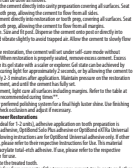
SYMBOLS DESCRIPTION
Full explanation of symbols used on our packaging located at:
http://www.kerdental.com/symbols-glossary

	Caution
	Consult instructions for use
	Temperature Storage Limitations: Low 4°C/39°F and High 25°C/77°F
	Manufacturer
	One-by-date
	Keep away from sunlight
EC REP	Authorized representative in the European Community
LOT	Batch code.
REF	Catalogue number
MD	Medical Device
CE 2797	European conformity
	Importer

CONTENTS



Maxcem Elite™
Universal Resin Cement

Instructions For Use

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Kerr

CE 2797

en - ENGLISH

MAXCEM ELITE™
Universal Resin Cement

GENERAL INFORMATION
Maxcem Elite is a radiopaque universal resin cement that can be used in self-adhesive mode or used with an adhesive and can be used in all-can-at-light-cure mode, allowing for maximum flexibility. Maxcem Elite is packaged in a dual barrel syringe with single use automix tips and optional intraoral mini-cure adhesive pen tip to allow user to deliver desired volume of cement directly into restoration and tooth preparation. Maxcem Elite can be used with all types of restorations.

PRODUCT COMPOSITION
Maxcem Elite is a methacrylate resin based cement containing more than 60% glass filler.

INDICATIONS FOR USE
Maxcem Elite is indicated for cementation of all indirect restorations including ceramic, resin, and metal-based inlays/onlays, crowns, bridges, posts, and veneers*. Additional indications include one body-up and cementation of crowns in implants.*
*Adhesive application on the preparation is required for veneer cementation using Maxcem Elite.

CONTRAINDICATIONS
None known.

WARNINGS
1. Do not use this product on patients with known methacrylate allergies.
2. Avoid product application in direct contact with pulp tissue since exposure to this product may cause pulp necrosis.
3. Avoid skin, eye, and soft tissue exposure to this product since uncured methacrylate may cause an irritation reaction. Wash thoroughly with water which contact. Get medical attention for eyes. Do not take internally.

PRECAUTIONS
1. This product is intended to be used by qualified dental professionals on a general patient population.
2. Wear personal protective equipment when using and handling this product.
3. Suitable protective eyewear for patients and medical staff is mandatory when light curing the cement.
4. Use a rubber dam to isolate the treated tooth. Moisture contamination may affect bonding material placement.
5. Do not treat or clean the prepared tooth or metal-based restorations with phosphoric acid or hydrofluoric acid (HF) which can negatively impact adhesion.
6. Do not use hydrogen peroxide (H2O2) on the preparation as its residues can adversely affect the setting reaction and adhesion of the material.
7. Do not use provisional cements containing eugenol as these materials can inhibit the polymerization of Maxcem Elite.
8. Do not open cement foil package until initial use. Use the product within 6 months of opening the pouch, but always ensure that the cement is not past the expiration date printed on the syringe label.
9. Automix, intraoral, and root-canal tips are for single patient use only to prevent cross-contamination between patients.
10. Bleed the syringe before initial use.
11. Work time is based on material at 23°C. Clean-up time is based on material at 37°C. This time may vary based on storage conditions, temperature, humidity, and age of product.
12. Protect the dispensed cement from ambient light that may initiate polymerization.
13. Allow the cement to fully cure before finishing and polishing or adjusting occlusion to avoid potential debonding.
14. Leave the cast mining tip on the syringe as a cap until the next application.

