Instructions for Use Champions® Implant (R)Evolution

The Item numbers can be found in the current product catalog.

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

Please Note:

It is essential to read these instructions for use prior to the application of the Champions® implant system. 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 alone are not sufficient to ensure a professional application for doctors inexperienced in Implantology. The Champions® 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. 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. Champions® implants are not approved as temporary implant due to its excellent osseointegration.

Indications:

Surgery: Depending on the indications, the ø 3.5 mm-(R)Evolution implants can be used for all single-tooth restorations in the maxilla and mandible, except for single-molar restorations. For single-molar restorations, a 4.0 mm-diameter (R)Evolution should be used. In the D3/D4 bone, the condensers with diameters of 3.0 mm, 3.8 mm, 4.3 mm, and 5.3 mm respectively are used to condense bone until primary stability is achieved.

If primary stability of 30 Ncm is achieved with the ø 3.8 mm-Condenser, the ø 4.0 mm-implant should be used.

If primary stability of 30 Ncm is achieved with the ø 4.3 mm-Condenser, the ø 4.5 mm-implant should be used.

Finally, if primary stability of 30 Ncm is achieved with the ø 5.3 mm-Condenser, the ø 5.5 mm-implant should be used.

Basic rule: in the D1/D2 bone a ø 3.5 mm-implant shall be used first to preserve peri-implant bone and to ensure optimal nutrition. An increased BIC is not beneficial.

The objective of an implantation should be to achieve primary stability at a torque of at least 30 Ncm through the spongy bone. Strong pressure should not be exerted crestally. Primary stability should not depend on the crestal bone site. The Champions drill and Condenser protocols shall be considered. For a narrow jaw ridge width (< 5.5 mm) the MIMI®-Flapless II method (horizontal bone distraction) shall be applied.

Removable prostheses on at least 4 primary splinted implants with a bar (does not apply to telescope/Locator or Ball-Head Abutment restorations)

Prosthetic Concept: single-tooth prosthetic restorations, fixation of bridges and full prostheses

Prosthetic restoration: Immediate non-functional loading, immediate functional loading (taking care to avoid micromovement of the primary stable implant in its surrounding bone and mechanical, prosthetic over-loading). Time of Implantation: Immediate implantation, delayed immediate implantation, delayed implantation. Healing: Subgingival & transgingival with gingiva-forming elements (Shuttle or Gingiva-Clix)

Contraindications / Restriction of Use:

General contraindications for dental/surgical treatments are to be considered for patient selection. These are amongst others: Infections and inflammations in the oral cavity such as periodontitis, gingivitis, reduced blood clotting, e.g.: anticoagulants therapy, congenital or acquired disorder in coagulation, acute or chronic infection in the field of surgery (soft tissue infection, inflammable/bacterial bone disease, osteomyelitis), severe metabolic disorder, such as serious or 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 bone offering (also close to vital structures such as the mandibular nerve, sub-lingual 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 preparedness for oral overall rehabilitation, with poor patient compliance. Relative contraindications are existent with patients with bruxism, allergies, alcohol or nicotine abuse.

Side Effects:

With any surgical treatment, the following side effects may occur: local/temporary 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 over twisted implant mount screw, aspiration or swallowing of components which are used inside the patient's mouth, in cases of extreme adverse load conditions (prosthetic overload, serious bone loss) a breakage of the implant body may occur rarely.

Diagnostics / Clarification:

Detailed anamnesis, clinical examination, radiological examination using small picture x-ray, orthopantomogram as well as CT- or volumetric tomograph examination, if necessary, and preoperative situation models of the patient are essential for accurate diagnostics. A medical check-up by a general practitioner is recommended. An 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 sterilized again. 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 original and closed blister packaging.

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

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

Implants are for single use only.

Storage:

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

Implantation Methods:

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

The implant site is to be prepared under local anesthesia with various condensation burrs, 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 condensation burr for any implant size. Afterwards, the black condensation burr is required for the mandible and D1/D2 bone. The red and green drills (with length scale) are designed for thread lengths of 16 mm and longer. For mainly cortical bone (D1), there are two further twist drills (2.8 & 3.25 mm). Depending on the implant diameter, the implant site is to be prepared according to the depth needed. Pay attention to the depth markings of the drill. The twist drills 2.8 & 3.25 mm are used for larger implant diameters for reducing the insertion torque.

