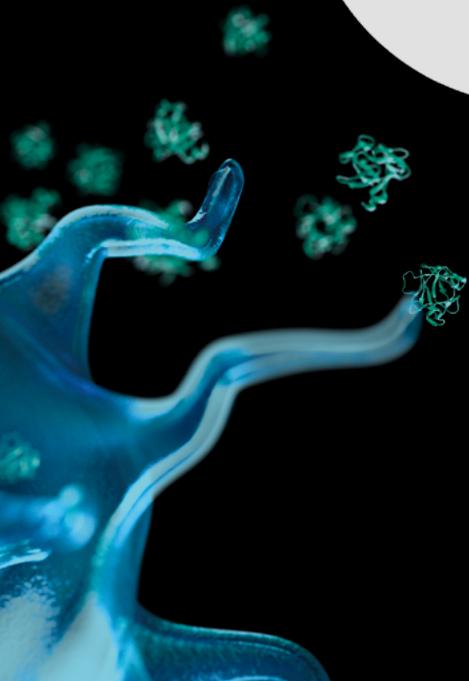
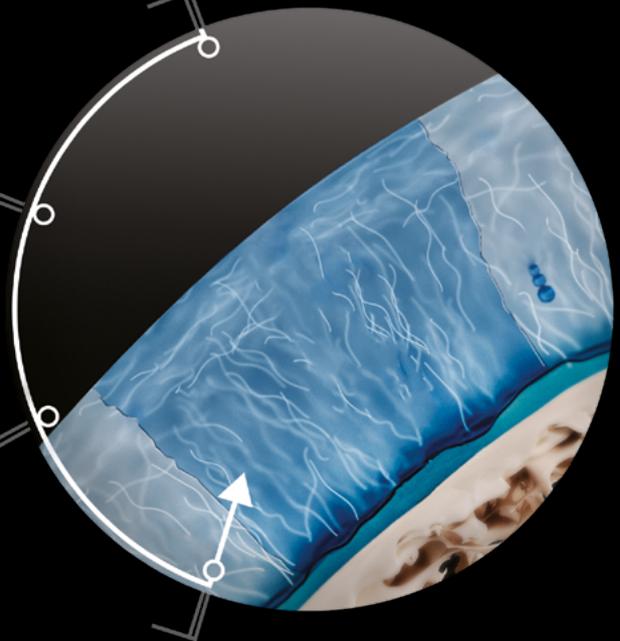


AutoCart™

Single-Stage Articular Cartilage Repair



The AutoCart surgical technique is for the treatment of symptomatic articular cartilage defects. This surgical approach is a single-stage, matrix-augmented, autologous chondrocyte transplantation that combines articular cartilage collected using the GraftNet™ device with BioCartilage® extracellular matrix (ECM). When the GraftNet-collected autologous osteochondral tissue, mixed with BioCartilage ECM, is combined with Arthrex ACP® platelet-rich plasma (PRP) then sealed in the prepared defect with Thrombinator® autologous thrombin serum, this technique offers a single-stage, biologic option for treating focal osteochondral defects.

Scientific Support for the AutoCart Procedure

Massen FK,
Inauen CR,
Harder LP,
Runer A,
Preiss S,
Salzmann GM

Analysis of the One-Stage Autologous Particulate Cartilage Implantation

One-step autologous minced cartilage procedure for the treatment of knee joint chondral and osteochondral lesions: a series of 27 patients with 2-year follow-up. *Orthop J Sports Med.* 2019;7(6):2325967119853773. doi:10.1177/2325967119853773

- Prospective clinical trial of single-stage reimplantation of autologous cartilage particles for chondral/osteochondral lesions of the knee joint in 27 patients with a follow-up period of 2 years
- The surgical procedure proved to be safe and showed no failure rate; patient-reported NAS pain scores showed significant improvement from 7.2 ± 1.9 to 2.3 ± 2.0 at 1 year and 1.8 ± 1.6 at 2 years; patient-reported functional scores showed similar results
- After treatment, 92.6 % of patients reported that they would choose the surgical procedure again

Takeaway

Based on the short-term clinical results of this study, the authors concluded single-stage autologous chondrocyte transplantation has been shown to be a safe and well-accepted procedure for the treatment of focal cartilage damage. The patient-relevant assessments regarding postoperative pain and function show promising results.

Chondrocyte Collection and Viability With the GraftNet Device

Chondrocytes from device-minced articular cartilage show potent outgrowth into fibrin and collagen hydrogels. *Orthop J Sports Med.* 2019;7(9):2325967119867618. doi:10.1177/2325967119867618

- Investigated the effect of arthroscopic minced cartilage removal on chondrocyte viability and migration potential of chondrocytes into a surrounding scaffold
- After 7 days of growth, chondrocyte viability was similar to hand mincing and a biopsy punch of intact cartilage
- Chondrocytes had similar migration into the surrounding scaffold regardless of collection by device or hand mincing

Takeaway

Whether the cartilage is removed by hand mincing or with an arthroscopic shaver, the chondrocytes maintain their viability at a level comparable to that achieved with a biopsy punch of intact cartilage. Chondrocytes show the ability to migrate to the surrounding area regardless of the mincing type.

