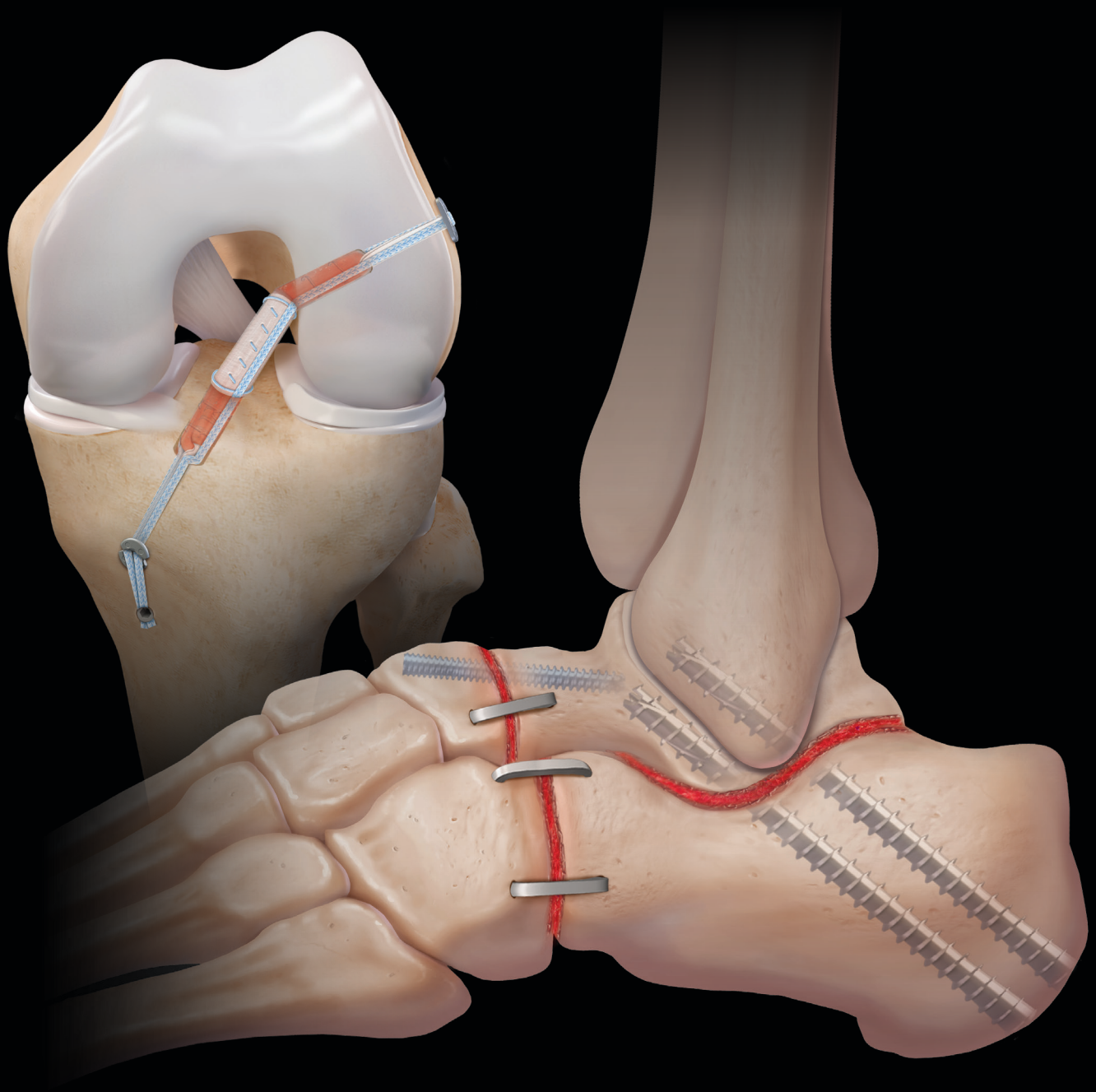
AlloSync™

Bone Grafting Solutions



Arthrex®

Helping Surgeons Treat Their Patients Better™

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better. We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simple, safe, and more reproducible. Each year, we develop more than 1000 new innovative products and procedures to advance minimally invasive orthopedics worldwide.

Arthrex has always remained a privately held company, which allows for the rapid evaluation of new technologies and ideas and the freedom to develop products and techniques that truly make a difference. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the health care providers who use our products and the millions of patients whose lives we impact.

The medical significance of our contributions serves as our primary benchmark of success and will continue into the future as the legacy of Arthrex.

Table of Contents

AlloSync™ Bone Grafting Solutions

The AlloSync bone grafting solutions line is a comprehensive offering of allograft bone for various bone grafting needs. AlloSync bone grafts contain osteoconductive and verified osteoinductive properties, providing the optimal signaling and scaffold for bone remodeling.

AlloSync™ Expand Demineralized Cortical Fibers

AlloSync Expand fibers are 100% demineralized bone ideal for intraoperative handling and controlled expansion into bone voids. Its unique structure of long fiber gives it cohesive and moldable handling characteristics that allow for expansion of demineralized bone matrix (DBM) post-implantation in order to improve the fill of bone voids. In a recent study, manual palpation and micro-CT results showed a statistically higher fusion rate of 100%, compared to that of multiple competitor products.[1]

100% Demineralized Bone Fibers

- No added fillers for maximum demineralized bone content and osteoinductive potential
- Specific fiber geometry provides exceptional handling and controlled expansion
- Lyophilized fibers extend shelf life while preserving the osteoinductive potential

Expands to Fill Gaps

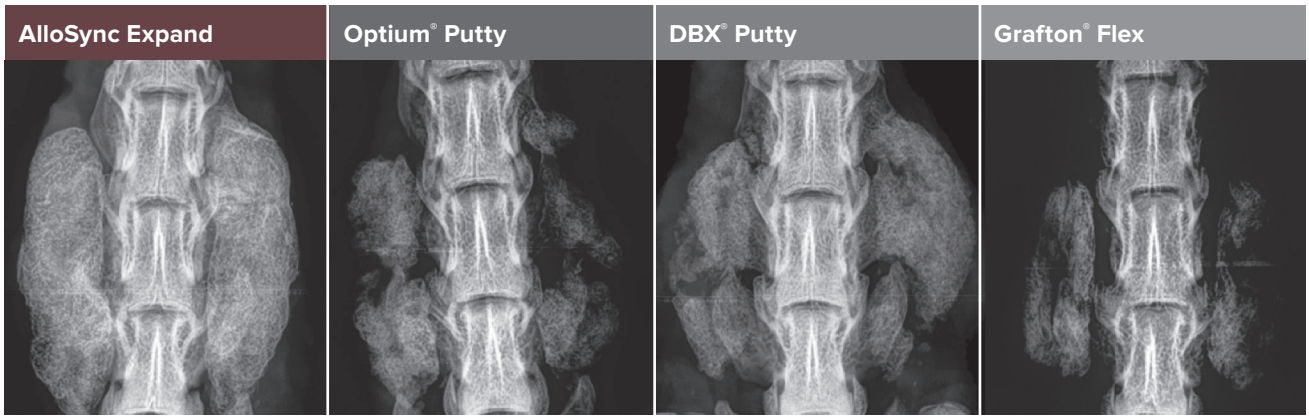
- Wicks blood, bone marrow, and other physiological fluids that allow the graft to expand and improve fill

