

TRADE NAME: *Everest IX+*.

DESCRIPTION

Glass ionomer restorative cement of packable viscosity with increased wear resistance, for production of restorations on I, II and V classes. Also, for filling in the area of molar teeth, primary teeth, as well as for restoration of the tooth stump and dentin replacement with the "sandwich technique"

INDICATIONS TO USE

- sealing and restoration of cavities of I, II and V classes (on G.V. Black classification)
- ART technique of sealing
- sealing of primary teeth
- sealing of fissures
- facing for composite restoration
- luting

POTENTIAL CONSUMERS

The qualified medical personnel.

AREA OF USE

Dentistry.

COMPOSITION

Glass ionomer cement Everest IX+ color according to VITA (A1, A2, A3, A3.5, OA2), powder:

Specially prepared ionomer glass, Pigment.

Glass ionomer cement Everest IX+, liquid:

Distilled water, Polyacrylic acid.

PROPERTIES:

Execution form	Maximum thickness of a film, micron	Curing time net, min.		Minimum compression strength, MPa	Maximum acid erosion, mm/h
		min	max.		
<i>Glass ionomer cement Everest IX+</i>	-	2.0	6.0	100	0.17

Mixing

Glass ionomer cement Everest IX+:

a) Mixing of the material is carried out on a dry glass slab on a smooth surface with a plastic or steel spatula at a temperature of 18–23 ° C. At a room temperature above 25 ° C, the slab should be cooled. To achieve a comfortable consistency, the ratio should be observed: for 1 measuring scoop of powder - 2 drops of liquid

b) First, half of the powder is mixed with the liquid, the rest powder incorporated into liquid in small increments until a homogeneous mix with a glossy surface is obtained. Mixing time approx. 20 sec. The time of using the mix is 1.5-2 minutes.

c) The treatment is carried out for 10 seconds, then the cavity is washed and dried. Filling of the cavity is allowed in 2-3 doses.

d) The curing time of the filling in the oral cavity is 2-6 minutes. Final modeling and polishing of the filling carried out after complete curing of the material.

e) After the work complete, it is recommended to cover the surface of the seal with a protective varnish, that protects it from moisture exposure during the curing process

ATTENTION

When using material as liner use of the conditioner is not obligatory. In this case, the material first apply to the bottom of the cavity, then the cavity is etched and then it is necessary to act according to the instructions for use of filling material.

PACKAGE CONTENTS

Glass ionomer cement Everest IX (powder/liquid), for each color option according to VITA (A1,A2,A3,A3.5,OA2):

- 1 piece x 15 g of powder
- 1 piece x 10 ml of liquid
- 1 piece x dropping tube
- 1 piece scoop
- 1 piece mixing pad
- 1 pieces x instruction for use

CONTRAINDICATIONS

Individual intolerance to the components of a medical product;

Use of a medical product as pulp capping

Treatment of patients, whom have had a history of allergic reactions to glass ionomer cements.

SIDE EFFECTS

Can cause reaction in patients with hypersensitivity to any of the ingredients. In this case it is not recommended to use the material.

Can cause irritations as a result of direct contact with a pulp.

PRECAUTIONS

Wear suitable protective clothing and gloves before use.

If contact with eyes or skin occurs immediately to remove material and to wash with water.

Do not use material for pregnant women (due to lack of clinical data).

If allergic reactions occur in particularly sensitive patients, the material should be removed and its further use should be discarded.

Do not add too much material to avoid irritation of the pulp.

If the integrity of the crown is compromised, the patient should consult a doctor.

TERMS OF USE












Use the products at a temperature from + 18°C to + 25°C and the relative air humidity of 40-65%.



STORAGE CONDITIONS

To store and transport at a temperature from 4°C to 25°C and relative humidity it is not higher than 85%.

Period of validity 3 years from the date of production

Applicable Symbols

	<p>Manufacturer</p>
	<p>Date of production</p>
	<p>Protect from moisture</p>
	<p>Avoid exposure to sunlight</p>
	<p>Upper limit of temperature range</p>
	<p>Refer to instruction for use</p>
	<p>Non- sterile product</p>
	<p>Caution! Refer to instruction for use</p>
	<p>European conformity mark to standards and identification number of authorized Authority. The product conforms to the essential requirements of the Medical Devices Directive (93/42/EEC)</p>
	<p>Lot number</p>
	<p>Medical Device</p>

	<p>Do not use if the package is damaged</p>
	<p>Shelf life M- month Y- year</p>

ENVIRONMENTAL PROTECTION REQUIREMENTS

Products at room temperature do not emit toxic substances into the environment and do not have a harmful effect on the human body upon direct contact.

STERILITY INFORMATION

Non-sterile

MAINTENANCE AND REPAIR

Nonrepairable

UTILIZATION

The product does not belong to hazardous waste. To utilize according to the standard medical practice and applicable local, state and federal laws and regulations. A hazard class for medical waste taking into account the specification of morphological structure : Class A

MANUFACTURER (DEVELOPER) OF A MEDICAL DEVICE

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PLACE OF PRODUCTION OF THE MEDICAL PRODUCT

Neue Straße 67, 99846 Seebach, Germany

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