



Zimmer®
DeNovo® NT
Natural Tissue
Graft

Surgical Technique



Biologic treatment for early intervention and cartilage repair.



Overview

DeNovo® NT Natural Tissue Graft (Fig. 1) is an off-the-shelf human tissue, consisting of viable, juvenile hyaline cartilage pieces and is intended for the repair of articular cartilage defects in a single-stage procedure. The *DeNovo* NT Graft surgical technique mitigates the need for harvesting and suturing of a periosteal flap, unlike autologous chondrocyte implantation (ACI), as it employs a fibrin sealant to secure the minced tissue pieces into the defect.



Fig. 1

DeNovo NT Graft (1 package per 2.5cm² defect area)

Fibrin preparation:

Prepare fibrin adhesive components in advance per appropriate instructions. Allow adequate time for frozen or refrigerated materials to warm up per instructions.



DeNovo NT tissue adhered to the defect site with fibrin (shown in patellar defect).

Defect preparation:

Perform a miniarthrotomy using a tourniquet (does not have to be inflated). Mark the defect area with a sterile surgical marker and remove the cartilage tissue within the defect area with a curette to create a well-defined vertical defect perimeter.

Clear the defect base carefully to remove the calcified cartilage layer, but take care to avoid violating the subchondral cortical bone. If subchondral bone bleeding occurs, it must be stopped before implantation of the *DeNovo* NT graft. Fibrin sealant may help facilitate this. Irrigate the defect and surrounding cartilage frequently with normal saline to prevent cartilage desiccation.

(Fig. 2)



Fig. 2

Clear the defect and irrigate (shown in trochlear defect).

Defect sizing:

Measure the approximate surface area of the defect to determine how many *DeNovo* NT Graft packs (one pack for every 2.5 cm² of defect area) will be needed. Document the defect with a photo (film or digital) with ruler showing two dimensions at 90 degrees to each other as per ICRS sizing. (Fig.3)

With the aid of a sterile flat-ended rod, press a thin sterile foil into the defect so that the outer shape of the foil fits snugly into the defect base and vertical wall. Remove the foil defect sizing template from the defect and place on sterile gauze or pad. (Fig. 4)

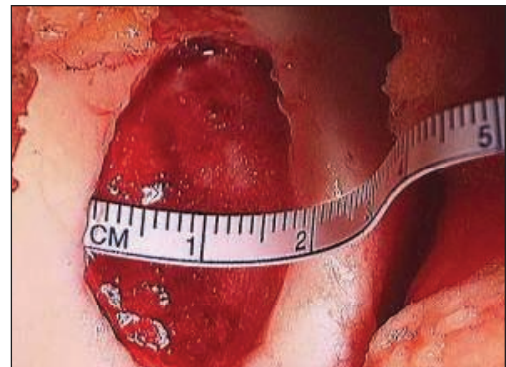


Fig. 3

Document the defect.

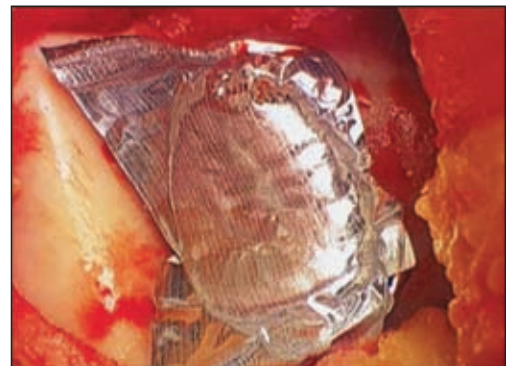


Fig. 4

Create a foil replica of the defect.

DeNovo NT Graft Preparation

Peel open the lid of the primary packaging of the *DeNovo* NT Graft. Using a thin sterile tube or needle <1mm in diameter (i.e., 18ga. angiocath tip and syringe), remove as much storage fluid from the *DeNovo* NT Graft packaging as possible, being sure that the *DeNovo* NT Graft tissue pieces remain. (Fig. 5)

Transfer *DeNovo* NT Graft cartilage pieces into the foil mold and disperse *evenly* across base of the mold. Aspirate any remaining fluid from the foil mold, or simply use a small diameter needle to gently poke a few holes in the base of the foil template to drain any remaining fluid. (Fig. 6)



Fig. 5a

Remove fluid.



Fig. 5b

Only cartilage should remain.



Fig. 6

Place and distribute cartilage evenly into foil mold.

Gently apply fibrin glue to embed the particulated tissue pieces so that the tissue/fibrin construct fills approximately 2/3 to 3/4 of the depth of the mold. **(Fig. 7)** Let the fibrin set for 5-10 minutes, or per fibrin preparation instruction.

Once fibrin has set, gently pull the edges of the foil mold to straighten the foil so that the tissue/fibrin construct separates from the vertical wall of the foil mold. **(Fig. 8)** Use a sterile flat instrument to gently lift the construct from the mold base. The graft is now ready for implantation. **(Fig. 9)**



Fig. 7

Apply fibrin glue.



Fig. 8

Allow fibrin to sit for several minutes to fully cure. Then pull edges of foil until taut.



Fig. 9

Separate foil from the graft. Graft is now ready to implant.

Fixation of DeNovo NT Graft into the Cartilage Defect

Gently dry the defect area using sterile surgical gauze.

Apply a very thin fresh layer of fibrin glue to cover the entire base of the defect to provide a tacky surface. (Fig. 10)

Immediately place the graft in the defect, ensuring full contact with the fresh fibrin. Gently hold the graft (Fig. 11) in close contact with the base and edges of the defect (i.e., using a finger). The implant should be recessed by approximately 0.5mm relative to surrounding native cartilage.



Fig. 10

Apply a thin layer of fibrin to the base of the defect to provide a tacky surface.



Fig. 11a

Immediately transfer the graft to the defect.

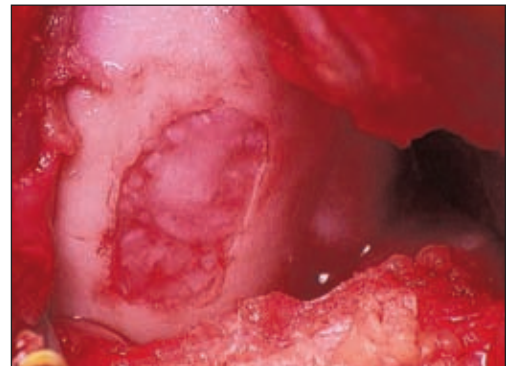


Fig. 11b

Implant in position (shown in condylar defect).

Allow adequate time for fibrin to fully cure (typically at least 3-5 minutes). (Fig. 12) The graft should not be manipulated or dislodged during the curing. Document the implant with a photo (film or digital). Cycle the joint a few times through the range-of-motion to ensure that the tissue construct is stably in place.

Wound Closure

Based on surgeon's judgment and standard of care, insert drains within the wound site and close the joint capsule, fascial layers and skin using standard suture and surgical technique.

Rehabilitation

Rehabilitation protocols should consider guidelines per alternative cartilage restoration techniques, with the use of non-weight-bearing periods, continuous passive motion (CPM) and rehabilitative exercises dependent upon such factors as defect location, pre-surgery condition and level of activity, etc.



Fig. 12a

Implant in position (shown in patellar defect).



Fig. 12b

DeNovo NT tissue is adhered to the defect site with fibrin (shown in patellar defect).

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