# Opus™ Flex

Osteoconductive Scaffold

## INSTRUCTIONS FOR USE

## DEVICE DESCRIPTION

Opus™ Flex is a collagen mineral composite matrix processed into strips, pads, or granular form for surgical implantation. The principle components of Opus™ Flex 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 55% bone mineral and 45% collagen. Opus™ Flex is provided as a sterile, dry material that is hydrated with autogenous bone marrow at the point of use. Opus™ Flex can be cut into shapes and are designed to retain their shape and physical integrity following implantation into a bony site. Opus™ Flex is fully resorbed during the natural process of bone formation and remodeling.

## INDICATIONS

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

Opus™ Flex 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™ Flex 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™ Flex should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. Opus™ Flex 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.

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

Opus™ Flex 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™ Flex. 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™ Flex 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™ Flex 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™ Flex 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™ Flex to be used based on the size or volume of the defect to be filled.
2. For Opus™ Flex aspirate bone marrow to matrix on a 1:1 basis (e.g., use approximately 5 mL bone marrow for each 5 cc strips or pads).
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™ Flex with bone marrow just prior to implantation-NOTE: Hydration should require less than 1 minute.
6. For Opus™ Flex gently pack the defect maintaining the structure of Opus™ Flex and the saturated bone marrow aspirate.
7. If irrigation is used, it must be performed prior to placement of Opus™ Flex.

## HOW SUPPLIED

Each package of Opus™ Flex contains either two strips (2 cm x 5 cm x 0.5 cm, 5cc each), two pads (2 cm x 2 cm x 0.5 cm, 2cc each), or one pad (2 cm x 2 cm x 0.5 cm, 2 cc)

Each package of Opus™ Flex contains either 2 cc, 5 cc, or 10 cc granular material.

Opus™ Flex 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 |
| 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