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BioGraft® - HABG *Active*

BIOACTIVE COMPOSITE GRANULES

SYNTHETIC GRAFT MATERIAL FOR DENTAL APPLICATIONS

Osteo-integrating bioceramic in fine granule form
containing hydroxyapatite and bioactive glass

- Ideal for repairing infra-bony defects
- Tested for safety
- Clinically proven
- Conforms to International Standards

Granule size : **150-700** microns
GAMMA STERILIZED
Packing : 0.5 cc, 1 cc & 2 cc

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What is new with this product ?

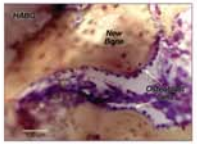
BioGraft® HABG Active is a unique bioactive composite which is osteo-integrating and resorbable. This material has been developed and patented in India by a dedicated biomaterials research team*. It is a new generation bone graft substitute which can lead to faster healing of the defect. ***BioGraft® HABG Active*** is specially designed for repairing infra-bony defects.

What it contains ?

The material contains synthetic hydroxyapatite (bone mineral) and calcium-phospho-silicate, a fast resorbing bioactive glass. The ratio of these components is tuned for optimal bioactivity and resorption.

What is the safety ?

The material has undergone extensive safety and biocompatibility tests as per ISO 10993 - including Cytotoxicity, Haemolysis, Acute Systemic Toxicity, Intracutaneous Reactivity, Implantation in Muscle, Maximization Sensitization and Pyrogenicity. The material has successfully passed all the tests.



Evidence of osteo-integration in animal experiments - histology of rabbit bone after 3 months.

How efficacious is this product ?

Extensive in vitro and in vivo experiments have been done to study its bioactivity and osteo-integrating capability. The efficacy of the material in repairing infra-bony defects has been established through human clinical trials†.

In what form the product is supplied ?

BioGraft® HABG Active is prepared in fine granule form, in the size range 150-700 microns. This ensures effective condensation of the material at the site. The granules are microporous in structure. The glassy part will resorb first, leaving gaps and pores for the new bone to grow.

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

†Source : Arun Sadasivan and K. Nandakumar. "Comparative Evaluation of HABG Composite Ceramic Granules and Perioglass in the Management of Periodontal Infra-bony Defects : A Clinical Study", MDS Thesis, 2001, Government Dental College, Trivandrum, India.

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DESCRIPTION : ***BioGraft® HABG Active*** is a synthetic bioceramic composite intended for surgical implantation. It is supplied in the form of sterile porous granules in the size range 150-750 microns. The material contains hydroxyapatite and calcium-phospho-silicate glass in a optimum ratio. It has been tested for the chemical contents and trace element levels, as per International Standards. The biocompatibility has been evaluated as per ISO 10993. The osteointegration ability of the material has been tested in animal models and the efficacy in treating infra-bony defects has been proven through human clinical trials.

INDICATIONS : ***BioGraft® HABG Active*** is indicated for the repair of periodontal infra-bony defects and periapical cysts and for filling the extraction sockets.

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

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

INSTRUCTIONS FOR USE : Standard surgical procedures are recommended. The granules could be directly delivered to the prepared defect site. If necessary, they could be mixed with patients own blood or sterile saline in a sterile dish and condensed in the defect using appropriate instrument.

PRECAUTIONS : Due care should be exercised to prevent infection. Avoid long exposure of material to the atmosphere before the implantation. Appropriate packings should be given to the surgical site post-operatively and the patient should be kept under strict oral hygiene.

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

Do not reuse the granules. Do not use the contents of an opened or damaged package.

Do not use after expiration date. Do not resterilize and use.

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