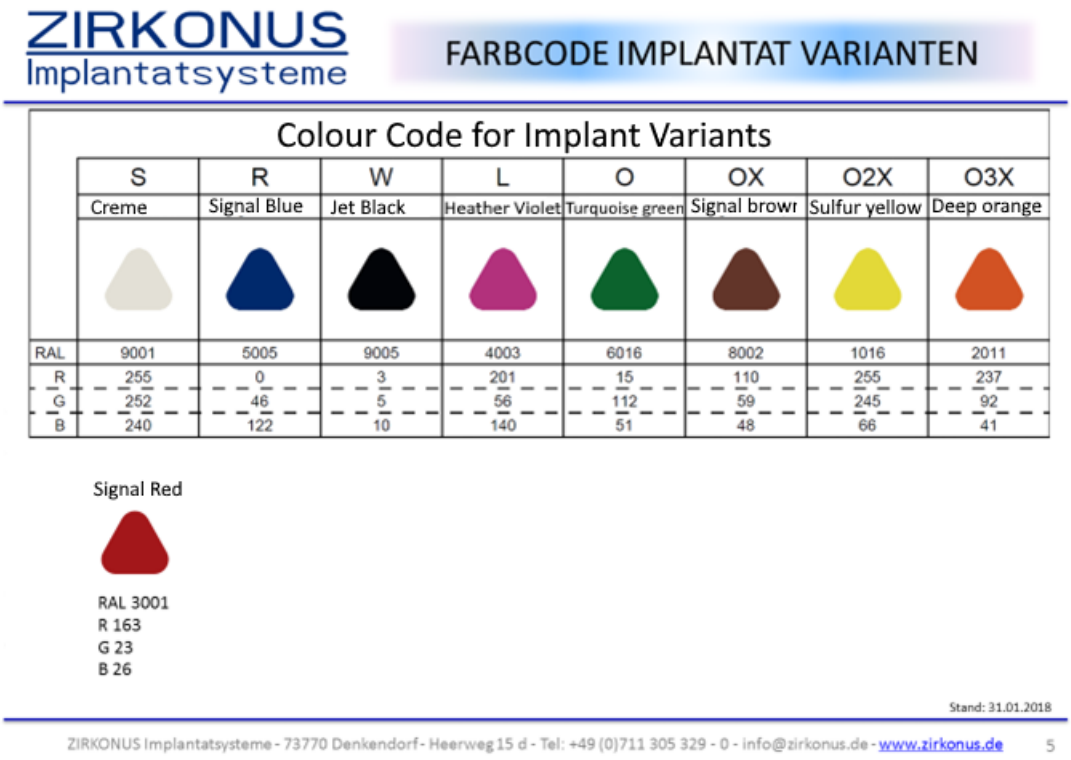


Fig. 2.4-01

The color coding makes it easier to assign system components to the implant variants. The implant diameters are color-coded on the implant shoulder.

3. Procedure of the treatment

3.1. Bone preparation

Drilling should always be carried out intermittently (drill the drill should also be pulled completely out of the bore-hole), whereby drilling should only be carried out for 2 to 3 seconds and under low pressure to the desired depth at speeds according to Fig. 3.1-02 with a maximum drilling depth increase of 1-2 mm. It is important to ensure that the outer area, the drill and the cavity are constantly cooled with pre-cooled (5°C to 8°C) sterile physiological saline solution in order to prevent excessive heating and possible damage to the bone tissue. In addition, bone chips can be removed or rinsed off.

In addition, care must be taken to ensure that the drill does not tilt and get stuck during use (risk of breakage).

At the location of the planned borehole, the drilling site should first be marked with a rose drill by inserting a small trough in order to prevent slipping during the (first) pilot drill.

After the pilot drilling, the core hole diameters are extended to the desired depth between 6 mm and 14 mm in ascending order to the desired core hole diameter between 3 mm and 10 mm with appropriate bone drills and final drills.

The bone bed is then conically shaped with the moulding cutters. This guarantees an optimal fit of the implant in the bone.

A thread is then pre-cut for REGULAR, WIDE and LARGE implants. The SMALL and OVERSIZE implants are self-tapping, no thread needs to be pre-cut.

*This **Surgical Manual** is an **Instruction for use and handling** of the ZIRKONUS implant system*

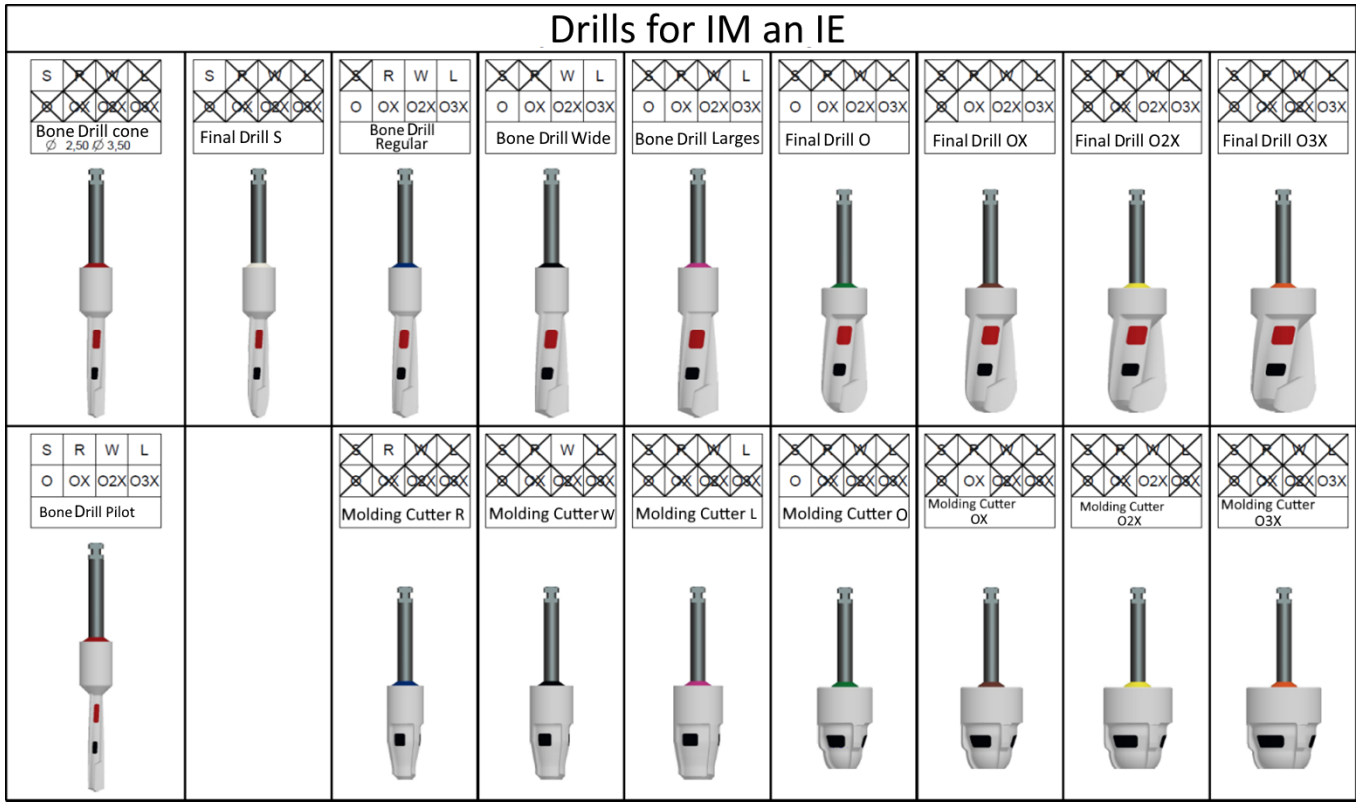


Fig. 3.1-01

Speed recommendations

	Designation	MatchCode	Speed-ecommendation [rpm]		Designation	MatchCode	Speed Recom-mendation [rpm]
1	Bone Drill Pilot	KB-P	800				
2	Bone Drill Cone	KB-K	800				
3	Final Drill Small	FB-S	600				
4	Bone Drill Regular	KB-R	600		Moulding Cutter R	FF-R	300
5	Bone Drill Wide	KB-W	400		Moulding Cutter W	FF-W	300
6	Bone Drill Large	KB–L	400		Moulding Cutter L	FF-L	250
7	Final Drill O	FB–O	250		Moulding Cutter O	FF-O	250
8	Final Drill OX	FB–OX	200		Moulding Cutter OX	FF-OX	200
9	Final Drill O2X	FB–O2X	200		Moulding Cutter O2X	FF-O2X	200
10	Final Drill O3X	FB–O3X	200		Moulding Cutter O3X	FF-O3X	200

Fig. 3.1-02

See also the instructions for use and preparation attached to the appendix.

3.2. Detachment from the packaging / attachment of the tool in the case of one-piece and multi-part systems

This is followed by the removal of the sterilized implant body from the blister packaging.

In the one-piece system, the screw-in adapter made of PEEK is pre-mounted on the implant. The ratchet adapter must be attached to the screw-in adapter with light pressure (see Fig. 3.2-01). The implant can then be removed from the implant holder and screwed into the prepared bone cavity.

In the multi-part system, the screw-in tool, consisting of ratchet adapter and screw-in adapter, is placed on the implant fixed in the implant holder (see Fig. 3.2-02) so that the recess of the screw-in adapter lies on the nose of the implant holder and the marking of the implant.

Then the coupling bolt is pushed through into the insertion tool from above and screwed to the anchor part located in the implant until the insertion tool is completely coupled to the implant.

Without having to touch the implant with your fingers, it can be pulled out of the holder sideways with a jerk.

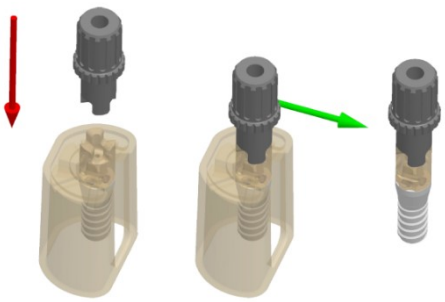


Fig. 3.2-01 One-piece system

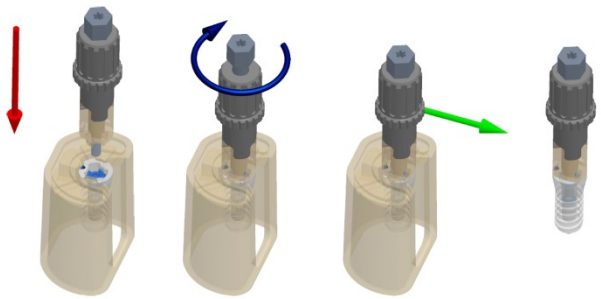


Fig. 3.2-02 Multi-part system

3.3. Insertion of the implant into the prepared bone cavity

The implant insertion tool – complex is inserted into the pre-prepared bone storage and then the implant is screwed into the final position using the ratchet. The maximum insertion torque of 35 Ncm must not be exceeded.

The screw-in tool is then decoupled and removed.

Fig. 3.3-01 One-piece systemFig. 3.3-02 Multi-part system

Subsequently, the implant can be closed with a cap for subgingival healing or with a gingival abutment for transgingival healing after insertion.

See Figures 2.3-17, 2.3-18, 2.3-19 in Chapter 2.3.3.

For wound care, it is important not to use any keratinized mucous membrane – for example by punching the mucous membrane – but to transfer it to the vestibular by means of mucosal flap plasty.

Monofilament or braided suture material is recommended for fixation.

3.4. Exposing

After the healing period/healing phase (usually 6 to 12 weeks), the implant is exposed with the removal of the sealing cap or the healing cap.

See figures in Chapter 2.3.3.

3.5. Support / fastening of the temporary supply:

The basic planning elements are suitable for attaching the temporary/waxup. The basic planning element is designed in such a way that the mucous membrane is kept away from the implant shoulder.

Until the ceramic abutments / scaffolds are delivered, a temporary/waxup is made for the patient on the planning base elements (PBE). This is the time at which the patient loses his removable temporary, which has been supported on the mucous membrane since then. The new fixed temporary prosthesis is now supported by the implants that have been placed.

See Figure 20 in Chapter 2.3.3.

3.6. Model production / procedure of the production of a superstructure

Insertion of an impression post

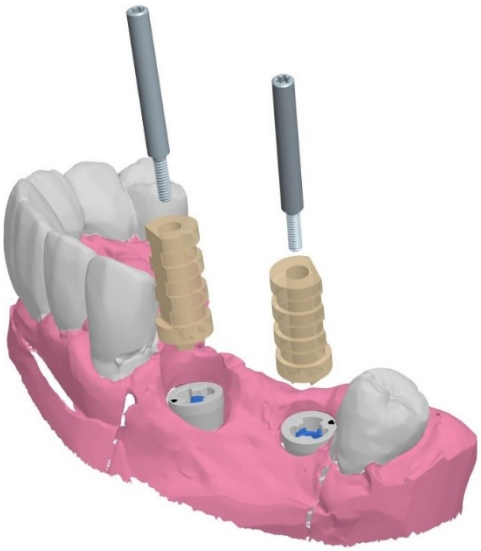


Fig.3.6-01

mounted scanbody

Fig. 3.6-02

After an individual spoon has been produced, an impression of the jaw situation with the implant positions is taken using a conventional impression technique with plastic impression material.

After the plaster model has been made using the ZIRKONUS manipulation implants, the scan bodies are placed and coupled on the manipulation implants located in the plaster model by means of web bolts.

Now the 3D model creation is carried out in the usual way with a suitable scanner (Imetric, ZFX, Evolution or 3Shape 900 series).

First of all, the external geometry of the desired bridge construction must be determined with a suitable dental planning software (e.g. Exocad, etc.). This data must then be transmitted to the company ZIRKONUS Implantatsysteme via ZIRKONUS UPLOADER using the website www.zirkonus.de by data transfer. From there, the data is transferred to the ZIRKONUS planning program and further processed.

The geometry of the individual abutments as well as that of the crowns and bridge construction, including the framework holders, are finally planned at ZIRKONUS and prepared for subsequent production in all-ceramic (zirconium oxide). An intermediate impression is no longer necessary.

