PearlMatrix™
P-15 Peptide Enhanced Bone Graft

Cerapedics™

PearlMatrix™ Bone Graft Instructions for Use

DESCRIPTION

PearlMatrix Bone Graft is a bone graft substitute material comprised of porcine-derived anorganic bone mineral particles (pABM) coated with P-15, a synthetic peptide. The pABM/P-15 particles are embedded in a carrier consisting of bovine-derived Type I dermal collagen that aids in the handling and containment of the particles within the intended surgical site. Upon implantation in a bony site, PearlMatrix Bone Graft is remodeled into new native bone by cell-mediated resorption during the natural healing process.

The pABM component of PearlMatrix Bone Graft is a natural form of hydroxyapatite (calcium phosphate), which is the main mineral component of bone. P-15 is a synthetically derived fifteen amino acid polypeptide that mimics the cell binding domain of human Type I collagen, and serves as an attachment site for osteogenic cells. The pABM/P-15 particles are naturally porous, radiopaque, and sized at 106-1000 microns (nominal average = 481 microns). PearlMatrix Bone Graft is composed of 80% pABM/P-15 particles and 20% bovine collagen.

PearlMatrix Bone Graft is provided as a freeze-dried material that, when hydrated, forms a moldable putty that can be shaped as desired. PearlMatrix Bone Graft is provided sterile and is intended for single use only.

INDICATIONS FOR USE

PearlMatrix Bone Graft Bone Graft is intended to fill bony voids or gaps in extremities and spine that are not intrinsic to the stability of the bony structure. Sufficient internal or external fixation is required.

PearlMatrix Bone Graft may be mixed with autogenous bone and/or autogenous bone marrow aspirate (BMA).

INTENDED USER

PearlMatrix Bone Graft is a bone graft substitute material for use only by a qualified Orthopedic surgeon, Neurosurgeon, or Spine surgeon.

CONTRAINDICATIONS

Use of PearlMatrix Bone Graft is contraindicated for any of the following:

- Absence of load bearing structural support at the graft site
- Patients with known sensitivity to any components of PearlMatrix Bone Graft
- Active infection at the operative site
- Operative site subject to excessive impact or stress
- Significant vascular impairment proximal to the graft site

- Use in direct contact with articular spaces
- Presence of segmental defects
- Metabolic or systemic disorders that affect bone or wound healing
- Compromised renal function
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol

WARNINGS AND PRECAUTIONS

- PearlMatrix Bone Graft is not intended to provide load-bearing structural support during the healing process. Rigid fixation techniques are recommended as needed to ensure stabilization of the bony structure in all planes.
- PearlMatrix Bone Graft should only be used in surgical procedures where it can be adequately contained at the bony void or defect. Inadequate containment of PearlMatrix Bone Graft could result in product migration from the intended bony defect site. If product migration occurs, clinical outcomes may be compromised by the lack of bone graft material in the appropriate space. Potential patient adverse events caused by inadequate containment and migration of PearlMatrix Bone Graft may include, but are not limited to the following: pain, neural impingement, physical impairment, irritation or wear of an articulating joint, or loss of function; any of which may require revision surgery.
- Avoid overfilling the bone void or pressurizing the treatment site.
- As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes, but is not limited to, individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy or high dosage radiation therapy.
- The use of PearlMatrix Bone Graft when mixed with other bone graft substitute products has not been evaluated; therefore, the effectiveness of PearlMatrix Bone Graft when used in this manner is unknown.
- The effect of PearlMatrix Bone Graft on pregnant or nursing patients has not been evaluated.
- **DO NOT USE IF STERILE PACKAGING IS OPENED OR DAMAGED.** Discard or return damaged packaging and all contents.
- PearlMatrix Bone Graft is designed for single patient use only. Do not attempt to re-sterilize or re-use.
- Do not use after the printed expiration date on the label.
- Discard any unused graft material.

POTENTIAL ADVERSE EVENTS

As with any surgery involving bone graft material, the following potential adverse events may occur. Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of PearlMatrix Bone Graft.

Potential adverse effects associated with surgical procedures to fill bony voids and gaps in the spine and extremities include:

- Extrusion or migration of the bone graft material resulting in pain, neural impingement, physical impairment, irritation or wear of an articulating joint, or loss of function
- Wound complications including hematoma, superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, cellulitis, site drainage, or wound dehiscence
- Incomplete or lack of osseous ingrowth into the graft site
- Excessive or abnormal bone formation in an unintended location
- Delayed union, nonunion, or malunion
- Loss of reduction, refracture, cyst recurrence
- Arthritis or other disorders in bone formation
- Transient hypercalcemia
- Localized immunological reactions consisting of transient localized edema, swelling, and rash have been reported to occur with bone void fillers containing collagen. Although there is no evidence that the device will be unsafe or ineffective in such patients, the safety and effectiveness of the device in these patients has not been established.
- Renal problems
- Nervous system problems

Potential adverse effects specific to PearlMatrix Bone Graft:

- Allergic reaction to components of PearlMatrix Bone Graft

STORAGE

Store PearlMatrix Bone Graft in its original packaging at ambient room temperature. Do not freeze or expose to extreme heat.

DIRECTIONS FOR USE

Familiarization with PearlMatrix Bone Graft and proper bone grafting and rigid fixation techniques are extremely important. Radiographic evaluation of the planned graft site is essential for accurately assessing the desired surgical outcome, and to aid in the selection and placement of PearlMatrix Bone Graft along with any fixation devices.

To prepare PearlMatrix Bone Graft, hydrate the PearlMatrix Bone Graft material with either

sterile saline or autogenous bone marrow aspirate (BMA) using the following recommended fluid volumes:

PearlMatrix Bone Graft	Fluid volume (saline or BMA)
1.0 cc	1.0 cc
2.5 cc	2.4 cc
5.0 cc	4.4 cc
10.0 cc	9.6 cc

Once PearlMatrix Bone Graft has hydrated, knead the material to a putty-like consistency for at least 60 seconds and mold into the desired shape. Insert the bone graft into the surgical site.

Fixation of the implant site must be sufficient to prevent collapse and deformity secondary to functional loading. Anatomical reduction and rigid fixation in all planes must be obtained to ensure that the graft is not supporting load.

Postoperative patient management should follow the same regimen as with other bone grafts or autogenous bone graft. Standard postoperative practices should be followed, particularly as applicable to surgical procedures involving the use of fixation devices.

WARRANTIES

All warranty rights are lost if modifications are made to this product. The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with the instructions for use.

PRODUCT COMPLAINTS

Any health care professional using PearlMatrix Bone Graft who has complaints about the product, or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Cerapedics. Further, if any of the implanted product ever “malfunctions”, i.e., does not meet any of its performance specifications or otherwise does not perform as intended, or may have caused or contributed to the death or serious injury of a patient, Cerapedics should be notified immediately by telephone, or through written correspondence via email or fax. When filing a complaint, please provide the product name, the product reference code, lot number, your name and address, and the nature and details of the complaint.

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FURTHER INFORMATION

Symbol	Symbol title	Symbol	Symbol title
	Catalogue number		Sterilized using irradiation
	Batch code		Sterile barrier system with protective packaging inside
	Use-by date		Consult electronic instructions for use
	Manufacturer		Contains biological material of animal origin
	Temperature limit		Do not re-use
	Do not use if package is damaged		

If further information is required, please contact Cerapedics at the address below.

 **MANUFACTURED BY:**

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