

Instructions for Use Champions® WIN!® PEEK Implants

Safety Instructions

It is essential to read these Instructions for Use prior to the placement of the implant.

The WIN!® PEEK System may only be used by dental and maxillo-facial surgeons and dentists who are familiar with dental surgery, including diagnosis and preoperative management, considering its indication and general guidelines for dental/surgical applications as well as regulations for safety at work and prevention of accidents. Prior to each surgical treatment, ensure that all required parts, instruments and devices are complete, functioning, and available at the required quantity. The Instructions for Use only are not sufficient to ensure a professional application for practitioners inexperienced in Implantology. Therefore, we recommend a course of instruction for the handling by an experienced user. The WIN!® PEEK implant system may only be used if in a sound condition. All components used inside the patient's mouth have to be protected from aspiration and swallowing. If in doubt regarding indication or application, refrain from usage until all items are clarified. As the application of this product takes place beyond our control, any kind of liability for damage caused in this connection is excluded. The user accepts and takes full responsibility.

Product Description:

The WIN!® PEEK system is a dental implant system for endosseous dental implantation. The system contains surgical, prosthodontic and laboratory technical components and instruments. The WIN!® PEEK implant system is suitable for one-stage implantation procedures and immediate implantation. WIN!® PEEK implants are made under validated GMP-conditions. They can be shortened to the minimum insertion length of 6 mm, 2nd marking B (see graphic further below), measured from the upper edge of the upper groove on the head. The implants can also be shortened with sterile, sharp, cutting, or rotating instruments until the minimum insertion length is achieved. The practitioner is solely responsible for complying with the minimum insertion length. The minimum insertion length is measured from the upper edge of the groove A (see graphic further below). It is absolutely necessary to follow these guidelines.

Number of Implants/Indications:

The minimum number of endosseous implants per jaw should be determined by the recognized standards of the Implantology Consensus Conference. For patients, the WIN!® PEEK implant can only be used with an original zircon Prep-Cap. Only then should a prosthodontic restoration be fitted.

Surgery: The implants are to be used intra-orally. These implants are used for the following indications:

- Single-tooth prosthodontic restorations (per missing tooth: one WIN! PEEK implant!)
- Single-molar prosthodontic restorations: if possible, place two WIN!® PEEK implants (If there is approx. 9 mm or more between the roots of the adjacent teeth).
- Fixed prosthodontic restorations, for a splinted and passively fitted prosthodontic restoration
- Removable prostheses, for at least 4 primarily or secondarily splinted implants

Prosthodontic Concept: single-tooth prosthodontic restorations, fixation of bridges and full and partial prostheses

Prosthodontic Restorations: Immediate non-functional loading, immediate functional loading (taking care to avoid relative movement/micro-movement of the primary stability of the implant in its surrounding bone and mechanical prosthodontic over-loading).

Time of Implantation: Immediate implantation, delayed immediate implantation, delayed implantation

Healing: Transgingival (with ø 4 mm punch) with original Champions zircon Prep-Caps

Contraindications / Restrictions of Use:

General contraindications for dental/surgical treatments are to be considered for patient selection. These are amongst others: infections and inflammation in the oral cavity such as periodontitis, gingivitis, reduced blood coagulation, e.g.: anticoagulant therapy, congenital or acquired disorder in coagulation, acute and chronic infections in the field of surgery (soft tissue infection, inflammable/bacterial bone disease, osteomyelitis), severe metabolic disorder such as unstable diabetes mellitus, calcium metabolic disorder, treatment with steroids and other pharmaceuticals intervening the calcium metabolism, immunosuppressive therapy such as chemo and radiation therapy, endocrinological bone disease, insufficient local bone availability (also close to vital structures such as the mandibular nerve, sublingual artery, maxillary sinus etc.), insufficient soft tissue coverage, unstable occlusion and/or articulation as well as small interocclusal distance, psychological disorder, pain syndrome, poor oral hygiene and inadequate preparation for oral overall rehabilitation, with poor patient compliance. Relative contraindications exist in patients with bruxism, allergies, alcohol, or nicotine abuse.

Adverse Events:

The following side effects may occur with any surgical treatment: temporary local swelling, edemas, hematomas, temporary reduction of sensation, temporary limitation of chewing performance.

Complications:

During the placement of endosseous implants the following complications have been observed in occasional cases: postoperative bleeding, infections, suture dehiscences, iatrogenic traumas, insufficient osseointegration, periodontal complications due to insufficient width of mucogingival attachments, jammed or overtwisted implant insertion posts, aspiration or swallowing of components which are used inside the patient's mouth, in rare cases extreme adverse load conditions (prosthodontic overload, significant bone loss) may lead to deformation of the implant body.