Example of a standard abutment:

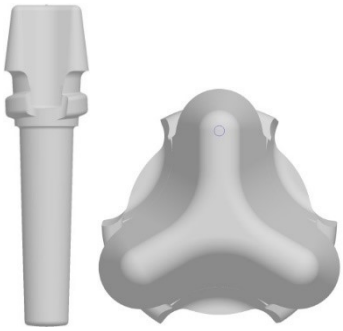


Fig. 3.6-13

Example of an individual abutment:

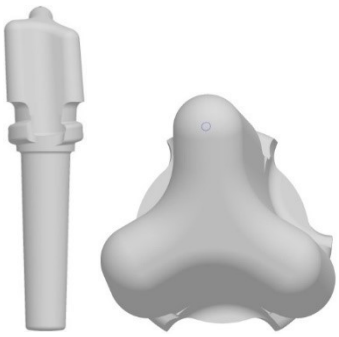


Fig. 3.6-14

Procedure for the production of a superstructure

Abb. 3.6-03 Planung

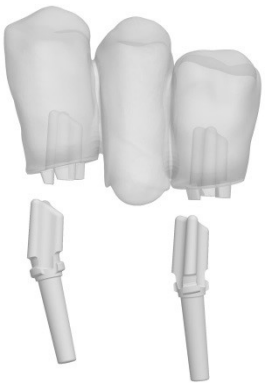


Fig. 3.6-04 Production

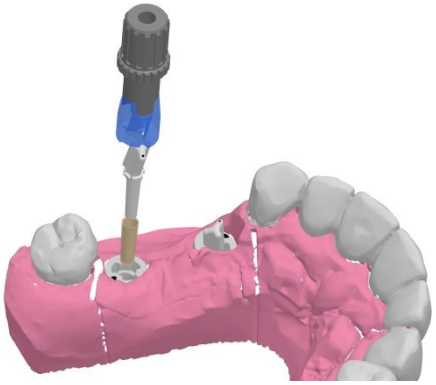


Fig. 3.6-05 Abutment and sleeve

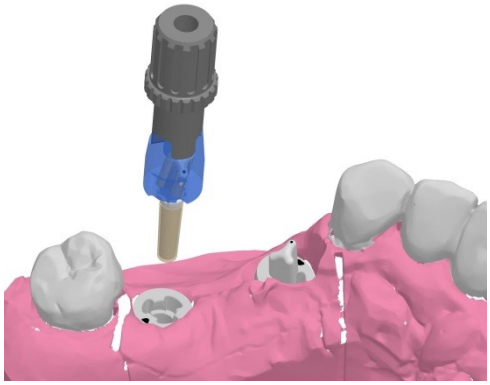


Fig. 3.6-06 Insertion

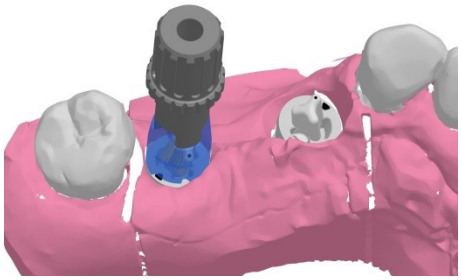


Fig. 3.6-07 inserted, before final popsition

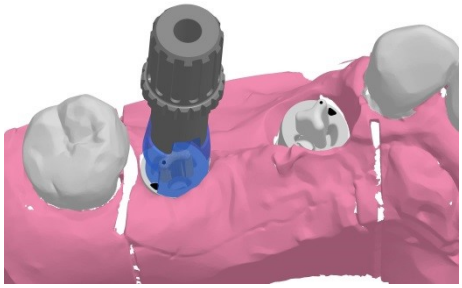


Fig. 3.6-08 inserted, in the end position (60°)

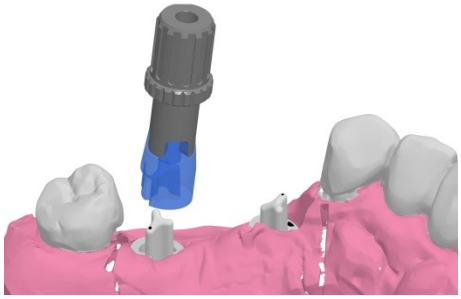


Fig. 3.6-09 Distance adapter

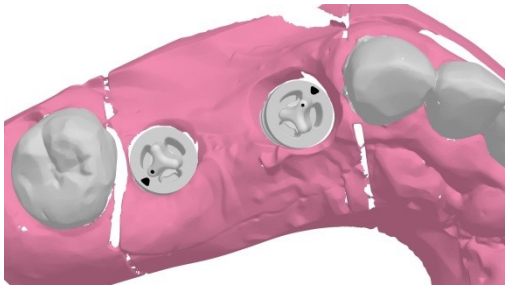


Abb. 3.6-10 Abutment in Endposition

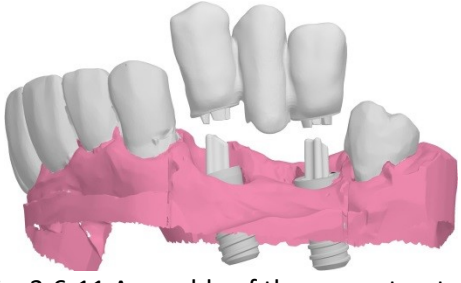


Fig. 3.6-11 Assembly of the superstructure

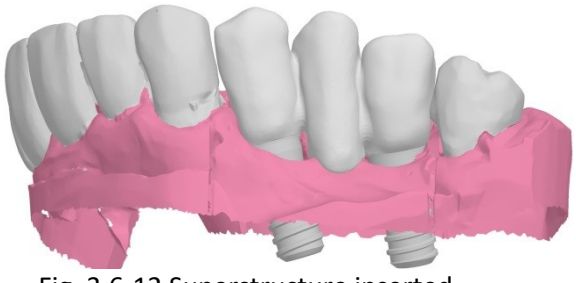


Fig. 3.6-12 Superstructure inserted

3.7. Insertion of the abutments / scaffold construction, replacement of the anchor part

After completion of the abutment and scaffolding construction, the anchor parts must first be removed from the implants.

To this end, the following procedure must be followed:

- Removal of the temporary solution
- Removal of the planning base elements from the implants (loosen screw connections)
- Attaching the anchor unscrewing tool and screwing in the coupling bolt for a firm coupling to the anchor part, see Fig. 3.7-01.
- Left rotation by 60° (see marking of the viewing window)
- If the **triangle mark** on the top of the implant shoulder is partially concealed on the left edge of the viewing window in the viewing window, the anchor unscrewing tool can be pulled out with the lever part unlocked, see Fig. 3.7-01.

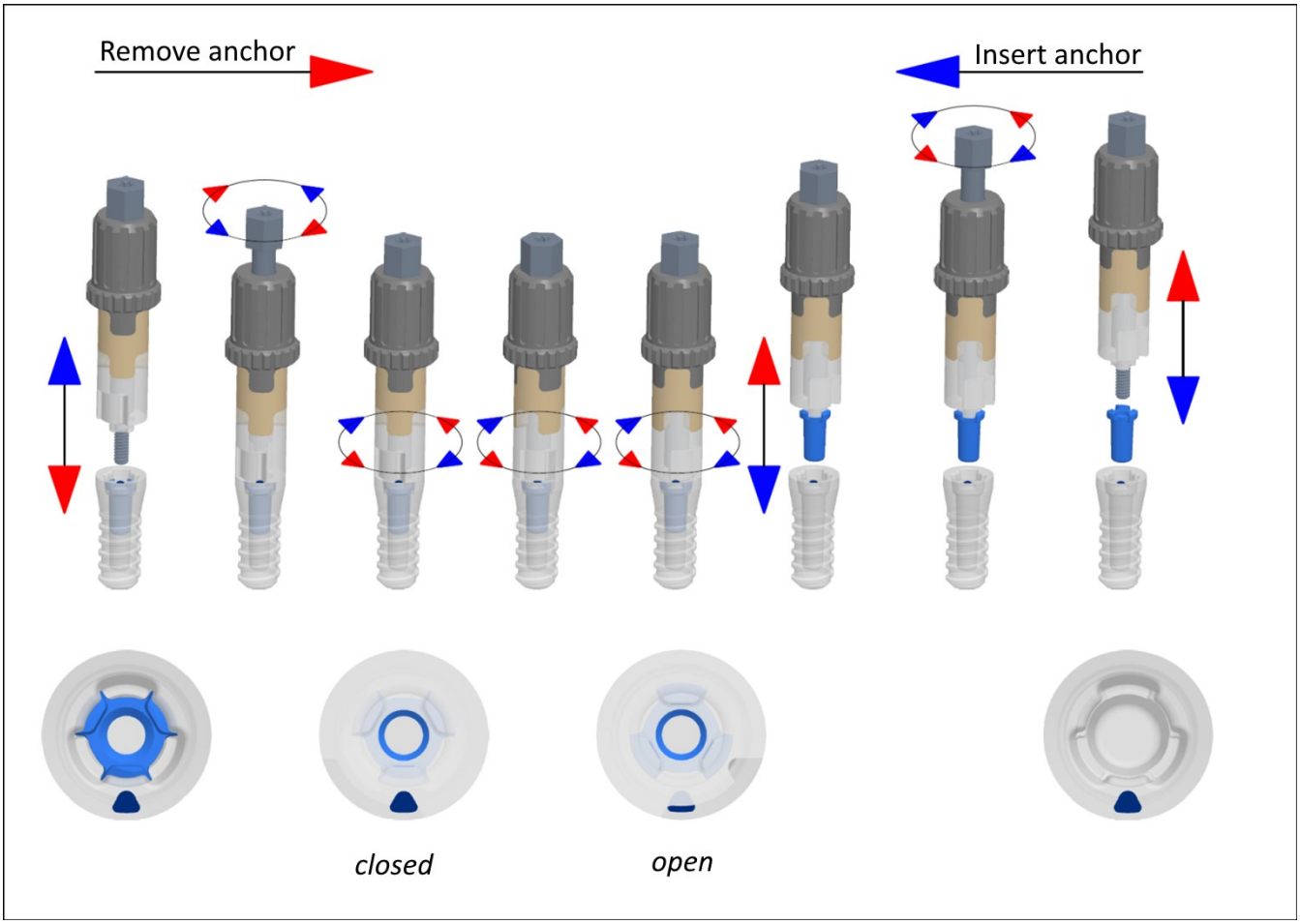


Fig.: 3.7-01

3.8. Insertion of the sleeve/abutment/temporary or superstructure

Insertion of the abutment and sleeve using the supplied coupling parts and screw-in tools (please note: the mark must be completely visible in the viewing window (see Fig. 3.8-01)!

Normally, the bridge that has already been made can be inserted without an intermediate impression and the case is thus closed.

In the event that paint or other corrections to the bridge construction are necessary, the following measures will be necessary:

1. Removal of the abutments including sleeves (by means of coupling part, back rotation, left rotation by 60 degrees)
2. Reinsertion of the anchor parts, see Fig. 3.8-01 → Implementation in reverse order!
3. Reattachment of the planning base elements (PBE) or sealing caps in the case of removable interim prosthetics
4. Insertion of the temporary bridge restoration or insertion of the removable interim prosthetics
5. Re-appointment of the patient for definitive insertion of the abutments and bridge construction after correction

   (see 3.7. Insertion of the abutments / scaffold construction)

The illustration shown below is the procedure for the multi-part system!

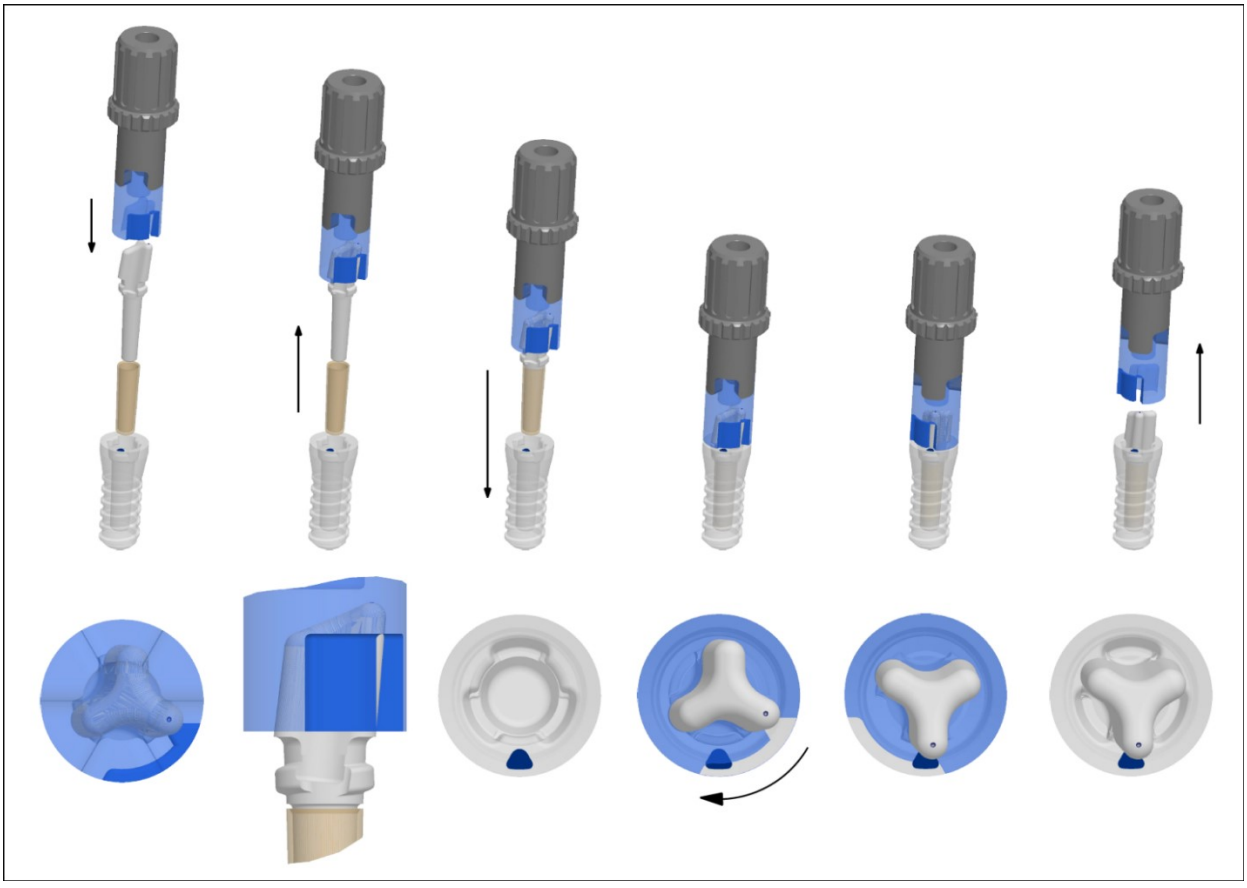


Fig.: 3.8-01

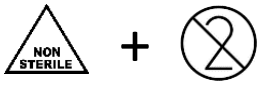
Colour marking fully visible in the viewing window Abutment in correct position

*This **Surgical Manual** is an **Instruction for use and handling** of the ZIRKONUS implant system*

With **the one-piece** system, there is no need to insert the abutment, as the implant body and abutment already form a single unit.

4. Reprocessing of surgical instruments and system components

Surgical instruments and drills supplied by ZIRKONUS are delivered non-sterile and are reusable. The products must be subjected to a complete reprocessing process before their first and each subsequent application.



Prosthetic and system components supplied by ZIRKONUS are also delivered non-sterile and are designed for single use. These products must not be reused and must be subjected to a complete reprocessing process once before use.

