

Chondrofix[®] Osteochondral Allograft

Surgical Technique



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Introduction

Arthroscopic or Mini Arthrotomy Procedures for the Repair of Osteochondral Defects in the Femoral Condyle

The Zimmer Chondrofix Osteochondral Allograft is a decellularized allograft consisting of hyaline cartilage and cancellous bone. The grafts are provided precut 10 mm in length and 7 mm, 9 mm, 11 mm or 15 mm in diameter.

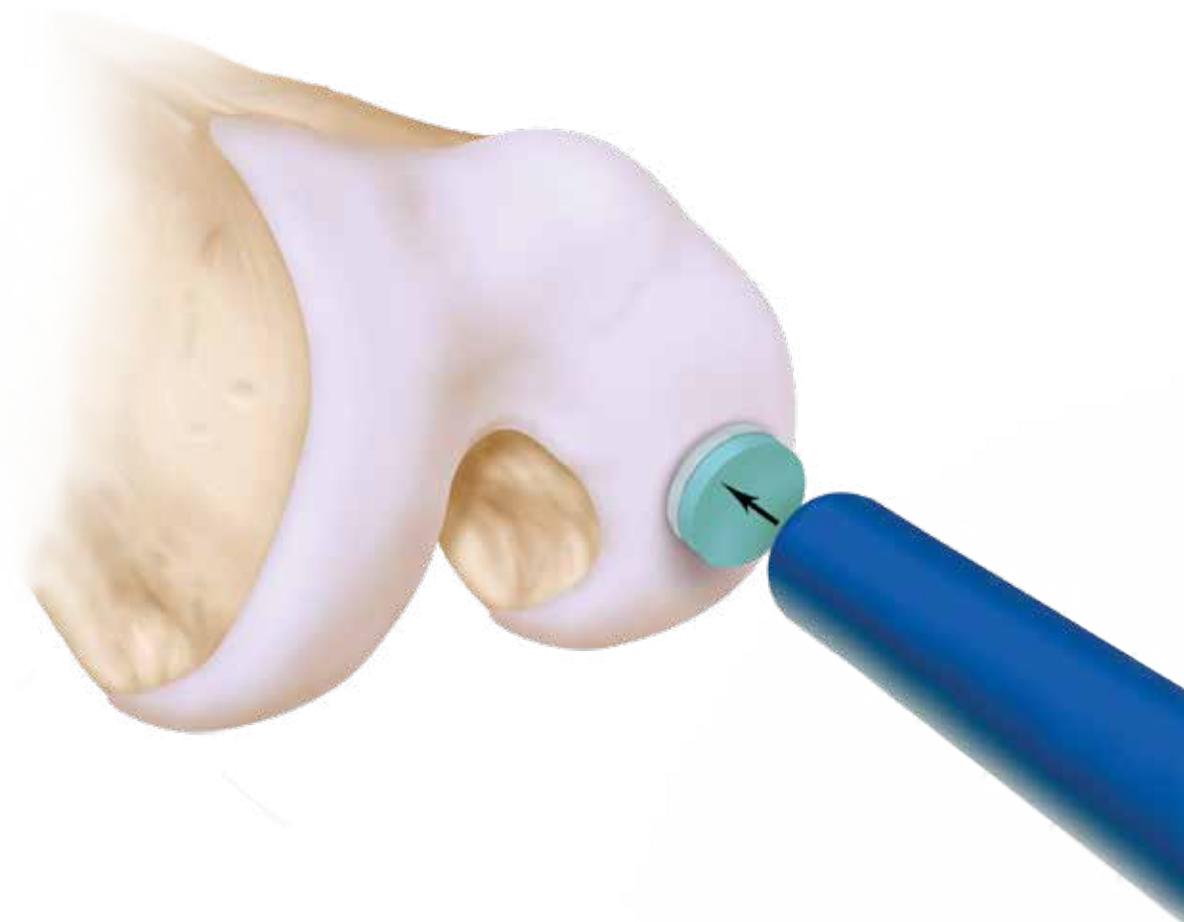
Grafts and instrumentation kits are color matched by size

