



Light-Cured Pit and Fissure Sealant

General Information

Seal·it™ is light-cured, methacrylate based pit & fissure sealant indicated for caries preventions. Its viscosity allows a complete sealing to the depths of pits and bonds well to the enamel surface. The addition of nano fillers make Seal·it™ resistant to abrasion and polymerization shrinkage.

Composition

Organic Matrix : Bis-EMA, TEGDMA, UDMAInorganic Fillers : Micro / Nano silica

· Additives : Initiator, Catalyst, Stabilizer, Others

Indications

- · Sealing/Filling of pit and fissure
- Filling of small caries
- · Filling of deciduous teeth
- Sealing of margin leakage

Precautionary Information

- ${\bf 1.}\ Check\ the\ expiration\ date\ and\ appearance\ condition\ of\ product\ and\ package.$
- 2. Follow the application after being well acquainted with the Instruction for Use.
- Sealants are sensitive to light. Exposure to the clinic room may cause color changes and curing.
- 4. Clinical dentists and patients should wear ultraviolet safety goggles when curing the polymeric sealant.
- Check the condition of any syringe flow before applying it in the oral cavity. If you feel resistance, replace the tip and check again. Use only the recommended tips.

Application

- Isolate teeth being treated to avoid saliva and blood contamination.
 The tooth surface should be dried.
- 2. Thoroughly clean teeth to remove plaque and debris from enamel surfaces and fissures. The morphology of pits and fissures should be adequately deep.
- 3. Isolate teeth being treated to avoid saliva contamination.
- Apply etchant, e.g. FineEtch®, to all enamel surfaces to be sealed for 20 seconds.
- Thoroughly rinse teeth with air/water spray to remove etchant. Remove rinse water with suction and dry the etched surfaces.
- *Note: Do not use any cleaning medium that may contain oils. If cleaning teeth using an air-polisher that utilizes sodium bicarbonate, it is recommended to repeat steps 4 and 5 or apply hydrogen peroxide to the surface for 10 seconds to neutralize the sodium bicarbonate, then rinse thoroughly with water.
- 6. Using the syringe needle tip of a brush, slowly introduce Seal·it™ directly to the prepared pit and fissure. Stirring the sealant with the syringe-tip during placement or gentle scrubbing with a disposable brush post placement helps eliminate any possible bubbles, and enhance its flow into the deeper pits and fissures.
- $7. \ Cure \ the \ sealant \ with \ a \ suitable \ polymerization \ light \ for \ approximately \ 20 \ seconds.$
- 8. Check seal and occlusion.

Conformity with CE Co	munaute Europeenne
Temperature limit	2°C 27°C
Keep away from sunlight	类
Keep dry	
Authorized representative in the European Comn	nunity EC REP
Federal law prohibits dispensing without a prescr	ription Rx Only

Manufacturer

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

EC REP EU representative

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

Caution

- Seal · it™ is designed for sale and use by licensed dental care professionals only.
 It is not designed for sale nor is it suitable for use by non-dental care professionals
- Seal · it™ contains methacrylic monomer. Some patients can cause allergic reaction to monomer.
- 3. Do not use Seal·it™ for patients allergic to or hypersensitive to methacrylic monomers.
- 4. If Seal·it™ causes an allergic reaction or oversensitivity, discontinue its use immediately.
- 5. Avoid contact of Seal · it™ with eyes, mucosal membrane, skin and clothing.
- 6. If Seal·it™ comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- 7. Use a rubber dam to protect the throat.
- 8. DO NOT use Seal · it™ after the indicated expiration date on the syringe.
- 9. If refrigerated storage is used, allow product to reach room temperature prior to use.

Storage & Use

Seal·it™ is designed to be used at room temperature. If refrigerated storage is used allow product to reach room temperature prior to use. Shelf life at room temperature is 36 months. See outer package for expiration date. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life. Do not expose restorative materials in proximity to products containing eugenol.

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.

Disposal

It should be handled according to local laws and regulations.

Batch code	LOT
Date of manufacture	3
Used-by date	Σ
Caution	Ţ
Manufacturer	***
Medical Device	MD