stryker

Augment®

Satisfaction Guarantee

An unparalleled partnership in the pursuit of the best clinical outcomes

- Supported by the **only** level 1 evidence in hindfoot and ankle fusion
- Proven equivalent improvements in clinical outcomes, compared to the gold standard autograft[1]

Augment
Injectable

Augment
Bone Graft

Augment® Satisfaction Guarantee

Stryker will provide a replacement Augment® kit(s) to a facility where an on-label surgical procedure is performed using Augment® if the patient develops a nonunion at one or more of the hindfoot or ankle joints where Augment® was implanted and if the requirements of the Augment® Satisfaction Guarantee Terms and Conditions are fully satisfied.[2,3]

Brief summary of important product information

Indications for Use

Augment Bone Graft and Augment Injectable are 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 and Augment Injectable should not:

- be used in patients who have a known hypersensitivity to any of the components of the product or are allergic to bovine collagen Augment Injectable only) or 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 aspect 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 and Augment Injectable. The immune response to rhPDGF-BB was evaluated for Augment injectable in two studies, and for Augment Bone Graft (which contains the identical rhPDGF-BB) in two pilot and one pivotal study 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 oy 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 or Augment injectable 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 or Aligment Injectable. 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 efiectiveness of Augment Bone Graft or Augment Injectable 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 or Augment Injectable 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 or Augment Injectable have not been established.

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

Augment Bone Graft or Augment Injectable do not have any biomechanical strength and must be used in conjunction with standard orthopedic hardware to achieve rigid fixation.

The ß-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 ß-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.

Please refer to the full package insert for more information.

Part no.	Description	Volume
K30001510	Augment Injectable	1.5cc
K30003010	Augment Injectable	3.0cc
K20001510	Augment Bone Graft	1.5cc
K20003010	Augment Bone Graft	3.0cc

References:

1. DiGiovanni CW, et al. JBJS, 2013
2. The Augment® Satisfaction Guarantee Terms and Conditions are provided with Augment® Bone Graft kits shipped during the period for which the Augment® Satisfaction Guarantee is in effect.
3. The Augment satisfaction guarantee is only applicable to U.S. customers (continental United States, AK & HI). Please refer to the Augment satisfaction guarantee terms and conditions for further information.

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