Levinson C,
Cavalli E,
Sindi DM,
Kessel B,
Zenobi-Wong M,
Preiss S,
Salzmann G,
Neidenbach P

Acevedo L,
Iselin L,
Berkelaar MHM,
Salzmann GM,
Wolf F,
Feliciano S,
Vogel N,
Pagenstert G,
Martin I,
Pelttari K,
Barbero A,
Arnold MP

[Comparison of human articular cartilage tissue and chondrocytes isolated from peripheral versus central regions of traumatic lesions.](#) *Cartilage*. 2021;13(2_suppl):68S-81S. doi:10.1177/1947603520958154

- Analyzed cartilage from the central and peripheral regions of traumatic joint injuries for tissue quality, viability, and proliferation capability of the minced cartilage
- Peripheral cartilage had similar cellularity and proliferation rate to the central cartilage samples
- Peripheral cartilage had increased cartilage quality compared to central cartilage, while central cartilage had an increase in cartilage viability; however, the peripheral cell viability was still at 96.8 % viability, which is well above the acceptable percentage for implantation

Takeaway

Peripheral cartilage surrounding a traumatic lesion may provide cartilage with high quality, acceptable chondrocyte viability, and acceptable cellularity. It also maintains proliferative potential.

Autologous Graft Stability and Fixation With the Thrombinator™ Device

[The clot thickens: autologous and allogeneic fibrin sealants are mechanically equivalent in an ex vivo model of cartilage repair.](#) *PLoS One*. 2019;14(11):e0224756. doi:10.1371/journal.pone.0224756

- Study comparing allogeneic fibrin glue and autologously produced fibrin/thrombin scaffold from platelet-poor plasma (PPP)/PRP
- The autologous scaffold fixation with PPP/PRP showed the same mechanical quality as an allogeneic product in all aspects considered

Takeaway

The use of an autologous fixation solution of cartilage particles in the regenerate allows equal mechanical stability and autograft integration, with lower thrombin/fibrin concentration than allogeneic fixations. This may lead to better integration of the autograft and defect healing.

Clinical Results for the AutoCart™ Procedure

[Outcomes after a single-stage procedure for cell-based cartilage repair: a prospective clinical safety trial with 2-year follow-up.](#) *Am J Sports Med*. 2011;39(6):1170-1179. doi:10.1177/0363546511399382

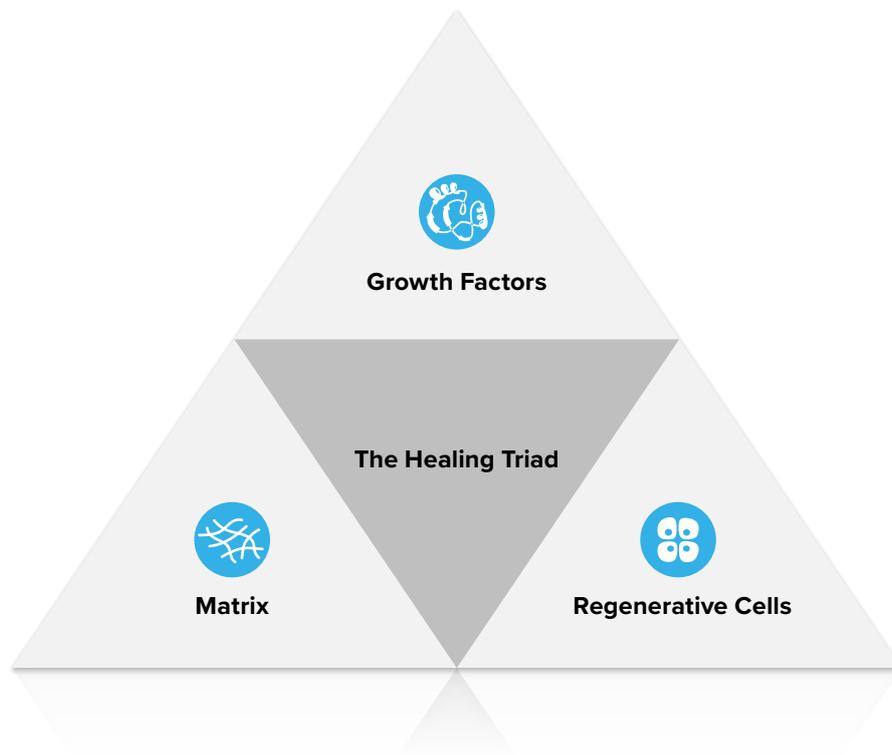
- Analysis of the safety and clinical outcomes of a single-stage cartilage autograft implantation system
- After 24 months, the single-stage autograft implantation technique provided significantly improved IKDC and KOOS patient scores when compared to microfracture
- Single-stage autograft implantation showed a decreased incidence of intralesional osteophyte formation at 6- and 12-month follow-ups

Takeaway

Compared to microfracture, single-stage autograft cartilage implantation provides superior patient outcomes and decreased negative outcomes associated with osteophyte formation.

