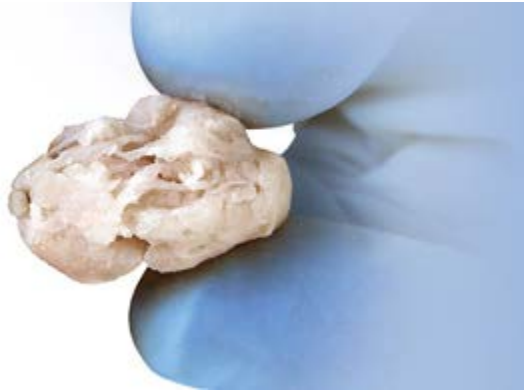




# CARTIMAX PLAYBOOK



## What's Our Strategy and Who Are we Targeting?

### INTRODUCTION

CartiMax Viable Cartilage Allograft from CONMED, in partnership with MTF Biologics, offers an off-the-shelf solution for treating cartilage lesions in the knee, foot, and ankle. CartiMax is viable, cartilage fibers combined with cartilage allograft matrix to make a biologically active scaffold with putty-like handling characteristics used to treat focal cartilage defects. This product offers the potential to facilitate cartilage healing and regeneration along with ease of use.

CartiMax Viable Cartilage Allograft is a kit composed of Viable Cartilage Fibers (Fibers), Cartilage Allograft Matrix (CAM), and CartiMax Accessories (Accessories). The Accessories include a strainer cap and a spatula. The Fibers and the CAM are mixed together using the Accessories; the result is a product with a putty-like consistency. The amount and size of allograft necessary for a surgical procedure is based upon an individual surgeon's preference and the size of the defect. The description of the tissue, serial numbers, expiration dates, product codes and additional information are printed on the allograft container labels.

### CartiMax Key Messaging

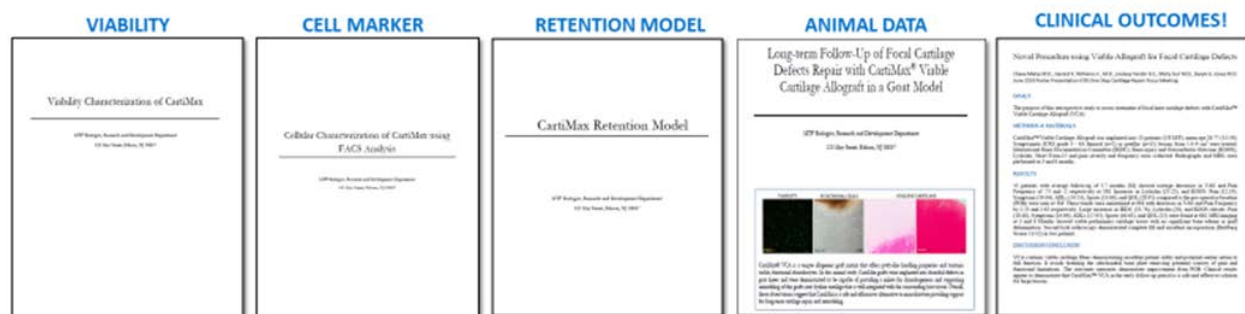
1. **Viable Chondrocytes** – CartiMax contains functioning viable chondrocytes and chondrogenic growth factors that secrete components found in articular cartilage. The viable cartilage chondrocytes produce components of hyaline cartilage such as Collagen II and Proteoglycans.
2. **Optimal Handling Properties** – putty-like handling properties and easily conforms to defects of different shapes and sizes
3. **24 Month Shelf-Life** – ready to go, out of the freezer, off the shelf solution with stable viability up to 24 months
4. **High Volume Material** – CartiMax contains enough cartilage matrix to fill up to a 5cm<sup>2</sup> defect

## Key Differentiating Features of CartiMax

CartiMax combines the clinical benefits of live, viable cartilage cells with optimal putty-like handling properties that are designed to easily fill defects of different shapes and sizes—flexibility and versatility that other allograft products just do not have. CartiMax eliminates two-stage procedures which help patients get back to their daily activities faster. A low volume of material and handling characteristics were identified in a 658 surgeon survey as pain points with current solutions. With a 24-month shelf-life, putty-like handling, and a high volume of material, CartiMax is designed to relieve these pain points and easily fill defects of different shapes and sizes.

