

Integrity®

Temporary Crown & Bridge Material

DIRECTIONS FOR USE - ENGLISH

Caution: U.S. federal law restricts this device to sale by or on the order of a dentist.

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 DENTSPLY visible light cured composites (see complete *Directions for Use* of selected composite) for marginal repair and aesthetic contouring of temporary crowns.

To simplify delivery and minimize product waste, Integrity® Temporary Crown & Bridge Material is packaged in Cartridge or dual barreled mini-Syringe.

COMPOSITION

Barium glass
Fumed Silica
Methacrylate Monomers
Catalyst
Stabilizers

INDICATION FOR USE

Direct fabrication of temporary (limited term) provisional veneers, inlays, onlays, crowns or bridges used in indirect restorative procedures.

CONTRAINDICATIONS

None known.

WARNINGS

- Integrity® Temporary Crown & Bridge Material contains polymerizable monomers. Avoid prolonged or repeated contact with skin (allergic contact dermatitis), oral soft tissues, and eyes. Avoid prolonged inhalation. Do not take internally.
Eye contact: Integrity® Temporary Crown & Bridge Material contains methacrylates which may be irritating to eyes. Before using this product wear protective glasses as well as covering the patient's eyes to protect from splashing material. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
Skin contact: Integrity® Temporary Crown & Bridge Material contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.
Oral mucosa contact: Avoid contact with oral soft tissues. If accidental contact occurs, flush mucosa with plenty of water and expectorate water. If sensitization of mucosa persists, seek medical attention immediately.
- Integrity® Temporary Crown & Bridge Material should not be used with patients who have a history of severe allergic reaction to any of the components.

PRECAUTIONS

- This product is intended to be used only as specifically outlined in the *Directions for Use*. Any use of this product inconsistent with the *Directions for Use* is at the discretion and sole responsibility of the practitioner.
- Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- Material should extrude easily: **DO NOT USE EXCESSIVE FORCE.** Excessive

pressure may result in unanticipated extrusion of the material or cause cartridge/syringe rupture.

STORAGE

Integrity® Temporary Crown & Bridge Material should be stored in the original cartridge/syringe only, kept out of direct sunlight and stored in a well-ventilated place. Store at temperature not exceeding 23°C/77°F (50°-73°F/10°-23°C). Refrigerated storage is not required, but is acceptable when not in use. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

At room temperature the following times are recommended:

- Immediately before each use Bleed cartridge prior to inserting new mix tip
- 0-5 secondsMaterial dispensed into preliminary impression
- 5-45 secondsMaterial inserted into mouth
- 2-3 minutesRemoval from mouth
- 6 minutesRemove O₂-inhibited layer and begin to trim excess with rotary instruments
- 7 minutesComplete contours and polish

ADVERSE REACTIONS

Product may irritate the eyes and skin. **Eye contact:** irritation and possible corneal damage. **Skin contact:** irritation or possible allergic response. Reddish rashes may be seen on the skin. **Mucous Membranes:** inflammation, edema, sloughing. (See *Warnings*)

INTERACTIONS

- Integrity® Temporary Crown & Bridge Material will adhesively bond to most dental adhesives. Use of a dentin/enamel adhesive on the preparation prior to restoration fabrication may make restoration removal and cleanup difficult.
- Integrity® Temporary Crown & Bridge Material may adhesively bond to freshly placed methacrylate and composite core buildup materials. Buildups should be fully cured, prepared, and rinsed thoroughly with forceful air/water spray before application of Integrity® Temporary Crown & Bridge Material. If surfaces were not prepared or instrumented, wipe thoroughly with alcohol soaked gauze, then rinse with air/water spray.
- Eugenol containing materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
- Residual Integrity® Temporary Crown & Bridge Material may interfere with the setting of some Vinyl Polysiloxane impression or bite registration materials. After initial restoration fabrication, prior to impression/registration, tooth preparations should be wiped thoroughly with alcohol soaked gauze, then rinsed with air/water spray.

CARTRIDGE DISPENSING GUN INSTRUCTIONS

- Raise the release lever vertically upward, while simultaneously pulling the plunger all the way back in the dispenser handle.
- Cartridge Loading
 - Open cartridge lock by lifting up top clasp.
 - Orient and insert cartridge with notch facing down.
 - Close the top clasp to lock cartridge into dispenser gun.
 - Remove the cartridge cap by turning 90° counterclockwise. Discard the cartridge cap. The used mixing tip can be disinfected and left in place until the next use to serve as a self-sealing cap.
- Dispensing
 - Dispense and discard a "pea" size amount of base and catalyst before installing mix tip to ensure even flow from cartridge. Use gentle pressure. Be sure no plug is present. If any plug blocks flow, clear with an

instrument. Wipe away excess from the cartridge carefully so base and catalyst do not cross contaminate and cause obstruction of the nozzle.