For clear identification of the products, please note the information and symbols on the labelling as well as the respective information in the product-specific instructions for use, which is included with each product. For information on validated processes for the preparation of the products, please refer to the corresponding product-specific instructions for use, which are included with each product:

Product group	Delivery form	Again-applicability	Preparation	Directions for use
ZIRKONUS Prosthetic and System Components (Abutments, healing caps, screws, caps, sleeves	Unsteril 	Single use 	• Machine cleaning • Thermal disinfection • Sterilisation (Dampf)	A 201 - Instructions for use implant system
ZIRKONUS Drill Bit (bone drills, moulding cutters, final drills)	Unsteril 	Max 20 treatment cycles	• Machine cleaning • Thermal disinfection • Sterilisation (Dampf)	A 200 - Instructions for use and preparation
ZIRKONUS surgical instruments (Adapter, Twist Wrench, Thread Cutter	Unsteril 	Max 20 treatment cycles	• Machine cleaning • Thermal disinfection • Sterilisation (Dampf)	A 200 - Instructions for use and preparation

5. Transport and storage of implants

Transport and storage of the packaged sterile goods is dust, moisture and recontamination protected.

The delivery condition of the ZIRKONUS implants is sterile. The implants are sterilely packaged in a special blister and colour-coded. The selected implant is only removed from the sterile packaging immediately before insertion.

The implants must be stored in their intact sealed packaging in a dry place protected from light and moisture under the following storage conditions:

Instructions for use: A 201 - Instructions for use implant system

- Temperatur: +10°C bis +30°C
- Relative humidity [RH]: 30% - 65%

6. Marking / Symbols


Manufacturer within the meaning of Directive 93/42/EEC

Note: NOT STERILE

LOT number

Article


Follow the instructions for use


Attention: Observe warnings!

Note: Sterilized with ethylene oxide

YYYY-MM
Expiration date


Note: do not reuse!


Note: do not resterilize!


Note: protect from moisture


Note: Protect from direct sunlight


Note: do not use in case of damaged sterile packaging


Note: Storage Conditions Temperature


Note: Storage conditions Humidity

CE mark with identification number of the notified body

0483 mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart


ZIRKONUS Implantatsysteme GmbH & Co. KG
Bahnhofstraße 18
D-71034 Böblingen / Germany

7. Specific error possibilities when dealing with the system

The colour marking on the implant shoulder is a new development. It serves as a guide for the insertion of auxiliary parts and definitive prosthetic parts. With the help of coupling parts, for example, abutments are brought into the correct position. In the viewing window, it is then clearly visible when the correct position of the abutment has been achieved with a 60° rotation, see also Figs. 3.6-05 to Figs. 3.6-10 and also Figs. 3.8-01. It is important that this is done exactly. The use of magnifying glasses is recommended. An instrument with a viewing window display is also available for the anchor part, see Fig. 3.7-01.

Furthermore, it is essential to ensure that while screws are screwed in, the auxiliary part/attachment part lies firmly on the implant shoulder, otherwise there is a risk that the anchor part inside the implant is turned into the wrong position (see Fig. 5.0-01). If the anchor part is in the extension position, it must be rotated clockwise by 60° to the correct position (Fig. 5.0-02) using the anchor ON-OFF rotary tool.

Incorrect seat of the anchor part

(Anchor part unlocked)

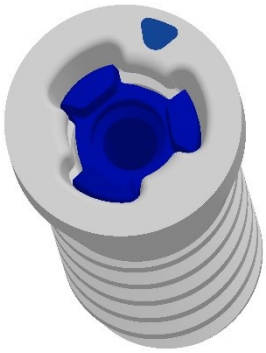


Fig.: 5.0-01

Correct fit of the anchor part

(anchor part locked)

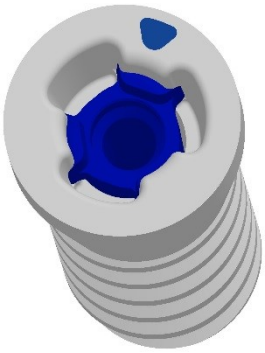


Fig.: 5.0-02

Please note:

- Appropriate measures must be taken to avoid the risk of aspiration when using all system components and prosthetic parts.
- Never bring ceramic parts together with steel parts, not even when cleaning, disinfecting and sterilizing.
- No use of force if, for example, parts do not fit together exactly, e.g. because mucous membrane has become trapped between the implant and the gingival aformer.
- For tightening and loosening the ceramic screws, e.g. for fastening HDK and PBE, only the PEEK BIT may be used, never the ceramic BIT
- Ceramic screws can only be screwed in and out with the PEEK bits.
- For impressions with impression posts, the steel screws "Screw Impression Post" (S-AFP) should be used.

  Never use the BIT rotary wrench in the ceramic version for metal screws! This is only to be used in emergencies to loosen ceramic screws that are stuck due to concrements.
- The metal screw does not match the ZrO2 screw for attaching the HDK & PBE.
- When taking impressions, when positioning the PEEK impression posts, care must be taken to ensure that they sit on the implant shoulder without gaps, i.e. there must be no mucous membrane trapped

between the components. This is the only way to ensure that the 3D model later matches the situation in the jaw. The positioning of the impression post (flattening aligned to the color dot on the implant shoulder) ensures that the exact alignment of the manipulating implant on the model corresponds to the situation in the jaw. This later makes it easier to install the individual abutments in the respective implant.

- We recommend having the zirconium superstructure fully anatomical in the molar area, reduced in the front area for cosmetic reasons for the burning of a glass-ceramic because of the better translucency.
- If the peri-implant bone resorption exceeds 3 mm above shoulder height, the patient must be informed by the practitioner that there is an incalculable risk that the implant construction will break, fall out, or aspirate or be swallowed.

8. Imprint

Company:

ZIRKONUS Implantantsysteme GmbH & Co. KG

Bahnhofstraße 18

D-71034 Böblingen

Permanent business establishment:

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D-73730 Denkendorf

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Fax: +49 (0)711 305329 – 29

Email: info@zirkonus.de

Website: www.zirkonus.de

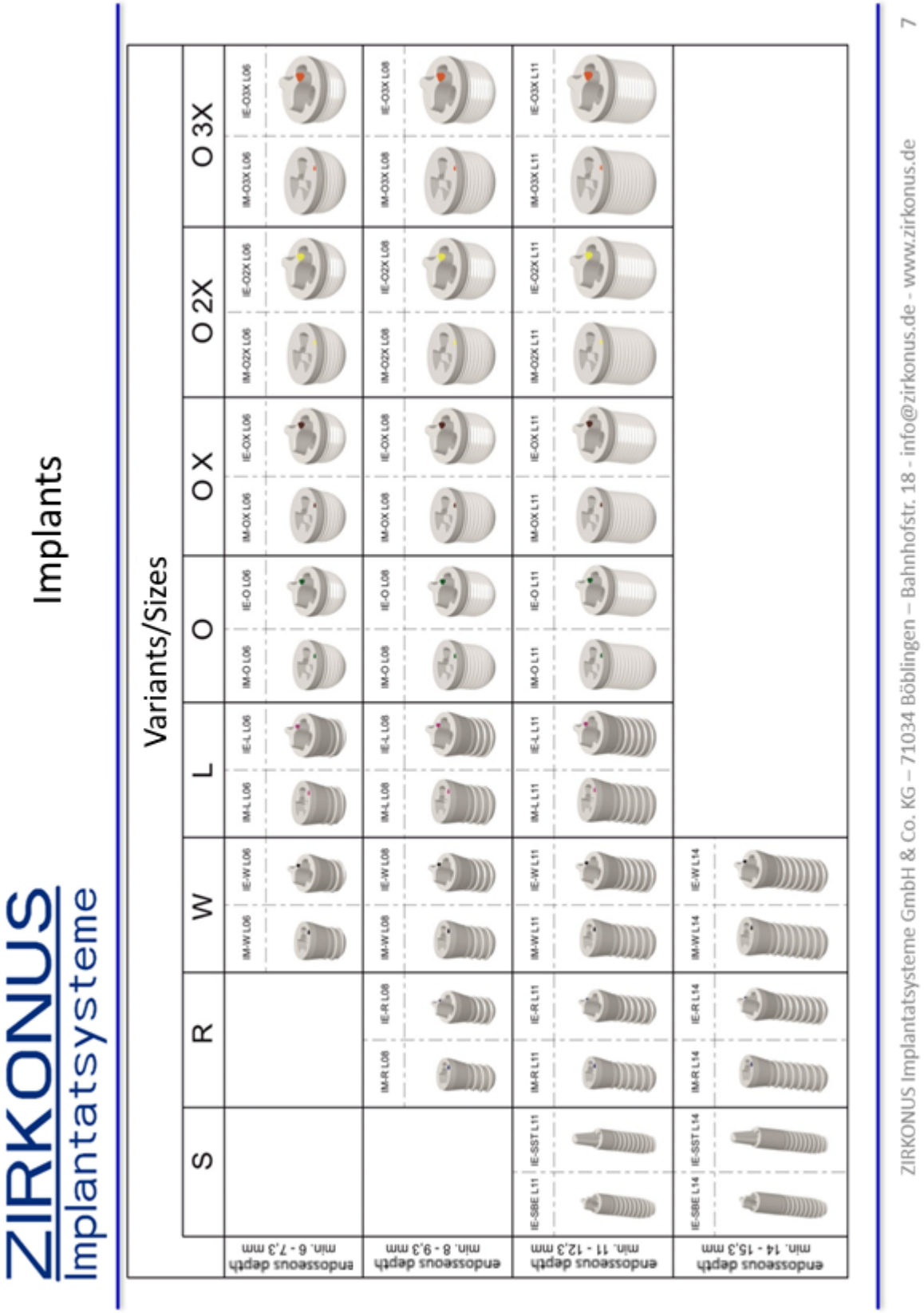
District Court Stuttgart HRA 736740

Managing Director: Dr. Dr. Gerd Axel Walther

Top-IdNr.: DE329492060

9. Grounds:

9.1. Overview Implant Variants and Sizes



9.2. Overview of multi-part implants

ZIRKONUS Implantatsysteme

Implants

Multi-part system

Size-Variants

Ø5,50 Ø4,60 Ø4,05	Ø6,50 Ø5,60 Ø5,05	Ø7,50 Ø6,60 Ø6,05	Ø8,50 Ø7,70 Ø6,90	Ø9,50 Ø8,70 Ø7,90	Ø10,50 Ø9,70 Ø8,90	Ø11,50 Ø10,70 Ø9,90	Plate Ø Cylinder Ø Drill Ø	Min. Enossal	Length				Colour Code	
Regular	Wide	Large	Oversize	Ovesize X	Oversize 2X	Oversize 3X			6 mm	8 mm	11 mm	14 mm		
	IM-W L06 (5606501)	IM-L L06 (5607501)	IM-O L06 (5608501)	IM-OX L06 (5609501)	IM-O2X L06 (5610501)	IM-O3X L06 (5611501)								
IM-R L08 (5605502)	IM-W L08 (5606502)	IM-L L08 (5607502)	IM-O L08 (5608502)	IM-OX L08 (5609502)	IM-O2X L08 (5610502)	IM-O3X L08 (5611502)								
IM-R L11 (5605503)	IM-W L11 (5606503)	IM-L L11 (5607503)	IM-O L11 (5608503)	IM-OX L11 (5609503)	IM-O2X L11 (5610503)	IM-O3X L11 (5611503)								
IM-R L14 (5605504)	IM-W L14 (5606504)													

9.3. Overview Implants One-Piece

ZIRKONUS Implantatsysteme

Implants

Single-part System

Size-Variants

Small Bridge Extension	Small Single Tooth	Regular	Wide	Large	Oversize	Ovesize X	Oversize 2X	Oversize 3X	min. Enossal	length				Colour Code	
										6 mm	8 mm	11 mm	14 mm		
Ø3,50 Ø3,50 Ø3,20	Ø3,50 Ø3,50 Ø3,20	Ø5,50 Ø4,60 Ø4,05	Ø6,50 Ø5,60 Ø5,05	Ø7,50 Ø6,60 Ø6,05	Ø8,50 Ø7,70 Ø6,90	Ø9,50 Ø8,70 Ø7,90	Ø10,50 Ø9,70 Ø8,90	Ø11,50 Ø10,70 Ø9,90	Plate Ø Cylinder Ø Drill Ø						
			IE-W L06 (5606506)	IE-L L06 (5607506)	IE-O L06 (5608506)	IE-OX L06 (5609506)	IE-O2X L06 (5610506)	IE-O3X L06 (5611506)							
		IE-R L08 (5605507)	IE-W L08 (5606507)	IE-L L08 (5607507)	IE-O L08 (5608507)	IE-OX L08 (5609507)	IE-O2X L08 (5610507)	IE-O3X L08 (5611507)							
IE-SBE L11 (5603508)	IE-SST L11 (5603510)	IE-R L11 (5605508)	IE-W L11 (5606508)	IE-L L11 (5607508)	IE-O L11 (5608508)	IE-OX L11 (5609508)	IE-O2X L11 (5610508)	IE-O3X L11 (5611508)							
IE-SBE L14 (5603509)	IE-SST L14 (5603511)	IE-R L14 (5605509)	IE-W L14 (5606509)												

