



**Zimmer®
Foot and Ankle
Solutions**



In step with standards of care



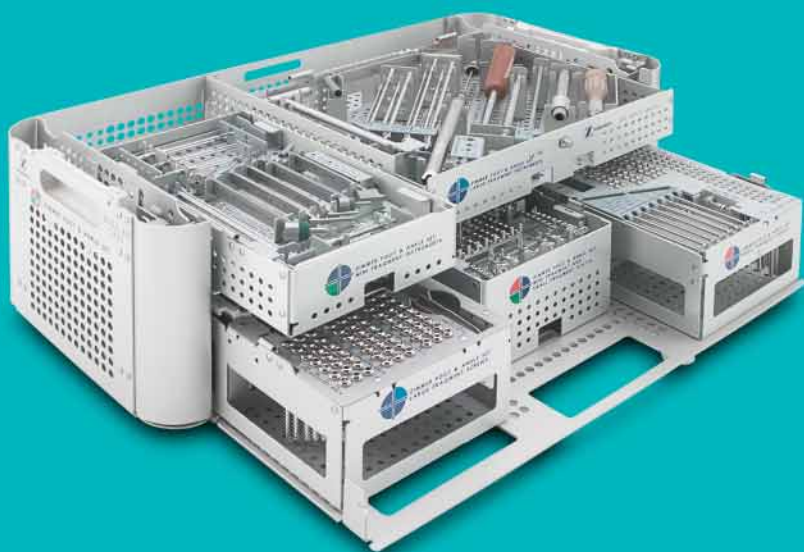


The Standard For

Care

Improving Order in the OR

In today's operating room the name Zimmer represents the very best in foot and ankle solutions. Surgeons around the world turn to Zimmer to help them stabilize damaged bone and support the natural healing process. And, when it comes to simplifying organization in the OR and delivering a comprehensive choice of products to match any surgical procedure, Zimmer sets the standard.



The Standard For

Zimmer® Foot & Ankle Solutions

The *Zimmer* Plates and Screws Foot & Ankle System offers complete implant and instrument portfolios in sterilization cases featuring unequalled convenience, storage, and flexibility.

This Foot & Ankle System eliminates the need for a large number of plate, screw, and instrument sets to be brought into the OR. These products are condensed into modules designed for the specific needs of the foot and ankle surgeon. And because the system is modular, the base case can be customized by procedure type, surgery schedule, and other unique clinical demands simply by changing the modules.

Choice





The Standard For





Design

Zimmer® Periarticular Plating System

The design of the *Zimmer* Periarticular Plating System offers surgeons a number of anatomic plate choices: two distal tibial plates, two distal fibular plates, and a calcaneal plate. This system gives surgeons the ability to fix most periarticular fractures with pre-contoured plates that closely follow the shape of the bone. A fit is created that requires little or no bending and shaping like conventional plates. And, because *Zimmer* Periarticular Plates are thinner near the joint line and feature low-profile bone screws, soft tissue irritation is minimized.



The Standard For

StayFuse® Inter-Digital Fusion System

The *StayFuse* System is a two-piece screw device designed to stabilize and hold small bones in alignment during the healing process. The system is indicated as a replacement for the 1.1mm K-wire used during fusion or fracture fixation of small bones. Made of biocompatible titanium, the *StayFuse* device helps eliminate “pin tract” infection and healthy joint disruption and comes in a variety of diameters and lengths necessary for proper anatomical fit. The Hex-Lok feature is uniquely designed to control rotation, and improve system performance and chances for a successful clinical outcome.



Fusion



The Standard For





Stability

Zimmer® Locking Blade Plate

The *Zimmer* Locking Blade Plating System offers surgeons a range of blade length options to deliver maximum bone contact for differing fracture patterns.

The 90- and 95-degree fracture system offers an innovative locking design for improved axial load support and increased torsional stiffness to comparable devices.

In addition, the system's fully threaded strut screw provides maximum bone contact for a stiffer, triangular construct.