Irwin RM,
Bonassar LJ,
Cohen I,
Matuska AM,
Commins J,
Cole B,
Fortier LA

Cole BJ,
Farr J,
Winalski CS,
Hosea T,
Richmond J,
Mandelbaum B,
De Deyne PG



The Healing Triad

Successful tissue formation requires 3 main components: a scaffold, growth factors, and regenerative cells. These components form the “healing triad.” A scaffold is needed to provide a structure for tissue growth. It assures mechanical integrity and provides a substrate for cell growth. Growth factors are bioactive signaling molecules. They induce differentiation, proliferation, and metabolic activity and determine the phenotype of the cells. Regenerative cells, such as vital chondrocytes, also stimulate tissue regeneration.

In the case of cartilage restoration, the healing triad describes the combined use of vital chondrocytes and osteocytes (regenerative cells), PRP (growth factors), extracellular chondral fragments, and an autologous thrombin solution (scaffolds).

Augmentation with BioCartilage® extracellular matrix (ECM) may act as a scaffold to improve graft handling during delivery and aid tissue fill of the prepared osteochondral defect.¹⁻⁵



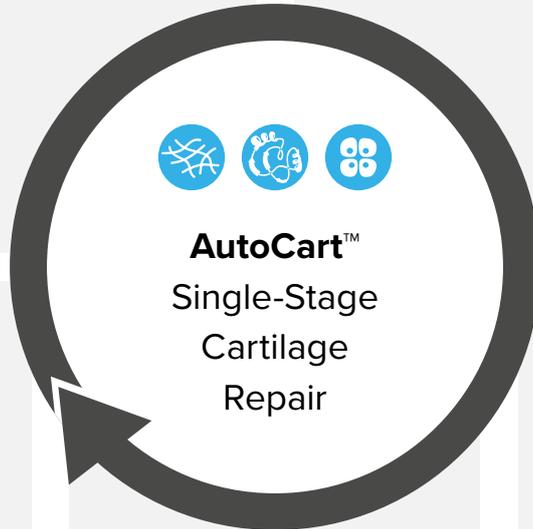
Shaver Blades

For harvesting chondrocytes and autologous cartilage tissue



GraftNet™

Autologous tissue collector



BioCartilage® ECM

For the preparation of growth factors to be mixed with the osteochondral graft



Arthrex ACP®

Platelet-Rich Plasma
For the preparation of growth factors



Thrombinator™ System

For the preparation of autologous thrombin serum

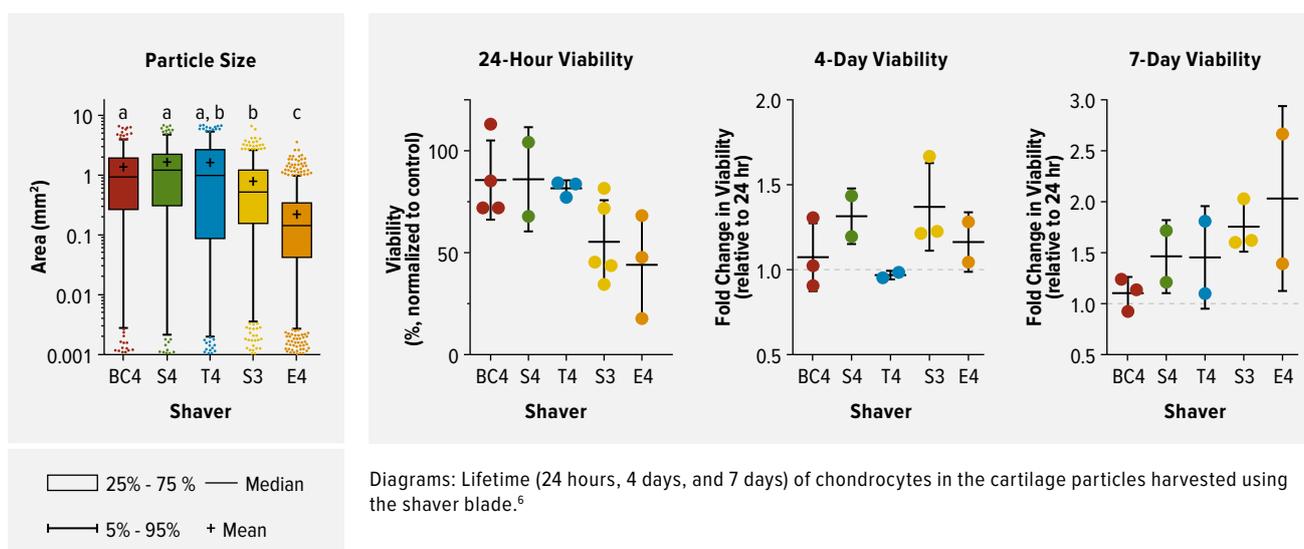
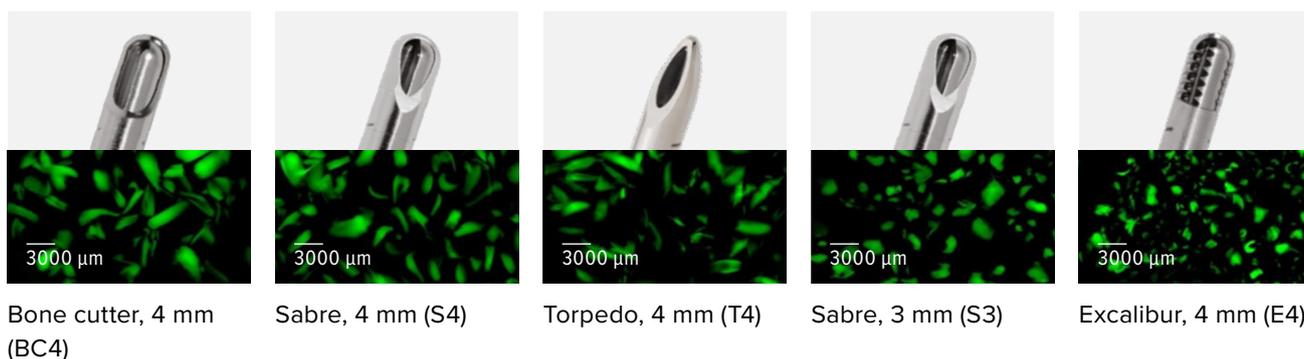
Shaver Blades



