Instruction for Use Champions® Implant Square/Ball-Head

Item numbers can be found in the current product catalog.

STERILE: Do not use the product if the sterile package is damaged.

Please Note:

Please read these Instructions for Use prior to the application of the Champions® implant system. Please also follow the Champions® Condensers Instructions for Use and protocol for the manual and mechanical use of the Champions® Condensers, explaining the procedure for using the condenser sequences for insertion.
The Champions® implant system may only be used by dental surgeons and doctors 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. These Instructions for Use only are not sufficient to ensure a professional application for doctors inexperienced in Implantology. The Champions® implant system may only be used if in good condition. All components used inside the patient's mouth have to be protected from aspiration and swallowing. Therefore, we recommend a course of instruction for the handling by an experienced user. If in doubt regarding indication or application, refrain from usage until all items are clarified. As the application of the 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 Champions® implant system is a system for endosseous dental implantation. The system contains surgical, prosthetic and laboratory technical components and instruments. The Champions® implant system is suitable for one-stage implantation procedures and immediate implantation.

Champions® implants are made from titanium (titanium grade 4) under validated GMP-conditions and are available in various lengths and diameters. In order to avoid mix-up of different component diameters, the components are color-coded through the packaging.

Due to their excellent osseointegration, Champions® implants shall not be used as temporary implants.

Indication / Purpose:

Surgery: The implants are to be used intra-orally.

Indications are the following:

- Dentures for replacing a single lateral incisor in the maxilla & mandible as well as a single central incisor in the mandible
- Splinted fixed dentures
- Removable dentures, for at least 4 primary splinted implants with a bar (does not apply to telescope restorations)

Prosthodontic Concept: Single-tooth prosthodontic restorations, fixation of bridges and full dentures

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

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

Healing: Transgingival with gingiva-forming elements

Contraindications / Restriction 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 disorders such as serious or unstable diabetes mellitus, calcium metabolic disorder, treatment with steroids and other pharmaceuticals intervening in the calcium metabolism, immunosuppressive therapy such as chemo and radiation therapy, endocrinological bone disease, insufficient 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 inter-occlusal distance, psychological disorder, pain syndrome, poor oral hygiene and inadequate preparation for overall oral rehabilitation, with poor patient compliance.

Relative contraindications are existent with patients with bruxism, allergies, alcohol or nicotine abuse.

Side Effects:

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

Complications:

During the application of endosseous implants the following complications have been observed in isolation: postoperative bleeding, infections, suture dehiscence, iatrogenic trauma, insufficient osseointegration, periodontal complication due to insufficient width of mucogingival attachments, jammed or overtwisted implant mount screw, aspiration or swallowing of components that are used inside the patient's mouth, in rare cases extreme adverse load conditions (prosthetic overload, intense bone reduction) may lead to breakage of the implant body.

Diagnostics/Clarification:

In-depth medical history, clinical examination, radiological examination using small image X-rays, orthopantomogram as well as, if necessary, a CT- or volumetric tomograph examination, and preoperative situation 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 as well). Concerning the method of giving consent please refer to the respective jurisdiction.

Shelf Life:

All components are supplied in a sterile condition. Sterile products are labeled with the STERILE sign.

Sterile products may not be resterilized. If medical devices are resterilized by the end-user, any responsibility will be void – regardless of the sterilization method.

The medical devices are only sterile if still in their closed original blister packaging.

The shelf life until the first use of the product is indicated on the label. The hourglass symbol refers to the expiry date.

Do not use the sterile products after the expiry date indicated on the packaging. The indication LOT refers to the lot number.

Implants are for single use only.

Storage:

The product has to be stored in a dry place in its original package at room temperature. Unsafe storage can cause product failure and damage to the material.

Implantation Methods:

1) Preparation of the Implant Site / Condensation Bur – Sequence

The implant site is to be prepared under local anesthesia with various condensation burs, considering screw size and bone density. It is absolutely necessary to avoid overheating and overloading of the bone. The recommended drilling speed is 250 rpm. Only new instruments (not exceeding five bone preparations of firm, cortical bone) should be used for drilling, applying minimal pressure, utilizing intermittent and sufficient external cooling with pre-cooled, physiological saline solution.

The initial pilot drill is to be made with the yellow Conical Triangular Drill (ø 2.3 mm) for any implant size.

