ArthroCell™ and ArthroCell Plus™ Allografts

Viable Bone Matrices

Arthrex®

ArthroCell™ and ArthoCell Plus™ Viable Bone Matrices

Features and Benefits

ArthroCell and ArthroCell Plus allografts are moldable, viable allogenic bone matrices for use in bone defects and remodeling for a variety of orthopedic applications.

- ArthroCell and ArthroCell Plus allografts are HCT/P allogenic bone scaffolds
- Available as separate components or premixed
- Final products are moldable for optimal handling (Figures 1 and 2)
- Cell viability and function are preserved using a novel cryoprotectant that is DMSO-free and does not require decanting prior to use
- Product shelf life is 3 years from date of processing when stored at -65 ˚C or colder
- Preparation time on a back table is less than 20 minutes. Both products have a 4-hour working window for implantation after thaw without loss of cell viability.
- ArthroCell and ArthroCell Plus allografts are nonimmunogenic alternatives to autograft
- Donors processed for ArthroCell and ArthroCell Plus allografts undergo rigorous screening, testing, and culturing that meet FDA regulations and American Association of Tissue Banks (AATB) guidelines

Figure 1. ArthroCell allograft components

Figure 2. Premixed ArthroCell Plus allograft

Arthrocell and Arthrocell Plus allografts provide the essential elements for optimal bone repair:

- An osteoconductive, 3-dimensional scaffold with cortical and cancellous components[1]
- A demineralized bone component with osteoinductive potential, which provides exposure of signaling molecules and bone morphogenetic proteins[2]
- Viable endogenous bone cells to support osteogenic healing processes[3-5]

Figure 3. ArthroCell and Arthrocell Plus allograft final product

ArthroCell™ ArthroCell Plus™

Cellular Advantage

ArthroCell™ and ArthroCell Plus™ allograft cellular advantages

Cellular component is recovered from donors, frozen, and packaged within 120 hours postmortem

- Cells are recovered from the vertebral body region, an area known to be rich in MSCs[6]
- Cells are preserved in a novel cryoprotectant to preserve cellular identity after thaw
  - DMSO-free
  - Nontoxic
  - Decanting not required prior to use
- Additional cell population includes[7]:
  - MSCs
  - Osteoprogenitor cells
  - Flow cytometry analysis demonstrates high expression of markers for pluripotent cells and MSCs (including CD44, CD73, CD90, CD166, and SSEA-4)

	ArthroCell Plus Allograft Cellular Components
CD44	+++
CD73	+++
CD90	+++
CD166	+++
CD105	+++
CD34	–
CD45	–

+++ Expression between 80%-100%
++ Expression between 60%-80%
+ Expression between 40%-60%
– Expression lower or equal to 5%

Figure 4. Surface marker expression for ArthroCell Plus allograft.

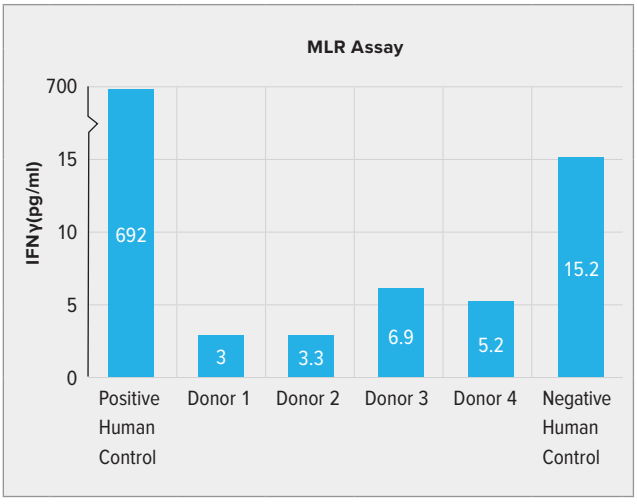


Figure 5. MLR assay performed by VIVEX Biologics for ArthroCell Plus allograft.

