

SURGICAL TECHNIQUE

AUGMENT[®]

Bone Graft

THE **FIRST** AND **ONLY**
PROVEN ALTERNATIVE TO
AUTOGRAFT IN ANKLE AND
HINDFOOT ARTHRODESIS



The Time Has Come to Augment Your Fusion.

AUGMENT® Bone Graft is the only **proven** alternative to autograft in ankle and hindfoot arthrodesis.

Proven

Level 1 evidence of safety and effectiveness as a replacement to autograft in the largest F&A clinical trial ever conducted

Unique

The only biologic product specifically engineered, proven, and approved for hindfoot and ankle fusions

Labeled

Class III combination product specifically proven in, and labeled for, hindfoot and ankle arthrodesis via a rigorous PMA regulatory pathway

Safe

Proven safe through multiple clinical trials and successful commercial use since 2009 in Canada and 2011 in Australia and New Zealand, while eliminating the proven risks, morbidities, and costs associated with autograft harvest



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Wright recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on wmt.com under the link for Prescribing Information.

Please contact your local Wright representative for product availability.

AUGMENT® Bone Graft is a bioengineered and proven alternative to autograft in ankle and hindfoot fusions.

The product consists of two primary components:

- » β -TCP granules (1000-2000 μm)
- » rhPDGF-BB solution (0.3 mg/mL)

At the point of use, the two components are combined, mixed and subsequently applied to the surgical site. The β -TCP component of AUGMENT® Bone Graft provides a porous, osteoconductive scaffold to support cell attachment and delivery of the rhPDGF-BB molecule. AUGMENT® Bone Graft is designed for use in open orthopedic surgical procedures.

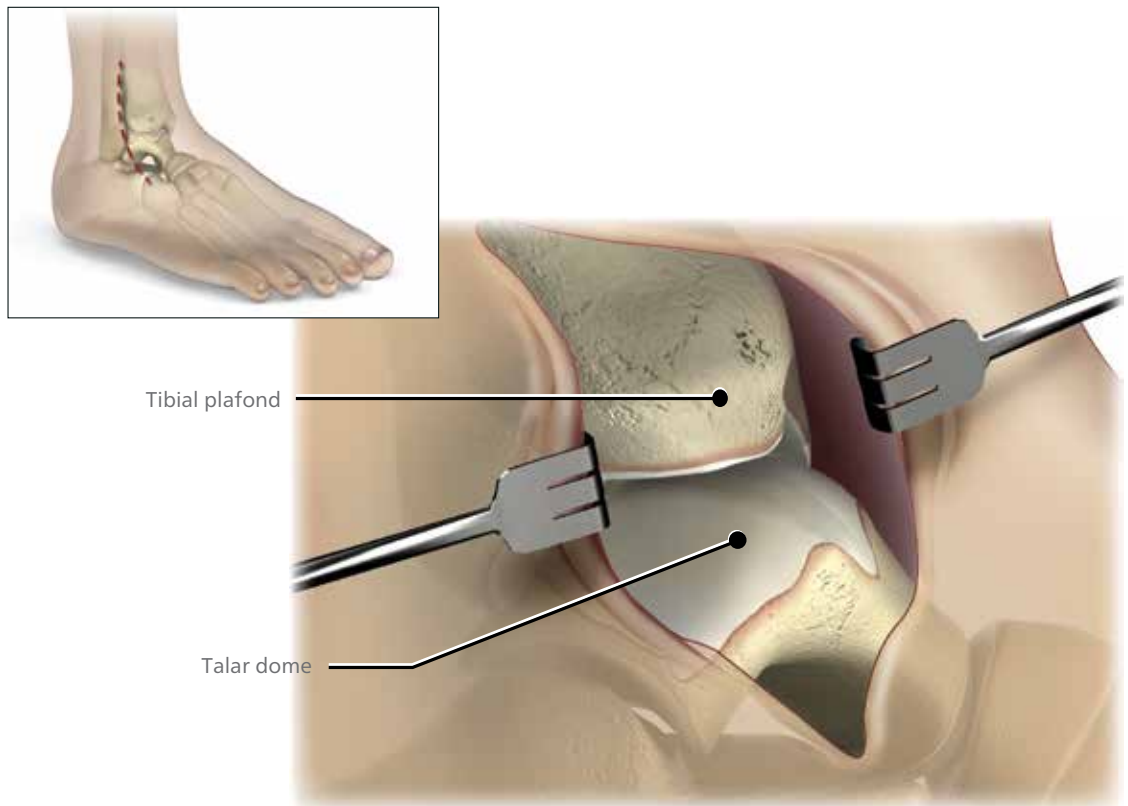
AUGMENT® Bone Graft was evaluated in a prospective, randomized, controlled, multi-center clinical trial to compare its safety and effectiveness as an alternative to autogenous bone graft in tibiotalar, talocalcaneal, talonavicular, and calcaneocuboid arthrodesis procedures.¹ The study was conducted in medical centers located in the United States and Canada. This document illustrates the general surgical technique used in this trial. This document is for informational and educational use only, and is not intended as medical advice. The information contained within this document should not substitute your own professional judgment when choosing the course of treatment for a particular individual.



