



BioGraft[®] - HA^{NEW}

POROUS HYDROXYAPATITE GRANULES

SYNTHETIC GRAFT MATERIAL FOR DENTAL APPLICATIONS

Osteo-integrating synthetic hydroxyapatite
in fine porous granule form

- ◆ 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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This product contains *hydroxyapatite*, the bone mineral, synthetically prepared through a patented process* and made into porous granule form. It is specially designed for the repair of infra-bony defects. The size range of 150-700 microns ensures effective condensation of the granules at the defect site. The surfaces are *osteoconductive* and the *porosity* allows the in-growth of the *new bone*, thereby providing excellent *osteointegration*.

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

The bioactivity and osteointegration of the material has been studied through *in vitro* and *in vivo* experiments. The efficacy in repairing infra-bony defects has been established through human clinical trials.



SAFE

*Synthetic Material.
Tested for phase purity.
No biological content.*

BIO-COMPATIBLE

*Chemical composition
similar to bone mineral
No foreign-body reaction.*

READY TO USE

*Optimised particle size
grade. Supplied sterile.
No special instrument
required.*

RELIABLE

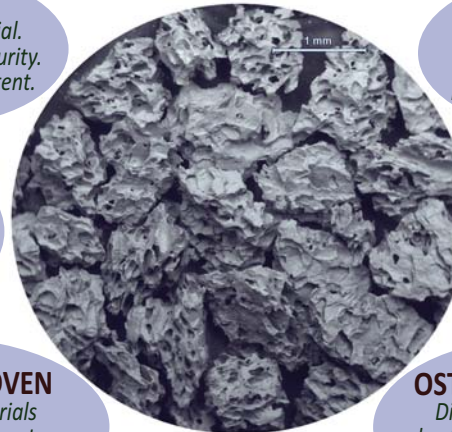
*Material tested and
validated following
International Standards.*

CLINICALLY PROVEN

*Successful clinical trials
conducted at reputed centers.
Evidence of bone regeneration.*

OSTEO-INTEGRATING

*Direct bonding with the
host bone. Porous structure
supports new-bone growth.
Faster healing.*



Conforms to
ASTM F1185

The management of periapical cyst
- Surgery and radiograph



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

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DESCRIPTION : *BioGraft® HA^{NEW}* contains synthetic *hydroxyapatite*, intended for surgical implantation. It is supplied in the form of sterile porous granules in the size range 150-700 microns. It has been tested for the phase purity 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® HA^{NEW}* is indicated for the repair/management 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. *BioGraft® HA^{NEW}* 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 post-operatively to the surgical site and the patient should be kept under strict oral hygiene.

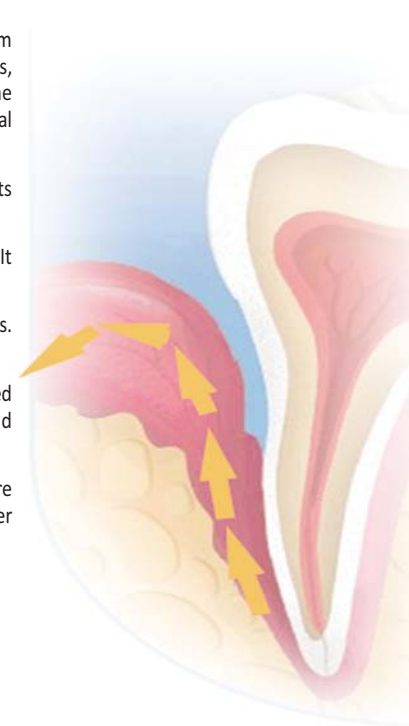
The safety and effectiveness have not been established in pregnant women or children.

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.

DISCLAIMER : IFGL Refractories Ltd (IFGL) has exercised maximum possible care in the production and packing of this product. IFGL 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 shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use or this product. IFGL neither assumes nor authorize any person to assume for it, any other or additional liability or responsibility in connection with this product.





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Authorised Dealer / Distributor

Manufactured in India by :

IFGL Refractories Limited - Unit I

www.ifglref.com

Mfg Licence No. : 796-OR

Marketed by :

IFGL Bio Ceramics Limited

3 Netaji Subhas Road, Kolkata 700 001, INDIA

Phone : +(91) (33) 2248 2411, Extn : 114 / 161

E-mail : ifglbioho@bajoria.in, ragarwal@bajoria.in

www.ifglbioceramics.com