PF SEAL

LIGHT CURED PIT AND FISSURE SEALANT

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description : PF Seal is designed to provide superior protection against occlusal decay. This micro filled material offers the perfect combination of flow, opacity and wear resistance. This product is available in three shades.

Composition : Urethane Dimethacrylate, Triethylene Glycol Dimethacrylate, Radiopacifiers, Fillers, 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, soon after 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.

Etching : Apply Actino 37% etching gel (or liquid), work in with a short-haired disposable brush and let it act for 15 - 30 sec according to the condition of the enamel. Thoroughly rinse with water spray and dry. The etched enamel should have an opaque and matte-white appearance or frosted appearance.

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

Light-curing :

Polymerize PF Seal for 40 sec per surface and check the sealing. Conventional polymerization devices are suitable for light curing this material. The light output should be at least 500mW/cm2 on halogen polymerization devices and 300 mW/cm2 on LED devices. Re-seal undercuts, remove excess cautiously (e.g., finishing diamond), polish if necessary (rubber polisher). Then apply a fluoride varnish on the treated and neighbouring teeth. The dispensed material shall not be placed back in the container and the dose once applied or 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, burns of 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 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 : Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool and dry place.

Shelf Life :

3 years from the date of manufacturing

Presentation :

Ref : 20012-1

Trial Pack : 1 x 2g Syringe, 5 x Applicator Tips.

Ref : 20012

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

Shades : Clear, Opaque and Translucent.

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

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

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

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

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

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

Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" MD 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.