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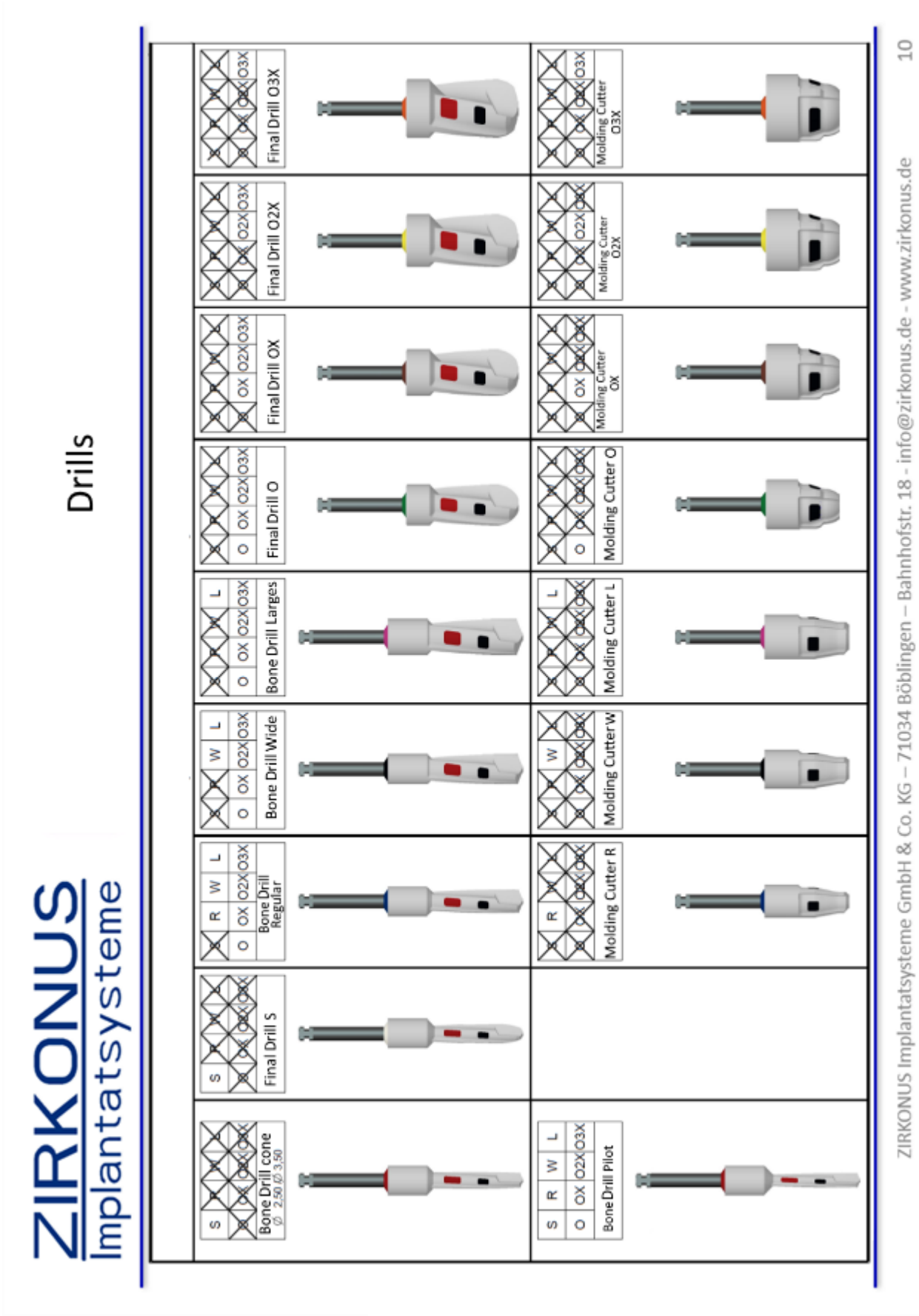
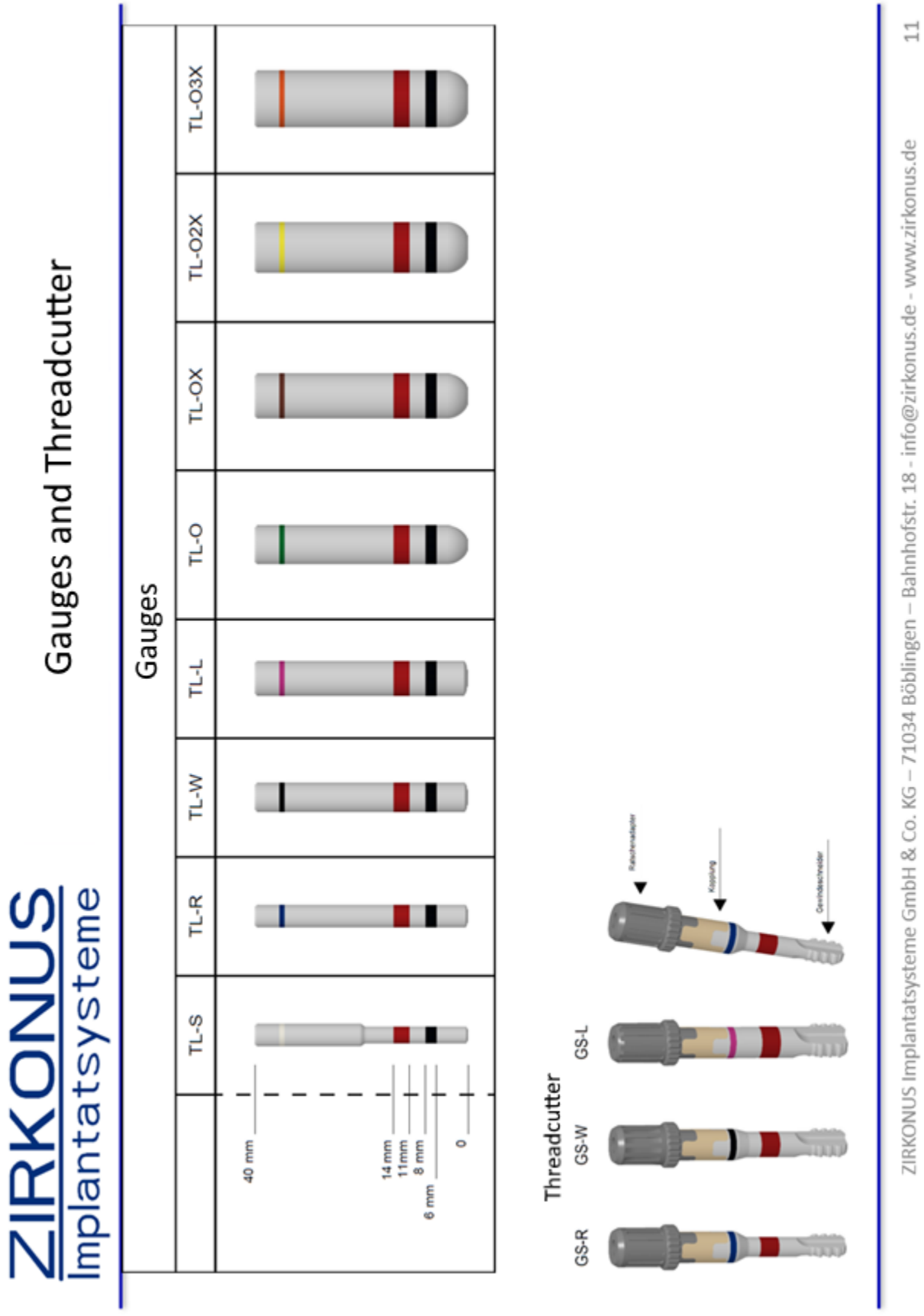
8

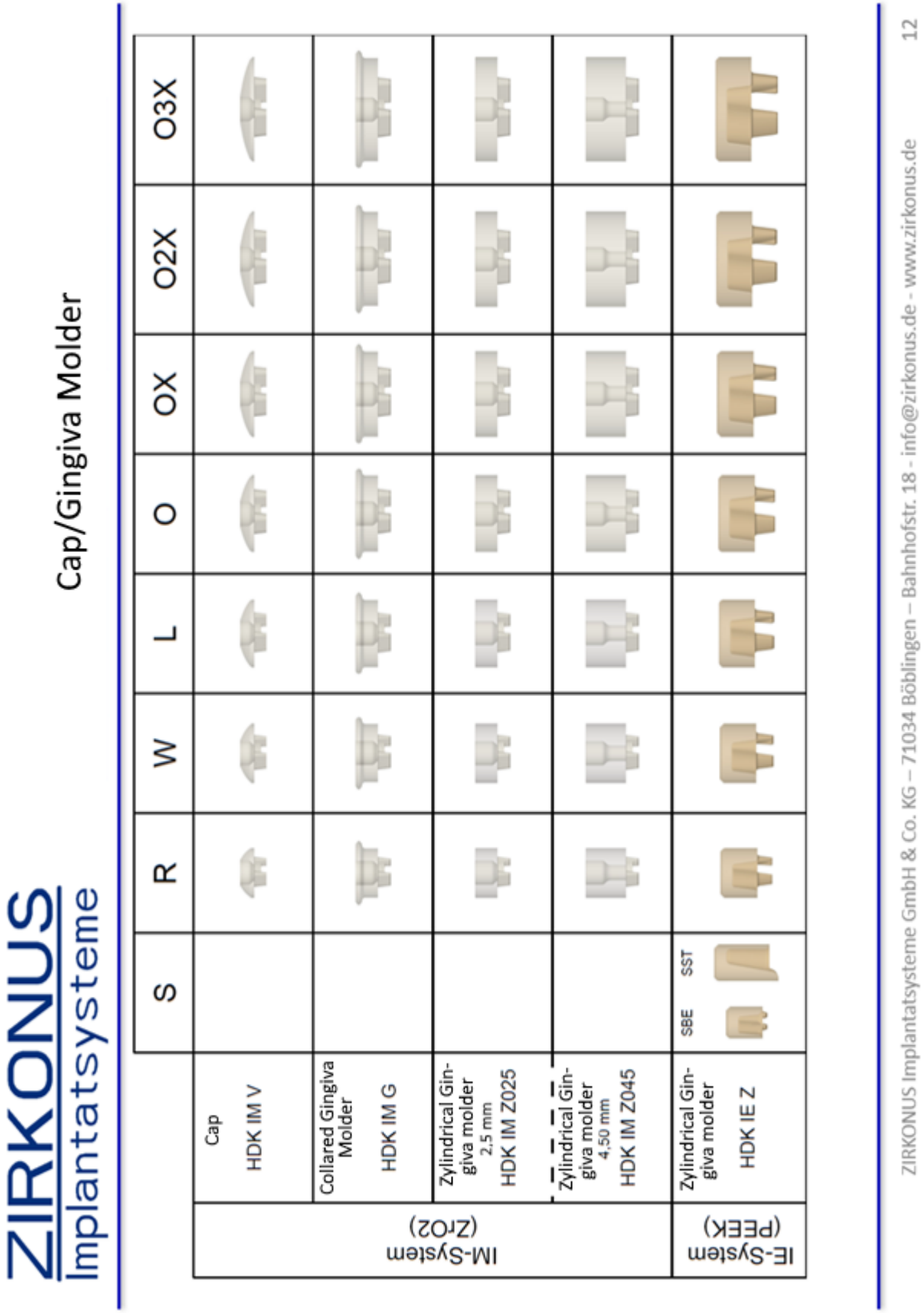
9.4. Overview of rotating instruments



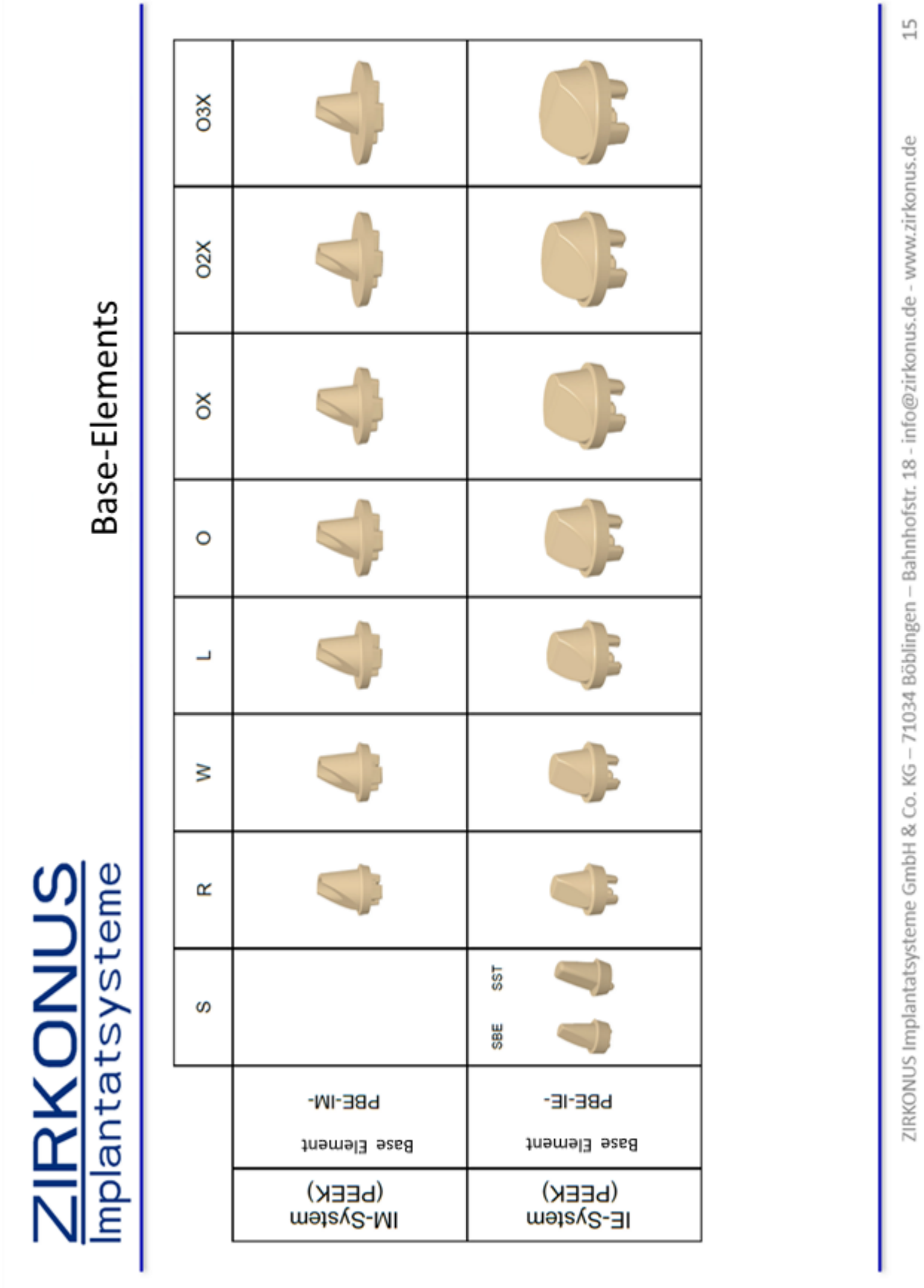
9.5. Overview of depth gauges and thread cutters



