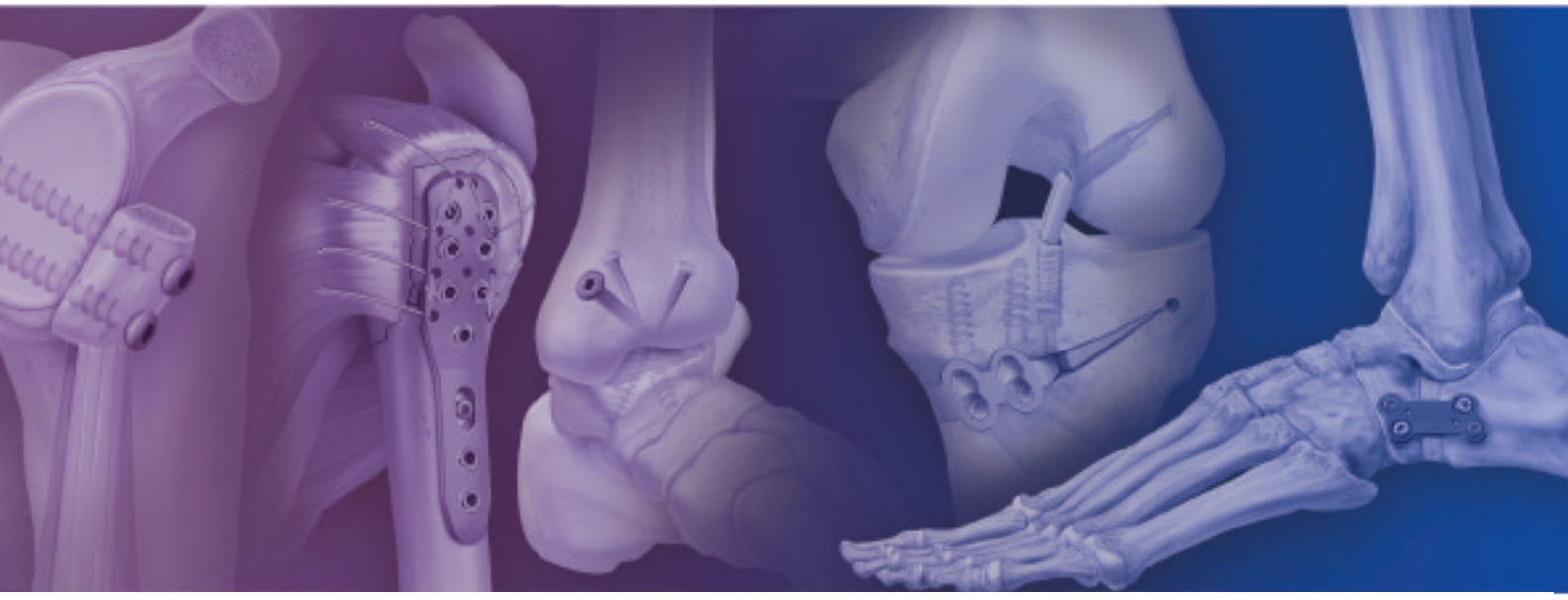
STIMUBLAST®



Demineralized Bone Matrix

Arthrex®

Features and Benefits

StimuBlast Provides Osteoinductive and Osteoconductive Properties:

- Osteoinduction – signaling molecules such as bone morphogenetic proteins (BMPs) that aid in cell differentiation down osteoblastic pathways
- Every lot of the final product is tested with an *in vivo* model to ensure osteoinductive potential
- Osteoconduction – scaffolding from DBM particles for osteoblasts to form new bone
- Additional scaffolding properties are provided in StimuBlast CB with the addition of cancellous bone chips

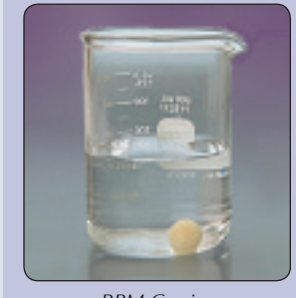
Superior Handling Characteristics via the Reverse Phase Medium (RPM) Carrier:

- RPM is an inert, biocompatible co-polymer made from polypropylene oxide and polyethylene oxide
- Material is flowable at room temperature and thickens to become more viscous at body temperature
- RPM allows the DBM graft to be moldable and packed into any defect size or shape
- StimuBlast will resist irrigation and can be used in a fluid environment without the fear of graft migration, unlike some other DBMs

