Instruction for Use **Champions®- Implants**

Safety Instructions
It is essential to read this 'Instruction 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 actions 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 'Instruction for Use' only, is 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:
Prosthetic Concept: single-tooth dentures, fixation of bridges and full dentures
Prosthetic Supply: Immediate non-functional loading, immediate functional loading (when avoiding relative movements 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: transgingival with gum-shaping elements

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 part infection, inflammable/bacterial bone disease, Osteomyelitis), severe metabolic disorder, like severe and difficult or not controllable 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 endangered structures like N. mandibularis, A. sublingualis, Sinus maxillaries etc.), insufficient soft tissue coverage, lacking occlusion and/or articulation as well as small interocclusal distance, mental disorder, pain syndrome, poor oral hygiene and poor preparedness for oral overall rehabilitation, absent patient compliance.
Relative contraindications are existent with patients with bruxism, allergies, alcohol or nicotine abuse.

Adverse Events:
Following accompaniment of surgical treatment may occur: local/temporary swelling, edemas, bruises, temporary limitation of sensibility, temporary limitation of chewing performance.

Complications:
During the application of endosseous implants the following complications have been observed isolatedly: postoperative hemorrhage, 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 rare cases extreme adverse load conditions (prosthetic overload, intense bone reduction) may lead to breakage of the implant body.

Diagnostics / Clarification:
In-depth anamnesis, clinical examination, roentgenological examination using small picture x-ray, orthopantomogram as well as CT- or volumetric tomograph examination, if necessary, and preoperative diagnostic models of the patient are essential for accurate diagnostics. A medical check-up by a general practitioner is recommended. An implantation requires a substantial clarification for the patient: economic clarification (also costs for implant aftercare), therapeutic clarification (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 way/method of clarification please refer to the respective jurisdiction.

Shelf Live:
Five years from sterilization. The medical device has to be stored in a cool and dry place in its covering box. Implants are only sterile if still in their original packaging and unopened blister packaging. If implants are resterilized by the end-user, any responsibility is declined, regardless of the sterilization method. Sterile products are labeled with the STERILE sign. The expiry date is indicated by the hour glass. The description LOT refers to the batch number. Implants are for single use only.

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 precooled, physiological irrigation solution (sodium chloride).
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 16mm and longer.

C are Champions®-Implants with grooved square with prevention of rotation.
TKI are tulip-shaped implants.

Please note that the given sequences are practical values, however, should be adjusted individually for each patient due to the diverse bone structures. A 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 eventually 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 passage located between 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 glas with a quarter 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 an insertion aid, such as a hand wheel resp. a wrench and 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 bone compacta is recommended in order to achieve bicortical stability. To minimize frictional heat, the implant should be inserted slowly and without heavy 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 bone augmentation material 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'**: (‚MIMI': Minimal-Invasive Method of Implantation) If existence of good bone offering is provided (mesial/distal as well as buccal/lingual), a transgingival implantation under minimal invasive criteria, without opening the oral mucosa (flapless insertion), is recommended.
Punching of the mucosa tissue with corresponding mucous membrane 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 (flap operation, augmentation with bone material and absorbable membrane). 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 suture gum closed over the implant.

c) An **Immediate Implantation** should, in any case, only be done in a non-inflammatory site. After gentle extraction (no dislocating movements) proceed with proper curettage of the fresh alveolus, removing granulation tissue and with drilling slightly lingual/palatinal 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 lateral condensing 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 augmentation material in combination with collagen. Using absorbable membrane, ideally prevents epithelial growing into the alveolus. At this stage an immediate implantation of one-piece, ball- implants (tulip-shaped) with immediate load is not recommend.

Prosthetic Supra-Structure:

1) Fixed Dentures:

a) An adequate amount of endosseous implants for fixed dentures is ideally determined according to basic principle: The amount of missing, natural, mesio-distal tooth roots is to be replaced with Champions® -Implants. Moreover, the recognized standards of Consensus Conference Implantology 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 solution for multiple abutments (VW-2) should preferably be tension-free, but primarily interlocked, like the subsequent final supra-structure. When removing the temporary implant, also make sure no shear force is applied to the implant. Micro-movements of the implant must be entirely eliminated until completion and integration of the final, preferably interlocked, however, tension-free dental prosthesis, 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 mandible after sufficient primary stability and conservation of further success parameters (x-ray check: all thread segments must be fixed osseous, interlocking of abutments for prevention of micro movements) and consideration of above mentioned, defined prosthetic guidelines (possibly further interlocking of implants with each other and the remaining teeth existence, no highly distinctive occlusal cusp, fissures). All structures are inserted with final cement or equivalent fixing materials. Conventional, dental metal alloy (non-ferrous incl. Titan, high gold-bearing alloy) or zirconium oxide are recommended as framework. Ceramic and/or advanced synthetic materials are recommended as facing material.

2) Removable Denture on ‚Tulip Head' - Champions:

d) Prosthesis on tulip head implants should be abraded and respectively smoothly relined until final secondary interlocking can take place with metal matrixes and o-rings, which are worked into the prosthesis. C-Caps are deliberately flat with rough surface and furnished with retention mechanism in order to considerably ease its incorporation and a possible impression. For chair side imbedding of the metal matrix into polymer (incl. O-ring) the tulip head area should be sealed with an o-ring and rubber dam, hereon the positioning of the metal matrix (incl. O-ring) onto the tulip head is carried out. The prosthesis must be grinded generously 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 lingual and/or vestibular, in order for excess to drain off. Alternatively, the imbedding into polymer after denture relining may also take place at a dental laboratory. It is recommended to connect the metal matrix with a clamp or small non high-noble alloy model casting primary in the prosthesis.

Information:

- The type of implant used and its lot number have to be recorded in the patient's file after implantation. For simplification respective 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 its shelf live 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-ray) and necessary medical actions have to be undertaken.
- After insertion of the supra-structure 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 supra-structure) 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 iatrogenic caused injuries of special anatomic structures (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.

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Signs and Symbols:

⌛ Expiry date
△ Follow Instruction for Use
STERILE R Gamma sterilized
② For single use only
LOT Batch Number

CE 0297