

TempFIT Temporary Crown and Bridge Resin

Instructions for Use

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The product should be used by a dental professional according to the instructions. Prior to use the product, please read the instruction carefully. TempFIT Temporary Crown and Bridge Resin (Temporary Resin) is a self-curing composite for the fabrication of temporary crowns, bridges, inlays, onlays and veneers. The product is suitable for the fabrication of temporary restorations in the stress areas of posterior teeth.

The mixing ratio, based on volume, base paste: catalyst paste =1:1 or 10:1.

Indications for Use

The product is a self-curing composite for the fabrication of temporary crowns, bridges, inlays, onlays and veneers.

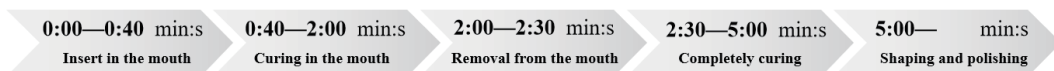
Structure and composition

TempFIT Temporary Crown and Bridge Resin is composed of double pastes of Base and Catalyst. Base pastes include TEGDMA, Bis-EMA, Bis-GMA, accelerator, inhibitor, pigments, silane treated barium glass, silane treated silica, etc.. Catalyst pastes include TEGDMA, Bis-EMA, UDMA, initiator, inhibitor, silane treated barium glass, silane treated silica, etc..

The inorganic filler of Temporary Resin loading is about 40% by weight having particle size range of about 0.01µm to 5µm.

Performance and characteristics

The working and setting times depend on the ambient and oral temperature. Higher temperature shortens those times, lower temperature increase those times. Under experimental conditions of (23±2) °C / (50±10)% relative humidity, this product has a working time of no less than 50 seconds and an intraoral self-curing time of no more than 3 minutes. The time parameters are as follows:



Operating procedures

1.Impression of teeth

Before preparing the crown or bridge or prior to extraction of a tooth, take an impression using alginate, silicone or a thermoplastic impression material. Please strictly follow the appropriate manufacturer's instructions.

!Note: Using a silicone impression, undercuts have to be blocked out and if necessary pressure relief channels may have to be cut in. To create a connection with the abutment teeth in the case of a gap in the molar region, cut a channel in the impression.

2.Preparation of teeth

Prepare the tooth and dry it, and apply a separating agent (e.g., Vaseline) on the residual root and surrounding tissue of the tooth or any composite core build-ups.

3.Insert in the mouth

Select the Temporary Resin with the required shade and place into the Auto-mix dispenser. Remove and discard the sealing cap or used helical mixer, and squeeze out part of the material until the Base paste and Catalyst paste are level. Subsequently, attach a new helical mixer and fasten.

Fill the impression with Temporary Resin. Dispense the material onto the occlusal surface of the impression first then to the gingival margin. Within 40 seconds of starting mixing, place the impression in mouth and secure it in place. To avoid bubbles, it is important that the end of the helical mixer always remains immersed in the material during application.

!Note: Recommend VITA Classical Shade Guide for color selection.

!Note: When stored in a refrigerator, the product should be returned to room temperature before use.

!Note: The used helical mixer can be used as cap to seal the Temporary Resin until the next application.

4.Removal from the mouth

The temporary must be removed from the mouth during the elastic phase, i.e. during the period from 2 to 2.5 minutes after start of mixing.

!Note: The curing process has to be monitored by the spilled material in the mouth, because the curing is significantly affected by the temperature in the mouth and the temporary can only be removed during its elastic phase.

5.Shaping and polishing

To improve the precision of the temporary, they can be put back into the impression after removal from the mouth until reaching its final hardness, i.e. 5 minutes after start of mixing.

Remove the oxygen inhibition layer from the surface of the temporary with alcohol. The temporary can be finished using crossing-toothed grinders, flexible disks, etc..

Check occlusion. If necessary, polished with suitable instruments.

6.Bonding

Thoroughly remove the separating agent, clean the tooth and dry. Cement the temporary.

7.Repair

7.1 Repair of a freshly-made temporary

Apply Temporary Resin directly to the area to be repaired, and repair the area with conventional methods after the material is completely cured.

7.2 Repair of a used temporary

Roughen the temporary slightly using a grinder or a sand blaster at the appropriate points. Then apply a bonding agent according to manufacturer's instructions. Apply Temporary Resin to the repair area. After the material is completely cured, repair the area with conventional methods.

[Note: To speed up the polymerization, the finished temporary can be placed in warm water at 50 ℃ for a few minutes. Alternatively, the temporary can also be customized or repaired using the light-curing flowable composite. Please strictly follow the appropriate manufacturer's instructions for use.

Notes

1. Please pay attention to the expiration date on the outer packaging of the materials and do not use expired materials. Used packaging materials, accessories and remaining waste or expired products should be disposed of in accordance with local regulations.
2. Helical mixers are disposable devices to prevent cross-contamination between patients.
3. Phenolic substances (such as eugenol and holly oil) and hydrogen peroxide will interfere with the curing of the product. Materials containing the above substances, such as oral rinses and temporary cements, should be avoided during the process.
4. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact. The use of protective gloves is recommended.
5. When working on the temporary, wear face masks and goggles to prevent sanding dust may get into the eyes and respiratory tract.
6. For professional use only. Carry out daily maintenance as prescribed by dentist.
7. Keep material out of children's reach.

Contraindications

Do not use the material in cases of allergies to any of the substances contained or, as can occur in rare cases, in the event of contact allergy discontinue use.

Side effects

This product or one of its components may cause hypersensitive reactions.

Adverse event

There are no clinical cases of adverse events for this product.

Storage

Store the product with the cap closed tightly at 2-25 ℃, away from direct light and high humidity.

Shelf life: 2 years.

Warranty

Rizhao HuGe Biomaterials Co., Ltd. warrants this product is free from defects in material and manufacture.

HUGE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and HUGE's sole obligation shall be repair or replacement of the HUGE product.

Limitation of Liability

Except where prohibited by law, HUGE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Symbols for use in the Packaging/Labeling

-  -Use-by date;  -Caution;  -Batch code;  -Temperature limit;  -Country of manufacture;
-  -Consult instructions for use;  -Keep dry;  -Keep away from sunlight;  -Unique device identifier;
-  -Medical device;  -Manufacturer;
- Rx**
ONLY -Caution: U.S.Federal Law restricts this device to sale by or on the order of a dentist or professionals.



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