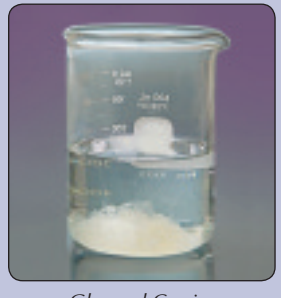
StimuBlast Offers Ease of Use and Terminal Sterility:

- Provided as a ready-to-use, off-the-shelf product that requires no thawing or premixing preparation
- Terminal sterilization using electron beam results in a Sterility Assurance Level (SAL) of 10^6 – process is not harmful to the DBM or its bioactivity
- Some competitive DBM products are only offered as aseptically processed products – SAL of 10^3
- Room temperature storage

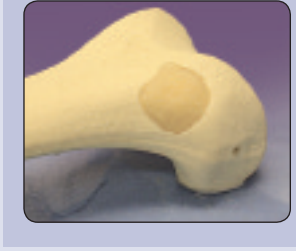
Comparison of Two DBM's

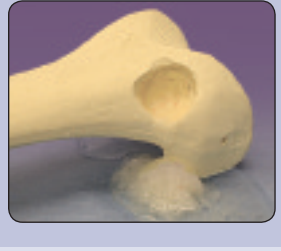


RPM Carrier



Glycerol Carrier





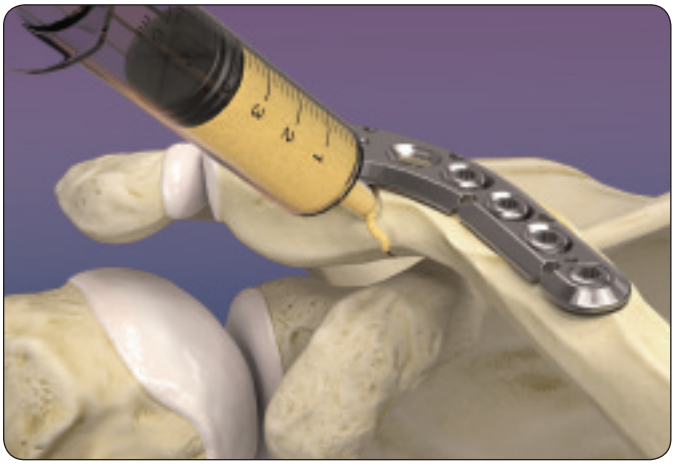
5 minutes hydration time

StimuBlast Gel

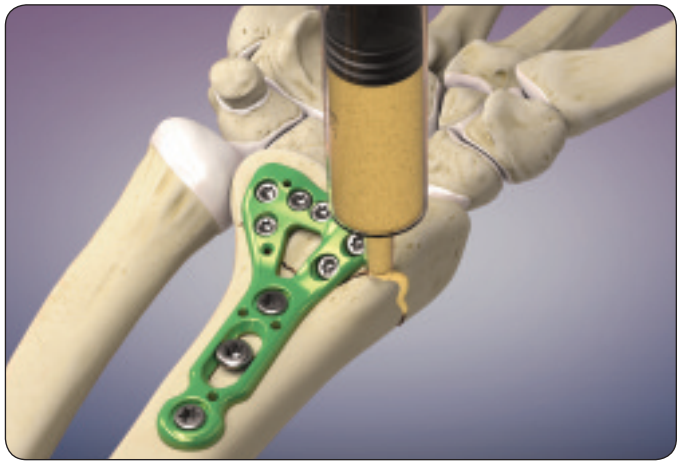
StimuBlast Putty

Surgical Applications

Promote Osseous Regeneration Across Upper Extremity Fracture Site Voids with DBM

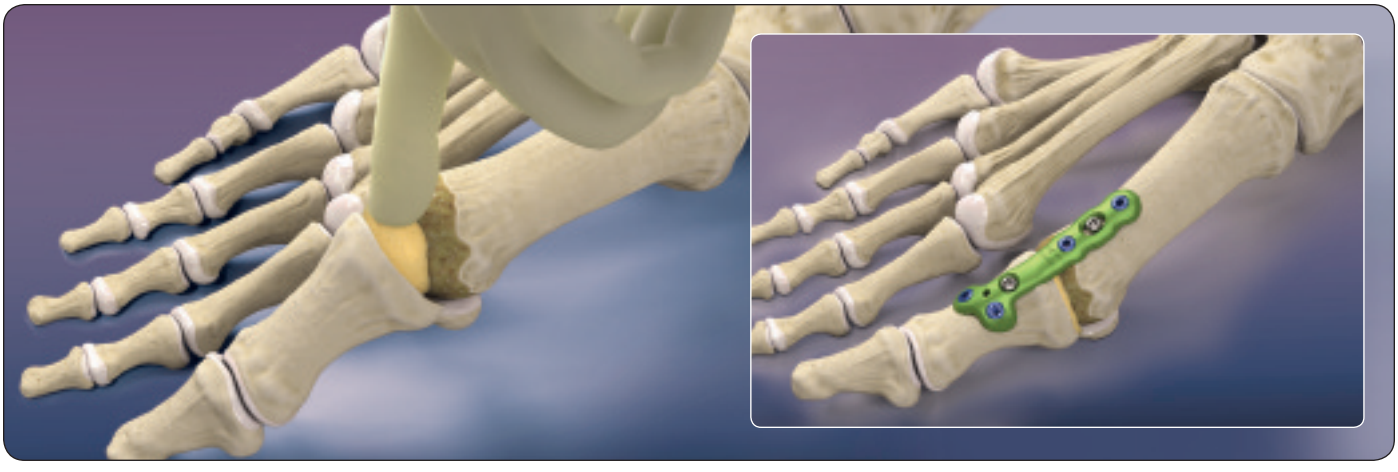


StimuBlast can be utilized to help treat clavicle fractures along with the Clavicle Plate and Screw System (refer to complete surgical technique brochure, LT1-0255-EN).



