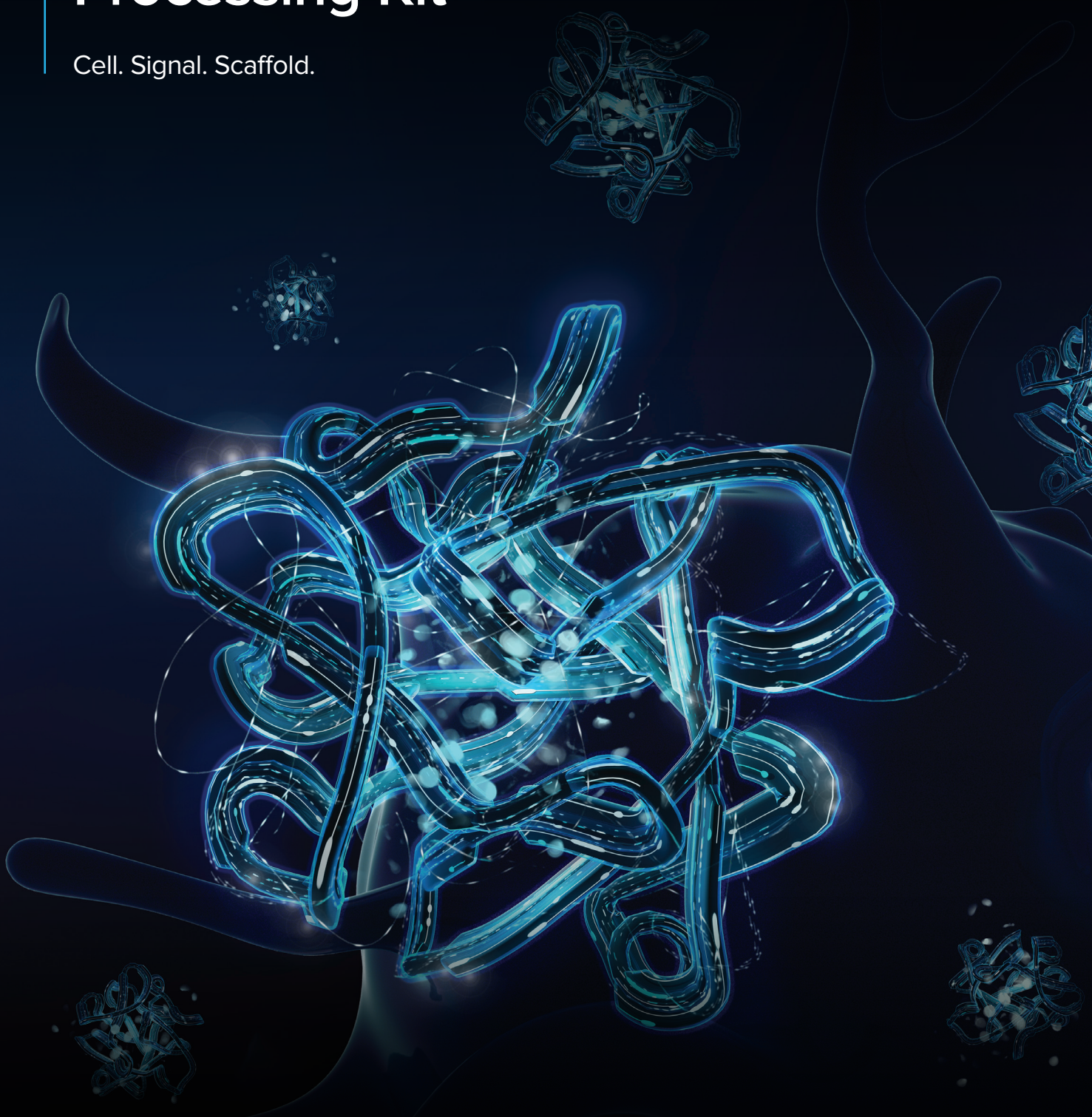
BioSurge™ Cell and Bone Graft Processing Kit

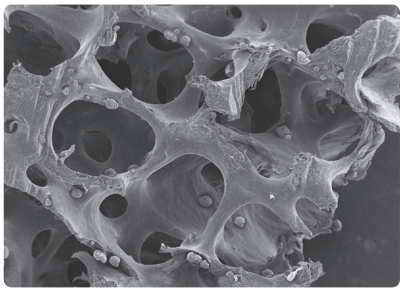
Cell. Signal. Scaffold.