## Clinical Information

### KEY SCIENTIFIC CHARACTERIZATION



## Cell Marker Study

**Purpose:** Determine if viable chondrocytes remain post cryopreservation

Chondrocytes express CD44 and CD49e cell surface markers, but do not express CD45 as it is a blood cell marker. In order to determine cell viability post-cryopreservation studies were done to test the cell markers. Analysis via flow cytometry revealed that the isolated cells express CD44, CD49e and do not express CD45.

**Outcomes:** The above study verifies that cells present on the viable cartilage fibers are a homogenous population of chondrocytes. This means we still maintain viable chondrocytes post cryopreservation.

## Viability Study

**Purpose:** Determine the viability and cell function post cryopreservation.

Samples of cryopreserved viable cartilage fibers were thawed, rinsed of cryopreservation media, and assessed for cartilage viability through live/dead staining and assessing cell function and production of hyaline components. 86.6% cell viability was found with these cells migrating & proliferating after 6 months cryopreservation.

**Outcomes:** The data generated in this study demonstrates that cells from cryopreserved viable cartilage fibers are viable, have the ability to migrate out of the cartilage fiber and proliferate. They are also producing collagen type II and proteoglycans, which are components of hyaline cartilage.

## Retention Model

Purpose: Determine the retention and integrity of Cartimax putty under cyclic mechanical testing

A cadaver knee was used for mechanical testing with a medial femoral condyle (MFC) defect and patella defects. Fibrin glue was not used. The knee was closed and subjected to 500 cycles for MFC defect and 100 for the patella

Outcomes: The data demonstrates CartiMax is fully retained in various chondral defects after extensive cyclic testing, without the use of fibrin glue.

## Animal Data

Purpose: Evaluate the safety and efficacy when implanted in goat knees in comparison to microfracture.

Microfracture was performed in the trochlea sulcus to represent a clinically similar and challenging control group while CartiMax was implanted in a MFC defect in the same goat. Once implanted into a cartilage defect, the combination of the viable chondrocytes and the natural cartilaginous matrix provide a milieu for chondrogenesis and supported remodeling of the graft into hyaline cartilage that is well-integrated with the surrounding host tissue. Microfracture yielded incomplete fill and diffuse proteoglycan and collagen type II staining.

Outcomes : These observations in an animal model suggest that CartiMax VCA is a safe and efficacious treatment for cartilage defects yielding durable cartilage unlike microfracture.

## Clinical Data

Purpose: Retrospectively assess treatment of focal cartilage defects

The average follow up is 2 years in this 20 patient case series of patients with symptomatic grade 3/4A lesions in the femoral condyle or patella and treated with CartiMax. Metrics included patient safety & functional score as well as pain frequency, return to sports and activities of daily living amongst others.

Outcomes: Improved functional scores were seen at 6 and 12 months post=op and maintained at 24 months. MRI revealed no significant bone edema or delamination. Cartimax is an off-the-shelf, single-stage, conformable allogenic graft that safely treats chondral defects.

## Key Targets

1. Surgeons using Denovo, CarGel, BioCartilage or C.A.M for Cartilage procedures
2. Surgeons doing microfracture but looking for better outcomes
3. Surgeons looking for a cell-based solution for cartilage defects
4. Surgeons treating cartilage defects that do not include a bony defect
5. Surgeons performing Meniscal Allograft Transplants

## Probing Questions

1. **How often do you see cartilage lesions?**
2. **Are you currently treating cartilage defects?**
3. **How are you currently treating cartilage defects?**
  - a. If they respond with Microfracture – what are your typical outcomes with microfracture? Do you often see fibrocartilage within these patients? Are you happy with your outcomes?
  - b. If Osteochondral Allografts – is that for all defects or only bony involvement? What do you do if there's no bony involvement?
4. **Are you doing meniscal transplants?**
  - a. If they are, they probably see some cartilage lesions – how do they treat them?

