Instruction For Use For POWERBONE Crunch (Stick)

Classification

POWERBONE Crunch (Stick) products are Class III medical devices (Synthetic bone graft), not a drug.

Material

POWERBONE Crunch (Stick) products are Beta Tricalcium phosphate (β-TCP) based porous bone graft substitutes with specific geometric shapes (Stick forms) including ZrO_2 particles for antibacterial efficacy.

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

General Description

POWERBONE Crunch (Stick) products are pure β-TCP based resorbable temporary bone space filler materials. 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 and it has been subjected to extensive, successful clinical studies for many years. It leads to the regeneration of tissues instead of solving the problem of interfacial stability. POWERBONE Crunch (Stick) products contain no tissue of human or animal origin therefore carries no risk of disease transmission. POWERBONE Crunch (Stick) 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

POWERBONE Crunch (Stick) products can be premixed with bone marrow aspirate and other clinically known bone grafts. It is biologically compatible and biodegradable. Sticks can be varied as Block, Bar, Cylinder and Wedge to fit the defect area. These grafts can be used for the reduced infection risk with enhanced antibacterial efficacy, increased bone growth and regeneration. Intended for the repair or filling of craniofacial defects and craniotomy cuts, augment or reconstruct periodontal or bony defects of the oral and maxillofacial region.

Contraindications

POWERBONE Crunch (Stick) products are not indicated for any other usages than the ones stated here. It should not be used when there is any contraindication. POWERBONE Crunch (Stick) products are 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 Crunch (Stick) products are only intended for the use of (professional use) surgeons familiar with, and skilled in techniques of bone repair and replacement.
The effect of POWERBONE Crunch (Stick) 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 Crunch (Stick) products are provided in a double sealed blister package; the products are sterilized via Gamma Irradiation. Since POWERBONE Crunch (Stick) products are opaque to x-rays, areas under or above the implant may be masked on the radiography. Sticks must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. POWERBONE Crunch (Stick) products are for single use only. Do not use if opened, punctured or damaged product. DO NOT STERILIZE AGAIN AND DO NOT USE AGAIN. Read the expiration date before use and DO NOT USE BEYOND THE EXPIRATION DATE. The Crunch(Stick) 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. Select the type of graft as you would fit in the defect area. The graft should be placed gently and carefully on the part to be implanted. POWERBONE Crunch (Stick) is in direct contact with the surface of the defect area.

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 graft is not positioned satisfactorily remove the implant and start over with a new dose of POWERBONE Crunch (Stick).

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 Crunch (Stick), Bar, Cylinder, Block, Wedge formed products are 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.

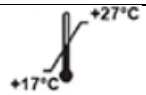
Sterility:

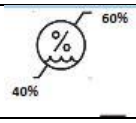
POWERBONE Crunch (Stick) is sterilized by exposure to gamma radiation, using a validated process to ensure a SAL of 10^{-6}. Do not re-sterilize Sterility is guaranteed unless blister package is opened or damaged

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
	Warnings
	Keep Away From Sunlight
	Keep Dry

PLEASE READ BEFORE USE.

BONEGRAFT BİYOLOJİK MALZEMELER SAN. VE TİC. A.Ş.
Ege Üniversitesi Sit İdeege Teknoloji Geliştirme Bölgesi A.Ş. Erzene Mah. Ankara Cad. No:172/67 BORNOVA / İZMİR / TURKEY P.C.35100
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