

PROVISA PLUS

TEMPORARY CROWN & BRIDGE MATERIAL

INSTRUCTIONS FOR USE

General Information

ProvisaPLUS is temporary crown and bridge resin that is used temporarily before repairing a permanent restoration. It can be self-cured resin. Filler size ranges from 16nm~1.2um, resulting in good ratio-opacity and high flexural strength. Various shades of TW, A1, A2, A3, B1, C2, and AO3 for esthetic crown are provided. ProvisaPLUS contains about 40% inorganic filler.

Intended Purpose

ProvisaPLUS is a self-curing temporary crown resin that is used temporarily before repairing a permanent restoration.

Intended User

Dentist.

Target Patient Group

Dental patients.

Composition

Organic Matrix: Bis-GMA, UDMA

Inorganic Fillers: Micro Silica(Ba glass) (16nm~50um, nano silica filler, Ba glass filler, 62% by volume)

Additives: Initiator, Stabilizer, Others.

Performance Characteristics

1. Water Sorption($\mu\text{g}/\text{mm}^3$) by ISO 10477:
standard: $\leq 40\mu\text{g}/\text{mm}^3$.
2. Solubility ($\mu\text{g}/\text{mm}^3$) by ISO 10477:
standard: $\leq 7.5\mu\text{g}/\text{mm}^3$.
3. Flexural strength (MPa) by ISO 10477:
standard: $\geq 50\text{MPa}$.
4. Surface finish: It shall have a glossy surface.
5. Color (shade consistency): It shall show no more than a slight difference with the color indicated.
6. Color stability: It shall show no more than a slight change in color.

Precautionary Information

1. Check the expiration date and appearance condition of product and package. DO NOT use after the indicated expiration date.
2. Observe the instruction for use after being well acquainted with the instruction for use.
3. Do not use if the material has been cured.

TEMPORARY CROWN AND BRIDGE 1:1 MATERIAL

Precautionary Information continued

4. When the product has any problem, user should stop using it and contact with our company.

Application

1. Before making crowns or bridges, make a mold to shape your teeth using an impression or other matrix.
2. After isolating the teeth with the rubber dam, dry the teeth and lightly lubricate the areas to be applied with baseline or similar materials.
3. Select the appropriate color, mount the cartridge on the dispenser gun (1:1) and remove the cap from the front of the cartridge. Squeeze out some small amounts of content so that both sides of the product flow in the same amount. Fit the Benco Dental's mixing tip packed together to the cartridge in a groove, turn it 90° to unlock.
4. Squeeze some of the material from the mixing tip to ensure the mixture is well mixed during application. Then apply to the prepared impression or matrix. Fill in the deep part to prevent air bubbles from occurring at this point, the impression or matrix is firmly fixed. Keep the mixing tips used after application attached to the cartridge until the next time. If the mixing tip needs to be replaced, turn it 90° counterclockwise, remove the mixing tip and replace it with a new one, and turn it 90° clockwise.
5. ProvisaPLUS remains paste for approximately 30 seconds after the initial application. Apply to your teeth before curing begins.
6. Wait approximately 1 minute after completing the application of the teeth. At this point, remove excess ProvisaPLUS that does not apply with the appropriate tool. Then remove the ProvisaPLUS from the teeth. Take care not to fully cure ProvisaPLUS within the mouth.
7. ProvisaPLUS is fully cured within approximately 2 minutes 30 seconds application. After curing, remove ProvisaPLUS from the impression or matrix using a suitable instrument. If necessary, alcohol can be used to remove the hardened layer. However, in this case, evaporate the alcohol completely and remain dry before adjusting the joint with the teeth.

Application continued

- Check the occlusion and polish or adjust the finished crown with the appropriate tool.
- Apply the appropriate temporary cement to the finished crown and apply it to the teeth.

Application	Time
Insertion in the mouth	0:00-0:30
Removal from the mouth	1:30-1:45
End of setting	2:20-2:30

Side Effect

Secondary caries, postoperative sensitivity. These are two known side effects associated with composite resins, but they may be caused by the operator's technique or use with other devices.

Contraindication

This material contains methacrylic monomer. Some patients can cause allergic reaction to monomer.

Do not use this material for patients allergic to or hypersensitive to methacrylic monomers.

CAUTION

- This material is intended to be use by licensed dentist only. Do not use for other purposes.
- This material contains methacrylic monomer. Some patients can cause allergic reaction to monomer.
- Do not use this material for patients allergic to or hypersensitive to methacrylic monomers.
- If this material causes an allergic reaction or oversensitivity, discontinue its use immediately.
- Avoid contact of this material with eyes, mucosal membrane, skin, and clothing.
- If this material comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- Use a rubber dam to protect the throat.
- DO NOT use this material after the indicated expiration date on the cartridge.
- If this material is refrigerated, allow it to reach room temperature prior to use.

Storage & Use

- Do not expose restorative materials to elevated temperatures, or to intense light.
- Store this material at a temperature between 2-27°C.

Storage & Use continued

- Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life.
- Shelf life at room temperature is 24 months.
- See outer cartridge for expiration date.
- Do not store materials in proximity to products containing Eugenol.

Sales Unit

Sales Unit	Components	Shade Provided
Box package	<ul style="list-style-type: none"> 50 ml cartridge Mixing tip (10 each) Instruction for use (1 each) 	TW, A1, A2, A3, B1, C2, AO3

Warranty

Benco Dental warrants this product will be free from defects in material and manufacture. Benco Dental 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 product for user's application. If this product is defective within the warranty period, your exclusive remedy and Benco Dental's sole obligation shall be repair or replacement of the Benco Dental product.

Limitation of Liability

Except where prohibited by law, Benco Dental 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.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.
















Disposal

It should be handled according to local laws and regulations.

Devices Used Together

1. Dental impression materials.
2. Temporary cement.

Pictogram

	Temperature limitation
	Batch code
	Manufacturer
	Date of manufacture
	Use By
	Caution
	EU Representative
	Keep away from sunlight
	Keep Dry
	Medical Device
	Consult Introductions for Use
	Unique Device Identifier
	Importer
	Distributor
	RX Only

If any serious incident should occur while using this product, our company will work with the appropriate representatives in accordance with the vigilance procedure.

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