BioSurge™ Cell and Bone Graft Processing System

Surgical Technique

Arthrex®

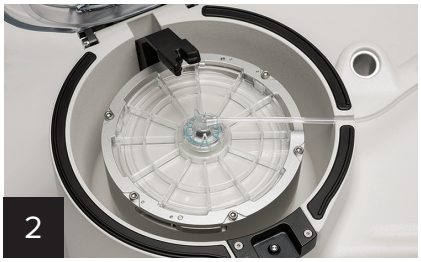
BioSurge

Cell. Signal. Scaffold.

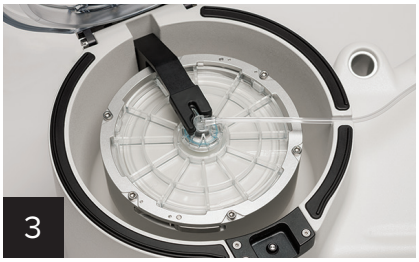
The Arthrex BioSurge™ system combines the superior matrices of the AlloSync™ bone grafting solutions line with the Angel® system's proprietary technology to prepare customized platelet-rich plasma concentrate (cPRP) from bone marrow aspirate (BMA). Hydrated AlloSync bone grafts provide the optimal scaffold for cPRP from BMA, which is a rich source of platelets, and nucleated and progenitor cells.

Instructions for Use

Remove the Angel cPRP processing set from the tray and place it on top of the machine.



Insert the variable-volume separation chamber into the centrifuge adapter by aligning the notches.



Once aligned, press down and turn clockwise until the position indicators snap into place. Place the tube leading from the separation chamber through the centrifuge well slot.

Lower the centrifuge stator arm and align it with the raised tab on top of the separation chamber. Close the centrifuge lid.

Place the pump loop tubing over the pump rotor. The pump loop will automatically load when the processing cycle is initiated.

Press down firmly on the backside of the platelet cuvette until the assembly is snapped in place.

Note: It is essential that the platelet cuvette/valve assembly seats fully on the machine to obtain proper sensing of blood components.

Hang the 3-compartment reservoir bag on the 2 support pins located on the side of the Angel® system.

Prepare the heparin flush. Dilute 5000 units of heparin (1000 U/mL) with 5 mL of sterile saline to achieve a final concentration of 500 units per mL. Transfer heparin flush to the sterile field. Transfer anticoagulant citrate dextrose solution A (ACD-A) to the sterile field. Each 60 mL syringe will contain 8 mL ACD-A, while 30 mL syringes will contain 4 mL of ACD-A and 20 mL syringes will contain 3 mL of ACD-A.

At the sterile field, draw the heparin flush in the first 30 cc collection syringe. Flush the bone marrow harvest needle. Return the remaining heparin flush solution to the medicine cup. Draw 4 mL of ACD-A into the first 30 cc collection syringe and cap.

Instructions for Use (Cont.)

At the sterile field, use the second 30 cc collection syringe to draw the remaining heparin solution. Flush the bone marrow processing filter. Discharge the remaining heparin solution. Draw 4 mL of ACD-A into the second 30 cc collection syringe and cap.

Bone Marrow Aspirate Harvest Guideline

Harvest Site	Approximate BMA Harvest Volume*
Iliac crest	60 mL to 100 mL
Distal femur	60 mL to 80 mL
Proximal tibia	40 mL to 60 mL
Proximal humerus	20 mL to 40 mL
Calcaneus	15 mL to 30 mL

*Guideline only. Actual results may vary.

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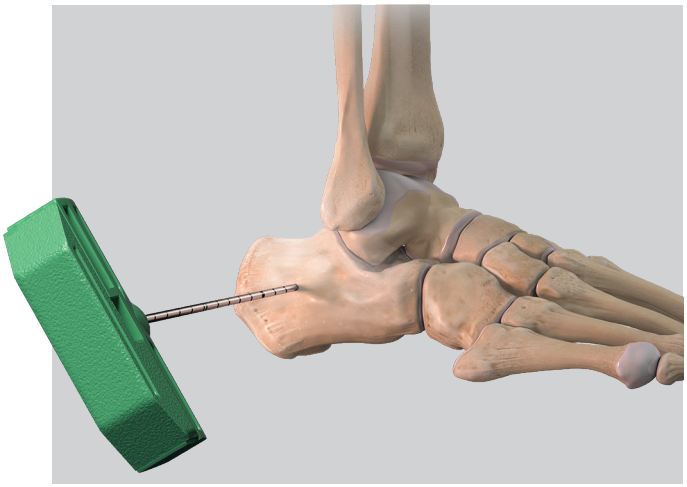
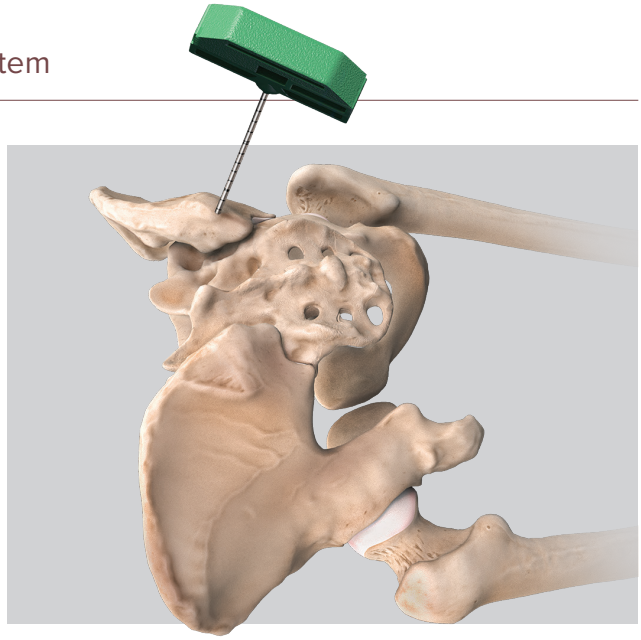