Safety

Donor tissue processing

- ArthroCell allograft is processed at VIVEX Biologics in an aseptic manner in Class 100 clean rooms using proprietary procedures and screening criteria that meet AATB requirements
- ArthroCell allograft is collected from donors who have been screened by licensed laboratories and physicians following a process that meets FDA regulations and AATB requirements for testing
- Donor testing includes nucleic acid and/or antibody tests for the following pathogens:
  - HIV-1 and -2
  - Hepatitis B and C
  - Human T-lymphocyte virus
  - Syphilis rapid plasma screen
  - T. pallidum IgG screen
  - Cytomegalovirus, (CMV) Ab (IgG and IgM)
- Donor screening:
  - Medical and social history review
  - Physical examination
  - Medical record evaluation, including autopsy (if performed)
  - Licensed physician review of donor record
- Mixed lymphocyte reaction (MLR) assay
  - MSCs are known to be immune-privileged cells that do not elicit an immune response.[8] To ensure complete safety of the cell component, an MLR assay was performed to assess the potential for activation of T-cell proliferation on samples of ArthroCell allograft along with positive and negative controls.[9]
  - Because the test samples (donors 1-4) did not stimulate a significant response compared to the negative control, the MLR assays demonstrated that the viable allogeneic bone scaffold is not immunogenic and does not stimulate an immune response (Figure 5).

ArthroCell™ Allograft Preparation

1

The product, with all components, will arrive frozen in a sealed pouch. Product consists of 3 components to be transferred aseptically into the sterile field.

2

Components include a cell vial, particulate bone, and gel.

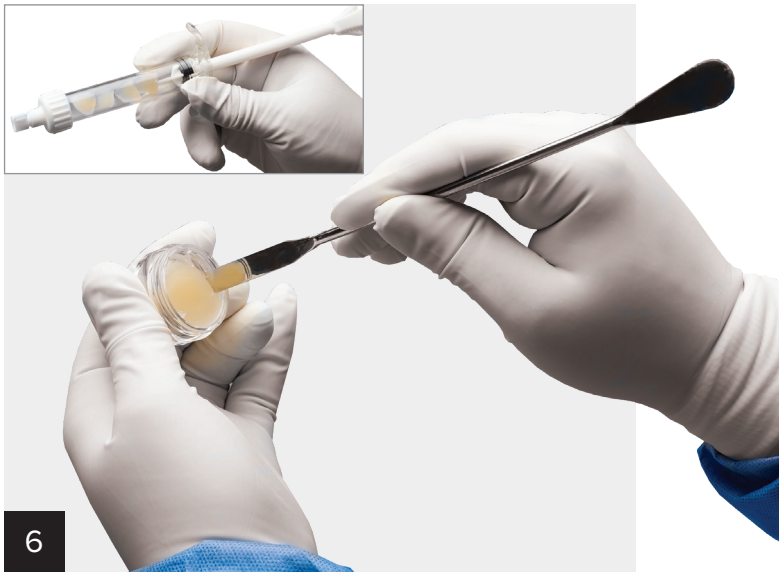
3

Thaw the cell vial (~5 minutes) and gel container (~20 minutes) in a room temperature sterile saline or sterile water bath.

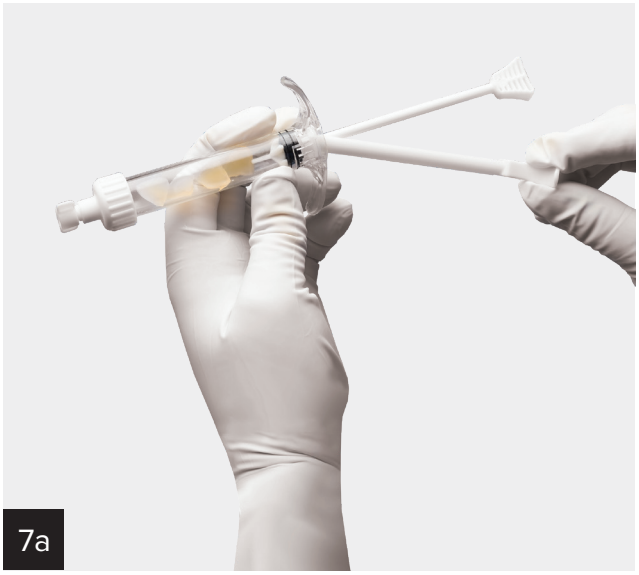
4

While the cell vial and gel container are thawing, remove the inner and outer lids of the bone particulate jar. Mix the saline and the particulate thoroughly using a spatula.

