












Read this package insert completely before use and comply with the instructions for use.

Foramic® Bone Substitute Granules

DOH-MD-No. 001198

GRAPHICAL SYMBOLS

	Single use only		Catalog number
	Read instructions before use		Lot number
	Sterilization by Irradiation		15-30°C (59-86°F)
	Do not re-sterilize		Keep away from sunlight
	Use by expiry date		Do not use if package is damaged
	Manufacturer		

Description

Foramic® is a biphasic mixture with a composition of 60% hydroxyapatite and 40% β-tricalcium phosphate. These materials have been the topic of extensive clinical studies for a several decades. Foramic® is safe and has excellent biocompatibility. Once implanted, the implant is resorbed and replaced with natural bone.

Foramic® can eliminate the trauma and complication for second site surgery in order to harvest the patient's own autograft. It also avoids potential transmission of diseases from allografts taken on human or animal cadavers.

Indications

Foramic® is an osteoconductive bone substitute shaped as granules or blocks (cancellous, cortical or cortico-cancellous) that are intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure.

These gaps or voids may be located in the extremities, spine, pelvis, or cranium. The granules or blocks may be pressed into the void or into the surgical site by hand. The Foramic® granules or blocks provide void filling material that acts as a temporary support medium. The granules or blocks are not intended to provide structural support during the healing process. The implant is radio-opaque. Foramic® is biocompatible and resorbable in the body as bone ingrowth occurs.

Contraindications

Foramic® is not designed or sold for any use except as indicated. Do not use Foramic® in the presence of any contraindication. Foramic® is contraindicated where the device is intended as structural support in the skeletal system (e.g. mandibular segment replacement).

Other conditions representing relative contraindication 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, alcohol and smoking.
- Hypercalcemia, abnormal calcium metabolism
- Existing acute or chronic infection, especially at the site of the operation
- Inflammatory bone disease such as osteomyelitis
- Severely impaired renal function

Precaution

Foramic® is not intended for load-bearing uses. It is important to ensure that the area where the granules or blocks have been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. Attempts should not be made to modify the size of the granules or to change their shape. It is important to maximize contact between existing bone and the implant to ensure proper bone regeneration.

The effect of Foramic® on patients with the following conditions is unknown:

- Documented renal disease
- Pregnancy and nursing
- Radiation bone therapy
- Long-term infection
- Cardiovascular disease precluding elective surgery
- Malignant tumors

The effect of Foramic® in pediatric patients is not known. The effect of mixing Foramic® with other substances (e.g. antibiotics or serum) is not known.

Adverse Reaction

Successful results may not be achieved for every surgical case. Re-operation 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

Administration

Step 1: Open both outer and inner pouches. Open the container. Note that glass containers are naturally dark as a result of the γ-sterilization process.

Step 2: Implant. Secure the surgical site after implanting to prevent micromotion and implant migration. When excess fluid is present in the surgical field, the surgeon may use cauterization, suction, and application of bone wax (if needed) to reduce bleeding. If the material is not positioned satisfactorily, remove the implant and start over with a new dose of Foramic® Bone Substitute Granules.

Storage

Store in a dry place at room temperature. Optimal Storage Conditions is between 15-30°C (59-86°F), with less than 70% relative humidity.

Shelf Life and Disposal

The expiration date is printed on the label. Do not use Foramic® after the expiration date. Foramic® is environment-friendly. No special disposal is necessary. Packaging material is recyclable.

Specifications

Product type	Specification	Quantity /Box
FM-G-0025	0,25cc (0.5 - 1 mm)	4
FM-G-0050	0,5cc (0.5 - 1 mm)	2
FM-G-0100	1cc (0.5 - 1 mm)	1
FM-G-0200	2cc (0.5 - 1 mm)	1
FM-01	1cc (1 - 3.35 mm)	1
FM-02	2cc (1 - 3.35 mm)	1
FM-05	5cc (1 - 3.35 mm)	1
FM-08	8cc (1 - 3.35 mm)	1
FM-10	10cc (1 - 3.35 mm)	1
FM-15	15cc (1 - 3.35 mm)	1
FM-20	20cc (1 - 3.35 mm)	1

Warning

Content of package is sterile unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded. It is recommended to use Foramic® Bone Substitute Granules within one hour of opening the package. Foramic® Bone Substitute Granules is opaque to X-rays. This may mask areas under or above the implant on the radiograph. Granules or blocks must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. Foramic® Bone Substitute Granules cannot be re-use, the patients may expose to the risk of diseases and have the possibility of cross-infection may lead to death. In addition, Foramic® Bone Substitute Granules should not be re-sterilized. Only professional doctors of surgery are permitted use the devices.

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