Arthrex®

BioSurge™ Kit

The BioSurge kit combines the superior matrices of the AlloSync™ bone grafting solutions line with the Angel® system's proprietary technology to customize the preparation of concentrated platelet-rich plasma (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 progenitor cells.



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

BioSurge
Cell and Bone Graft Processing Kit

Angel® cPRP and Bone Marrow Processing System

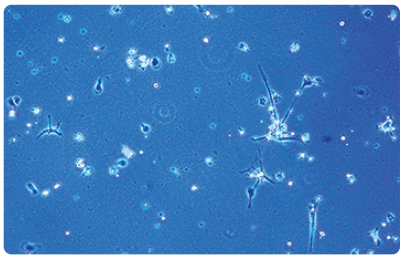
Advanced technology sets the Angel system apart from the competition. The Angel cPRP and bone marrow processing system uses a proprietary platelet sensor and one-button automation to prepare customized cPRP from BMA.

Bone marrow is a rich source of platelets and nucleated progenitor cells. The Angel device is the only system of its kind to provide cPRP from BMA with adjustable cellular levels.

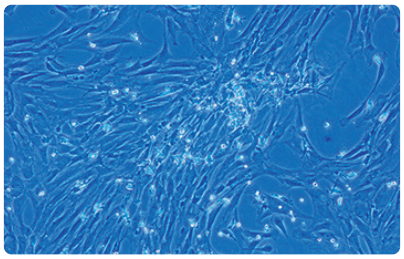
- Proprietary platelet sensor system
- Adjustable platelet concentrations
- Adjustable white blood cell (WBC) concentration
- Flexible processing volume of 40-180 mL
- Ability to process three cycles per kit (up to 180 mL) per patient
- Programmable system capable of storing up to 30 custom processing protocols
- Closed system that delivers platelet-rich plasma (PRP), platelet-poor plasma (PPP), and red blood cells (RBCs) into separate, sterile compartments

Angel cPRP and BMA tray

In vitro culture expansion of progenitor cells over 96 hours



48 hours



96 hours

Precision Separation

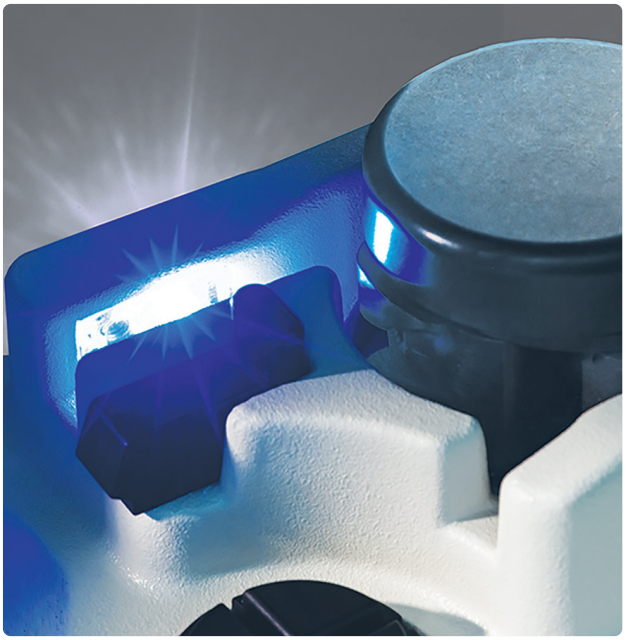
Advantages of 3-Sensor Technology (3ST)

- No syringe switching
- No manual steps to prepare PRP
- Delivers PRP, PPP, and RBCs into separate, sterile compartments
- Ability to modulate platelet, leukocyte, and RBC content
- Consistent PRP output

High-specificity 3ST light sensing and automated valve actuation are the foundation of the Angel® cPRP system. These features help deliver a high yield of PRP and PPP from whole blood.

