EXACTECH| BIOLOGICS

Surgical Technique





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Surgical Technique for Particulated Autologous Cartilage for Chondral Defect Repair

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OVERVIEW OF PARTICULATED AUTOLOGOUS CARTILAGE IMPLANTATION (PACI) THERAPY

Prepare as standard of care for application for biological therapy to the affected site.

INTENDED USE

The Reveille® Cartilage Processor is used for intra-operative resizing of autologous tissue into particles for use in autologous cartilage grafting.

This surgical technique was prepared in conjunction with surgeons Jack Farr, MD and Bert R. Mandelbaum, MD. Exactech does not practice medicine and is not responsible for recommending the appropriate surgical technique for use on a particular patient. These guidelines are intended to be solely informational and each surgeon must evaluate the appropriateness of these guidelines based on his or her personal medical training and experience. Prior to use of the Reveille Cartilage Processor instrument, the surgeon should refer to the Reveille Cartilage Processor Instructions for Use.

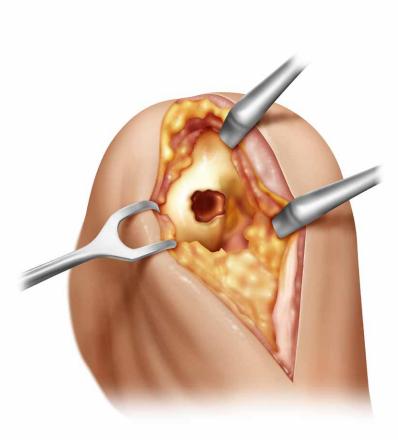


Figure 1
Debride and Prepare Lesion

1. DEFECT PREPARATION AND SIZING

a. For lesions involving only the chondral layer:

- Perform a mini-arthrotomy. Demarcate the lesion with a #15 scalpel blade and remove the cartilage tissue within the defect area with a curette to create a well-defined vertical defect perimeter.
- ii. Clear the defect base carefully to remove the calcified cartilage layer. With the tourniquet down, a slight blush will be noted, but take care to avoid violating the subchondral cortical bone.
- iii. Measure the approximate surface area of the debrided lesion. Record the lesion size.

b. For osteochondral lesions:

 Perform a mini-arthrotomy. Demarcate the lesion with a #15 scalpel blade and remove the cartilage tissue within the defect area with a curette to create a well-defined vertical defect perimeter.

- ii. Using a curette, remove fibrous tissue/scar from the bone base as appropriate to establish a healthy bed.
- iii. Measure the area of the lesion and the depth bone loss measured to the subchondral plate.
- iv. If the lesion extends more than 4mm below the cartilage layer, fill the osteochondral portion of the lesion using autograft cancellous bone, which is tamped into place for bone stability.
- v. If the lesion does not extend more than 4mm below the cartilage layer, bone grafting is not necessary. Proceed to treat the lesion as described below.

2. PREPARE FIBRIN GLUE PER MANUFACTURER'S INSTRUCTIONS

1

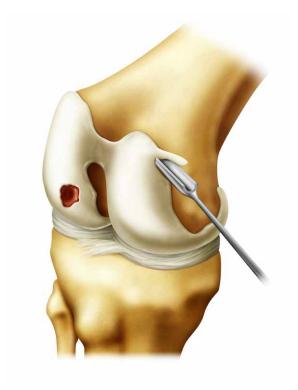


Figure 2
Harvest Cartilage From Non Weight-bearing Area

3. AUTOGRAFT HARVEST AND PREPARATION

- a. Use standard harvesting procedures. That is, harvest approximately 300mg (equal to 0.2 to 0.3 cc) of cartilage, which is usually obtained with a biopsy measuring 4mm x 25mm from the lateral wall of the intercondylar notch or margins of the trochlea.
- b. Prepare particulated autologous cartilage according to the Reveille Cartilage Processor Instructions for Use.
- c. For lesions larger than 4cm², repeat steps 3a. and 3b. using additional harvested cartilage and a second Reveille Cartilage Processor unit.

