

SureFil® SDR™ flow

Posterior Bulk Fill Flowable Base



DIRECTIONS FOR USE - ENGLISH

For Dental Use Only
USA: Rx Only

1. PRODUCT DESCRIPTION

SureFil® SDR™ flow Posterior Bulk Fill Flowable Base is a one-component, fluoride-containing, visible light cured, radiopaque resin composite restorative material. It is designed to be used as a base in Class I and II restorations. SureFil® SDR™ flow material has handling characteristics typical of a "flowable" composite, but can be placed in 4mm increments with minimal polymerization stress. SureFil® SDR™ flow material has a self-leveling feature that allows intimate adaptation to the prepared cavity walls. Available in one universal shade, it is designed to be overlaid with a methacrylate based universal/posterior composite for replacing missing occlusal/facial enamel.

1.1 Delivery forms

SureFil® SDR™ flow material is available in:

- Pre-dosed Compula® Tips for direct intra-oral application
- One universal shade

1.2 Composition

Barium-alumino-fluoro-borosilicate glass; Strontium alumino-fluoro-silicate glass; Modified urethane dimethacrylate resin; ethoxylated Bisphenol A dimethacrylate (EBPADMA); Triethyleneglycol dimethacrylate (TEGDMA); Camphorquinone (CQ) Photoinitiator; Butylated hydroxyl toluene (BHT); UV Stabilizer; Titanium dioxide; Iron oxide pigments

1.3 Indications

SureFil® SDR™ flow material direct restorative:

- Base in cavity Class I & II direct restorations
- Liner under direct restorative materials – Class II box liner

1.4 Contraindications

SureFil® SDR™ flow material is contraindicated for:

- Use with patients who have a history of severe allergic reaction to methacrylate resins

1.5 Compatible adhesives

SureFil® SDR™ flow material is used following application of a suitable dentin/enamel adhesive and is chemically compatible with conventional methacrylate-based dentin/enamel adhesives including DENTSPLY adhesives designed for use with visible light cured composite restoratives (see complete directions for use of selected adhesive).

1.6 Compatible enamel replacement restoratives

SureFil® SDR™ flow material is used in conjunction with a suitable universal/posterior restorative material as an occlusal/facial enamel replacement (see Step-By-Step Instructions) and is chemically compatible with conventional methacrylate-based composite restorative materials including DENTSPLY visible light cured universal/posterior composite restorative materials designed for posterior Class I & II occlusal restorations (see complete directions for use of selected occlusal restorative material).

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other sections of these directions for use.

2.1 Warnings

SureFil® SDR™ flow material contains polymerizable methacrylate monomers which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.

- **Avoid Eye Contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
- **Avoid Skin Contact** to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs immediately remove material with cotton and alcohol and wash well thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.
- **Avoid Contact with Oral Soft Tissues/Mucosa** to prevent inflammation. If accidental contact occurs, immediately remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

2.2 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. Contact with saliva and blood during composite placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
3. Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
4. SureFil® SDR™ flow material should extrude easily, DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause the Compula® Tip to eject from the Compules® Tips Gun.
5. Compula® Tips are designed for one time use. Discard after use. Do not reuse.
6. Use of Compula® Tips with the DENTSPLY Compules® Tips Gun is recommended.
7. SureFil® SDR™ flow material is available in one, semi-translucent universal shade. If placed to the cavosurface margin, e.g., occlusal margins or wide proximal box extension cavities, the tooth/restorative demarcation may be visible. Heavily stained dentin may be visible through the cured SureFil® SDR™ flow material. Use of an appropriately shaded and/or opaque restorative material of adequate thickness in visible areas/surfaces is recommended where esthetics is paramount.
8. When placing SureFil® SDR™ flow material, allow at least 2mm for selected occlusal restorative material.
9. Interactions:
 - Eugenol- and hydrogen peroxide-containing materials should not be used in conjunction with this product since they may interfere with hardening and cause softening of the polymeric components of the material.
 - SureFil® SDR™ flow material is light-cured material. Therefore, it should be protected from ambient light. Proceed immediately once the material has been placed.
 - If mineral-impregnated (e.g., ferric compounds) retraction cords and/or hemostatic solutions are used in conjunction with adhesive procedures, marginal seal may be adversely affected, allowing microleakage, subsurface staining and/or restoration failure. If gingival retraction is necessary, use of plain, non-impregnated cord is recommended.

2.3 Storage conditions

SureFil® SDR™ flow material should be kept out of direct sunlight and stored in a well ventilated place at temperatures between 2°-24°C/35°-75°F. 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.

2.4 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 (see Warnings).

3. STEP-BY-STEP INSTRUCTIONS FOR USE

3.1 Cavity preparation

1. Prepare the cavity so that no residual amalgam or restorative material is left.
2. Rinse surface with water spray and carefully dry it with air spray. Do not desiccate the tooth structure.
3. Use a dental dam or cotton rolls to isolate the cavity from contamination.

