Explanation of Symbols

Do not use if package is damaged

STERILE R

Sterilized using irradiation

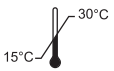
Do not re-use

Caution. Consult the Instructions for Use

Use by Date

℞

Prescription Only



Temperature Limit

Do not resterilize

This product is to be handled or implanted by trained qualified persons having read these Instructions for Use.

bioventus®

4721 Emperor Blvd. Suite 100. Durham, NC 27703 USA
1-800-637-4391 • www.BioventusSurgical.com

10-0112 2019-06-03

osteomatrix+™

Biphasic Bone Graft

OMP - 09	Contents: 1 Strip, 9cc
OMP - 18	Contents: 2 Strips, 18cc

Instructions for Use

Caution:Federal Law (U.S.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner)

IMPORTANT PRODUCT INFORMATION
Please read before use

A. General Information

Device Generic Name: Biphasic Bone Graft
Device Trade Name: OSTEOMATRIX+

Bioventus, LLC
4721 Emperor Blvd, Suite 100
Durham, NC 27703

B. Materials & Device Description

OSTEOMATRIX+ is a bone graft substitute comprising biphasic mineral granules suspended in a porous type I collagen matrix. The device is provided sterile and is to be combined with autologous bone marrow aspirate prior to use to facilitate packing into bony defects. The device provides an osteoconductive scaffold that resorbs and guides host bone regeneration during the healing process.

C. Indications for Use

OSTEOMATRIX+ is a bone graft substitute intended for use in bony voids or gaps of the skeletal system not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or result from traumatic injury to the bone. OSTEOMATRIX+ is indicated to be combined with autologous bone marrow aspirate and packed into osseous defects of the extremities, pelvis and posterolateral spine. When used in the posterolateral spine, OSTEOMATRIX+ is to be used as an autograft extender. The device resorbs and is replaced by host bone during the healing process.

D. Contraindications

OSTEOMATRIX+ is not designed or sold for any use except as indicated. Do not use OSTEOMATRIX+ in the presence of any contraindication. OSTEOMATRIX+ is contraindicated where the device is intended as structural support in the skeletal system. OSTEOMATRIX+ must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or patients that are being treated for desensitization to meat products. Other conditions representing contraindications include:

- Necrosis or infection at the graft site
- Malignant tumors
- Intra-articular implantations
- Severe vascular or neurological disease proximal to the graft site
- Hypercalcemia, abnormal calcium metabolism
- Inflammatory bone disease such as osteomyelitis
- Metabolic or systemic bone disorders that affect bone or wound healing
- Patients unwilling or incapable of following post-operative instructions

E. Warnings & Precautions

- Content of package is provided STERILE. DO NOT USE if opened or damaged.
- Read expiration date before use. Do not use if expiration date has been exceeded.
- The device is for SINGLE USE ONLY. DO NOT attempt to re-sterilize or reuse.
- OSTEOMATRIX+ is intended for use by surgeons familiar with bone grafting procedures.
- OSTEOMATRIX+ is not intended for load-bearing uses. The area where OSTEOMATRIX+ is to be implanted must be mechanically secured with rigid fixation to strengthen the surroundings.
- The safety and effectiveness of OSTEOMATRIX+ is unknown in patients with chronic pathological conditions, metabolic bone disease, in pregnant women, or children.
- OSTEOMATRIX+ contains bovine collagen and must not be used in patients with a history of allergies to any bovine products.
- OSTEOMATRIX+ should only be used in defects where the graft can be adequately contained or where soft tissue coverage cannot be achieved.
- Fully fill the bony defect to ensure maximal contact between OSTEOMATRIX+ and host bone.
- DO NOT overfill the bony defect 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 may cause damage to the surrounding tissues.
- OSTEOMATRIX+ is radiopaque until resorbed. This may mask underlying pathological areas and must be considered during radiographic evaluation.

F. Possible Complications

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

- Wound complications including hematoma, edema, swelling, and fluid accumulation, adverse tissue reaction, bone fracture, infection, and other complications possible with any surgery
- Localized hypersensitivity to bovine collagen including edema, swelling, and rash
- Incomplete or lack of bone formation
- Delayed union or non-union
- Transient hypercalcemia
- Fracture of the newly formed bone.

G. Instructions for Use

1. Peel open outer pouch and transfer inner pouch to the sterile field.
2. Peel open inner pouch and remove implant.
3. Hydrate implant with bone marrow aspirate in a 1:1 volume ratio.
4. Manipulate and shape the implant as desired.
5. When using in the posterolateral spine, mix with autograft bone in a 1:1 volume ratio.
6. Secure the surgical site after implanting to prevent micro-motion and implant migration. Should the implant not be positioned satisfactorily, remove the implant and start over with a new package of OSTEOMATRIX+.

H. Storage Conditions

OSTEOMATRIX+ should be stored at controlled room temperature. Do not expose to excessive heat. Optimal storage conditions are 15-30°C (59-86°F).

I. Shelf Life and Disposal

The expiration date is printed on the label. Do not use OSTEOMATRIX+ after the expiration date. The contents of each pouch are sterile unless opened or damaged. Discard any unused portion immediately after use.