7 mm – Red

9 mm – Blue

11 mm – Purple

15 mm – Orange



Arthroscopic Repair of Osteochondral Lesions Using Punch Instrumentation

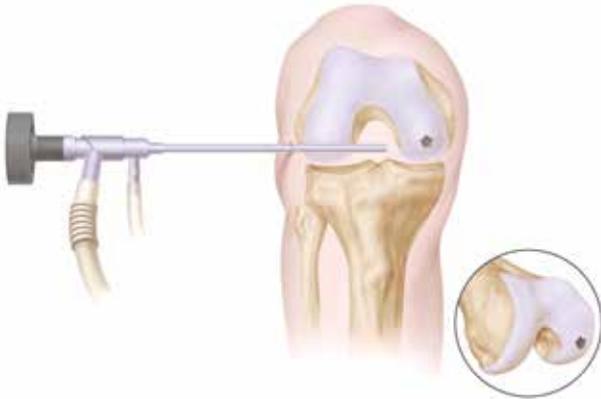


Figure 1

Examine the articular cartilage being treated.



Figure 2

Determine the size of the lesion.

Establish Arthroscopic Portals

Establish arthroscopic portals that optimize access to the lesion. Consider debriding the fat pad to allow for easier access to the lesion. With the scope in place, examine the affected articular cartilage to be treated (Figure 1).

Determine the Size of the Lesion and Necessary Graft Configuration

Determine the size of the lesion and necessary graft configuration by covering the defect area with a Sizer(s) of corresponding diameter. Insert the Sizer(s) into the joint and cover the lesion area with the tip of the Sizer(s) (Figure 2). The Sizer kit includes instruments of 7 mm, 9 mm, 11 mm and 15 mm diameters. Once the size of the lesion and graft configuration has been determined, remove the Sizer(s) and retain for Step 6.

Arthroscopic Repair of Osteochondral Lesions Using Punch Instrumentation

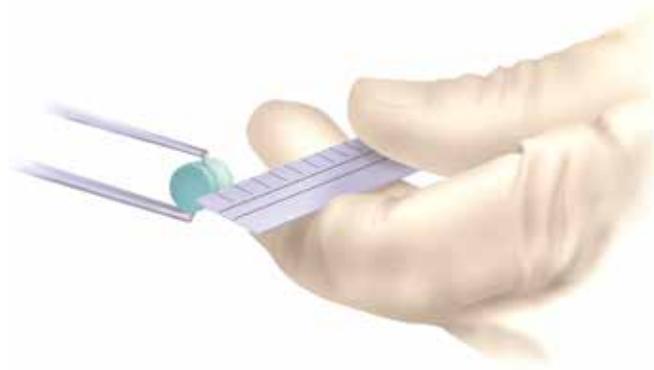


Figure 3

Select the appropriate size graft(s).

Select the Appropriate Graft and Instrumentation

Select the appropriate diameter graft(s) and corresponding instrumentation kit(s). Measure the length of the graft(s) from the apex to the bone base to determine maximum depth of the recipient hole (Figure 3).

Note: Slight variability exists among graft lengths. It is important to measure the lengths of ALL grafts being used prior to creating the recipient site.



Figure 4

Prepare the recipient site.

Prepare the Recipient Site

Prepare the recipient site by introducing the Punch with the Obturator into the portal and locating the lesion site. When positioned at the lesion site, remove the Obturator from the Punch by twisting the Obturator 45 degrees CCW to unlock. This will expose the cutting edge of the Punch to the articular cartilage. Replace the Obturator with the Impaction Cap and lock into place; twist 45 degrees CW (Figure 4).

- ⓘ **Note:** Do not mallet the Punch without the Impaction Cap in place.
- ⓘ **Note:** Before advancing the Punch, make sure to position it perpendicular to the articular cartilage surface at the lesion site.

The Punch has circumferential markings at the cutting end in 2 mm increments from 2 mm – 12 mm to aid in depth identification and perpendicularity assessment. With the Impaction Cap in place, mallet the top surface of the cap to advance the Punch into the bone. Periodically check the depth measurements around the circumference to ensure perpendicular alignment.

- ⓘ **Note:** Do not drive the Punch to a depth greater than the length of the longest graft to be used.

Arthroscopic Repair of Osteochondral Lesions Using Punch Instrumentation



Figure 5

Use Drill Bit to remove bone within the Punch.

