SonicFill™ 3

Bulk Fill Composite

Instruction For Use

Kerr Corporation

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DMC3493_Rev.00



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SonicFill 3 Nanohybrid Bulk Fill Composite

DEVICE DESCRIPTION

SonicFill 3 is a light-cured, low-shrink, resin-based, dental restorative designed for direct placement. SonicFill 3 is used in combination with the SonicFill Handpiece and offers sonically activated delivery. This delivery produces a significant drop in viscosity upon extrusion, allowing intimate adaptation of the composite to the cavity walls. When the cavity is filled and the Handpiece is deactivated, the viscosity of the restorative resin increases regaining ideal handling properties. The non-sticky, non-slumping nature of the material allows for quick, easy shaping and sculpting. These benefits combined with a high depth of cure and low shrinkage stress allow a technique in which a cavity up to 5mm in depth can be filled and cured in a single bulk increment.

INDICATIONS FOR USE

SonicFill 3 is indicated for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include: base/liner material, repair of enamel defects, repair of provisionals, repair of porcelain restorations, minor occlusal build-ups, pit and fissure sealant, luting of composite/ceramic veneers, core build-ups and incisal abrasions.

CONTRAINDICATIONS

None known.

WARNINGS

Do not use this product on patients with known methacrylate allergies. Uncured methacrylate resin may cause contact dermatitis and damage to the pulp. Avoid contact with skin, eyes, and soft tissue. Wash thoroughly with water after contact. Get medical attention for eyes. Do not take internally.

PRECAUTIONS

Kerr recommends the following precautions when using SonicFill 3 or any other composite material:

- · Provide the patient with protective eyewear
- · Use a rubber dam to isolate the oral cavity

The $Unidose^{\mathbb{M}}$ tips are designed for SINGLE PATIENT USE ONLY to prevent cross-contamination between patients.

Note that SonicFill 3 has somewhat higher translucency than other composites to facilitate a greater depth-of-cure (5 mm). This translucency may limit clinical applications in some class IV restorations or other anterior applications where the restorative material is not surrounded by tooth structure. In these instances, please check to make sure the translucency meets esthetic requirements before bonding the composite material.

ADVERSE REACTION

None Known.

INSTRUCTIONS FOR USE

SonicFill Handpiece

The SonicFill Handpiece is packaged with a Use and Care guide. To receive the best use from your Handpiece, read and follow the use and care instructions included with the device.

Using SonicFill 3

Setup

- 1. Select the desired shade. If Class II, place matrix of choice.
- 2. Verify air pressure of dental unit is between 40 and 70 PSI (276 kPa 483 kPa).
- Accurately position the Handpiece on the coupling and press it firmly until securely (audibly) locked.
- 4. Remove red protective covers from tip by pulling them straight off without twisting to prevent disassembling the tip. Discard any disassembled tips.
- 5. Insert Unidose capsule with moderate pressure and rotate SonicFill Handpiece into tip in a clockwise direction this will screw tip into place. If the tip will not screw on easily, it has likely cross-threaded. Unscrew the tip and start again. If you are not able to easily screw the tip onto the handpiece, discard the tip.
- 6. Once tip has been placed on handpiece, remove red cover at the end of the tip.

Bonding

 Complete bonding procedure with product of choice. SonicFill 3 is compatible with all methacrylate-based adhesive products.

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- 8. Using foot pedal, briefly activate handpiece outside mouth to ensure tip is fully engaged and does not dislodge when pressed by the piston.
- 9. The dispensing rate/speed is set with the switch at the bottom of the Handpiece. Setting 5 is the fastest speed; setting 1 is slowest. Set desired speed at base of Handpiece. For your first several uses, you may wish to place the speed at setting "3" until you become familiar with the flow rate. When you are comfortable with the device, setting "5" will be appropriate for many restorations.
- 10. Place Unidose® tip one-half millimeter above the deepest part of the preparation to avoid trapping air and ensure proper liquefaction of the composite material.
- 11. Activate SonicFill Handpiece by fully depressing foot pedal and fill entire cavity (up to 5 mm). It is recommended to use full air pressure when activating the Handpiece. Full pressure ensures adequate liquefaction and adaptation. Use the dispensing rate switch to control the flow rate and speed of the device. Be sure to keep the dispensing tip inside the material at all times while the handpiece is activated. Doing so will ensure that the material is continually liquefied during placement, which helps ensure adequate adaptation to all internal line and point angles. In a deep cavity (>5mm) or when placing core buildup in a deep pulp chamber, 2 separately cured increments are recommended.
- 12. After placement, press and sculpt, defining anatomy using hand instrument(s). SonicFill 3 will provide a minimum of 60 seconds working time.
- 13. Liaht Cure*.
- 14. Adjust occlusion, finish and polish in the usual manner.
- 15. Remove tip by unscrewing it counterclockwise with finger pressure. Between patients, follow the infection control and maintenance guidelines specified in the SonicFill Handpiece Use and Care Guide.

*Recommended Curing Times

Adequate curing is essential for restorative function. Uncured or undercured composite material is far more likely to experience some form of clinical failure. Kerr recommends regular inspections of your curing lights to ensure they are functioning and providing the expected irradiance. SonicFill 3 is intended to be cured by a halogen or LED light with a minimum light intensity of 650 mW/cm2 and a light wavelength output within the 400-520 nm range. Please refer to the table below for curing recommendations. All times refer to a single occlusal surface cure. In any posterior restoration, Kerr recommends additional 10 second cures on both the buccal and lingual surfaces of the tooth.

Curing Method	All Shades
Demi Ultra / Demi Plus (or light with output >1000 mW/cm2)	10 Seconds

Storage and Shelf Life

SonicFill should be stored at ambient temperature. The expiration date is marked on packaging. Do not use after expiration date. Every effort should be made to protect the

composite from visible light prior to use.

LIMITED WARRANTY - LIMITATION OF KERR'S LIABILITY

Kerr's technical advice, whether verbal or in writing, is designed to assist dentists in using Kerr's product. The dentist assumes all risk and liability for damages arising out of the improper use of Kerr's product. In the event of a defect in material or workmanship, Kerr's liability is limited, at Kerr's option, to replacement of the defective product or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to Kerr. In no event shall Kerr be liable for any indirect, incidental, or consequential damages.

EXCEPT AS EXPRESSLY PROVIDED ABOVE, THERE ARE NO WARRANTIES, BY KERR, EXPRESS OR IMPLIED, INCLUDING WARRANTIES WITH RESPECT TO DESCRIPTION, QUALITY, OR FITNESS FOR A PARTICULAR PURPOSE

SYMBOLS DESCRIPTION

<u> </u>	Warning or Caution
2	Do Not Reuse
•••	Manufacturer
誉	Keep away from sunlight
REF	Part Number
Rx ONLY	CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A DENTIST.
[www]	Consult Instructions for Use at www.kerrdental.com/resource-center
	SonicFill Handpiece
	Practice Tooth
	SonicFill Unidose composite tips