Instructions for Use Champions® Gingiva-Clix

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® Gingiva-Clix are part of the Champions® implant system.

Gingiva-Clix are PEEK Classix forming caps. After implantation, they are clicked on the Shuttle of the Champions (R)Evolution® implant system and allow for widening the emergence profile during the whole healing phase of max. 180 days.

Gingiva-Clix are available in different diameters and gingival heights, the variant Provi-Clix comes in straight angulated at 15°.

The Gingiva-Clix are made from PEEK Classix™ (polyetheretherketone) and supplied in sterile packaging.

1.1. Material

PEEK Classix™ (polyetheretherketone)

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® Gingiva-Clix 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

Champions® Gingiva-Clix made of PEEK Classix™ titanium are supplied sterile and are 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 clinical processing of Champions® products, originally supplied sterile, by the end user.

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 impair 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 expiry of 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® Gingiva-Clix can optionally be placed on the implant Shuttle after insertion of immediate implants or approximately 7 days before impression-taking (healing phase) to enhance the emergence profile in the gingiva. This ensures optimal aesthetics for the subsequent denture.

4. Indication

Champions® Gingiva-Clix variants are designed for use in combination with the two-piece Champions® implant system after insertion and during the healing phase to improve the emergence profile. They are intended for the functional and aesthetic rehabilitation of the gingiva 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 of the polyetheretherketone (PEEK) 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) 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 Application instructions for Champions® Gingiva-Clix in combination with the Champions (R)Evolution® implant system

Note:

For delayed implants and thick gingiva, it is recommended to punch or laser the gingiva around the Shuttle to ensure that the Gingiva-Clix is clicked onto the Shuttle. Use diamond-coated forceps or transfer key (laboratory) to secure the Gingiva-Clix.

The Gingiva-Clix should be positioned equigingivally or at a maximum of 1 mm supragingivally so that the Champions (R)Evolution® implant should ultimately be positioned at a minimum of 0.5 mm subgingivally for the Gingiva-Clix +1/+1!

Application:

1. Select the appropriate Gingiva-Clix from the available range. Press them manually onto the circular groove of the Shuttle. The gingiva variants "Provi-Clix" (0° and 15°) are also clicked into the circular groove of the Shuttle. These allow quick connection to the temporary restoration.
2. The Gingiva-Clix can remain on the Shuttle throughout the entire healing phase.
3. In order to check primary stability (tightening test about 3-4 weeks post-surgery), you can remove the perforated cover of the Gingiva-Clix using the Ø 2.4 mm Condenser. To do this, screw the Ø 2.4 mm Condenser about 0.5 mm into the center of the Gingiva-Clix. Once the Condenser is retained, remove the Gingiva-Clix cover.
4. Then, remove the Gingiva-cover. The Shuttle is now accessible for impression-taking or later removal.




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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