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
1. **Restoration Preparation and Restoration Surface Preparation**
   1. Remove temporary restorations and thoroughly clean the tooth with fluoride-free pumice paste. Rinse thoroughly with water and gently dry with air.
   2. Evaluate fit. Make any necessary adjustments.
   3. Select the appropriate tip (Fig. 4).
   4. Prepare the internal surface of the restoration per manufacturer's instructions.
   Here are some general rules:
   Ceramic/Porcelain/Composite Restorations: Sandblast the surface with 50µ aluminum (with a pressure of about 30 psi/2.1 bar). Or hydrofluoric acid etch. Or silane treatment and etch. Or silane treatment with hydrofluoric acid for 1 minute or per manufacturer's instructions.
   Metal-based, Zirconia-based, Alumina-based restorations: Sandblast the internal surface with 50µ alumina (with a pressure of about 30 psi/2.1 bar).
2. **Cement Application to Indirect Restorations (Excluding Veneers)**
   1. Use a rubber dam to isolate the treated tooth.
   2. Make sure that the tooth is free from remnants of the temporary cement, dry in paste and other debris. Thoroughly wash and lightly dry with air.
   3. **Choose of an adhesive option:** Optibond™ Universal, Optibond™ Solo Plus or Optibond™ XT. Follow the Optibond™ Universal IFU with Maxcem Elite. Light cure(s) the adhesive to optimize bond strength. Maxcem Elite Self-Adhesive Universal is provided below. If other Optibond™ adhesives are used, please refer to their respective Instructions For Use. This material is compatible with other self-etch universal adhesive. If use, please refer to the respective universal adhesive instruction for use.
   OPTIBOND™ UNIVERSAL - Instructions
   3.1.1 **For Self-Etch Technique**, proceed to Step 3.2.
   3.1.1.A) Selective Enamel Etch Technique:
   Etch enamel margins with a 37% phosphoric acid gel etchant for 15 seconds, then rinse thoroughly, and gently air dry without collapsing the dentin.
   3.1.1.B) Total Etch Technique
   Etch enamel and dentin surfaces with a 37% phosphoric acid gel for 15 seconds, then rinse thoroughly, ensuring all etchant has been removed. Proceed to Step 3.2.
   3.1.2. Gently dry with the air (excess solvent will be removed).
   3.1.3. Shake the Optibond Universal adhesive bottle briefly.
   Note: Upon first use, shake Optibond™ Universal adhesive bottle vigorously for 10 seconds.
   3.1.4. Dispense/Activate. Open the bottle and dispense 2–3 drops of Optibond™ Universal adhesive into a dispensing dish. Activate the adhesive by rubbing it onto the prepared tooth surfaces for 20 seconds.
   OPTIBOND™ UNIVERSAL - Instructions
   3.1.5 **For Self-Etch Technique**, proceed to Step 3.2.
   3.1.5.A) Selective Enamel Etch Technique:
   Etch enamel margins with a 37% phosphoric acid gel etchant for 15 seconds, then rinse thoroughly, and gently air dry without collapsing the dentin.
   3.1.5.B) Total Etch Technique
   Etch enamel and dentin surfaces with a 37% phosphoric acid gel for 15 seconds, then rinse thoroughly, ensuring all etchant has been removed. Proceed to Step 3.2.
   3.1.6. Gently dry with the air (excess solvent will be removed).
   3.1.7. Shake the Optibond Universal adhesive bottle briefly.
   Note: Upon first use, shake Optibond™ Universal adhesive bottle vigorously for 10 seconds.
   3.1.8. Dispense/Activate. Open the bottle and dispense 2–3 drops of Optibond™ Universal adhesive into a dispensing dish. Activate the adhesive by rubbing it onto the prepared tooth surfaces for 20 seconds.
   Optibond™ Solo Plus: Follow the Clinical Guide for Optibond™ Solo Plus. Dispense the Optibond™ Solo Plus adhesive into a dispensing dish. Apply the adhesive to the prepared tooth surfaces for 20 seconds.
   Optibond™ XT: Follow the Clinical Guide for Optibond™ XT. Dispense the Optibond™ XT adhesive into a dispensing dish. Apply the adhesive to the prepared tooth surfaces for 20 seconds.
   Note: Optional scrubbing time is recommended for optimal performance.
   3.2. Dispense the cement into a mixing dish or into a mixing pad. Dispense equal lengths of both pastes. Do not use the cement if one paste is depleted.
   3.3. Mix the cement for 20 seconds. Mix the cement with a mixing spatula or a disposable brush. Ensure that the cement is thoroughly mixed and free of streaks.
   3.4. Apply the cement to the prepared surfaces of the restoration. Place the restoration into the cavity. Remove excess cement with a brush.
   3.5. Light cure the cement for 2 seconds, allowing the cement to fully gel. Remove excess cement. Light cure all margins for 20 seconds, ensuring the cement is fully cured. Do not light cure through the restoration.
   3.6. Apply glycerin gel or other oxygen barrier to the margins. Light cure for 20 seconds.
   3.7. Remove the rubber dam. Remove any excess cement with a scaler or floss.
   3.8. Check the bite and adjust if necessary.
   3.9. Finish and polish the restoration and margins after 24 hours.
   3.10. Place the syringe back into the provided storage sleeve.
   3.11. Leave the mixing tip on the syringe as a cap until the next application.
   Note: If the cement is difficult to remove, it may be in the early gel phase. Allow the cement to fully cure and try again

