**Instruction For Use For POWERBONE Granule (Crunch)**

**Classification**

POWERBONE Granule (Crunch) is a medical device (Class III), not a drug.

**Material**

POWERBONE Granule (Crunch) products are Beta Tricalcium phosphate (β-TCP) based porous bone graft substitutes including $ZrO_2$ particles for antibacterial efficacy. POWERBONE Granule (Crunch) is a resorbable temporary bone space filler material. β -TCP is one of the most important biomaterials based on phosphates, currently recognized as ceramic material that significantly simulates the mineralogical structure of bone. POWERBONE Granule (Crunch) supports new bone formation in the defect area.

**Product Components of POWERBONE Granule (Crunch):**
1.) ß-TCP (Beta-Tri Calcium Phosphate)
2.) ZrO2 (Zirconium (IV) oxide) (%0,1)
3.) Distilled Water
4.) Silicon Dioxide (%1)

**General Description**

POWERBONE Granule (Crunch) is unique micro and macroporous structures that most closely resemble the architecture of natural human bone. It gradually dissolves in the body, promoting new bone formation through the release of calcium and phosphate ions. In time, the porous structure becomes completely infiltrated with, and replaced by, healthy viable bone.
POWERBONE Granule (Crunch) contains no tissue of human or animal origin therefore carries no risk of disease transmission. Beta-tricalcium phosphate (β-TCP) ceramics with high porosity are highly biocompatible, osteoconductive support matrix. POWERBONE Granule (Crunch) maintains its architecture and structural integrity for 16-24 weeks after implantation with complete bioresorption occurring between 6-12 months.

**Product General Features**

- Biodegradable,
- Biocompatible,
- Support bone growth,
- Radiopaque,
- Antibacterial,
- Easy implantation.

**Indications- For Use**

Granules may be premixed with bone marrow aspirates and other clinically known bone grafts. POWERBONE Granule (Crunch) is biologically compatible and biodegradable. The granules can be shaped to conform to the defect area. These grafts can be used for the reduced infection risk with enhanced antibacterial efficacy, increased bone growth and regeneration. Granule is designed for use in a broad range of non-load bearing osseous repair defects such as: traumatology (fracture repair), revision surgery, non-unions, spinal fusion, open wedge osteotomy.

**Contraindications**

POWERBONE Granule (Crunch) is not indicated for any other uses than the ones stated here. It should not be used when there is any contraindication. POWERBONE Granule (Crunch) is contraindicated where the device is intended to provide structural support in the skeletal system, and must not be used to gain screw fixation. Other contraindications are shown in below;

- Poorly vascularized implantation site
- Severe vascular or neurological disease
- Physical problems such as excessive obesity
- Inflammatory bone disease
- Hypercalcemia, abnormal calcium metabolism
- Malignant tumors
- Osteomyelitis
- Severely impaired renal function
- Severe degenerative diseases
- Immune deficiency
- Open epiphyseal plates in pediatric patients
- Uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol.

Use of Synthetic Bone Graft Substitutes are contraindicated in the presence of active infection where purulence is produced.

**Precautions**

POWERBONE Granule (Crunch) is only intended for the use of (professional use) surgeons familiar with, and skilled in techniques of bone repair and replacement

The effect of POWERBONE Granule (Crunch) on patients with the following conditions is unknown:

- Pregnancy and nursing
- Radiation bone therapy
- Cardiovascular disease
- Metabolic bone disease
- Documented renal disease

**Possible Adverse Effects**

Reoperation to remove or replace an implant may be required, due to specific medical conditions or device failure. Possible adverse effects may include, and are not limited to:

- Allergic reaction to the product,
- Wound complications including hematoma, swelling and fluid accumulation, edema, tissue thinning, bone fracture, and other complications that are possible with any surgery,
- Disintegration of the implant with or without generation of particulate debris due to a load being applied,
- Bone deformity and loss of contour at the site.

**Warnings**

POWERBONE Granule (Crunch) products are provided in a double sealed blister package; the products are sterile.POWERBONE Granule (Crunch) may be masked on the radiography areas under or above the implant. Macro and micro Granules must be secured to prevent potential migration, and should only be used in surgical procedures where bone grafts are adequately contained. POWERBONE Granule (Crunch) is for single use only. DO NOT USE IF OPENED, PUNCTURED OR DAMAGED PRODUCT. Read the expiration date before use and DO NOT USE BEYOND THE EXPIRATION DATE. DO NOT STERILIZE AGAIN AND DO NOT USE AGAIN. The Granule (Crunch) is being used adults whom are over 18 years old.

**Application**

**Step 1:** Open the inner and outer blister just a few minutes before the implantation. Open both the packages in sterile area.

**Step 2**: Implant the graft. Graft may be gently shaped to fit the defect area, and can be mixed with bone marrow aspirate and may be gently and carefully tamped into the place.

**Step 3:** Secure the surgical site after implanting in order to prevent motion and implant migration .When excess fluid is present in the surgical field ,the surgeon may use proper measures (i.e. cauterization, suction and application of bone wax) to reduce bleeding. If the graft is not positioned satisfactorily, remove the implant and start over with a new dose of POWERBONE Granule (Crunch).

**Storage**

Store in a DRY PLACE AT ROOM TEMPERATURE. Optimal storage conditions: +17ºC - +27ºC, 40-60% relative humidity. Direct contact with heating systems or storage under direct sunlight should be avoided.

**Shelf Life and Disposal**

The expiration date is 5 years and printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. POWERBONE Granule (Crunch) is environment-friendly. No special disposal is necessary. Packaging material is recyclable.

**Packaging:**

Implants are delivered in sterile packages. Gamma radiation sterilization method is used. Packaged implants must be stored unopened in their original packaging. The implants must not be mechanically machined or changed in any way. Damaged products and packages must not be used and they must be returned to BONEGRAFT A.Ş.. The implants are single-use. A removed implant must never be implanted again.

**Sterility:**

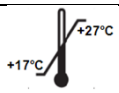
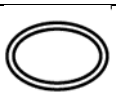
POWERBONE Granule (Crunch) is sterilized by exposure to gamma radiation, using a validated process to ensure a SAL of $10^{-6}$. Do not re-sterilize Sterility is guaranteed unless blister package is opened or damaged.

**Further Information:**

For further information on the product and its uses, please contact Bonegraft Biyolojik Malzemeler San. Tic. ve A.Ş.. The address is printed on this information sheet.

**Pictogram For Product**

| Pictogram | Explanation |
|---|---|
|  | Expire Date |
|   | Sign of Conformity |
|  | Do Not Use If Damaged |

| | |
|---|---|
|   | Sterilization by Gamma Radiation |
|  | Consult Instruction for use |
|   | Temperature Limit |
|   | Humidity Limit |
|  | Manufacturer |
|   | Batch Code |
|  | Do Not Reuse |
|   | Do not Re-Sterilize |
|   | Catalog Number |
|   | Date of Manufacture Manufacturer Country |
|  | Warnings |
|  | Keep Away From Sunlight |
|  | Keep Dry |
|   | Medical Device |
|  | Double Sterile Barrier System |
|   | Unique Identifier Information |

| Prepared by | Approved by |
|---|---|
| QUALITY MANAGEMENT REPRESENTATIVE<br>Burak TÜLÜ | GENERAL MANAGER<br>Zafer ÇAVUŞ |

| | |
|---|---|
|  | QR Codes |

**PLEASE READ BEFORE USE.**


**BONEGRAFT BİYOLOJİK MALZEMELER SAN. VE TİC. A.Ş.**
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