Champions (R)Evolution® Implants Instructions for Use

You can find article numbers in the current Product Catalog.

Please Note:

Please read these Instructions for Use before using the Champions® implant system. Please also follow the Champions® Basic Rules, Champions® Condensers Instructions for Use as well the Champions® Condenser Protocol for manual and mechanical use, explaining Condenser sequences for insertion.

The use of the Champions® implant system is restricted to dentists 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, check that all required parts, instruments, and auxiliary devices are complete, functioning correctly, and available in sufficient quantity. Use the Champions® system only if it is in good condition.

Care should be taken to protect the components used inside the patient's mouth against aspiration and ingestion. Therefore, we recommend that you should undergo proper training by users with the necessary relevant experience. If in doubt regarding indication or application, refrain from usage until all items are clarified.

These Instructions for Use alone are not sufficient to ensure a professional application for treating practitioners inexperienced in Implantology. As the application of the product takes place beyond our control, we disclaim any liability for damage caused.

The treating practitioner takes sole responsibility.

1. Product description

Champions (R)Evolution® implants are part of the Champions® implant system.

The Champions (R)Evolution® implant is a titanium endosseous two-piece implant, which is available in various lengths and diameters.

The implant is factory-fitted with a healing abutment (Shuttle) and a Screw and designed with a rotation-proof hybrid internal connection. The internal connection consists of a hybrid between the cone and hexagon. The implant surface is etched and blasted for anchorage in the bone.

With the Champions (R)Evolution® implant system, a wide range of secondary components is available and can be used for the laboratory and for prosthetic restorations for single crowns, bridges as well as partial or full dentures.

Champions® implants can be used after extraction or loss of natural teeth to restore the mastication function. The implant remains as a long-term implant in the jawbone and can be placed in all maxillary and mandibular bone quality types (D1–D4) and all jaw regions, with or without augmentation.

The Champions® implant system is suitable for one-stage implantation procedures and immediate implantation.

Prosthetic concept: single-tooth dentures, fixation of bridges, bars, and removable dentures

Prosthetic fixation options: screw-retained and/or cement-retained

Time of implantation: immediate implantation, delayed immediate implantation, delayed implantation

Healing: subgingival and transmucosal with gingiva-forming components (Shuttle or Gingiva-Clix)

1.1. Material

The implants are manufactured from grade 4 titanium according to ISO 5832-2 and ASTM F 67.

1.2. Accessories

You can find detailed information and details about further system components in the current Product Catalog.

2. Delivery terms

All supplied components are sterile. Sterile products are labeled with the STERILE R symbol (gamma method).
The symbol LOT refers to the batch code.

2.1 Cleaning, disinfection, and sterilization

The supplied Champions® dental implants are sterile and intended for single use. They may not be cleaned, disinfected, and resterilized. Champions-Implants disclaims any responsibility for a clinical preparation of the supplied originally sterile Champions® products by the end user.

2.2 Storage, shelf life, packaging, and return

The product is to be stored in its original package and kept dry at room temperature and kept away from direct sunlight. Incorrect or unsafe storage can damage essential material characteristics and cause product failure.

The shelf life until the first use of the product is indicated on the label.

The use by date is indicated by the hourglass symbol. Do not use the sterile products after the use by date indicated on the packaging.

Only medical devices in their closed original blister packaging are sterile.

Do not perform a treatment with these components in case of an opened or damaged package, otherwise sterility and/or integrity of the products can be impaired.

These products are excluded from an exchange.

3. Intended purpose

Champions® dental implants and secondary components are designed for oral insertion in the human jawbone and serve as a load-bearing support structure for a prosthetic restoration as a fixed and/or removable denture.

4. Indication

The Champions (R)Evolution® implant system is designed for the functional and esthetic rehabilitation of completely or partially edentulous upper and lower jaws.

Champions® dental implants are suitable for one-stage implantation procedures and immediate implantation.

