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Augment®

Regenerative Solutions

Augment
Bone Graft

Augment
Injectable

Choosing the appropriate graft for **Hindfoot and Ankle Fusion Surgery**

With the myriad of bone graft options available and continuing to grow, it has become increasingly difficult for surgeons and hospitals to avoid confusion and maintain a clear understanding of the clinical value, specific features, benefits, and appropriate uses of available graft choices.

	Categorization	Characteristics	Regulatory pathway and clinical burden of proof	Examples
Recombinant growth factors	Proven alternative to autograft[1]	True biologic: Combination products with consistent, highly active signal proteins that drive bone regeneration[4]	Pre-market approval (PMA) Safety and efficacy in large pivotal clinical trial[5]	Augment Regenerative Solutions (rhPDGF-BB/ß-TCP) InFuse Bone Graft (rhBMP-2/ACS)
Allograft tissue	Bone void fillers[2]	Osteoconductive and weakly osteoinductive putties with variable handling Cell-containing products include various claims of cell viability at point of use	Human tissue products (361 HCT/Ps) – No proof needed[6] Devices containing human tissue (351 HCT/Ps—more than minimally manipulated)—510(k)[11]	BIO4, Allomatrix, DBX, Trinity Elite, Accell, Osteocel Plus, Grafton, Osteosponge, Fusionflex, Allograft chips, femoral head allograft, Allopure wedges
Synthetic scaffolds	Bone void fillers[3]	Passive osteoconduction and fills space	Synthetics—510(k)[7]	Pro-Dense, Osteoset, Vitoss BA, Hydroset XT, Norian Drillable Inject

1. Combination Growth Factor products composed of biologically active signals that promote chemotaxis, mitogenesis, angiogenesis, and/or osteoinductivity, rigorously reviewed by FDA and proven to be non-inferior to the Gold Standard, autograft in specific approved indications.
2. Void fillers with mineralized or demineralized bone, with or without cryopreserved cells from same donor intended for treatment of musculoskeletal defects.
3. Physical scaffolds composed of synthetic materials (e.g. calcium phosphate) intended to be used to fill bone voids.
4. Platelet-derived growth factor (rhPDGF-BB) and bone morphogenetic protein-2 (rhBMP-2) have been tested, reviewed and established as alternatives to autograft in multiple clinical studies for specific indications in foot & ankle (rhPDGF-BB only), spine/orthopaedic trauma (rhBMP-2 only) and dental (rhPDGF-BB & rhBMP-2).
5. Multiple clinical trials culminating in a large pivotal trial are typically required to prove that the combination device is both safe and efficacious in the specified indications.
6. Human tissues designated as 361 HCT/Ps are not regulated as medical devices and do not require a submission and/or review for commercialization. Tissue processors are required to register with FDA and follow Good Tissue Practices (GTP) per 21 CFR 1271.
7. A 510(k) clearance demonstrates that the device is substantially equivalent to a legally marketed device.

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This guide is intended to offer some perspective on how to better understand the three basic categories of commercially available bone graft products, and to offer a method of applying four simple, overarching questions that will allow you to make better informed purchasing decisions:

1 What is the evidence?

2 How was it approved?

3 How should it be used?

4 How does it work?

1 What is the evidence?

Augment is the first and **only** proven alternative to autograft in hindfoot and ankle arthrodesis.

- The role of PDGF in bone repair and regeneration is documented in over 20 peer-reviewed publications including three large-scale randomized, controlled clinical trials involving rhPDGF-BB.
- Level-I clinical data is considered the most reliable quality of data based upon standards for peer-reviewed evidence.