3.2 Placement of matrix

For optimal proximal contacts proceed as follows:

1. Place a matrix (e. g. AutoMatrix® matrix system or Palodent® matrix system) and wedge. Burnishing of the matrix band will improve contact and contour. Pre-wedging/BITine® ring placement is advocated.
2. In Class II cavities use a deadsoft, thin matrix band.

3.3 Pulp protection, tooth conditioning/dentin pretreatment, adhesive application:

Refer to adhesive manufacturer's directions for pulp protection, tooth conditioning and/or adhesive application. Once the surfaces have been properly treated, they must be kept uncontaminated. Proceed immediately to placement of SureFil® SDR™ flow material.

3.4 Dispensing SureFil® SDR™ flow material



Danger of injury due to excessive force

Apply slow and steady pressure on the applicator gun
Do not use excessive force – Compula® Tip rupture or ejection from applicator gun may result.

The pre-dosed Compula® Tip provides the combination of a unit dose Compules® Tip with a metal cannula applicator tip.

1. Load Compules® Tips Gun with pre-dosed Compula® Tip. Insert Compula® Tip into the notched opening of the Compules® Tips Gun barrel. Be certain that the collar on the Compula® Tip is inserted first.
2. Remove the colored cap from the Compula® Tip. The Compula® Tip may be rotated 360° to gain the proper angle of entrance into the cavity.
3. Dispense the material into the cavity preparation using a slow, steady pressure. DO NOT USE EXCESSIVE FORCE.
4. To remove the used Compula® Tip, be sure that the Compules® Tips Gun plunger is pulled back completely by allowing the handle to open to its widest position. Apply a downward motion to the front end of the Compula® Tip and remove.

3.5 Placement of SureFil® SDR™ flow material

NOTE: As SureFil® SDR™ flow material is designed to conform to cavity shape, proper contact areas must be established with the matrix system selected. Material will not distend matrix band. If needed, manually distend matrix band with a suitable hand instrument such as a condenser or ball burnisher prior to and/or during light curing.

1. Dispense SureFil® SDR™ flow material directly into preparation site/ tooth surface from the Compula® Tip using slow, steady pressure. Begin dispensing at the deepest portion of the cavity, keeping tip close to cavity floor. Gradually withdraw tip as cavity is filled. Avoid lifting the tip out of dispensed material while dispensing to minimize air entrapment. At the completion of dispensing, wipe tip against cavity wall while withdrawing from the operative field.
2. Within a few seconds, dispensed SureFil® SDR™ flow material will self-level, eliminating the need for further manipulation with hand instruments. In case of overflow or excess on occlusal margins, use a flocced applicator tip wetted with residual adhesive to remove excess. Any visible air bubbles should be pierced with a clean, sharp explorer prior to curing.
3. When used as a Bulk Fill Base material, most cavities may be filled in one bulk increment (up to 4mm) as needed to fill the cavity 2mm short of the occlusal cavosurface. In deeper preparations, place material in 4mm increments, thoroughly light curing each increment.
4. Alternatively, SureFil® SDR™ flow material may be placed in a thin layer as a traditional "flowable" liner on exposed dentin.

3.6 Curing

SureFil® SDR™ flow material is designed to be cured in increments up to a 4mm depth/thickness. Light cure each area of the restoration surface with a suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. spectral output containing 470nm. Minimum light output must be at least 550mW/cm² exposure for at least 20 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations.



Inadequate polymerization due to insufficient curing

Check compatibility of curing light
Check curing cycle
Check curing output before each procedure

3.7 Completion

1. Proceed immediately to complete the restoration using a methacrylate based universal/posterior restorative material following manufacturer's Directions For Use. **Technique Tip:** In most applications, a body shade of occlusal restorative material provides the best esthetic result. In case of heavily stained dentin, use of an opaque shade may be required. Do not disturb or allow contamination of cured surface or exposed adhesive. If contamination occurs, follow adhesive manufacturer's directions for use for re-application of adhesive. If surfaces remain undisturbed, additional application of adhesive between increments is neither necessary nor recommended.
2. If contouring, finishing, and/or polishing of cured SureFil® SDR™ flow material is necessary, use traditional rotary devices following manufacturer's Directions For Use.

4. HYGIENE

Sterilizing the Compules® Tips Gun

Disassembling

1. Partially close the applicator gun and place your thumb on the rear part of the hinge.
2. Push upwards and lift hinge. The applicator gun is separated in two parts and the plunger is exposed.
3. Remove restorative material with a soft paper tissue and alcohol of 70%.

Sterilization

Sterilize the applicator gun by steam autoclave (2.1-2.4 bar and 135-138°C, 30-35 PSI and 275-280°F). It is not recommended to submerge Compules® Tips Gun into disinfection solutions.

Reassembling

1. After sterilization insert plunger into the applicator gun cylinder.
2. Press components together and snap hinge mechanism in place.
3. Do not continue to use damaged or soiled applicator guns.




Cross-contamination

Do not clean, disinfect or reuse Compula® Tips
Properly dispose of the used and/or contaminated or expired Compula® Tips in accordance with local regulations

5. LOT NUMBER AND EXPIRATION DATE

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

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