The Titanium Volar Distal Radius Plating System includes a graft window for fragment manipulation and bone grafting (refer to complete surgical technique brochure, LT1-0416-EN).

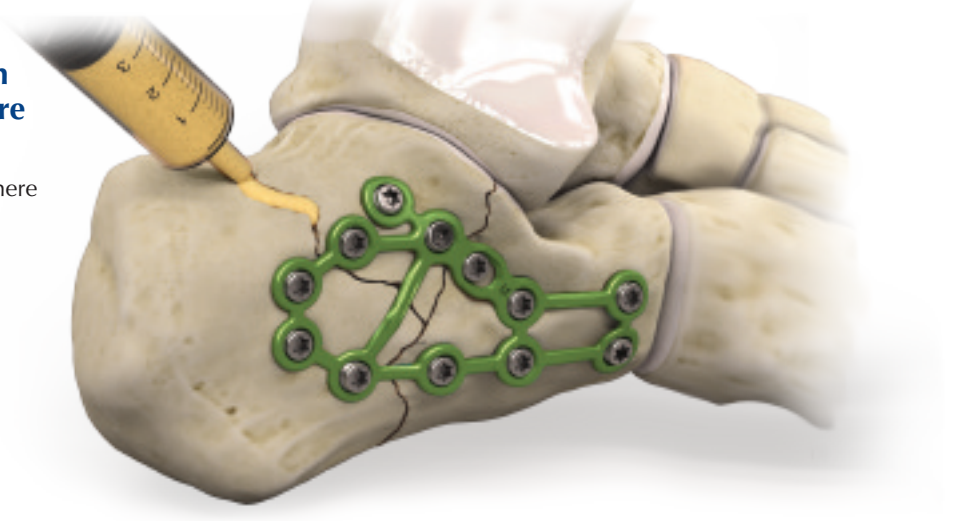
Promote Osseous Regeneration Across Fusion Site Voids with DBM



After preparing the first metatarsal phalangeal joint for an arthrodesis, StimuBlast can be inserted into the joint before final fixation with the Low Profile MTP Plate. The addition of DBM will provide osteoinductive properties to the fusion site.

Promote Osseous Regeneration Across Lower Extremity Fracture Site Voids with DBM

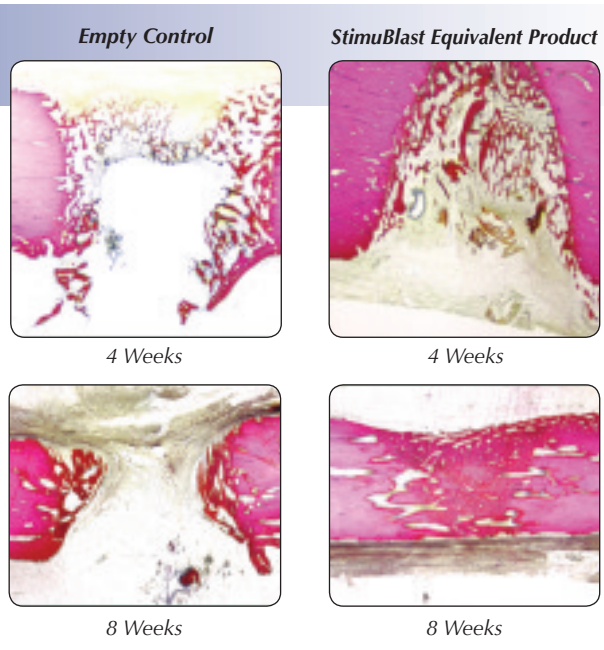
Calcaneal fractures often have defects where the addition of an osteoconductive and osteoinductive graft like StimuBlast is useful. For final fixation, the Calcaneal Fracture System provides a very comprehensive solution for all classifications of calcaneal fractures.



