

Instructions for Use Champions® Prep-Caps (Zircon Dioxide or Titanium Grade 5)

You can find item numbers in the current product catalog.

STERILE: Do not use the product if the sterile packaging of the titanium Prep-Cap is damaged.

The zircon dioxide Prep-Caps are supplied in a non-sterile state.

Please Note:

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

In order to prevent accidental swallowing or aspirating, use a rubber dam for the Prep-Cap-Abutments (R)Evolution and when fitting the Prep-Caps on the one-piece Champions® Implant Square.

Product Description:

In Implantology, Prep-Caps are used to compensate insertion divergences and to widen the clinical crown. They are cemented on the abutment (square implant). Then, they can be shaped like a tooth.

The individual Prep-Caps allow you to manufacture a cost-efficient and customized individual abutment relatively quickly.

The Prep-Caps are available in different gingival heights and angle degrees. After checking the gingival margin, adjusting the Prep-Cap length and making further adjustments with a turbine, the Prep-Cap can be bonded. Then, you can prepare on the Prep-Cap as usual.

The Prep-Caps are available in two materials: zircon dioxide (non-sterile) and titanium-grade 5 (sterile).

Indications:

The Prep-Caps are made from zircon dioxide or titanium-grade 5. The individual abutment consists of a Prep-Cap in combination with the Prep-Cap-Abutment or the square implant abutment. The Prep-Caps, which are cemented or bonded on the abutments, are used to support crowns or bridges and to compensate insertion divergences or to widen the clinical crown.

Side Effects:

None

Complications:

None

Shelf Life:

The shelf life indication of the zircon dioxide Prep-Caps (non-sterile) is not necessary.

The reuse of single-use products can pose a risk of infection for the patient and dentist.

Titanium-grade 5 - Prep-Caps 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.

The Prep-Caps are single-use products.

Storage

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

Application Instructions

One-Piece Champions® Implant Square:

1. The Prep-Caps are designed for the one-piece square implant abutment.
2. Select the Prep-Cap from the product range. Adjust it to the implant abutment. Check the height of the gingival margin.
3. Prepare the Prep-Caps for bonding.
4. Cover the gingival shoulder of the abutment with synthetic material or sticky wax.
5. Gently blast inside the Prep-Cap at about 1-1.5 bar with 50 µm-aluminium oxide. Alternatively, you can also blast with CoJet (3M Espe) or with Rocatec Soft. Then, degrease the inner part of the Prep-Cap (e.g. Acetone).
6. Degrease the abutment. Do not touch the parts with your fingers anymore.
7. Condition the abutment with a Metal Primer (e.g. Alloy Primer (Kuraray) / Metal Primer (GV)).
8. Mix the glue according to instructions of the manufacturer (e.g. Panavia SA of Kuraray).

Advice: Preheat the glue. Scientific studies have shown that cements and composites that are preheated at 50°C reach a higher degree of polymerization than those that are used at room temperature. After using the glue, store it in the refrigerator.

Apply the glue mixture evenly on the abutment and inside the Prep-Cap without causing air bubbles (probe, brush, small spatula).

9. Set the Prep-Cap onto the abutment and fix it with pressure. After about 30 seconds (Panavia SA of Kuraray is cured in the anaerobic area), only expose external excess glue surfaces with a light polymerization device until the glue has slightly thickened and cured. Then, you can remove excess glue. The final chemical polymerization is performed with the Panavia SA dual cement.
10. After the glue has cured, remove excess glue with rotating instruments.
11. If necessary, the Prep-Cap can be customized. Then, the final prosthodontic restoration can be made using the CAD/CAM procedure.

Two-Piece Champions® Implant (R)Evolution

1. Remove the Shuttle from the Champions Implant (R)Evolution®. Screw the Prep-Cap-Abutment on the Champions Implant (R)Evolution® or the Laboratory Analog.
2. Select the Prep-Cap from the product range. Adjust it to the abutment. Check the height of the gingival margin. If necessary, treat the Prep-Cap with a turbine.
3. Prepare the abutment for bonding the Prep-Cap.
4. Cover the gingival shoulder of the abutment with synthetic material or sticky wax.
5. Gently blast inside the Prep-Cap at about 1-1.5 bar with 50 µm-aluminium oxide. Alternatively, you can also blast with CoJet (3M Espe) or with Rocatec Soft. Then, degrease the inner part of the Prep-Cap (e.g. Acetone).
6. Degrease the abutment. Do not touch the parts with your fingers anymore.
7. Condition the abutment with a Metal Primer (e.g. Alloy Primer (Kuraray) / Metal Primer (GV)).
8. Mix the glue according to instructions of the manufacturer (e.g. Panavia SA of Kuraray).

Advice: Preheat the glue. Scientific studies have shown that cements and composites that are preheated at 50°C reach a higher degree of polymerization than those that are used at room temperature. After using the glue, store it in the refrigerator.

Apply the glue mixture evenly on the abutment and on the inner part of the Prep-Cap without causing air bubbles (probe, brush, small spatula).

9. Set the Prep-Cap onto the abutment and fix it with pressure. After about 30 seconds (Panavia SA of Kuraray is cured in the anaerobic area), only expose external excess glue surfaces with a light polymerization device until the glue has slightly thickened and cured. Then, you can remove excess glue. The final chemical polymerization is performed with Panavia SA dual cement.
10. After the glue has cured, remove excess glue with rotating instruments.
11. If necessary, the Prep-Cap can be customized. Then, the final prosthodontic restoration can be made using the CAD/CAM procedure.

Advice:

- The Prep-Cap-Abutment and Prep-Cap must be stored closed in a dry place. The blister package may only be opened directly before the application.
- The manufacturer reserves the right to amend the product design, the components or the package, and to revise the Instructions for Use. 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



Zircon dioxide Prep-Caps



Titanium Prep-Caps sterilized using irradiation

RX only

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



Bar code