**Collagraft® Bone Graft Matrix Strip**

**DESCRIPTION**
Collagraft® Bone Graft Matrix Strip (Collagraft® Strip) is a mixture of purified fibrillar collagen (PFC) and hydroxyapatite/tricalcium phosphate ceramic (HA/TCP), and is supplied sterile in a premixed strip form. Three package sizes are available. The large package contains three (3) Collagraft® Strips. The single package contains one (1) Collagraft® Strip. PFC is highly purified bovine collagen, purified bovine dermal collagen which is primarily (>95% percent) Type I collagen with a small amount (>5% percent) of Type III collagen. The HA/TCP, which is composed of approximately 65 percent hydroxyapatite (HA) and 35 percent beta tricalcium phosphate (TCP). Hydroxyapatite is a polycrystalline, radiopaque substance which is biocompatible and is minimally resorbed. The HA/TCP is radiopaque. In addition, it is biodegradable, and its degradation products can be reconstituted by the body to form new bone mineral allowing for bone deposition.

Collagraft® Strip is a premixed formulation of Collagraft® Bone Graft Matrix (Collagraft), which is supplied in ready to-mix kits (one package of HA/TCP and one syringe of PFC). Collagraft® and Collagraft® Strip are the subjects of Phase 1 and 2, respectively, of the Collagraft Implant Two-Year Multicenter Study. Phase 1 Collagraft® Implant Two-Year Multicenter Study was a two-year, randomized, investigator-initiated study to compare the safety and effectiveness of Collagraft® and autogenous bone grafting. Phase 2 (Collagraft® Strip) is a two-year open enrollment study to evaluate the safety and effectiveness of Collagraft® Strip.

**INDICATIONS**
Collagraft® Strip, when coagulated with autogenous bone marrow, is indicated for use in acute long bone fractures and traumatic osseous defects to provide a matrix for the repair process of bone. Collagraft® Strip treated fractures must be externally or internally fixed and the fracture defect treated should not be greater than 30mL.

Collagraft® Strip, when coagulated with autogenous bone marrow, is also indicated for use in bone voids or gaps that are not internal to the stability of the bone structure. Collagraft® Strip should be gently packed into bone voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to bone. No defect should be greater than 30mL. Collagraft® Strip provides a bone void filler that resorbs and is replaced with bone during the healing process.

**INSTRUCTIONS FOR USE**
Collagraft® Strips are provided in a tray in which the strips may be prepared prior to use. Not included, but required if bone marrow is obtained by aspiration, is a sterile syringe with needle.

1. **PREPARATIVE PROCEDURE**
In the case of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

2. **SURGICAL PROCEDURE**
All procedures should be performed in the operating room under aseptic conditions. Follow accepted procedures for grafting with fixation. Bone marrow may be obtained from the iliac crest, fracture, or other source. Use standard bone marrow collection techniques. Exercise care not to collect blood. If marrow from the fracture site is used, it is important that the marrow has not been contaminated. Using the tray provided, add sterile saline to the side holding the strips and allow them to hydrate for 1 to 2 minutes. Transfer strips to the side containing marrow and coat all surfaces of the strips with marrow. The strips may be used as is or molded into the desired shape. It is important to mold gently to avoid crushing the granules or damaging the marrow cells.

It is important to fill the defect as completely as possible. In the Collagraft Implant Two-Year Multicenter Study, the surgical time was found to be reduced to 20 minutes when using Collagraft® compared to autogenous bone grafting.

**CONTRAINDICATIONS**
As with any bone grafting procedure, Collagraft® Strip must not be used in patients with current osteomyelitis or open bone fractures.

Collagraft® Strip must not be used in patients with severe allergies manifested by a history of anaphylaxis, history of multiple severe allergies, or known allergies against bovine collagen.

Collagraft® Strip must not be used in patients known to be undergoing desensitization injections to meat products, as these injections can contain bovine collagen.

Conditions representing relative contraindications include severe vascular or neurological disease, uncontrollable diabetes, severe degenerative bone disease, pregnancy, uncooperative patients who will not or do not follow postoperative instructions, including individuals who abuse drugs and/or alcohol, and hypercalcemia.

**WARNINGS**
As with all surgical procedures, caution should be exercised when treating individuals with bleeding diatheses of any etiology and in individuals receiving anticoagulants, nonsteroidal anti-inflammatory therapy, drugs containing aspirin, long term steroid therapy, or immunosuppressive therapy. Collagraft® Strip should not be used in patients with infections or contamination at the implant site, clothing disorders, fractures of the ephypophysis plate, or significant vascular impairment proximal to the graft site. Collagraft® Strip is intended for use by surgeons familiar with bone grafting and rigid fixation techniques. Complete postoperative wound closure is essential.