Diagnostics / Clarification:

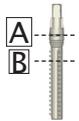
In-depth review, clinical examination, radiological examination using small image X-rays, orthopantomogram as well as, if necessary, a CT- or volumetric tomograph examination, and preoperative diagnostic models of the patient are essential for accurate diagnostics. A medical check-up by a general practitioner is recommended. Implantation requires substantial considerations for the patient: economical considerations (also costs for implant aftercare), therapeutic considerations (alternative treatments and possible consequences and risks of an implantation have to be pointed out and explained as for any other surgical procedure). Concerning the method of giving consent please refer to the respective jurisdiction.

Shelf Life:

Five years from sterilization. The medical device has to be stored in a cool and dry place in its original box.

Implants are only sterile if still in their unopened original blister packaging. If implants are resterilized by the end-user, any responsibility is void, regardless of the sterilization method. Sterile products are labeled with the STERILE sign. The expiration date is indicated by the hour glass. The description LOT refers to the batch number. Implants are for single use only because their reuse leads to a modification of the sub-crestal surface structure (retentive WIN!® PEEK wing) and the implant geometry, which can cause implant loss. In addition, there is a risk of residual contamination.

Implantation Methods:



- 1) **„MIMI®-Flapless“:** (Minimally Invasive Method of Implantation) If there is adequate bone (mesial/distal as well as buccal/lingual), a transgingival implantation using the minimal invasive criteria, without opening the mucosa (flapless insertion), can be recommended. Punching the mucosal tissue with a corresponding mucous membrane punch is necessary when performing a WIN!® PEEK implantation! The one-stage „MIMI®“ shows advantages related to the regeneration of the soft tissue versus the conventional two-stage procedure. If intraoperative complications occur (e.g. vestibular fenestration > 1 mm), you will be advised to continue with the conventional method (flap operation, augmentation with bone substitutes and resorbable membrane). An X-ray check is also required for „MIMI®-flapless“ in order to verify the complete insertion.
- 2) **Conventional:** Alternatively, the implantation (especially with poor horizontal bone availability) can be conducted with conventional flap of the mucosa. After completed implantation, perform a primary closure (saliva-closed) suture.
- 3) An **immediate implantation** should only be done in a non-inflammatory site. After gentle extraction of the tooth (preferably no luxation movements), proceed with proper curettage of the fresh alveolus by removing granulation tissue. Drill slightly lingually/palatally in continuation of the alveolus axis (for protection of the buccal bone wall). The WIN!® PEEK implant should be implanted at least 1/3 of its insertion length in extension of the original length of the tooth root. Patient selection is critical before performing an immediate implantation with immediate loading. The implant length should be chosen considering the maximum height of the available bone.

1) Preparation of the Implant Site / Soft Tissue Management and Superstructure:

Under local anesthesia, the implant site is to be prepared for the WIN!® PEEK implant. For this, the whole implant working length is prepared with conical triangular drills and cylindrical drills in the crestal portion (4 mm). It is absolutely critical to avoid overheating and overloading the bone.

Only new instruments should be used for drilling, applying minimal pressure, utilizing intermittent and, if necessary, sufficient external cooling with a pre-cooled, physiological saline solution.

First, a mucous membrane punch with \varnothing 4.0 mm or – for a strong gingiva – with \varnothing 5.5 mm is used until the periosteum is reached. This punched, fixed mucosa is removed with an appropriate tissue forcep or rongeur.

The initial pilot hole is to be made with the conical triangular yellow Champions drills by preparing to the whole implant working length. Using external water cooling, the yellow condensation bur is operated at a maximum drilling speed of 250 rpm in the approx. 2 mm-wide compact cortical bone. Then, the preparation is done in the cancellous bone at 70 rpm. Next, the whole working length is drilled with the black condensation bur at approx. 70 rpm. For all drills, there are Champions multiple drill stop sleeves with depth markings every 2 mm, according to the laser markings of the drills. Pay attention to the depth markings of the drills.