Promote Bone Regeneration

Scientific Support for StimuBlast

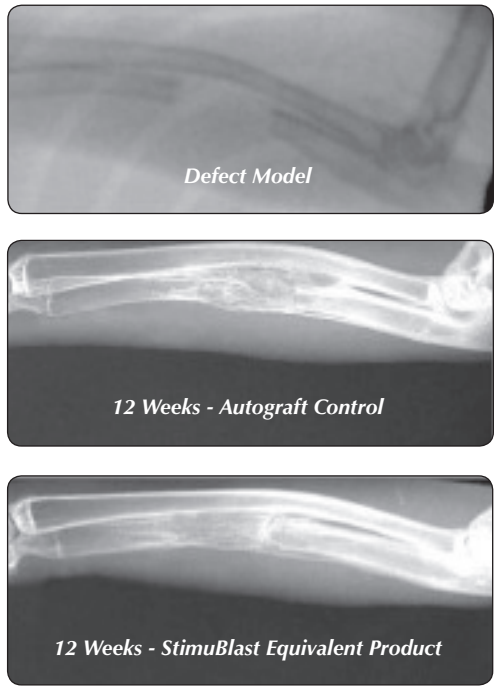
An equivalent DBM/RPM ratio to StimuBlast DBM was evaluated in a skeletally mature sheep model. Species-specific DBM was compared to an empty control and autograft. Transcortical defect holes were created in the tibial and metatarsal diaphysis; histology was assessed at 4, 8, and 16 weeks for bone regeneration and graft incorporation. Bone formation was either delayed or unable to bridge the gap within the empty control. The StimuBlast equivalent product was able to provide a scaffold and induce osseous bridging across the defect site similar to autograft. This study simulates that StimuBlast is an effective bone grafting material.*



Scientific Support for StimuBlast CB

A rabbit ulna critical-sized defect model was used to evaluate a product equivalent to StimuBlast CB DBM (species-specific) as a bone graft extender and bone graft substitute. A critical-sized mid-diaphyseal ulna defect was created. The following groups were compared to the intact ulna: 100% StimuBlast CB equivalent, 50/50 mixture of StimuBlast CB equivalent and autograft, and 100% autograft. The DBM was created from rabbit long bones in order to ensure a species-specific animal model. At 12, 18, and 26 weeks the ulnas were evaluated with radiography, histology, and mechanical testing. Radiographic assessment was able to show bone incorporation and bridging across the defect site at 12 weeks for both groups containing the StimuBlast CB equivalent product which was similar to the autograft alone group (Fig. 1). The mechanical testing at 12 weeks was able to reveal statistical equivalence between the DBM groups and autograft alone. The DBM groups were also statistically equivalent to the intact ulna (Table 1). This study model was able to simulate that StimuBlast CB functions as well as a bone graft extender with an autograft and as a stand-alone bone graft substitute.*

Fig. 1



Human Clinical Comparison Between Two DBMs

Independent clinical studies demonstrate that the DBM/RPM ratio contained within StimuBlast CB DBM is a safe and effective bone grafting option.

Patients treated prospectively for periarticular fractures[1]

- A successful graft is one that heals on the first grafting attempt without complications determined by radiography and clinical evaluation
- The StimuBlast CB equivalent product was successful for 15/15 patients and Grafton was successful for 9/13 patients (p = 0.035, likelihood ratio = 6.918)

Heavy tobacco users treated for nonunion revisions[2]

