BioGraft® - CPC

Calcium Phosphate Cement for Dental Applications
Calcium Phosphate Cement (CPC) - An introduction

- New generation synthetic bone substitute.
- Aqueous-based self-setting material.

A two-component (POWDER-LIQUID) System.
Putty form or paste – sets into HYDROXYAPATITE (the basic bone mineral)

ADVANTAGES:
- Mouldable
- Biocompatible
- Osteoconductive.

First invented in 1984. Now a few CPC products are in the International market, approved by USFDA.

CLINICAL USE: As bone defect filler, graft extender
BioGraft®-CPC is a novel patented* formulation of calcium phosphate cement developed indigenously in India by the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, for the use in dentistry.

This is a two-component cementing composition having a powder part (containing dry calcium salts) and an wetting liquid (aqueous phosphated solution), which produce a self-setting putty or paste. During setting the cement mass get converted to hydroxyapatite, the basic inorganic component of bone and teeth.
COMPONENTS

Powder Part

Calcium Hydrogen Phosphate Dihydrate [CaHPO$_4$•2H$_2$O]
Tetracalcium Phosphate [Ca$_4$(PO$_4$)$_2$O]
Sodium Alginate (as Gelling Agent)

Liquid Part

A solution containing 0.2 molar
Disodium hydrogen phosphate (Na$_2$HPO$_4$)

Powder + Liquid → Self setting putty

Calcium Phosphate powder mix
Phosphate solution

Calcium hydroxyapatite
Ca$_{10}$(PO$_4$)$_6$(OH)$_2$

2 CaHPO$_4$•2H$_2$O + 2 Ca$_4$(PO$_4$)$_2$O → Ca$_{10}$(PO$_4$)$_6$(OH)$_2$ + 2H$_2$O
PACKING
INSTRUCTIONS FOR USE

DESCRIPTION: BioGraft® CPC is a calcium phosphate cement intended for surgical implantation. The product is supplied as a powder-liquid system, to be mixed at the time of surgery. It consists of inorganic compounds with calcium and phosphate ions, and free from organic or polymer contents. The set cement forms hydroxyapatite, the bone mineral. BioGraft® CPC has been developed and tested as per International Standards.

INDICATIONS: BioGraft® CPC is indicated for filling the bone cavities and defects arising due to cyst, tumor or trauma. It is recommended for furcation perforation sealing, extraction socket filling and periodontal osseous defect repair. BioGraft® CPC could also be used for pulp capping and root apexification.

CONTRA-INDICATIONS: This product should not be used in patients with underlying pathological conditions (e.g. infections). It is not advised in the case of pre-existing calcium metabolic disorder (e.g. hypercalcemia).

ADVERSE REACTIONS: The material satisfies the toxicological safety criteria stipulated by International Standards, which has been established through animal studies. No adverse reactions were reported in human clinical trials.

INSTRUCTIONS FOR USE: Prepare the cement in the following steps:

(i) Transfer the contents the powder pouch into a sterile dish.
(ii) De-seal the liquid vial and take the liquid in a sterile syringe.
(iii) Add it into the powder and mix with spatula till a putty is formed.
(iv) The putty could be further worked for consistency (3-5 minutes). Finally, condense it in the defect using appropriate instrumentation.

PRECAUTIONS: Due care should be exercised to prevent infection. Avoid long exposure of the material to atmosphere before the implantation. Appropriate wound dressing should be given post-operatively. Do not use the contents of an opened or damaged package. Do not use after the expiration date. The packing is for single use only. Dispose the remaining material into the bin. Do not resterilize and use. Do not mix any additional substances (saline, blood and blood components or drugs) into the cement. Apply only in dry surgical field. Wet fields may alter the setting properties. Do not irrigate the repair site during or after the application of the cement putty.

The safety and effectiveness of the product is not established in pregnant women or in young children.

SHELF-LIFE AND STORAGE: A shelf life of 12 months from the sterilization date, is prescribed for the packing. The unopened packs should be stored in dry and cool condition. Do not store in refrigerator or freezer. The packs should be opened only at the time of the surgery.
Uses of BioGraft®-CPC in Dentistry

- Alveolar ridge augmentation
- Periapical cyst management
- Extraction socket filling
- Supporting oral implants