

### Interactions

To date, there are no known interactions with drugs or other medical products apart from those mentioned under Contra-indications.

### Dosage, directions for use and duration of administration:

#### Amount and frequency of use

The amount of hydroxyapatite ceramic needed depends on the size of the bone defect. Alpha-Bio's GRAFT Natural Bovine Bone is intended for single use and is grafted during the surgical intervention. The ceramic is intended for permanent implantation in patients.

#### Type and timing of use

Prerequisite for a successful use is a stable implantation of Alpha-Bio's GRAFT Natural Bovine Bone into a vital, well-perfused osseous cavity with moderate biomechanical loading. Alpha-Bio's GRAFT Natural Bovine Bone is especially suited for filling cancellous bone defects and should always be grafted in a way that, if possible, the entire surface is in direct (press-fit) contact with natural bone tissue.

The bone defect has to be filled as entirely as possible with Alpha-Bio's GRAFT Natural Bovine Bone or a mixture of Alpha-Bio's GRAFT Natural Bovine Bone and autograft/allograft to ensure a stable implantation. The site for the implant has to be prepared by freshening of the adjacent bone. The respective surgical approach is dependent on the localisation as well as the type and extent of the bone defect.

The aim of a stable intraosseous implantation is a direct osseous contact between the ceramic and the natural bone without an intermediate layer of connective tissue. The macroporous interconnecting architecture of Alpha-Bio's GRAFT Natural Bovine Bone ensures its function as an osteoconductive matrix or guiding structure for ingrowing new osseous tissue in order to create a durable bond between Alpha-Bio's GRAFT Natural Bovine Bone and the adjacent bone.

Until the bony consolidation has been completed, stabilizing measures (e.g. plaster splint, metal osteosynthesis) may be necessary to reduce mechanical loading of the implant site.

During the grafting procedure, there is a risk that macro or micro particles of the product may be displaced into the surrounding soft tissue - these have to be removed.

Coating hydroxyapatite ceramics with bone marrow has proven benefits as it improves the biological value of the ceramic in cases where extensive bone defects have to be filled or the quality of the graft site is poor.

Hydroxyapatite ceramics are generally regarded as non-absorbable in specialist literature. These ceramics are roentgenopaque. Alpha-Bio's GRAFT Natural Bovine Bone does not pose a safety risk in a magnetic resonance environment. Alpha-Bio's GRAFT Natural Bovine Bone does not emit a signal in magnetic resonance imaging and can be displayed only by use of special procedures (STIR-sequence, administration of contrast agent), if necessary.

If ceramic granulate is used in combination with autogenous cancellous bone, it is recommended in the specialist literature to use a mixing ratio of about 1 volume part cancellous bone in 1 volume part ceramic granulate.

#### Duration of use

Permanent (lifelong) implantation.

### Shelf life

The expiration date is printed on the folded box, the secondary packaging as well as the primary packaging. Alpha-Bio's GRAFT Natural Bovine Bone must not be used after the expiration date printed on the packaging.

### Restrictions or loss of usability even prior to expiration date

In case of damage to the primary packaging (bottle) or the secondary packaging (peel-off packaging), the sterility of the ceramic is no longer ensured. Under such circumstances, Alpha-Bio's GRAFT Natural Bovine Bone must no longer be used. The content of unused but opened or damaged packages must not be re-sterilized and has to be discarded.

### Storage

Alpha-Bio's GRAFT Natural Bovine Bone is stored between +5°C and +30°C.

Avoid contact with sources of heat or storing the product in direct sunlight, because this may cause damage to the packaging, which in turn may result in a loss of sterility.

### Methods of sterilization

Alpha-Bio's GRAFT Natural Bovine Bone is provided sterile in a sealed bottle (primary packaging), as well as in a sealed secondary packaging (peel-off packaging). Both the content of the primary packaging and the content of the outer peel-off packaging (secondary packaging) are sterile and are enclosed in a non-sterile carton. This product is sterilized with gamma rays.

### Safe disposal


Residuals are to be discarded with the hospital waste.

