

IFU Size : 161 H x 104 W

FUSION I-SEAL

Light Curing Glass Ionomer Composite Cement



Product Description : Fusion I-Seal is a single component, light cured glass ionomer cement for lining, extended fissure sealing and smaller lesions.

Composition : Urethane Dimethacrylate resin, Bisphenol A Glycidyl Methacrylate, FluoroAluminoSilicate Glass Powder, Radiopacifiers, Fillers, Photoinitiators and Stabilizers.

Intended Purpose / Intended Use : It is intended to be used as a lining under all types of composite and conventional restorative material.

Indications for Use : ♦ Lining under all kinds of filling materials ♦ Extended fissure sealing ♦ Restoration of smaller lesions ♦ Restoration in permanent and deciduous teeth.

Instructions for Use : Thoroughly clean and air dry the cavity. Apply material to the cavity directly with the help of applicator tip. Do not exceed the thickness of 1mm. Light cure for 30- 40 sec using standard curing light and proceed with standard restoration technique. 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, 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 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 : Eugenol containing material should not be used with this products because they may effect polymerization and interfere with the hardening process. Being sensitive to heat and light, the syringes should be kept away from direct sunlight.

Contraindications : Fusion I-Seal is contraindicated for use in patients with known allergies to methacrylate or any other if its components.

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 dry place.

Shelf Life : 3 years from the date of manufacturing.

Presentation :

Ref: 30002-1

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

Ref: 30002

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

Ref: 30003

Economy Pack : 4 x 2g Syringes, 20 x Applicator Tips.

Ref: 30003-1

Intro Pack : 1 x 3g Syringe, 10 x Applicator Tips.

Ref: 30003-2

Kit Pack : 2 x 3g Syringes, 20 x Applicator Tips.

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

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CE
0123
Issue/Revision : 01/01
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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

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

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

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

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

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