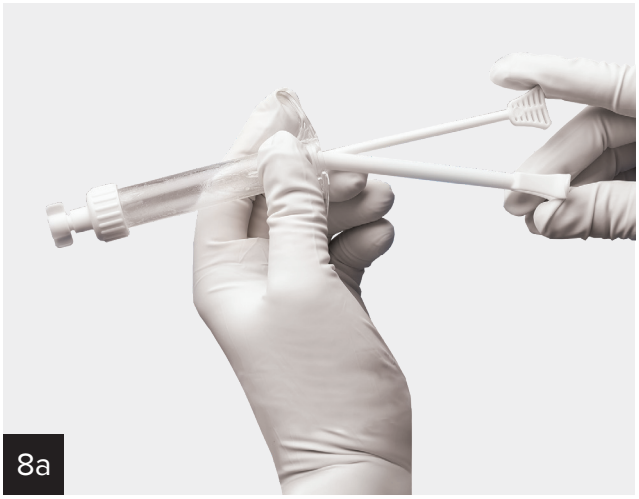
Once the cell vial has thawed, pour the contents of the vial directly into the bone particulate/saline mixture. Mix the cell contents and bone particulate/saline thoroughly using a spatula. Once fully mixed, cap the container and set aside for at least 10 minutes.



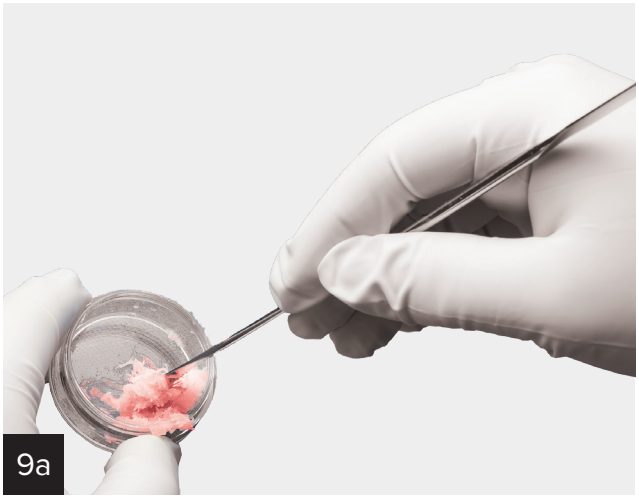
Divide the thawed gel into 3 to 4 pieces and transfer to sterile mixing syringe (ABS-2000).



Unsnap the pushrod from the mixing element. Mix the gel component by pushing/pulling on the mixing element until a paste consistency is obtained, which should occur within 60 seconds of continuous mixing.



Snap the pushrod back into the mixing element and remove the syringe end cap. Dispense the paste onto the cell/particulate matrix.



Using a spatula, mix the cell/particulate/paste matrix thoroughly until all components are incorporated. The matrix can then be molded further in a gloved hand until the desired configuration is obtained.

The final product is moldable and can be stored capped at room temperature until needed. Total time from cell vial thaw to placement at the surgical site should not exceed 4 hours.

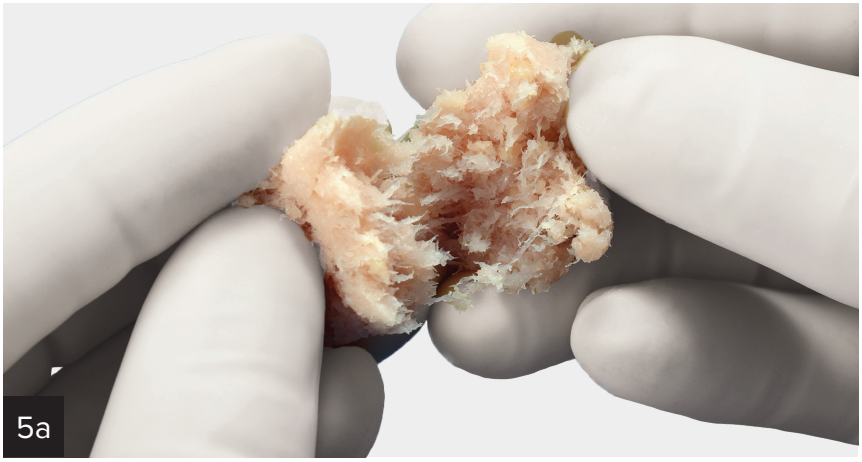
ArthroCell Plus™ Viable Allogeneic Bone Matrix Preparation Guide