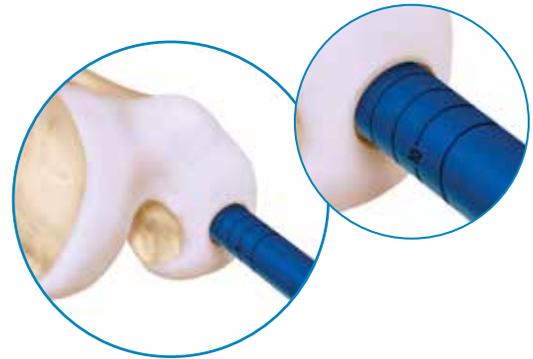


Figure 6

Using Sizer, verify depth of recipient site.

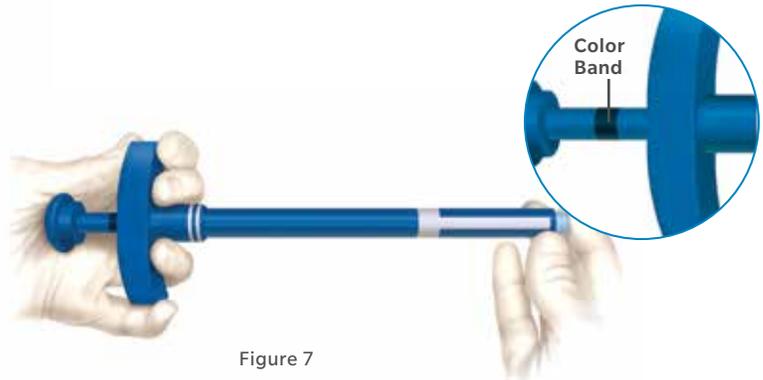


Figure 7

Insert the cartilage end of the graft into the open end of the Delivery Device.

Remove the Bone Within the Punch

Once the Punch has been advanced to the appropriate depth, remove the Impaction Cap. Connect the Drill Bit of corresponding size to the chuck on the surgical drill. Insert the Drill Bit into the shaft of the Punch. The Punch will function as the drill guide maintaining axial alignment between the Drill Bit and the drill. Advance the Drill Bit into the bone to remove the bone within the Punch until the physical stop on the Drill Bit contacts the Punch handle (Figure 5). Remove the Punch and Drill Bit assembly. Inspect the recipient site for loose debris; remove if present.

Verify the Depth of the Recipient Site

Before implanting the graft, verify the depth of the recipient site with the Sizer of corresponding diameter used in Step 2 (Figure 6). If necessary, the bone portion of the graft can be trimmed with rongeurs, small bone saws or bone cutters to match the depth of the recipient site.

Loading the Graft into the Delivery Device

With Delivery Device in hand, depress the Plunger until the middle of the colored band on the Plunger shaft is positioned at the opening of the Delivery Device T-handle. This will expand the metal springs at the open end of the Delivery Device and allow for insertion of the graft. Make sure to insert the cartilage end of the graft first into the open end of the Delivery Device (Figure 7). Once the graft is inserted, retract the Plunger in order to contract the metal springs to hold the graft. At this point the graft is captured in the Delivery Device and is ready for implantation.



Figure 8

Depress the Plunger on the Delivery Device.

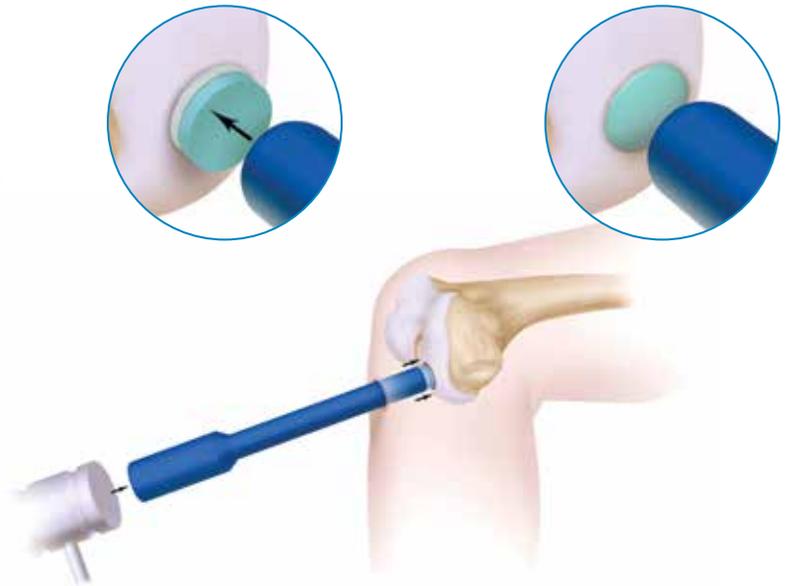


Figure 9

Insert Tamp and gently tap until graft is flush.

