

CE₁₀₂₃**BioGraft® - HA^{NANO}****SYNTHETIC NANO CRYSTALLINE HYDROXYAPATITE GRANULES****INSTRUCTIONS FOR USE, CAUTIONS AND WARNINGS****Product Description**

BioGraft® - HA NANO (Synthetic Nano Crystalline Hydroxyapatite) is bio-compatible, non toxic, non inflammatory and bio-active. It causes no immunological, foreign body or irritating response and has excellent osteoconductive ability.

Method of Application

BioGraft Synthetic Nano Crystalline Granules are generally wetted with patient's blood or saline solution and are placed directly on application area followed by sutures. Nano Crystalline structure promotes colonization of Osteogenic cells from the patients blood, can also be used in conjunction with resorbable or non-resorbable membrane for guided tissue regeneration (GTR).

Precautions

- Not intended for immediate load bearing applications
- Do not over fill defects
- Do not leave defect open
- Do not compromise blood supply to the defect area
- Please apply immediately to application area on opening the sterilized pack
- Surgical process should be carefully planned by surgeon to avoid infection and should not be used in infected area or secondary wounds

To be used by qualified medical practitioner aware of applications of the device.

Complications

BioGraft HA Nano is subject to usual complications/risks associated with medication and methods utilized in surgical procedure, as well as patients response, reaction or degree of intolerance to foreign objects implanted into the body.

Properties

- Bio Compatible - Excellent bio compatiability and binds directly to bone
- Non Immunogenic - Surrounded by Cellular infiltrate which is predominantly fibroblastic
 - No lysis of RBC
 - No Cytotoxic effect on surrounding cells
 - No tissue necrosis

Osteo-integrating bioceramic in Granules containing Synthetic Nano Crystalline Hydroxyapatite

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

GRANULES SIZE :
150 to 700 microns

GAMMA STERILIZED PACKING
Granules : 0.5cc, 1cc, 2cc



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

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- Osteo Conductive - Bonding with Bone commences within three months, fastest of all Ceramic constituents
 - Ca/P ratio is similar to that of human bone
 - Crystalline structure and morphology similar to natural bone

Indications

- Filling of post extraction socket
- Alveolar ridge augmentation
- Treatment of Periodontal defects
- Sinus Floor elevations
- Alveolar ridge preservation
- Filling of bony void defects
- Root amputation defects/Hemi-section defects
- Treatment for ridge reconstruction
- Formation of hard tissue base for dental implant
- Surgical reconstruction in oral and maxillofacial surgeries.
- Treatment of defect following endodontic surgeries
- Filling donor site bony defects

Contra Indications

- Infections, Sepsis
- Load bearing Bone defects with no external and/or internal support
- Abnormal metabolism of bone elements such as Ca/P
- Metabolic disorders which may impair bone formation

The user must inform the patient about the Indications for use and the user must take care of the selection of the implant based on the patient health and patient status, immunological tolerances etc. In case of any manufacturing related problems, the distributor or directly the Manufacturer be contacted.

Pack Type and Sterilization

Three layer pack in crystal tray with shrink wrap and Gamma Ray sterilized

Shelf Life & Disposal

The expiration date is printed on the label. DO NOT USE BioGraft® HA NANO AFTER THE EXPIRATION DATE. BioGraft® HA NANO is environmental friendly. No special disposal is necessary. Packing material is recyclable.

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

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