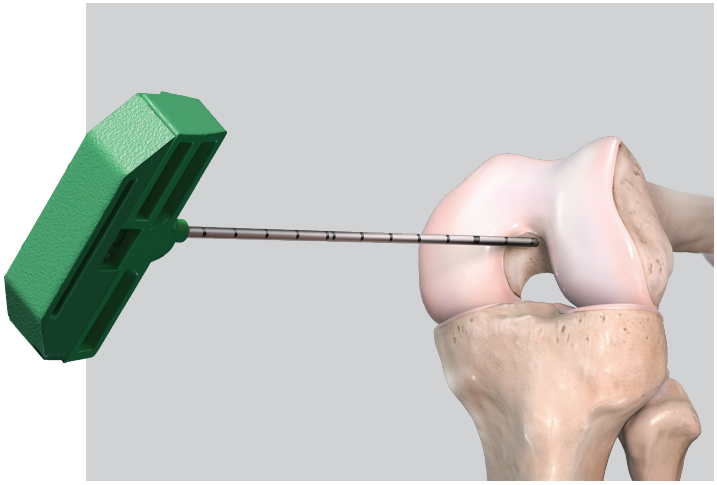
Calcaneus Harvest Technique

Make a small incision 1 cm anterior and 1 cm plantar to the insertion of the Achilles tendon over the lateral portion of the calcaneus, taking care to avoid the sural nerve. When inserting the needle, do not exceed a depth of 3 cm. Aspirate a small volume of bone marrow, redirecting as necessary until the desired volume of BMA is obtained.



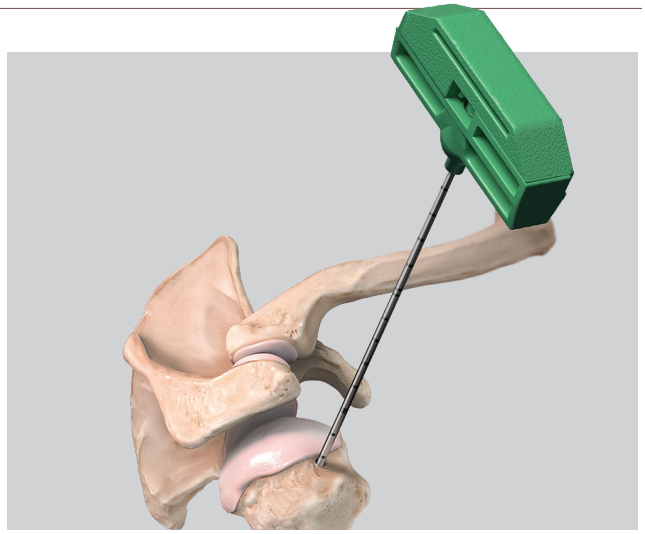
Posterior Iliac Crest Harvest Technique

Make a small incision at the desired location over the posterior superior iliac spine of the iliac crest. Use the needle tip to locate the center of the iliac crest. Insert the needle and advance 3 cm. Aspirate the bone marrow slowly, redirecting as necessary. Repeat until the desired volume is obtained.



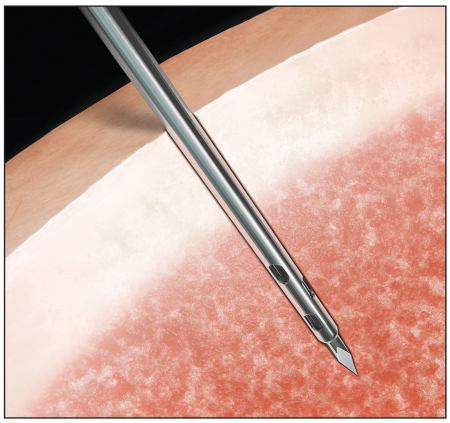
Arthroscopic Distal Femur Harvest Technique

Bone marrow aspiration should occur before drilling tunnels. Arthroscopically insert the needle in the apex of the femoral notch to a depth of 3 cm. Turn off the arthroscopic fluid before removing the trocar and attaching the syringe. Slowly aspirate the bone marrow. In order to obtain the desired volume, it may be necessary to rotate 90° or withdraw the needle 0.5 cm when aspirating; do not withdraw the needle past the 2 cm mark.