Cellular Highways

- Fibers have demonstrated superior bone-forming capacity compared to standard particulate demineralized bone marrow[2]
- Entangled fibers create a 3D interconnected matrix to promote cell migration and fusion

Simplicity of Hydration

- Luer lock portal delivers a simple yet thorough hydration process
- Flexibility to select various hydration fluids



Ordering Information

Product Description	Item Number
AlloSync Expand Demineralized Cortical Fibers, 1 cc	ABS-2017-**01**
AlloSync Expand Demineralized Cortical Fibers, 2.5 cc	ABS-2017-**02**

Product Description	Item Number
AlloSync Expand Demineralized Cortical Fibers, 5 cc	ABS-2017-**05**
AlloSync Expand Demineralized Cortical Fibers, 10 cc	ABS-2017-**10**

AlloSync™ Pure Demineralized Bone Matrix

ALLOSYNC PURE

AlloSync Pure is a dehydrated osteoinductive DBM derived from 100% human allograft bone with no extrinsic carriers. AlloSync Pure bone matrix resists irrigation and can be used in a fluid environment (Figure 1). The clinician can control the handling properties of AlloSync Pure bone matrix, which includes decreasing the viscosity for injectable applications or increasing the viscosity to add autograft and/or allograft. The proprietary rice-shape fiber technology used to process AlloSync Pure increases the osteoinduction and osteoconductive surface area to accelerate cellular ingrowth.

- Derived from 100% human allograft bone without any extrinsic carriers
- Post-sterilization, every lot is tested in vivo to ensure osteoinductivity
- Demineralization process preserves native bone morphogenetic proteins (BMPs) and growth factors
- Resists irrigation
- Histologically proven to contain all 5 elements of bone formation including new bone, bone marrow, osteocytes, chondrocytes, and cartilage post-implantation at 28 days[2] (Figure 2)
- May be hydrated with bone marrow aspirate (BMA), platelet-rich plasma (PRP), blood, saline, or other cellular components
- Sterile to device-grade standards (10^{-6}) and stored at ambient temperature
- Provided in a ready-to-use mixing jar
- Four sizes available
- 5-year shelf life

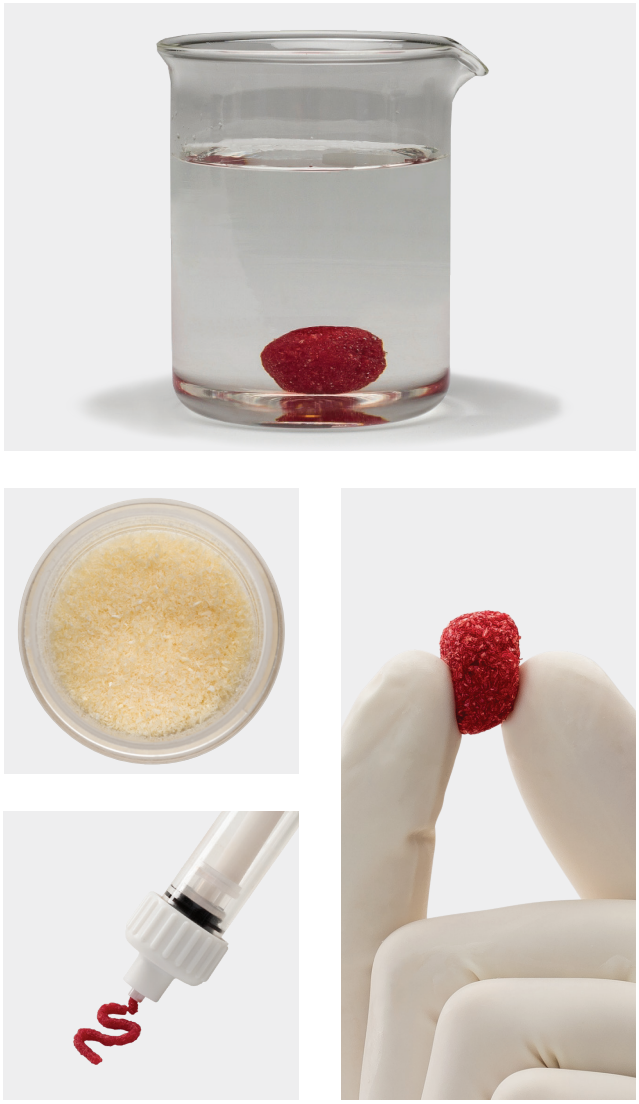
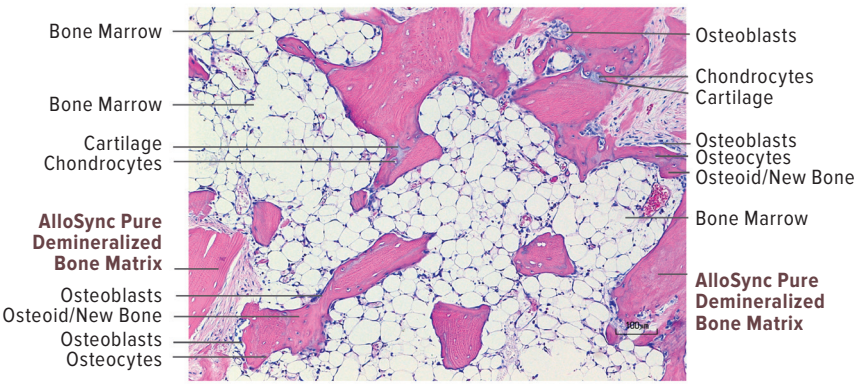
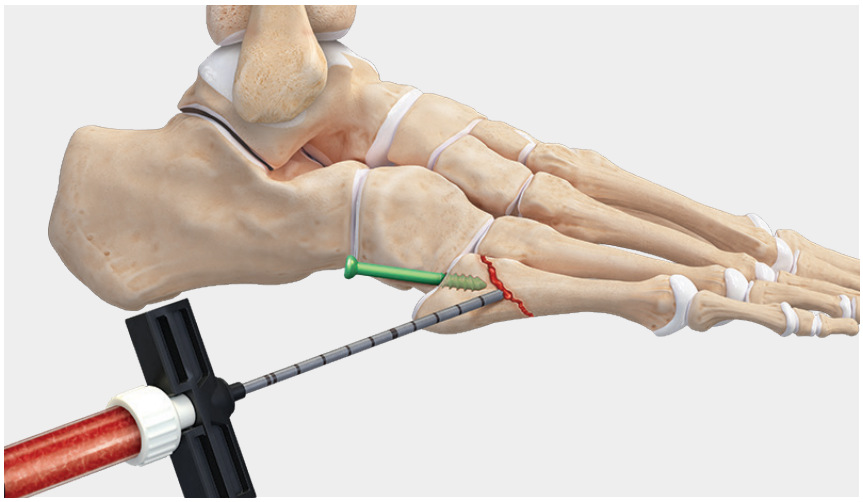