Implanting the Graft

Introduce the Delivery Device into the surgical site. When the Delivery Device is positioned over the recipient site, release the graft into the recipient hole by depressing the Plunger on the Delivery Device (Figure 8). The Delivery Device will leave the graft 1 mm proud in the recipient hole. To advance the graft the remaining 1mm, remove the Delivery Device and insert the Tamp of corresponding size (Figure 9). Gently tap the head of the Tamp until the graft is flush with the surrounding articular cartilage.

ⓘ **Note:** When using a Chondrofix Allograft, it is important to make sure the graft is flush with and matches the surface contour of the surrounding articular cartilage.

Remove Tamp.

Multi-Graft Implantation Technique

Repeat Steps 3- 8.

- ⓘ **Warning:** Graft is not recommended for Mosaicplasty graft constructs.
- ⓘ **Note:** Before reusing a Punch or Drill Bit during the same procedure, inspect the cutting edges of the instruments to ensure that the surfaces have not been damaged.

Arthroscopic Repair of Osteochondral Lesions Using Punch Instrumentation

Close the Portal

Once the grafts has been implanted, do a final check of the graft position relative to the surrounding cartilage. Close the portals and drain the joint through the superior portal.

Post-Operative Care

The rehabilitation protocol is at surgeon discretion. General post-operative guidelines include:

	Weight Bearing	ROM	Exercise
Phase I 0–6 weeks	Weight bearing as tolerated	Progress ROM as tolerated, consider CPM Machine (condylar)	Biking with no resistance, straight leg raises, open chain exercises
Phase II 6–12 weeks	Full weight bearing	Increase ROM, progress to full ROM	Closed chain exercises, initiate weight shifts, begin w/b exercises weeks 8–10 progressing to week 12
Phase III 12–26 weeks	Full weight bearing	1	Continue progressive exercises

Mini Arthrotomy Repair of Osteochondral Lesions Using Cannulated Instrumentation



Figure 1
Determine size of the lesion.

Create a Mini Arthrotomy

Create a medial or lateral arthrotomy based on lesion location.

Determine the Size of the Lesion and Necessary Graft Configuration

Determine the size of the lesion and graft configuration by covering the defect area with a Sizer(s) of corresponding diameter. The Sizer kit includes instruments of 7 mm, 9 mm, 11 mm and 15 mm diameter. Insert the Sizer into the joint and cover the lesion area with the tip of the Sizer (Figure 1). Once the lesion size and graft configuration have been determined, remove the Sizer and retain for Step 6.

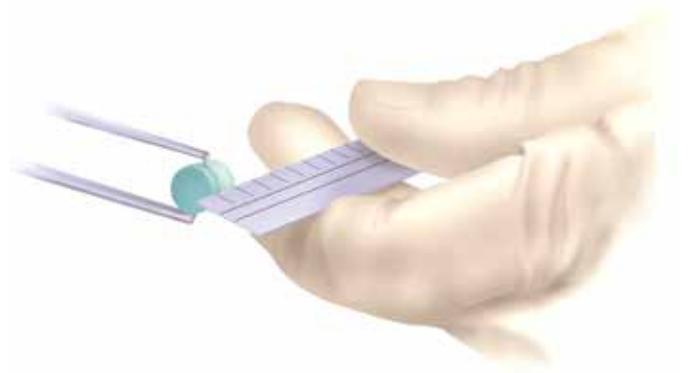


Figure 2
Select the appropriate size graft(s).

Select the Appropriate Graft and Instrumentation

Select the appropriate diameter graft(s) and corresponding instrumentation kit(s). Measure the length of the graft(s) from the apex to the bone base to determine maximum depth of recipient hole (Figure 2).

- ⓘ **Note:** Slight variability exists among graft lengths. It is important to measure the lengths of ALL grafts being used prior to creating the recipient site.

Mini Arthrotomy Repair of Osteochondral Lesions Using Cannulated Instrumentation



Figure 3

Advance Guide Pin into the lesion.



Figure 4

Drill into bone tissue to the desired depth.

