Viable Osteochondral Allograft
Features and Benefits

Cartiform is a cryopreserved osteochondral allograft composed of viable chondrocytes, chondrogenic growth factors and extracellular matrix proteins. While maintaining an intact cartilage structure (Figure 1), the bony portion of the osteochondral allograft is minimal and the graft is porated to offer unique handling characteristics and simple fixation techniques.

Cartiform is recovered with minimal bone and porated for a variety of reasons:

1. The minimal bone and pores impart flexibility to the allograft, thereby improving handling characteristics for implantation and fixation (Figure 2)

2. The pores increase the surface area and allow for the proprietary cryopreservative solution to penetrate the tissue and preserve chondrocyte viability throughout the allograft

3. The pores facilitate enhanced growth factor release from Cartiform and allow for progenitor cell migration into the graft following implantation in the osteochondral lesion

Cartiform combines the safety and success of traditional fresh stored osteochondral allografts with ease of use as the graft is trimmable and flexible to match any lesion size and contour.

Stored in a proprietary cryopreservative solution, Cartiform is readily available with a two-year shelf life when stored at -80°C. Experimental testing of Cartiform indicates that > 72% cell viability, post-thaw, is maintained beyond two years (Figure 3).¹
Scientific Support for Cartiform®
Cartiform was designed to provide a flexible, trimmable and readily available osteochondral allograft with viable chondrocytes to surgeons for the treatment of articular cartilage repair.

As a cryopreserved, viable osteochondral allograft, Cartiform builds upon more than 40 years of safety and efficacy of fresh stored osteochondral allografts.2 In situations of minimal bone loss, Cartiform has been shown to improve the tissue quality in a properly prepared articular cartilage lesion and integrate into the surrounding host tissues.

Cartiform was implanted into osteochondral lesions (6 mm diameter) in a goat model to demonstrate safety, integration and the induction of tissue formation due to Cartiform.

a. At three months, the lesions treated with Cartiform had a significantly improved gross morphology and overall lesion fill compared to microfracture controls (Figure 4).

b. At 12 months, the lesions treated with Cartiform were filled with highly cellular, hyaline-like repair tissue. Aggrecan content increased and cellular morphology and distribution were comparable to the morphology of normal articular cartilage (Figure 5).4

Figure 4. Gross morphology and type II collagen staining of cartilage defect three months post-surgery

Marrow stimulation and Cartiform
Marrow stimulation alone

Figure 5. Histological staining in tissue section taken 12 months following Cartiform implantation in goat model.

H & E
Safranin O

Type I Collagen
Type II Collagen

Host Tissue
Repair Tissue
Host Tissue

References
1 Study conducted by Osiris Therapeutics, Inc. Full study details in Cartiform white paper - LA1-00007-EN.
**Recovery and Quality Control Process**

Cartiform is recovered from donated human cadaveric tissue that contains pristine articular cartilage upon gross evaluation. The tissue is processed using a proprietary technique, resulting in a porated, cryopreserved allograft, consisting of full thickness articular cartilage and a thin layer of bone. Cartiform is readily available with a two year shelf life when stored at -80°C.

1. Extensive sterility testing is performed on each lot to ensure the allograft tissue is safe for clinical use.

2. Prior to release for clinical use, characterization testing for the presence of viable cells, and presence of residual bone is performed for each donor.

**Preparation Guide**

*NOTE: Graft color may vary as human articular cartilage color varies.*

*Please consult the Instructions For Use packaged with the product for a full list of instructions and warnings.*

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1. Remove package insert, patient labels and Cartiform pouch from box.

2. Peel back chevron pouch.

3. Using aseptic technique, transfer jar into sterile field.

4. Place the sterile jar into a sterile basin.

5. Using aseptic technique, add sterile saline until volume is below the lid. Incubate for ~10 minutes until no ice crystals are visible.*

6. Take the thawed Cartiform jar from the basin and unscrew the lid.

7. Using sterile forceps, remove Cartiform from the jar and place in a sterile rinse basin at room temperature containing sterile saline for 1 minute. It can be kept in sterile saline for up to two hours at room temperature prior to implantation.*

8. Once rinsed, Cartiform is ready to use. The side with the score mark is the bottom of the graft.

* Temperature of thawing solution should not exceed 39°C (102°F). Do not thaw for longer than 30 minutes.
Debride the articular cartilage defect to a stable border with perpendicular margins. A scalpel can be used to create vertical margins and a curette can be used to debride the calcified cartilage layer at the base of the defect.

Perform bone marrow stimulation, if desired, using the PowerPick™ while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledges as needed.