Collagraft® Strip should not be used in patients with an incomplete fracture or bone cyst, a pathological fracture secondary to malignancy, a delayed union or nonunion of the fracture site, or an open Type III B or C bone fracture, i.e., a either a severe open segmental fracture or an open fracture with extensive soft tissue damage unless the fracture can be converted to a Type III A or Type II fracture. No defect should be greater than 30mL.

**ADVERSE EFFECTS**
Nearly all patients treated with bone marrow containing collagen products, including but not limited to collagen, have some degree of hypersensitivity response. Therefore, the possibility of developing a hypersensitivity response exists.

There have been reports from in vivo and in vitro studies that microfibrillar collagen used to arrest bone healing during surgery may pass through filtration filters. 10-11 Although Collagraft® Strip contains collagen, no data exist regarding concurrent use with blood saving devices. As the effects are unknown, it is recommended that caution always be exercised with concurrent or postoperative use of autotransfusion devices with Collagraft®. For additional information, labeling and/or package inserts for autotransfusion devices should be consulted.

**PRECAUTIONS**
The safety and effectiveness of Collagraft® Strip have not been established in patients with pathological fractures caused by seve microwave bone disease, pre-existing severe vascular or neurological disease. The affected limb as a result of uncontrollable diabetes, alcoholism, or other pathology, or in patients with clinically significant immune mediated systemic disease, or diseases of bone. The safety and effectiveness have also not been established in pregnant women or in children.

There are no data with respect to treating cartilaginous joint fractures, use in treating individual defects greater than 30mL, or a total use of greater than 42mL of Collagraft® in one patient.

Clinical evidence of hypersensitivity reactions to Collagraft® Strip was not observed in the two-year clinical study. Hypersensitivity reactions consisting of erythema, swelling, induration, and/or urticaaria at implantation sites have been reported with use of other products containing bovine collagen; therefore, the possibility of developing a hypersensitivity response exists.

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**REFERENCES**
Collagraft® is a registered trademark of Zimmer, Inc. © 2003, 2007 Zimmer, Inc.

**STORAGE**
Do not freeze or expose to extreme heat, such as steam autoclaving. DO NOT RESTERILIZE.

Collagraft® Strip should be stored at controlled room temperature conditions between 15° and 30°C (59° and 86°F). Store container in its original unopened package in a dry place.

In the event that the package is damaged, do not use, as sterility cannot be assured.

**ADVERSE EFFECTS**

Collagraft® Strip and autogenous bone grafting (Phase 1) and an open enrollment study to evaluate the safety and effectiveness of Collagraft® Strip are identical to those encountered in autogenous bone grafting procedures and include superficial wound infection, deep wound infection with or without osteomyelitis, wound dehiscence, delayed union, malunion, or nonunion, loss of reduction, refracture, cyst recurrence, heterotoma, cellulitis, and reoperation and/or implant removal.


**STORAGE**
Do not freeze or expose to extreme heat, such as steam autoclaving. DO NOT RESTERILIZE.

Collagraft® Strip should be stored at controlled room temperature conditions between 15° and 30°C (59° and 86°F).

Contact your Zimmer representative or visit us at www.zimmer.com

**CONTACT**
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AUTOGRAFT

... the standard for rapid healing and successful fusion,
... but availability is limited, and harvesting has risks and complications.

ALLOGRAFT

... solves the problems of availability and harvesting,
... but fusion rates are variable, healing can be delayed and there is a potential for viral transmission.

COLLAGRAFT

... is clinically proven to provide healing and fusion rates equivalent to autograft.
... is readily available – with consistent quality.
... eliminates donor site morbidity problems.
... eliminates the risk of viral transmission that can be associated with allograft bone.
Collagraft
Bone Graft Matrix

- Clinically proven equivalent in efficacy to autograft when used in treatment of acute long bone fractures.
- Osteoconductive and osteoinductive when used with bone marrow.
- 7 years of successful clinical experience.
- Dependable product quality eliminates allograft safety and consistency concerns.
- Autograft harvest site morbidity eliminated.
- Now indicated for use in extremities, spine, and pelvis.3

1. 400 Patient randomized, prospective, multi-center clinical trial. Data on file at Zimmer, Inc.
3. Collagraft Strip, when coated with autogenous bone marrow, is also indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. Collagraft Strip should be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to bone. No defect should be greater than 30mL. Collagraft Strip provides a bone void filler that resorbs and is replaced with bone during the healing process.
INSTRUCTIONS FOR USE

STEP ONE
Aspirate marrow or obtain locally.

STEP TWO
Using the divided tray provided, add sterile saline to the side holding the strips and allow them to hydrate for 1-3 minutes.

STEP THREE
Add the appropriate amount of bone marrow to the opposite side of the tray.

STEP FOUR
Transfer each of the strips to the side containing marrow and coat all surfaces of the strips with marrow.

STEP FIVE
Ready for use. The strips may be used as is or molded into the desired shape.