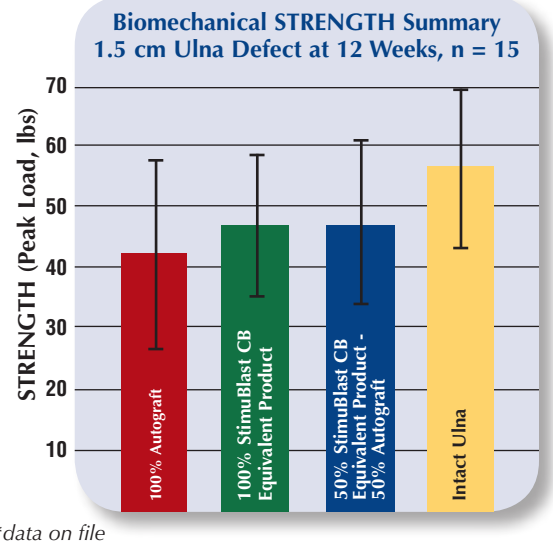
- A successful graft is again defined as one that heals on the first attempt without complications
- The success rates for the StimuBlast CB equivalent product and Grafton were 85% and 52%, respectively, (p = 0.077, likelihood ratio = 4.2)

Patients treated with complex ankle or hindfoot fusions[3]

- Patients treated with Grafton resulted in a 14% nonunion rate (5/37), while patients treated with the StimuBlast CB equivalent product resulted in an 8% nonunion rate (2/26)

Table 1

StimuBlast Equivalent Product Efficacy



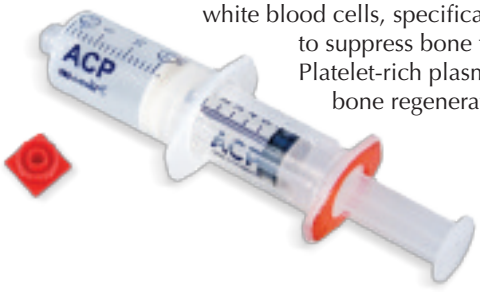
**data on file*

Combining Allograft DBM with Autologous Products

Allograft DBM is optimal for containment of additional biologically active products. In order to provide a composite graft and enhance the biologic nature of the graft, combine osteogenic, autologous bone marrow and/or autologous platelet-rich plasma.

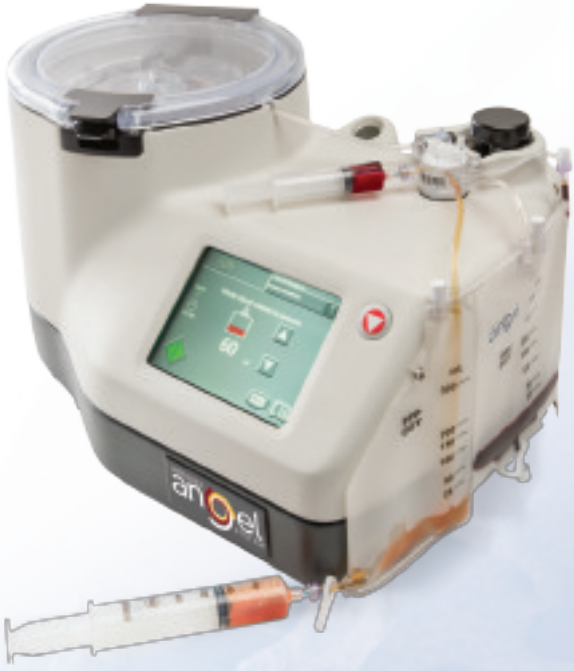
Autologous Conditioned Plasma (ACP)

A double syringe system that allows for rapid and efficient concentration of platelets and growth factors within a plasma-based, platelet-rich plasma. White blood cells are NOT concentrated within the ACP system. Concentrated white blood cells, specifically neutrophils, have been shown to suppress bone formation and bone healing.[4,5] Platelet-rich plasma has been found to improve bone regeneration.[6-9]