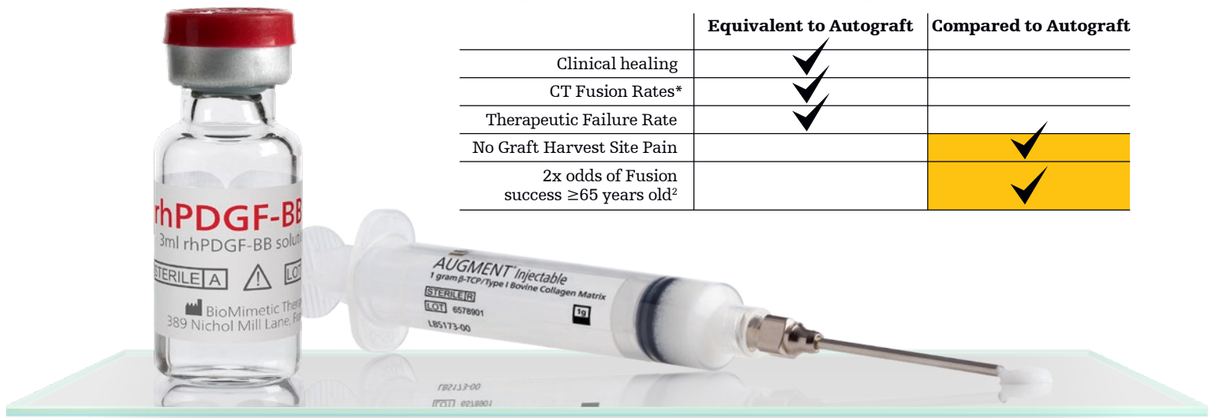
2 How was it approved?

Augment was approved via the rigorous PMA pathway by the U.S. FDA as a Class III combination medical device/drug product.

- The PMA application was supported by two pilot clinical trials, the largest prospective, randomized, controlled clinical trial in foot and ankle history, and numerous preclinical studies. The PMA supplement for Augment Injectable was supported by two additional randomized, controlled clinical trials.

Augment® vs. autograft results

	Equivalent to Autograft	Compared to Autograft
Clinical healing	✓	
CT Fusion Rates*	✓	
Therapeutic Failure Rate	✓	
No Graft Harvest Site Pain		✓
2x odds of Fusion success ≥65 years old[2]		✓



***FDA did not base its approval of Augment Bone Graft on radiologic findings from the pivotal study, but instead relied on clinical outcomes.**

3 How should it be used?

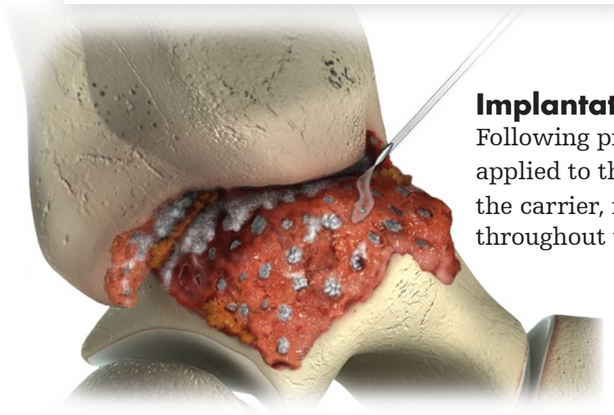
Among the criteria for which patients undergoing hindfoot and ankle arthrodesis should receive **Augment**, the following factors should be considered:

- In the randomized, controlled pivotal trial conducted to support U.S. FDA approval of Augment Bone Graft, 75% of the treated patients had one or more risk factors for non-union. Augment Bone Graft treated patients were found to have equivalent improvements in clinical outcomes and a better overall safety profile versus autograft (due to the elimination of harvest site pain and morbidity).[1,**]
- A natural deficiency in PDGF-BB has been found to be correlated with non-union and poor bone formation in clinical and pre-clinical studies involving subjects with diabetes, osteoporosis and smokers.[2,3,4]
- Unlike growth factors such as the bone morphogenetic proteins (BMPs), which lead solely to osteoblastic differentiation of cells at the implantation site, there are no reported incidences of ectopic bone formation.[5]

1. DiGiovanni CW, et al., JBJS (2013)
2. Verma, et al., Curr Orthop Pract (2011)
3. Hollinger, et al., JOR (2008)
4. Al-Zube, et al., J Orthop Res (2009)
5. Carragee EJ, et al., Spine J (2011)

