

PF SEAL SE

Self Etch Light cured Pit and Fissure Sealant

Product Description : PF Seal SE is a light curing self etch pit and fissure sealant fortified with active hydroxyapatite that has ability to re-mineralize. This nano filled material offers the perfect combination of flow, opacity, and wear resistance. This product is available in three shades (Clear, Opaque and Tinted).

Composition : Urethane Dimethacrylate, Triethylene Glycol Dimethacrylate, 10-Metharyloyloxydecry Dihydrogen Phosphate, Silanated Barium Glass Powder Amorphous Silica, Curing Agents and Stabilizer.

Intended Use/Intended Purpose: It is intended to fill & seal pit & fissures depression of teeth to prevent cavities.

Indications for Use : 1. Sealing/filling of pits and fissures. 2. Sealing/facing of damaged enamel surfaces. 3. Covering of caries predilection sites during orthodontic treatment. 4. Sealing of deciduous teeth.

Instructions for Use : Fissures should be sealed as early as possible, as soon as the eruption of the tooth allows treatment and moisture control is possible. After isolating the operating site, thoroughly clean the surfaces to be sealed (rotating brush/cleaning paste free of fluorides), spray and dry. In case of incipient carious lesions or unclear diagnosis, extend the fissure with a fine instrument, if necessary.

Application : Remove the protective cap from the syringe. Screw a new applicator tip onto the PF Seal SE syringe. PF Seal SE flows homogeneously from the applicator tip upon medium pressure and thus is very easy to dispense accurately. Apply PF Seal SE from the margin into the fissure or cavity and allow it to penetrate for 15 - 20 sec. Remove air bubbles with the fine applicator tip.

Light-curing : Polymerise PF Seal SE for 40 sec per surface and check the sealing. Conventional polymerisation devices are suitable for light curing this material. The light output polymerisation devices should be above 800 mW/cm². Remove excess material cautiously (e.g. finishing diamond), polish if necessary (rubber polisher). Then apply a FLUORODIP BIOACTIVE on the treated and neighbouring teeth.

The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings : Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take internally. Contact with the skin may cause irritation and hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue the use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

Precautions : Avoid contact of unpolymerized material with skin/mucous membrane or eyes. Unpolymerized PF Seal SE may cause slight irritation and, in rare cases, may lead to a sensitization against methacrylates. Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

Contraindications : Do not apply directly over exposed pulp tissue.

Storage Conditions :

1. Close PF Seal SE syringe immediately after use. 2. Store material at 10°C(50°F) to 24°C(75°F). 3. Syringes should not be disinfected with oxidizing disinfection agents. 4. Keep away from moisture, stores in a cool dry place. If not to be used for a longer duration, keep them in refrigerator. Allow material to reach room temperature prior to use. Keep material out of the reach of children! For use in dentistry only.

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Shelf Life : 3 years from the date of manufacturing.

Presentation :

Ref. : 20012-2

Trial pack : 1 x 2g Syringe, 5 x Applicator Tips

Ref. : 20012-3

Intro Pack : 2 x 2g Syringe, 10 x Applicator Tips.

Ref. : 20012-4

Intro Pack : 2 x 2g Syringe, 10 x Applicator Tips.

Available Shades : Clear, Opaque & Tinted.

Disposal conditions :

To be disposed off based on the prevailing rules of the country in which it is used.

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Revision :	05
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 Symbol for "UNIQUE DEVICE IDENTIFIER"

 Symbol for "BATCH CODE"  Symbol for "USE-BY DATE"  Symbol for "NON STERILE"  Symbol for "KEEP DRY"

 Symbol for "CAUTION"  Symbol for "CONSULT INSTRUCTION FOR USE"  Symbol for "CATALOGUE NUMBER"

 Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

 Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"  Symbol for "KEEP OUT OF THE REACH OF CHILDREN"  Symbol for "MANUFACTURER"

 Symbol for "TEMPERATURE LIMIT"  Symbol for "KEEP AWAY FROM SUNLIGHT"  Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.