

Instruction for Use



Temporary Crown and Bridge Resin

General Information

Hexa-Temp™ 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 ~ 1.2 μm, resulting in good radio-opacity and high flexural strength. Various shades of TW, A1, A2, A3, B1, C2 and AO3 for esthetic crown are provided. Hexa-Temp™ contains about 40% inorganic filler.

Intended Purpose

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

Intended User

Dentist

Indication

Dental caries, pulpitis

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

- **Water Sorption ($\mu\text{g}/\text{mm}^3$)** by ISO 10477 : standard: $\leq 40\mu\text{g}/\text{mm}^3$
- **Solubility ($\mu\text{g}/\text{mm}^3$)** by ISO 10477 : standard: $\leq 7.5\mu\text{g}/\text{mm}^3$
- **Flexural strength (MPa)** by ISO 10477 : Standard : ≥ 50 MPa
- **Surface finish** : It shall have a glossy surface
- **Color(shade consistency)** : It shall show no more than a slight difference with the color indicated
- **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.
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 colour, 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 Spident®'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. Hexa-Temp™ 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 Hexa-Temp™ that does not apply with the appropriate tool. Then remove the Hexa-Temp™ from the teeth. Take care not to fully cure Hexa-Temp™ within the mouth.
7. Hexa-Temp™ is fully cured within approximately 2m 30s application. After curing, remove Hexa-Temp™ 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.
8. Check the occlusion and polish or adjust the finished crown with the appropriate tool.
9. 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. There 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

1. This material is intended to be use by licensed dentist only. Do not use for other purpose.
2. This material contains methacrylic monomer. Some patients can cause allergic reaction to monomer.
3. Do not use this material for patients allergic to or hypersensitive to methacrylic monomers.
4. If this material causes an allergic reaction or oversensitivity, discontinue its use immediately.
5. Avoid contact of this material with eyes, mucosal membrane, skin and clothing.
6. If this material comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.

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Manufacturer

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7. Use a rubber dam to protect the throat.
8. DO NOT use this material after the indicated expiration date on the cartridge.
9. If this material is refrigerated, allow it to reach room temperature prior to use.

Storage & Use

1. Do not expose restorative materials to elevated temperatures, or to intense light.
2. Store this material at a temperature between 2 - 27°C.
3. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life.
4. Shelf life at room temperature is 24 months.
5. See outer cartridge for expiration date.
6. Do not store materials in proximity to products containing Eugenol.

Sales unit

Sales unit	Components	Shade provided
Box package	• 50 ml cartridge • Mixing tip 10 ea • Instruction for use 1ea	TW, A1, A2, A3, B1, C2, AO3

Warranty

Spident® warrants this product will be free from defects in material and manufacture. Spident® MAKES NO OTHER WARRANTIES INDLUDING 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 Spident®'s sole obligation shall be repair or replacement of the Spident®'s product.

Limitation of Liability

Except where prohibited by law, Spident® 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

Conformity with Comunaute Europeenne			Authorized representative in the European Community		
	Temperature limit		Batch code		Importer
	Keep away from sunlight		Date of manufacture		Distributor
	Keep dry		Used-by date		Caution
	Medical Device		Manufacturer		Consult Instructions for use
	Federal law prohibits dispensing without a prescription				

※ If there has been occurred any serious accident in relation to the our device released in market, the quality management representative of our company will notify the Notified Body & the competent authority of any serious accident in accordance with the vigilance procedure.