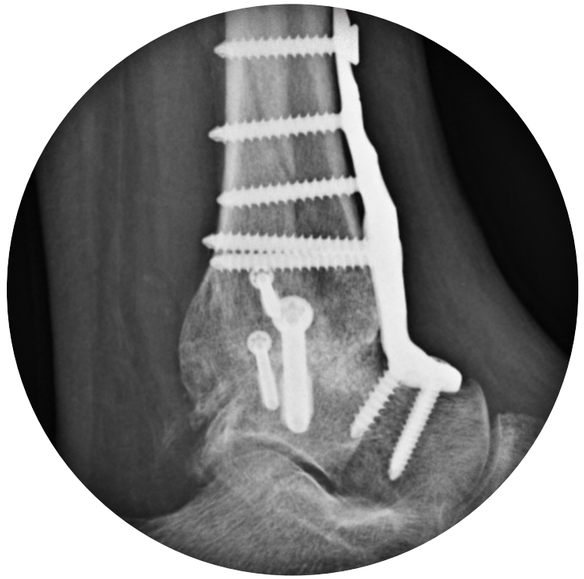
** A majority of patients studied in the two pivotal studies evaluating Augment Injectable also presented with one or more risk factors for non-union.

4 How does it work?



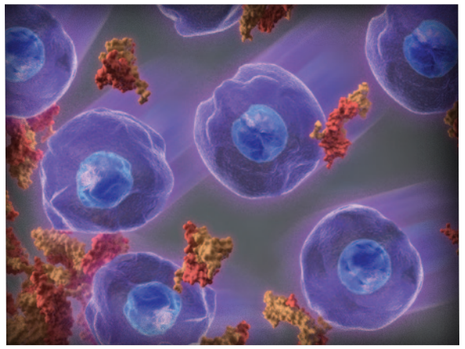
Implantation

Following preparation of the bony surfaces, Augment is applied to the fusion site. The rhPDGF-BB releases from the carrier, forming a concentration gradient as it migrates throughout the local environment.



Completion of the Bone Formation Process

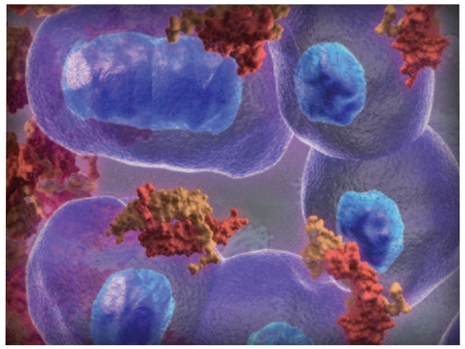
These mature osteoblasts will then lay down new bone to create a continuous scaffold, fusing the bony surfaces.



Chemotaxis

(cell movement)

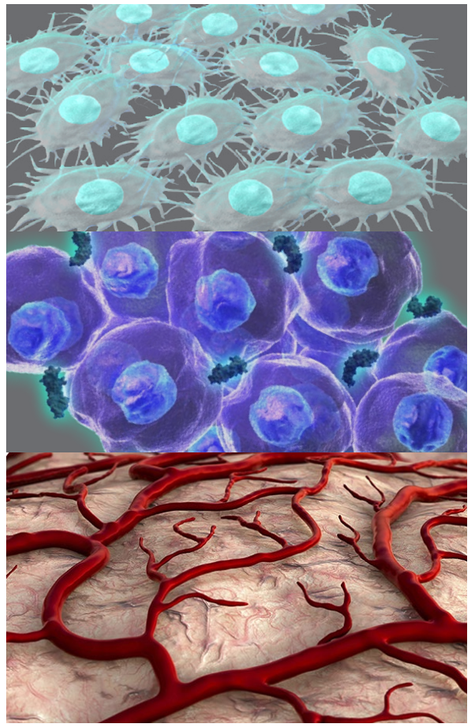
Mesenchymal Stem Cells (MSCs) are attracted to the fusion site by the increase concentration of rhPDGF-BB from bleeding bone, muscle and the periosteum.



Mitogenesis

(cell division)

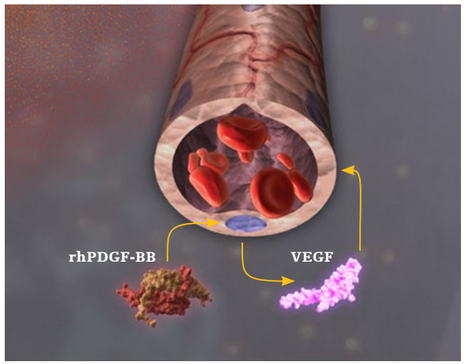
MSCs are stimulated to divide and proliferate in the presence of the higher concentration of rhPDGF-BB in the graft site.



