

Instructions for Use Champions® PEEK Classix Gingiva-Clix

The item numbers 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 accidental swallowing or aspiration, use rubber dam when placing Gingiva-Clix on the endosseous two-piece Champions® (R)Evolution implant.

Product Description:

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

The Gingiva-Clix are supplied in a sterile state.

Indications:

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 prosthodontic restoration.

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 number.

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.

Advice:

- 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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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