

Instructions for Use Champions® Abutments / Titanium Grade 5 Screws

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® Abutments / screws.

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

Product Description:

Abutments/screws are prefabricated posts that can be screwed. They are directly connected with the endosseous dental implant. They support the denture.

The Abutments/screws are supplied in a sterile condition.

Indication / Purpose:

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:

Titanium grade 4 or titanium alloy grade 5 intolerances and sensitivities are possible in individual cases.

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 closed original 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 code.

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 Prosthetic Driver at a maximum of 30 Ncm.

Before fixing the abutment, remove the Gingiva-Shuttle from the implant. For fixing the abutment, the previously removed fixation screw can be used. In order to improve cement retention, it is recommended to roughen the abutment surface with a diamond or NEM tool by means of a red handpiece.

Advice:

- After insertion of the superstructure, it might be useful to conduct a radiological check for cement or plastic residues.
- It is recommended to seal the screw channel with temporary plastic material before cementing the crown or bridge. If necessary, the screw can be loosened again more easily then.
- Even after proper surgical and prosthetic procedure a horizontal and vertical bone loss is possible (as with any other dental implants as well). Kind and complexity of the bone loss cannot be anticipated. In cases of severe bone loss, fractures in the micro-thread area can be caused through leverage with angled abutments in combination with small-diameter implants.
- 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.
- 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.

Cleaning / Desinfecting /Sterilizing

- Before use in the patient's mouth, the practitioner (dentist) must respect the required sterilization!
- Before use in patients, the dental laboratory must clean and disinfect the abutments and abutment screws after processing. We recommend an additional sterilization.
- Users are responsible for the sterilization of the abutments and screws. For sterilization they must use only suitable devices and material and validated product-specific processes. Equipment and devices are to be maintained regularly and kept in good condition.
- **Observe the information about the preparation that is described in the "Preparation Instructions of Champions Implant System"!**

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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