Instructions for Use Champions® Prep-Caps

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.

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®-Prep-Caps are part of the Champions® implant system.

Prep-Caps are prefabricated, customizable caps made of zirconia or grade 5 titanium. In combination with the Abutment Prep-Cap or with the abutment of the one-piece Champions implant system, they form a Dual Abutment.

In Implantology, Prep-Caps help correct teeth/implant insertion divergences and widening clinical crowns. They are cemented or bonded onto the abutment of the one-piece Champions® implant system and can then be reshaped like a natural tooth.

Individual Prep-Caps allow for fabricating an individual Dual Abutment.

Prep-Caps are available in different Gingival Heights and angulation degrees as well as in two material variants.

Champions® Prep-Caps made of titanium are supplied sterile, Prep-Caps made of zirconia are supplied non-sterile.

1.1. Material

Grade 5 titanium

Zirconia

1.2. Accessories

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

2. Delivery terms

Champions® Prep-Cap components come in two material variants.

Prep-Caps made of zirconia are supplied non-sterile.

Prep-Caps made of titanium are supplied 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

Champions® prosthetic components made of titanium are supplied sterile and designed for single use. Reusing single-use devices poses a potential risk of infection to patients and users. They may not be cleaned, disinfected, and resterilized. Champions-Implants disclaims any liability for the clinical handling of originally supplied sterile Champions® products by the end user.

Champions® prosthetic components made of zirconia are supplied non-sterile, are intended for single use, and may not be reused. Reusing single-use devices poses a potential risk of infection to patients and users.

Champions® prosthetic components made of zirconia are packaged under cleanroom conditions, and their microbiological and toxicological cleanliness has been verified.

Note:

Before using it in the patient's mouth, the practitioner (dentist) must comply with sterility requirements! The dental laboratory must disinfect the prosthetic components after processing and before use on the patient.

Additional sterilization is recommended. Users are responsible for ensuring sterility. For sterilization, they must use only suitable equipment and materials and adhere to validated procedures specific to the product. Equipment and devices must be properly maintained and regularly serviced. Refer to the information about sterilization in the preparation guide of the Champions® implant system!

2.2 Storage, use by date, 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 use by date for the first use of the product is indicated on the label.

The use by date is represented 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.

A use by date is not required for Champions® prosthetic components made of zirconia (non-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® Prep-Caps can be used to compensate for implant/teeth insertion divergences to widen the clinical crown and serve as a load-bearing support structure for a prosthetic restoration as fixed denture.

4. Indication

Champions® Prep-Caps variants, in combination with the Abutment Prep-Cap (REF 3107) or directly with the abutment of the one-piece Champions® implant system, are used to compensate for divergences in the insertion of single crowns, to expand the clinical crown, and for the functional and aesthetic rehabilitation of the upper and lower jaws in edentulous or partially edentulous patients.

5. Target patient group and intended user

Champions® prosthetic components 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. Contraindication

Allergies or hypersensitivity to chemical components to the zirconia or titanium material used.

7. Warnings

- For intraoral 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.
- 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.
- 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 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) I 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 side effects

Clinical benefit:

The clinical benefit of the Champions® implant system for the patient is the replacement of missing teeth and/or the restoration of prosthetic superstructures.

Adverse side effects:

When using Champions® secondary parts, the following possible complications have been observed in isolated cases:

- Temporary problems with chewing/biting/speaking
- Fracture/Loss of the implant
- Swallowing/aspiration of components used in the patient's mouth
- Prosthetic overload and loss of prosthetic components
- Unsatisfactory esthetic outcomes
- Systemic or local infections including periimplantitis, periodontitis, gingivitis, fistulas, and minor bleeding
- Temporary local swelling
- Hypersensitivity/allergic reactions
- Toxic reactions
- Gum injuries
- Irritations
- Edema
- Hematomas
- Periodontal complications due to the insufficient width of the mucogingival attachment

9. Information about compatibility

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

You can find detailed instructions on process engineering in the Champions® – Basic Rules. You can find further information about 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 "Media Library / Instructions for Use", in the Champions (R)Evolution® Step-by-Step User Guide, and in different informative user videos in the Champions® Media Library.

10.1 Instructions for use for Champions® Prep-Caps in combination with the one-piece Champions® implant system

1. Select the Prep-Cap from the product range. Fit it onto the implant Abutment. Check the height of the gingival margin.
2. Prepare the Prep-Cap for bonding.

Bonding:

3. Dry the implant Abutment and do not touch the treated surfaces anymore.
4. Condition the implant Abutment according to the adhesive manufacturer's instructions. Follow the adhesive manufacturer's procedure and processing guidelines for bonding the Prep-Cap onto the implant Abutment.
5. After final polymerization and curing of the adhesive, the Prep-Cap can be customized if required.
6. Then, the final denture can be fabricated, including via CAD/CAM technology.

10.2 Instructions for use for Champions® Prep-Caps in combination with the Champions (R)Evolution® implant system

1. Screw the Prep-Cap-Abutment on the Champions (R)Evolution® implant (the Shuttle is to be removed before) or on the Laboratory Analog.
2. Select the Prep-Cap from the product range. Fit it onto the Abutment. Check the height of the gingival margin. If necessary, adjust the Abutment using a water turbine.

Bonding:

3. Dry the Abutment Prep-Cap and do not touch the treated surfaces anymore.
4. Condition the Prep-Cap Abutment according to the adhesive manufacturer's instructions. Follow the adhesive manufacturer's procedure and processing guidelines for bonding the Prep-Cap on the Abutment.
5. After final polymerization and curing of the adhesive, the Prep-Cap can be customized if required.
6. Then, the final denture can be fabricated, including via CAD/CAD technology.

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	Sterile packaging
SBS	Protective packaging with sterile barrier system inside
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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