Nice pomoc.

UPOZORNIA

1. Ak sa pri prípravovaní zmesi vyskytnú problémy, prípadne ak sa vyskytne alergia na materiál, ihneď prestaňte s prácou a vyhľadajte lekársku pomoc. Pri prípravovaní zmesi nie je vhodné používať na ruky ochranné rukavice.
2. Zabezpečte vhodnú ventiláciu počas pracovného miesta.
3. Nepoužívajte nástroje bez ochrany pred korozívnymi vplyvmi zmesi.
4. Nepoužívajte zmesi po uplynutí doby použiteľnosti.
5. Nemiešajte materiál s iným materiálom okrem tu uvedených prípadov.
6. Nedodržanie pracovného postupu môže ovplyvniť kvalitu výsledkov.

ČISTENIE I DEZINFEKCIA

Všetky nástroje používané na prípravu zmesi treba vždy dôkladne umyť a dezinfikovať. Na dezinfekciu môžete použiť napríklad 70% roztok etanolu.

SKLADOVANIE I DOLAGANIE U OTPADU

Pripravené vo skladovacích nádobách v chladničke (+4 °C) sú vhodné na ďalšie použitie. Pred ich ďalším použitím treba zmes dôkladne premiešať, aby sa zmiešali rôzne vrstvy, ktoré sa v nádobe vytvorili. Nepoužité zmesi treba vyhodiť do kanalizácie.

ZDRAVOTNÁ ZAŤAŽENOSŤ

Pri dodržaní pracovného postupu a pracovnej ochrany je zdravotná záťaž minimálna.

ZVYŠNÝ ODPAD

Zvyšný materiál sa nedá ďalšie použiť. Nepoužitý materiál treba vyhodiť do kanalizácie.

ZVYŠNÝ OBAL

Prázdne vrecká sú bežným komunálnym odpadom.

ZVYŠNÝ OBSAH

Zvyšný obsah vrecka treba vyhodiť do kanalizácie.

ZVYŠNÝ OBSAH OBALU

Zvyšný obsah obalu

Maxcem Elite™
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Instructions For Use

Universal Resin Cement

Maxcem Elite™

Kerr

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Universal Resin Cement

Maxcem Elite™

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Осторожно установите ресторайзер на подготовленное место, положите оливковую ветвь в сосуд, вставьте в сосуд.

Корона — навесите цветной чехол ресторайзера и ресторайзер готов к отпаривающей цветной лампе сборник, чтобы не повреждается поверхности. Осторожно установите ресторайзер на подготовленное место, положите оливковую ветвь в сосуд, вставьте в сосуд.

Штатив — подготовьте рабочее место. Подгоните штатив по размеру. Наклоните цветной чехол ресторайзера в вертикальное положение. Установите штатив в основу оливковой ветвь, чтобы удобнее пользовать модуль. Дайте возможность цветному ресурсному выполнить в сосуд.

Штатив — подготовьте рабочее место. Подгоните штатив по размеру. Наклоните цветной чехол ресторайзера в вертикальное положение. Установите штатив в основу оливковой ветвь, чтобы удобнее пользовать модуль. Дайте возможность цветному ресурсному выполнить в сосуд.

2. Встроенная ресторайзер на основе ресурсного основного и его отличительная ресурсная цветная лампа. Ресурсный основной ресурсный ресурсный ресурсный