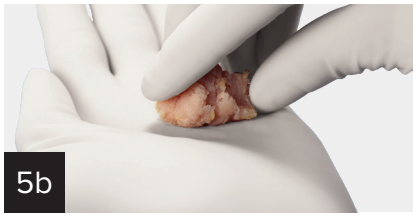
Open the pouch and remove the syringe. Confirm the syringe cap is securely locked.

Place the syringe in the ambient sterile bath for 10-15 minutes, ensuring the contents are submerged.

Remove the syringe from the sterile bath and unscrew the syringe cap from the top as shown above.

Apply slight pressure to the plunger and extrude product out of the syringe into the palm of your hand.

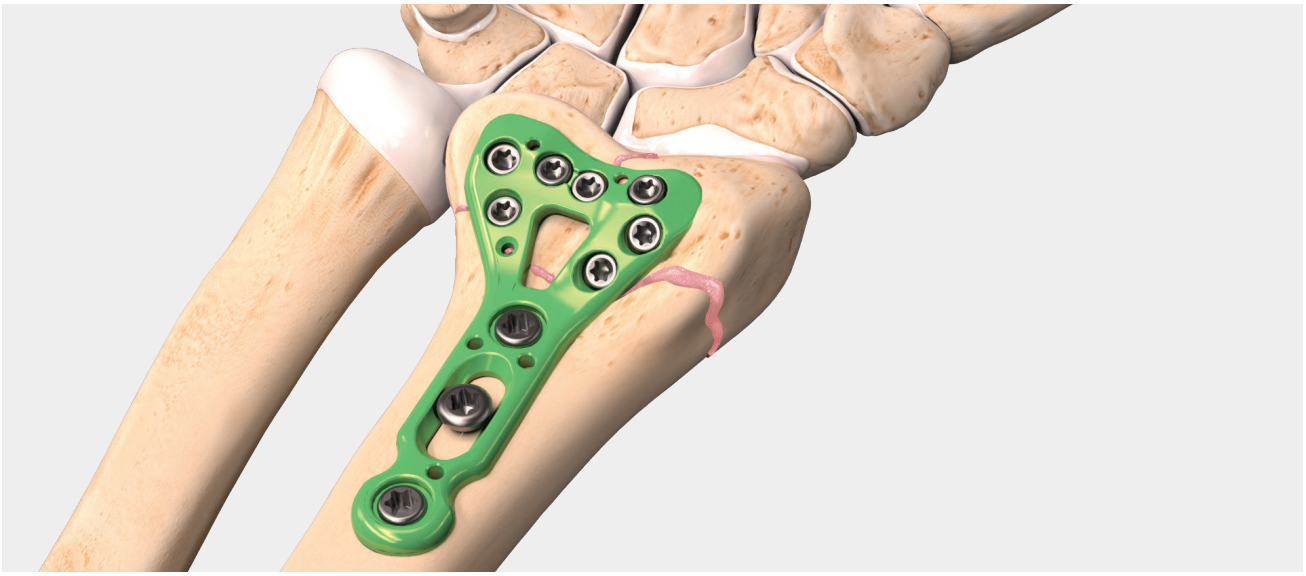