Prepare the Recipient Site

Prepare the recipient site. In a mini-arthrotomy procedure, the Sizer and Guide Pin function similarly to the Punch used in the arthroscopic procedure with the Guide Pin determining the depth of the recipient site and the Sizer assisting in perpendicular alignment. Slide the Guide Pin through the hole in the center of the Sizer. Locate the center of the lesion site with the Guide Pin. Orient the Sizer perpendicular to the cartilage surface.

ⓘ **Note:** Perpendicular positioning during recipient site creation is critical to this procedure and the appropriate fit of Chondrofix Osteochondral Allografts.

Advance the Guide Pin into the lesion to the desired depth (Figure 3). Guide Pin depth should be approximately 10 mm greater than the recipient site depth in order to ensure stability during reaming.

ⓘ **Note:** Do not over advance the Guide Pin.

Drill to Desired Depth

Once the Guide Pin has advanced to the appropriate depth, slide the Sizer off the Guide Pin and remove from the joint. Connect the Cannulated Drill Bit of corresponding diameter to the chuck of the surgical drill. Slide the Cannulated Drill Bit over the Guide Pin and into the surgical site.

ⓘ **Warning:** Do Not Use the Drill Bit Without the Guide Pin.

The Guide Pin functions to maintain perpendicular alignment and keeps the drill bit centered on the lesion. Drill into the bone tissue to the desired depth, but take precautions not to drill beyond the length of the longest graft to be implanted (Figure 4). The Cannulated Drill Bit has 3 depth markings that can be used to visually assist in achieving desired site depth: the base is 6mm, the middle marking on the side is 8mm and the top is 10 mm.

ⓘ **Warning:** There is no physical stop for the cannulated drill bit. Extra attention must be given to ensure that the site is not over drilled.

Periodically clean the drill bit of loose debris to maintain clear visibility of drill depth markings.

Remove the Guide Pin and Drill Bit assembly. If any loose fragments or tissue debris remain, remove from the recipient site.

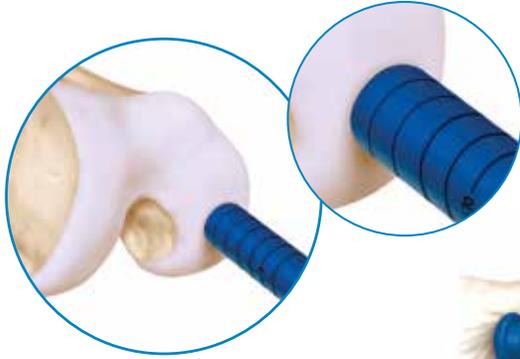


Figure 5
Using Sizer, verify depth of recipient site.

Verify the Depth of the Recipient Site

Before implanting the graft, verify the depth of the recipient site with the Sizer of corresponding diameter used in Step 2 (Figure 5). If necessary, the bone portion of the graft can be trimmed with rongeurs, small bone saws or bone cutters to match the depth of the recipient site.

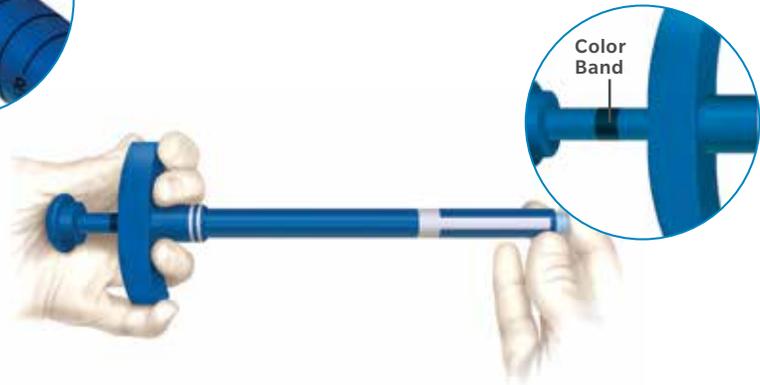


Figure 6
Insert the cartilage end of the graft into the open end of the Delivery Device.

Loading the Graft into the Delivery Device

With Delivery Device in hand, depress the Plunger until the middle of the colored band on the Plunger shaft is positioned at the opening of the Delivery Device T-handle. This will expand the metal springs at the open end of the Delivery Device and allow for insertion of the graft. Make sure to insert the cartilage end of the graft first into the open end of the Delivery Device (Figure 6). Once the graft is inserted, retract the Plunger in order to contract the metal springs to hold the graft. At this point the graft is captured in the Delivery Device and is ready for implantation.

