

# Instructions for Use PEEK Classix Champions® Gingiva-Clix

The references can be found in the current product catalog.

STERILE: Do not use the product if the sterile package is damaged!

## Please Note:

It is essential to read the Instructions for Use prior to the application of the Champions®-Gingiva-Clix.

In order to prevent aspiration, secondary components must be secured during intraoral application.

For delayed implantation and a dense gingiva, it is recommended that the gingiva should be removed or laser treated around the Shuttle in order to allow the Clix to be clicked on the Shuttle. In order to fix the Clix, use diamond-coated forceps or a transfer key (laboratory).

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

## Product Description:

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

The Gingiva-Clix are supplied in a sterile state.

## Indication / Purpose:

Gingiva-Clix protect the implant Shuttle after insertion and shape the gingiva during the healing phase. They ensure optimal aesthetic results in combination with the later denture.

## Side Effects:

None

## Complications:

None

## Shelf Life:

All components are supplied in a sterile condition. Sterile products are labeled with the STERILE sign.

Sterile products may not be sterilized again. If medical devices are resterilized by the end-user, any responsibility will be rejected – regardless of the sterilization method.

The medical devices are only sterile if still in their closed original blister packaging.

The shelf life until the first use of the product is indicated on the label. The expiry date is indicated by the hourglass symbol.

Do not use the sterile products after the expiry date indicated on the packaging. The indication LOT refers to the batch code.

Gingiva-Clix are single-use products.

## Storage:

The product is to be stored in its original package in a dry place at room temperature. Unsafe storage can cause product failure and damage to the material.

## Application Instructions:

Choose the Gingiva-Clix from the available range. By applying pressure, click it manually on the circular groove of the Shuttle.

The "Provi-Clix" (0° and 15°), which are Gingiva-Clix variants, are also clicked on the circular groove of the Shuttle. They can be rapidly connected to the temporary restoration. The Gingiva-Clix can remain on the Shuttle during the whole healing phase. In order to check primary stability ("Erni-Test" by tightening up the implant about 3-4 weeks after surgery), you can remove the perforated cover of the Gingiva-Clix by means of the Ø 2.4 mm Condenser. For this, screw the Ø 2.4 mm Condenser at about 0.5 mm in the center of the Gingiva-Clix. After retention of the Condenser, remove the cover of the Gingiva-Clix.



Then, remove the Gingiva-cover. The Shuttle is now accessible for an impression or later removal.

### Advice:

- All Champions products are to be used and restored only with the original Champions instruments intended for this purpose such as Drills, Condensers, Insertion Aids, and Prosthetic Drivers.
- After accidental swallowing of implants, abutments, or equipment, the destination of the subject is to be identified (e.g. X-rays), and necessary medical action has to be undertaken.
- Gingiva-Clix are intended for use in the patient's mouth within maximally 180 days. The residence time of the product is not supposed to be longer.
- Gingiva-Clix must be stored closed in a dry place. The blister package is only to be opened directly before use.
- The manufacturer reserves the right to amend the product design, the components or the package, to revise the Instructions for Use as well as prices or delivery terms. Liability is limited to the replacement of defective products.
- Further claims of any kind are excluded.
- Disposal: dispose of and decontaminate waste in conformity with the local, regional, or national regulations.

### Manufacturer in the EU:

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 Champions-Implants GmbH

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### Symbols:



Manufacturer



Use by



Do not reuse



Keep dry



Consult instructions for use



Batch code



Catalog number



Sterilized using irradiation

**RX only**

Caution: Federal law restricts this device to sale by or on the order of a dentist (licensed healthcare practitioner)



Bar code