Instruction for Use for POWERBONE β-TCP Flexible Silicat Add.

Classification

POWERBONE β-TCP Flexible Silicat Add. is a medical device (Class III), not a drug.

Material

POWERBONE β-TCP Flexible Silicat Add.is synthetic bone void filler manufactured from POWERBONE beta tricalcium phosphate (β-TCP) granules and resorbable polymer poly [(lactide-co-ε-caprolactone)]. The polymer of the Flex is metabolite lactic acid and is degraded to CO_2 and H_2O. The basic polymer has a long history of safe medical use.

Product Components of POWERBONE β-TCP Flexible Silicat Add. :
1.) ß-TCP (Beta-Tri Calcium Phosphate)
2.) Poly [(lactide-co-ε-caprolactone)] polymer (%12,5)
3.) Silicon Dioxide (%1)
4.) Chloroform
5.) Sucrose (Progen)
6.) Distilled Water

General Description

POWERBONE β-TCP Flexible Silicat Add. is unique micro and macro porous 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 cells and replaced by healthy viable bone.
POWERBONE β-TCP Flexible Silicat Add. contains no tissue of human or animal origin therefore carries no risk of disease transmission. The result is a flexible, osteoconductive, three-dimensional composite with excellent characteristics that conforms to implant site, allowing site-specific placement. POWERBONE β-TCP Flexible Silicat Add start being active in 5 seconds after surgery. Although the activity of graft products mainly completed 4-6 months, some parts of the grafting site bone regeneration process still continuous until complete resorption of the grafts up to 18 months.

Product General Features

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

Indications- For Use

POWERBONE β-TCP Flexible Silicat Add. may be premixed with bone marrow aspirates and other clinically known bone grafts. POWERBONE β-TCP Flexible Silicat Add. is biologically compatible and biodegradable. POWERBONE β-TCP Flexible Silicat Add. can be shaped to conform to the defect area. These grafts can be used for the increased bone growth and regeneration. POWERBONE β-TCP Flexible Silicat Add. Also indicated for;

- To fill cavities or defects resulting from cysts, tumors, or other causes major disc collapse. Settings requiring reconstruction or repair of missing bone can vary from filling small cavities to replacing large segments of bone.
- To stimulate healing of fractures either fresh fractures or fractures that have failed to heal after an initial treatment attempt.
- To bridge joints and thereby provide arthrodesis.
- To bridge major defects or establish the continuity of a long bone,
- To provide bone blocks to limit joint motion (arthrorisis),
- To establish union in a pseudarthrosis,
- To promote union or fill defects in delayed union, malunion, fresh fractures, or osteotomies,
- To plastic arthrosis of acetabulum for congenital dislocation of the hip and untreated perthes disease,
- For vertical and horizontal augmentation of the mandible and maxilla.

Contraindications

POWERBONE β-TCP Flexible Silicat Add. is not indicated for any other uses than the ones stated here. It should not be used when there is any contraindication. POWERBONE β-TCP Flexible Silicat Add. 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 β-TCP Flexible Silicat Add. 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 β-TCP Flexible Silicat Add. on patients with the following conditions is unknown:

- Pregnancy and nursing (Its use is at the discretion of the doctor.)
- Long term infection
- 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 β-TCP Flexible Silicat Add. products are provided in a double sealed blister package; the products are sterile. POWERBONE β-TCP Flexible Silicat Add. may be masked on the radiography areas under or above the implant. POWERBONE β-TCP Flexible Silicat Add. 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. POWERBONE β-TCP Flexible Silicat Add. are 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. If there is instability, stabilize the operative area using appropriate osteosynthesis procedures and hardware fixation.

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 β-TCP Flexible Silicat Add.

Storage

Store in a DRY PLACE. 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 3 years and printed on the label. DO NOT USE AFTER THE EXPIRATION DATE. POWERBONE β-TCP Flexible Silicat Add. is environment-friendly. No special disposal is necessary. The used injector should be disposed of as clinical waste.

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.

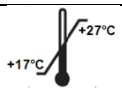
Sterility:

POWERBONE β-TCP Flexible Silicat Add. 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

Prepared by	Approved by
QUALITY MANAGEMENT REPRESENTATIVE Burak TÜLÜ	GENERAL MANAGER Zafer ÇAVUŞ

	Keep Dry
	Medical Device
	Double Sterile Barrier System
	Unique Identifier Information
	QR Codes

PLEASE READ BEFORE USE.

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

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