Step 1 - Expose Joint

Fully expose the joint to be fused using standard surgical techniques.

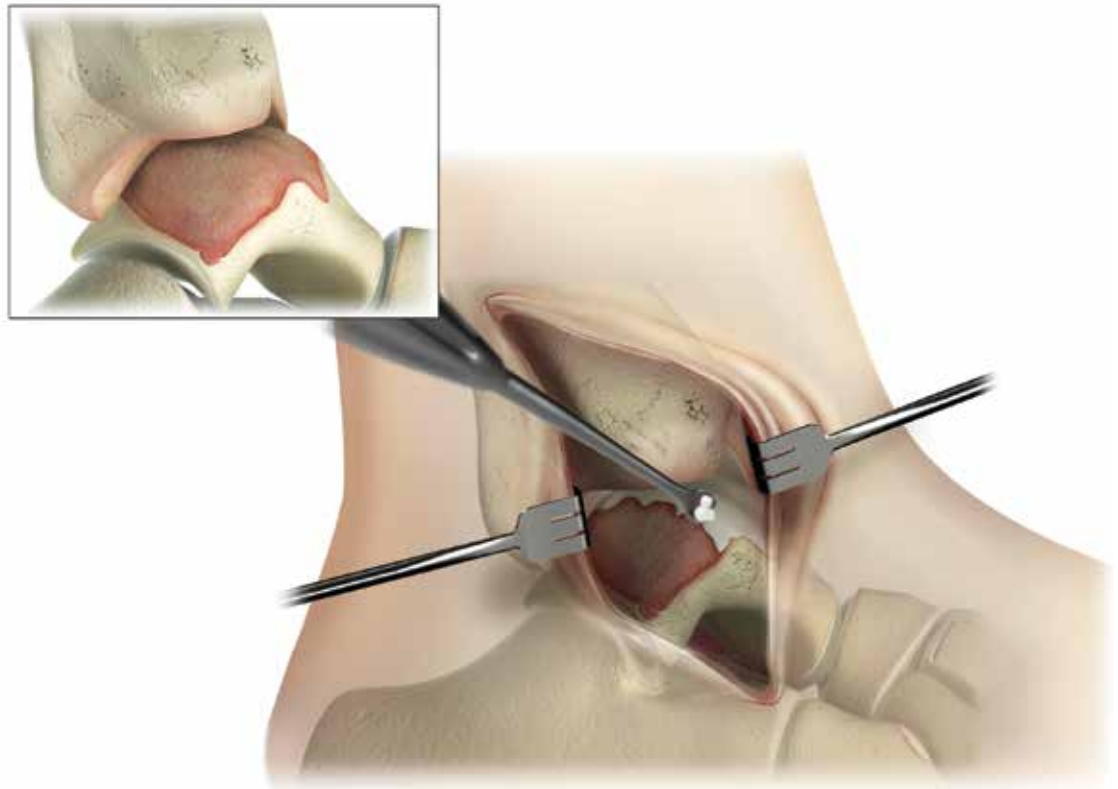
NOTE: The ankle joint (tibiotalar) is shown in this example. Talocalcaneal, talonavicular, and calcaneocuboid arthrodesis procedures were also performed in the AUGMENT® Bone Graft clinical trial.¹



