

Package Insert

Zavation Uni-FuZe®-C Bone Strip

Device Description:

Uni-FuZe®-C Bone Strip is a resorbable bone void filler made from a matrix of purified bovine collagen (ASTM F2212), beta tricalcium phosphate (TCP per ASTM F1088), and Bioglass 45S5 (ASTM F1538). The implant is provided as sterile and is for single-use.

Intended Use:

Uni-FuZe®-C Bone Strip is an implant intended to fill bony voids or gaps of the skeletal system (i.e., the extremities, and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Uni-FuZe®-C Bone Strip resorbs and is replaced with bone during the healing process.

Materials:

Uni-FuZe®-C Bone Strip comprised of: a matrix of purified bovine collagen per ASTM F2212, beta tricalcium phosphate (TCP per ASTM F1088), and Bioglass 45S5 per ASTM F1538.

Contraindications:

Uni-FuZe®-C Bone Strip is not intended to provide structural support during the healing process; therefore, Uni-FuZe®-C Bone Strip is contraindicated where the device is intended as structural support in the skeletal system. Conditions representing relative contraindications include:

- 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
- any case not described in the indications.

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®-C Bone Strip is not intended for load-bearing uses. It is important to ensure that the area where Uni-FuZe®-C Bone Strip 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®-C Bone Strip 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®-C Bone Strip and the host bone. Do not over stuff the bony defect site as this may lead to damage to the surrounding tissues, or may lead to fat embolization or embolization of the device into the bloodstream.

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

Directions for Use: Implant Uni-FuZe®-C Bone Strip preferably in contact with spongy autologous bone.

- 1) A thorough surgical debridement must be performed and the surface of the bone needs to be refreshed before implantation.
- 2) Freshen the bone wall being in contact with Uni-FuZe®-C Bone Strip.
- 3) Saturate Uni-FuZe®-C Bone Strip with whole blood from the patient. (Note: It is mandatory that Uni-FuZe®-C Bone Strip be mixed with whole blood).
- 4) Once whole blood is applied, allow the product to visibly hydrate prior to implantation. Adequate soaking has occurred once whole blood coats all surfaces.
- 5) Gently pack the site, but avoid overfilling the bone void, or compressing the treatment site.
- 6) Remove excess material from the treatment site.
- 7) Close the site using standard closure techniques and discard any unused Uni-FuZe®-C Bone Strip.

MR safety: The device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating, migration or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.

Sterilization: Uni-FuZe®-C Bone Strip is provided sterile in sealed sterile packaging (gamma irradiation).

Storage: Store at room temperature (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
	Consult instructions for use



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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 11:16
Send for Required Approval(s)	ELKE CARTER	VP OF REGULATORY	09-Jan-2025 11:38
Approve	ELKE CARTER	VP OF REGULATORY	09-Jan-2025 12:01
QA Approval	FELICIA SMITH	VP OF QUALITY	09-Jan-2025 13:44

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