

BioGraft® - CPC

CALCIUM PHOSPHATE CEMENT

What are CPCs and what is the specialty of BioGraft® CPC?



Calcium phosphate cements (CPCs) are new generation bone graft materials with unique combination of mouldability, biocompatibility and osteoconductivity. A typical CPC is powder-liquid system forming a self-setting putty, which gets converted to **hydroxyapatite**, the bone mineral. The class of CPCs is identified as promising alloplastic repair material in dentistry for endodontic and periodontal applications.

BioGraft® CPC is a patented **calcium phosphate cement** formulation developed indigenously in India*, for the use in dentistry. This product is specially designed for better consistency and efficacy, following International Standards.

What it contains ?

BioGraft® CPC is a two-component inorganic system having a powder part and a liquid part. The cement powder is composed mainly of calcium phosphates and the liquid is an aqueous solution of phosphate salts. Gelling agents and setting modifiers are added to get optimum properties. Mixing the components will form a putty which sets into a microcrystalline mass of hydroxyapatite.

How to prepare and apply BioGraft® CPC ?

The components of **BioGraft® CPC** are to be mixed as per instructions provided. The resultant putty will have a working time of 6 minutes and the final setting time of 20 minutes. However, the putty should be condensed to the defect not later than 16 minutes.

What is the safety and efficacy of this product ?

BioGraft® CPC has passed the various tests stipulated in the Standard ISO 7405, viz. In vitro Cytotoxicity, Acute Systemic Toxicity, Pyrogenicity, Maximization Sensitization Test, Intracutaneous Reactivity, Implantation in Muscle and Endodontic Usage Test. Efficacy of the material in repairing periodontal defects has been established through human clinical trials¹.



Evidence of repair of periodontal intraosseous defect using BioGraft® CPC

Please visit www.ifglbioceramics.com for more details

* *Know-how developed by the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, India*

¹**Source** : JB Rajesh, K Nandakumar, HK Varma, Manoj Komath, Calcium phosphate cement as a "barrier-graft" for the treatment of human periodontal intraosseous defects, Indian J Dent Res, 20(4), 2009, 471-479.

MOULDBLE OSTECONDUCTIVE GRAFT MATERIAL FOR DENTISTRY

- ♦ Self-setting powder-liquid system
- ♦ Osteo-integrating and resorbable
- ♦ Tested for safety
- ♦ Clinically proven
- ♦ Conforms to International Standards

PUTTY FORM
POWDER + LIQUID
TO MAKE 2 cc

GAMMA STERILIZED PACKING



STERILE R Gamma Sterilized Single use only. Do not resterilize Do not store above 30°C Keep away from sunlight Keep away from moisture Do not use if package is damaged

BioGraft[®] - CPC

CALCIUM PHOSPHATE CEMENT

INSTRUCTIONS FOR USE

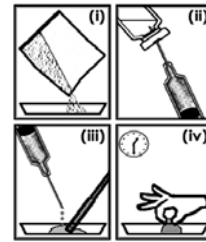
DESCRIPTION : *BioGraft[®] CPC* is a **calcium phosphate cement** intended for surgical implantation. The product is supplied as a powder-liquid system, to be mixed at the time of surgery. It consists of inorganic compounds with calcium and phosphate ions, and free from organic or polymer contents. The 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. Also could be used for pulp capping and root apexification.

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

PREPARATION OF THE CEMENT : The preparation could be done as follows -

- i. Transfer the contents of 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. The setting time of the cement is 20 minutes. However, the putty should be applied before 16 minutes.



PRECAUTIONS : Due care should be exercised to prevent infection. Avoid long exposure of material to the 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 expiration date. The packing is for single use only. Dispose the left out material. 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.

The safety and effectiveness have not been established in pregnant women or children.

SHELF-LIFE AND STORAGE : The packing has a shelf life of **12 months** from the sterilization date. Unopened packs should be stored in dry, cool condition. Do not store in refrigerator or freezer. The packs should be opened only at the time of the surgery.

The product should be distributed to, and used by a licensed medical practitioner only.

DISCLAIMER : The manufacturer has exercised maximum possible care in the production and packing of this product. IFGL Ltd. excludes all warranties, whether expressed or implied by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. IFGL Ltd. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use of this product. IFGL Ltd. neither assumes nor authorize any other person to assume for it, any other or additional liability or responsibility in connection with this product.



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Odisha (India)

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