# Instructions for Use



#### **SYNCA**

337 Marion, Le Gardeur, QC, Canada, J5Z 4W8 For professional use only. Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a dentist.

# Description

Biolight Temp® is a highly esthetic composite for fabricating temporary restorations. The two-component system based on a multifunctional acryl composite is produced using no Bisphenol-A or Bisphenol-A precursors in the manufacturing process. It has similar properties to a filling material and is available in the following shades: A2 & B1.

Biolight Temp® temporary restorations can also be adjusted and customized using flowable light-curing composites.

#### Indications

- Fabrication of temporary prostheses, such as crowns, partial crowns, bridges, inlays, onlays and veneers, for use until a permanent restoration is fabricated.
- Customization of prefabricated acrylic and metal crowns.
- Fabrication of long-term temporary restorations.

#### Warnings

- Do not use if there is a known allergy to methacrylic acid esters.
- Allergic reactions to the product cannot be ruled out with sensitive persons.
- Temporary luting cements that contain eugenol can inhibit the curing of

# Side effects:

With the current state of knowledge, there are no known side effects.

# Precautions

- sulcus/on the tooth or oral cavity.
- problems arise or persist.
- Do not inhale grinding dust. Use safety glasses and face mask.
- spaces should be blocked out in the usual way.
- Avoid contact with clothing, as the material cannot be removed by dry cleaning.

### Working and setting times

placement in the mouth

Curing in the mouth

01:30-02:30 min.: sec. Removal from the mouth

From 04:30 min.: sec.

- · Sensitization possible through skin contact.
- Biolight Temp® temporary restorations are intended for use as temporary restorations and not as permanent restorations.
- permanent composite cements, which may be used later for fi nal cementation.

- Do not use after expiration date.
- Do not leave any residue of the temporary crown and bridge material in the
- Do not swallow the material! If swallowed accidently: consult a doctor if
- Avoid contact with the eyes. On accidental eye contact: rinse immediately carefully and thoroughly with eye wash or water. Consult a doctor if problems
- Any area of the impression with severe undercuts and very wide interdental

#### 00:00-00:40 min.: sec. Pouring Biolight Temp® into the impression and

Full curina

Preparation of the temporary restoration

Working times apply for products, which have been stored and processed at a temperature of 23°C/74°F and a relative humidity of 50%. Higher temperatures shorten the working time and lower temperatures extend the working time.

#### Preliminary impression

All standard impression materials can be used for fabrication of a temporary crown, bridge, inlay or onlay. A matrix material is ideal for taking a preliminary impression. As an A-silicone it remains dimensionally stable for several weeks. If a temporary restoration requires remaking, the matrix material impression can be reused.

### Instructions for use:

### Preparation

- First, take a preliminary impression of the dentition.
- A laboratory fabricated, vacuum-formed splint or, in the case of single crowns, a prefabricated metal or plastic crown can be used instead of an impression for forming the shape.
- The impression can be cut out before use to remove any undercuts and increase the stability of the temporary restoration. A channel can be cut into the impression to create a bar-shaped connection between spaced abutment teeth. Denture teeth can also be used as space maintainers in the anterior region before taking the impression

### Dispensing and mixing

Dispense and mix the pastes using a DS-50 4:1/10:1 dispensing gun and corresponding mixing tips. Only use the mixing tips included!

#### Initial dispensing

- 1) Insert the cartridge into the dispensing gun.
- 2) Remove the cartridge seal and do not use it to reseal the cartridge to avoid trapping air bubbles.
- 3) Before fi tting a mixing tip for the first time, advance the plunger into the cartridge and extrude a small amount of material until both materials are dispensed uniformly. Then discard the dispensed paste.

# Application

- To ensure optimal results we recommend using vinvl or latex gloves.
- Place the mixing tip on the cartridge, turn the cap clockwise by 90° until it
- With the mixing tip in place, the material requires a certain time before flowing out.
- The material stops flowing immediately once the pressure on the dispenser handle is reduced. Do not use force to press out any material that has set in the mixing tip, as it may damage the cartridge and mixing tip! Compomer, resinmodified glass ionomers or composite preparation surfaces must be isolated before application of Biolight Temp®, e.g. using Vaseline.
- 1) Extrude an approximately pea-sized amount of material before each use and discard.

- 2) Fill the dried impression, vacuum-formed splint or preformed crown, beginning at the base. Leave the mixing tip immersed in the material during filling to avoid trapping air bubbles.
- 3) The filled mold must be placed in the mouth using light pressure within 40 seconds.
- 4) The material attains an elastic consistency in the mouth 1 min. 30 sec. after the beginning of mixing and should be removed from the mouth together with the impression or vacuum-formed splint by 2 min. 30 sec. after the beginning
- Check the condition of the material in the mouth using the excess material, e.g. with a probe, to avoid it curing too much before removal.
- 6) Leave the filled mixing tip on the cartridge after use as a seal.
- 7) Remove the used mixing tip and dispose of it before reusing the cartridge. Fit a new mixing tip and proceed as instructed.

- Completely wipe off the inhibition layer after the material has fully cured, e.g. with alcohol.
- Once the material has cured fully, finish the temporary restoration, e.g. using cross-cut burs and polishers.

## Cleaning/Disinfection

If required, Biolight Temp® can be disinfected using standard aqueous disinfectant solutions.

#### Customization/ Recontouring

The use of a bonding agent is not necessary when using a filling composite in combination with Biolight Temp® for customization and adjusting the shape. Please adhere to the respective instructions for use with other products.

#### Cementation

- 1) Remove any residual separating agent from the prepared tooth before temporary cementation.
- 2) Standard temporary luting materials can be used for cementation.
- 3) Residue of temporary cements that contain eugenol can impair the curing of composite cements used for subsequent permanent luting. If the plan is to use composite cements, the use of a eugenol-free temporary cement is recommended.

#### After cementation

Carefully check the sulcus and surrounding areas and remove any remaining residue of the temporary material or cement.

#### Repair

- 1) Roughen the fracture site and create mechanical retention on the adjoining
- 2) Clean using alcohol and then air dry.
- 3) Join or add to existing restorations using Biolight Temp® or the combination of a flowable, light-curing filling composite and a bonding agent.

- 4) Cure Biolight Temp® or composite according to the respective instructions
- 5) Prepare in the usual way after curing.

### Storage conditions

Store in a dry place, protected against sunlight and at room temperature (18°C/ 64°F – 25°C /77°F). Avoid exposure to extreme temperature fluctuations. Do not store in a refrigerator.

### Disposal

Dispose of the product in accordance with local regulations.

# Cleaning and disinfection of the dispensing gun:

- 1) Remove the cartridge.
- 2) Remove any uncured paste using a cloth soaked in alcohol.
- 3) The dispensing gun is reusable after disinfection, although it should be replaced if visible signs of wear appear. Disinfection can be carried out using a commercially available dipping disinfectant. It is recommen dable to use glutaraldehyde-based solutions.

Product reserved exclusively for dental usage. Keep out of the reach of children.



Avoid exposure to light.





# Limitation of liability

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64°F 18°C Store between 64°F and 77°F (18°C and 25°C)