Introduction

Use a 3 mm Sabre shaver blade or 4 mm bone cutter shaver blade to harvest autologous chondral and osteochondral fragments. Tissue is harvested either from the edge of the lesion or from a non-loadbearing area. Using these shaver blades produces fragments approximately 1 mm across while maintaining good chondrocyte vitality.³

Arthroscopic Shaver Blades With Cartilage Fragments⁶



Particle size distribution (area) for various shaver blades⁶



Introduction

The suction-activated GraftNet device allows for efficient collection of autologous tissue to incorporate the patient's own cells into the graft. After mounting the GraftNet tissue collector between the shaver handpiece and the suction system, the autologous osteochondral fragments are collected in an easily accessible, sterile filter chamber. Open the tissue collector and remove the filter chamber and osteochondral fragments.

Features and Benefits

- Universal adapters make for easy assembly
- Harvest autologous bone or cartilage fragments
- Quick access to the harvested tissue
- Control over particle size when using a shaver blade system

Composition

- BioCartilage ECM contains the ECM that is native to articular cartilage, including key components such as type II collagen (Figure 1), proteoglycans (Figure 2), and additional cartilaginous growth factors
- After processing, the dehydrated allograft cartilage has a particle size of 100 µm-300 µm:
 - The small particle size improves its injectable nature after it is mixed with an autologous blood solution, allowing easier delivery to the defect site
 - The small particle size also increases the surface area, providing attachment sites for the patient's bone marrow cells^{7,8} (figures 3 and 4 depict the ability of progenitor cells to attach to BioCartilage ECM)

Processing

- BioCartilage ECM is terminally sterilized using electron beam (e-beam) irradiation to a sterility assurance level (SAL) of 10^{-6} . The graft is packaged to allow for ambient temperature storage with a shelf life of 5 years.

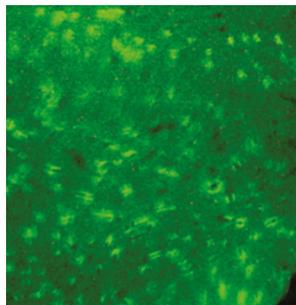


Figure 1. Immunohistochemistry staining for type II collagen

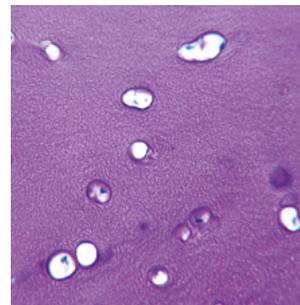


Figure 2. Proteoglycan content as evidenced by the presence of interterritorial granular matrix via toluidine blue staining

Attachment of Progenitor Cells to BioCartilage ECM

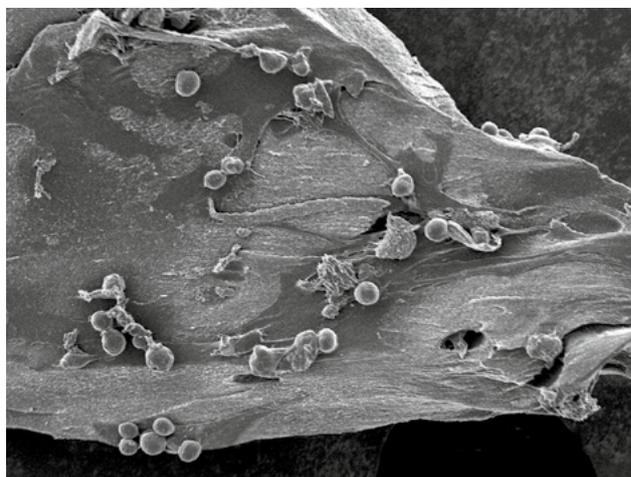


Figure 3.

