

# Integrity® TempGrip™

## Temporary Crown & Bridge Cement Zinc Oxide Non-Eugenol

### DIRECTIONS FOR USE – ENGLISH

Integrity® TempGrip™ Temporary Crown & Bridge Cement Zinc Oxide Non-Eugenol is a temporary cement used to lute indirect provisional (temporary) restorations or limited term cementation of final restorations. The physical properties have been optimized to allow secure retention of restorations, and to allow easy restoration removal and cleanup from the restoration and preparation. Since reation of the restoration is desired for only a limited time frame, a dentin/enamel adhesive is **not** recommended for use with Integrity® TempGrip™ Cement.

Integrity® TempGrip™ Cement is an automatically mixed two component material in 1:1 9g dual barreled syringe based on Zinc Oxide/organic acids. Due to its non-eugenol formulation, it does not influence the setting of resin-based filling and luting materials.

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

### COMPOSITION

Organic acids; Zinc oxide; Methacrylates; Catalyst; Stabilizer

### INDICATIONS

Temporary cementation of provisional acrylic and composite indirect restorations. Provisional or trial cementation (limited time) of ceramic, porcelain, composite, PFM (porcelain fused to metal) and all metal crowns and bridges.

### CONTRAINDICATIONS

None known.

### WARNINGS

1. Integrity® TempGrip™ Cement contains polymerizable monomers and methacrylates. Avoid prolonged or repeated contact with skin and eyes. Do not take internally.

**Eye Contact:** Integrity® TempGrip™ Cement 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® TempGrip™ Cement 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.

2. Integrity® TempGrip™ Cement should not be used with patients who have a history of severe allergic reaction to any of the components.

### PRECAUTIONS

1. This product is intended to be used 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.

2. Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
3. Integrity® TempGrip™ Cement should extrude easily. **DO NOT USE EXCESSIVE FORCE.** Excessive pressure may result in unanticipated extrusion of the material or cause syringe rupture.

### STORAGE

Integrity® TempGrip™ Cement should be stored in the original syringe only, kept out of direct sunlight and stored in a well ventilated place at temperatures between 8-25°C/46-77°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

### 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

1. Integrity® TempGrip™ Cement will adhesively bond to most dental adhesives. Use of a dentin/enamel adhesive may make restoration removal and cleanup difficult.
2. Integrity® TempGrip™ Cement may adhesively bond to freshly placed methacrylate and composite core buildup materials and provisional restorations. Buildups and provisional restorations should be fully cured, prepared, and rinsed thoroughly with forceful air/water spray before cement application. If surfaces were not prepared or instrumented, wipe thoroughly with alcohol soaked gauze, then rinse with air/water spray.
3. 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.

### STEP-BY-STEP INSTRUCTIONS

*Provisional, temporary, or periodic term restoration cementation*

1. **Treatment of the Preparation**
  - 1.1 Following tooth preparation and fabrication of the provisional restoration, clean enamel, dentin, any buildup material and provisional restoration thoroughly with water spray. Blot dry with a moist cotton pellet until there is no pooling of water, leaving a moist, glistening surface. **Do not desiccate.** Etching of tooth surfaces is NOT recommended. For direct and indirect pulp capping, cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner (Dycal® Liner) following manufacturer's directions for use.
2. **Treatment of the Restoration**
  - 2.1 Check the fit and esthetics of the provisional 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.
3. **Cementation Technique**
  - 3.1 Remove syringe's cap and discard cap. The used mixing tip can be disinfected and left in place until the next use to serve as a self-sealing cap. Dispense and discard a small amount of material from the dual barreled syringe. Be sure material is flowing freely from both ports. Holding syringe vertically, carefully wipe away excess so base and catalyst do not cross contaminate and cause obstruction of the ports.

- 3.2 Install a mixing tip on the cartridge by lining up the v-shaped notch on the outside of the mix tip with the v-shape notch on the syringe flange. Turn colored mix tip cap 90 degrees in a clockwise direction to lock in place on syringe.
  - 3.3 Gently depress syringe plungers to begin the flow of material. DO NOT USE EXCESSIVE FORCE. If force is encountered, remove syringe from operating field, remove and discard mix tip. Check for obstruction and confirm material is flowing from both syringe barrels. Wipe barrels and install new mix tip as outlined above. Dispense a small amount through the mix tip onto a mixing pad and discard.
  - 3.4 Without delay, using gentle pressure, apply a thin, uniform layer of cement to the entire internal surface of the restoration directly from the mix tip. At room temperature, Integrity® TempGrip™ Cement offers a work time of 1-1½ minutes.
  - 3.5 Seat the restoration with gradual pressure. A gentle rocking or vibratory motion may be helpful to insure optimal seating. Following placement, Integrity® TempGrip™ Cement will self-cure set in the mouth in approximately 2-3 minutes. Protect restoration from contamination and movement during the setting time.
  - 3.6 Remove gross excess from marginal areas. Use an instrument such as a blunted explorer, periodontal probe or a clean, dry brush tip. Restoration should not be moved or torqued during removal of gross excess cement. Special attention should be paid to interproximal areas using floss to remove excess cement.
  - 3.7 Following the self-cure set of approximately 5 minutes from start of mix, check and adjust occlusion and polish as necessary. Patient may then be dismissed.
- 4. Restoration Removal**
- 4.1 Using hemostats, Baade pliers, or other suitable crown removal instrument, gently grasp and remove restoration along the path of insertion. Avoid twisting or rocking of provisional to avoid preparation and/or restoration damage. **Technique Tip:** For final restorations requiring periodic removal for periodontal maintenance procedures, etc., features incorporated in the restoration design which facilitate removal such as dimples or cast removal buttons are strongly recommended.
  - 4.2 Following removal of the restoration, residual cement remaining on the preparation and/or internal surfaces of the restoration, may be removed with a sharp scaler, explorer or other suitable hand instrument.
  - 4.3 Clean enamel and dentin with a rubber cup and pumice or a cleaning paste such as Nupro® Prophylaxis Paste. Wash thoroughly with water spray and blot dry.
  - 4.4 Proceed to final cementation according to cement manufacturer's instructions, or repeat limited term cementation with Integrity® TempGrip™ Cement by following steps above.

#### **CLEANING**

The 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**

The syringe and used mixing tip left in place on the 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 the syringe by spraying the syringe 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.

#### **LOT NUMBER AND EXPIRATION DATE**

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

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Printed in U.S.A.  
 Form #566402 (R 11/2/06)