

Instruction for Use



Self-Adhesive Resin cement

General Information

EsCem® is a dual-cured resin cement that can be self-etched and self-adhesive. It is classified as type 2 and class 3 according to ISO 4049. It is easy to handle with 'one step' system that does not need pre-treatment process. It is easy to remove excess cement, so it is possible to perform quick operation. It is also easy to identify because it has a radio-opacity(1.3 mm Al). And it offers various shades for aesthetics and color stable.

Intended Purpose

Final cementation of all-ceramic, metal based inlays, onlays, posts, crown and bridge.

Intended User

Dentist

Target patient group

Adult dental patients

Indication

Dental caries, Pulpitis

Composition

- Organic Matrix: TEGDMA, UDMA, HEMA, 10-MDP
- Inorganic Fillers: 16 nm ~ 0.7 μm micro-Silica (53 vol%)
- Additives: initiator, catalyst, stabilizer, others

Shade

A2, A3, TW

Precautionary Information

1. Please check the expiration date of the product before use and the abnormal condition of the product and packaging. It is prohibited to use it after the expiration date.
2. After you have read the instruction for use of the product, observe how to use it.
3. If refrigerated storage is used, the temperature of the product should be raised to room temperature before use.
4. This product is medical device for licensed dental professionals (Dentist) only.
5. If the cavity is deep and close to the pulp, protect the pulp with a baseliner.

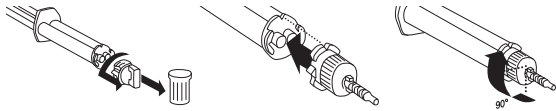
Application

Tooth preparation

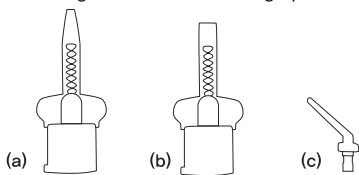
1. Remove temporary restorations and residues of the tooth to be treated. Prepared teeth are wiped with pumice and water. A clean surface is the most important for optimum adhesion
2. Wash the teeth thoroughly with water. And gently blow the oil-free air to dry enough. (A completely dry condition can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

Mixing procedure Using 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 Regular Automixing tip with the groove in the inlet of the syringe and insert the mixing tip and turn it 1/4 clockwise.
4. When you press the piston, EsCem® is mixed and dispensed.

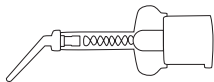


<Figure 1. How to use Mixing Tip>



<Figure 2. The composition and name of tips:
(a) Regular Automix Tip (b) Wide Automix Tip (c) Endo Tip>

5. If it is applied to a narrow space such as a root canal, Connect the Endo Tip to the Wide Automix Tip and insert it to the syringe instead of the Regular Automix Tip.



<Figure 3. Combination of Endo Tip and Wide Automix Tip>

Cementation

1. Apply cement to the inside surface of the restoration. For inlays it is easier to apply 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 seconds using light curing machine to remove excess cement.

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Manufacturer

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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.

Wavelength	Minimum intensity	Curing time
440 ~ 490 nm	≥1200 mW/cm²	20 sec

5. For self curing, see the table below.

Working time	Minimum 60 seconds
Setting time	Within 5 minutes

6. Check the occlusion and, if necessary, arrange adjacent areas and margins using appropriate tools.
Note: EsCem® has excellent adhesion to zirconia and metal prostheses because it contains adhesive monomers that can chemically bond with metal oxides.

Contraindications

1. Pulp capping
2. This product shall not be used on patients who are allergic to methacrylate resin as it may cause contact dermatitis.

Caution

1. Verify flow of all syringes prior to applying intraorally. If resistance is met, replace tip and re-check. Use only recommended tips.
2. Use a rubber dam to protect the throat.
3. Ambient lighting can shorten your working time. During the cementation process it is better to reduce or turn off the illumination.
4. If the cavity is deep and close to the pulp, protect the pulp with a baseliner.
5. Do not use substances containing eugenol. Polymerization can be suppressed.
6. Avoid contact of this material with eyes, mucosal membrane, skin and clothing. If in eyes, wash eyes thoroughly and seek medical attention immediately.
7. If this material comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
8. If this material causes an allergic reaction or oversensitivity, discontinue its use immediately and take action emergency
9. It must be reported to the authority any serious side effects and accidents that may occur.
10. Performance characteristics are not claimed when contravening the storage & use in this document.
11. The side effects may occur as follows: Debonding, discomfort, chipping, core fracture, discolor.
12. Regular automix tip, Wide automix tip, Endo tip are single use accessories. Dispose the used Mixing tip and Endo tip.

Storage & Use

1. Avoid high temperature and intense light.
2. Keep clean the syringe outlet and the lid closed immediately after use.
3. Store in dry place at room temperature(2~27°C/35~80°F).
4. Expiration date is 2 years from the date of manufacture.

Components

- 8.0 g Dual syringe 1ea
- Regular Automix Tip 5ea
- Wide Automix Tip 5ea
- Endo Tip 5ea
- Mixing Pad 1ea
- Instruction For Use 1ea

Warranty

Spident® warrants this product will be free from defects in material and manufacture. Spident® MAKES NO OTHER WARRANTIES INDLUDING 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 Spident®'s sole obligation shall be repair or replacement of the Spident®'s product.

Limitation of Liability

Except where prohibited by law, Spident® 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

It should be handled according to local laws and regulations

Pictogram

Conformity with Comunaute Europeenne			Authorized representative in the European Community	
	Temperature limit		Batch code	Importer
	Keep away from sunlight		Date of manufacture	Distributor
	Keep dry		Used-by date	Caution
	Medical Device		Manufacturer	Consult Instructions for use
Federal law prohibits dispensing without a prescription				

※ If there has been occurred any serious accident in relation to the our device released in market, the quality management representative of our company will notify the Notified Body & the competent authority of any serious accident in accordance with the vigilance procedure.