- 3.2 Install a mixing tip on the cartridge by lining up the notch on the outside rim of the mix tip with the notch on the cartridge flange. If mix tip does not seat easily, be sure the internal end view of the mix tip is aligned correctly. The mix tip itself can turn in its cap. The two holes should line up with the piece that is on the outside rim of the mix tip cap to facilitate inserting. Turn tip to align in its cap.
- 3.3 When mix tip notch is lined up with the notch on the cartridge flange, turn mix tip cap 90° in a clockwise direction to lock in place on cartridge.
- 3.4 Squeeze dispenser trigger with moderate and even pressure to begin mixing/dispersing material. Material will stop flowing after trigger is released. Disinfect barrels and used mix tip for storage. Immediately prior to next use, bleed syringe and install new mix tip as outlined above.
4. To remove cartridge, push up lever and pull slide flush. Lift plastic lever on the top of gun and remove cartridge.

DUAL BARREL mini-SYRINGE INSTRUCTIONS

1. Remove the mini-Syringe cap by turning 90° counterclockwise. Discard the mini-Syringe cap. The used mixing tip can be disinfected and left in place until the next use to serve as a self-sealing cap.
2. Dispense and discard a "pea" size amount of base and catalyst before installing mix tip to ensure even flow from cartridge. Use gentle pressure. Be sure no plug is present. If any plug blocks flow, clear with an instrument. Wipe away excess from the mini-Syringe carefully so base and catalyst do not cross contaminate and cause obstruction of the nozzle.
3. Install a mixing tip on the mini-Syringe by lining up the notch on the outside rim of the mix tip with the notch on the mini-Syringe flange. If mix tip does not seat easily, be sure the internal end view of the mix tip is aligned correctly. The mix tip itself can turn in its cap. The two holes should line up with the piece that is on the outside rim of the mix tip cap to facilitate inserting. Turn tip to align in its cap.
4. When mix tip notch is lined up with the notch on the mini-Syringe flange, turn mix tip cap 90° in a clockwise direction to lock in place on mini-syringe.
5. Gently depress mini-Syringe plungers to begin the flow of material. DO NOT USE EXCESSIVE FORCE. If excessive force is encountered, remove mini-Syringe from operating field, remove and discard mix tip. Check for obstruction and confirm material is flowing from both mini-Syringe barrels. Disinfect barrels and used mix tip for storage. Immediately prior to next use, bleed mini-Syringe and install new mix tip as outlined above.

STEP-BY-STEP INSTRUCTIONS

1. Preliminary Impression

- 1.1 Prior to preparation of the tooth/teeth, evaluate existing contours and anatomy. To duplicate existing anatomy proceed to primary impression. If contours or anatomy are deficient, light cured composite may be placed and cured without bonding agent on the tooth/teeth as a mock up to approximate the desired contours. A missing tooth may be temporarily replaced with an acrylic denture tooth prior to preliminary impression.
- 1.2 Make an alginate or silicone impression of the quadrant including tooth/teeth to be prepared following manufacturer's *Directions for Use*.
- 1.3 When removed from the mouth, trim the inter dental gingival areas out of the preliminary impression in the area(s) to be restored to provide bulk for the later finishing of the Integrity® temporary restoration. In molar areas with absent teeth that were not replaced prior to impression, 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. **Technique Tip:** Alternatively, a vacuum-formed matrix may be constructed on a cast (with diagnostic wax-up, contour modification as indicated).

2. Prepare tooth/teeth

- 2.1 If pre-impression mock up composite was placed, it should be removed. Prepare tooth/teeth, and build up as needed following manufacturer's *Directions for Use*. Ensure adequate reduction for material thickness, especially on functional occlusal surfaces.
- 2.2 Trial-fit impression (or vacuum-formed matrix) made in Step 2.1 to ensure adequate orientation. Rinse impression and lightly air dry.
- 2.3 Block out preparation undercuts with wax or suitable material, clean tooth/teeth preparation with alcohol soaked gauze and/or air water spray and lightly dry. Do not desiccate tooth structure. **Technique Tip:** A thin layer of water-soluble lubricating medium may be applied to the tooth preparation to facilitate removal of the curing Integrity® material.

3. Mixing and Application

NOTE: Allow Integrity® Temporary Crown & Bridge Material to reach room temperature prior to use. Higher temperatures reduce work times and

laboratory bench set times (faster), lower temperatures increase them (slower). Clinically, intraoral set time is unaffected within the range of allowable storage and initial mixing temperatures.

- 3.1 Follow instructions for cartridge and dual barrel mini-Syringe loading, bleeding and mix tip installation. Use only the supplied mixing tips. Mixing tips from other systems will not fit the Integrity® Temporary Crown & Bridge Material delivery systems.

- 3.2 Dispense a small amount through the mix tip onto a mixing pad and discard. Without delay, begin dispensing Integrity® Material directly into the preliminary impression into the area of the preparation 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 in the proper relative position within 45 seconds of the start of mix.

