DO NOT USE IF PACKAGE IS DAMAGED.

Explanation of Symbols

STERILE R

Sterilized by Radiation

Single Use Only

See Instructions for Use

Use by Date

℞ ONLY

Prescription Only

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

BIOSTRUCTURES®

1201 Dove Street
Suite 470
Newport Beach, CA 92660

ph: 949-553-1717
fx: 949-553-0407
www.biostructures.net

Part Number: 10-0052

SILHOUETTE™
Mineralized Collagen Strip
STRIP

SIL-045	Contents: 4.5 cc
SIL-090	Contents: 9 cc
SIL-180	Contents: 18 cc

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: MCS Bone Graft
Device Trade Name: Silhouette Mineralized Collagen Strip

Manufactured for: BioStructures, LLC,
1201 Dove Street, Suite 470
Newport Beach, CA 92660

B. Materials and Device Description

Silhouette is a resorbable bone void filler device comprised of biphasic mineral granulate suspended in a porous type I collagen matrix. The implant is designed to be hydrated with bone marrow aspirate prior to implantation to facilitate handling and placement in bony defects. Once implanted, the device provides an osteoconductive scaffold that is resorbed and replaced with host bone during the healing process.

C. Indications for Use

Silhouette is a bone void filler device intended for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Silhouette is indicated to be packed gently into bony voids or gaps of the skeletal system (i.e., extremities and pelvis) and is used mixed with bone marrow aspirate. Once implanted, the device resorbs and is replaced with host bone during the healing process.

D. Contraindications

Silhouette is not designed or sold for any use except as indicated. Do not use Silhouette in the presence of any contraindication. Silhouette is contraindicated where the device is intended as structural support in the skeletal system. Silhouette 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.
- Silhouette is intended for use by surgeons familiar with bone grafting procedures.
- Silhouette is not intended for load-bearing uses. The area where Silhouette is to be implanted must be mechanically secured with rigid fixation to strengthen the surroundings.
- The safety and effectiveness of Silhouette is unknown in patients with chronic pathological conditions, metabolic bone disease, in pregnant women, or children.
- Silhouette contains bovine collagen and must not be used in patients with a history of allergies to any bovine products.
- Silhouette 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 Silhouette 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.
- Silhouette 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 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. Secure the surgical site after implanting to prevent micro-motion and implant migration. If the material is not positioned satisfactorily, remove the implant and start over with a new package of Silhouette.

H. Storage Conditions

Silhouette should be stored in a secure, dry environment at ambient temperature. Do not expose to excessive heat. Optimal storage conditions 15-30°C (59-86°F).

I. Shelf Life and Disposal

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