Step 2 - Preparation of the Joint(s): Debridement

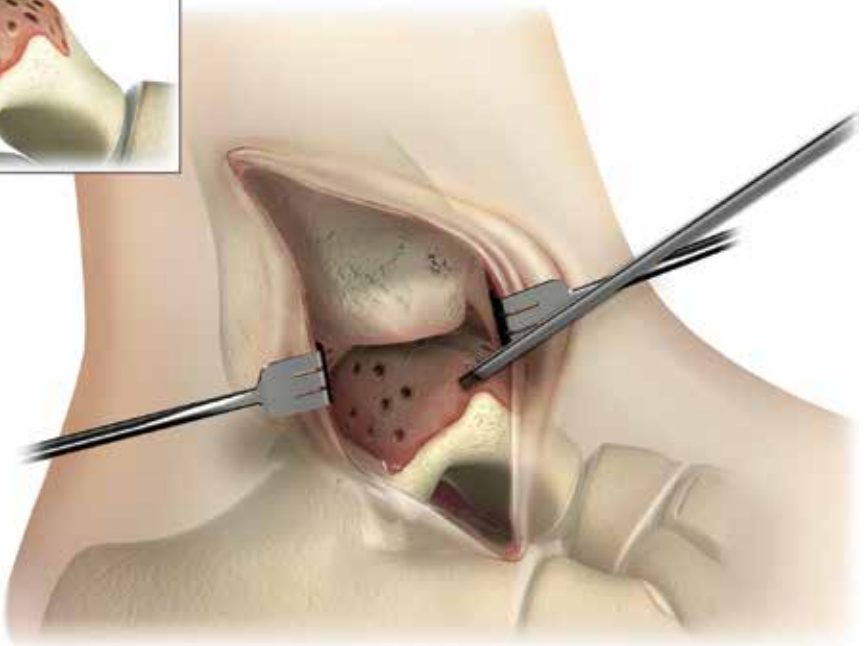
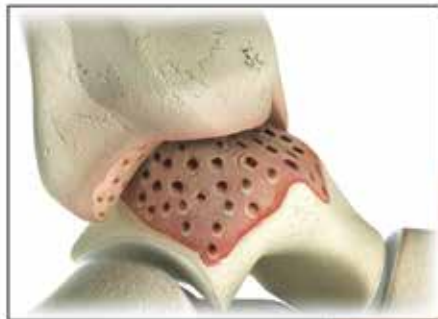
In standard fashion for arthrodesis surgery, debride and denude all articular surfaces by exposing viable host bone and decorticating these surfaces. This will maximize an osseous healing response. Following exposure of the joint(s) intended for arthrodesis, all remaining cartilage should be removed. The opposing bony surfaces should be adequately prepared to optimize the osseous healing response and allow apposition of healthy, vascularized bone.

Debridement should be performed by feathering and/or perforating the subchondral plate of all exposed articular surfaces intended for arthrodesis. This can be accomplished by using any standard technique and preferred combination of curettes, burrs, drill bits, and/or osteotomes as a means of maximizing the surface area of exposed bleeding bone (see steps 2A and 2B).