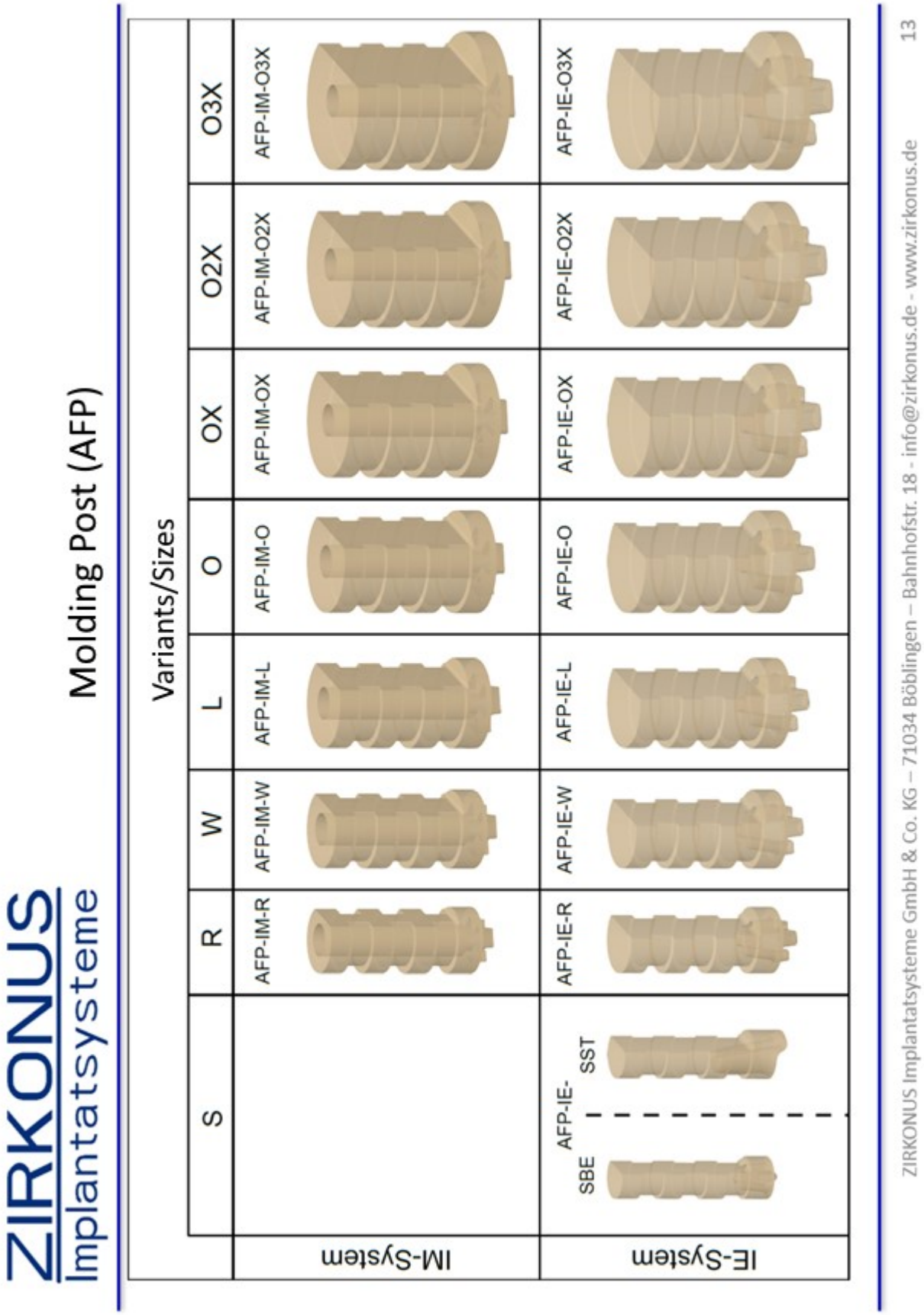
9.6. Overview Cap - Gingival Abutment



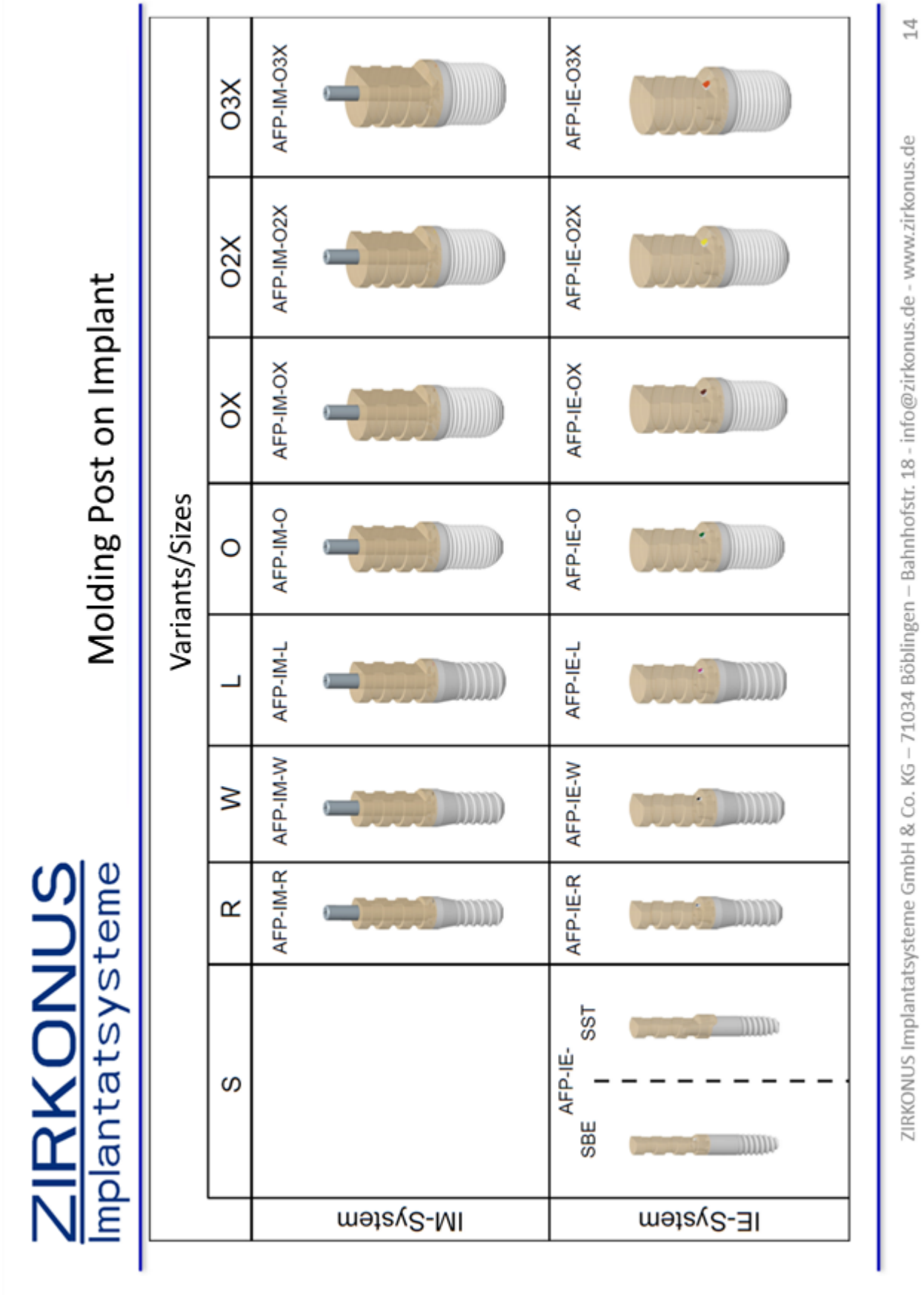
9.7. Overview of planning basic elements



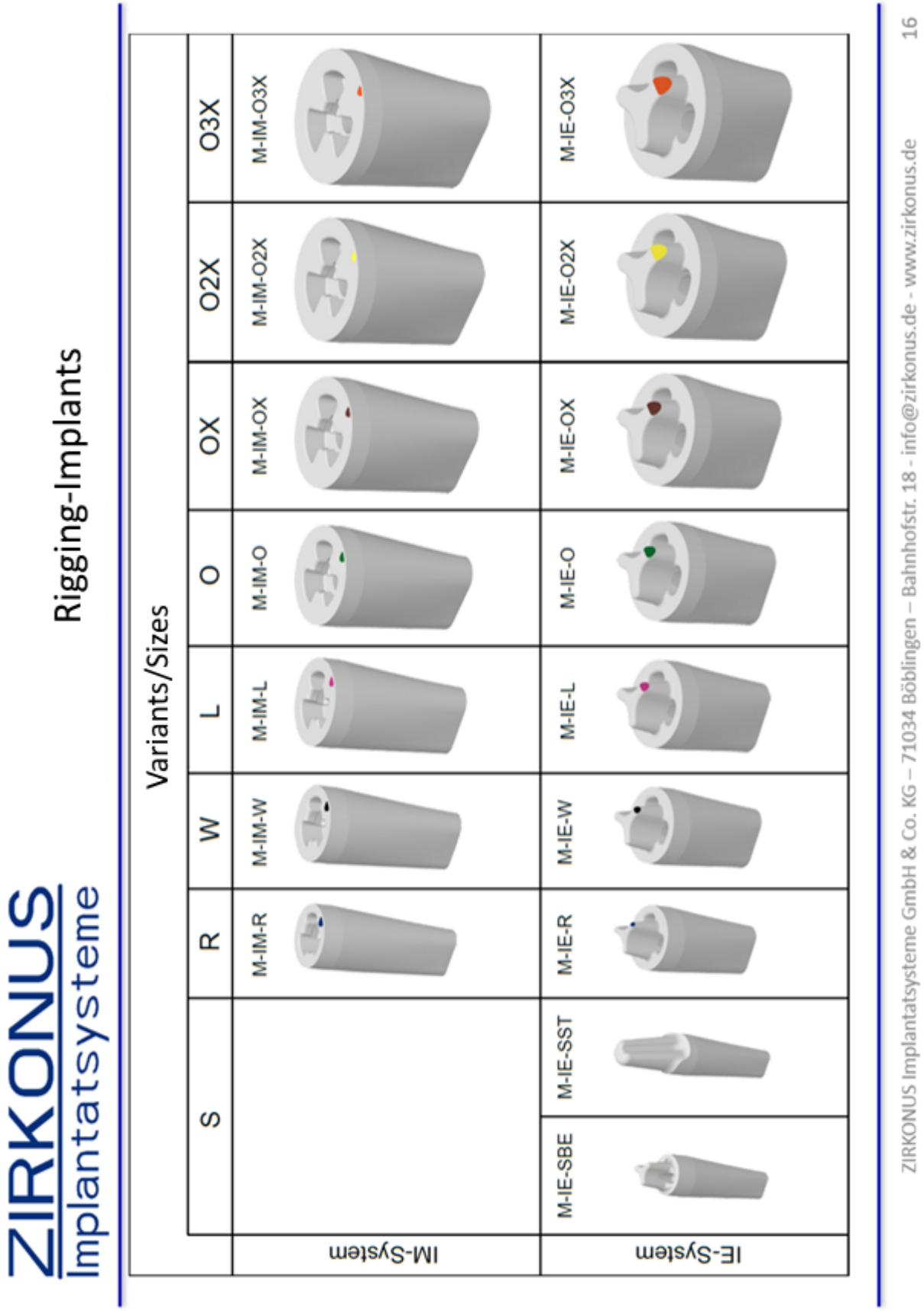
9.8. Overview of impression posts



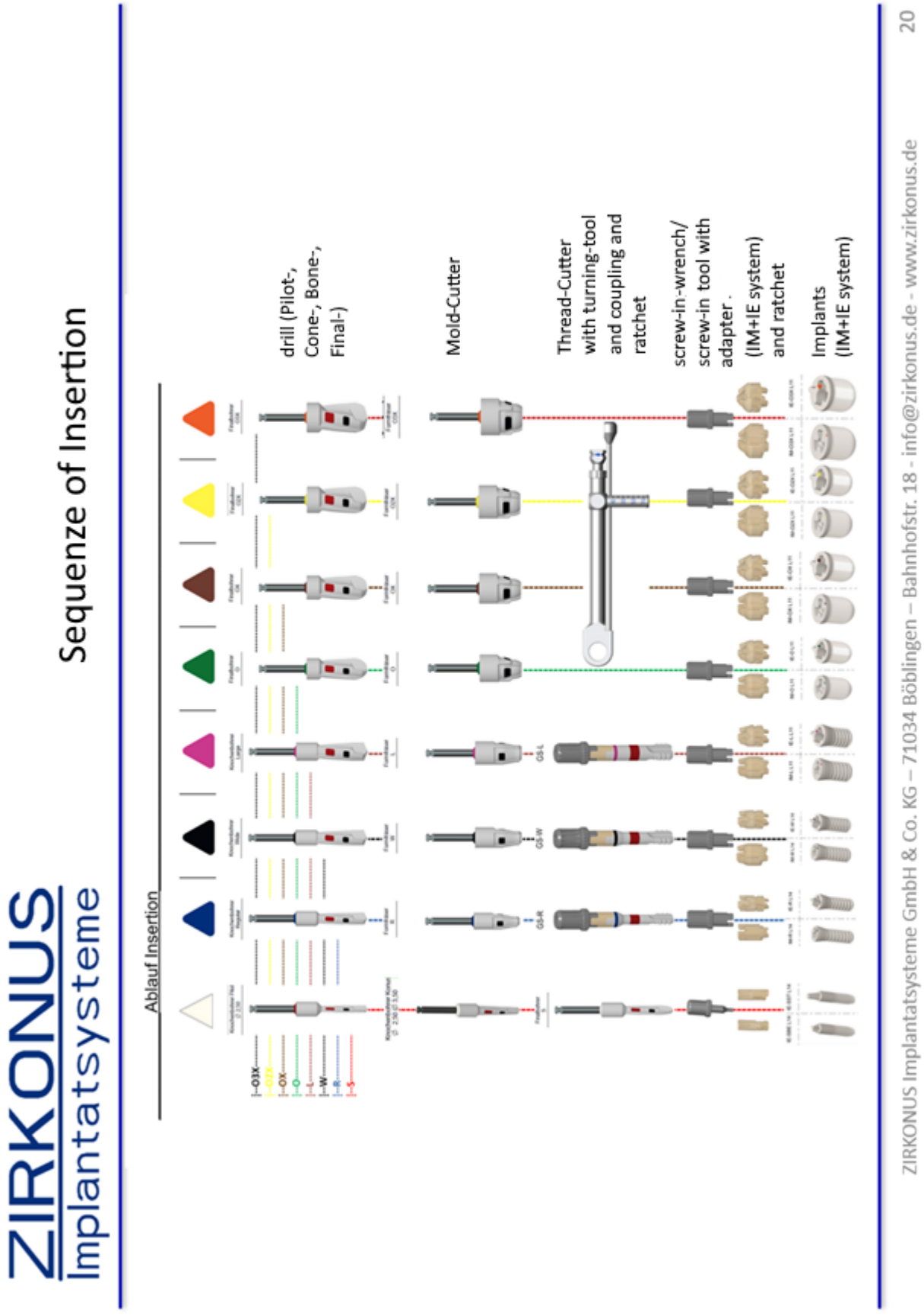
9.9. Overview of impression posts on implants



