

Self-Adhesive Resin Cement

Instructions for Use

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The cement should be used by a dental professional according to the instructions. Prior to use the cement, please read the instruction carefully.

Product Description

Self-Adhesive Resin Cement is a dual-curing (chemical and/or light cure) luting cement, the curing reaction occurs inside or outside the oral cavity, and can be used to bond all-ceramic, composite, metal restorations, fiber posts. When this cement is used, bonding and conditioning of the tooth structure are not necessary.

The cement contains inorganic fillers, and the inorganic filler loading is about 40% by volume having particle size range of about 0.01 to 5 microns. The mixing ratio, based on volume, is 1 part base paste: 1 part catalyst paste.

Classification

Type 2 Class 3

Indications

-Cementation of all-ceramic, composite, and metal crowns, bridges, inlays, onlays, dental posts; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (contraindicated for patients with bruxism or periodontitis).

-Cementation of fiber posts.

-Cementation of all-ceramic, composite, and metal restorations on implant abutments.

Notes: Indications of Maryland/inlay/onlay bridges demand especially high adhesive bond strength due to these indications may be exposed to a high risk of decementation. Regardless of the manufacturer of the cement and restoration. To achieve an optimal result, please refer to the sections "1.4 Preparation of teeth suitable for Maryland/inlay/onlay bridges" and "3.5 Preparation of Maryland/inlay/onlay bridges".

Structure and Composition

Self-Adhesive Resin Cement is composed of double pastes of Base and Catalyst. The main components of the Base include glycerol dimethacrylate (GDMA), UDMA, silane treated glass powder, silane treated silica, pigments, photoinitiator and stabilizer. The main components of the Catalyst include phosphorylated methacrylate (MDP), glycerol dimethacrylate (GDMA), UDMA, silane treated glass powder, silane treated silica, glass powder, pigments, initiator and stabilizer.

Performance and Characteristics

The cement has chemical affinity with metals, zirconia, etc., and has radio-opacity for future identification. Flexural strength of the cement is not less than 50MPa. Dental adhesive is not necessary, it is enormously saving operation time that the cement assist with helical mixer can be directly applied to the restoration. Inorganic filler has small particle size

and the cement has ideal film thickness and fluidity after mixing. The cement has sufficient clinical operation time, has good bio-compatibility, low irritation to pulp, low solubility, and good cementation with tooth, metals, zirconia, etc.. The cement contain fluorinated fillers, which can continuously release fluoride ions to reduce secondary caries.

Reaction Mechanism

The reaction mechanism of the cement is the free radical polymerization. Free radical polymerization usually occurs on unsaturated molecules containing double bonds, which can be accelerated by light, peroxides, etc.. The acidic functional monomer can mineralize and penetrate into mineralization gaps to form mechanical chimerisms, and chemically bonding with the hydroxyapatite in teeth. Also, the acidic functional monomer can form chemical bonds with the surface of zirconia, metal and other materials. The micropores generated after the coarsening treatment of the restoration surface can provide a larger adhesive area to form mechanical chimerisms to bond the restoration to the tooth surface.

Times

The working and setting times depends on the ambient and oral temperature. The times shown are based on actual using conditions. The cement is a dual-curing product, which is sensitive to natural and artificial light. The working and setting times will be significantly reduced if the cement is used under operating light.

The working and setting times under experimental conditions are as follows:

Working time (23°C)	From start of mixing	2min
Self-curing time (37°C)	Setting time after start of mixing	6min
Light-curing time	Single surface, from occlusal surface	20sec
	Fiber posts, from occlusal surface	40sec

Notes: We recommend that the output power of the light-curing device is $\geq 800\text{mW/cm}^2$, with a wavelength range of 400-500nm. During light-curing, the light source should be close to the restoration, and the maximum distance between the light source and the restoration should not exceed 5mm.

Physical Properties

Compressive Strength (MPa)	≥ 100
Flexural strength (MPa)	≥ 50
Water sorption ($\mu\text{g/mm}^3$)	≤ 40
Solubility ($\mu\text{g/mm}^3$)	≤ 7.5

Operating procedures

1. Tooth Preparation

1.1 Preparation of cavities/teeth

Remove the temporary bonding material, clean the cavity or tooth thoroughly with pumice slurry, rinse with a water spray, and then use oil-free and water-free air or cotton pellets to dry.

