

SealEDPLUS

Instruction For Use

SealEDPLUS is a flowable, light curing, radiopaque, fluoride releasing sealant. It is designed to protect the fissures of teeth against caries by forming an impermeable layer. The sealant acts as a preventive measure by not allowing food or bacteria to enter the fissure. Therefore, fissure sealing plays a key role in the prevention of caries.

SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

Product Name	SealEDPLUS
Distributor	Perfection Plus Ltd
Address	6 Westwood Court, Brunel Road, Totton, Hampshire, SO40 3WX, UK
Phone No.	+44 (0) 2380 866 677

PRODUCT CODE - **REF**

PP010/1215 SealEDPLUS Fissure Sealant 2x2g Syringe & 5 Tips Opaque

Intended Use: Dental sealant

Use environment: Dental practice

Patient target group: People treated in the course of a dental procedure with no limitations in age or gender.

COMPOSITION

Methacrylate monomers (including Bis-GMA, TEGDMA)

Inorganic fillers

Fluoride salts

INDICATIONS

- Pits and fissures of molars and premolars
- Fissures on the lingual sides of anterior teeth

APPLICATION

Clean the enamel surface of the tooth thoroughly with a prophylaxis paste or pumice in order to remove any plaque residue. Isolate the teeth to be sealed with a rubber dam or with cotton rolls and aspirator tip. A dry working field is needed for successful sealing. Conduct etching following the corresponding instructions of use. After etching has taken place rinse surface thoroughly with water. Dry with oil-free clean dry air. The area will have a chalky white appearance. If not, saliva contamination may have occurred and etching should be repeated. Check that area to be sealed is dry.

SYRINGE (Take appropriate measures to avoid cross contamination between patients):

Remove cap of SealEDPLUS syringe and place a disposable syringe tip firmly onto syringe. Apply sealant directly to the fissure in a thin layer without air bubbles. Allow 15 seconds for the resin to penetrate the fissure and pores in the enamel. Light cure keeping the tip of the light as close to the surface as possible. In case oxygen inhibition layer is formed wipe off with cotton pellet and dry the cavity. Remove syringe tip and place cap on syringe immediately after use. The syringe tip is for single use only. Be aware that polymerization may be started by ambient lighting or the dental operating light.

Light cure each layer with a halogen, LED light ($\geq 400\text{mW/cm}^2$). Curing wavelength $470\pm 20\text{nm}$.

Curing Time

40 seconds ($400\text{-}1000\text{mW/cm}^2$) / 20 seconds ($>1000\text{mW/cm}^2$)

Examine the sealant both visually and with an explorer. The whole process will have to be repeated if part of the sealant can be dislodged.

STORAGE

Store at $4\text{-}25^\circ\text{C}$ ($39\text{-}77^\circ\text{F}$). If temperature exceeds this, storing in refrigerator is recommended.

Caution: Do not freeze, do not expose to direct light or other heat sources. Return to room temperature before use.

Keep material out of children's reach.

LOT NUMBER AND EXPIRY DATE

The above are printed on each package and should be quoted in all correspondence which requires identification of the product.

PRECAUTIONS

- Use of protective gloves and a no-touch technique is recommended
 - Do not use any resin to adjust viscosity of composite material
 - Replace cap immediately after use
 - Neither store the composite material in proximity of eugenol containing products, nor let the composite come into contact with materials containing eugenol. Eugenol can impair the hardening of the composite and causes discoloration
 - Avoid contact with skin and eyes. In case of contact, rinse immediately with plenty of water and consult a physician if necessary
 - Seek immediate medical attention in case of ingestion
 - Do not use after the use-by date
- EMERGENCY MEASURES**
Ingestion: Seek immediate medical attention.

CONTRAINDICATIONS

Application of the above material is contraindicated:

- If a dry working field cannot be established
- If a patient is known to be allergic to any of the ingredients

DISPOSAL

Dispose of the product according to local regulations as applicable

USERS / FOR PROFESSIONAL USE ONLY

These materials have been developed for use exclusively by dental professionals and must be handled according to the instructions of use. The recommendations included in the instructions correspond to the actual state of knowledge regarding dental techniques. This does not relieve the user from determining the suitability of the product for its intended purpose. The manufacturer cannot be held responsible for damages caused by other uses or incorrect handling.
















REPORTING OBLIGATIONS:

Should a serious incident in relation to this product occur, it should be reported to the manufacturer and the competent authority.

NOTE

The Summary of Safety and Clinical Performance (SSCP) can be found at the European Database on Medical Devices (EUDAMED) at <https://ec.europa.eu/tools/eudamed>. Basic UDI-DI: 5206569COMP44SE

SYMBOLS GLOSSARY

	Medical device		Catalogue number
	Consult instructions for use		Batch code
	Caution		Use-by date
	Keep away from direct sunlight		Unique device identifier
	Temperature limit		Manufacturer
	Do not re-use		EU conformity mark
	Distributor		



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