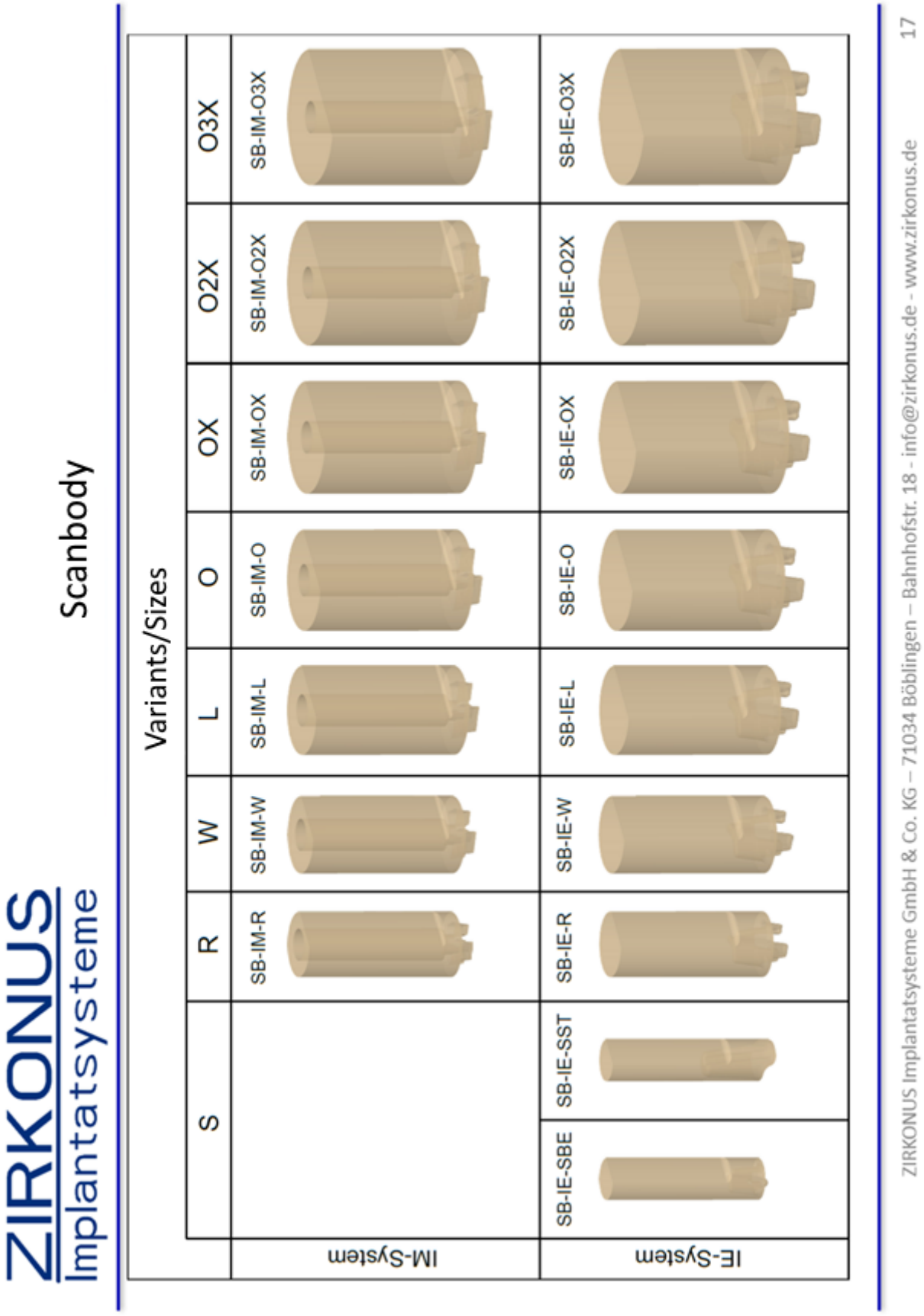
9.10. Overview of Manipulating Implants



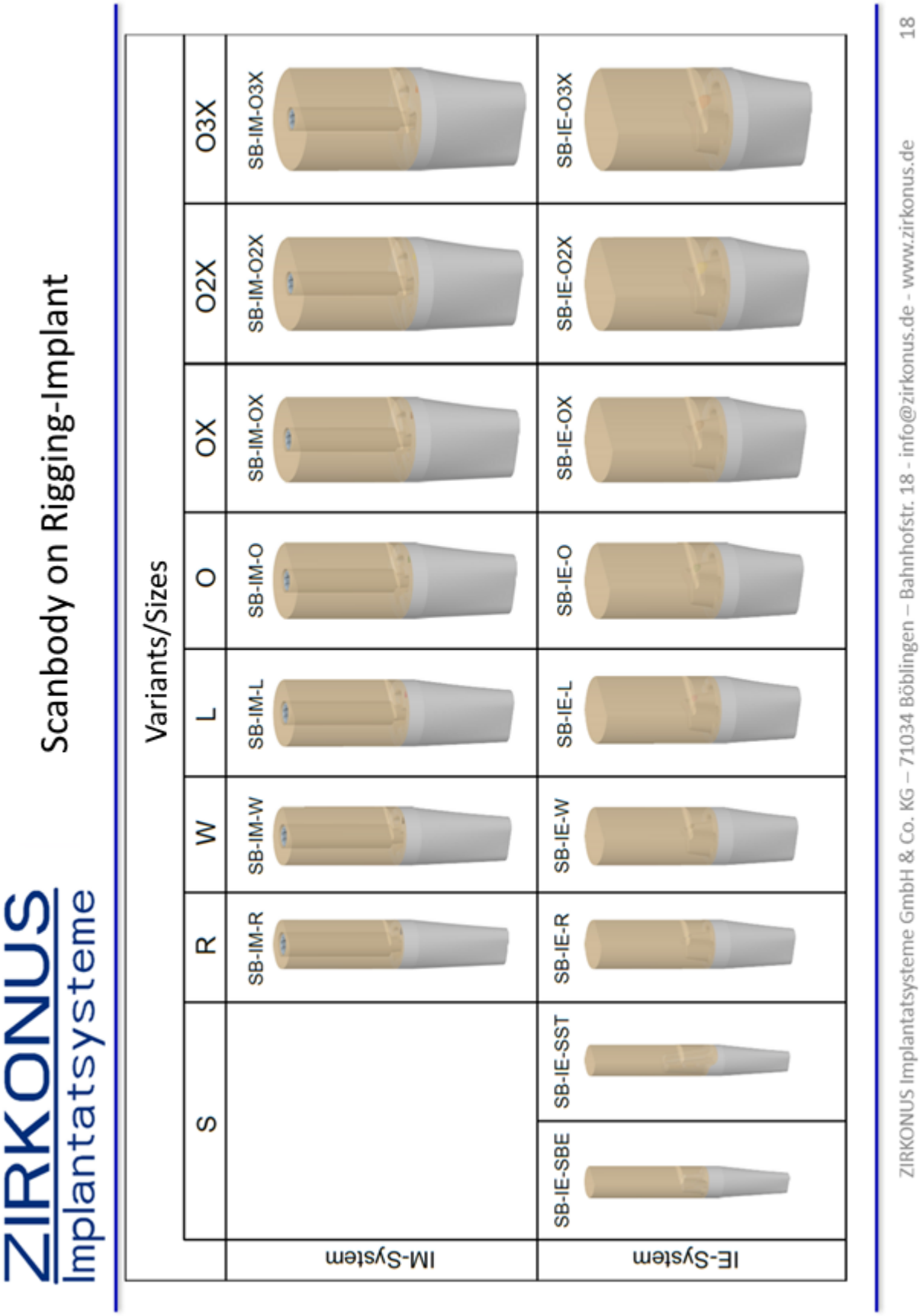
9.11. Insertion process



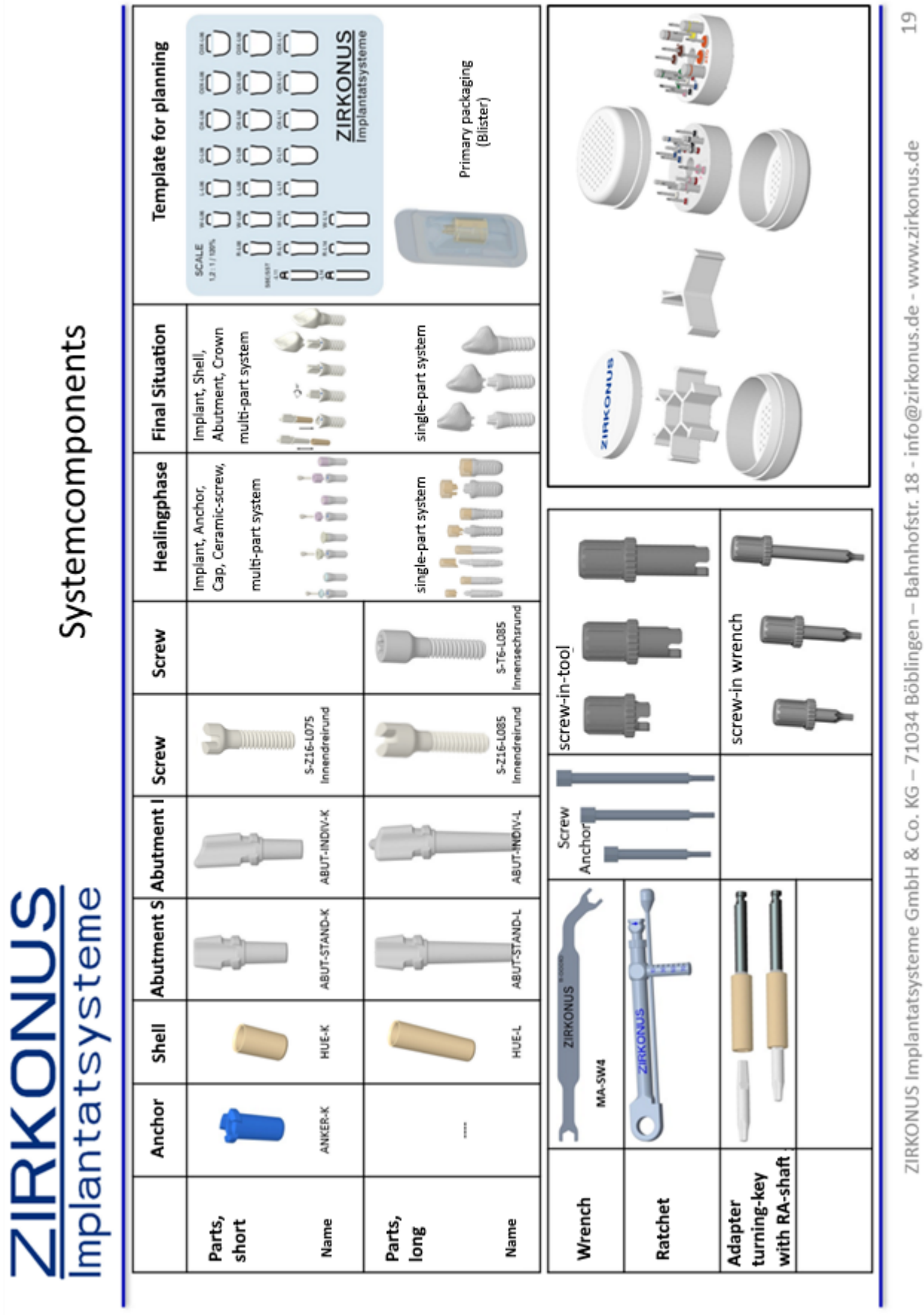
9.12. Overview Scanbody



9.13. Overview Scanbody on Manipulating Implant



9.14. Overview of System Components



Gebrauchs- und Aufbereitungsanweisung chirurgische Instrumente und Systemkomponenten

Geltungsbereich

Diese Herstellerinformation gilt für alle von Zirkonus Implantatsysteme gelieferten Instrumente, die in Verbindung mit der chirurgischen Einbringung von Dentalimplantaten und deren Zubehör der Zirkonus Implantatsysteme angewendet werden. Sofern für bestimmte Produkte (z.B.: Drehmomentratsche) davon abweichende Hinweise zu beachten sind, wird mit einer gesonderten Gebrauchs- bzw. Aufbereitungsanweisung hierauf hingewiesen.

⚠ **WARNHINWEISE**

Alle in dieser Gebrauchsanweisung aufgeführten Instrumente und Systemkomponenten werden unsteril ausgeliefert. Sie sind vor ihrem ersten und jeder folgenden operativen Anwendung gemäß unserer Aufbereitungs-anweisung zu reinigen, desinfizieren und zu sterilisieren. Die Reinigung, Desinfektion und Sterilisation darf erst nach Entfernen der Transportschutzverpackung durchgeführt werden. Eine wirksame Reinigung und Desinfektion ist eine unabdingbare- Voraussetzung für eine effektive Sterilisation.

Einschränkung der Wiederaufbereitung:

Die maximal zulässige Anzahl von 20 Aufbereitungsvor-gängen für die rotierenden Instrumente (Bohrer, Fräser und Gewindeschneider) aus Zirkondioxid ist zu beachten!

Bei einer Verwendung über die zulässige Lebensdauer hin-aus besteht ein erhöhtes Risiko für Beschädigungen an den Produkten, was zu einem erheblichen Verletzungs-risiko beim Patienten führen kann. Eine Verwendung über die angegebene Lebensdauer der Produkte hinaus ist daher nicht zulässig.

Produkte.

Knochenbohrer
Art Nr.: 5600104; 5600103, 5600105; 5600106; 5600107

Finalbohrer
Art Nr.: 5600139, 5600135; 5600136; 5600137; 5600138

Formfräser
Art Nr.: 5600120; 5600121; 5600122; 5600123; 5600124; 5600125; 5600126

Gewindeschneider
Art Nr.: 5600127; 5600128; 5600129

Tiefenlehre
Art Nr.: 5600182; 5600183; 5600184; 5600185; 5600186; 5600187; 5600188; 5600189

Handinstrumentarium:
Ratsche, Art.Nr.: 5600023
Maulschlüssel SW4, Art Nr.: 5600010

Zweckbestimmung

Das Zirkonus Bohrsystem dient zum zylindrischen Aufbohren von Pilotbohrungen beziehungsweise zum Aufbohren vorangegangener Knochenbohrungen im Kieferknochen bis der durch das einzusetzende Implantat geforderte Durchmesser und Tiefe erreicht ist.

Kontraindikation

Die Produkte sind ausschließlich zu denen in der Indikation beschriebenen Verfahren in Zusammenhang mit dem Einsatz des Zirkonus Dentalimplantatsystems ausgelegt und für alle anderen Anwendungen sowie die Verwendung in Verbindung mit anderen Systemen als dem Zirkonus Implantatsystem kontraindiziert.

