

Package Insert

Zavation Uni-FuZe®-P Bone Putty

Device Description:

The Zavation Uni-FuZe®-P Bone Putty is a bioactive osteoconductive, resorbable, biocompatible bone graft substitute in putty form. The product is composed of a matrix of bovine collagen per ASTM F2212, porous beta tricalcium phosphate (TCP per ASTM F1088), Bioglass 45S5 per ASTM F1538, and polyethylene glycol (PEG). Uni-FuZe®-P Bone Putty can be applied directly to the defect site as a moldable and malleable material. Uni-FuZe®-P Bone Putty is pre-loaded into the syringe applicator, sterile, ready for use.

Intended Use:

Uni-FuZe®-P Bone Putty is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Uni-FuZe®-P Bone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process. Uni-FuZe®-P Bone Putty should be administered to patients who are skeletally mature (>18 years of age or radiographic evidence of closure of epiphyses).

Materials:

Bone Putty containing: Bovine collagen per ASTM F2212, porous beta tricalcium phosphate (TCP per ASTM F1088), Bioglass 45S5 per ASTM F1538, and polyethylene glycol (PEG).

Contraindications:

- severe vascular or neurological disease
- uncontrolled diabetes
- severe degenerative disease
- uncooperative patients who cannot or will not follow post-operative instruction, including individuals who abuse drugs and/or alcohol
- hypercalcemia, abnormal calcium metabolism
- existing acute or chronic infections, especially at the site of the operation
- inflammatory bone disease such as osteomyelitis
- malignant tumors
- severely impaired renal function.

Potential Adverse Events:

Successful results may not be achieved in every surgical case. Reoperation to remove or replace an implant may be required due to specific medical conditions or device failure. Possible adverse effects may include but are not limited to:

- wound complications including hematoma, edema, swelling and fluid accumulation, tissue thinning, bone fracture, infection, and other complications that are possible with any surgery

- fracture of the implant with or without generation of particulate debris
- bone deformity at the site, delayed or non-union, and/or transient hypercalcemia.

Warnings and Precautions:

Uni-FuZe®-P Bone Putty is not intended for load-bearing uses. It is important to ensure that the area where Uni-FuZe®-P Bone Putty has been implanted be properly secured mechanically with rigid fixation to strengthen the surroundings. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration. The effect of Uni-FuZe®-P Bone Putty on patients with the following conditions is unknown:

- documented renal disease
- metabolic bone disease
- pregnancy and nursing
- radiation bone therapy
- long-term infection
- cardiovascular disease precluding elective surgery.

Content of package is STERILE by prior exposure to gamma radiation unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.

The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. Fully fill the bony defect ensuring maximal contact between Uni-FuZe®-P Bone Putty and the host bone. Do not overfill or attempt to pressurize the bony defect site, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues, or may lead to fat embolization or embolization of the device into the bloodstream.

Dosage is for SINGLE USE ONLY. Do not attempt to re-sterilize or re-use.

Directions for Use: Non-hardening and ready-to-use paste for filling bony voids and gaps. No mixing, moistening or other preparation is needed prior to application.

- 1) A thorough surgical debridement must be performed, and the surface of the bone needs to be refreshed before implantation.
- 2) Peel open the pouch and aseptically remove the syringe.
- 3) Unscrew the cap and push the plunger rod to force the putty to a sterile cup and subsequently perform the implantation with a sterile instrument.
- 4) Push the plunger rod to gently fill the defect with the putty.

Sterilization: The Uni-FuZe®-P Bone Putty is provided sterile in sealed sterile packaging (gamma irradiation).

MR Safety Information: Uni-FuZe®-P Bone Putty is MR safe.

Storage: Store at room temperature 59°-86°F (15°-30°C). Do not freeze or expose to extreme heat.

Product Complaints: Any Healthcare Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Zavation Medical Products LLC, 3670 Flowood Dr., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Further Information: A recommended surgical technique for the use of this system is available upon request from Zavation Medical Products, LLC, 3670 Flowood Dr., Flowood, MS 39232, USA, Telephone: 601-919-1119.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Symbol Index	
	Manufacturer
	Caution
	Single Use
	For use by a licensed clinician only
	Use by date
	Temperature Limitation
	Sterilized using irradiation



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Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	FELICIA SMITH	VP OF QUALITY	09-Jan-2025 11:38
Send for Required Approval(s)	ELKE CARTER	VP OF REGULATORY	09-Jan-2025 12:28
Approve	ELKE CARTER	VP OF REGULATORY	09-Jan-2025 14:36
QA Approval	STEPHEN C. GORDON	CHIEF QUALITY OFFICER	24-Jan-2025 14:38

* Dates are displayed according to the system time zone: (GMT-06:00) Central Standard Time (America/Chicago)