

ArthroCell™ Allograft

Viable Bone Matrices



Features and Benefits

ArthroCell™ allograft is a moldable viable allogenic bone matrix intended for use in bone defects and remodeling for a variety of orthopedic applications.

- ArthroCell allograft is an HCT/P allogenic bone scaffold
- Final product is 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 back table is less than 20 minutes, and ArthroCell allograft has a 4-hour working window for implantation after thaw without loss of cell viability
- ArthroCell allograft is a safe, non-immunogenic alternative to autograft
- Donors processed for ArthroCell allograft undergo rigorous screening, testing, and culturing that meet FDA and AATB guidelines

ArthroCell allograft provides the essential elements for optimal bone repair:

- An osteoconductive 3-dimensional scaffold with cortical and cancellous components¹
- A demineralized bone component with osteoinductive potential, which provides exposure of signaling molecules and bone morphogenetic proteins²
- Cells to support osteogenic healing processes³⁻⁵



Figure 1. ArthroCell allograft final product.



Figure 2. ArthroCell allograft components.

Cellular Advantage

Background:

Mesenchymal stem cells (MSCs) are a type of adult stem cell present in ArthroCell™ allograft that have the ability to self-renew and differentiate into bone, cartilage, fat, muscle, and tendon.⁶

- MSCs are the osteogenic cells required for bone repair, remodeling, and maturation
- MSCs can differentiate into osteoblasts that subsequently make new bone
- MSCs do not stimulate allogenic rejection and are not eliminated by the host immune system⁷

ArthroCell™ allograft cellular advantage:

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 MSCs⁸
- 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:
 - MSCs
 - Osteoprogenitor cells
 - Flow cytometry analysis demonstrates high expression of SSEA-4, a marker for pluripotent cells and MSCs

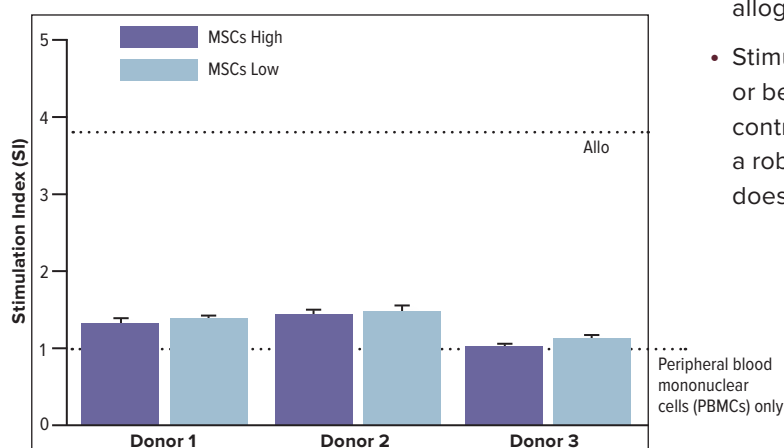


Figure 3.

SI of PBMCs with UMTB test MSCs from 3 donors (high and low)⁹

Stimulation index calculated from BrdU ELISA ABS450 relative to PBMCs. Dotted line at SI 3.84 represents response of positive 2-way allogeneic MLR response. Dotted line at 1.00 represents response of the negative control. Stimulation indices for test samples range from 1.02 to 1.35.

Safety

Donor tissue processing:

- ArthroCell allograft is processed at Vivex Biomedical, Inc. in an aseptic manner in Class 100 clean rooms using proprietary procedures and screening criteria that meet the requirements of the American Association of Tissue Banks (AATB)
- ArthroCell allograft is collected from donors who have been screened by licensed laboratories and physicians following a process that meets FDA 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.⁷ To ensure complete safety of the cell component, a 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
 - Stimulation indices for the test samples were near or below that for the negative control, while positive controls performed as expected and demonstrated a robust response. ArthroCell allograft therefore does not stimulate an immune response (Figure 3).

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.



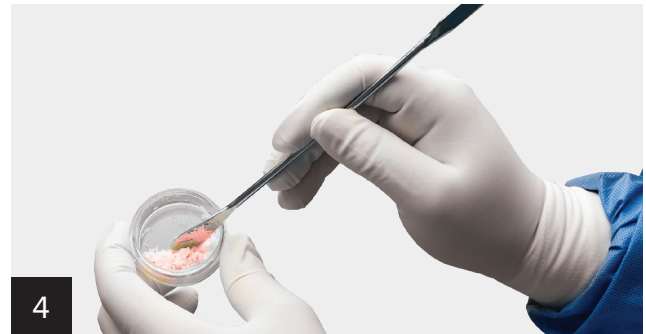
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Components include a cell vial, particulate bone, and gel.



3

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



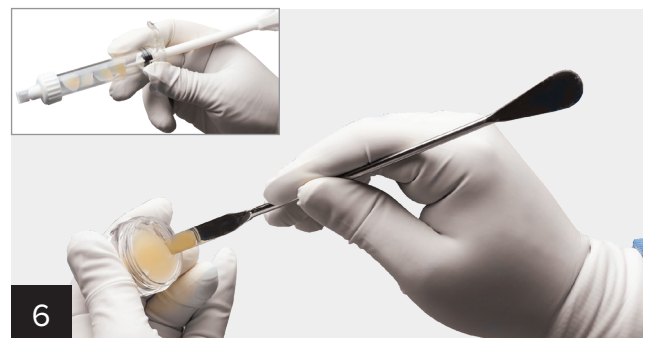
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While the cell vial and gel container are thawing, remove the inner and outer lids of the bone particulate jar and add the recommended saline volume directly to the bone particulate. Mix the saline and the particulate thoroughly using a spatula.