Anwendung / Behandlungsablauf

Siehe hierzu chirurgisches OP-Handbuch, zu finden unter: https://www.zirkonus.de

⚠ **Anwendungshinweise**

Das ZIRKONUS Bohrsystem dient der Herstellung einer Osteotomie im Kieferknochen des Patienten zur Aufnahme eines ZIRKONUS-Keramikimplantats. Durch diesen Vorgang kommt es zwangsläufig zu einem Wärmeeintrag in umliegendes Knochengewebe. Eine zu hohe Wärmeentwicklung kann zur Schädigung, bis hin zu Osteonekrose an umliegendem Knochengewebe führen. Dies kann die Wahrscheinlichkeit einer erfolgreichen Osseointegration des Implantats drastisch verringern. Um ein Risiko einer zu hohen Temperaturentwicklung während des Bohrvorganges so weit wie möglich zu reduzieren, sollte die Verwendung des ZIRKONUS Bohrsystems stets unter Beachtung folgender Vorsichtsmaßnahmen erfolgen:

- Eine strikte Einhaltung des im OP-Handbuch vorgeschrieben Bohrprotokolls ist zwingend erforderlich.
- Vermeiden Sie Belastungs-Spitzen durch die Verwendung zu großer Bohrer oder das Auslassen von Bohrstufen.
- Vermeiden Sie die Verwendung stumpfer, verschlissener oder beschädigter Bohrer
- Sorgen Sie stets für ausreichende Kühlung und Spülung der Knochenkavität und der Spannuten mittels physiologischer Kochsalzlösung während des intermittierend durchzuführenden Bohrvorganges. Dies wird erreicht, indem der Bohrer nach maximal 2 mm komplett aus der Kavität entfernt wird.

⚠ **Hinweise zum Produkt**

Nach dem Erhalt und vor jedem Einsatz der Produkte sind diese auf Unversehrtheit, Identität und Vollständigkeit zu überprüfen. Besonders ist hierbei auf Korrosion, beschädigte Oberflächen, Absplitterungen, Verschmutzungen sowie Verfärbungen zu achten. Beschädigte Produkte müssen ausgesondert und ersetzt werden.

Bei jeder Anwendung ist darauf zu achten, dass verschmutzte Instrumente getrennt gesammelt und nicht wieder zurück in das Instrumententray gelegt werden, um eine Kontamination des bestückten Instrumententray zu vermeiden.

Nach erfolgter Reinigung und Desinfektion sind die Instrumente wieder in das Instrumententray einzusortieren. Anschließend wird das vollständig bestückte Instrumententray sterilisiert.

ZIRKONUS Implantatsysteme schließt jegliche Gewährleistungsansprüche aus und übernimmt keine Haftung für unmittelbare Schäden oder Folgeschäden, welche durch zweckentfremdete oder unsachgemäße Anwendung, unsachgemäße Aufbereitung und Sterilisation, unsachgemäße Wartung und Reparaturen sowie das Nichtbeachten dieser Aufbereitungsanweisung entstehen.

Nach jeder Anwendung an Patienten mit Creutzfeldt-Jacob-Krankheit (CJK) oder deren Varianten lehnen wir jede Verantwortung für die Wiederverwendung ab! Wir empfehlen die Vernichtung der Instrumente. Eine Aufbereitung und Wiederverwendung auch entsprechend der RKI-Richtlinie erfolgt gänzlich in eigener Verantwortung!

Grundlagen zur Reinigung und Desinfektion

Für die Reinigung und Desinfektion sollte nach Möglichkeit ein maschinelles Verfahren (RDG (Reinigungs- und Desinfektionsgerät)) eingesetzt werden. Ein manuelles Verfahren – auch unter Verwendung eines Ultraschallbads – sollte aufgrund der deutlich geringeren Wirksamkeit und Reproduzierbarkeit nur bei Nichtverfügbarkeit eines maschinellen Verfahrens eingesetzt werden und erfordert eine spezifische Entwicklung und Validierung in alleiniger Verantwortung des Anwenders. Eine Vorbehandlung ist in beiden Fällen durchzuführen.

- Demontierbare Instrumente komplett zerlegen

Manuelle Vorreinigung

Direkt nach der Anwendung (innerhalb von maximal 2 h) müssen grobe Verunreinigungen von den Instrumenten entfernt werden:

Ablauf

1. Spülen Sie die Instrumente mind. 1 min unter fließendem Wasser (Temperatur < 35 °C/95 °F)
2. Legen Sie die zerlegten Instrumente für die vorgegebene Einwirkzeit in das Vorreinigungsbad[1] ein, so dass die Instrumente ausreichend bedeckt sind. Achten Sie dabei darauf, dass die Instrumente sich nicht berühren. Unterstützen Sie die Vorreinigung durch vollständiges Abbürsten aller Oberflächen (zu Beginn der Einwirkzeit)
3. Entnehmen Sie die Instrumente anschließend dem Vorreinigungsbad und spülen Sie diese mind. dreimal gründlich (mind. 1 min) mit Wasser nach. Bewegliche Teile beim Nachspülen mind. dreimal hin und her bewegen

Bei der Auswahl des eingesetzten Reinigungsmittels [1] ist darauf zu achten,

dass dieses grundsätzlich für die Reinigung von Instrumenten aus Metallen und Kunststoffen geeignet ist und dass das Reinigungsmittel mit den Instrumenten kompatibel ist (siehe Kapitel "Materialbeständigkeit"). Die vom Hersteller des Reinigungs- bzw. Reinigungs- und Desinfektionsmittel angegebenen Konzentrationen, Temperaturen und Einwirkzeiten sowie Vorgaben zur Nachspülung müssen unbedingt eingehalten werden. Verwenden Sie nur frisch hergestellte Lösungen, nur steriles oder keimarmes (max. 10 Keime/ml) sowie endotoxinarmes (max. 0,25 Endotoxineinheiten/ml) Wasser (z.B. purified water/highly purified water) bzw. zum Trocknen nur ein weiches, sauberes und fusselfreies Tuch und/oder gefilterte Luft.

[1] Wenn Sie – z.B. aus Arbeitsschutzgründen - hierfür ein Reinigungs- und Desinfektionsmittel verwenden, berücksichtigen Sie bitte, dass dieses aldehydfrei sein sollte (ansonsten Fixierung von Blut-Verschmutzungen), eine geprüfte Wirksamkeit besitzen sollte (z.B. VAH/DGHM-Zulassung bzw. CE-Kennzeichnung), für die Desinfektion der Instrumente geeignet ist und mit den Instrumenten kompatibel sein (siehe Kapitel "Materialbeständigkeit"). Bitte beachten Sie, dass das bei der Vorbehandlung eingesetzte Desinfektionsmittel nur dem Personenschutz dient und den späteren – nach erfolgter Reinigung – durchzuführenden Desinfektionsschritt nicht ersetzen kann.

Maschinelle Reinigung und Desinfektion (RDG)

Ablauf

1. Legen Sie die Instrumente unter Verwendung eines Kleinteilekorbs in das RDG ein. Achten Sie dabei darauf, dass die Instrumente sich nicht berühren
2. Starten Sie das Programm
3. Entnehmen Sie die Instrumente nach Programmende dem RDG
4. Kontrollieren und verpacken Sie die Instrumente möglichst umgehend nach der Entnahme (siehe Kapitel "Kontrolle", "Wartung" und "Verpackung", ggf. nach zusätzlicher Nachtrocknung an einem sauberen Ort)

Der Nachweis der grundsätzlichen Eignung der Instrumente und Systemkomponenten für eine wirksame maschinelle Reinigung und Desinfektion wurde durch ein unabhängiges, behördlich akkreditiertes und anerkanntes (§ 15 (5) MPG) Prüflabor unter Verwendung des RDGs G 7836 CD (thermische Desinfektion, Miele & Cie. GmbH & Co., Gütersloh) und des Vorreinigungs- und Reinigungsmittels Neodisher Mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg) erbracht. Hierbei wurde das oben beschriebene Verfahren berücksichtigt.

Kontrolle

Nach Abkühlung auf Raumtemperatur müssen die Instrumente visuell auf Beschädigung und Verschleiß überprüft werden. Besonders ist auf Brüche, Risse und Absplitterungen zu achten. Schneiden sollten keine Kerben aufweisen und gleichmäßig sein. Beschädigte Produkte müssen sofort ausgesondert und ersetzt werden. Noch verschmutzte Instrumente müssen erneut gereinigt und desinfiziert werden.

Wartung

Instrumentenöle dürfen nicht eingesetzt werden.

Montage

Demontierte Instrumente wieder montieren.

Verpackung

Es ist eine für das Instrument und Sterilisationsverfahren geeignete Verpackung zu wählen.
Einzelverpackung: Die Verpackung muss so groß sein, dass die Versiegelung nicht unter Spannung steht.
Im Set: Instrumente in das dafür vorgesehene Tray einsortieren oder auf Allzweck-Sterilisationstrays legen.
Die Instrumente müssen geschützt sein. Zum Verpacken ist ein geeignetes Verfahren anzuwenden, das folgenden Anforderungen entsprechen (Material/Prozess):

Allgemeine Hinweise

Alle in dieser Gebrauchsanweisung aufgeführten Systembestandteile werden unsteril geliefert. Sie sind vor ihrem ersten und jedem weiteren Einsatz zu reinigen, desinfizieren und zu sterilisieren.

Für die Vorreinigung der Keramik Instrumente dürfen nur Reinigungsbürsten mit metallfreien Borsten verwendet werden, da diese keine abriebbedingten Verfärbungen am Instrument erzeugen.

Beachten Sie die in Ihrem Land gültigen, rechtlichen Bestimmungen zur Wiederaufbereitung von Medizinprodukten (z.B. www.rki.de).

Seitens des Herstellers ist sichergestellt, dass die angeführten Aufbereitungsverfahren für die Aufbereitung der genannten Instrumentengruppe für eine Wiederverwendung geeignet sind. Der Aufbereiter ist dafür verantwortlich, dass die tatsächlich durchgeführte Wiederaufbereitung mit verwendeter Ausstattung, Materialien und Personal in der Wiederaufbereitungseinrichtung die gewünschten Ergebnisse erzielt.

Dafür sind normalerweise routinemäßige Kontrollen der validierten maschinellen bzw. der standardisierten manuellen Aufbereitungsverfahren erforderlich. Ebenso sollte jede Abweichung von den hier angeführten Verfahren (z.B. Verwendung anderer Prozesschemikalien) sorgfältig durch den Aufbereiter auf ihre Wirksamkeit und mögliche nachteilige Folgen ausgewertet werden.

- DIN EN ISO 11607
- für die Dampfsterilisation geeignet (Temperaturbeständigkeit bis mind. 142 °C ausreichende Dampfdurchlässigkeit)
- ausreichender Schutz der Instrumente bzw. Sterilisationsverpackungen vor mechanischen Beschädigungen

Dampfsterilisation

- fraktioniertes Vakuumverfahren[2] (mit ausreichender Produkttrocknung)
- Dampfsterilisator entsprechend DIN EN 13060 / DIN EN 285
- entsprechend DIN EN ISO 17665 validiert (gültige IQ/OQ (Kommissionierung) und produktspezifische Leistungsbeurteilung (PQ))
- maximale Sterilisationstemperatur 138 °C (zzgl. Toleranz entsprechend DIN EN ISO 17665)
- Sterilisationszeit (Expositionszeit bei der Sterilisationstemperatur):

Land	fraktioniertes Vakuumverfahren
Europa	mind. 5 min bei 134 °C

[2] mind. drei Vakuumschritte

Transport und Lagerung

Transport und Lagerung des verpackten Sterilguts erfolgt staub-, feuchtigkeits- und rekontaminationsgeschützt.

Materialbeständigkeit

Achten Sie bei der Auswahl der Reinigungs- und Desinfektionsmittel bitte darauf, dass folgende Bestandteile nicht enthalten sind:

- stärkere organische, mineralische und oxidierende Säuren (minimal zulässiger pH-Wert 5,5)
- starke Laugen (maximal zulässiger pH-Wert 11, neutraler/enzymatischer oder alkalischer Reiniger empfohlen)
- organische Lösungsmittel (z.B. Alkohole, Ether, Ketone, Benzine)
- Oxidationsmittel (z.B. Wasserstoffperoxide)
- Halogene (Chlor, Jod, Brom)
- aromatische/halogenierte Kohlenwasserstoffe

Bitte berücksichtigen Sie bei der Auswahl der Detergentien zusätzlich, dass Korrosionsinhibitoren, Neutralisationsmittel und/oder Klarspüler möglicherweise kritische Rückstände auf den Instrumenten hinterlassen können.

- Saure Neutralisationsmittel bzw. Klarspüler dürfen nicht eingesetzt werden.
- Reinigen Sie alle Instrumente nie mit Metallbürsten oder Stahlwolle.
- Alle Instrumente dürfen nur Temperaturen nicht höher als 142 °C (288 °F) ausgesetzt werden!

Wiederverwendbarkeit

Die Instrumente können – bei entsprechender Sorgfalt und sofern Sie unbeschädigt und unverschmutzt sind – bis zu 20mal wiederverwendet werden; jede darüberhinausgehende Weiterverwendung bzw. die Verwendung von beschädigten und/oder verschmutzten Instrumenten ist nicht zulässig, s.a. WARNHINWEISE

Bei Missachtung wird jede Haftung ausgeschlossen.

Drehzahlempfehlung

Bezeichnung Instrument	max. [U/min]
KB-P	800
KB-K	800
KB-R	600
KB-W	400
KB-L	400
FB-S	600
FB-O	250
FB-OX	200
FB-O2X	200
FB-O3X	200

Bezeichnung Instrument	max. [U/min]
FF_R	300
FF-W	300
FF-L	250
FF-O	250
FF-OX	200
FF-O2X	200
FF-O3X	200

Kennzeichnung / Symbole

	Hersteller i.S. RL 93/42/EWG
NON STERILE	Hinweis: NICHT STERIL
LOT	LOT Nummer
REF	Artikelnummer
	Gebrauchsanweisung beachten
CE XXXX	CE-Zeichen mit Kennnummer der Benannten Stelle mdc

ZIRKONUS Implantatsysteme GmbH & Co. KG
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71034 Böblingen
Deutschland

Art.Nr.: 0600001
Stand: 2020-07-15
A200 Rev-02-00

ZIRKONUS Implantatsysteme	Gebrauchsanweisung ZIRKONUS Implantatsystem	A 201 (Rev-03-00)

Gebrauchsanweisung ZIRKONUS Dental Implantatsystem

Geltungsbereich

Diese Herstellerinformation gilt für alle von ZIRKONUS Implantatsysteme gelieferten Dentalimplantate sowie temporäre und permanente Aufbauten, welche in Verbindung mit einteiligen und mehrteiligen Implantaten der ZIRKONUS Implantatsysteme angewendet werden.