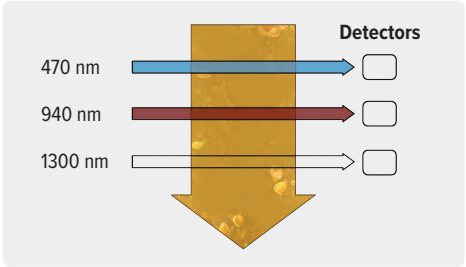
3ST Technology

The Angel system incorporates three sensors to accurately separate blood components using cell-specific wavelengths of light, increasing cellular yields. Absorption of light at 470 nm is used to detect platelets and leukocytes, absorption at 940 nm is used to detect erythrocytes, and absorption at 1300 nm corrects for ambient light and air bubbles.



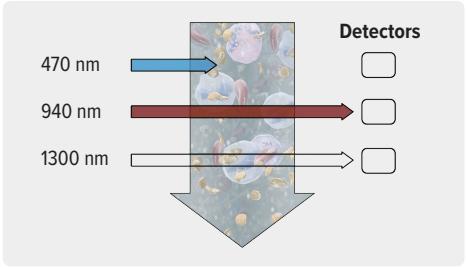
High-specificity 3ST light sensor technology

Plasma



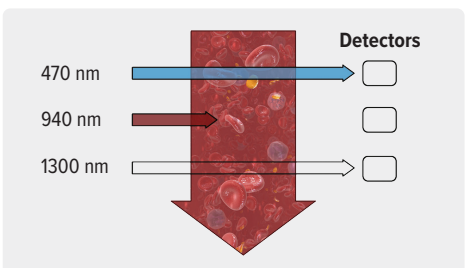
When plasma is present, all three light beams pass through to reach the detector. The Angel device recognizes the presence of plasma and turns the valve to collect PPP, which is deposited in the PPP collection reservoir.

Platelets and Nucleated Cells



When platelets and nucleated cells are present, the 470 nm wavelength of light is absorbed. The absence of the 470 nm beam at the detector signals the Angel system to stop collecting PPP. The system then actuates the valve to collect PRP, which is directed into the collection syringe on top of the unit.

RBCs



The 940 nm wavelength is absorbed by RBCs. When the detector no longer detects the 940 nm beam, the Angel system allows a percentage of RBCs to pass through into the PRP collection syringe. The percentage of RBCs collected in the PRP syringe is determined by the hematocrit (HCT) setting selected by the operator.