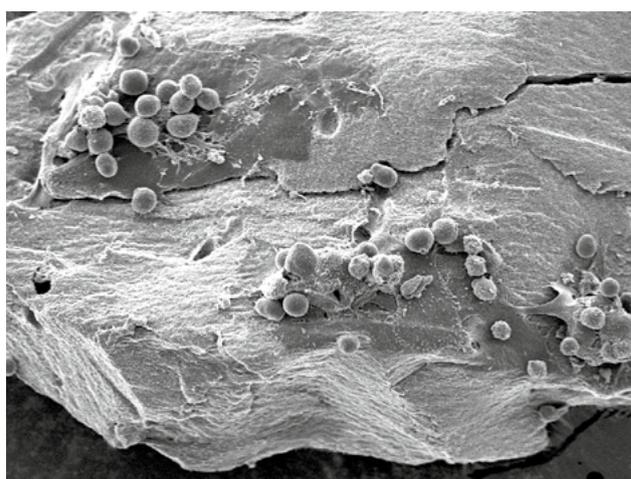


Figure 4. The tissue was stained after dehydration, before micronization

Arthrex ACP® Double Syringe



Introduction

The Arthrex ACP double syringe is used for the preparation of PRP and associated concentrated growth factors.

How It Works

Platelets release proliferative and morphogenetic proteins. These proteins appear to work in synergy to produce the following positive effects:⁹⁻¹¹

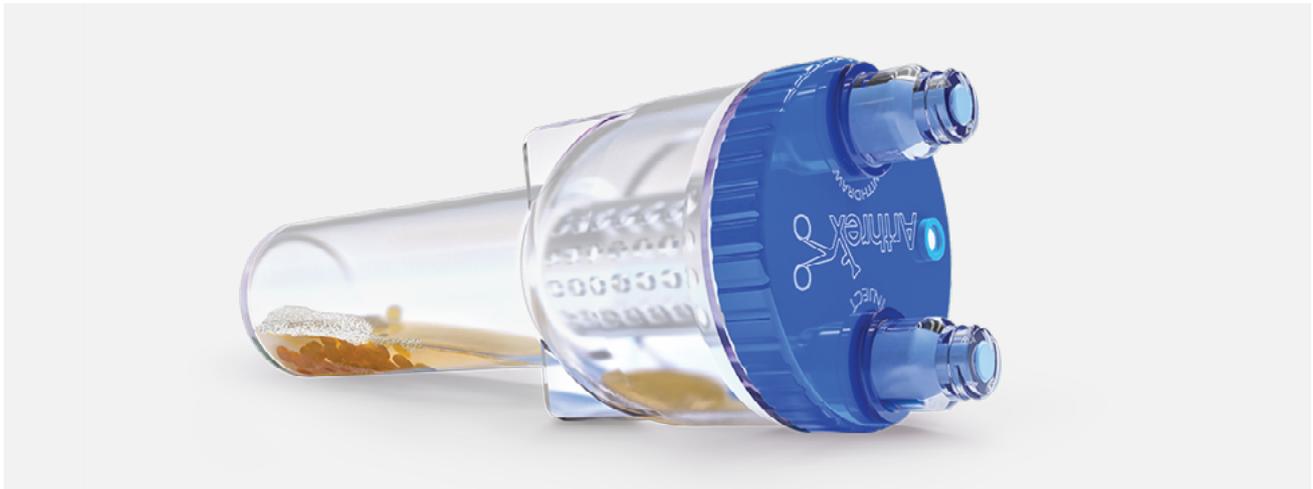
- Induce proliferation and differentiation of various cell types (such as progenitor cells, osteoblasts, and epidermal cells)
- Enhance/modulate production of collagen, proteoglycan, and tissue inhibitors of metalloproteinases (TIMP)
- Stimulate angiogenesis and chemotaxis

Features and Benefits of the Arthrex ACP Double Syringe

- Unique 2-in-1 system for preparation of ACP
- ACP preparation and use takes just minutes
- Closed, sterile system
- Simple, practical, and easy to use

Thrombinator™ System

For Preparation of Autologous Thrombin Serum



Introduction

The Thrombinator system, for use with the Arthrex PRP systems, is designed to obtain an autologous thrombin solution directly at the point of care. Autologous thrombin solution improves handling and fixation by causing platelets to form a gel that serves as a binding agent for bone/cartilage graft material when treating an osteochondral defect.

The Thrombinator process uses the clotting cascade mechanism to produce an autologous thrombin solution and avoids the use of aggressive chemical reagents such as ethanol. The design of the Thrombinator device eliminates the need for prolonged incubation times and heating. An autologous thrombin solution can be produced in as little as 22 minutes.

Features and Benefits

- Preparation from whole blood (WB), PRP, or PPP
- Produces clotting in as little as 15 seconds
- Does not require centrifugation or heating

User Instructions

Preparation of ACP



Draw 15 mL venous blood using Arthrex ACP® double syringes, then seal the double syringes using the red caps.

Note: Depending on the desired volume of autologous fluid necessary for the Thrombinator™ device and when mixing with the autograft tissue, adjust the starting volume of whole blood and processing times as needed.



Centrifuge at 1500 rpm for 5 minutes.