Afterwards, the white Conical Triangular Drill (ø 3.3 mm) is required for placing Square implants in the D1/D2 bone. For placing Ball-Head implants starting from ø 3.0 mm in the D1/D2 bone, the white Conical Triangular Drill is used.

C-Square refers to the Champions® Implant Square with grooved square and prevention of rotation.

C-Ball-Head refers to the Champions® Implant Ball-Head.

Please note that the given sequences are practical values, however, should be adjusted individually for each patient due to the varying bone anatomy. Very firm bone (D1) requires more advanced preparation than a D2 bone. For D4 the bur condensation can already be completed with preparation "yellow". Ideally, a Champions® implant should be completely inserted in bone at a torque of 20 Ncm minimum to 40 Ncm maximum.

During condensation drilling pay attention that the countersink of the instruments is not exceeding the respective implant length. The given length of the instruments is defined by the edge at the transition from the working part to the shaft.

After choosing the relevant implant, remove the covering box only immediately before implantation, open the blister packaging and untwist the sterile glass with a ¼ rotation. The first implant rotation into the prepared implant bed should

be done by the implantologist, wearing sterile gloves, using the guiding key on which the implant has already been fixed (the endosseous part of the implant should not be touched). Once a further insertion is manually not possible, the implant should slowly be inserted into its final position using a metal Insertion Tool with a Torque Wrench. Here an increasing stability is noticeable due to the lateral condensation of the bone. Once the manually adjusted torque has been reached, the scale sleeve bends around the axis of the wrench head. This releasing is audible, visible, and tangible. When releasing the articulated arm, the wrench moves back into its straight initial position.

2) Soft Tissue- and Bone Management:

The length of the implant should be chosen considering the maximum height of the available bone.

An implantation up to the opposite cortical bone is recommended in order to achieve bicortical stability. To minimize frictional heat, the implant should be inserted slowly and without high pressure. The bone density must be adequate in order to ensure primary stability at a torque of 20 Ncm minimum to 40 Ncm maximum. Implants with insufficient primary stability (periotest > 0.6 or tightening torque < 20 Ncm) have to be removed again: such cases have to be provided with a larger implant diameter, or the created hole has to be filled with a bone substitute for a future implantation or conventional crown or bridge work.

The Champions® implant in its final position must be inserted in a way that the top thread of the micro-thread is completely countersunk into the bone. A bright bone echo verifies total osseointegration as well as high primary stability of the Champions® implant.

a) "MIMI®" (Minimally Invasive Method of Implantation): If existence of good bone offering is provided (mesially/distally as well as buccally/lingually), a transmucosal implantation under minimally invasive criteria, without opening the oral mucosa (flapless insertion), is recommended. Punching of the mucosa tissue with corresponding Mucosal Punches is often advisable for mucous membranes of the maxilla with a thickness of > 2 mm. The one-stage MIMI® shows advantages related to the regeneration of the soft tissue versus the classic two-stage procedure.
If operative complications occur (like vestibular fenestration > 1 mm), it is advised to continue with the conventional method (raising a flap, augmentation with bone substitutes and a [resorbable] membrane). An X-ray check is also required for MIMI® in order to verify a complete, osseous countersink of the thread.

b) Conventional: Alternatively, the implantation (primarily with minor horizontal bone offering) can be conducted by conventionally raising a flap of the oral mucosa. After completed implantation, perform a saliva-closed suture.

c) An immediate implantation should, in any case, only be done in a non-inflammatory site. After gentle extraction of the tooth (no luxation movements), proceed with proper curettage of the fresh alveolus, removing granulation tissue and with drilling slightly lingually/palatally in continuation of the alveolus axis (for protection of the buccal bone wall). The crestal implant diameter should possibly be close to the crestal alveolus diameter or even slightly laterally condensing it in order to gain respective primary stability and preferably many prompt osseous bridge connections. The Champions® thread should be implanted at least 1/3 of its thread length in extension of the original length of the tooth root, and the remaining alveolus should be filled densely with fine grained bone substitutes in combination with collagen. Using a resorbable membrane ideally prevents epithelial growing into the alveolus.

At this stage an immediate implantation of the one-piece Ball-Head implants with immediate loading is not recommended.

