



SPIDENT CO., LTD. www.spident.co.kr
203 & 312, Korea Industrial Complex, 722, Gojan-Dong,
Namdong-Gu, Incheon, Korea 405-821
TEL. +82-32-821-0071 FAX. +82-32-821-0074



AR EXPERTS B.V. (tradename : CE Medical)
Amerlandseseweg 7, 3621 ZC, Breukelen, the Netherlands
TEL. +31 (0)85 007 32 20

Resin Based Sealer/Root Canal Sealing Material

General Information

VioSeal® is the epoxy resin-based root canal sealer in the dual syringe for easy mixing and injection and is mixed with the 1:1 mixing ratio. It contains inorganic fillers which has good biocompatibility, physical and chemical properties and produces a complete obturation. Therefore, VioSeal® has good biocompatibility with the root canal tissues.

Intended Purpose

VioSeal® is used for permanent sealing of root canal in endodontic treatment. This material is intended to be used with the Gutta percha for perfect root canal filling and sealing.

Intended User	Indication	Target patient group
Dentist	Pulpitis	Adult dental patients

Composition

Epoxy Resin, Amine Catalyst, Filler (Zirconium Oxide, Hydroxyapatite, β -TCP)

Performance Characteristics

Working time	Within 70min(23°C, 55%)
Setting time	Within 120min(37°C, 98%)
Radiopacity	8.0 mm Al

Precautionary Information

1. Check the expiration date and appearance condition of the product and package. If there is any problem with the product, do not use it.
2. Before using VioSeal®, read the instruction for use and follow the application method in the instruction for use.
3. Before the treatment, apply a rubber dam to protect the patient's throat.

Application

[Using Mixing tip]

1. After completely remove the residues in the root canal, sterilize, clean and dry the root canal with the Hypochlorous acid or EDTA solution.
2. Before using VioSeal®, first open the Syringe cap, dispense a small amount on the mixing pad to make sure both base and catalyst are dispensing 1:1 ratio and dispose of it. After then, assemble Mixing tip and dispense VioSeal® mixture with the 1:1 mixing ratio on the Mixing pad. (The mixture must be used within the working time presented.)
3. Measure the root canal length using root canal length measurement device or file.
4. In accordance with the gutta percha application method used in this treatment, apply a small amount of mixed VioSeal® on the gutta percha and insert it into the root canal very slowly.
5. After inserting the gutta percha, take dental X-ray picture to check the filling condition of the root canal.
6. Dispose of the used Mixing tip, close the Green cap and store VioSeal® at a temperature between 15 - 25°C.



[Using Eco tip]

1. After completely remove the residues in the root canal, Sterilize, clean and dry the root canal with the Hypochlorous acid or EDTA solution.
2. Before using VioSeal®, first open the Syringe cap, assemble the Eco tip, dispense a small amount on the mixing pad to make sure both base and catalyst are dispensing 1:1 ratio and dispose of it.
3. Dispense VioSeal® on the Mixing pad with the 1:1 mixing ratio and mix the 1:1 ratio of the base and catalyst for 10-20 seconds using Mixing spatula to make a uniform mixture. (The mixture must be used within the working time presented.)
4. Measure the root canal length using root canal length measurement device or file.
5. In accordance with the gutta percha application method used in this treatment, apply a small amount of mixed VioSeal® on the gutta percha and insert it into the root canal very slowly.
6. After inserting the gutta percha, take dental X-ray picture to check the filling condition of the root canal.
7. Do not remove Eco tip and close the Green cap. Store VioSeal® at a temperature between 15 - 25°C.



Side Effects

Spontaneous pain, Abscess, Pain from percussion and palpation, Post-operative sensitivity.

Contraindication

If the patient has allergic reaction or oversensitivity to VioSeal®, epoxy resin or gutta percha, do not use VioSeal® to those patients.

Caution

1. Since VioSeal® is designed to be used by licensed dentists only, prohibit to use for other purposes or use by non-dental care professionals.
2. Some patients may cause the allergic reaction or oversensitivity to VioSeal®.
3. If VioSeal® causes an allergic reaction or oversensitivity, discontinue its use immediately.
4. Avoid contact of VioSeal® with eyes, mucosal membrane, skin and clothing.
5. If VioSeal® comes in contact with eyes, or skin, thoroughly flush eyes with water and immediately contact an ophthalmologist.
6. If VioSeal® has any problem, the user should stop using it and contact with our company.
7. VioSeal® is multi-dose device. You may use the product until it runs out.



When using dental root canal filling materials, be careful not to extrude the filling material out of the root canal.

If the root canal filling material were extruded excessively out of the root canal beyond the apical due to overfilling, extreme pain, delayed recovery, and sensory abnormalities may occur depending on the amount of extrusion and surrounding anatomical structures.

Storage & Use

1. Keep away from the high temperature and strong light.
2. Keep clean the syringe outlet and the lid closed immediately after use.
3. Store VioSeal® at a dry and cool place. (15 - 25°C)
4. Shelf life at room temperature is 36 months.

Sales Unit

- 10 g Dual Syringe x1 (Base 5 g, Catalyst 5 g)
- Mixing tip, Eco tip, Mixing pad, Green cap

Warranty

Spident® warrants this product will be free from defects in material and manufacture. Spident® 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 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.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Disposal

It should be handled according to local laws and regulations.

Devices used together

Gutta percha

Conformity with	CE Comunaute Europeenne	LOT	Batch code
	Temperature limit		Date of manufacture
	Keep away from sunlight		Used-by date
	Keep dry		Caution
	Manufacturer	MD	Medical Device
EC REP	Authorized representative in the European Community		
Rx Only	Federal law prohibits dispensing without a prescription		