Notes: ①Do not overdry. Overdrying can easily lead to post-operative sensitivity. The degree of dryness is optimal when the surface of the tooth has a glossy appearance.

②Do not use disinfectants, desensitizers, dentin sealants, rinsing solutions containing EDTA, scanning powder, etc., after pumice slurry and water cleaning. Their residues may have an effect on the bonding strength and curing reaction of the cement.

1.2 Pulp Protection

To avoid pulpal irritation during tooth preparation, cover areas in close proximity to the pulp by applying small amounts of hard-setting calcium hydroxide material. To avoid bite increases during the cementing process of the restoration, the same pulp protection should be applied prior to taking an impression for the final restoration.

1.3 Preparation of root canals

After root canal treatment, clean the root canal with a 2.5% -5.25% solution of NaClO, rinse immediately with water and dry with paper points or cotton spill.

Notes: We recommend to use rubber dam during the process to prevent the pollution.

1.4 Preparation of teeth suitable for Maryland/inlay/onlay bridges

The tooth suitable for Maryland/inlay/onlay bridges must have an adequate enamel surface for bonding, and must be healthy and the periodontal tissue should be good. It is the sole responsibility of the dentist to ensure proper selection of indication and technique.

- Prepare retentive elements such as cingular rests and/or approximal grooves.
- Use a rubber dam and keep the cavity free of any contamination during cementation.
- Etch the enamel surface: Etching process in accordance with the instructions of the phosphoric acid, or etch the enamel surface of the cavity with 37% phosphoric acid for 15 to 20 sec (e. g., P-Etchant Phosphoric Acid Etching Gel). Then rinse immediately with water and then use oil-free and water-free air or cotton pellets to dry. In the case of exposed dentin, be careful to etch the enamel surface and not to touch other areas, to avoid post-operative sensitivity.

2. Try-in restorations

- Remove the temporary restoration and thoroughly clean the tooth surface of any residue from the temporary cement.
- Make a trial insertion of the final restoration, check its marginal adaptation, contact points, and occlusion.
- For glass-ceramic restorations, the occlusion inspection shall be conducted after final cementation to avoid the breakage of restoration that may occur if done prior to being cemented in place.

- Avoid any contamination whatsoever of the tooth surface to be treated during the process of try-in restorations and until the final cementation finished.

3. Preparation of restorations

Please follow the manufacturer's instructions for use of the restoration material. In the absence of deviating instructions, we recommend the following procedure:

3.1 Preparation of metal, alumina/zirconia ceramic restorations

- Use alumina (particle size $\leq 40\mu\text{m}$) to sandblast bonding surfaces of the restoration until a roughened matte surface generated.
- Rinse with alcohol thoroughly and then use oil-free and water-free air to dry.

3.2 Preparation of glass ceramic restorations

- Etch bonding surfaces of the restoration in accordance with the instructions of the hydrofluoric acid. (e. g., HF-Etchant Hydrofluoric Acid Etching Gel).
- Rinse with water thoroughly and then use oil-free and water-free air to dry.
- Apply silane coupling agent to bonding surfaces in accordance with the instructions of the silane coupling agent (e. g., Top CEM Ceramic Primer Ceramic Coupling Agent), and use oil-free and water-free air to dry.

3.3 Preparation of composite resin restorations

- Use alumina (particle size $\leq 40\mu\text{m}$) to sandblast bonding surfaces of the restoration until a roughened matte surface generated.
- Rinse with alcohol thoroughly and then use oil-free and water-free air to dry.

Notes: For the inlays and veneers made from composite, breakage of restoration may occur during sandblasting. We recommend rinse directly with alcohol and then use oil-free and water-free air to dry.

3.4 Preparation of fiber posts

- Rinse with alcohol and then use oil-free and water-free air to dry.
- Preparation of fiber posts shall be done in accordance with the instructions of the fiber post.

3.5 Preparation of Maryland/inlay/onlay bridges

Please refer to the preparation for the relevant restorative material (such as metal, zirconia and glass ceramic).

3.6 Preparation of implant abutments

Please refer to the preparation for the relevant restorative material (such as metal, zirconia).

4. Product Application

4.1 Preparation of cement

Select the cement with the required shade and store it at room temperature ready for use. If the cement is refrigerated, restore to room temperature before application. Subsequently, attach a new helical mixer to the syringe and fasten. Squeeze out a peppercorn-size quantity of cement to ensure that the two pastes of the cement can mix evenly.

