

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

Opus™ Strip is a collagen mineral composite matrix processed into strip form for surgical implantation. The principle components of Opus™ Strip are bovine type I collagen and anorganic bovine bone mineral. The mineral particles are dispersed within collagen fibers forming a three-dimensional open porous matrix consisting of 80% bone mineral and 20% collagen. Opus™ Strip is provided as a sterile, dry material that is hydrated with autogenous bone marrow at the point of use. Opus™ Strip is fully resorbed during the natural process of bone formation and remodeling.

INDICATIONS

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

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

WARNINGS

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

Use of Nonsteroidal 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.

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

Opus™ Strip cannot be 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™ Strip. 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, thrombophlebitis, 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 pseudoarthrosis. These complications may require re-grafting or revision. In addition, in some instances Opus™ Strip 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™ Strip 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™ Strip 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™ Strip to be used based on the size or volume of the defect to be filled.
2. Aspirate bone marrow to matrix on an estimated 1:1 basis (e.g., use approximately 8-10 mL bone marrow for each Opus™ Strip).
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™ Strip with bone marrow just prior to implantation-NOTE: Hydration should require less than 1 minute.
6. Gently pack the defect maintaining the structure of Opus™ Strip and the saturated bone marrow aspirate.
7. If irrigation is used, it must be performed prior to placement of Opus™ Strip.

HOW SUPPLIED

Each unit of Opus™ Strip contains single or multiple strips (2 cm x 6.25 cm x 0.8 cm) and is approximately 10cc in volume. Opus™ Strip is provided in a sterile, double peel-pouch.

Opus™ Strip is sterile, non-pyrogenic, and for one time use only.

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
	Sterilized using irradiation
	Lot number
R_x Only	Federal (USA) law restricts this device to sale by or on the order of a physician or dentist
	Reference number
	Temperature Limitation
	Manufacturer



Manufacturer:

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

Distributed by:



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Lewisville, TX 75056 USA

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