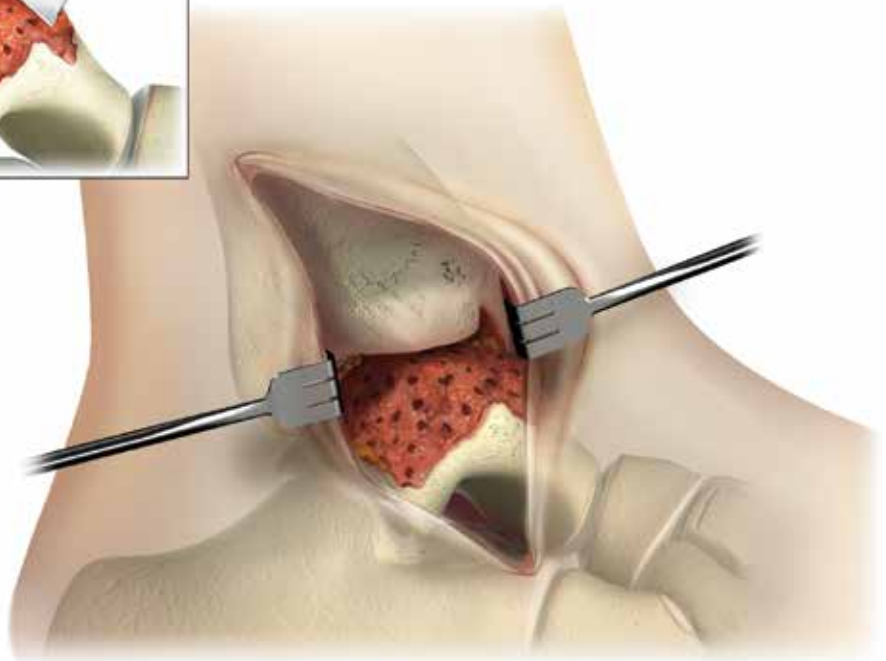
Step 2A - Perforation

Some surgeons may prefer to perforate the cortical bone with drilling prior to placement of the AUGMENT® Bone Graft material. Drilling of the bone surface helps to create a bleeding bone environment to promote fusion.



Step 2B - Feathering

Alternatively, other surgeons may choose to create subchondral exposure by using a burr, osteotome and/or curette to roughen and “feather” the joint surface to maximize the surface area of bleeding bone. It does not matter which method is chosen (2A or 2B), as long as one of these two joint preparation techniques is employed subsequent to denuding all remaining joint cartilage and prior to implantation of any AUGMENT® Bone Graft.



TIP: In more severe deformities, portions of the talar head may need to be resected to reduce the deformity and create a good bone-on-bone interface.

Step 3 - Application of Graft Material

Irrigate and then remove all fluid from the surgical site one final time after joint preparation is complete and immediately prior to AUGMENT® Bone Graft implantation.

Assess the fusion site. Determine where all the bony defects (e.g., subchondral voids and surface irregularities) are which will need to be filled with AUGMENT® Bone Graft.

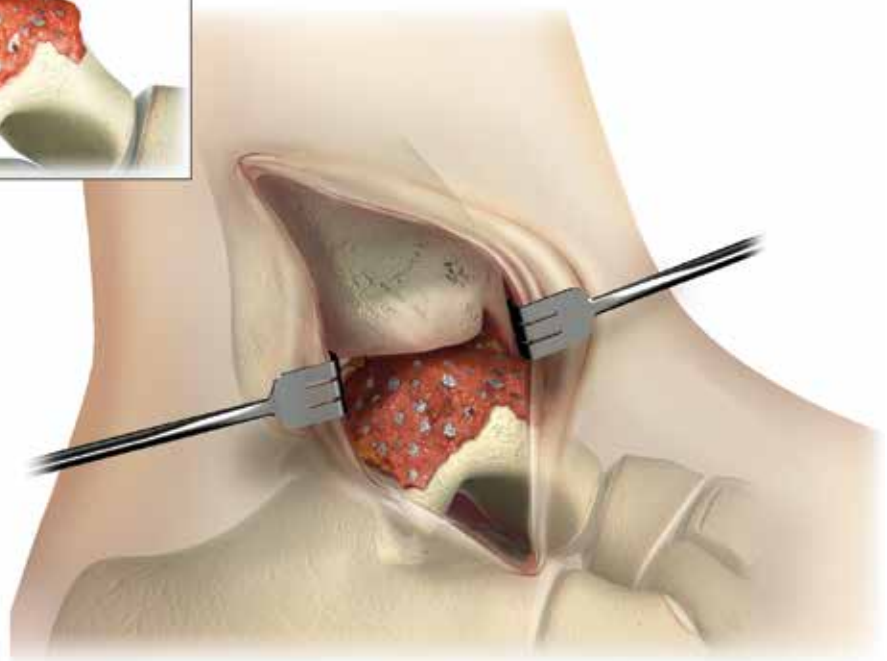
Manually pack AUGMENT® Bone Graft into, not around, all these bony defects throughout the joint(s) intended for arthrodesis. Be sure to place AUGMENT® Bone Graft wherever there is not direct host bone to host bone apposition.