The Standard For

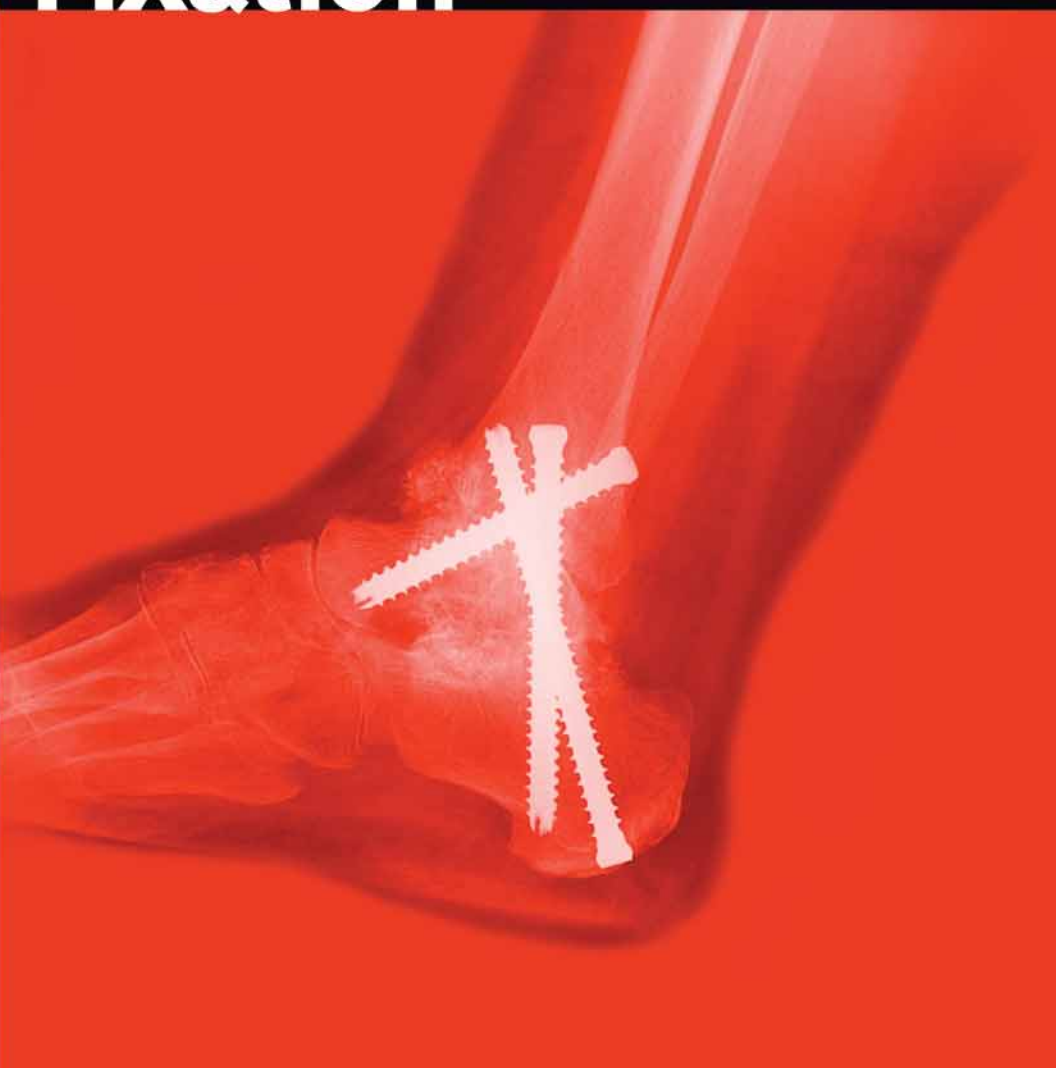
Zimmer® Cannulated Screw System

The *Zimmer* Cannulated Screw System is designed to address most clinical situations and place intraoperative solutions in the surgeon's hands. The system's minimally invasive instrumentation and surgical technique help minimize additional trauma through percutaneous guides and small incisions. Partially threaded and fully threaded designs in a comprehensive range of sizes allow the surgeon to cover the spectrum of applications. *dur*® 108 Alloy allows the *Zimmer* Cannulated Screw System to feature a larger cannula without compromising screw strength. The larger cannula accommodates a larger/stiffer guide wire for greater accuracy in screw placement.

* Trademark of Carpenter Technology Corporation



Fixation





The Standard For

TransFx™ External Fixation System

The *Zimmer TransFx* External Fixation System is a modular system that provides complete physician choice in frame construction, simplicity in frame components, and ease of transition in frame sizes, based upon anatomy and fracture type. The system's innovative clamp design offers choice and control in frame construction. Simple unilateral frames to complex modular frames are easily constructed for stabilization of long bone fractures. In addition, transitioning in dimensional planes is simplified through a comprehensive offering of single and multi-pin clamps, pins, and carbon fiber rods.

