

# Instructions for Use Champions® Abutments / Titanium Grade 5 Screws

Caution: Federal law restricts this device to the sale by or on the order of a dentist.

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® Abutments / screws.

In order to prevent accidental swallowing or aspiration, use rubber dam when placing Abutments/screws on the endosseous two-piece Champions® (R)Evolution implant.

## Product Description:

Abutment/screws are prefabricated posts that can be screwed. They are directly connected with the endosseous dental implant. They support the prosthodontic restoration.

The Abutments/screws are supplied in a sterile condition.

## Indications for Use:

Champions 1-Piece and (R)Evolution Dental Implants are intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. Champions 1-Piece and (R)Evolution Dental Implants are intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

## Intended Use:

Abutments/Screws, which serve as transmucosal extension, are fixed on the implant after the implant placement. The Gingiva-Shuttle prevents the mucosa from growing on the platform, and – in combination with the Gingiva-Clix, it provides room for a later impression and optimal aesthetics.

For covered healing, you can use the surgical screw instead of the Gingiva-Shuttle after implant placement and removal of the Shuttle.

## Indications:

Abutments/screws, which are fixed on the implant after the implant placement, serve as a transmucosal extension. The Gingiva-Shuttle prevents the mucosa from growing on the platform. In combination with the Gingiva-Clix, it provides room for a later impression and optimal aesthetics.

For covered healing, you can use the surgical screw instead of the Gingiva-Shuttle after placing the implant and removing the Shuttle.

## 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 re-sterilized by the end-user, any responsibility will be rejected – regardless of the sterilization method.

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

The shelf life until its first use is indicated on the label. The expiry date is indicated on the hourglass.

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

Abutments are for single use only.

## Storage

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

## Application Instructions

Choose available Abutments /screws from the range and fix them with the screwdriver at 30 Ncm.

After tightening the corresponding Abutment at 30 Ncm, the "preparable Abutments" are prepared with the red handpiece under sufficient water cooling (corresponding to the preparation of a natural tooth to support the crown) and by means of the conventional hard metal drills and/or diamonds. The preparation margin can be fixed 0.5 – 1 mm subgingivally (below the gingiva), equigingivally (at the level of the gingiva), or also supragingivally (above the gingiva). When preparing, please note that the V-shaped preparable Abutment can be shaped up to 30° maximally, according to the drawing 1 a).

The short, preparable Abutments can be prepared occlusally to half of the whole length so that there is a potential 3.5 mm-retention for cementing the (laboratory ready-made) crown. For short clinical crowns with a height of < 3.5 mm the Multi-Unit Abutments of GH1 are recommended, on which the dental crown is screwed occlusally and not cemented.

The long, preparable Abutments (12 mm) can be prepared occlusally up to 3.5 mm of the remaining Abutment height.

## Advice:

- Abutments/screws must be stored closed in a dry place. The blister package is only to be opened directly before application.
- 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.

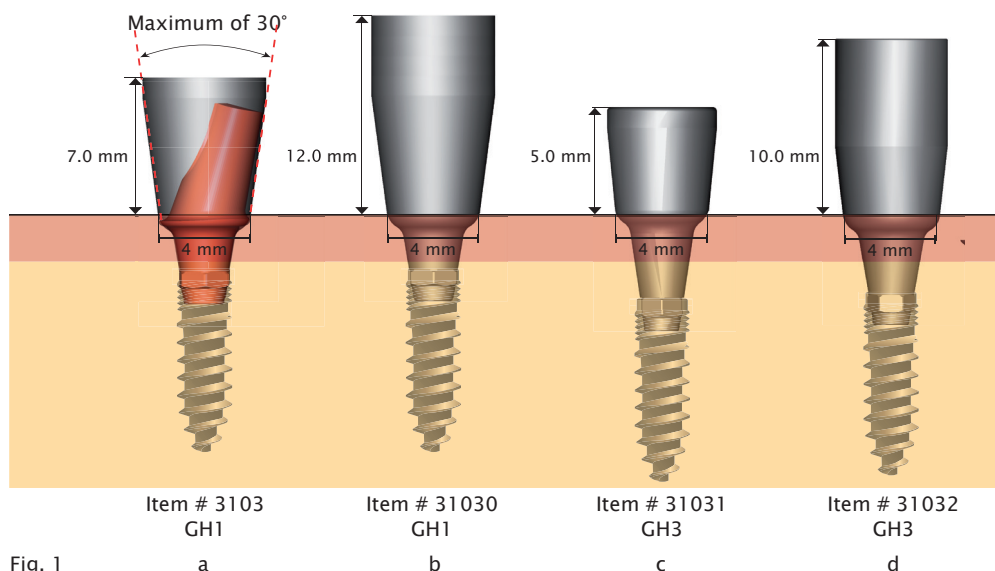


Fig. 1

### Manufacturer in the EU:

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Champions-Implants GmbH

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### Symbols:



Manufacturer



Use by



Single use only



Keep dry



Observe the Instructions for Use



Batch number



Article number



Gamma-sterilized

**RX only**

Application restricted to dentists or specialists



Bar code