Care should be taken to ensure that all AUGMENT® Bone Graft material is contained within the perimeter of these bony defects and that the graft remains saturated during the surgical procedure.

REMEMBER: It is important to ensure that all bony defects are grafted. Adequate graft fill is needed to optimize results with any grafting material.

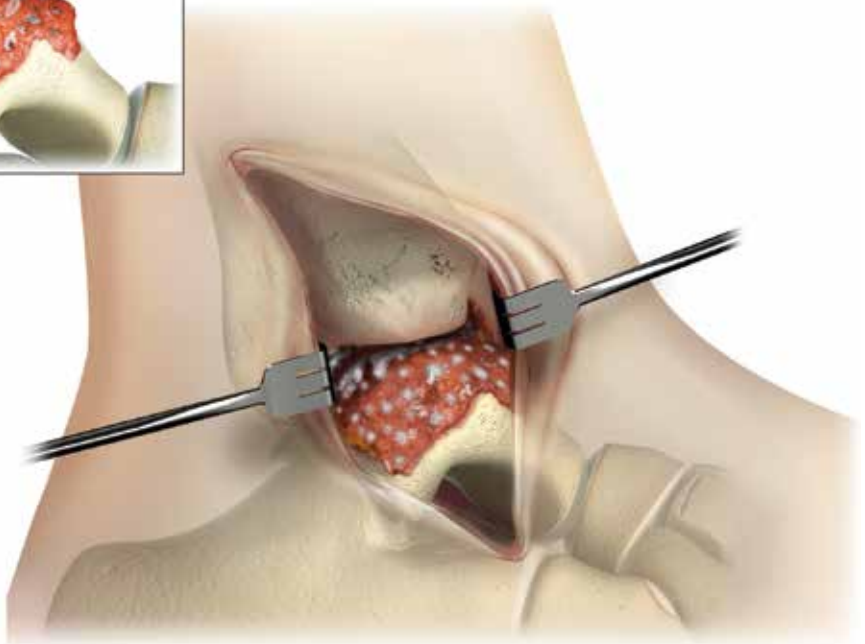


NOTE: Overfilling or “overstuffing” of the joint space with this material is unnecessary, and should be avoided, particularly to the extent that direct host bone to host bone apposition is prevented. In order to achieve adequate closure and containment of the material, however, it is imperative that the material be contained with a meticulous soft tissue and capsular closure. This will keep the material from the surrounding soft tissue, in order to achieve appropriate containment within the desired peri-articular site.