Simplicity



The Standard For





Compression

Herbert™ Cannulated Bone Screw System

Developed by Dr. Timothy Herbert, the original *Herbert* Cannulated Bone Screw offers management of fractures where minimal tissue coverage makes standard screw use inappropriate or where extreme precision in fragment alignment is imperative. The headless design of the *Herbert* Screw means that the screw is completely embedded in the bone, without any protrusions to cause tissue irritation even in intra-articular placement. Guide pins hold fracture fragments and act as drill, tap, and screw guides to insure accurate placement. As the proximal threads of the screw engage the bone, the fracture is drawn together, helping to create and maintain stability.



The Standard For

Collagraft® Bone Graft Matrix

The *Collagraft* Matrix is clinically proven to provide healing and fusion rates equivalent to autograft¹, but without harvesting risks. A combination of highly purified Type 1 bovine dermal fibrillar collagen and approximately 65% hydroxyapatite and 35% tricalcium phosphate, *Collagraft* Matrix has excellent biocompatibility and closely resembles natural bone. Unlike autograft, *Collagraft* Matrix is readily available and eliminates donor site morbidity problems. It also eliminates the risk of viral transmission that can be associated with allograft bone.

1. 400 Patient randomized, prospective, multi-center clinical trial. Data on file at Zimmer, Inc.



Healing

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 six (6) *Collagraft* Strips. The small package contains three (3) *Collagraft* Strips. The single package contains one (1) *Collagraft* Strip. PFC is highly purified bioresorbable lyophilized bovine dermal collagen which is primarily (>95 percent) Type I collagen with a small amount (<5 percent) of Type III collagen. The HA/TCP is composed of approximately 65 percent hydroxyapatite (HA) and 35 percent beta-tricalciumphosphate (TCP). Hydroxyapatite is a polycrystalline, radiopaque substance which is biocompatible and is minimally resorbed. Tricalcium phosphate is also radiopaque and biocompatible. 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.¹ Phase 1 (*Collagraft*) is a two-year prospective, randomized 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 coated 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 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

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. PREOPERATIVE 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 sites, using 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 provide, add sterile saline to the side holding the strip(s) and allow them to hydrate for 1 to 3 minutes. To the opposite side of the tray add 1mL of bone marrow for 1-3 strip(s), 2mL for 4-6 strip(s), 3mL for 7-9 strip(s), or 4mL for 10-12 strip(s). After hydration, transfer each of the strip(s) to the side containing marrow and coat all surfaces of the strip(s) with marrow. The strip(s) 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 by 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 at the operative site.

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, uncontrolled diabetes, severe degenerative bone disease, pregnancy, uncooperative patients who will not or cannot 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 steroidal therapy, or immunosuppressive therapy. *Collagraft* Strip should not be used in patients with infections or contamination at the implant site, clotting disorders, fractures of the epiphyseal 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., 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. Type III implies there is crushed devitalized muscle in the wound.

Collagraft Strip should not be used in patients with a simple fracture such as a nondisplaced transverse fracture that would heal without operative reductions or surgical intervention, or when the interval from injury to bone grafting and/or operative reduction is more than 30 days.

Although hypersensitivity reactions to *Collagraft* Strip were not observed in the two-year clinical study, it is possible that additional complications may occur in patients with a history of allergies to any bovine, or theoretically, porcine or human, collagen product, including but not limited to collagen injectables, collagen implants, hemostatic sponges, and collagen-based sutures, because these patients are likely to have hypersensitivity to *Collagraft* Strip.

Some physicians have reported the occurrence of connective tissue diseases such as rheumatoid arthritis, systemic lupus erythematosus, polymyositis (PM), and dermatomyositis (DM) subsequent to intradermal collagen injections in patients with no previous history of these disorders. Conflicting studies have been published^{2,3} in peer reviewed journals regarding the association between PM/DM and injectable collagen. A causal relationship between collagen injections and the onset of PM/DM, or the other connective tissue diseases listed, has not been established.

