

Radiopaque Hydroxyapatite

Modified-Glass Ionomer Cement, Restorative

Product Description : Crysta Bioactive is a radiopaque, Hydroxyapatite Modified-Glass Ionomer Cement for restoration of primary teeth, core build up, restoration of class I, limited class II cavities and as a base and liner material. Hydroxyapatite provides a positive environment and indirectly decreases the caries susceptibility of individuals. It has excellent tooth adhesion, sustained fluoride release, high compressive strength and mineralizing potential.

Composition :

Powder : FluoroAlumino Silicate Glass Powder, Hydroxyapatite Powder.

Liquid : Polyacrylic acid solution.

Intended Purpose / Intended Use : It is intended to be used as a restorative material in primary and permanent teeth.

Indications for Use :

1. Core build-up.
2. Restoration of primary teeth.
3. Cases where radiopacity is required.
4. As a base or liner.
5. Class I, limited Class II, temporary fillings, etc.
6. Long term temporary replacement of cusps.
7. Intermediate restoratives and base material for class I and II cavities using the sandwich technique.
8. Class V restorations in non-aesthetic situations.
9. Restorative in the field using the ART technique.
10. Temporary endodontic fillings.

Instructions For Use :

1. Powder And Liquid Dispensing :

- a) The recommended powder to liquid ratio is 2 level scoops of powder to 2-3 drops of liquid.
- b) For accurate dispensing of powder, lightly tap the bottle against the hand. Do not shake or invert.
- c) Hold the liquid bottle vertically and squeeze gently.
- d) Close bottles immediately after use.
- e) Shake the powder bottle occasionally.

2. Mixing :

Dispense powder and liquid onto pad or glass slab. Divide the powder into 2 equal parts. Mix the first portion with all of liquid for 15-20 seconds. Incorporate the remaining portion and mix the whole thoroughly for 20 seconds.

3. Restorative Technique :

- a) Prepare tooth using standard techniques. Extensive mechanical retention is not necessary. For pulp capping, use ApaCal Art / Cal LC as a base or liner.
- b) Wash and dry but do not desiccate. Crysta Dentin Conditioner is recommended to remove the smear layer.
- c) Mix the required amount of cement. Higher temperatures will shorten working time.
- d) Transfer cement to the preparation using a suitable placement instrument. Avoid air bubbles.
- e) Form the contour.
- f) Setting time is 1:30 to 2:00 minutes from start of mixing.
- g) The dispensed material shall not be placed back in container and the dose once applied and used 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 :

1. Do not mix the powder or liquid of Crysta Bioactive with any other glass ionomer products.
2. Direct contact with eugenol-based products is to be avoided. Eugenol slows the setting of glass ionomer cements.

Contraindications : In rare cases, the product may cause sensitivity to some persons. If such reactions are experienced, discontinue the use of product and refer to a physician.

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 : 30019

1 x 15g Powder, 1 x 10ml Liquid, 1 x Mixing Pad, 1 x Spoon.

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

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LOT Symbol for "BATCH CODE" **MD** Symbol for "MEDICAL DEVICE" **UDI** Symbol for "UNIQUE DEVICE IDENTIFIER" **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/REF 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 DAMAGED** Symbol for "DO NOT USE IF PACKAGE IS DAMAGED"

TEMPERATURE LIMIT Symbol for "TEMPERATURE LIMIT" **KEEP AWAY FROM SUNLIGHT** Symbol for "KEEP AWAY FROM SUNLIGHT" **FLAMMABLE** Symbol for "FLAMMABLE"

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.