- Single-tooth restoration: depending on their indication, the 3.5 mm-diameter Champions (R)Evolution® implants can be used for all single-tooth restorations in the upper jaw and in the lower jaw, except for single-molar restorations. For single-molar restorations, a 4.0 mm-diameter Champions (R)Evolution® implant should be placed.
  Prosthodontics – fixed denture, for splinted prosthetic restorations
- Partially edentulous and edentulous jawbone restorations: depending on their indication, Champions (R)Evolution® implants are designed for a partially edentulous and edentulous bone in the upper jaw and in the lower jaw.
  Prosthodontics:
  - Fixed denture, for splinted prosthetic restorations and/or
  - Removable denture, according to the directives of the "Konsenskonferenz Implantologie" (Implantology Consensus Conference) concerning the minimum supporting teeth/implants per jaw:
    This does not apply to telescope constructions.

5. Target patient group and intended user

Champions® implants are intended for use in patients with reduced or missing residual teeth. It is recommended that you should perform this treatment only in patients whose jawbone has reached maturity.

The use of the Champions® implant system is restricted to dental implantologists and dentists who are familiar with dental surgery, including diagnosis and preoperative management, considering its indication and general guidelines for dental/surgical applications.

Compliance with the Champions®-Basic Rules is a prerequisite for professional and safe use of the Champions® implant system.

6. Contraindications

- Insufficient jawbone quantity and/or poor bone quality; local root residues
- Serious internal diseases
- Uncontrollable bleeding disorders
- Inadequate wound healing capacity
- Immature upper jaw and lower jaw
- Bad general state of health
- Medication, drug, or alcohol abuse
- Psychoses
- Persistent therapy-resistant functional disorders
- Xerostomia
- Weakened immune system
- Diseases requiring the regular use of steroids
- Uncontrolled endocrine diseases
- Allergies or hypersensitivity to chemical components of the grade 4 titanium material used

7. Warnings

- For intra-oral use, Champions® products must be protected from aspiration. After accidental swallowing of products, the destination of the object is to be identified (e.g. X-rays), and necessary medical action must be undertaken.
- When preparing the implant site and implant insertion, pay attention to the proximity of special structures (incl. nerve, maxillary sinus, adjacent teeth). Reversible or irreversible impairment (damage) of these structures can occur.
- It is crucial that you avoid overheating and overloading of the bone (bone necrosis).
- Champions® Basic Rules explain the use of the Champions® instruments, the drilling, Condenser, and insertion techniques, and the recommended insertion torque for transmucosal, minimally invasive treatment methods.
- All Champions® products should be used and restored only with the original Champions® instruments intended for this purpose such as Drills, Condensers, Insertion Aids, and Prosthetic Drivers/Screwdrivers.
- Non-osseointegrated or inflamed implants must be removed under local anesthesia in due time in order to prevent serious bone loss. As a rule these implants can be easily unscrewed (possibly after removing the superstructure) with the implant equipment or common Crampon pliers. The time of extraction is 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 is not predictable.
- Iatrogenic injuries of special anatomic structures (incl. nerves, adjacent teeth, maxillary sinus) can result in a reversible or irreversible impairment of these structures.
- Information about safety of MRT (Magnetic Resonance Tomography)

  The effects of the MR-environment on this product have not been assessed. This product has not been tested for heating or migration in the MR-environment.

7.1 Advice

- After implantation, the type of implant and the batch code must be recorded in writing in the patient's file. For simplification, respective self-adhesive labels with implant data are included in the covering box and can be glued in the patient's file.
- After fitting the superstructure, it might be useful to conduct a radiologic check for cement or plastic residues.
- The prosthetic transition from primary to secondary stability (4–6 weeks after surgery) should also be checked clinically (possibly also through a radiologic check).
- Regular clinical and radiologic check-ups as well as admission of the patient to a prophylaxis program are highly recommended.
- 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 delivery terms.
- Liability is limited to the replacement of the defective product. Further claims of any kind are excluded.
- Problems with Champions® products must be notified with details of the product (article number, batch code) to Champions-Implants GmbH, Flonheim. Serious incidents must be notified to the company Champions-Implants GmbH and to the competent statutory and regulation authorities.
- Within the framework of the EU Medical Device Regulation (MDR, 2017/745) l Article 32, Champions-Implants GmbH prepares the required brief report / SSCP (Summary of Safety and Clinical Performance) on the safety and clinical performance of the respective device. This is an important source of information for users of medical devices.

  You can find a summary of the safety aspects and clinical performance at the following link: http://ec.europa.eu/tools/eudamed Notes: EUDAMED (European Database on Medical Devices) link has been available only after introducing EUDAMED to the market.