Prosthetic Superstructure:

1) Fixed Dentures:

a) An adequate number of endosseous implants for fixed dentures is ideally determined according to basic principle: The number of missing, natural, mesio-distal tooth roots is to be replaced with the same number of Champions® implants. Moreover, the recognized rules of the Consensus Conference Implantology ("Konsenskonferenz Implantologie") apply.

b) The immediate temporary solution for single-root implants (VW-1) is to be adjusted to NON-occlusion and Non-Balance for 9-24 weeks. The immediate temporary prosthetic solution for multiple support teeth/implants (VW-2) should preferably be passively fitted but primarily splinted, like the subsequent final superstructure. When removing the temporary restoration, also make sure no shear force is applied to the implant. In order to prevent connective tissue encapsulation, micro-movements of the implant must be entirely eliminated until completion and integration of the final, preferably splinted, however, passively fitted denture.

c) For fixed and bar prosthetic, removable dentures, a final denture (also on occlusion, without healing phase and signs of inflammation) can be fitted quickly after implantation in the maxilla as well as in the mandible after sufficient primary stability and conservation of further success parameters (X-ray check: all thread segments must be anchored in bone, splinting of support teeth/implants for prevention of micro-movements) and consideration of above mentioned, defined prosthetic guidelines (possibly further splinting of implants with each other and the remaining teeth, no pronounced occlusal cusp and fissure reliefs). All structures are inserted with final cement

or equivalent fixing materials. Conventional metal dental alloys (NE incl. titanium, high gold-bearing alloys) or zirconia are recommended as framework. Ceramic and/or advanced synthetic materials are recommended as facing material.

2) Removable Dentures on Champions® Implant Ball-Head

d) Dentures on the Ball-Head implants should be shaped and respectively smoothly relined for at least six weeks until the final secondary splinting can take place with the Metal Matrices and O-Rings, which are worked into the denture. C-Caps are deliberately flat with a rough surface and furnished with a retention mechanism in order to considerably ease its incorporation and a possible impression. For chairside polymerization of the Metal Matrices (incl. O-Rings), the inverse conical Ball-Head area should be sealed with an O-Ring and cofferdam. Then, the positioning of the Metal Matrices (incl. O-Rings) onto the ball-head is carried out. The denture must be largely shaped in the area of the Metal Matrix, adequately furnished with cold polymer and relocated in the mouth. In order to prevent bite elevation in the area of the crescent heads, drainage possibilities should be available towards the lingual and/or vestibular side in order for the excess to drain off. Alternatively, the polymerization after the relining impression may also take place at a dental laboratory. It is recommended to primarily connect the Metal Matrices with a clamp or a small NEM model cast in the denture.

Please Note:

- **All Champions® products are to be used and restored only with the original Champions® instruments intended for this purpose such as Drills, Condensers, Insertion Tools, and Screwdrivers.**
- The type of implant used and its lot number have to be recorded in the patient's file after implantation. For simplification respective label stickers with implant information are included in the covering 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 osseous, roughened implant with foreign substances is to be eliminated before implantation.
- After accidental swallowing of implants, 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 might be useful to conduct a radiological check for cement or plastic residues.
- The prosthetic 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 a prophylaxis program are highly recommended.
- Non-osseointegrated or inflamed implants must be removed in a timely manner under local anesthesia in order to prevent considerable 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 prosthetic procedure horizontal and vertical bone loss is possible (as with any other dental implants as well). Kind 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 of 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 of and decontaminate waste in conformity with the local, regional, or national regulations.

Symbols Glossary

You can find the following symbols on the product labels or on the accompanying product information.

CE 0297	CE Marking with notified body reference
	Manufacturer
REF	Reference
LOT	Lot Number
	Date of Manufacture
MD	Medical Device
	Non-Sterile
STERILE R	Sterilized Using Irradiation
	Expiry Date
	Do not resterilize
	Do not reuse
	Caution
	Consult Instructions for Use
	Do not use if package is damaged
	Temperature limit
	Keep away from sunlight
	Keep dry
SBS	Sterile packaging
SBS	Protective packaging with sterile barrier system inside
R_x only	Caution: US law (FDA) restricts this device to sale by or on the order of a dentist (licensed healthcare practitioner)
QTY	Quantity
	Max. rotation speed

Manufacturer in the EU:
Champions-Implants GmbH
Managing Director: Dr. med. dent. Armin Nedjat
Im Baumfeld 30 | Champions Platz 1
D-55237 Flonheim
Germany
Tel. 0049 6734 - 91 40 80 | Fax 0049 6734 - 10 53
info@champions-implants.com
www.champions-implants.com

CE 0297

Rev. 7/2021-07