

DC Resin Elite IFU

Dual Cure Resin Instructions for Use

U.S. Federal Law restricts this device to sale by or on the order of a dental professional. Prior to use the product, please read the instruction carefully.

General Description

DC Resin Elite dual cure resin cement is the ultimate dental dual cure (chemical and/or light cure) cement containing both base and catalyst in a convenient double-barrel auto-mix syringe! The double-barrel auto-mix syringe delivers the perfect 1:1 ratio, based on volume. The principal organic components are a mixture of dental methacrylate resins (TE GDMA, EBPADMA and UDMA). The inorganic filler loading is about 40% by volume with a particle size range of approximately 0.01 to 3 microns.

DC Resin Elite dual cure resin cement is available in two shades: TR (Translucent) & White (White Opaque).

DC Resin Elite dual cure resin cement is radiopaque, for radiographic identification.



Working & Setting Times

DC Resin Elite dual cure resin cement working and setting times depend on environment. Environmental variances, such as ambient temperature and humidity may change working and setting times. Once Dual Cure Resin Cement has been dispensed from the dual-barrel auto-mix syringe and slightly hand-mixed, the following times apply:

Working time:	>60s Room Temperature (23°C)
Setting time: (Includes working time)	<4.5 minutes intraorally (37°C)



Indications

DC Resin Elite dual cure resin cement is designed for the cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental post and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations.

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Contraindications

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| <p>DC Resin Elite dual cure resin cement should not be used with:</p> | <ul style="list-style-type: none"> • Patients known to be allergic to methacrylate resins. • Exposed pulp or pulpitis needing treatment. |
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Side Effects

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

Intraoral Procedures

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| <p>Cementation of all ceramic/porcelain restorations</p> | <ul style="list-style-type: none"> • Prep-1: Apply dental adhesive to the tooth surface according to the Directions for Use. • Prep-2: Apply the Ceramic Coupling Agent to the internal surface of the ceramic restoration and leave for 60 seconds before drying with compressive air, • Placement: place a 1:1 mixture of DC Resin Elite dual cure resin cement onto the prepared surface and seat on the tooth position. • General Dry Time: In general, the setting time for DC Resin Elite dual cure resin cement is about 4 to 5 minutes from the point of mixture in typical oral temperature. • Light Curing: If the restoration is translucent enough, DC Resin Elite dual cure resin cement may be light cured through the restoration surface for 20 seconds with a light output of <1000 mw/cm² or 10 seconds with a light output of >1000 mw/cm². |
| <p>Cementation of posts made from fiber composites or ceramics, or metals</p> | <ul style="list-style-type: none"> • Tooth Prep-1: After trial, adjust the occlusal as needed, then apply dental adhesive to the tooth surface/s according to the Directions for Use. The ceramic priming agent should be applied to the ceramic post surface for 60 seconds before drying. • Placement: Place (1:1 mixture) DC Resin Elite dual cure resin cement into the canal using helical mixer, apply additional cement as needed to the post and seat the post into the canal. The cement will set in about 4 to 5 minutes. |
| <p>Cementation of metal restorations</p> | <ul style="list-style-type: none"> • Prep-1: Apply dental adhesive to the tooth surface according to the Directions for Use. Apply a thin layer on the restoration internal surface and air dry. • Placement: place a 1:1 mixture of DC Resin Elite dual cure resin cement inside the prepared surface and seat on the tooth position. Apply even pressure with a bite stick, allowing access cement to vent. • General Dry Time: In general, the setting time for DC Resin Elite dual cure resin cement is about 4 to 5 minutes from the point of mixture in typical oral temperature. • For easy and clean removal of the cement access, one can light cure the access for 1 second and then remove it with an explorer. |

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Intraoral Procedures

Notes:

- Refer to outer package for expiration date. Do not use after expiration date.
- For dental use only. Do not use for indications or applications that are not specifically noted in the instructions for use.
- Follow the Operating Procedures when using.

Precautions

- 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.
- Dispose in accordance with local regulations.
- Helical mixers are for single use only, to prevent cross-contaminations between patients.
- Keep material out of children's reach.
- Recommend to store in a refrigerator when not in use for better life.
- Do not use if a dry working field cannot be established or the stipulated working technique cannot be applied.

Storage

- Store Dual Cure Resin Cement at 2-25°C, away from direct light with the cap closed tightly. Use the material at normal room temperature.
- Shelf life: 2 years from date of manufacture