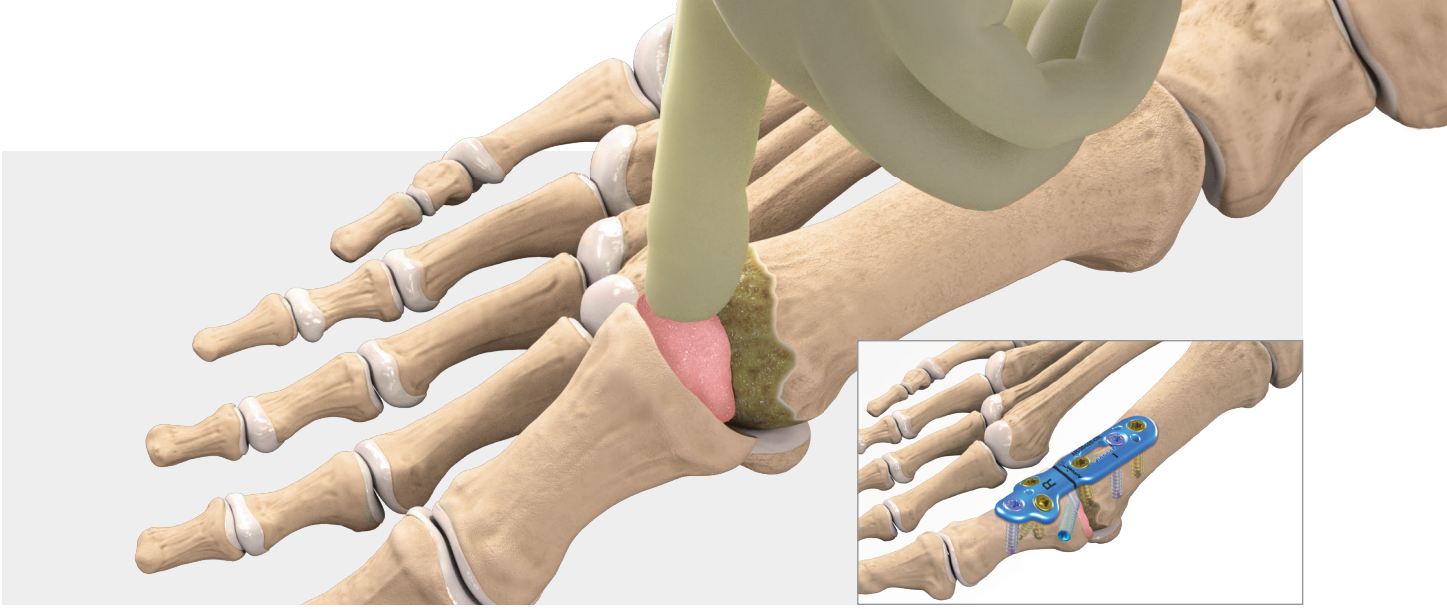


ArthroCell Plus™ allograft is now ready to mold to desired shape. Product remains viable for up to 4 hours on the back table in an operative field.

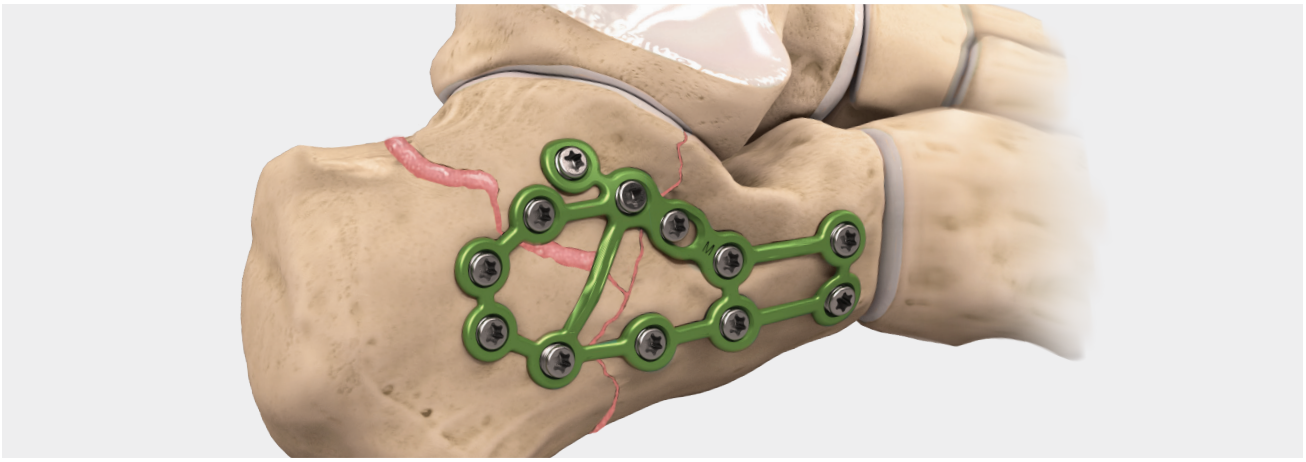
Potential Surgical Applications

Promote Osseous Regeneration Across Upper Extremity Fracture Site Voids
ArthroCell™ and ArthroCell Plus™ allografts can be used as a bone void filler to help treat clavicle fractures alongside 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).