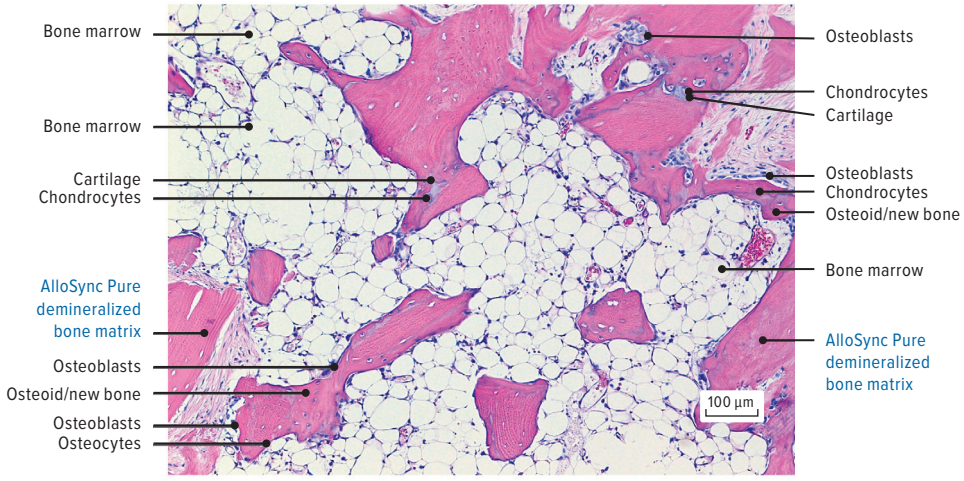
AlloSync™ Bone Grafting Solutions

The AlloSync bone grafting solutions line is a comprehensive offering of osteoinductive bone matrices. The AlloSync demineralization process preserves native bone morphogenetic proteins (BMPs) and growth factors and provides an ideal scaffold for cellular attachment and proliferation.

AlloSync™ Pure Demineralized Bone Matrix
AlloSync Pure demineralized bone matrix (DBM) is a dehydrated osteoinductive demineralized bone matrix derived from 100% human allograft bone. When prepared with a biologic fluid, such as cPRP from BMA, AlloSync Pure DBM resists irrigation and can be used in a fluid environment.

AlloSync Pure DBM has been histologically proven to contain all five elements of bone formation post-implantation, including new bone, bone marrow, osteocytes, chondrocytes, and cartilage.[1]

AlloSync Pure DBM can be used in an arthroscopic environment

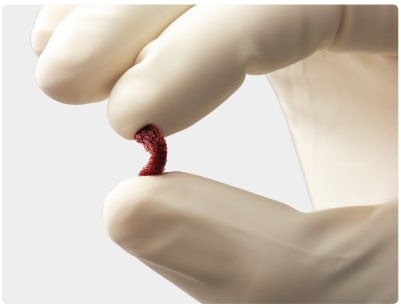


AlloSync Pure DBM histology

AlloSync Cortical Fibers and Cancellous Strips
AlloSync demineralized cancellous strips and cortical fibers maintain the natural bone architecture with interconnected porosity and contain exposed natural growth factors with verified osteoinductivity. These strips and fibers naturally absorb and retain bioactive fluids such as cPRP from BMA. After rehydration, the graft is compressible like a sponge, allowing it to conform to and fill a variety of bone defects.

AlloSync™ Button

The AlloSync button is a 12 mm diameter, 3 mm thick demineralized cancellous bone disc. This disc maintains the same superior handling characteristics as the AlloSync demineralized cancellous sponges. Because it is compressible, it can be delivered to the 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.[2]



BioSurge™ Cell and Bone Graft Processing Kit	
BioSurge I Kit, I, 2.5 cc AlloSync Pure DBM w/ Angel® cPRP and BMA tray	ABS-2016-01
BioSurge II Kit, 5.0 cc AlloSync Pure DBM w/ Angel cPRP and BMA tray	ABS-2016-02
BioSurge III Kit, 15 mm × 40 mm × 3 mm AlloSync DBM cancellous strip w/ Angel cPRP and BMA tray	ABS-2016-03
BioSurge V Kit, 12 mm × 3 mm AlloSync button disc w/ Angel cPRP and BMA tray	ABS-2016-05
BioSurge graft w/ AlloSync Pure DBM, 10 cc	ABS-2016-11
BioSurge graft w/ cortical fibers, 2.5 cc	ABS-2016-12
BioSurge graft w/ cortical fibers, 5 cc	ABS-2016-13
BioSurge graft w/ cortical fibers, 10 cc	ABS-2016-14

References

1. CellRight Technologies, LLC. Data on file (ConCelltrate® 100 histology and in-vitro alkaline phosphate induction assay). Universal City, TX; 2017.
2. 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 a preclinical canine model. *J Orthop Res.* 2018;36(3):906-912. doi:10.1002/jor.23680

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

Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)

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