

**dextaCEM®**

Self-adhesive resin cement ISO/TS 16506 Polymer-based luting materials containing adhesive components, Class 3 (dual cure luting material)

**GENERAL INFORMATION**

dextaCEM cement is a self-adhesive resin cement indicated for the cementation of most types of restorations. Its high bond strength and low expansion makes dextaCEM cement the perfect choice for most of your cementation needs. By eliminating the need for etching and bonding, dextaCEM cement reduces both postoperative sensitivity and chair time. dextaCEM cement is available in 3 shades and is packaged in our popular double barrel syringe with autotmix tips, providing versatility, speed and accuracy during placement.

**PRODUCT COMPOSITION**

dextaCEM is methacrylate resin based cement containing up to 65% filler. None of the ingredients in the product contain pharmacologically active compounds.

**INDICATIONS FOR USE**

dextaCEM is intended for cementation of porcelain, resin and metal-based inlays, onlays, crowns, bridges and posts.

**CONTRAINDICATIONS**

The material is not recommended for use on veneer restorations.

**WARNINGS**

- Do not use this product on patients with known methacrylate allergies.
- Avoid product application in direct contact with pulp tissue since exposure to this product may injure the pulp.
- Avoid skin, eye, and soft tissue exposure to this product since uncured methacrylate may cause an irritation reaction. Wash thoroughly with water after contact. Get medical attention for eyes. Do not take internally.
- Do not use dextaCEM self-adhesive cement for cementation of porcelain veneers, feldspathic porcelain restorations, and all-ceramic restorations that require bonding.

**PRECAUTIONS**

- This product is intended to be used by qualified dental professionals on a general patient population.
- Wear personal protective equipment when using and handling this product.
- Protective eyewear for patients and medical staff is recommended when light curing the material.
- Use a rubber dam to isolate the treated tooth and avoid fluid contamination during material placement.
- Bleed the syringe before initial use.
- Protect the dispensed material from ambient light that may initiate polymerization.
- Replace the syringe cap after each use to prevent the resin from hardening in the syringe or leave the used mixing tip on the syringe as a cap until the next application.
- Auto-mix tips and intra-oral tips are intended for single patient use only, to prevent cross contamination between patients.
- Do not use this product near eugenol-containing products and do not use provisional cements containing eugenol prior to this product application.
- Do not use phosphoric acid to etch dentin when using dextaCEM self-adhesive cement, as this may cause post-operative sensitivity.
- Do not use hydrogen peroxide as its residues can adversely affect the setting reaction and adhesion of the material.
- Allow the cement to fully cure before finishing and polishing or adjusting occlusion to avoid potential debonding.

**ADVERSE EVENTS**

If a serious incident occurs with this medical device, report it to the manufacturer and to the competent authority for that country in which the user and/or patient is established.

**STEP-BY-STEP INSTRUCTIONS****RESTORATION PREPARATION**

- Trial seal the restoration prior to cementation to ensure proper fit and clean thoroughly.
- Select the desired shade of the cement.
- Prepare the restoration according to the manufacturer's instructions.
- **Silane application to an all-ceramic restoration (porcelain or lithium disilicate):** Prior to Silane application, sandblast and etch the internal surface of the restoration per manufacturer's instructions. Apply Silane to the internal surface of restoration. Leave Silane on for 60 seconds. Dry the Silane with a jet of air. **Note:** Do not use Silane on zirconia restorations.
- Prepare and clean the tooth to be restored. Rinse the prepared tooth thoroughly and remove excess water by briefly drying it with a 2 second stream of air. Do not over dry the tooth.
- **Important Note:** Although there is no separate etching or bonding procedure when using dextaCEM cement, the tooth surface should be free from any contamination such as saliva, blood, eugenol, or any other substance that may interfere with the setting and/or bonding of resin adhesives.

**RESTORATION CEMENTATION**

- Prepare the syringe of dextaCEM cement for initial use.
  - Remove the cap from the syringe. Bleed the syringe before initial use.
  - Attach the mixing tip to the syringe.**Note: Mixing tips with intra-oral tips are enclosed, if preferred for cement application.**
- Gently dispense the cement directly into the restoration.
 **Note:** If cementing a post, use a lentulo spiral to completely coat the canal walls with cement. Use of the intra-oral tips noted above is recommended.
- Place the restoration firmly and carefully on the prepared tooth and ensure that it is fully seated within a minimum of 1 minute from initial mixing.
 **Important Note:** When placing multiple units, it may be necessary to replace the mixing tip during use. The working time of dextaCEM cement is a minimum of 1 minute which begins as soon as material is first dispensed through the mixing tip. As a result, working time decreases with each unit that is placed.
- Light cure the margins of the restoration for one second to gel the cement and facilitate clean up.
- Remove excess cement with a scaler or explorer. Maintain restoration with moderate pressure while cleaning excess cement. Make sure that there is no overhang of the cement left along the gingival margins.
 **Note:** dextaCEM Self-Adhesive Resin Cement will completely set within 4 minutes. If the restoration is translucent, it may be light cured to achieve an immediate set. Refer to the table at the end of this section for recommended curing times.
- Verify the occlusion.

**WORKING CHARACTERISTICS**

Mode of Cure:	Dual cure
Method of Mixing:	Auto-Mix
Mixing Ratio (base: catalyst)	1:1
Working Time (minimum)	1 minute
Intra-oral Setting Time (from initial mix)	Within 4 minutes

**Note:** Working time and intra-oral setting time may vary based on storage conditions, temperature, humidity, and age of product.

**\*Recommended Curing Times for translucent restorations**

Dexter recommends regular inspections of your curing lights to ensure they are functioning and providing the expected irradiance. dextaCEM is intended to be cured by a LED light with a minimum light intensity of 1,000 mW/cm<sup>2</sup> and a light wavelength output within the 400-520 nm range. Please refer to the table below for curing recommendations.

Curing Light	Curing Time for translucent restoration
Demi™ Plus (or light with output >1,000 mW/cm <sup>2</sup> )	20 seconds per surface

Demi™ by Kerr Corporation. For all other lights, see manufacturer's recommendation.

**CLEANING AND DISINFECTION**

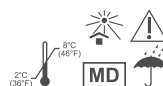
**Cement syringes:** To prevent syringes from getting contaminated with saliva or other body fluids, use protective barriers. Always handle the syringe with clean/disinfected gloves. Do not reuse if it becomes contaminated.

**STORAGE AND DISPOSAL**

Product should be stored between 2°C to 8°C (36°F to 46°F). Allow the product to reach room temperature prior to use. Every effort should be made to protect the cement from visible light prior to use. The expiration date is marked on packaging. Do not use restorative after expiration date. For proper disposal always follow your local and national regulations.

**SYMBOL DESCRIPTION**

	Caution
	Consult Instructions for use
	Manufacturer
	Use-by date
	Batch code
	Authorized representative in the European Community
	Catalogue number
	Do not re-use
	Medical device
	Temperature Storage Limitations: Low 2 °C / 36 °F and High 8 °C / 46 °F
	European conformity
	Keep away from sunlight
	Importer
	Keep away from water



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Insert translations.

Une explication complète des symboles utilisés sur l'emballage Pentron est disponible en visitant: <http://www.pentron.com/symbols-glossary>

FOR PREVIEW ONLY