



SDR[®]

Posterior Bulk Fill Flowable Base

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CAUTION: For dental use only.
In the USA: Rx only

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1 Product description

SDR[®] 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. It is also suitable as a stand-alone restorative material in non-occlusal-contact applications.

SDR[®] material has handling characteristics typical of a “flowable” composite, but can be placed in 4 mm increments with minimal polymerization stress.

SDR[®] material has a self-leveling feature that allows intimate adaptation to the prepared cavity walls. It is available in one universal shade. When used as a base/liner, it is designed to be overlaid with a methacrylate based universal/posterior composite for replacing missing occlusal/facial enamel.

1.1 Indications

- Base and liner for direct Class I and II restorations.
- Restorative (without the need of an additional occlusal material) for direct, small class I restorations of permanent molars and for class I and II restorations of deciduous molars.
- Pit and Fissure sealant.
- Core build-up.

1.2 Contraindications

SDR[®] material is contraindicated for:

- Use with patients who have a known hypersensitivity to methacrylate resins.

1.3 Delivery forms

SDR[®] material is available in:

- Predosed Compula[®] Tips for direct intraoral application
- Small syringes for direct intraoral application
- One universal shade

1.4 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
- Photoaccelerator
- Butylated hydroxyl toluene (BHT)
- UV Stabilizer
- Titanium dioxide
- Iron oxide pigments
- Fluorescing agent

1.5 Compatible adhesives

SDR[®] material is used following application of a suitable dentin/enamel adhesive and is chemically compatible with conventional methacrylate-based dentin/enamel adhesives including Dentsply Sirona adhesives designed for use with visible light cured composite restoratives (see complete Directions for Use of selected adhesive).

1.6 Compatible enamel replacement restoratives

SDR[®] material is used in conjunction with a suitable universal/posterior restorative material¹ as an occlusal/facial enamel replacement (see Step-by-step instructions) and is chemically compatible with conventional methacrylate-based composite restorative materials including Dentsply Sirona 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 Safety notes

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



Safety alert symbol.

- This is the safety alert symbol. It is used to alert you to potential personal injury hazards.
- Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

The material contains methacrylates and polymerizable monomers which may be irritating to skin, eyes and oral mucosa and may cause sensitization by skin contact and allergic contact dermatitis in susceptible persons.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse 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, remove material with cotton and alcohol and wash 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, remove material from the tissues. Flush mucosa with plenty of water and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

¹ Enamel replacement material overlay is not required for Pit and Fissure sealant, direct, small class I restorations of permanent molars, class I and II restorations of deciduous molars, or core build-up applications.

2.2 Precautions

This product is intended to be used as specifically outlined in these Directions for Use. Any use of this product inconsistent with these Directions for Use is at the discretion and sole responsibility of the practitioner.

- Contact with saliva and blood during composite placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
- Use protective measures for the dental team and patients such as glasses and rubber dam in accordance with local best practice.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- The syringes cannot be reprocessed. To prevent syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Discard syringes if contaminated.
- As additional precautionary measure, syringes may be protected from gross debris but not from all contamination by applying a protective barrier.
- Use of Compula® Tips with the Dentsply Sirona Compules® Tips Gun is recommended.
- The Compules® Tips Gun is only intended to be used with Dentsply Sirona Compules® or Compula® Tips.
- For further information please refer to the Compules® Tips Gun Directions for Use.
- The 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 rupture or to eject from the Dentsply Sirona Compules® Tips Gun.
- Tightly close syringes immediately after use. Do not allow dispensing tip to remain as a syringe cap. Replace original cap tightly after each use. Discard and properly dispose dispensing tips after use, as the tips may clog if material is allowed to dry or set inside.
- Dentsply Sirona supplies the appropriate dispensing tip for the SDR® composite restorative material syringe. This tip is the only tip that should be utilized for placement of the material.
- SDR® material is available in one, semi-translucent universal shade. If placed to the cavo-surface margin, e.g., occlusal surface or wide proximal box extension cavities, the tooth/restorative demarcation may be visible. Heavily stained dentin may be visible through the cured SDR® material. Use of an appropriately shaded and/or opaque restorative material of adequate thickness in visible areas/surfaces is recommended where esthetics is paramount.
- When placing SDR® material as a base or liner, allow at least 2 mm for selected occlusal restorative material.
- Insufficient data exist to support the use as a class I restoration with isthmus width beyond central groove areas, or when replacing a functional cusp. Excessive wear or restoration failure may result.
- Interactions:
 - Do not use eugenol- or hydrogen peroxide-containing materials in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
 - The restorative is a light cured material. Therefore, it should be protected from ambient light. Proceed immediately once cured 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 Adverse reactions

- Eye contact: Irritation and possible corneal damage.
- Skin contact: Irritation or possible allergic response. Reddish rashes may be seen on the skin.
- Contact with mucous membranes: Inflammation. (See Warnings)

2.4 Storage conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store in a well ventilated place at temperatures between 2 °C and 24 °C (36 °F and 75 °F).
- Allow material to reach room temperature prior to use.
- Keep out of direct sunlight and protect from moisture.
- Do not freeze.
- Do not use after expiration date.

