Allograft Particulate Cartilage Transplantation: 
*DeNovo Natural Tissue (NT) Graft*

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**INTRODUCTION: DENOVO NT GRAFT**

The *DeNovo* Natural Tissue (NT) Graft is derived from articular cartilage allograft. The allograft articular cartilage is mechanically particulated into pieces of tissue and stored in a proprietary storage medium developed by ISTO Technologies, Inc. (St. Louis, Mo., United States).

The tissue is procured from donors 13 years old or younger (no fetal tissue), as more robust collagen type II and proteoglycan production occurs in cartilage from donors in this age group than in adult cartilage tissue.

As an allograft tissue, *DeNovo* NT is not required to be preapproved for clinical use by the Food and Drug Administration (FDA) but complies with the FDA regulations for human tissue products and the American Association of Tissue Banks (AATB) standards. The packages of *DeNovo* NT graft are shipped in controlled temperature containers (distributed by Zimmer, Inc.).

As tissue comprising the *DeNovo* NT graft is analyzed in the same manner as fresh stored osteochondral allograft, per AATB standards and FDA regulations, it is released for use only after all viral screening and sterility tests are completed. Similar to other fresh allograft tissues such as fresh osteochondral allografts, the tissue has a limited shelf life.

The aseptically prepared *DeNovo* NT graft is placed in an inner sterile package filled with the storage medium. The sterile inner package is then sealed within a protective outer plastic package that is sterile inside.

Preoperatively, the lesion sizes are documented. The lesion areas are calculated and used to order the separate packets of *DeNovo* NT graft. Each package contains particulated cartilage pieces to cover an area of up to 2.5 cm².
The DeNovo NT graft has been implanted to repair cartilage defects in the knee, ankle, hip, shoulder, elbow, and great toe, with the earliest surgery performed in May 2007.

**TECHNIQUE OVERVIEW**

*Step 1.* Prepare the contained chondral lesions as standard for cell therapy techniques such as autologous chondrocyte implantation (ACI); vertical walls, with a clear base (Figs. 10-1 and 10-2).

*Step 2.* Achieve hemostasis with tourniquet deflated.

*Step 3.* Mold a sterile foil template into defect, and place template on sterile gauze (Fig. 10-3).

*Step 4.* Apply DeNovo NT graft pieces onto the foil mold base uniformly (Fig. 10-4).

*Step 5.* Use a needle to perforate the base of the foil mold to drain the storage medium transferred with the tissue pieces (dry field of DeNovo NT graft pieces) (Figs. 10-5 and 10-6).

*Step 6.* Apply a layer of fibrin glue to cover all pieces of cartilage (Fig. 10-7).

*Step 7.* Allow the fibrin glue to fully cure (Fig. 10-8).

*Step 8.* Gently elevate the fibrin glue/DeNovo NT graft construct from the floor of the mold.

*Step 9.* Dry the base of the chondral defect, and apply a thin layer of fibrin glue on this base.

*Step 10.* Remove the fibrin glue/DeNovo NT graft construct from the foil mold and place it in the cartilage defect, ensuring full contact with the fresh fibrin.

*Step 11.* Assure that the fibrin glue/DeNovo NT graft construct is below the shoulders of the lesion and will not see stress/shear from the opposing joint surface when motion is initiated (Fig. 10-9).

**FIGURE 10-1** A trochlear-contained defect with Grade 3a chondrosis.
FIGURE 10-2 The defect base is cleared of debris, walls are vertical, and hemostasis is achieved.

FIGURE 10-3 The sterile foil template is molded to fit the defect.

FIGURE 10-4 The DeNovo NT graft packet is removed from the protective sterile inside of the packaging.
Step 12. Allow the fibrin glue to fully cure.
Step 13. Check the stability of the implant with a controlled gentle trial of range of motion.

PEARLS AND PITFALLS

1. Normal cartilage vertical walls and clear base are as important as they are for all cell and implant cartilage surgery—do not compromise.
2. Containment is important for the current application.
3. The foil mold may require further sculpturing to mimic the defect.
4. Particulated cartilage is easiest to work with when a few drops of medium are still present—too much medium and the particulated cartilage flows; too little medium and it sticks to the dispersing tool.
5. All fibrin glues cure at a different rate; be patient for the construct to be fully cured and to allow ease of transfer.
6. Once in the defect, the fibrin glue/particulated cartilage construct can be plastically molded to optimally fill the defect.
7. Assure stability through range of motion trials.

FIGURE 10-5  The storage medium is aspirated, leaving a few drops that improve handling of the DeNovo NT graft pieces.
FIGURE 10-6 The DeNovo NT graft ready for transfer to the mold.

FIGURE 10-7 A thin layer of fibrin glue is applied to the DeNovo NT graft in the mold.

FIGURE 10-8 After the fibrin glue has cured, a Freer elevator is used to carefully detach the fibrin glue/DeNovo NT graft construct from the foil mold.
FIGURE 10-9 The fibrin glue/DeNovo NT graft construct is fixed into the defect with additional fibrin glue. The construct remains recessed from the defect shoulders.

POSTOPERATIVE MANAGEMENT AND REHABILITATION

Postoperative management and rehabilitation follow the same guidelines as with other cell-based therapies. It is important to document that the lesion is not subjected to disruptive forces during range of motion. If there is concern, motion may be limited to avoid loading of the implant region in the early phases of recovery. As for other cell-based treatments, protocols are modified according to the specifics of the patellofemoral or tibiofemoral compartment loading.

REFERENCES