To transfer the ACP from the larger outer syringe into the small inner syringe, slowly push down on the syringe's red wings.



Unscrew the small syringe from the large syringe.

Preparation of Autologous Thrombin Solution



Add 0.1 mL CaCl and 4 mL autologous blood fraction (PRP, PPP or WB) through the “Inject” port. The CaCl should be added first, followed by the autologous blood fraction.



Mix for 5 seconds.



Place the Thrombinator™ device flat with “Withdraw” side up and wait a minimum of 15-20 minutes or until signs of gelling occur. Avoid picking up the device during this time.



Shake for 5 seconds to break the clot.



Add 0.2 mL CaCl and 8 mL autologous blood fraction through the “Inject” port. The CaCl should be added first, followed by the autologous blood fraction.



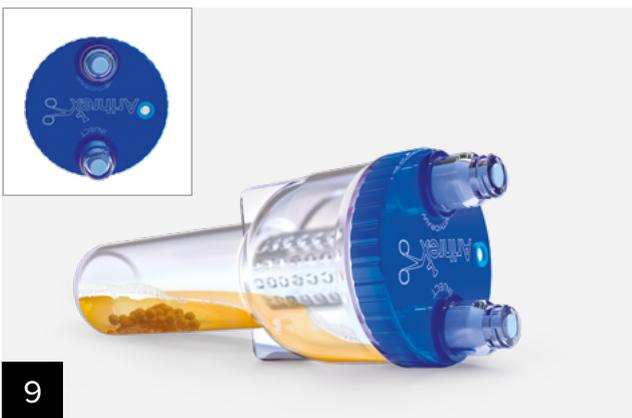
Mix for 5 seconds.



7 Place the Thrombinator™ device flat with “Withdraw” side up and wait 1-2 minutes. Avoid picking up the device during this time.



8 Shake for 5 seconds to break the clot.



9 Place the Thrombinator device flat with “Withdraw” side up and wait 1-2 minutes. Avoid picking up the device during this time.



10 Shake for 5 seconds to break the clot.



11 Connect the filter to the “Withdraw” port. Invert the device and withdraw serum through the filter.



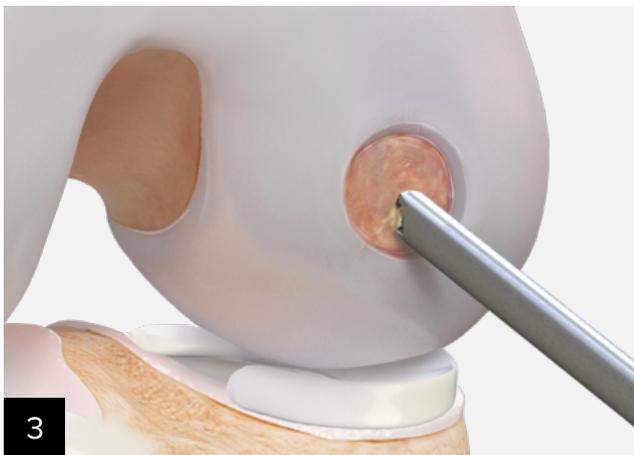
12 Use serum within 15 minutes of withdrawal from device.



Mount the GraftNet™ tissue collector between the shaver handpiece and tubing system.



Debride and prepare the cartilage defect as appropriate. Take care to create vertical margins.



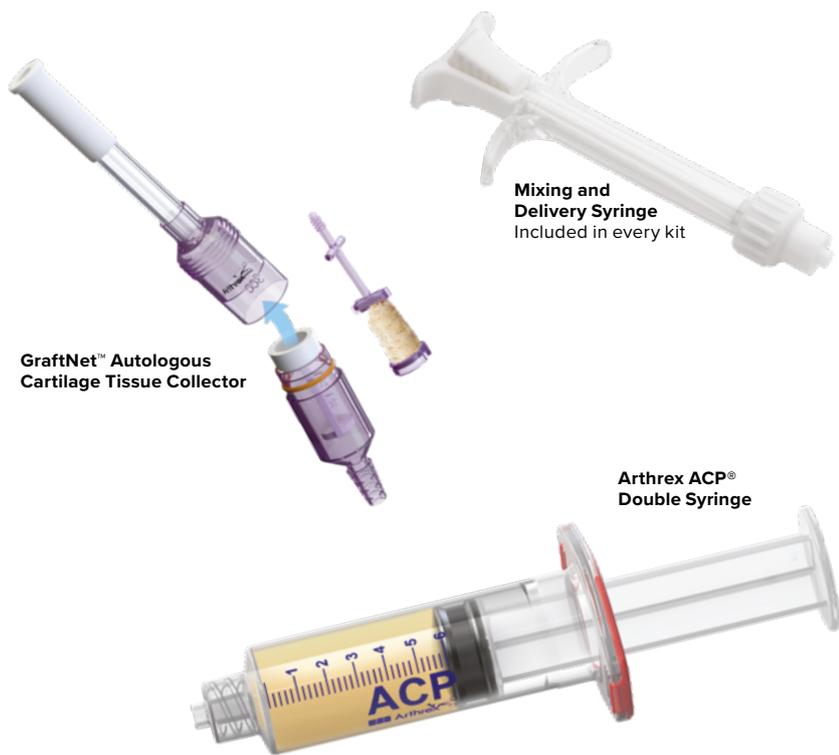
Harvest chondral fragments from around the lesion border. Alternatively, resect healthy osteochondral fragments from another typical osteochondral harvest location (ie, another place on the same knee).



