

CEMPOWER™

Dual Cured, Self-Adhesive Resin Cement

Instructions for Use



Caution: Federal law restricts this device to sale by or on the order of a licensed dentist.



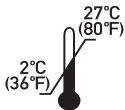
Medical device



Caution, Consult Instructions for Use



Non-sterile



Temperature limit

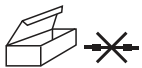


Keep dry



Keep away from sunlight

Rx Only



NONRETURNABLE IF SEAL IS BROKEN

General Information

CemPower Cement is a dual-cured resin cement that is self-etching and self-adhesive. It is easy to handle with a "one-step" system that does not need a pre-treatment process, and it is easy to remove excess cement, so it is possible to perform quick operation. Cempower is radiopaque therefore, easy to identify.

Composition

- Organic Matrix: TEGDMA, UDMA, HEMA
- Inorganic Fillers: micro silica
- Additives: initiator, stabilizer, others

Indications

Restorative materials made of metal, ceramic, and composite. Inlays, onlays, crowns, bridges, screw-type posts, and passive posts (including fiber posts). Final cemented of implant abutments. Shade A2, A3, White

Precautionary Information

1. Before use, please check the expiration date and for any possible of abnormal conditions of the product and packaging.
2. Read the instruction thoroughly, observing all precautions.
3. Ambient lighting can shorten your working time. During the cementation process, ideally reduce or turn off the illumination.
4. Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. Use only recommended tips.

Safety data sheets can be obtained from <http://edsdental.com/sds.html>.

Application

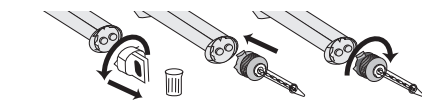
(Cementation of inlays, onlays, crowns and bridges, final cementation of implant abutment)

- Tooth preparation

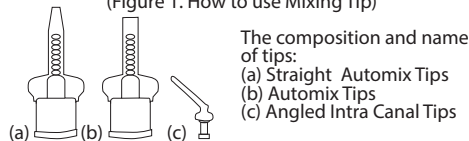
1. Remove temporary restorations and residues of the tooth to be treated. Prepared teeth are wiped with pumice and water. A clean surface is the most important for optimum adhesion.
2. Wash the teeth thoroughly with water and gently blow oil-free air to dry. (A completely dry condition can cause sensitivity after the procedure).
3. Do not use H₂O₂ or EDTA, as residues may adversely affect adhesion and curing reactions.

- Cement mixing procedure (Using Regular Automix Tip)

1. Remove the syringe cap by turning it 1/4 turn counterclockwise.
2. If the syringe is used for the first time or the usage term becomes longer, there may be a deviation in the mixing ratio (1:1) between Catalyst and Base. Therefore, before using the mixing tip, dispense a small amount into the mixing pad.
3. Align the v-shaped groove at the edge of the mixing tip with the groove in the inlet of the syringe and attach the mixing tip and turn it 1/4 clockwise.
4. When you press the piston, the CemPower Cement is mixed and dispensed.



(Figure 1. How to use Mixing Tip)



The composition and name of tips:

- (a) Straight Automix Tips
- (b) Automix Tips
- (c) Angled Intra Canal Tips

5. Timing

Working Time	Setting Time
> 1 Min	< 5 Min

Cementation

1. Apply CemPower to the inside surface of the restoration. For inlays it is easier to apply the cement to teeth.
2. Apply moderate pressure to the restoration. Then fix it firmly to the tooth and make sure it is in place.
3. Light cure unit for 1 to 2 seconds using light curing machine to remove excess cement.

4. Fix the restoration and cure all surfaces of the procedure tooth using a light cure unit. Refer to the following table for recommendations on luminosity and exposure time.

Minimum intensity	Curing time
≥1200mW/cm'	20 sec

5. Check the occlusion and, if necessary, arrange adjacent areas and margins using the appropriate instruments. (Cementation of Posts (Active/Passive, Metal/Fiber))

- Tooth preparation

1. Ensure a space within the root canal where the post can be applied.
2. Prepare the post according to the manufacturer's instructions, and wash and dry.

- Cementation

1. Instead of the Straight Automix Tip, connect the Angled Intra Canal Tips to the Automix Tip and attach it to the syringe. (See above cement mixing procedure)
2. Immediately after applying CemPower to the space within the root canal, insert the post so that no air enters. Do not use lentulo spirals to apply cement to the root canal. This can shorten the working time.
3. Maintain proper pressure to keep posts in place. Light cure for 1 to 2 seconds with a light cure unit to remove excess cement.
4. Follow the core build-up procedure afterward.

Contraindications or Caution

1. The use of CemPower Luting Cement must be a dental professional, and must follow instructions for use and precautions.
2. CemPower Luting Cement contains methacrylic monomers, and some patients may have allergies or hypersensitivity reactions. In this case, do not use this product.
3. CemPower Luting Cement is used only for hard tissue in the mouth. Avoid eye contact.
4. If CemPower Luting Cement comes into contact with eyes, flush your eyes thoroughly and seek medical advice immediately.
5. Do not use substances containing eugenol. Polymerization can be suppressed. Like all composite cements, CemPower Luting Cement has different working and curing times depending on ambient and oral temperature and humidity. It is fairly slow at room temperature but is accelerated in intraoral conditions.
6. CemPower Luting Cement should be used as directed and only by a licensed dental professional.
7. Always use rubber dam to protect your patient airways before procedures.
8. It is prohibited to use this product after the expiration date.
9. If refrigerated storage is used, the temperature of the product should be raised to room temperature before use.

Storage & Use

1. Avoid high temperatures and intense light.
2. Keep the lid closed immediately after use.
3. Store in a dry place at room temperature (2~27 °C/36~80 °F).
4. Expiration date is 2 years from the date of manufacture.

Warranty

EDS warrants this product will be free from defects in material and manufacture. EDS, 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 product for user's application. If this product is defective within the warranty period, your exclusive remedy and EDS's sole obligation shall be repair or replacement of the EDS's product.

Limitation of Liability

Except where prohibited by law, EDS 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.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Disposal

See the Material Safety Data Sheet (available at <http://edsdental.com/sds.html> or through your local subsidiary) for disposal information.



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