⚠

Die nachfolgenden Angaben beinhalten keine Hinweise zum Operationsprotokoll! Hinweise zur sicheren Anwendung aller Implantate und Systemkomponenten finden sich im chirurgischen Handbuch, unter: https://www.zirkonus.de/

ZIRKONUS Dentalimplantate, Einteilig:
Art Nr.: 5603508, 5603509, 5603510, 5603511, 5605507, 5605508, 5605509, 5606506, 5606507, 5606508, 5606509, 5607506, 5607507, 5607508, 5608506, 5608507, 5608508, 5609506, 5609507, 5609508, 5610506, 5610507, 5610508, 5611506, 5611507, 5611508

ZIRKONUS Dentalimplantate, Mehrteilig:
Art Nr.: 5605502, 5605503, 5605504, 5606501, 5606502, 5606503, 5606504, 5607501, 5607502, 5607503, 5608501, 5608502, 5608503, 5609501, 5609502, 5609503, 5610501, 5610502, 5610503, 5611501, 5611502, 5611503

Systemkomponenten

ZIRKONUS Abutments:
Art Nr.: 5600084, 5600403, 5600086, 5600405

ZIRKONUS Gingivaformer / Heildistanzkappen (HDK) / Verschlusskappen
Art Nr.: 5600067, 5600172, 5600173, 5600170, 5600171, 5600065, 5600066, 5600072, 5600073, 5600178, 5600179, 5600180, 5600181, 5600174, 5600175, 5600176, 5600177, 5600068, 5600069, 5600070, 5600071, 5600064, 5600168, 5600169, 5600166, 5600167, 5600062, 5600063, 5600237, 5600238, 5600240, 5600241, 5600239, 5600235, 5600234, 5600236, 5600243

Bestimmungsgemäßer Gebrauch

Zweckbestimmung Implantate
Das ZIRKONUS Implantatsystem dient durch chirurgische Einbringung im Ober- oder Unterkiefer des Patienten zur dauerhaften Fixierung von einzelnen Zahnprothesen oder vollständigen Brückenkonstruktionen bei partiellem oder vollständigem Zahnverlust.

Indikationen
- die Versorgung einzelner Zahnlücken.
- Brückenkonstruktionen über Schaltlücken und Freiendsituationen entsprechend allgemeinen und speziellen Grundsätzen prothetischer Behandlungsrichtlinien.
- Sanierung zahnloser Unter- und Oberkiefer.
- OVEERSIZE Implantate eignen sich primär für den OK Seitenzahnbereich, bei höhenreduziertem und stark abgeflachtem Alveolarfortsatz, sofern ein überwiegend spongiöser Knochen vorhanden ist.

Absolute Kontraindikation Implantate
Es gibt keine absoluten Kontraindikationen für die Anwendung von Zirkonus Dental-Implantaten außer denen, die für die Implantat Chirurgie im Allgemeinen gelten und Folgende:
- Ungenügendes Knochen- und Weichgewebsangebot und/oder inadäquate Knochenqualität
- Lokale Infektion der Implantationsstelle, schwerwiegende therapieresistente Funktionsstörungen, unkontrollierte Diabetes mellitus, Langzeit immunosuppressive Therapie, Bindegewebserkrankung/Kollagenosen,
- Blutkrankheiten (z.B. Leukämie, Hämophilie), intraorale Infektion oder Malignome, unkontrollierte
- parafunktionelle Gewohnheiten, behandlungsunfähige Okklusal- oder Artikulationserkrankungen,
- infizierte Extraktionsalveolen, größere apikale Ostitiden (Knochenentzündungen) und Knochendefekte.

Absolute Kontraindikation einteilige Implantate
Einteilige Implantate sind nicht zur Verwendung in Verbindung mit knochenaufbauenden Maßnahmen geeignet und für derartige Verfahren kontraindiziert. Sofern während der Einheilphase des Implantates aufgrund der Situation im Patientenkiefer eine Belastungsfreie Einheilung nicht sichergestellt ist, dürfen Einteilige Implantate nicht angewendet werden.

Relative Kontraindikationen Implantate
Allgemeine Erkrankungen und pathologische Erkrankungen des Kiefers: Eingeschränktes Heilungsvermögen und Nährstoffmangel aufgrund einer Erkrankung oder (Strahlen-) Therapie, sowie aufgrund von Alkohol- oder Drogenmissbrauch.
Rauchen sowie unzureichende Mundhygiene beeinträchtigt ebenfalls den Erfolg der Implantation.
Trotz biokompatiblem Material besteht ein geringes Risiko, dass das Implantat nicht in den Knochen einwächst.
Durch Überlastung des Knochens oder bakterielle Infektion können bisweilen Implantate oder Knochenaufbauten verlorengehen, selten kann es zur Schädigung von Gefühlsnerven oder benachbarter Zahnwurzeln kommen.
Bei durchschnittlicher Kompakta im Unterkiefer (UK) Seitenzahnbereich sind OVERSIZE Implantate nicht einzusetzen.
Auf Grund des in der Regel schmalen Alveolarfortsatzes sind OVERSIZE Implantate im Front- und Prämolarenbereich nicht geeignet.

Zweckbestimmung Abutments
ZIRKONUS Abutments dienen zur Wiederherstellung der Kaufunktion durch Herstellung einer festsitzenden Fixierung einer Zahnkrone auf einem chirurgisch in den Kieferknochen des Patienten eingebrachten Implantats.

Kontraindikationen Abutments
ZIRKONUS Abutments dürfen ausschließlich für eine permanente Versorgung in Verbindung mit hierfür vorgesehenen, mehrteiligen Implantaten von ZIRKONUS Implantatsysteme verwendet werden und sind für jegliche Anwendung mit Fremdsystemen kontraindiziert.

Zweckbestimmung Gingivaformer / HDK
ZIRKONUS Gingivaformer / Heildistanzkappen dienen durch temporäre Fixierung auf chirurgisch in den Kieferknochen des Patienten eingebrachten Implantaten zur Förderung einer kontrollieren Wiederherstellung des Weichgewebes (Gingiva) zur späteren permanenten prothetischen Versorgung mittels einer Zahnkrone oder Brücke.

Kontraindikationen Gingivaformer / HDK
ZIRKONUS Gingivaformer / Heildistanzkappen dürfen ausschließlich zur Vorbereitung einer permanenten Versorgung in Verbindung mit hierfür vorgesehenen Implantaten von ZIRKONUS Implantatsysteme verwendet werden und sind für jegliche Anwendung mit Fremdsystemen kontraindiziert.

Operationstechnik / Behandlungsablauf
Siehe hierzu chirurgisches Handbuch, zu finden unter: https://www.zirkonus.de/

⚠ **Allgemeine Warnhinweise**

Zirkonus-Implantate sind Bestandteil eines Komplettsystems und dürfen nur mit den dazugehörenden Originalkomponenten und Instrumenten verwendet werden. Die Verwendung von systemfremden Komponenten schließt jede Garantie- und Ersatzleistung aus.

Das ZIRKONUS Implantatsystem ist ausschließlich für Ärzte und Zahnärzte bestimmt, die mit der zahnärztlichen Implantologie einschließlich Diagnose, präoperativer Planung, chirurgischer Vorgehensweise und prothetischer Versorgung vertraut sind. Der Anwender stellt vor Gebrauch sicher, dass er sich die von ZIRKONUS zur Verfügung gestellten Gebrauchsanweisungen, Handbücher und anderen produktbegleitenden Informationen erarbeitet und verstanden hat. Vor Anwendung sollte der Behandler unbedingt einen der von ZIRKONUS angebotenen Aus- und Fortbildungskurse für die Anwendung des ZIRKONUS Dentalimplantatsystems besuchen, um die für das System sicherste Technik zu erfahren, da die Gebrauchsanweisungen und Handbücher unmöglich alle Eventualitäten bei der sicheren Anwendung abdecken und die persönliche Erfahrung der Tutoren ersetzen können.

Unsachgemäße Anwendung des ZIRKONUS Implantatsystems kann zu Implantatverlust, Knochenverlust oder unbefriedigenden ästhetischen Ergebnissen führen.

Zirkonus Implantate sind zur einmaligen Verwendung an einem Patienten bestimmt. Da das Implantat bei der Insertion und während des Einsatzes starken mechanischen Belastungen ausgesetzt ist und dazu bestimmt ist osseointegriert zu werden, ist eine Mehrfachverwendung ausgeschlossen.

Verpackung und Lagerung von sterilen Produkten
Der Auslieferungszustand der Zirkonus Implantate erfolgt steril. Die Implantate sind in einem speziellen Blister steril verpackt und farblich codiert. Das gewählte Implantat wird erst unmittelbar vor der Insertion aus der Sterilverpackung entnommen und ohne direkten Kontakt zur Implantatoberfläche in die aufbereitete Knochenkavität eingebracht.
Die Implantate müssen in Ihrer intakten versiegelten Verpackung trocken sowie licht- und feuchtigkeitsgeschützt gelagert werden.

⚠ **ACHTUNG**

Das Implantat wurde durch Gassterilisation (Ethylenoxid) sterilisiert und darf nach Ablauf des Verfallsdatums nicht mehr verwendet werden.
Das Implantat darf auch nicht verwendet werden, wenn die Verpackung angebrochen oder beschädigt ist.
ZIRKONUS Implantatsysteme übernimmt keine Haftung für Implantate die vom Anwender sterilisiert oder aufbereitet wurden.

Gebrauchsanweisung ZIRKONUS Dental Implantatsystem

Systemkomponenten

WARNHINWEISE

Alle in dieser Gebrauchsanweisung aufgeführten Systemkomponenten werden unsteril ausgeliefert. Sie sind vor ihrer ersten Anwendung gemäß unserer Aufbereitungsanweisung zu reinigen, desinfizieren und zu sterilisieren. Sie sind für die Einmalverwendung ausgelegt und dürfen nicht wiederverwendet werden. Die Reinigung, Desinfektion und Sterilisation darf erst nach Entfernen der Transportschutzverpackung durchgeführt werden. Eine wirksame Reinigung und Desinfektion ist eine unabdingbare- Voraussetzung für eine effektive Sterilisation.

Grundlagen zur Reinigung und Desinfektion

Für die Reinigung und Desinfektion sollte nach Möglichkeit ein maschinelles Verfahren (RDG (Reinigungs- und Desinfektionsgerät)) eingesetzt werden. Ein manuelles Verfahren – auch unter Verwendung eines Ultraschallbads – sollte aufgrund der deutlich geringeren Wirksamkeit und Reproduzierbarkeit nur bei Nichtverfügbarkeit eines maschinellen Verfahrens eingesetzt werden und erfordert eine spezifische Entwicklung und Validierung in alleiniger Verantwortung des Anwenders. Eine Vorbehandlung ist in beiden Fällen durchzuführen.

Maschinelle Reinigung und Desinfektion (RDG)

Ablauf

1. Legen Sie die Instrumente unter Verwendung eines Kleinteilekorbs in das RDG ein. Achten Sie dabei darauf, dass die Systemkomponenten sich nicht berühren
2. Starten Sie das Programm
3. Entnehmen Sie die Systemkomponenten nach Programmende dem RDG
4. Kontrollieren und verpacken Sie die Systemkomponenten möglichst umgehend nach der Entnahme

Der Nachweis der grundsätzlichen Eignung der Systemkomponenten für eine wirksame maschinelle Reinigung und Desinfektion wurde durch ein unabhängiges, behördlich akkreditiertes und anerkanntes (§ 15 (5) MPG) Prüflabor unter Verwendung des RDGs G 7836 CD (thermische Desinfektion, Miele & Cie. GmbH & Co., Gütersloh) und des Vorreinigungs- und Reinigungsmittels Neodisher Mediclean forte (Dr. Weigert GmbH & Co. KG, Hamburg) erbracht. Hierbei wurde das oben beschriebene Verfahren berücksichtigt.

Materialbeständigkeit

Achten Sie bei der Auswahl der Reinigungs- und Desinfektionsmittel bitte darauf, dass folgende Bestandteile nicht enthalten sind:

- stärkere organische, mineralische und oxidierende Säuren (minimal zulässiger pH-Wert 5,5)
- starke Laugen (maximal zulässiger pH-Wert 11, neutraler/enzymatischer oder alkalischer Reiniger empfohlen)
- organische Lösungsmittel (z.B. Alkohole, Ether, Ketone, Benzine)
- Oxidationsmittel (z.B. Wasserstoffperoxide)
- Halogene (Chlor, Jod, Brom)
- aromatische/halogenierte Kohlenwasserstoffe

Bitte berücksichtigen Sie bei der Auswahl der Detergentien zusätzlich, dass Korrosionsinhibitoren, Neutralisationsmittel und/oder Klarspüler möglicherweise kritische Rückstände auf den Instrumenten hinterlassen können.

- Saure Neutralisationsmittel bzw. Klarspüler dürfen nicht eingesetzt werden.
- Reinigen Sie alle Instrumente nie mit Metallbürsten oder Stahlwolle.
- Alle Instrumente dürfen nur Temperaturen nicht höher als 142 °C (288 °F) ausgesetzt werden!

Verpackung

Für die Systemkomponenten und Sterilisationsverfahren ist eine geeignete Verpackung zu wählen.
Einzelverpackung: Die Verpackung muss so groß sein, dass die Versiegelung nicht unter Spannung steht.
Zum Verpacken ist ein geeignetes Verfahren anzuwenden, das folgenden Anforderungen entsprechen (Material/Prozess):

- DIN EN ISO 11607
- für die Dampfsterilisation geeignet (Temperaturbeständigkeit bis mind. 142 °C ausreichende Dampfdurchlässigkeit)
- ausreichender Schutz der Instrumente bzw. Sterilisationsverpackungen vor mechanischen Beschädigungen

Dampfsterilisation

- fraktioniertes Vakuumverfahren[2] (mit ausreichender Produkttrocknung)
- Dampfsterilisator entsprechend DIN EN 13060 / DIN EN 285
- entsprechend DIN EN ISO 17665 validiert (gültige IQ/OQ (Kommissionierung) und produktspezifische Leistungsbeurteilung (PQ))
- maximale Sterilisationstemperatur 138 °C (zzgl. Toleranz entsprechend DIN EN ISO 17665)
- Sterilisationszeit (Expositionszeit bei der Sterilisationstemperatur):

Land	fraktioniertes Vakuumverfahren[2]
Europa	mind. 5 min bei 134 °C

[2] mind. drei Vakuumschritte

Transport und Lagerung

Transport und Lagerung des verpackten Sterilguts erfolgt staub-, feuchtigkeits- und rekontaminationsgeschützt.

Hersteller

ZIRKONUS Implantatsysteme GmbH & Co. KG
Bahnhofstraße 18
71034 Böblingen
Deutschland

Art.Nr.: 0600002
Stand: 2021-01-12
A201 Rev-03-00

Kennzeichnung / Symbole

	Hersteller i.S. RL 93/42/EWG
LOT	LOT Nummer
REF	Artikelnummer
	Gebrauchsanweisung beachten
	Achtung: Warnhinweise beachten!
STERILE EO	Hinweis: Sterilisiert mittels Ethylenoxid
NON STERILE	Hinweis: NICHT STERIL
YYYY-MM	Haltbarkeitsdatum
	Hinweis: nicht wiederverwenden!
	Hinweis: nicht resterilisieren!
	Hinweis: vor Feuchtigkeit schützen
	Hinweis: vor direkter Sonneneinstrahlung schützen
	Hinweis: nicht verwenden bei beschädigter Sterilverpackung
	Hinweis-Lagerbedingungen Temperatur
	Hinweis-Lagerbedingungen Feuchtigkeit
CE XXXX	CE-Zeichen mit Kennnummer der Benannten Stelle