Figure 1. AlloSync Pure DBM can be used in an arthroscopic environment

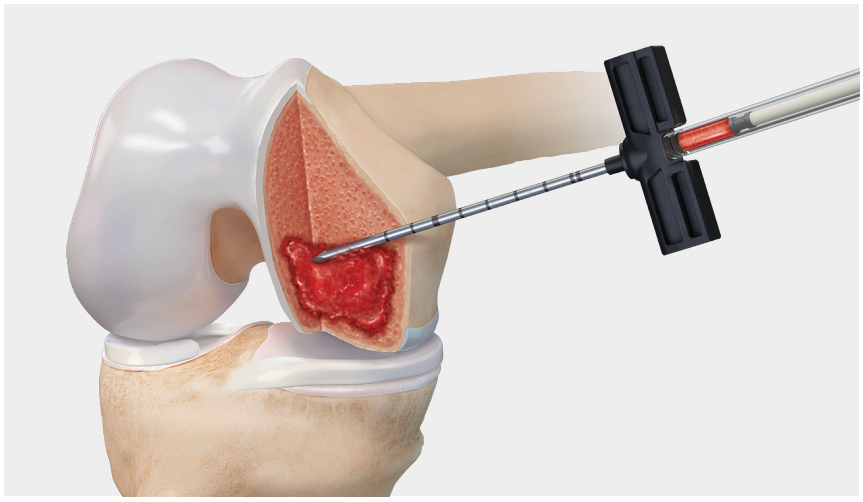
Figure 2. AlloSync Pure DBM histology



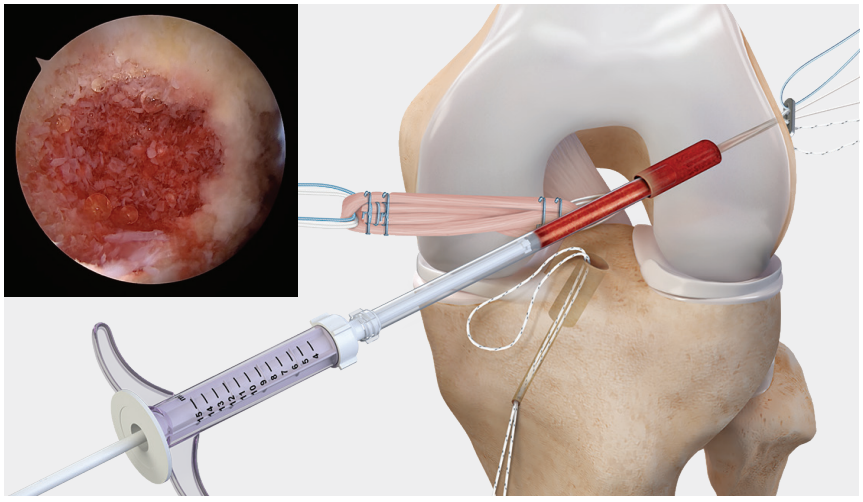
AlloSync™ Pure DBM Surgical Applications



AlloSync Pure DBM's viscosity can be adjusted and made flowable for a variety of percutaneous applications.



AlloSync Pure DBM can be delivered to treat bone marrow lesions using the IntraOsseous BioPlasty® technique.



The rice-shape fiber technology used to process AlloSync Pure DBM allows the graft to be implanted in an arthroscopic environment without fear of graft washout. This delivery can be achieved using the BioXpress™ graft delivery device.

AlloSync™ Demineralized Cancellous Sponges and Cortical Fibers

- Post-sterilization, every lot is tested in vivo to ensure osteoinductivity
- Demineralized cancellous matrix is composed of 100% cancellous bone
- Maintains natural bone architecture with interconnected porosity
- Provides optimal scaffold for cellular attachment and proliferation
- Contains exposed natural growth factors with verified osteoinductivity
- Naturally absorbs and retains bioactive fluids like PRP and BMA
  - After rehydration, the product can be compressed like a sponge, allowing for flexibility to fit in and around different types of bone defects
- Sterile to device-grade standards (10^{-6}) and stored at ambient temperature

Osteoinductivity Testing[3]

- The AlloSync demineralized sponge was tested in an intramuscular nude rat bioassay via histological evaluations
- After 28 days, the following findings were observed within the AlloSync demineralized sponge group (Figure 3):
  - The porous osteoconductive trabecular bone structure of the implant was maintained and found to be evident within the histological sections (black arrow)
  - Osteoblast-like cells were found lining the trabecular bone network (blue arrow)
  - Cellular infiltration and neovascularization were apparent along the edges of the implant but also could be observed throughout the interior portion of the implant (red arrow)

Strips - Two Thicknesses	
3 mm Thick	**7 mm Thick**
10 mm × 10 mm × 3 mm	26 mm × 19 mm × 7 mm
15 mm × 40 mm × 3 mm	10 mm × 20 mm × 7 mm

Cubes - Three Sizes	Chips - 1 mm - 4 mm, 3 Volumes
8 mm × 8 mm × 8 mm	1 cc
10 mm × 10 mm × 10 mm	2.5 cc
12 mm × 12 mm × 12 mm	5 cc

Demineralized Fibers - Four Sizes
1 cc
2.5 cc
5 cc
10 cc

Demineralized Fibers Features and Benefits

- New form of 100% DBM offering excellent handling characteristics without the need for an additional carrier
- Osteoconductive and verified osteoinductive properties
  - The cortical fibers are demineralized using CellRight Technologies' proprietary process, optimizing the residual calcium level and osteoinductivity
  - Demineralized cortical fibers provide an optimal scaffold for cellular attachment and proliferation
- Customizable hydration: naturally wicks up bioactive fluids such as PRP and BMA
- Sterile to device-grade standards (10^{-6}) and stored at ambient temperature