- 3.3 Leave impression 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

- 4.1 Remove the impression containing the Integrity® Material restoration 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. If the material remains on the preparation when the impression is removed, gently tease the restoration off with gauze. Use finger pressure only, and dislodge along the path of insertion. Do not rock or torque restoration off the preparation. Avoid the use of hemostats or other pliers that may distort the setting Integrity® Material restoration.

- 4.2 At this elastic phase, gross excess may be quickly trimmed with sharp scissors, being careful not to distort the restoration or margins.

5. Preparing the Temporary Restoration

- 5.1 If restoration remains within impression, allow restoration and impression to remain undisturbed until initial set, approximately 2-3 minutes from start of mix. If restoration is already out of the impression, place setting restoration in warm water and allow to set.
- 5.2 At the completion of set (approximately 6 minutes from start of mix), remove restoration from impression. Remove the oxygen-inhibited layer with alcohol-soaked gauze or by the process of finishing and polishing. Remove the excess material and proximal undercuts with rotary instruments.
- 5.3 Once curing is complete (7 minutes from start of mix), further refinements and polishing of the temporary restoration can be made.
- 5.4 Restoration may be polished with flour of pumice and acrylic polish or by use of Enhance® Finishing System and PoGo® Polishing System or Prisma®•Gloss™ Composite Polishing Paste System. (See complete *Directions for Use* supplied with polishing product chosen)

6. Luting the Temporary Restoration

- 6.1 Check the fit and esthetics of the Integrity® Temporary Crown & Bridge Material provisional restoration. If additions are necessary, see *Step 7, Repairing/Modifying the Temporary Restoration*. If increased retention is desired, microetching (sandblasting) with 50µ alumina the internal surfaces of the restoration is recommended. The internal surface of the restoration should be clean and dry prior to cementation.
- 6.2 Integrity® Temporary Crown & Bridge Material temporary restorations can be cemented with most commonly used temporary luting agents. See manufacturer's complete *Directions for Use* for compatibility and specific technique. Most eugenol-containing temporary cements are compatible with Integrity® Material. However, they can have a deleterious influence on resin-containing luting systems chosen for final restoration cementation.

7. Repairing the Temporary Restoration

- 7.1 Freshly made restorations: Freshly made Integrity® temporary restorations are compatible with many visible light cured composite restorative materials. For adjustment of margin discrepancies, roughen the area, extending slightly beyond the margin onto restoration surface. Apply a compatible flowable composite and light cure as outlined in the complete *Directions for Use*. For surface contour and/or esthetic adjustment, cut back area to be modified with a coarse diamond. Apply and cure desired shade(s) of characterization material as outlined in the complete *Directions for Use*. Adhesive/Bonding agent application is not necessary for modifications to freshly made Integrity® temporary restorations. Finish, polish and cement as outlined above.
- 7.2 Restorations in service: Integrity® temporary restorations are characterized by excellent mechanical properties. However, should breakage occur, the following procedures are recommended.

Roughen the surfaces of the breakpoint with a coarse diamond bur and place undercuts in the adjacent areas. Prepared parts may be placed intraorally to assure fit and proper alignment. If fractured sections do not approximate, consideration should be given to remaking, rather than repairing the restoration.

Use freshly mixed Integrity® Material to connect the parts. Hold in place for 1 minute and allow to fully cure for a minimum of 7 minutes. Remove and finish and polish as outlined above.

Technique Tips to avoid breakage:

- Be sure adequate preparation reduction/occlusal clearance exists
- Adjust occlusion removing undesirable contacts
- Allow adequate bulk for connectors in multiple unit provisional restorations
- Avoid squeezing the Integrity® Material restoration with pliers when removing restoration
- Integrity® Temporary Crown & Bridge Material restorations are durable under usual provisional conditions. Many factors contribute to the longevity, thus no definitive lifespan can be stated. However, if final restorations are not planned to follow in timely succession, consideration must be given to subsequent removal and restoration remake.

CLEANING

The cartridge/mini-Syringe may be cleaned using a disposable towel soaked with hot water and soap or detergent. Excess material may be removed with an alcohol-moistened gauze.

DISINFECTION

Dispensers, cartridges, mini-Syringe and used tips left in place on cartridge/mini-Syringe for storage, if exposed spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternaries are approved disinfectants.

Disinfect by spraying with any recommended hospital-level surface disinfectant for the contact time recommended by the disinfectant manufacturer for optimum results. Spraying with glutaraldehyde is not recommended. Some phenolic-based agents and iodophor-based products may cause surface staining. Agents containing organic solvents, such as alcohol, may tend to dissolve the plastic. The disinfectant manufacturer's directions should be followed properly for optimum results. Water-based disinfectant solutions are preferred.

Note: Wipe cartridge/mini-Syringe GENTLY, vigorous wiping may destroy the label.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:
 - Reorder number
 - Lot number on package
 - Expiration date

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