Alternatively: with the MIMI®-Flapless II method (horizontal distraction), sterile diamonds are used with an air turbine to cut both gingiva and cortical bone. Adequate water cooling should be used while cutting with the turbine. Then, following horizontal distraction and widening, the whole bone cavity depth is condensed with the ø 2.4 mm Champions condenser. Then, the blue drill (ø 2.8 mm) is used with the drill stop, adjusted to the 4 mm laser marking – working length. This means that only the crestal bone is prepared with the blue drill, at 70 rpm. Due to the low speed, external and internal water cooling is not necessary. Finally, the brown drill (ø 3.25 mm) with the corresponding drill stop set to the 4 mm laser marking – working length is used at 70 rpm in the crestal bone portion. Please note that the given sequences are practical values. However, they should be adjusted individually for each patient due to the varying bone anatomy.

Remove the implant from the original packing box only immediately before implantation of the WIN!® PEEK implant. Open the blister packaging and untwist the sterile glass with a ¼ rotation. Wearing sterile gloves, holding the plastic key the implant is attached to, the dentist can shorten the WIN!® PEEK implant to the working length corresponding to the prepared bone cavity depth. For this, the following instruments can be used: a sterile endodontic gauge and very sharp pair of sterile medical scissors, a sterile medical guillotine, or a sterile milling device. The minimum endosseous working length for placing the WIN!® PEEK implant is 6.3 mm, measured from the upper edge of the upper groove (line A) to the end of the 2nd marking from above (line B). It is recommended that the implant working length should be adapted to the one of the Champions drills, i.e. working length of 6, 8, 10, 12, 14, 16, 18 or 20 mm.

An implantation up to the opposite cortical bone is recommended in order to achieve bicortical stability. Before the insertion of the implant, make sure that the flat square part is in a buccal/vestibular position so that insertion divergences can be compensated and corrected with the Prep-Cap. When removing, shortening, resetting the metal insertion aid, or inserting, the endosseous portion of the implant should not be touched with the gloves. The final insertion depth is reached by exerting suitable pressure on the WIN!® PEEK implant or on the plastic or metal insertion aid. Here an increasing stability is noticeable due to the lateral anchorage in the bone. The WIN!® PEEK implant in its final position must be inserted in a way that the upper edge of the bone apposition groove (A) is completely countersunk into the bone. A single-tooth X-ray check is to be made.

The original Champions zircon Prep-Cap is cemented with a dual hardening cement (e.g. Panavia SA of Kuraray). When choosing the zircon Prep-Caps, make sure that there is a sufficient retention surface for the superstructure above the gingiva. It is recommended that single-tooth X-ray checks should be made again after cementing the Prep-Caps. Careful attention should be used to remove all cement debris from under the Prep-Cap to prevent gingival irritation.

Information:

- The type of implant used and its lot number should be recorded in the patient's file after implantation. For simplification, respective removable labels with implant information are included in the original packing box and can be glued into the patient's file.
- Implants may only be used during their shelf life period.
- Implants must be stored closed in a dry place. The blister package is only to be opened immediately before insertion of the implant. Any kind of contact of the WIN!® PEEK implant with foreign substances is to be eliminated.
- After accidental swallowing of implants, Abutments, Prep-Caps or equipment, the destination of the subject is to be identified (e.g. X-rays), and necessary medical action has to be undertaken.
- After insertion of the superstructure, it may be useful to conduct a radiological check for cement or plastic residues.
- The prosthodontic transition period from primary to secondary stability (4-6 weeks post surgery) should also be checked clinically (possibly also radiologically).
- Clinical and radiological check-ups on a regular basis as well as admission of the patient to recall and prophylaxis programs are highly recommended.
- Non-osseointegrated or inflamed implants must be removed in a timely manner under local anesthesia in order to prevent serious bone loss. Those implants can usually be easily unscrewed (possibly after removal of the superstructure) with the implant equipment or common universal pliers. The time of extraction is to be determined by the dentist.
- Even after proper surgical and prosthodontic procedures horizontal and vertical bone loss is possible (as with any other dental implants). Type and complexity of the bone loss cannot be anticipated.
- If iatrogenically caused injuries of special anatomic structures (nerves, neighboring teeth, maxillary sinus etc.) occur, a reversible or irreversible damage of these structures may occur.

- The manufacturer reserves the right to change the design of the product, components or its packaging, to revise Instructions for Use as well as pricing and terms of delivery. Liability is limited to replacement of defective products.
- Further claims of any kind are excluded.
- Disposal: dispose and decontaminate waste in conformity with the local, regional, or national regulations.

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Symbols:

-  Manufacturer
-  Use by
-  Single use only
-  Store in a dry place
-  Observe the Instructions for Use
-  Batch number
-  Article number
-  Gamma sterilized
-  Do not use in case of damaged packaging
-  Application restricted to dentists or specialists
-  Bar code