3 Step-by-step instructions

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. Mylar, AutoMatrix® matrix system or Palodent® matrix system) and wedge. Burnishing of the matrix band will improve contact and contour. Pre-wedging ring placement is recommended.
2. In class II cavities use a deadsoft, thin matrix band.

3.3 Pulp protection, tooth conditioning/dentin pre-treatment, adhesive application

Refer to adhesive manufacturer's instructions 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 restorative material.

3.4 Placement



Excessive force.

Injury.

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

Compula® Tips

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.

Syringes

1. Remove cap from the end of the syringe. To assure free flow of material from syringe, express a small amount onto pad, away from the patient field.
2. Attach disposable, black dispensing Tip to end of the syringe. Turn Tip clockwise $\frac{1}{4}$ to $\frac{1}{2}$ turn to assure that it is fully seated. Tug on Tip to be sure that it is locked into the collar of the syringe.
3. Material should flow freely with gentle pressure. DO NOT USE EXCESSIVE FORCE. If more than gentle pressure is required, remove from patient field and check for obstruction.
4. DISCARD AND PROPERLY DISPOSE DISPENSING TIP IMMEDIATELY AFTER USE. REPLACE ORIGINAL CAP. Do not store syringe with black dispensing Tip in place. STORE ONLY WITH ORIGINAL CAP.

Note: It is recommended to pull back slightly on the syringe plunger after use to prevent excessive flow of material.

3.5 Placement of SDR[®] material

Note: As SDR[®] 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 SDR[®] material directly into preparation site/tooth surface 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 SDR[®] material will self-level, eliminating the need for further manipulation with hand instruments. In case of overfill, use a flocked 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 4 mm as needed to fill the cavity 2 mm short of the occlusal cavosurface². In deeper preparations, place material in 4 mm increments, thoroughly light curing each increment.
4. Alternatively, SDR[®] material may be placed in a thin layer as a traditional “flowable” liner on exposed dentin.

3.6 Curing

SDR[®] material is designed to be cured in increments up to a 4 mm depth/thickness.

1. 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 470 nm. Minimum light output must be at least 550 mW/cm² exposure for at least 20 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations.

Insufficient curing.



Inadequate polymerization.

1. Check compatibility of curing light.
2. Check curing cycle.
3. Check minimum irradiance.
4. Cure each area of each increment for the recommended curing time.
5. Check distance to surface to be cured.

² When used as a Pit and Fissure sealant, direct, small class I restorations of permanent molars, class I and II restorations of deciduous molars or core build-up material, material may be placed to full contour including up to the occlusal cavosurface margin.

3.7 Completion

1. When used as a base/liner, 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 SDR[®] material is necessary, use traditional rotary devices following manufacturer's Directions for Use.

4 Hygiene

Cross-contamination.



Infection.

- Do not reuse single use products. Dispose of in accordance with local regulations.
- The syringes cannot be reprocessed. Dispose of contaminated syringes in accordance with local regulations.
- Reprocess reusable products according to the instructions.

4.1 Syringes – cross-contamination

Cross-contamination.



Infection.

- The syringes cannot be reprocessed.
- To prevent the syringes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Do not reuse syringes if contaminated.
- Dispose of contaminated syringes in accordance with local regulations.

To prevent syringes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended. The use of protective barriers is an additional precautionary measure against gross debris but not against all contamination.

Incidental contact of the syringe with water, soap or a water-based hospital-level disinfection solution will not damage syringe body. Do not allow any solution contact with contained material. Discard composite material that has been in contact with any fluid or non-sterile instrument.

Repeated liquid contact may damage label. Dry the syringe with a lint-free single use cloth.

Note: Vigorous wiping can destroy the label. Wipe syringe gently.

4.2 Compules[®] Tips Gun

For reprocessing instructions please refer to the Directions for Use of the Compules[®] Tips Gun, which is available on our webpage at www.dentsplysirona.com and www.dentsply.eu/IFU. If requested, we will send you a free printed copy of the Directions for Use in the language you require within 7 days. In the USA, call 1-800-532-2855. Outside North America, use the order form provided on www.dentsply.eu/IFU for this purpose.

4.3 Compula® Tips – cross-contamination



Cross-contamination.

Infection.

- Do not reuse Compula® Tips. Dispose of Compula® Tips in accordance with local regulations.

5 Lot number (), expiration date () and disposal

1. Do not use after expiration date.
ISO standard is used: “YYYY-MM” or “YYYY-MM-DD”.
2. The following numbers should be quoted in all correspondence:
 - Reorder number
 - Lot number
 - Expiration date
3. Dispose in accordance with local regulations.

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[These Directions for Use are based on Master Version 01]



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