Morphogenesis

(Cell Transformation)

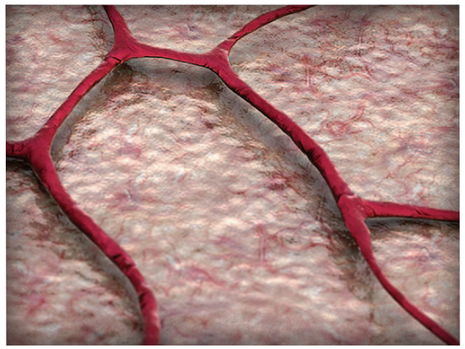
Once the colony of MSCs has divided repeatedly, native bone morphogenetic proteins (BMPs) induce MSCs to mature into osteoblasts.



Angiogenesis

(blood vessel formation)

In parallel with the effects of rhPDGF-BB in the bone formation cascade, the protein also promotes angiogenesis by increasing vascular endothelial cell, pericyte, and smooth muscle responses. Pericytes then synthesize VEGF, thereby enhancing the neovascular drive.



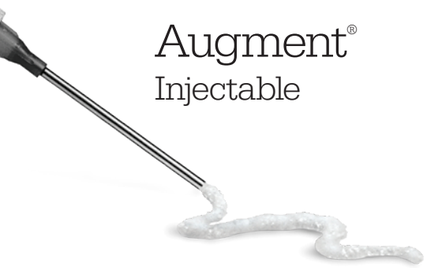
These newly formed blood vessels support the formation of bone by supplying oxygen and nutrients, carrying additional cells and signals to the healing environment, and eliminating local waste.

Competitive summary

	Augment	Infuse Bone Graft	DBM w/ allogenic cells	DBM	Allograft chips + BMA
Level I evidence demonstrating safe and effective use as alternative to autograft	✓	✓			
FDA approved for hindfoot and ankle fusions	✓				
MOA: Works early in healing cascade to impact multiple tissues involved in clinical healing (more than bone)	✓				
Consistent and reliable concentration, composition and activity	✓	✓			
Easy to administer/apply to surgical site	✓	✓		✓	
Off-the-shelf (minimal preparation required)	✓	✓		✓	
Regulatory classification	**Class III – PMA** **Required** safety and efficacy evidence required	**Class III – PMA** **Required** safety and efficacy evidence required	**HCT/P** (human tissue) for homologous use **No** safety or efficacy evidence required	**510k clearance** **No** clinical trials **HCT/P** (Human Tissue) for homologous use **No** safety or efficacy evidence required	**HCT/P** (human tissue) for homologous use **No** safety or efficacy evidence required

The same powerful protein **rhPDGF-BB**

Augment®
Injectable



- Carrier ß-TCP is 70-95% smaller than ß-TCP in Augment® Bone Graft
- ß-TCP is paired with collagen matrix to make flowable
- Resorbs and replaced with bone as site heals

Augment®
Bone Graft

- Carrier ß-TCP is an osteomimetic scaffold with long history of orthopedic use
- Resorbs and replaced with bone as site heals

Augment
Peer-reviewed Bibliography

Peer-reviewed clinicial evidence

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Trust Augment®

Proven
- Level 1 evidence from largest F&A clinical trial ever conducted
- Equivalent improvements in clinical outcomes, compared to the gold standard autograft[1]

Labeled
- Class III combination product labeled for ankle and hindfoot arthrodesis

Unique
- Bioengineered human PDGF-BB stimulates multiple aspects of healing in response to injury
- rhPDGF-BB is highly purified with consistent biological potency; allograft and autograft are highly variable in quality and potency[2,3,4,5]

Safe
- In commercial use since 2009 (Canada)
- Eliminates risks, morbidities, and costs associated with autograft harvest

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

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This document is intended solely for healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker's product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your sales representative if you have questions about the availability of products in your area.

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