The harvested osteochondral fragments are collected in the tissue collector.



Separate the tissue collector from the handpiece and tubing system. Open the collector and carefully take out the plunger.



Using the mixing and delivery system, first remove the syringe cap and snap on the funnel to the end of the mixing syringe. Make sure the plunger is at the end of the syringe. Empty the GraftNet autologous osteochondral tissue and BioCartilage® ECM from their container into the funnel. The desired ratio is 1:1.



Remove the funnel and add ACP into the mixing syringe with a 1:0.8 ratio (BioCartilage ECM and GraftNet–device–collected osteochondral tissue to autologous fluid). Twist on the syringe cap and Luer cap.



Unsnap the pushrod from the mixing element by pressing on the tip of the mixing element with counter-pressure on the tip of the pushrod.



9

Push and pull the mixing element back and forth while rotating it in a repeated left-to-right motion. Continue until thoroughly mixed.



10

Pull back on the mixing element to bring it back to its starting position.



11

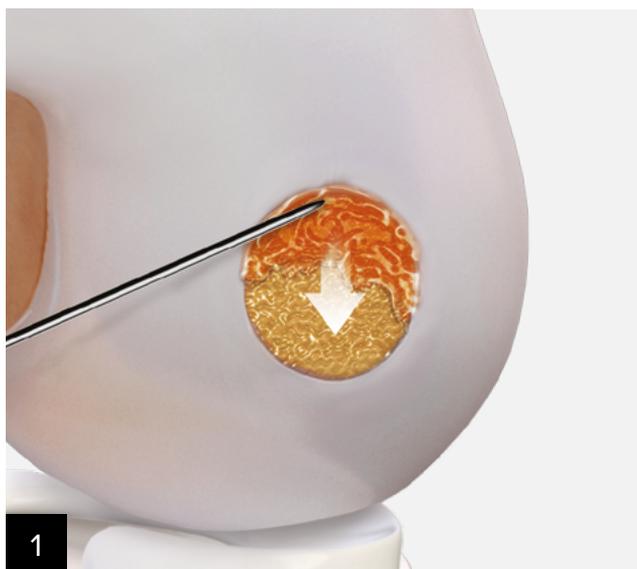
Snap the pushrod back onto the mixing element.



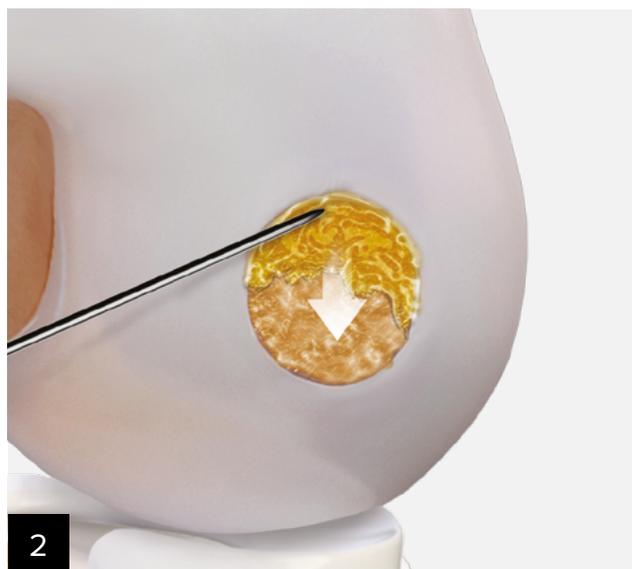
12

Ensure the defect is dry and prepared for graft delivery. Attach a delivery cannula and dispense the AutoCart graft out of the mixing syringe, use the obturator to deliver all the mixture.

Autologous Thrombin Mixture and Delivery



After preparing for graft fixation, carefully cover the fragment paste with the prepared thrombin serum. Start from the top. The Thrombinator™ method relies on the blood clotting cascade mechanism. The combination of the fibrinogen contained in the paste and the thrombin applied creates a stable clot that holds the osteochondral mixture in the lesion.



After mixing, apply the mixture quickly to the lesion from the top, drop by drop, then wait for approximately 2 minutes.

