

DIRECTIONS FOR USE

Integrity™_S

Temporary Crown & Bridge Material

Caution: U.S. Federal Law Restricts This Device To Sale By Or On The Order Of A Dentist.

Indications for use:

Integrity™ Temporary Crown & Bridge Material is an automixed two-component material based on multi-functional methacrylic esters, intended for use as both a short- and long-term temporary crown and bridge material. Integrity™ Temporary Crown & Bridge Material is compatible with light cured composites (TPH® and Esthet•X™ composite materials) for marginal repair and aesthetic contouring of temporary crowns.

Contraindications:

Integrity™ Temporary Crown & Bridge Material is contraindicated in patients with a history of severe allergic reaction to methacrylate resins.

Warnings:

Integrity™ Temporary Crown & Bridge Material contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. Wash thoroughly with soap and water after contact. If skin sensitization or other allergic reaction occurs, discontinue use.

Precautions:

- Cure rates are temperature dependent. Do not use bench cure rates to judge mouth cure rates. Use at room temperature. Refrigerated material is more viscous and will cure more slowly.

At room temperature (21° - 23°C) the following times are applicable:

Start Mix	• 0 sec.	Material dispensed into preliminary impression
	• 45 sec.	Material inserted into mouth
	• 2 min.	Removal from mouth
	• 6 min.	Remove O ₂ -inhibited layer and begin to trim excess with rotary instruments.
End Cure	• 7 min.	Complete contours and polish

- Uncured material can be removed with ethyl alcohol.
- After use, either recap the cartridge or leave the used mix tip in place to seal the cartridge.
- Always check both openings for blockage before attaching a mixing tip and remove even the smallest particles from the opening of the catalyst paste.
- Line-up the mixing tip properly when attaching to the cartridge.
- **Dispense material immediately following bleeding and attachment of mixing tip.**
- **Cartridge damage can occur if excessive force is used to extrude material.**

Adverse Reactions:

Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals.

Step-by-Step Instructions:

1. Preliminary Impression

Prior to preparation of the tooth, take an impression of the quadrant with alginate or silicone. Trim the inter dental gingival areas out of this impression to provide bulk for the later finishing of the Integrity™ temporary restoration. In molar areas with absent teeth, the carving in the interproximal areas should create a ridge for pontic contact between the prepared teeth.

Note: Store alginate impressions at 100% humidity until Integrity™ material is to be inserted.

2. Bleeding Cartridge

Remove the cartridge cap by turning 90° counterclockwise. Be sure that no plug is present. If any plug blocks flow, clear with an instrument. Dispense a small amount of base and catalyst. Make sure both have been dispensed. Wipe away excess from cartridge.

Note: The cartridge cap may be replaced on cartridge when storing the cartridge after use, or the used mixing tip may be left in place.

Note: Bleeding the cartridge should be done before each new tip installation.

3. Mixing and Application

Attach mixing tip on the cartridge by lining up the v-shaped notch on the outside colored rim of the mix tip with the v-shaped notch on the cartridge flange; turn colored mix tip 90° in a clockwise direction to lock in place on the cartridge. Use only Integrity mixing tips. Mixing tips from other systems will not fit the Integrity cartridge. Begin dispensing Integrity™ material by applying continuous, light pressure to the dispensing apparatus handle. As the material comes out of the mixing tip, inject it into the deepest portion of the preliminary impression and then into the gingival areas, keeping the mixing tip immersed in the material to prevent bubbles. Reseat the preliminary impression into the patient's mouth within 45 seconds and leave in place for approximately 2-3 minutes from the start of the mix.

Note: The use of lubricant may assist in removal from the mouth.

4. Removal from Mouth

Remove the Integrity™ restorative during the firm elastic stage. Monitor the curing process carefully because removal of the temporary restoration is only possible during the elastic phase.

Note: Mouth temperature significantly influences set time.

5. Preparing the Temporary Restoration

After removal of the temporary restoration from the preliminary impression or from tooth preparation, remove the excess material and proximal undercuts with rotary instruments. Once curing has been completed (7 minutes from start of mix), further refinements and polishing of the temporary restoration can be made. Remove the oxygen inhibited layer with an ethanol gauze or by the process of finishing and polishing.

6. Luting the Temporary Restoration

The temporary restoration can be cemented with commonly used luting agents. However, eugenol-containing cements can have a deleterious influence on composite resin luting systems.

7. Repairing the Temporary Restoration

Integrity™ temporary restorations are characterized by excellent mechanical properties. However, should breakage occur, the following procedures are recommended.

- Breakage of a newly made temporary restoration - Connect breakpoints with a fresh mix of Integrity™ material.
- Breakage of an older or worn temporary restoration - Roughen the surfaces of the breakpoint with a bur and place undercuts in the adjacent areas. Use freshly mixed Integrity™ material to connect the parts. Hold in place for 1 minute - allow to fully cure for 7 minutes.

VLC Composite may be used to add onto freshly cured Integrity™ temporary material.

Storage: Store Integrity temporary material at room temperature (23° C/ 73° F) Keep out of sunlight. Integrity temporary material can be stored up to eighteen months. Do not use after expiry date.

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