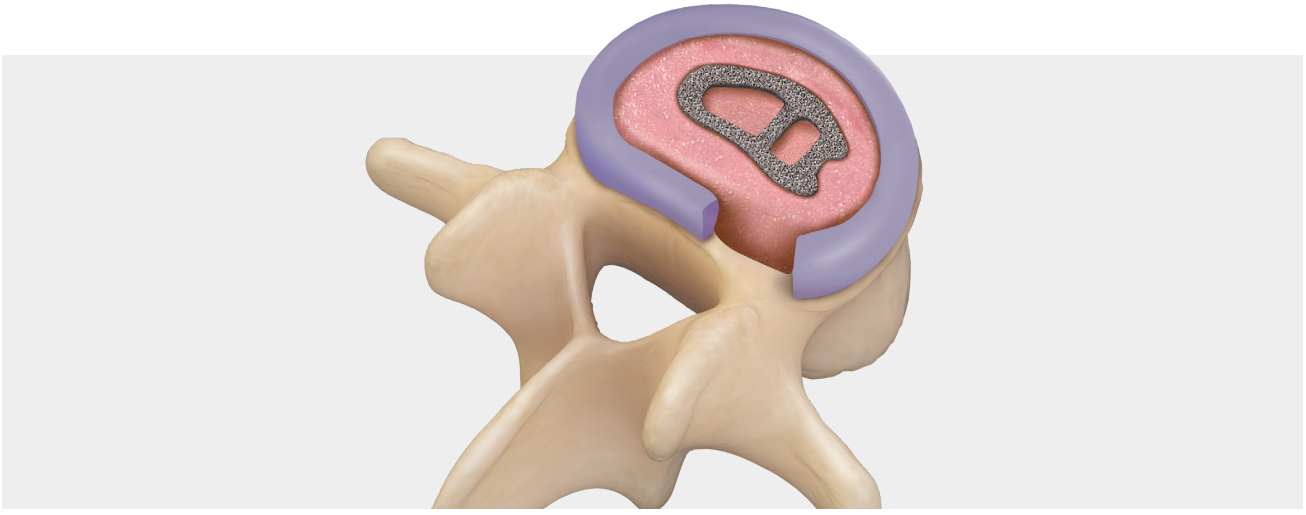




Promote Osseous Regeneration Across Fusion Site Voids
After preparing the 1st metatarsal phalangeal (MTP) joint for an arthrodesis, ArthroCell™ and ArthroCell Plus™ allografts can be inserted into the joint before final fixation with the low-profile MTP plate.



Promote Osseous Regeneration Across Lower Extremity Fracture Site Voids
Calcaneal fractures often have defects where the addition of a cellular bone graft like ArthroCell allograft is useful. For final fixation, the calcaneal fracture system provides a comprehensive solution for all classifications of calcaneal fractures.



Promote Osseous Regeneration Across Spine Fusion Sites
ArthroCell and ArthroCell Plus allografts can be packed into an interbody cage and in the posterolateral gutters to promote fusion and provide a viable scaffold for bone remodeling.

Ordering Information

ArthroCell™ Allograft

Product Description	Item Number
ArthroCell allograft, 2.5 cc	ABS-**2009-02**
ArthroCell allograft, 5 cc	ABS-**2009-05**
Mixing syringe, 14 cc (must be ordered for each graft size)	ABS-**2000**

ArthroCell Plus™ Allograft

Product Description	Item Number
ArthroCell Plus allograft, 1 cc	ABS-**2090-01**
ArthroCell Plus allograft, 2.5 cc	ABS-**2090-02**
ArthroCell Plus allograft, 5 cc	ABS-**2090-05**
ArthroCell Plus allograft, 10 cc	ABS-**2090-10**

References

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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