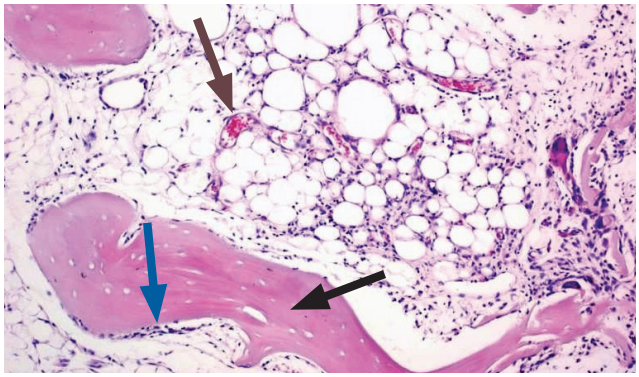
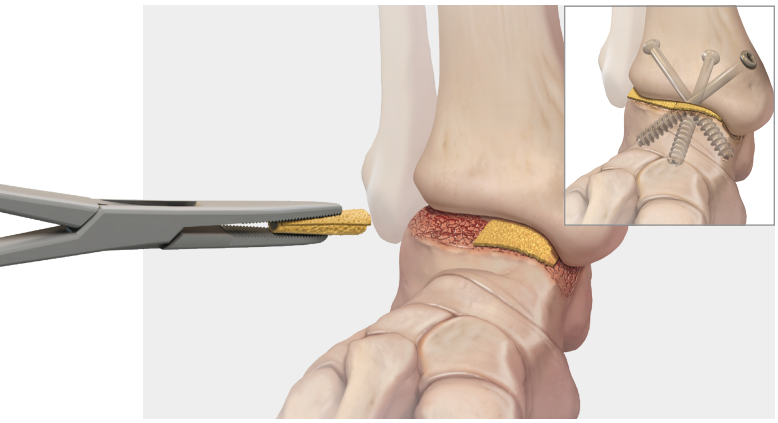
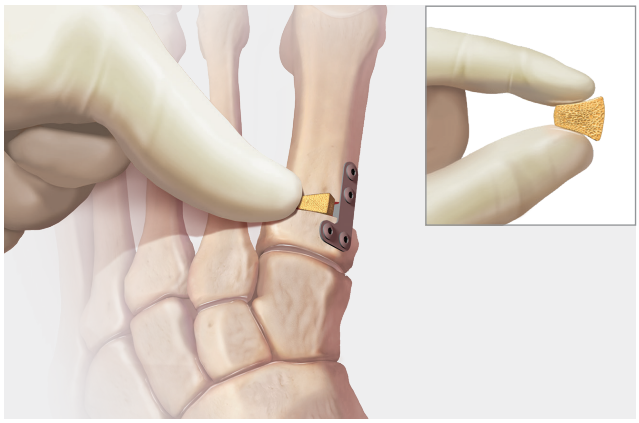


Figure 3.
Representative histology of demineralized sponge, H&E stained.

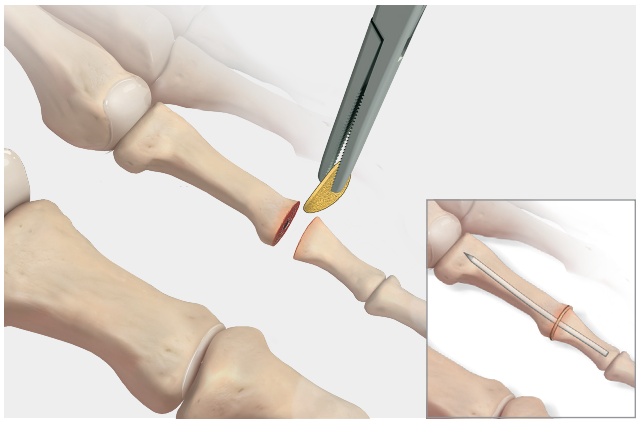
AlloSync™ Demineralized Cancellous Sponges and Cortical Fibers Surgical Applications



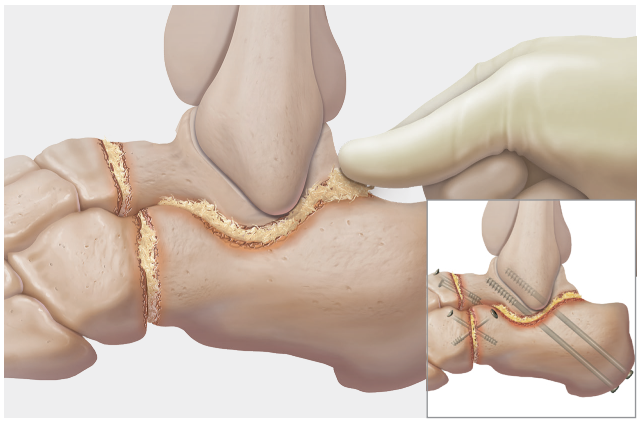
AlloSync demineralized strip used to augment an ankle arthrodesis procedure.



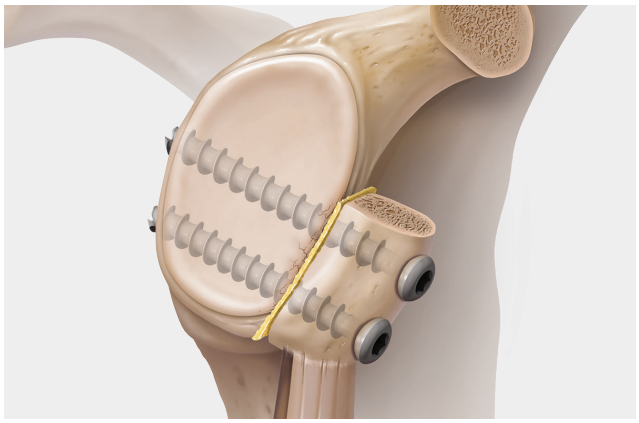
AlloSync demineralized cube used to augment a proximal metatarsal opening-wedge procedure.



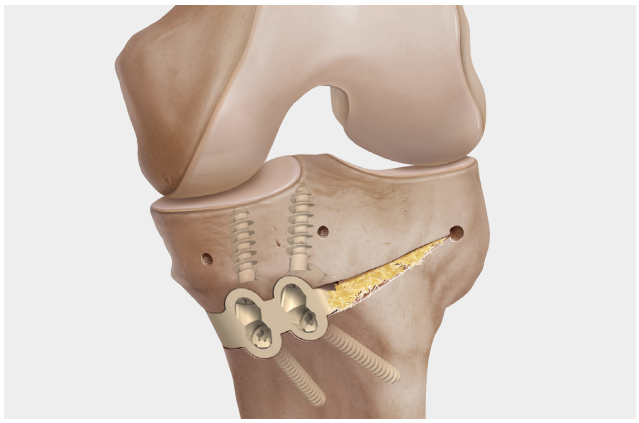
AlloSync demineralized strip used to augment proximal interphalangeal (PIP) joint arthrodesis procedures.



AlloSync demineralized fibers used to augment a triple-arthrodesis procedure.



AlloSync demineralized strip used to augment a Latarjet procedure.

