



## SURGICAL MATERIAL FOR RESTORATION OF HARD TISSUES DEFECTS

# GDT BOVINE BONE GRAFT

## INSTRUCTIONS FOR USE

### PURPOSE:

GDT Bovine Bone Graft is the osteoplastic material for optimisation of bone regeneration process in oral and maxillofacial surgery, as well as in traumatology and orthopaedics.

Made from bone tissue, purified by the method of chemical-enzymatic treatment with hydroxyapatite of biological origin and spatial architectonic that facilitates fixation of biologically active substances on the biomaterial structures without compromising their biological activity.

The unique manufacturing process results in the bone matrix that has interconnecting macro- and microscopic porous structure, supporting the formation and ingrowth of new bone at the implantation site.

GDT Bovine Bone Graft material produced in the form of:

- Bits (granules).
- Blocks and cones (deminerized).
- Gel ready to use in a syringe.

Based on a bovine 20/80 cortical-cancellous bone mineral matrix for use in guided bone regeneration procedures.

### INDICATIONS:

- Augmentation or reconstructive treatment of the alveolar ridge.
- Filling of infrabony periodontal defects.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling of extraction sockets to enhance preservation of the alveolar ridge.
- Sinus-lifting.
- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR).
- Guided Bone Regeneration (GBR).
- Filling of peri-implant defects.

### FEATURES

**Sterile and gradually resorbable bone substitute material. Have high biocompatibility with the surrounding tissues, contributing to the lack of immune response of the recipient, as well as combined with all kinds of transplants, implants and endo-fixators.**

The choice of graft form depends on the size and the location of the defect.

Native bovine bone graft composite for enhanced new bone formation for acceleration of physiological tissue healing process, Protection of grafting site from infection, hydrophilic property: optimal cell adhesion and blood absorption. It also has the unique capability to carry medication to the surgical site.

GDT Bovine Bone Graft exhibits the highest biocompatibility: absence of any foreign body response.

Fully absorbed in 6 to 8 months, osteoinductive hydroxyapatite components provide a native crystalline structure that guarantees long-term dimensional stability.

Granules dissolving process takes place in parallel with the regeneration.

**DIRECTIONS FOR USE:****1. GDT Bovine Bone Graft – Bits, blocks:**

After the necessary preparatory surgical procedures, the granules can be mixed with the patient's blood or with saline solution in a sterile Dappen dish, before being placed onto the operative site using a dental spatula. 80/20 Saline/Blood proportion is recommended. For large bone defects, Bovine Graft can be mixed with bone particles from the same patient (autologous bone).

**2. GDT Bovine Bone Graft – Bone gel in Syringe:**

The unique feature of the Bovine Graft syringe is the polymer that incorporates the graft granules into a homogenous paste. The polymer has reversed thermoplasticity – on the higher temperatures (on 25°C / 77°F it starts to harden, and becomes solid at intraoral environment).

It allows to achieve the immediate stability inside the defect after the placement and provides the doctor with a full control over the material viscosity: it gradually softens when cooled down, while becoming completely fluid on the 8°C/46°F temperature mark.

The material can overcome numerous cycles of liquid to solid.

Remove the sterile pre-loaded syringe from packaging and hydrate with patient's blood or sterile normal saline.

With the cap left on the syringe, immerse the tip of the syringe in the fluid, pull up on the plunger to draw the fluid into the syringe, push down on the plunger to expel excess fluid or air bubbles.

Pull and push action should be repeated until the material is fully hydrated.

Once ready, remove the perforated cap and deliver the hydrated granules to the defected site.

In any case, to assure the formation of new bone, Bovine Bone Graft should only be placed in direct contact with well-vascularized bone. Cortical bone should be mechanically perforated. The operative site is closed by joining together the wound edges (coaptation) with suture stitches. If it is impossible to achieve complete wound closure, make contouring flap or close the wound with the membrane.

**STERILITY:**

Blister package sterilized by gamma radiation.

**STORAGE:**

Do not use after the expiry date mentioned on the outer package.

Store in a dry and dark place in tightly closed containers at temperature (+5°C...+25°C).

Avoid contact with moisture! After opening, keep only in original container.

**PACKAGING:**

GDT Bovine Bone Graft	Type	Size	REF
	Granules	0.25 cc	GD-BG025
	Granules	0.5 cc	GD-BG050
	Granules	1.0 cc	GD-BG100
	Granules	2.0 cc	GD-BG200
	Granules	5.0 cc	GD-BG500
	Blocks, 4 pcs	□ 5 x 5 x 5 mm	GD-BG5x5
	Blocks, 2 pcs	□ 5 x 5 x 10 mm	GD-BG5x10
	Cones, 2 pcs	○ 5 x L 15 mm	GD-BG5x15
<b>GDT Bovine Bone Graft - Syringe</b>	Syringe	0.5 cc	GD-BP050
	Syringe	1.0 cc	GD-BP100

**STERILE R**

**ATTENTION!** The sterility of the product cannot be guaranteed if the package bears evidence of damage, has been opened previously or wet.

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material. The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.

