Instructions for Use Champions® Abutments

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® Abutments/Screws are part of the Champions (R)Evolution® implant system.

Abutments are prefabricated secondary components that can be screwed. They are directly connected to the endosseous dental implant via a Screw and serve as a support for the prosthetic rehabilitation. They are available in different varieties, including Gingival Heights (GH) of 1-6 mm and come in straight and angulated at 15°, 22.5°, and 30°. The Abutments are designed for the fabrication of single-tooth and multiple-unit restorations.

Champions® Abutments are provided sterile and can be used for immediate restoration after implantation.

1.1. Material

Grade 5 titanium

1.2. Accessories

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

2. Delivery terms

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

Note: Before using it in the patient's mouth, the practitioner (dentist) must comply with sterility requirements !

The dental laboratory must clean and 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 preparation 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.

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® Abutments, screwed with Champions (R)Evolution®, serve as a load-bearing support structure for a prosthetic restoration as a fixed and/or removable denture.

4. Indication

Champions® Abutment variants in combination with Champions (R)Evolution® implants are suitable for screw-retained crowns for single-tooth restorations or cemented crowns for multiple-unit prosthetic restorations. The Abutments are also intended for the functional and aesthetic rehabilitation of the upper jaw and lower jaw in fully or partially edentulous patients.

5. Target patient group and intended user

Champions® Abutments 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

Allergies or hypersensitivity to chemical components of the grade 5 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 methods.
- All Champions®-products should be used and restored only with the 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.
- In case of significant bone loss, the leverage effect can lead to a fracture in the micro-thread area of the Abutments in combination with small-diameter implants.
- 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. It is recommended to seal the screw channel with temporary plastic material before cementing the crown or bridge.
- 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 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 prosthestic 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 Traditional work process – Champions® Abutments / Secondary components

For the dentist:

Final Abutments can be used once the implant has achieved sufficient primary stability and/or is fully osseointegrated. Beforehand, an impression is taken using the Gingiva-Shuttle.

You can take the impression with the Impression Post Peek (REF 3122) without removing the Screw or with Impression Posts that can be screwed in the Shuttle.

You can find information about the impression in the Champions (R)Evolution® Step-by-Step User Guide.

1. Removing the Screw (REF 3085) of the factory-fitted Shuttle
   Using the Prosthetic Driver/Screwdriver (REF 3086/30861/30862), remove the Screw from the Shuttle-canal.
   The removed Screw can directly be reused for fixing the Abutment.

2. Removing the Gingiva-Shuttle
   Using the Shuttle-Extractor (REF 3087), screw the Shuttle clockwise (rotation on the right) from the implant floor and gently remove it from the implant.
3. Fixing the Abutment
   The final Abutment must be correctly positioned in the implant.
   Then, using the Prosthetic Driver, reinsert the previously removed Screw into the screw canal of the Abutment. Tighten it with a Torque Wrench at a maximum torque of 25–30 Ncm.
   Warning: Do not exceed the recommended torque of 30 Ncm for the Screw. Overtightening can cause the Screw to break. Falling below the recommended torque may lead to loosening of the Abutment, which can result in the failure of the secondary part and implant. To avoid wear, do not remove the Screw again after tightening it to the recommended torque.

For the dental technician:

In accordance with the material manufacturer's instructions, a denture should be fabricated according to the standard procedure.

Note on prosthetic restoration design in the traditional and digital workflow:

- All Champions® implants are intended to be used and restored only with the original Champions® instruments for this purpose such as Shuttle-Extractors and Prosthetic Drivers.
- In the digital workflow, several construction options are available in the 3shape and exocad libraries for performing prosthetic restorations using Champions® Abutments with the Scanbody Impression Post Peek (REF 3122) + Gingiva-Shuttle (REF 3100), or Scan-Abutment (REF 31230).

10.2 Healing phase

If the implant is fully osseointegrated or if there is sufficient primary stability, a final Abutment/secondary part can be placed in occlusion. The healing phase until complete osseointegration can vary and depends on the individual treatment and patient.

The surgeon/implantologist is responsible for deciding on the final implant loading.

10.3 More information

You can find more information about the use of different Champions® Abutment components 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 various informative user videos available in the Champions® Media Library.

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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