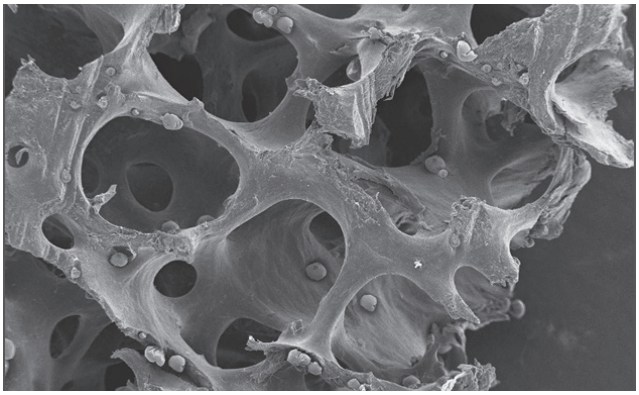


AlloSync demineralized fibers used to augment an iBalance® high tibial osteotomy (HTO) procedure.

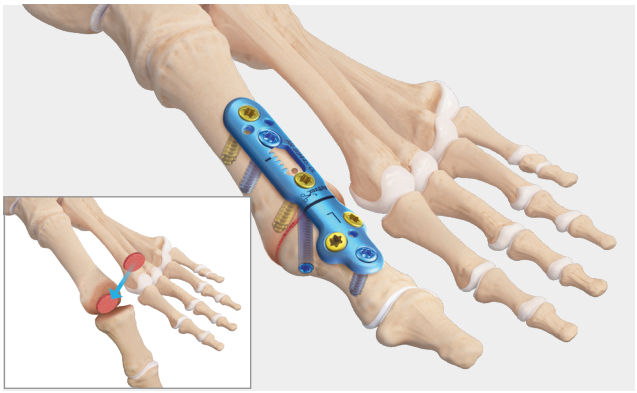
AlloSync™ Button

The AlloSync button is a demineralized cancellous sponge provided as a 12 mm round, 3 mm thick disc. The size and shape of the button make it the ideal interpositional graft for rotator cuff repair. Studies have shown that an interposed DBM sponge can lead to improved tendon-to-bone healing in rotator cuff tears.[4] This includes improved histology and strength when compared to a direct repair.

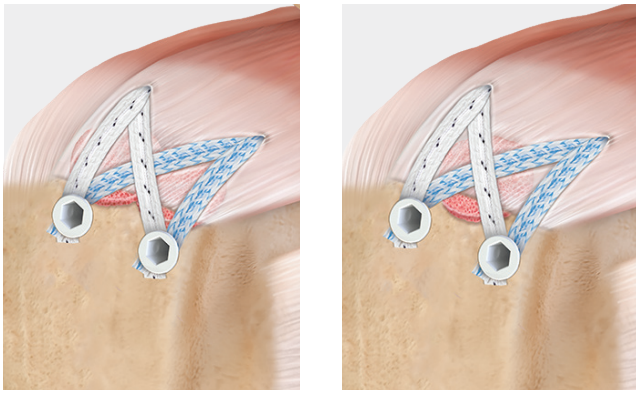
- Composed of 100% cancellous bone
- Provides a scaffold for cellular attachment and proliferation
- After rehydration, the product is compressible like a sponge
- Sterile to device-grade standards (10^{-6} SAL)
- Ambient temperature storage



Electron microscopy image showing several healthy cells attached to the AlloSync bone graft scaffold after hydration.



1st MTP arthrodesis with MaxForce MTP Fusion Plating augmented with AlloSync button.



SpeedBridge™ rotator cuff repair augmented with the AlloSync button.

AlloSync™ Putty, Gel, and Paste

AlloSync Bone Products May Provide Osteoinductive and Osteoconductive Properties:

- Osteoinduction – signaling molecules such as BMPs that aid in cell differentiation down osteoblastic pathways
- Every lot of DBM is tested for osteoinductive potential, using either an in vitro assay or in vivo model
- Osteoconduction – scaffolding from DBM particles for osteoblasts to form new bone
- Additional scaffolding properties are provided in AlloSync cancellous bone (CB) with the addition of cancellous bone chips

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

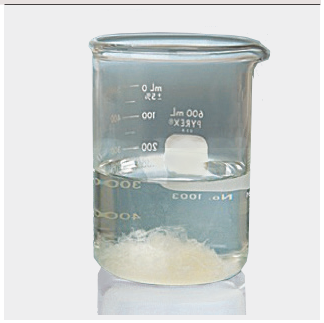
- RPM is an inert, biocompatible copolymer made from polypropylene oxide and polyethylene oxide
- Material is flowable at room temperature and thickens to become more viscous at body temperature
- RPM allows the DBM graft to be moldable and packed into any defect size or shape
- AlloSync bone products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

AlloSync Bone Products Offer Ease of Use and Terminal Sterility:

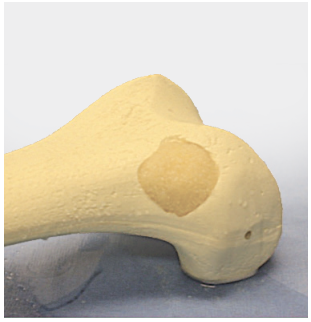
- Provided as a ready-to-use, off-the-shelf product that requires no thawing or premixing
- Terminal sterilization using electron beam results in a SAL of 10^{-6} – process is not harmful to the DBM or its bioactivity
- Some competitive DBM products are only offered as aseptically processed products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

Comparison of Two DBMs

RPM Carrier

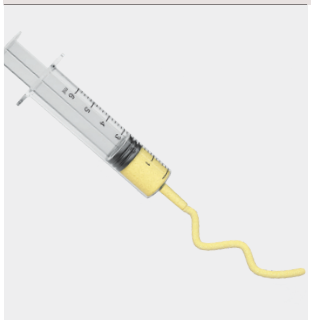


Glycerol Carrier



5 minute immersion time

AlloSync Putty, Gel, and Paste



AlloSync Gel

AlloSync Putty

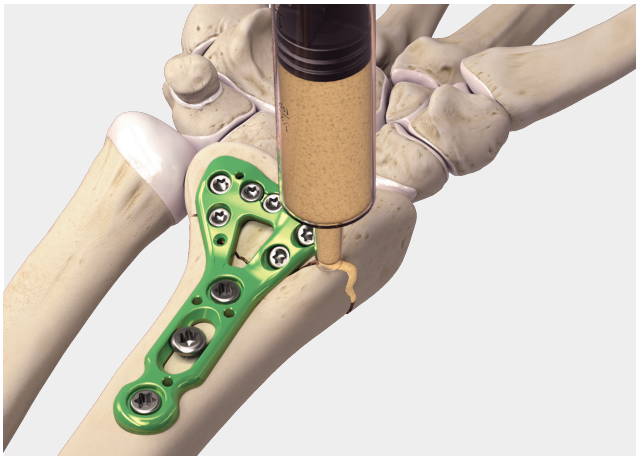
AlloSync DBM Putty - Four Sizes		AlloSync CB DBM Putty - Two Sizes
1 cc	5 cc	5 cc
2.5 cc	10 cc	10 cc