4. PREPARE THE LESION ENVIRONMENT FOR AUTOGRAFT HEALING

a. This can be accomplished by utilizing a standard of care marrow stimulation technique such as microfracture technique application of other bone marrow preparations.

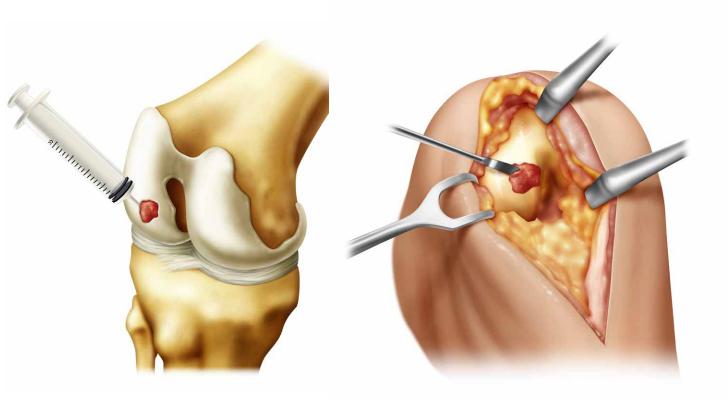


Figure 3
Implant Particulated Autologous Cartilage

Figure 4
Ensure the Defect Fill is Recessed by at Least 0.5mm From the Surrounding Cartilage Shoulders

5. APPLY THE PARTICULATED AUTOLOGOUS CARTILAGE INTO THE LESION(S)

- a. With the tourniquet deflated, secure hemostasis and gently dry the defect area using sterile gauze.
- b. Assure that the lesion area has been treated with the selected marrow stimulation technique.
- c. Apply the particulated autograft to the base of the lesion in a monolayer with near edge-to-edge apposition of the fragments.
- d. Apply a few drops of fibrin to cover the particulated autograft. Ensure the defect fill is recessed by at least 0.5mm from the surrounding cartilage shoulders.

- e. Allow adequate time for fibrin to fully cure (typically 3-5 minutes). The graft should not be manipulated during the curing.
- f. Cycle the joint a few times through the range of motion to ensure the tissue construct is stable.

6. CLOSE THE WOUND USING STANDARD TECHNIQUES

REVEILLE OPERATING TECHNIQUE



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5



Figure 6

- **Step 1:** Load harvested cartilage fragments onto particulator and spread evenly (*Figure 1*).
- Step 2: Thread particulator onto tissue holder (Figure 2).

Note: Once tissue chamber is threaded rotate metal shaft manually in both directions five times.

- **Step 3:** Fill collection tube up to etched fill line with sterile saline (*Figure 3*).
- **Step 4:** Insert particulator into saline-filled collection tube (*Figure 4*).
- Step 5: Thread particulator onto collection tube (Figure 5).
- **Step 6:** Connect metal shaft to the chuck of the drill.

 Particulate tissue for at least 2 minutes, with the recommended speed set at 1500rpm (Figure 6).

REVEILLE OPERATING TECHNIQUE



Figure 7



Figure 8



Figure 9



Figure 10

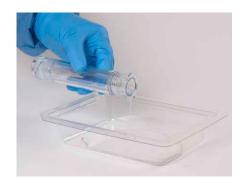


Figure 11



Figure 12

- **Step 7:** Unthread particulator from collection tube (*Figure 7*).
- Step 8: Insert filtration tube into collection tube (Figure 8).
- **Step 9:** Press filtration tube down until just above tissue, leaving 2-5mL of fluid (*Figure 9*).
- **Step 10:** Decant saline from filtration and plunging process (*Figure 10*).
- **Step 11:** Pull filtration tube back to just above the threads of the tissue collection cup (*Figure 11*).
- **Step 12:** Unthread collection cup from tissue collection tube. Particulated tissue is ready for transfer to desired treatment location (*Figure 12*).

REVEILLE PARTS LIST

	Α	Particulator
	В	Tissue Holder/Sieve
	С	CollectionTube
	D	Tissue Collection Cup
	Е	Filtration Tube



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