The two-piece Champions® (R)Evolution implants with their hybrid inner connection are rotation-proof. The inner connection has a hybrid between the cone and the hexagon.

Please note that the given sequences are practical values. However, they 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 burr condensation can already be completed with preparation "yellow". Ideally, a Champions® implant should be completely inserted between 30 – 50 Ncm. 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 between the working part and 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 further insertion is manually not possible, remove the guiding key from the Shuttle and replace it by the "golden" Insertion Aid. This Insertion Aid can be used either with a green handpiece or a Torque Wrench Adapter. 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 bone compacta is recommended in order to achieve bicortical stability. To minimize frictional heat, the implant should be inserted slowly and without strong pressure. The bone density must be adequate in order to ensure primary stability (tightening torque: 30 - 50 Ncm). 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 suitable 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 (mesial/distal as well as buccal/lingual), a transgingival 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 intra-operative complications occur (like vestibular fenestration > 1 mm), it is 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®" 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 with conventional flap operation 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 (preferably without luxation movements), proceed with proper curettage of the fresh alveolus, removing granulation tissue and the 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 condensing it laterally 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 one-piece Ball-Head implants with immediate loading is not recommended.

Prosthetic Superstructure:

1) Fixed Prosthetic Restorations:

a) An adequate number of endosseous implants for fixed dentures is ideally determined according to the 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 standards of the Consensus Conference Implantology ("Konsenskonferenz Implantologie") apply.

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

c) For fixed and bar prosthetic, removable dentures, a final solution (also on occlusion, without healing period and signs of inflammation) can take place 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 fixed osseously, splinting of support teeth/implants for prevention of micromovements) and consideration of above mentioned, defined prosthetic guidelines (possibly further splinting of implants with each other and the remaining teeth existence, no highly distinctive occlusal cusps and fissures). All structures are inserted with final cement or equivalent fixing materials. Conventional dental metal alloys (NE incl. titanium, high gold-bearing alloy) or zircon dioxide are recommended as framework. Ceramic and/or advanced synthetic materials are recommended as facing material.

2) Removable Prostheses on "Ball-Head" & "LOC® Abutments":

d) Prosthesis on planned "Ball-Head" implants & "LOC®-Abutments" should be shaped and respectively smoothly relined for at least six weeks until final secondary splinting can take place with Metal Matrices and O-Rings, which are worked into the prosthesis. C & LOC® caps are deliberately flat with rough surface and furnished with retention mechanism in order to considerably ease its incorporation and a possible impression. For "chairside" imbedding of the Metal Matrix (incl. O-Rings & LOC® inserts) into polymer, the abutment area should be sealed with an O-Ring and rubber dam. Here the positioning of the Metal Matrices (incl. O-Ring & LOC® inserts) onto the abutment is carried out. The prosthesis must be generously shaped in the area of the Metal Matrix, adequately furnished with cold polymer and repositioned in the mouth. In order to prevent bite elevation in the area of the crescent heads, drainage possibilities should be available in the lingual and/or vestibular position, in order to drain off surpluses. Alternatively, the imbedding into polymer after denture relining may also take place at a dental laboratory. It is recommended that you should primarily connect the Metal Matrix & LOC®-Caps with a clamp or small NEM alloy model casting in the prosthesis.

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 Aids, 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 self-adhesive labels 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 before implantation 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 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 a 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 (incl. nerves, neighboring teeth, maxillary sinus) 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.

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Symbols:

	Manufacturer
	Use by
	Do not reuse
	Keep dry
	Consult instructions for use
LOT	Batch code
REF	Catalog number
STERILE R	Sterilized using irradiation
	Do not use if package is damaged
RX only	Caution: Federal law restricts this device to sale by or on the order of a dentist (licensed health-care practitioner)
	Bar code

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