AlloSync DBM Gel - Three Sizes	AlloSync CB DBM Paste - Three Sizes
1 cc	1 cc
5 cc	3 cc
10 cc	8 cc

AlloSync™ Putty, Gel, and Paste Surgical Applications

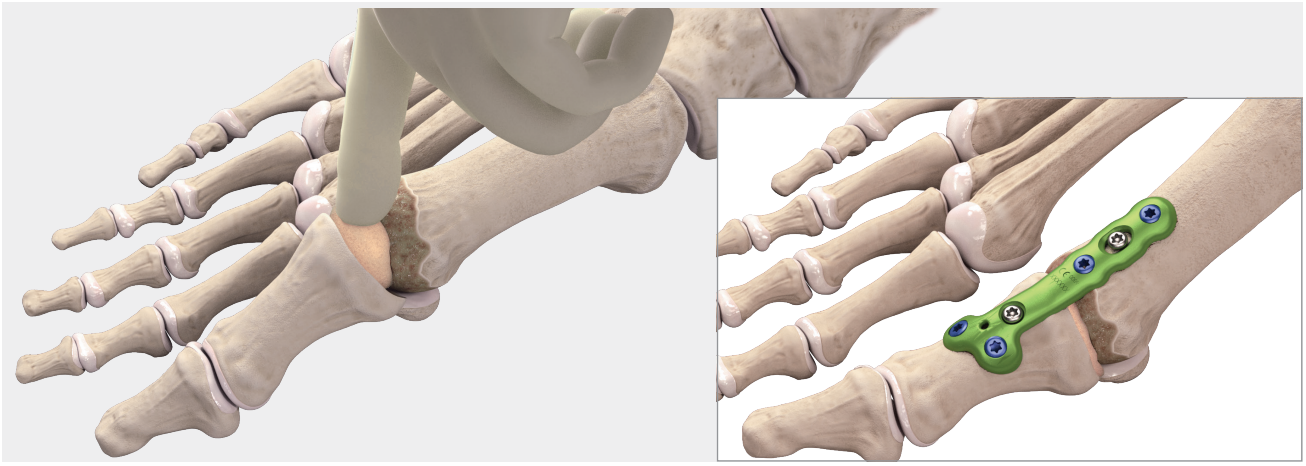
Promote Osseous Regeneration Across Upper Extremity Fracture Site Voids With DBM

AlloSync putty, gel, and paste products can be used 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).

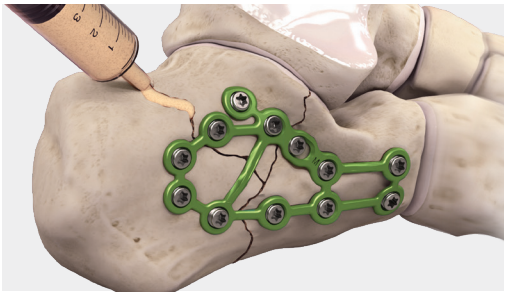
Promoting Osseous Regeneration Across Fusion Site Voids With DBM



After preparing the first metatarsal phalangeal joint for an arthrodesis, AlloSync bone products can be inserted into the joint before final fixation with the low-profile MTP plate. The addition of AlloSync 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 AlloSync DBM is useful. For final fixation, the Calcaneal Fracture System provides a comprehensive solution for all classifications of calcaneal fractures.



Scientific Support for AlloSync™ Bone Products
An AlloSync DBM equivalent product (same DBM/RPM ratio) 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 AlloSync equivalent product was able to provide a scaffold and induce osseous bridging across the defect site similar to autograft. This study indicates that AlloSync allograft bone is an effective bonegrafting material.[5]

Scientific Support for AlloSync DBM
A rabbit ulna critical-sized defect model was used to evaluate a product equivalent to AlloSync DBM (species-specific) as a bone graft extender and substitute. A critical-sized mid-diaphyseal ulna defect was created. The following groups were compared to the intact ulna: 100% AlloSync equivalent, 50/50 mixture of AlloSync equivalent and autograft, and 100% autograft. The DBM was created from rabbit long bones 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 showed bone incorporation and bridging across the defect site at 12 weeks for both groups containing the AlloSync equivalent product, which was similar to the autograft-alone group (Figure 4). The mechanical testing at 12 weeks revealed 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 demonstrated AlloSync functions as well as a bone graft extender with an autograft and as a standalone bone graft substitute.[7]