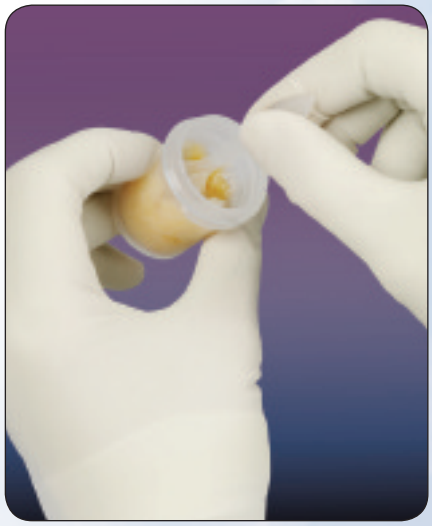


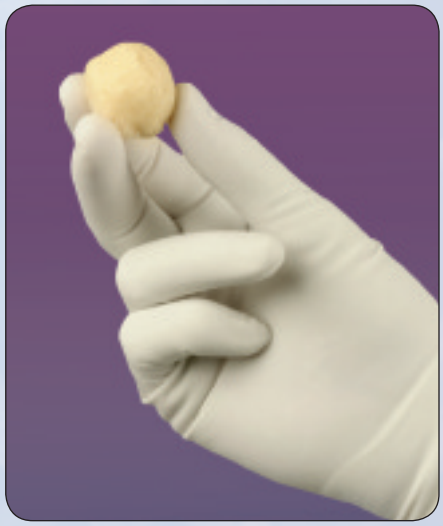
Arthrex Angel™ System

The Angel System utilizes a proprietary platelet sensor and one-button automation to deliver customized bone marrow concentrate (BMC). Bone marrow is a rich source of platelets, nucleated and progenitor cells. Angel is the only device that can concentrate bone marrow aspirate with adjustable cellular levels. Customization of cellular levels is necessary to reduce the number of neutrophils in BMC, which can be detrimental to bone healing.



DBM Mixed with PRP Derived From Whole Blood or Bone Marrow





DBM Putty and PRP combination can be molded to desired shape. Recommend a DB/PRP ratio of 2:1 (e.g. combine 5 cc putty with 2.5 cc of PRP). The properties of the DBM may be affected when mixed with a blood product.

References:

1 Cheung, et al, *Efficacy of Contained Metaphyseal and Periarticular Defects Treated with Two Different Demineralized Bone Matrix Allografts*, International Orthopaedics, 2003; 27: 56-59.
2 Ziran, et al, *Comparative Efficacy of Two Different Demineralized Bone Matrix Allografts in Treating Long-bone Nonunions in Heavy Tobacco Smokers*, The American Journal of Orthopedics, 2005; 34: 329-332.
3 Thordarson, et al, *Use of Demineralized Bone Matrix in Ankle/Hindfoot Fusion*, Foot & Ankle International, 2003; 24: 557-560.
4 Grogaard, et al, *The polymorphonuclear leukocyte: has it a role in fracture healing?* Archives of Orthopaedic and Trauma Surgery, 1990; 109: 268-271.
5 Voggenreiter, et al, *Immunosuppression with FK506 Increases Bone Induction in Demineralized Isogenic and Xenogenic Bone Matrix in the Rat*, Journal of Bone and Mineral Research, 2000; 15: 1825-1834.
6 Anitua, et al, *The Effects of PRGF on Bone Regeneration and on Titanium Implant Osseointegration in Goats*, Journal of Biomedical Materials Research, Part A, 2009; 91: 158-165.
7 Gallo, et al, *Autologous Platelet-rich Plasma: Effect on Sternal Healing in the Sheep Model*. Interactive CardioVascular and Thoracic Surgery, 2010; 11: 223-225.
8 Niemeyer, et al, *Comparison of Mesenchymal Stem Cells from Bone Marrow and Adipose Tissue for Bone Regeneration in a Critical Size Defect of the Sheep Tibia and the Influence of Platelet-rich Plasma*, Biomaterials, 2010; 31: 3572-3579.
9 Sanchez, et al, *Nonunions Treated with Autologous Preparation Rich in Growth Factors*, Journal of Orthopaedic Trauma, 2009; 23: 52-59.

Product and Ordering Information

StimuBlast DBM Gel	
1 cc Gel	ABS-2002-01
5 cc Gel	ABS-2002-05
10 cc Gel	ABS-2002-10
StimuBlast DBM Putty	
1 cc Putty	ABS-2001-01
2.55 cc Putty	ABS-2001-02
5 cc Putty	ABS-2001-05
10 cc Putty	ABS-2001-10
StimuBlast CB DBM Paste	
1 cc Paste	ABS-2004-01
3 cc Paste	ABS-2004-03
8 cc Paste	ABS-2004-08
StimuBlast CB DBM Putty	
5 cc Putty	ABS-2003-05
10 cc Putty	ABS-2003-10
5cc Cancellous Crushed	27715005

To order please call: 1-877-255-6727
Contact your local Arthrex Sales Representative for additional information.

StimuBlast is indicated for orthopaedic applications as filler for gaps or voids that are not intrinsic to the stability of the bony structure. StimuBlast is indicated to be packed gently into bony gaps in the skeletal system as a bone graft extender (extremities, spine and pelvis) and as bony void filler of the extremities and pelvis. These defects may be surgically created or from the result of traumatic injury to the bone.

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's Directions For Use.

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