Mini Arthrotomy Repair of Osteochondral Lesions Using Cannulated Instrumentation



Figure 7

Depress the Plunger on the Delivery Device.

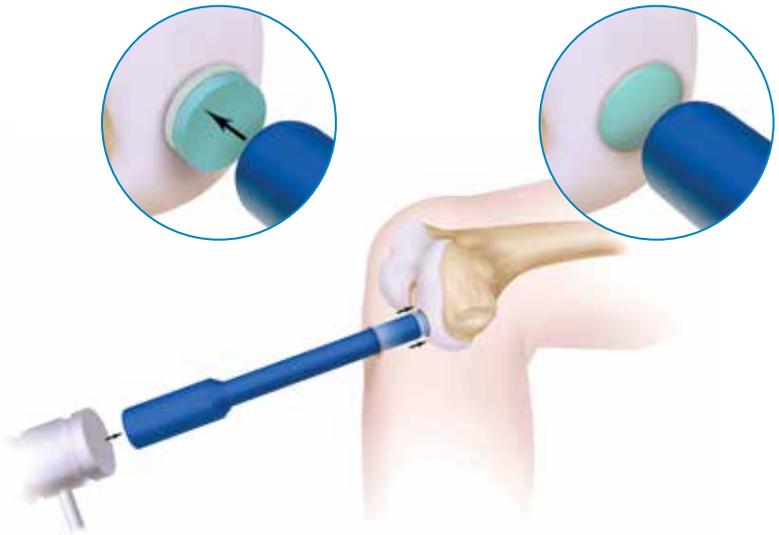


Figure 8

Insert Tamp and gently tap until graft is flush.

Implanting the Graft

Introduce the Delivery Device into the surgical site. When the Delivery Device is positioned over the recipient site, release the graft into the recipient hole by depressing the Plunger on the Delivery Device (Figure 7). The Delivery Device will leave the graft 1mm proud in the recipient hole. To advance the graft the remaining 1mm, remove the Delivery Device and insert the Tamp of corresponding size (Figure 8). Gently tap the head of the Tamp until the graft is flush with the surrounding articular cartilage.

ⓘ **Note:** When using a Chondrofix Allograft, it is important to make sure the graft is flush with and matches the surface contour of the surrounding articular cartilage.

Remove Tamp

Multi-Graft Implantation Technique

Repeat Steps 3–8.

ⓘ **Warning:** Graft is not recommended for Mosaicplasty graft constructs.

ⓘ **Note:** Before reusing a Punch or Drill Bit during the same procedure, inspect the cutting edges of the instruments to ensure that the surfaces have not been damaged.

Close the Incision

Once all the grafts have been implanted, do a final check of the graft position relative to the surrounding cartilage. Close the incision according to standard practices.

Post-Operative Care

The rehabilitation protocol is at surgeon discretion. General post-operative guidelines include:

	Weight Bearing	ROM	Exercise
Phase I 0–6 weeks	Weight bearing as tolerated	Progress ROM as tolerated, consider CPM Machine (condylar)	Biking with no resistance, straight leg raises, open chain exercises
Phase II 6–12 weeks	Full weight bearing	Increase ROM, progress to full ROM	Closed chain exercises, initiate weight shifts, begin w/b exercises weeks 8–10 progressing to week 12
Phase III 12–26 weeks	Full weight bearing	1	Continue progressive exercises

Warnings and Precautions:

- This graft is restricted for use by a licensed clinician only.
- This graft should be implanted only by surgeons familiar with osteochondral autograft or allograft implantation procedures. The medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation of the Chondrofix Allograft. The surgeon is responsible for informing the patient of the risks associated with the surgery and the possibility of complications or adverse events.
- The tissue may transmit infectious agents.
- The graft may contain trace amounts of processing reagents (methylene blue, methylene chloride, ethanol, phosphate buffered saline). Exercise caution if the patient has a known sensitivity to any of these chemicals.
- Once the packaging has been opened, the tissue graft must be used for the current procedure or discarded.
- Do not re-sterilize the graft.
- For single-patient use only.
- For single-occasion use only.
- Do not use the graft if damaged or expired.
- Do not use the graft if sterility is compromised.
- Do not use the graft if package integrity has been compromised.
- The Chondrofix Allograft is provided without any express or implied warranties. All statements or descriptions are informational only and not made or given as a warranty of tissue in any way.

Contraindications:

The graft should not be implanted when an active infection is present at the surgical site.

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