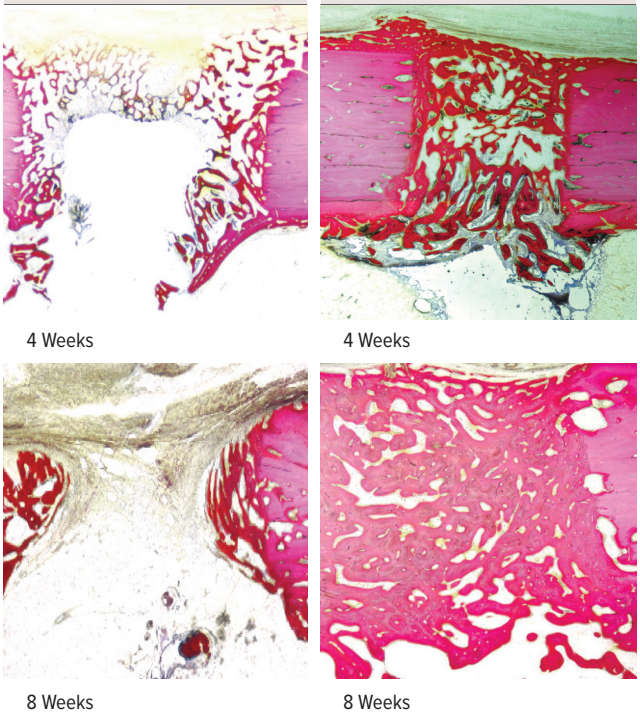


Figure 4

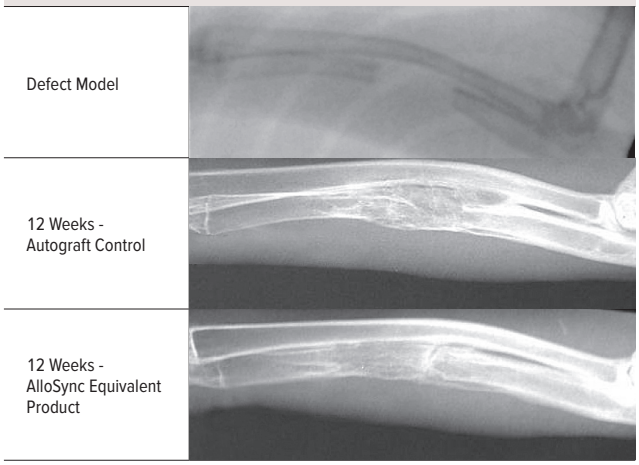
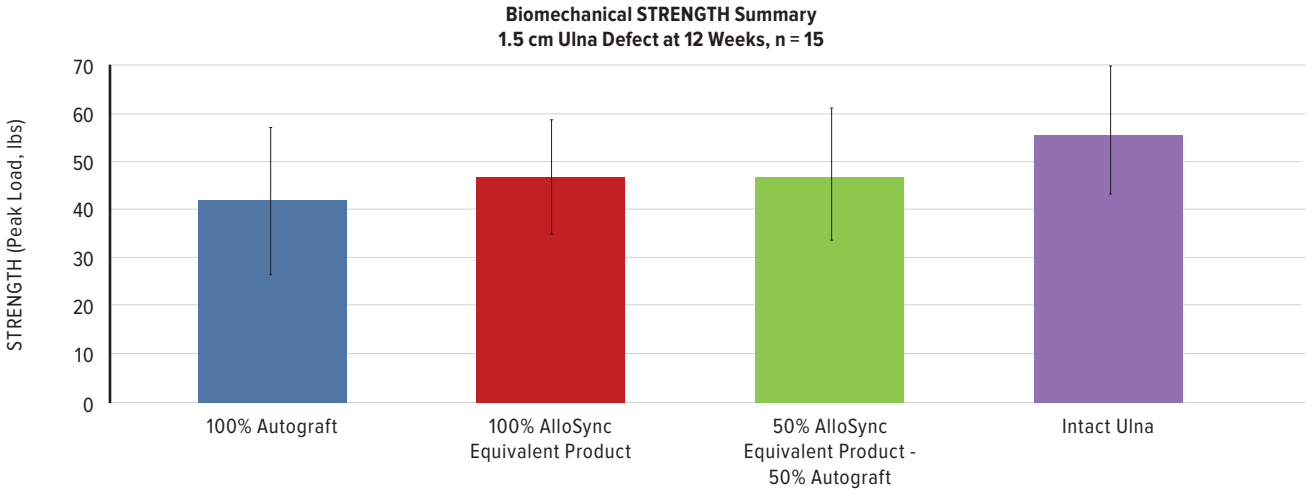


Table 1. AlloSync™ Bone Graft Equivalent Product



Human Clinical Comparison Between Two DBMs

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

Patients treated prospectively for periarticular fractures[7]

A successful graft is one that heals on the first grafting attempt without complications as determined by radiography and clinical evaluation.

- The AlloSync CB equivalent product was successful for 15/15 patients and Grafton DBM was successful for 9 of 13 patients (*P* = .035, likelihood ratio = 6.918)

Heavy tobacco users treated for nonunion revisions[8]

- A successful graft is again defined as one that heals on the first attempt without complications
- The success rates for the AlloSync CB equivalent product and Grafton DBM were 85% and 52%, respectively, (*P* = .077, likelihood ratio = 4.2)

Patients treated with complex ankle or hindfoot fusions[9]

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

Combining AlloSync™ Bone Products With Autologous Products

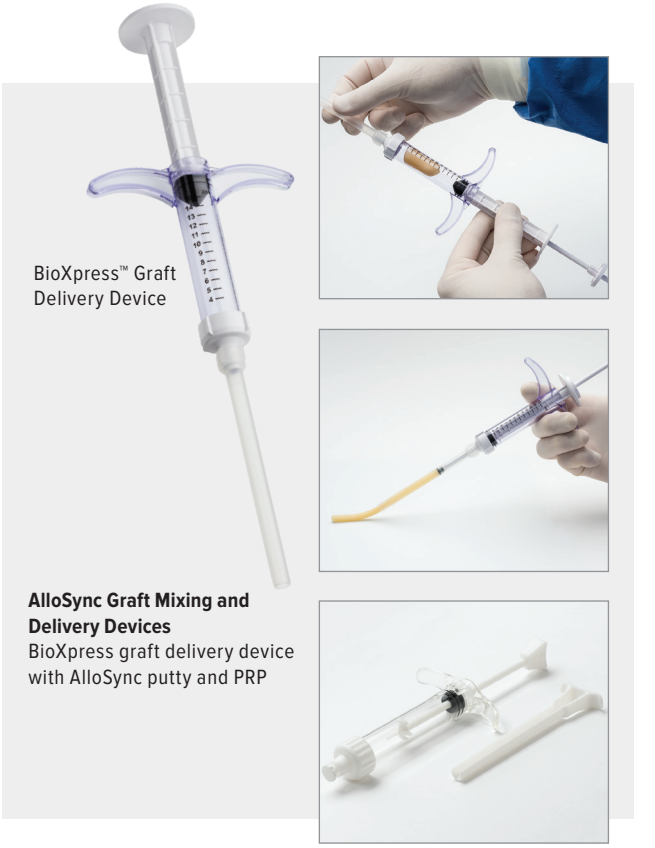
Allograft DBM is optimal for containment of additional biologically active products. In order to provide a composite graft and enhance the biologic nature of the graft, combine osteogenic components, autologous bone marrow, and/or autologous PRP.

Autologous Conditioned Plasma (ACP)

The Arthrex ACP® double-syringe system allows for rapid and efficient concentration of platelets and growth factors from autologous blood. White blood cells are NOT concentrated within the Arthrex ACP system. Concentrated white blood cells, specifically neutrophils, have been shown to suppress bone formation and bone healing.[10,11] PRP has been found to improve bone regeneration.[12-15]

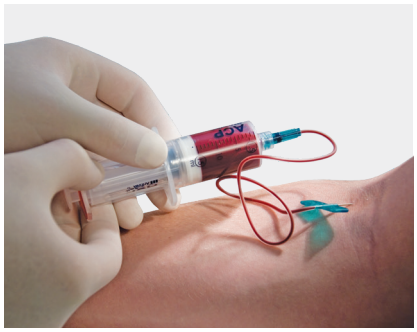
The Angel® cPRP System

The Angel cPRP system uses a proprietary platelet sensor and 1-button automation to deliver customized PRP concentrate from bone marrow aspirate ($cPRP_{BMA}$). Bone marrow is a rich source of platelets and nucleated and progenitor cells. The Angel cPRP system is the only device that can provide $cPRP_{BMA}$ with adjustable cellular levels. Customization of cellular levels is necessaryto reduce the number of neutrophils, which can be detrimental to bone healing.



AlloSync Graft Mixing and Delivery Devices
BioXpress graft delivery device with AlloSync putty and PRP

ACP Basic Preparation



Withdraw venous blood.

Centrifuge for 5 minutes at 1500 rpm.

Transfer 4 mL to 7 mL of supernatant (ACP) from the outer syringe into the small inner syringe.