8. Clinical benefit and adverse side effects

Clinical benefit:

The clinical benefit of the Champions® implant system for the patient is to replace missing teeth and/or restore prosthetic superstructures. The aim of each implantation should be primary stability in the spongy bone (without pressure) at a minimum torque of 20 Ncm to a maximum torque of 60 Ncm. Primary stability should primarily be achieved in dense bone (D1/D2) and therefore not from the crestal bone area.

Adverse side effects:

When using endosseous implants, the following complications have been observed in isolated cases:

- Postoperative bleeding
- Local infections
- Temporary local swelling
- Edemas
- Hematomas
- Temporary limitation of sensibility
- Temporary limitation of masticatory function
- Suture dehiscence
- Iatrogenic trauma
- Inadequate osseointegration
- Bone compression
- Periodontal complications due to the insufficient width of the mucogingival attachment
- Implant fracture
- Insertion Aid too tight
- Swallowing/aspiration of components used inside the patient's mouth
- Prosthetic overload
- Serious bone loss
- Implant loss

Advice: directly after the dental implant placement, you should avoid activities associated with hard physical efforts.

9. Information about compatibility

With our Champions® implant system, a wide range of components is available and can be used for surgery and prosthetic restorations.

Care should be taken to use only Champions® components with an original connection.

You can find detailed information and details about further system components in the current Product Catalog.

10. Implantation procedure

You can find detailed instructions on process engineering in the Champions® Basic Rules. You can find further information on the system and implantation methods as well as on the application and the different components of the Champions® implant system on our website champions-implants.com under the heading "Download / User Manuals and Instructions for Use".

10.1 Diagnosis/Clarification

Detailed medical history, clinical examination, radiologic examination using retro-alveolar X-rays, orthopantomogram as well as CT- or volumetric tomograph examination, if necessary, and preoperative situation models of the patient are essential for an accurate diagnosis. A medical check-up by a general practitioner is recommended. An implantation makes it necessary to provide the patient with detailed information: therapeutic information (alternative treatments and possible consequences and risks of an implantation, as is the case with any other surgical procedure) as well as economic information (costs also for implant aftercare) must be pointed out and explained. Refer to the competent jurisdiction over the type and scope of clarification.

10.2 Planning

The preoperative planning of the implant type, diameter, and length as well as of the position and number of implants should be performed taking into account the individual anatomy and intraoral space conditions of the affected patient.

10.3 Implant site preparation

The implant site is to be prepared under local anesthesia with various condensing drills, considering screw size and bone density. Only new instruments (not exceeding 5 bone preparations in dense cortical bone) should be used for drilling, applying minimal pressure. Do not exceed the maximum drilling speed of 250 rpm in the cortical bone and the maximum drilling speed of 70 rpm in the spongy bone. It is absolutely necessary to avoid overheating and overloading of the bone.

10.4 Implant insertion

Champions® implants can be placed manually with the Torque Wrench or with a green handpiece with a Torque Wrench Adapter.

The objective of an implantation should be to achieve primary stability through the spongy bone at a minimum torque of 20 Ncm to a maximum torque of 60 Ncm. Strong pressure should therefore not be exerted in the crestal area. Primary stability should therefore not primarily be achieved from the crestal bone area.

11. Important information for patients

Patients should be informed about the potential side effects and complications, contraindications, warnings, and precautions associated with the treatment with Champions® products. Advise the patient that Champions® products have not been tested for heating or migration in the MR-environment.

12. Disposal

Dispose of contaminated or no longer usable medical devices safely as (clinical) health care waste in accordance with local health care directives as well as rules and regulations or directives from the state and the authorities. When separating, recycling, or disposing of packaging material, observe, where applicable, local rules and regulations from the state and authorities on packaging and packaging waste.

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	Article number
LOT	Batch code
	Date of manufacture
MD	Medical device
	Non-sterile
STERILE R	Sterilized using irradiation
	Use by date
	Do not resterilize
	Do no reuse
	Caution
	Consult Instructions for Use
	Do not use if package is damaged
	Temperature limit
	Keep away from sunlight
	Keep dry
SBS	Single sterile barrier system
SBS	Single sterile barrier system with protective packaging outside
R_x only	Caution: U.S. law federal law restricts this device to sale by or on the order of a dental professional
QTY	Quantity
	Max. rotation speed
UDI	Unique Device Identifier

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