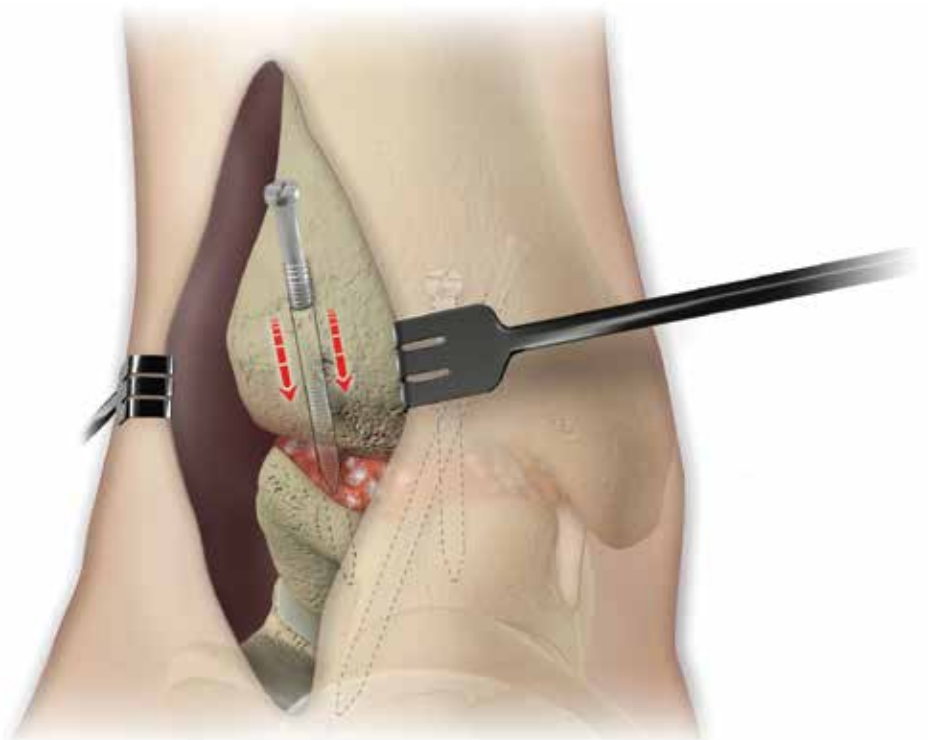
Step 4 - Hydration

Hydrate the implant site with any remaining rhPDGF-BB solution, if desired.



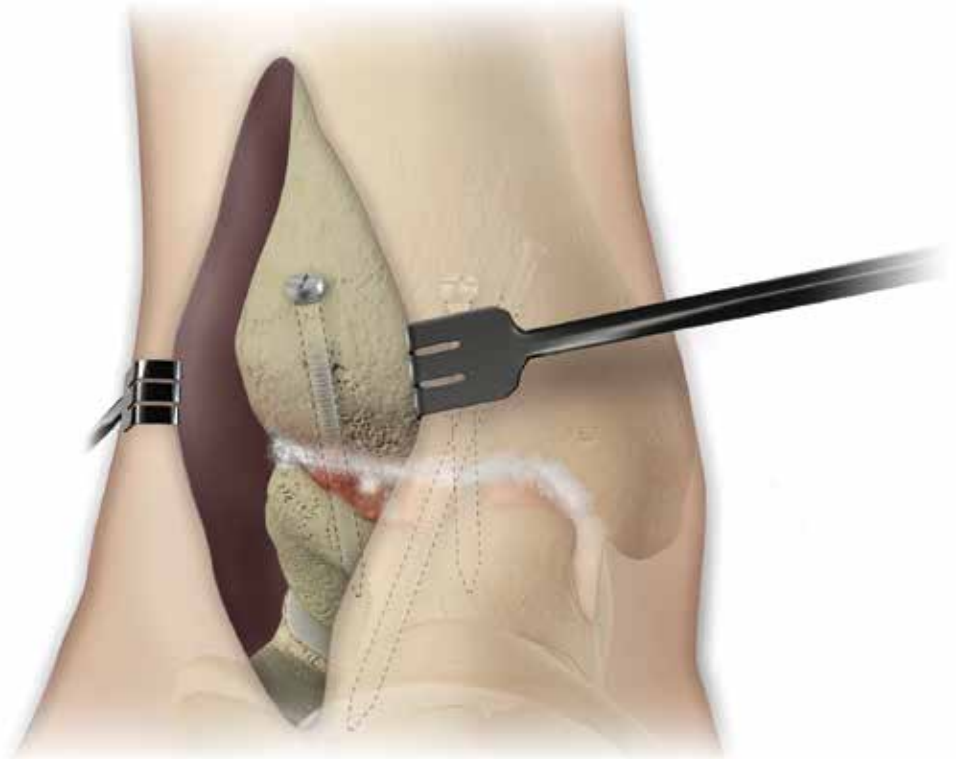
Step 5 - Fixation

Reduce the joint and apply rigid fixation.