Also, an increased incidence of cell-mediated and humoral immunity to various collagens has been found in systemic connective tissue diseases such as rheumatoid arthritis, juvenile rheumatoid arthritis, and progressive systemic sclerosis (scleroderma).⁴⁻⁹ Patients with these diseases may thus have an increased susceptibility to hypersensitivity responses and/or accelerated clearance of their implants when implanted with bovine dermal collagen preparations.

PRECAUTIONS

The safety and effectiveness of *Collagraft* Strip have not been established in patients with pathological fractures caused by severe degenerative bone disease, pre-existing severe vascular or neurological disease in the affected limb as a result of uncontrolled 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 38mL 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 urticaria at implantation sites have been noted with the use of other products containing bovine collagen; 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 bleeding during surgery may pass through transfusion filters.^{10,11} When collected and reinfused, blood contaminated with microfibrillar collagen has been associated with platelet aggregation leading to embolization.^{10,11} It has also been reported that the potential risk associated with collagen particulates being reintroduced into the vasculature can be significantly reduced by use of certain, currently available blood-transfusion filters.¹²

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.

ADVERSE EFFECTS

FRACTURE/DONOR SITE COMPLICATION PROFILE AS REPORTED IN THE COLLAGRAFT IMPLANT TWO-YEAR MULTICENTER STUDY

Complication Category	<i>Collagraft</i> Strip ^a		<i>Collagraft</i> ^b		Autogenous ^b	
	n	(%) ^d	n	(%) ^d	n	(%) ^d
Infection (Overall) ^{c,e}	6	(5.6)	9	(4.9)	24	(14.2)
• Fracture Site Infection ^{c,e}	6	(5.6)	9	(4.9)	22	(13.0)
• Iliac Crest Infection	0	(0.0)	0	(0.0)	2	(1.2)
Nonunion	5	(4.7)	9	(4.9)	9	(5.3)
Other ^e	5	(4.7)	10	(5.5)	5	(3.0)
Loss of Fixation	2	(1.9)	6	(3.3)	3	(1.8)
Hematoma	1	(0.9)	1	(0.6)	2	(1.2)
Neurological Complication	1	(0.9)	2	(1.1)	3	(1.8)
Fracture	1	(0.9)	5	(2.7)	2	(1.2)
Deformity	2	(1.9)	4	(2.2)	10	(5.9)
Delayed Union	0	(0.0)	5	(2.7)	9	(5.3)
Wound Drainage	0	(0.0)	1	(0.6)	3	(1.8)
Total Number of Complications	23	(21.5)	52	(28.4)	70	(41.4)
Total Number of Fractures in Study	107		183		169	

^a The data presented for *Collagraft* Strip is from Phase 2 of the *Collagraft* Implant Two-Year Multicenter Study.

^b The data presented for *Collagraft* Paste (an early, two-component version that was mixed at the time of use) and the autogenous group is two-year data from Phase 1 of the *Collagraft* Implant Two-Year Multicenter Study.

^c The *Collagraft* group had a statistically significant lower infection rate than the group treated with autogenous bone.

^d Percent of complication category is based on total number of fractures in study by treatment groups.

^e Three fractures treated with autogenous bone graft had six complications categorized as "Fracture Site Infection," and one fracture treated with *Collagraft* had two complications categorized as "Other."

The table above lists complications reported in the *Collagraft* Implant Multicenter Study, which was comprised of a prospective, randomized clinical study to compare the safety and effectiveness of *Collagraft* Paste and autogenous bone grafting (Phase 1)^{1,13} and an open enrollment study to evaluate the safety and effectiveness of *Collagraft* Strip (Phase 2).

The complications classified in the table as "Other" include: degenerative joint disease, cellulitis, wound dehiscence, loose hardware, synovitis, posttraumatic arthritis, odor, pain, and fixation device pain. In addition, as with other orthopedic surgical and grafting procedures, the following complications may occur: total resorption of the graft, malunion, pseudoarthrosis, hypersensitivity, bleeding at the bone marrow aspiration site, thrombophlebitis, embolus, and limb length discrepancies.

The potential complications associated with the use 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, hematoma, cellulitis, and reoperation and/or implant removal.

To report an adverse reaction to *Collagraft* Bone Graft Matrix Strip, phone NeuColl, Inc., at 408/583-3000.

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).

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

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

REFERENCES

1-13 Available upon request. Data on file at Zimmer.

NeuColl is a trademark of NeuColl, Inc.

Collagraft is a registered trademark of Zimmer, Inc.

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

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