Notes: ①When selecting a new cement, the sealing cap on the syringe should be removed and discarded to prevent the

reuse of the sealing cap from bringing air bubbles into the cement.

② Check the syringe openings for blockage, remove any blockage.

③ Due to the solidification of the cement inside the helical mixer, the helical mixer can be used as a cap to seal the syringe until the next application.

④ Protect the treating area from contamination of saliva, water, and blood during the application.

4.2 Application in root canals

Use a dedicated helical mixer for root canals to insert the cement into the root canal. (Do not use Lentulo-Spirals. The high-speed rotating Lentulo-Spirals may locally overheat lead to excessively accelerate setting of cement.)

Insert the helical mixer as deeply as possible in the root canal and apply the cement from the bottom. During the process of injection, keep the helical mixer immersed in the cement, and slowly move the helical mixer upwards as the level of the paste rises.

Apply a moderate quantity of cement to the post, place the post in the root canal filled with cement, and use moderate pressure to keep it in position. Rotating the post slightly during the process of position to avoid the inclusion of air bubbles.

4.3 Application in restorations

Apply the cement to the adhesive surface of the cavity/teeth and the restoration, and put the restoration on the tooth/implant abutment in position. Seat restoration and apply uniform pressure with a bite stick to remove excess cement.

4.4 Removal of excess

Irradiate the cement with the light-curing device for 1-2 sec, use a suitable instrument (e.g., scaler) to remove the pre-cured cement from the restoration. Alternatively, use a suitable instrument to remove the excess cement during the self-curing gel phase (about 3 min after beginning the mixing), or use a dental floss to remove the cement from proximal surface.

A soft instrument (e.g., cotton swab) can be used to remove the cement from posts.

Notes: ① Use a suitable instrument to hold the restoration in position during the process of removing excess cement.

② Oxygen will inhibit the polymerization of cement. During the curing, the surface layer of cement will contact with oxygen in the air to form an uncured oxygen resistance layer. We recommend to cover the edges of the restoration with an oxygen blocker, glycerin gel or medical vaseline to prevent oxygen inhibition after removing the excess cement, and rinse these substances with water after complete cured.

4.5 Curing phase

- Wait for the self-curing to completely finish after removing the excess cement, and the setting time in the oral cavity is less than 6 min.
- If the restoration is translucent enough, we recommend light-curing the cement on each surface of the restoration for 20 sec. (Start with the occlusal surface).

- For fiber piles, light-curing from the occlusal surface for 40 sec.

4.6 Shaping and polishing

Shape the edges of the restoration, recheck the occlusion, and polish any remaining uneven areas. After shaping, carefully check the dental sulcus and surrounding areas, pay attention to any residual cement, and any residual cement shall be removed.

Notes

1. Helical mixers are for single use only to avoid cross-contamination between patients.
2. Refer to outer package for expiration date. Do not use after expiration date.
3. Dispose of used packaging materials, accessories, and remaining waste or expired products in accordance with local regulations.
4. Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact. The use of protective gloves is recommended.
5. Materials containing phenolic substances (such as syringol and holly oil) and hydrogen peroxide should be avoided. The residues can adversely affect the adhesive strength and setting reaction of cement.
6. For professional use only. Carry out daily maintenance as prescribed by dentist.
7. Keep material out of children's reach.

Contraindications

Not for exposed pulp or pulpitis needing treatment.

Patient known to be allergic to methacrylate resins should be avoided to use this product.

Side effects

This product or one of its components may cause hypersensitive reactions.

Storage

Store cement with the cap closed tightly at 2°-25°C, away from direct light and high humidity.

Shelf life: 2 years.

Warranty

Rizhao HuGe Biomaterials Co., Ltd. warrants this product is free from defects in material and manufacture.

HUGE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and HUGE's sole obligation shall be repair or replacement of the HUGE product.

Limitation of Liability

Except where prohibited by law, HUGE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Symbols for use in the packaging/labeling

 -Use-by date;  -Caution;  -Batch code;  -Temperature limit;  -Country of manufacture;

 -Consult instructions for use;  -Keep dry;  -Keep away from sunlight;  -Unique device identifier;

 -Medical device;  -Manufacturer;  -Caution: U.S.Federal Law restricts this device to sale by or on the order of a dentist or professionals.



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