Step 6 - Apply Remaining Material

Following satisfactory joint reduction and hardware fixation of the arthrodesis site(s), any remaining (unused) AUGMENT® Bone Graft should be packed around the external perimeter of the treated joint(s).



Step 7 - Closure

Following reduction and fixation, perform a carefully layered periosteal and capsular closure with the overlying soft tissues to enclose and contain all graft material in its intended joint spaces(s). Employ standard surgical technique to complete any remaining portion of the procedure.

Apply the self-adhesive labels that indicate the lot number of each device to the patient's permanent records and discard any remaining AUGMENT® Bone Graft.



NOTE:

Please see the full AUGMENT® Bone Graft Instructions for Use for more information regarding contraindications, warnings, precautions and storage instructions.

Notes

Lined area for notes with horizontal dashed lines.

Blank lined area for notes or data entry.

Brief Summary of Important Product Information

Indications for Use

AUGMENT® Bone Graft is indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material.

Contraindications

Augment® Bone Graft should not:

- » be used in patients who have a known hypersensitivity to any of the components of the product or are allergic to yeast-derived products.
- » be used in patients with active cancer.
- » be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of closure of epiphyses).
- » be used in pregnant women. The potential effects of rhPDGF-BB on the human fetus have not been evaluated.
- » be implanted in patients with an active infection at the operative site.
- » be used in situations where soft tissue coverage is not achievable.
- » be used in patients with metabolic disorders known to adversely affect the skeleton (e.g. renal osteodystrophy or hypercalcemia), other than primary osteoporosis or diabetes.
- » be used as a substitute for structural graft.

Warnings

As with all therapeutic recombinant proteins, there is a potential for immune responses to be generated to the rhPDGF-BB component of AUGMENT® Bone Graft. The immune response to rhPDGF-BB was evaluated in two pilot and one pivotal studies for ankle and hindfoot arthrodesis procedures. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to AUGMENT® Bone Graft with the incidence of antibodies to other products may be misleading.

Women of childbearing potential should avoid becoming pregnant for one year

following treatment with AUGMENT® Bone Graft. The implantation of rhPDGF-BB in women and the influence of their development of anti-PDGF-BB antibodies, with or without neutralizing activity, on human fetal development are not known.

The safety and effectiveness of AUGMENT® Bone Graft in nursing mothers has not been established. It is not known if rhPDGF-BB is excreted in human milk.

The safety and effectiveness of AUGMENT® Bone Graft has not been established in anatomical locations other than the ankle or hindfoot, or when combined with autologous bone or other bone grafting materials.

The safety and effectiveness of repeat applications of AUGMENT® Bone Graft have not been established.

The safety and effectiveness of AUGMENT® Bone Graft in pediatric patients below the age of 18 years have not been established.

AUGMENT® Bone Graft does not have any biomechanical strength and must be used in conjunction with standard orthopedic hardware to achieve rigid fixation.

The β -TCP component is radiopaque, which must be considered when evaluating radiographs for the assessment of bridging bone. The radiopacity may also mask underlying pathological conditions. Over time, the β -TCP is intended to be resorbed at the fusion site and replaced by new bone. Under such circumstances, it would typically be indistinguishable from surrounding bone.

1. DiGiovanni CW, et. al. Recombinant Human Platelet-Derived Growth Factor-BB and Beta-Tricalcium Phosphate (rhPDGF-BB/ β -TCP): An Alternative to Autogenous Bone Graft. *J Bone Joint Surg* 2013; 95-A(13): 1184-1192.

Part No.	Description	Volume
K20003010	AUGMENT® Bone Graft	3cc



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