Augment® Bone Graft: Worldwide Clinical Evidence

Many musculoskeletal problems, such as fractures, arthritis requiring arthrodesis, and non-unions require bone graft to ensure adequate bone healing. One of the most widely used options for bone graft, and the “gold standard”, is autologous bone due to the fact that there is no risk of cross contamination with autologous bone in contrast to allografts or xenografts. However, clinical difficulties have been associated with autograft. Most of these difficulties result from the harvest of the bone graft, including: increased operative time and hospital stay, resulting in increased costs; increased blood loss; post-operative pain; risk of infection and/or fracture. Other reported complications associated with autograft include a potential nidus for infection associated with avascular bone, limited tissue supply, and variability in cellular activity of the bone graft. In addition to these complications, limitation exists in the amount of bone graft that may be harvested. The harvest site morbidity associated with autograft and the often limited volume available for harvest has directed surgeons to seek safe and reliable alternatives to autograft.

Augment™ Bone Graft is a combination device/drug product developed as a synthetic bone graft for orthopaedic applications. Augment Bone Graft is provided as a single use kit containing the following components:

- β-TCP in granule form (nominal particle size 1000 to 2000 µm)
- rhPDGF-BB (0.3 mg/mL)

At time of surgery, the two components are mixed together in the β-TCP cup or a surgical bowl, allowed to hydrate and applied to the affected area. Augment Bone Graft is intended for use as an alternative to autograft in procedures where the use of supplemental bone graft is indicated for use in bony procedures to repair and regenerate bone and surrounding tissue.

Several clinical trials have been conducted throughout the United States, Canada, and Europe to establish the safety and effectiveness of the Augment Bone Graft device, which is currently approved for use in Canada, Australia, and New Zealand. FDA approval is pending. Augment Bone Graft is the only commercially available device with level 1 evidence demonstrated to be a safe and effective alternative to autograft in hindfoot and ankle fusions. The following is a summary of the clinical studies conducted assessing the safety and efficacy of the β-TCP/rhPDGF-BB combination product.
Key References