5

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.



6

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

ArthroCell™ Allograft Preparation (Cont.)



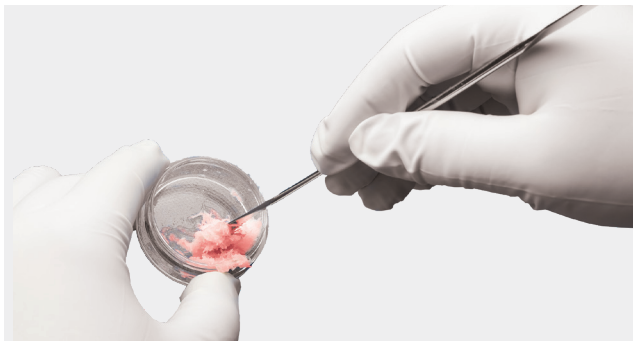
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Unsnap the pushrod from the mixing element. Mix the gel component by pushing/pulling on the mixing element until a paste consistency is obtained, which should occur within 60 seconds of continuous mixing.



8

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



9

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.

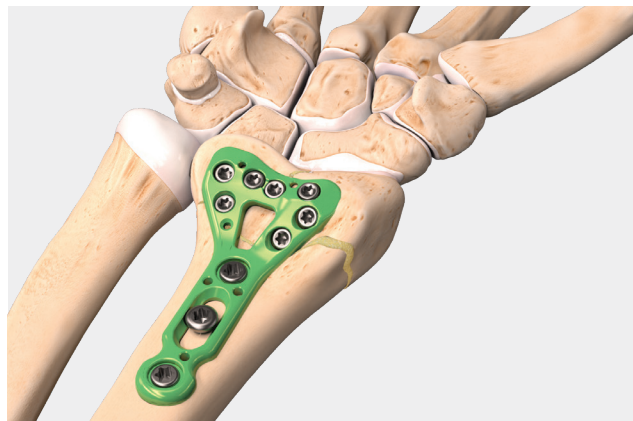


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The final product is moldable and can be stored capped at room temperature until needed. Total time from cell vial thaw to placement at the surgical site should not exceed 4 hours.

Surgical Applications

Over 25,000 units of the cellular and microparticulate components of ArthroCell™ allograft have been distributed for use as a bone void filler in clinical applications, including spinal fusion, extremity fracture, and oncological reconstruction.



Promote Osseous Regeneration Across Upper Extremity Fracture Site Voids With ArthroCell Allograft

ArthroCell allograft can be used as a bone void filler 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).

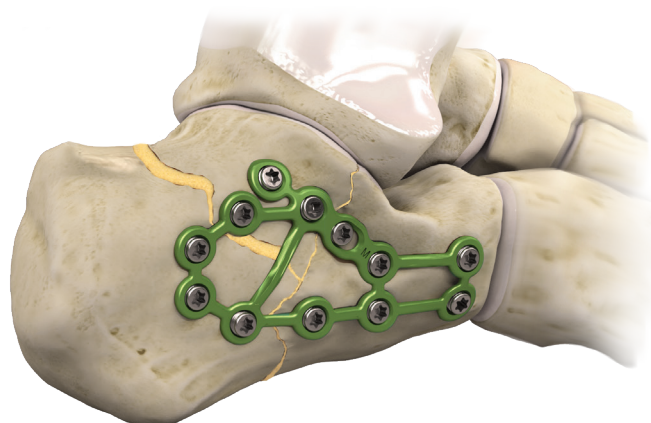


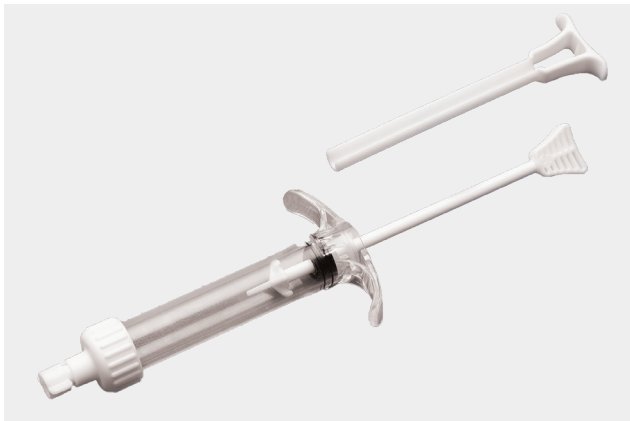
Promote Osseous Regeneration Across Fusion Site Voids With ArthroCell Allograft

After preparing the first metatarsal phalangeal joint for an arthrodesis, ArthroCell allograft can be inserted into the joint before final fixation with the low-profile MTP plate.

Promote Osseous Regeneration Across Lower Extremity Fracture Site Voids With ArthroCell Allograft

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.





Ordering Information

Product Description	Item Number
ArthroCell™ Allograft, 2.5 cc	ABS-2009-02
ArthroCell Allograft, 5.0 cc	ABS-2009-05
*Mixing Syringe, 14 cc	ABS-2000

To order please call Arthrex at 1.800.934.4404
or call your local Arthrex representative for
additional information.

Products advertised in this brochure/surgical technique guide may not
be available in all countries. For information on availability, please contact
Arthrex Customer Service or your local Arthrex representative.

References

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*The mixing syringe is required to be ordered for each graft size.

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