



BIOACTIVE BULK FILL COMPOSITE & RESIN CEMENT

DESCRIPTION:

RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement is a bulk fill, dual-cure composite that allows you to fill all classes of restorations without worrying about shrinkage or voids. RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement is ideal for all Class I, II, III, IV and V restorations.

INDICATIONS FOR USE:

RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement is a dual-cured (photo-initiated, free radical polymerization and/or peroxide tertiary amine initiated free radical polymerization) injectable composite material.

When utilized properly, it provides a material for direct dental restorations. RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement can also be used as a resin cement for the delivery of indirect restorations or as a core build up material. RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement is compatible with all other methacrylate based dental materials.

INSTRUCTIONS FOR USE:

NOTE: Due to the self-cure chemistry within RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement, a user may observe a thin layer of uncured material at the material and air interface during certain types of procedures. This is normal and is due to the formation of an oxygen inhibition layer at this interface. This can be immediately remedied with a quick five second cure using a dental curing light. Of course any remaining material in the bulk of the restoration will continue to self-cure appropriately.

Composite Fillings

1. Isolate and prepare the tooth surface to be restored.
2. Apply an adhesive, such as RE-GEN™ Universal Adhesive System or RE-GEN™ Self-Etch Adhesive System, according to the manufacturer's instructions (if RE-GEN™ Universal Adhesive or RE-GEN™ Self-Etch Adhesive is not chosen, be sure the adhesive of choice is recommended for use with self- and dual-cure products).
3. Bleed the RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement syringe by expressing a small amount of material onto a pad. This assures the material is being expressed from both side of the syringe equally.
4. Attach the mixing tip to the syringe and express a small amount of material onto a pad. This assures the material is flowing from the tip in a uniform manner. (*)
5. Insert the mixing tip to the bottom of the preparation and fill the entire prepared area with RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement. Light activate the surface for 20 seconds.
6. Shape and finish to desired level (if the material is not light activated, it will self-cure and set in 3 minutes).
7. After each use, leave the used mixing tip in place to seal the syringe.

() Material can also be extruded directly onto a pad for hand mixing and placement.*

NOTE: While the universal shade of RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement will produce exceptional results in most restorations, there may be cases that require a higher level of aesthetics. For highly aesthetic cases, it is recommend to leave a 1mm increment at the top of the preparation for a composite material, such as Exquisite Restoration™ Nanofill Composite, to provide a wider selection of shades. RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement is compatible with all methacrylate composite materials thus an incremental layer of the material of choice, such as Exquisite™, would simply be placed as the final layer and light activated according to the manufacturer's instructions.

NOTE: RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement is compatible with all dental adhesives that work with dual-cure materials. If not using RE-GEN™ Self-Etch Adhesive or RE-GEN™ Universal Adhesive, the adhesive should be used according to the manufacturer's instructions.

Cementation

1. Isolate and prepare the tooth surface to be restored.
2. Apply an adhesive, such as RE-GEN™ Universal Adhesive System or RE-GEN™ Self-Etch Adhesive System, according to the manufacturer's instructions (if RE-GEN™ Universal Adhesive or RE-GEN™ Self-Etch Adhesive is not chosen, be sure the adhesive of choice is recommended for use with self- and dual-cure products).

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3. Bleed the RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement syringe by expressing a small amount of material onto a pad. This assures the material is being expressed from both sides of the syringe equally.
4. Attach the mixing tip to the syringe and express a small amount of material onto a pad. This assures the material is being expressed from the tip in a uniform manner. (*)
5. Dispense RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement either into the restoration or into the preparation depending on ease of placement.
6. Deliver the restoration to the tooth and remove excess material.
7. After clean up, light activate all margins for 20 seconds.
8. After each use, leave the used mixing tip in place to seal the syringe.

(*) Material can also be extruded directly onto a pad for hand mixing and placement.

NOTE: RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement has been designed to have a working time of 90 seconds and fully cure in 3 minutes when used only in self-cure mode. (The setting time will be slightly less than 3 minutes in the oral environment).

NOTE: For the easiest clean up, wait for the 90 second working time to expire and the material to gel. Using an explorer, remove excess material from margins and floss between the contacts. Finally, light activate the facial and lingual (and occlusal if appropriate) surfaces for 10 seconds each.

Core Build-Ups

1. Isolate and prepare the tooth surface to be restored.
2. Apply an adhesive, such as RE-GEN™ Universal Adhesive System or RE-GEN™ Self-Etch Adhesive System, according to the manufacturer's instructions (if RE-GEN™ Universal Adhesive or RE-GEN™ Self-Etch Adhesive is not chosen, be sure the adhesive of choice is recommended for use with self- and dual-cure products).
3. Bleed the RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement syringe by expressing a small amount of material onto a pad. This assures the material is being expressed from both sides of the syringe equally.
4. Attach the mixing tip to the syringe and express a small amount of material onto a pad. This assures the material is being expressed from the tip in a uniform manner. (*)
5. Start the build up by applying a 1mm increment of RE-GEN™ Bioactive Bulk Fill Composite and Resin Cement and light curing for 20 seconds. After this initial layer has been placed, additional material should be added and built up to the desired level. Light activate for 20 seconds per surface and begin preparation procedure or wait for material to self-cure.
6. After each use, leave the used mixing tip in place to seal the syringe.

(*) Material can also be extruded directly onto a pad for hand mixing and placement.

NOTE: Shape before final curing using instruments, matrix bands or crown forms. Remove matrix band if used. Final crown preparation can be accomplished with your preferred procedures.

NOTE: If using a post or a pin, prepare and insert the post or pin according to the manufacturer's directions.



WARNING: Causes serious eye irritation. Wear eye/face protection. Prolonged or repeated skin contact may cause severe irritation. **FIRST AID: IF IN EYES:** Rinse cautiously with water for several minutes, also under eye lids. Remove contact lenses, if present and easy to do so. **IF INHALED:** Move to fresh air and keep at a rest position comfortable for breathing. **IF INGESTED:** Do not induce vomiting. Rinse mouth, drink plenty of water. Call a physician or POISON CONTROL CENTER immediately.



MANUFACTURER



TEMPERATURE
LIMIT



IRRITANT
(SKIN & EYES)



READ OPERATING
INSTRUCTIONS



DO NOT USE
IF PACKAGE
IS DAMAGED



KEEP AWAY
FROM SUNLIGHT



MEDICAL
DEVICE



PRESCRIPTION
ONLY



USE BY DATE/
EXP. DATE



LOT NUMBER /
BATCH CODE

VISTA APEX

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