### Information update

06/2011


### Used symbols


 Sterilized using irradiation

 Batch code


 Catalogue number

 Manufacturer

 Caution, consult accompanying documents

 Use by date

 Temperature limitation

 Keep away from sunlight

### Instructions for use

#### Material

Hydroxyapatite ceramic

#### Composition

1 cm<sup>3</sup> ceramic consists of 0.6-1.1g hydroxyapatite (pentacalcium hydroxide triphosphate) on average depending on the porosity of the ceramic.

#### Other components

According to specification and ASTM standard (F 1185-03) permitted fractions of e.g. other calcium phosphates and trace elements. Alpha-Bio's GRAFT Natural Bovine Bone is an interconnecting macroporous and microporous hydroxyapatite ceramic system, which is produced from bovine cancellous bone (spongiosa) in a high-temperature process (T > 1200°C) of several hours. The porosity (macroporosity) of the ceramic lies within a range of 65-80 vol.% and the pores size lies within a range of approximately 100-1500 µm.

#### Presentation and Content

##### Alpha-Bio's GRAFT Natural Bovine Bone

REF	Size of granules	Volume
3225	0,5 – 1,0 mm	1 x 0,5 ml
3236	0,5 – 1,0 mm	1 x 1,0 ml
3207	0,5 – 1,0 mm	1 x 2,0 ml
3209	0,5 – 1,0 mm	1 x 3,0 ml
3206	0,5 – 1,0 mm	1 x 5,0 ml

REF	Size of granules	Volume
3209	1,0 – 2,0 mm	1 x 0,5 ml
3210	1,0 – 2,0 mm	1 x 1,0 ml
3232	1,0 – 2,0 mm	1 x 2,0 ml
3211	1,0 – 2,0 mm	1 x 3,0 ml
3237	1,0 – 2,0 mm	1 x 5,0 ml

Granulate with varying sizes of the granules:

The sterile granules are packed in a bottle with a lid, that is sealed in two peel-off packagings.

#### Material class:

Bone substitute material made of calcium phosphate ceramic.

#### Responsible manufacturer

aop Biomaterials GmbH, Lagerstraße 11-15, D-64807 Dieburg

#### Indications

##### For permanent filling or reconstruction of aseptic bone defects

##### 1. in trauma and orthopedic surgery, e.g. for:

- Filling of bone defects in juxta-articular depressed fractures
- Filling of bone defects of the acetabulum on change of prosthesis
- Filling of defects caused by excision of benign bone tumors
- Filling of bone cysts

- Filling of tissue defects in cartilage and/or bone transplants
- Filling of bone defects at donor sites following harvest of autogenous cancellous bone

##### 2. in dental, oral and maxillofacial surgery, e.g. for:

- Filling of defects caused by excision of benign bone tumors or bone cysts
- Filling of bone defects following apicectomy
- Filling of alveolar defects following dental extraction
- Filling of defects following osteotomy of the jaw

##### Augmentation of material in cases of autogenous cancellous bone grafting in any of the surgical specialities

#### Contra-indications

##### Absolute contra-indications:

- Acute and chronic active infections at the site of the implant
- Defects in the area of open epiphyseal plates

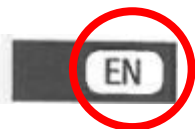
##### Relative contra-indications:

- Serious bone diseases of endocrine etiology
- Serious disturbances of bone metabolism
- On-going treatment with gluco- and mineralocorticoids and with agents affecting calcium metabolism (e.g. calcitonin)
- Severe or difficult to control diabetes mellitus
- Immunosuppressive therapy
- Malignancies (because the value of diagnostic X-ray examinations in case of a tumor recurrence at the site of the implant is reduced)

#### Side effects

In the course of surgical interventions, disturbances of wound healing and/or hematoma may occur that may increase the risk of an infection. In cases of implant instability, the possibility that material may be displaced and cause local irritation cannot be excluded. In individual cases, instability was observed following the use of autogenous cancellous bone combined with ceramic in arthrodeses.

#### Notes



# Alpha-Bio's GRAFT Natural Bovine Bone

## Instructions for use