Opus™ Putty

Osteoconductive Scaffold

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

Opus™ Putty is a collagen mineral composite matrix processed into a cylindrical matrix for surgical implantation. The principle components of Opus™ Putty are anorganic bovine bone mineral and bovine type I collagen. The mineral particles are dispersed within collagen fibers forming a three-dimensional open porous matrix consisting of 55% bone mineral and 45% collagen. Opus™ Putty is provided as a sterile, dry material that is hydrated with autogenous bone marrow at the point of use. Opus™ Putty can be molded to fit the bone defect. Opus™ Putty is fully resorbed during the natural process of bone formation and remodeling.

INDICATIONS

Opus™ Putty, combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

CONTRAINDICATIONS

Opus™ Putty must not be used in patients with osteomyelitis at the operative site.

Opus™ Putty must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or who are being treating for desensitization to meat products because this product contains bovine collagen.

WARNINGS

Opus™ Putty should not be used in fractures of the growth plate, segmental defects, direct contact with the articular space, and open fractures.

PRECAUTIONS

Caution should be exercised when treating individuals with bleeding diatheses of any etiology.

Opus™ Putty should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. Opus™ Putty must be used with internal or external fixation as indicated or required.

Use of Nonsteriodal Anti-inflammatory (NSAIDs) medications may delay graft healing. Use of alternate means of pain control should be considered whenever possible. Abstinence from smoking during and after treatment is highly advised.

Opus™ Putty cannot be re-used or re-sterilized. Open, unused product must be discarded. *In vivo* stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

ADVERSE EFFECTS

The complications and inherent risks associated with bone grafting surgery are not anticipated to increase with the use of Opus™ Putty. Potential complications of surgery include wound infection, reaction to medications or anesthesia, pain, thromboembolism, cardiac or pulmonary complications and blood loss. Potential postoperative risks include, but are not limited to hematoma, urinary retention, thombophlebitis, and continued pain. Also, all patients will be exposed to the same risks associated with any bone grafting procedure such as fracture, migration, resorption or rejection of the graft, delayed union, nonunion, or pseudoathrosis. These complications may require regrafting or revision. In addition, in some instances Opus™ Putty may need to be removed from the body, thus creating the need for a second surgery.

The possibility exists also for failure of the implant due to incorrect surgical technique, patient noncompliance during postoperative rehabilitation, and other unforeseen problems. A small number of patients may experience localized immunological reactions to this device that generally consist of transient localized edema, swelling and rash. 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.

Opus™ Putty has not been used in clinical studies to treat patients with metabolic bone disease, significant vascular disorders or clotting disorders, uncontrolled diabetes, ankylosing spondylitis, achondroplasia, or in patients undergoing anticoagulation therapy, immunosuppressive therapy, or steroid therapy. No clinical data exists for use of Opus™ Putty in children or pregnant women.

DIRECTIONS FOR USE

The procedure must be performed in an operating room under aseptic conditions. The patient should be anesthetized or sedated, as required. After adequately exposing the bone requiring grafting, the bones should be debrided until healthy bleeding bone is exposed throughout the graft site.

1. Determine the number of Opus™ Putty to be used based on the size or volume of the defect to be filled.
2. Aspirate bone marrow to matrix on a 1:1 basis (e.g., use approximately 5 mL bone marrow for each Opus™ Putty 5 cc cylinder matrix).
3. Transfer the aspirate immediately into a sterile bowl.
4. Add a small amount of heparin (20 units heparin/1mL marrow) to prevent the bone marrow aspirate from clotting.
5. Hydrate each Opus™ Putty with bone marrow just prior to implantation-NOTE: Hydration should require less than 1 minute.
6. Gently mold the Opus™ Putty and pack the defect maintaining the structure of Opus™ Putty and the saturated bone marrow aspirate.

HOW SUPPLIED

Each package of Opus™ Putty contains either a 2.5 cc or 5 cc cylinder matrix. Opus™ Putty is sterile, non-pyrogenic, and for single use only.

CAUTION: If there is any evidence of compromised sterility (e.g., torn packaging), the device must not be used.

STORAGE

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

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

PRODUCT COMPLAINTS

Any healthcare professional who has any complaints or is dissatisfied with this product should notify Orthofix US LLC, 3451 Plano Pkwy, Lewisville, TX 75056
Phone: (888) 298-5700
Email: Biologics-CustomerService@Orthofix.com

FURTHER INFORMATION

For product information, sales inquiries, customer service, or to obtain a surgical technique, please contact your sales representative or Orthofix US LLC Customer Service at Email: Biologics-CustomerService@Orthofix.com

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Use By Date
	Do Not Reuse
	Do not use if the product sterilization barrier or its packaging is compromised
	Consult instructions for use
STERILE R	Sterilized using irradiation
LOT	Lot number
R_X Only	Federal (USA) law restricts this device to sale by or on the order of a physician or dentist
REF	Reference number
	Temperature Limitation
	Manufacturer

Manufacturer:

Collagen Matrix, Inc.
15 Thornton Road
Oakland, NJ 07436 USA

Distributed by:

Orthofix US LLC
3451 Plano Parkway
Lewisville, TX 75056 USA