	<b>INSTRUCTION FOR USE FOR POWERBONE DENTAL PUTTY</b>	Dok.No / Doc. No	CE.TL.15.06
		Yay.Trh. / Pub. D.	17.08.2018
		Rev.No / Rev. No	04
		Rev.Trh. / Rev. D.	27.06.2024
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**Instruction for Use for POWERBONE Dental Putty**

**Classification**

POWERBONE Dental Putty is a medical device (Class III), not a drug.

**Material**

POWERBONE Dental Putty is an injectable and formable paste bone graft based on hydrogel and Beta-tricalcium phosphate ( $\beta$ -TCP) powder or granules, including ZrO<sub>2</sub> particles for antibacterial efficacy.

**Product Components of POWERBONE Dental Putty:**

- 1.)  $\beta$ -TCP (Beta-Tri Calcium Phosphate)
- 2.) Hydroxy Propyl Methyl Cellulose (HPMC)
- 3.) ZrO<sub>2</sub> (Zirconium (IV) oxide) (%0,1)
- 4.) Silicon Dioxide (%1)
- 5.) Distilled Water

**General Description**

POWERBONE Dental Putty is a safe and fully biocompatible material which is designed to act as an osteoconductive scaffold to support the ingrowth and fusion of adjacent viable bone when placed in an osseous environment. It is biocompatible, injectable osteoconductive support matrix which supports new bone formation in defect areas. POWERBONE Dental Putty is delivered ready for use directly in the injector. It does not take time and can be applied easily. Injectable bone putty is a combination of Beta-tricalcium phosphate ( $\beta$ -TCP) granules and hydrogel. POWERBONE Dental Putty contains no tissue of human or animal origin therefore carries no risk of disease transmission. POWERBONE Dental Putty is sterilized via Gamma Irradiation and can be easily applied to the defect area. POWERBONE Dental Putty 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
- Show to support bone growth
- Radiopaque
- Easy implantation

**Indications- For Use**

POWERBONE Dental Putty is a synthetic bone grafting material intended to fill, augment, and/or reconstruct maxillofacial osseous bone defects, including periodontal, oral, and craniomaxillofacial applications. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a synthetic bone grafting material that resorbs and is replaced by bone during the healing process. Dental Putty is designed for use in a broad range of non-load bearing osseous defects such as: spinal surgery (cage filling), osteotomies, bone cavity and defect filling, metaphyseal fractures, acetabulum reconstruction.

**Contraindications**

- 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 Dental Putty is for professional use only and is only intended for use by surgeons familiar with and skilled in the techniques of bone repair and replacement. POWERBONE Dental Putty is not intended for load bearing applications. It is important to maximize the contact surface between existing bone and the implant to ensure proper bone regeneration. Do not overfill the defect area and avoid leakage out of the defect area.

The effect of POWERBONE Dental Putty on patients with the following conditions is unknown:

- Pregnancy
- 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, infection, 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 Dental Putty is ready to use in the injector. POWERBONE Dental Putty is injectable during surgery. The contents of the package are double -sealed and sterile. POWERBONE Dental Putty is sterilized via Gamma Irradiation. POWERBONE Dental Putty is for single use only. **DO NOT USE IF OPENED PUNCTURED OR PRODUCT OR INJECTOR APPEARS DAMAGED OR PASTE HAS DRIED.** Read the expiration date before use and **DO NOT USE BEYOND THE EXPIRATION DATE.** The Dental Putty is being used adults whom are over 18 years old.

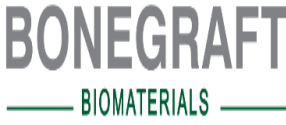
**Applications**

**Step 1:** Transfer the inner blister to the sterile environment by opening the outer blister in the operation room. Remove the cap from the injector in sterile field. POWERBONE Dental Putty is supplied as a paste in the injector ready for use.

**Step 2:** Fill the defect area completely or shape Putty according to the condition of the defect area. It should come into direct contact with all surfaces on the defect.

**Step 3:** Secure the surgical site after implanting in order to prevent motion, leakage or implant migration. When excess fluid is present in the surgical field, the surgeon may use proper measures (i.e. catheterization, suction and application of bone wax) to reduce bleeding.

Prepared by <b>QUALITY MANAGEMENT REPRESENTATIVE</b> Burak TULU	Approved by <b>GENERAL MANAGER</b> Zafar ÇAMUŞ
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**NOTE:** For the viscosity stability of the product, it is recommended to keep it in a deep freezer between (-5)-0 °C for 10 minutes before the operation.

**Storage**

Store in a DRY PLACE. Optimal storage conditions: +17°C - +27°C and 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 Dental Putty is environment-friendly. No special disposal is necessary. The used injector should be disposed of as clinical waste.

**Packaging**

POWERBONE Dental Putty are delivered in sterile packages. Gama radiation sterilization method is used. Packaged products must be stored unopened in their original packaging. Damaged products and packages must not be used but they must be returned to Bonegraft Biyolojik Malzemeler San. Tic. ve A.Ş.






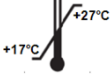


**Sterility:**













POWERBONE Dental Putty is sterilized by exposure to gamma radiation, using a validated process to ensure a SAL of 10<sup>-6</sup>. 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 and Country of Manufacture
	Warnings
	Keep Away From Sunlight
	Keep Dry
	Medical device
	Double sterile barrier system
	Unique device identifier
	QR codes

PLEASE READ BEFORE USE.

**BONEGRAFT BİYOLOJİK MALZEMELER SAN. VE TİC. A.Ş.**  
Keçiliköyosb Mahallesi İsmail Kahraman Cad. No: 1/1/A Yunusemre/Manisa.

Tel: +90232 373 33 38  
Fax: +90232 373 33 39  
E-mail: info@bonegraft.com.tr  
Web: [www.bonegraft.com.tr](http://www.bonegraft.com.tr)

Hazırlayan KALİTE YÖNETİM TEMSİLCİSİ Buğrak TULU	Onaylayan GENEL MÜDÜR Zafer ÇAVUŞ
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