## Objection Handling

### ***My surgeon is telling me that Denovo is cheaper than CartiMax.***

- Denovo only fills a 2.5cm<sup>2</sup> where CartiMax fills a 5cm<sup>2</sup> defect. Denovo also requires the use of Fibrin Glue, which is often difficult to handle. CartiMax does not require any Fibrin Glue. CartiMax does not require a template, it is easy to handle, and it can live in the hospital's freezer for up to 24 months.

### ***Who else in Canada is using this?***

- Please contact product management for most up to date list of Canadian surgeons using the system
- Globally, 749 units have been distributed to date

### ***My surgeon wants to try this in a lab setting first.***

- Suggest setting up a sawbones demo first where you can run through the procedure at their office with a CartiMax sample. Speak with your Sales Director about the potential opportunity of a lab based on their number of procedures. Samples can be ordered through Carol Martin in Med Ed.

### ***What clinical data do you have to support CartiMax?***

- You can direct your surgeons to our cell marker study, viability study, retention model study, animal data and most recently our clinical data. Please see Clinical Information section above for additional details regarding each study.

### ***My Surgeon is telling me that BioCartilage is much cheaper than CartiMax***

- BioCartilage is NOT a direct comparison to CartiMax. It does not contain any viable chondrocytes and requires microfracture.
- BioCartilage is comparable to our C.A.M (CARTILAGE ALLOGRAFT MATRIX) in that it serves as a scaffold over a microfractured defect, providing a tissue network that can potentially signal autologous cellular interactions. It is an augment to a traditional microfracture.

## Key Competitive Targets and Selling Messages

### 1. Zimmer Biomet – Denovo

- a. Contains Viable Chondrocytes like CartiMax
- b. Single-stage procedure like CartiMax
- c. Only has a 42 Day Shelf-Life
  - CartiMax has a 24-month shelf-life in a –70C freezer
- d. Fills a defect up to 2.5cm<sup>2</sup>
  - CartiMax fills up to a 5cm<sup>2</sup> defect
- e. Difficult to handle
  - CartiMax has putty-like handling characteristics which make it easy to mold to the defect
- f. Fibrin glue required
  - no fibrin glue required for CartiMax
- g. Requires a template

### 2. Smith and Nephew - CARGEL

- a. Single-stage procedure like CartiMax
- b. Readily available like CartiMax
- c. Liquid scaffold conforms to any lesion shape
  - CartiMax has putty-like handling characteristics which make it easy to mold to the defect
- d. Done Arthroscopic or mini-open
  - CartiMax is currently offered for open procedures
- o Requires Microfracture
  - Top cartilage experts are moving away from microfracture because it may be damaging bone and making future procedures less successful
  - You do not need to microfracture with CartiMax
- o Does not form hyaline-like cartilage
  - Their own animal study states only 1 of their 6 samples showed any hyaline cartilage
- o Is not cartilage

### 3. Arthrex – Biocartilage

- a. BioCartilage is NOT a direct comparison to CartiMax. It does not contain any viable chondrocytes and requires microfracture.
- b. BioCartilage is comparable to our C.A.M (CARTILAGE ALLOGRAFT MATRIX) in that it serves as a scaffold over a microfractured defect, providing a tissue network that can potentially signal autologous cellular interactions. It is an augment to a traditional microfracture.

## Sales Tools

[CONMED CartiMax Webpage](#)

[CartiMax Brainshark Curriculum](#)

[Updated Cartimax Brochure](#)

## Ordering Info

CartiMax™ Viable Cartilage Allograft

CAT # 401205

Service Fee: \$3,595

All Allografts are for single patient use only

## Storage

Storage temperature requirement is 70°C (-94°F) or below. It's the responsibility of the transport facility or clinician to maintain the tissue in the appropriate storage conditions. If compromised, the tissue should be discarded.