Template the lesion with sterile paper or foil. After thawing and rinsing Cartiform, use a scalpel or surgical scissors to trim the graft to match the template. Place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® fixation points.

Pass suture tails inferior to superior, then superior to inferior to create a mattress stitch in each quadrant of Cartiform to match the location peripheral pilot holes. Working sequentially, fixate each quadrant of Cartiform to the lesion. In knotless anchor configurations, ensure the anchor eyelet is seated deep prior to drawing tension on the suture, then implant the anchor to fixate. Note: The side of Cartiform with a score mark is the bottom (bone) side.

 Optionally, apply a thin layer of fibrin glue along the periphery of Cartiform. Use of a dual lumen applicator tip is recommended to apply the fibrin in order to prevent activation and clogging of the fibrin within the needle. Do not manipulate for five minutes after application. The knee may be gently ranged before closure to assure Cartiform fixation.

At the completion of surgery, a knee brace is utilized with limited range-of-motion and the patient is made nonweight-bearing or protected weight-bearing as determined by defect location. Thereafter, standard rehabilitation protocols used following osteochondral allograft implantation in the tibiofemoral and patellofemoral joint are implemented.
Debride the articular cartilage defect to stable borders with perpendicular margins. A Ring Curette and Cobb Elevator can be used to create vertical margins and debride the calcified cartilage layer at the base of the defect.

Optionally, perform bone marrow stimulation utilizing the PowerPick while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.

Template the lesion with sterile paper or foil. After thawing and rinsing Cartiform, use a scalpel or surgical scissors to trim the graft to match the template. Place a pilot hole in the center of the defect and implant the Knotless SutureTak. As necessary, place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock fixation points.

Pass the central anchor suture inferior to superior, then superior to inferior to create a mattress stitch on Cartiform. Fixate the suture strand in the anchor by passing the suture tail with the FiberLink shuttling suture to create a single suture loop. The suture tail is then passed inferior to superior through the center of Cartiform so tension on the strand may be drawn directly on top of the graft. Note: The side of Cartiform with a score mark is the bottom (bone) side.

As necessary, further stabilize the graft with peripheral fixation points. Create a mattress stitch in each quadrant of Cartiform to match the location of the anchor pilot holes. Sequentially, utilize the PushLock anchor to achieve knotless fixation. In this knotless configuration, ensure the anchor eyelet is seated deep in the pilot hole prior to tensioning the suture, then implant the anchor to fixate the graft. Optionally, use a free suture for...

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Apply distraction to the tibiotalar joint and debride the articular cartilage defect to a stable border with perpendicular margins. A Ring Curette can be used to create the vertical margins and debride the calcified layer at the base of the defect.

Perform bone marrow stimulation utilizing the PowerPick™ while applying irrigation fluid to avoid thermal necrosis. After microfracture, aspirate the fluid and dry the cartilage defect with pledgets as needed.

Template the lesion with sterile paper or foil. After thawing and rinsing Cartiform, use a scalpel or surgical scissors to trim the graft to match the template. Place pilot holes in each quadrant along the periphery of the defect to prepare for PushLock® fixation points.

In a knotted fashion, fixate a single suture strand with each PushLock anchor. The resulting tails from each anchor are set aside for assembly with Cartiform.

Each suture tail is passed inferior to superior through Cartiform to match the orientation and position of the anchor placement in the lesion. Working sequentially, simple knots are placed to fixate Cartiform to the lesion.

If desired, apply a thin layer of fibrin glue to the periphery of Cartiform. Do not manipulate for five minutes after application. The joint may be gently ranged before closure to assure Cartiform fixation. At the completion of surgery, the ankle is immobilized in neutral position and the patient is made nonweight-bearing. Thereafter, standard rehabilitation protocols similar to osteochondral allograft implantation procedures are implemented.
### Ordering Information

**Implants/Disposables**

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<tr>
<th>Product Description</th>
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<tr>
<td>Cartiform, 10 mm Disc</td>
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<td>Cartiform, 20 mm Disc</td>
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<td>Cartiform, 12 mm x 19 mm</td>
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<td>Chondral Pick, straight 30° tip</td>
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<tr>
<td>2-0 TigerWire, 18” w/Tapered Needle</td>
<td>AR-7220T</td>
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To order call Arthrex at 1.800.934.4404

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Cartiform®

Cartiform is a registered trademark of Osiris Therapeutics, Inc.

Cartiform® is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps). Osiris Therapeutics, Inc. is registered with the FDA as a tissue establishment and accredited by the American Association of Tissue Banks (AATB).

Store frozen -75°C to -85°C. Two-year shelf life.

Marketed by: Arthrex

Manufactured and distributed by: Osiris Therapeutics, Inc.

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.

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