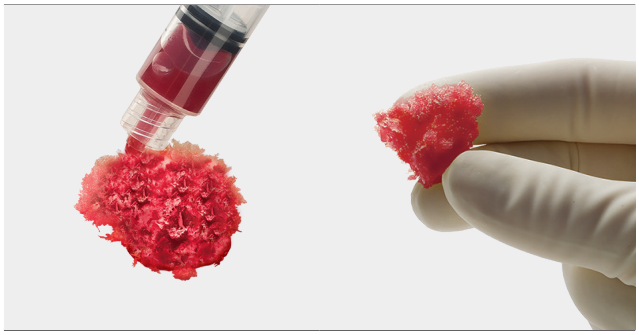
The Arthrex ACP® double-syringe system (ABS-10010S) can be used for the rapid and efficient concentration of platelets and growth factors within a plasma-based PRP:

- The unique double-syringe design provides a closed system that is easy to use with a quick procedure time
- White and red 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.[10,11]
- Leukocyte-reduced PRP has been found to improve bone regeneration within defect models[12-15]
- For more detailed instructions, follow the directions for use outlined in the Arthrex ACP technique brochure (LB1-0810-EN)

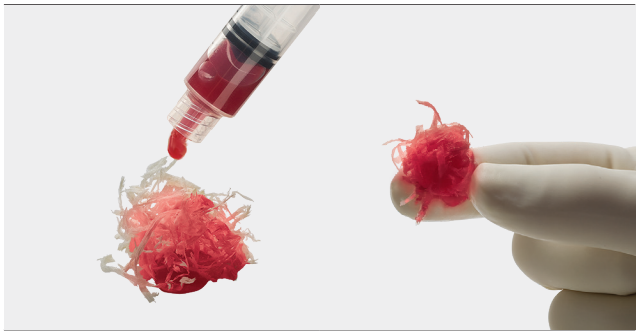
The Arthrex Angel® cPRP system (ABS-10060) is a convenient platform to provide PRP concentrate from BMA:

- Bone marrow is a source of autogenous progenitor cells that differentiate into a variety of tissues including cartilage, tendon, muscle, and nerve, in addition to bone[16-21]
- Bone marrow has been used successfully to augment a number of orthopedic procedures including fusions, nonunion grafting, and bridging of osseous defects[22-25]

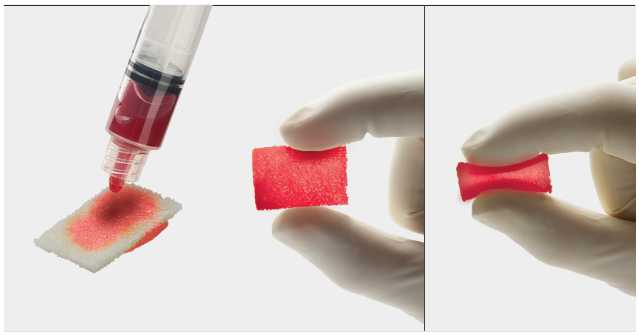
Chips



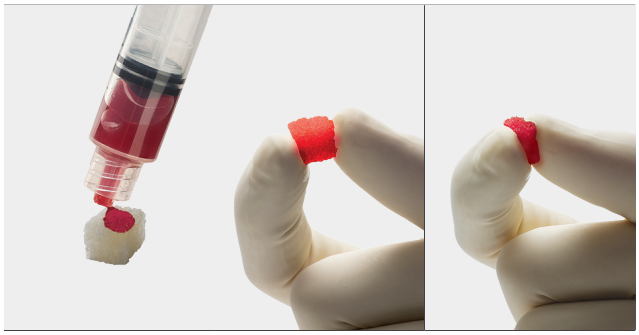
Fibers



Strips



Cubes



Ordering Information

AlloSync™ DBM Gel

Product Description	Item Number
1 cc Gel	ABS-2013-**01**
5 cc Gel	ABS-2013-**05**
10 cc Gel	ABS-2013-**10**

AlloSync DBM Putty

Product Description	Item Number
1 cc Putty	ABS-2012-**01**
2.5 cc Putty	ABS-2012-**02**
5 cc Putty	ABS-2012-**05**
10 cc Putty	ABS-2012-**10**

AlloSync CB DBM Paste

Product Description	Item Number
1 cc Paste	ABS-2015-**01**
3 cc Paste	ABS-2015-**03**
8 cc Paste	ABS-2015-**08**

AlloSync CB DBM Putty

Product Description	Item Number
5 cc Putty	ABS-2014-**05**
10 cc Putty	ABS-2014-**10**

BioXpress™ Graft Delivery Device

Product Description	Item Number
Blunt Tip Cannula, 10 cm	ABS-10053-**10**
Angled Tip Cannula, 10 cm	ABS-10053-10-**45**
Blunt Tip Cannula, 15 cm	ABS-10053-**15**
Angled Tip Cannula, 15 cm	ABS-10053-15-**45**

AlloSync Button

Product Description	Item Number
AlloSync Button	ABS-**2011**

Demineralized Sponges

Product Description	Dimension and Volume	Item Number
Cube	8 mm × 8 mm × 8 mm	ABS-2005-**01**
Cube	10 mm × 10 mm × 10 mm	ABS-2005-**02**
Cube	12 mm × x 12 mm × 12 mm	ABS-2005-**03**

Demineralized Sponges

Product Description	Dimension and Volume	Item Number
Strip	10 mm × 10 mm × 3 mm	ABS-2006-**01**
Strip	15 mm × 40 mm × 3 mm	ABS-2006-**02**
Strip	26 mm × 19 mm × 7 mm	ABS-2006-**03**
Strip	10 mm × 20 mm × 7 mm	ABS-2006-**04**

Demineralized Sponges

Product Description	Dimension and Volume	Item Number
Chips	(1 mm - 4 mm) 1.0 cc	ABS-2007-**01**
Chips	(1 mm - 4 mm) 2.5 cc	ABS-2007-**02**
Chips	(1 mm - 4 mm) 5 cc	ABS-2007-**03**

Demineralized Fibers

Product Description	Dimension and Volume	Item Number
Fibers	1 cc	ABS-2008-**01**
Fibers	2.5 cc	ABS-2008-**02**
Fibers	5 cc	ABS-2008-**03**
Fibers	10 cc	ABS-2008-**04**

AlloSync Pure DBM

Product Description	Item Number
1 cc	ABS-2010-**01**
2.5 cc	ABS-2010-**02**
5 cc	ABS-2010-**05**
10 cc	ABS-2010-**10**

AlloSync Expand Demineralized Cortical Fibers

Product Description	Item Number
AlloSync Expand Demineralized Cortical Fibers, 1 cc	ABS-2017-**01**
AlloSync Expand Demineralized Cortical Fibers, 2.5 cc	ABS-2017-**02**
AlloSync Expand Demineralized Cortical Fibers, 5 cc	ABS-2017-**05**
AlloSync Expand Demineralized Cortical Fibers, 10 cc	ABS-2017-**10**

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Notes

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