# Competitive Comparison

| Company & Product Name                                                                                      | Service Fee | Cellular? | Pros                                                                                                                                                      | Cons                                                                                                                                                                            |
|-------------------------------------------------------------------------------------------------------------|-------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Conmed CAM<br>           | \$          | No        | <ul style="list-style-type: none"> <li>Promotes growth of hyaline-like cartilage</li> <li>3- year shelf life</li> <li>MTF processed</li> </ul>            | <ul style="list-style-type: none"> <li>No viable cells</li> <li>Requires microfracture</li> </ul>                                                                               |
| Zimmer Denovo<br>        | \$\$        | Yes       | <ul style="list-style-type: none"> <li>Viable chondrocytes</li> <li>Single stage procedure</li> </ul>                                                     | <ul style="list-style-type: none"> <li>42-day shelf life</li> <li>2.5cm<sup>2</sup> volume</li> <li>Difficult to handle</li> <li>Fibrin glue &amp; template required</li> </ul> |
| S&N CARGEL<br>           | \$\$        | No        | <ul style="list-style-type: none"> <li>Readily available</li> <li>Low cost</li> <li>Conforms</li> </ul>                                                   | <ul style="list-style-type: none"> <li>Requires Mfx</li> <li>Not cartilage</li> <li>Surgical time</li> <li>Does not form hyaline cartilage</li> </ul>                           |
| Arthrex Cartiform<br>    | \$\$\$      | Yes       | <ul style="list-style-type: none"> <li>2-year shelf life</li> <li>Contains bone and can be billed as an OC</li> </ul>                                     | <ul style="list-style-type: none"> <li>Requires anchors and adds time and steps</li> <li>Come in disk shape making it difficult to fit to defect</li> </ul>                     |
| Arthrex Biocartilage<br> | \$          | No.       | <ul style="list-style-type: none"> <li>Equivalent to CAM. <u>Not the same as Cartimax</u> (no viable chondrocytes).</li> <li>5-year shelf life</li> </ul> | <ul style="list-style-type: none"> <li>No viable cells</li> <li>Required microfracture</li> </ul>                                                                               |

## Preparation

1. Remove the three (3) contents from the kit box. Viable Cartilage Fibers (Fibers), Cartilage Allograft Matrix (CAM) and CartiMax Accessories.
2. Using standard aseptic/sterile technique, open the packaging of the three contents and place into the sterile field. Put the CAM and Accessories to the side.
3. Thawing the fibers. Place the unopened jar containing the Fibers in a basin with warm sterile irrigant (saline or 5% Dextrose in lactated Thaw time is approximately 20 minutes (35°C to 39°C; 95°F to 102.2°F) until all ice dissolves. Thawing at cooler temperatures may extend thawing time. Note: Decant per procedure below immediately after thawing.
4. Immediately after thawing the Fibers, remove the cap. Put the strainer cap on the jar of the Fibers.
5. Decant the solution from the Fibers. Drain the fluid from the Fibers by inverting the jar and tapping on the bottom of the jar several times. After turning the jar upright, tap the bottom of the jar to the tabletop to return the fibers to the bottom of the jar.
6. Rinse the Fibers. Remove the strainer cap from the jar of the Fibers and fill jar with sterile irrigant (saline or 5% Dextrose in Lactated Ringers Solution).
7. Put the strainer cap back on the jar of the Fibers. Decant the sterile irrigant following the instructions from step 5. After repeating Step 5 once, the fibers are now ready to be mixed with CAM.
8. Open the CAM Bottle. Remove the white cap, aluminum collar and rubber stopper from the CAM bottle. Hold the container firmly on a hard surface while removing the stopper to prevent spillage.
9. Mix the CAM and the Fibers. Pour the CAM into the jar of Fibers. Using the spatula, mix the CAM and Fibers together, creating a puttylike consistency
10. Mold CartiMax into the desired shape. CartiMax Viable Cartilage Allograft is now ready for implantation.

## CARTIMAX PREPARATION GUIDE