Arthroscopic Proximal Humerus Harvest Technique

Bone marrow aspiration should occur before any fixation implants are inserted. Arthroscopically insert the needle in the location where the first anchor would be placed; do not exceed a depth of 3 cm. Turn off the arthroscopic fluid before removing the trocar and attaching the syringe. Aspirate the bone marrow slowly. In order to obtain the desired volume, it may be necessary to rotate 90° or withdraw the needle 0.5 cm when aspirating; do not withdraw the needle past the 2 cm mark.



AlloSync™ Grafts

AlloSync Pure

AlloSync Pure is a dehydrated osteoinductive demineralized bone matrix derived from 100% human allograft bone with no extrinsic carriers. AlloSync Pure can be hydrated with biologic fluids such as bone marrow concentrate. The proprietary rice-shaped fiber technology used to process AlloSync Pure enables the graft to resist irrigation and to be used in a fluid environment.

AlloSync Demineralized Cancellous Sponges

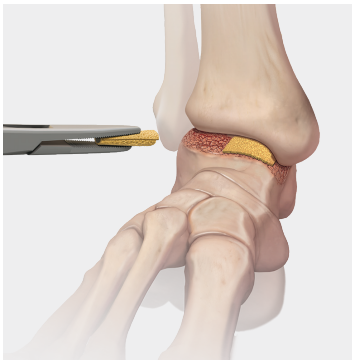
AlloSync demineralized cancellous sponges provide a scaffold that is rich in growth factors with a natural architecture and interconnected porosity. This scaffold is an optimal site for cellular attachment and proliferation. After hydration, the graft is compressible like a sponge, allowing for flexibility to fit in and around different types of bone defects.

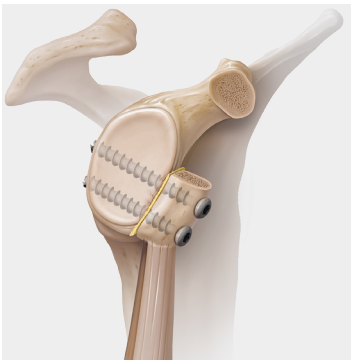
AlloSync Demineralized Cortical Fibers

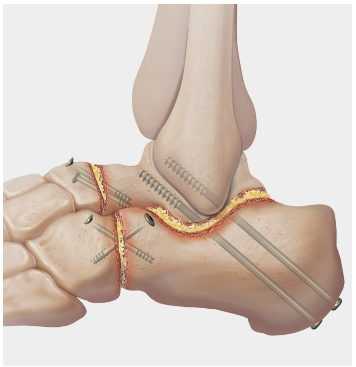
AlloSync demineralized cortical fibers are demineralized using a proprietary process that optimizes the residual calcium level and osteoinductivity. These fibers naturally wick up bioactive fluids such as bone marrow concentrate.

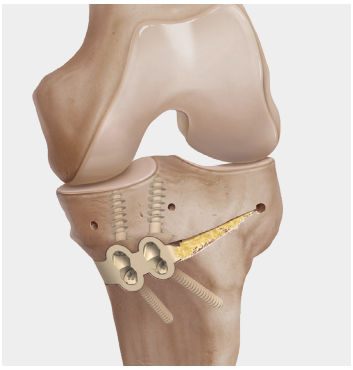
AlloSync Button

The AlloSync button is a 12 mm round by 3 mm thick demineralized cancellous bone disc. This disc maintains the same superior handling characteristics as the AlloSync demineralized cancellous sponges. The compressible nature of this graft allows it to be delivered to a repair site through an arthroscopic portal. Studies suggest that this demineralized bone disc, when used as an interpositional graft for rotator cuff repair, may help to induce more natural tendon-to-bone healing.[1]









Ordering Information

BioSurge™ Cell and Bone Graft Processing System

Product Description	Item Number
BioSurge I System, 2.5 cc AlloSync™ Pure with Arthrex Angel® cPRP and BMA tray	ABS-**2016-01**
BioSurge II System, 5.0 cc AlloSync Pure with Arthrex Angel cPRP and BMA tray	ABS-**2016-02**
BioSurge III System, 15 × 40 × 3 mm AlloSync DBM cancellous strip with Arthrex Angel cPRP and BMA tray	ABS-**2016-03**
BioSurge IV System, 5.0 cc AlloSync DBM cortical fibers and Arthrex cPRP and BMA tray	ABS-**2016-04**
BioSurge V System, 12 mm × 3 mm AlloSync button disc with Arthrex Angel cPRP and BMA tray	ABS-**2016-05**

Reference

1. Smith MJ, Pfeiffer FM, Cook CR, Kuroki K, Cook JL. Rotator cuff healing using demineralized cancellous bone matrix sponge interposition compared to standard repair in preclinical canine model. *J Orthop Res*. 2018;36(3):906-912. doi: 10.1002/jor.23680.

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. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.

View U.S. patent information at www.arthrex.com/corporate/virtual-patent-marking

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