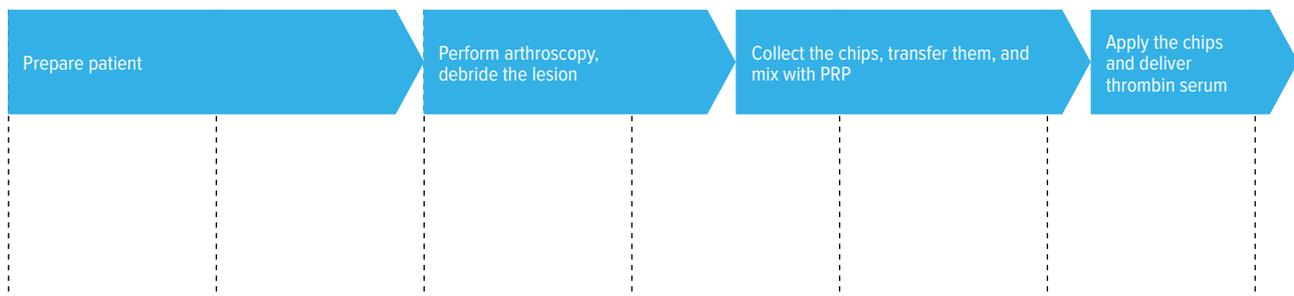


A 1:1 mixing and delivery applicator can be used to simultaneously deliver a fibrinogen source platelet-poor plasma, PRP, or whole blood with the thrombin serum.

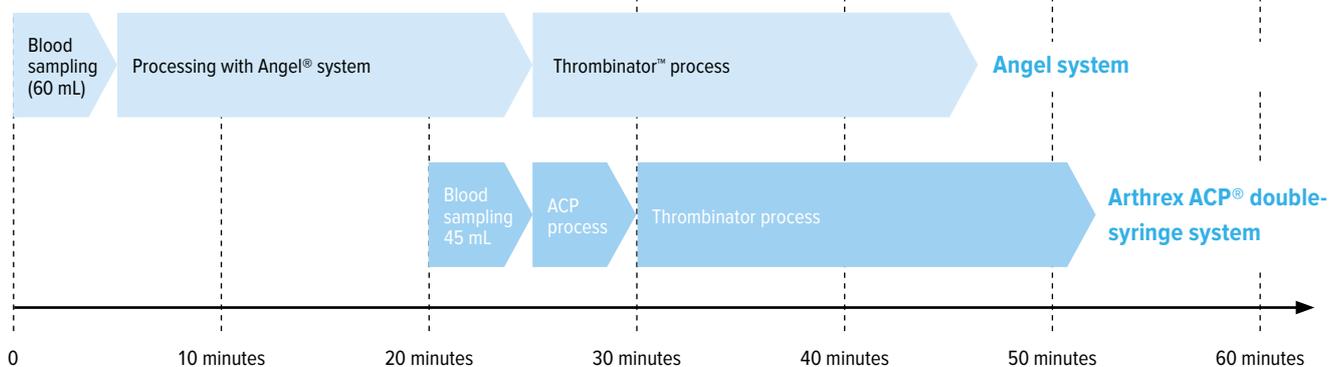
Quick Guide to Procedure

This diagram shows the approximate chronological sequence of the individual procedural steps and includes information about when blood must be processed in parallel (depending on the system selected). The times are for guidance only and may vary.

Workflow



Process the platelets in parallel



Ordering Information

Product Description	Item Number
GraftNet™ Device	
GraftNet autologous tissue collector	ABS-1050
BioCartilage® ECM	
BioCartilage ECM, 1 cc	ABS-1010-BC
Mixing and delivery kit, large joint (includes mixing syringe and arthroscopic delivery needle, obturator, funnel, fat pad retractor, and cannulated swabs)	ABS-1000-L
Mixing and delivery kit, small joint (includes mixing syringe and cap, arthroscopic delivery needle, obturator, funnel, fat pad retractor, and cannulated swabs)	ABS-1000-S
Mixing and delivery kit, hip joint (includes mixing syringe and cap, arthroscopic delivery needle, obturator, funnel, fat pad retractor, and suction adaptor)	ABS-1000-H
Arthrex ACP® Double-Syringe System	
Arthrex ACP double syringe	ABS-10014
Arthrex ACP kit, series I	ABS-10011
Arthrex ACP kit, series II	ABS-10012
ACP Max™ PRP System	
ACP Max PRP system w/ ACD-A	ABS-10015
ACP Max PRP system	ABS-10013

Product Description	Item Number
Angel® cPRP System	
Angel PRP kit	ABS-10061T
Thrombinator™ System	
Thrombinator autologous thrombin serum	ABS-10080
Viscous Delivery Systems	
Applicator assembly 10 cc, 1:1 ratio	SA-3310
Dual cannula, malleable, 20 ga × 5 cm (2 in)	SA-3615
Dual cannula, malleable, 20 ga × 10 cm (4 in)	SA-3618
Dual cannula, malleable, 20 ga × 26 cm (10.25 in)	SA-3620
Shaver Blades and Bone Preparation	
Sabre shaver blade, 3 mm × 7 cm	AR-7300SR
Sabre shaver blade, 4 mm × 13 cm	AR-8400SR
Bone cutter, 3.8 mm × 13 cm	AR-8380BC
Bone cutter, 4 mm × 13 cm	AR-8400BC
PowerPick™ instrument, 30°, 1.5 mm × 13 cm	AR-8150PP-30
PowerPick instrument, 45°, 1.5 mm × 13 cm	AR-8150PP-45
PowerPick XL instrument, 45°, 6 mm drill depth	AR-8150PX-45

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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.



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



US patent information

arthrex.com