



Zimmer®  
DeNovo® NT  
Natural  
Tissue Graft



Biologic treatment for early intervention and cartilage repair.





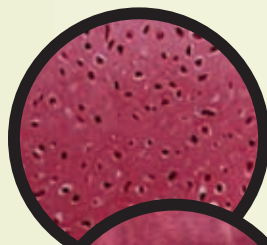
## DeNovo NT Graft – Advancing the Science of Cartilage Repair.

*DeNovo* NT Natural Tissue Graft is a juvenile cartilaginous allograft tissue intended to provide surgeons with an early-intervention option for the repair of articular cartilage in a wide range of anatomic focal cartilage defects. It offers a single-stage procedure with fibrin fixation that eliminates the need for harvesting a periosteal flap. With *DeNovo* NT Graft, Zimmer demonstrates its commitment to leadership in providing surgeons – and their patients – with a complete continuum of joint care.



### Juvenile Cartilage Tissue

*DeNovo* NT Graft consists of scaffold-free living articular cartilage, displaying biochemical properties similar to those of articular cartilage found in young, healthy joints.



Juvenile Cartilage  
400X



Adult Cartilage  
400X

### Cartilage Injury and Treatment

- Adult articular cartilage has limited capacity for self-repair.<sup>1</sup>
- Untreated focal defects begin a cycle of cartilage breakdown, arthritic degeneration and ultimately, the need for joint replacement.

*DeNovo* NT Graft offers a simple alternative to focal cartilage defect treatment.



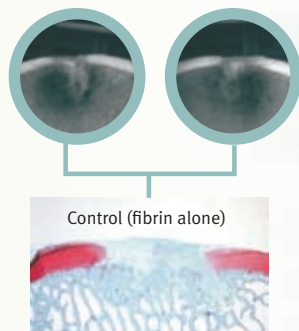
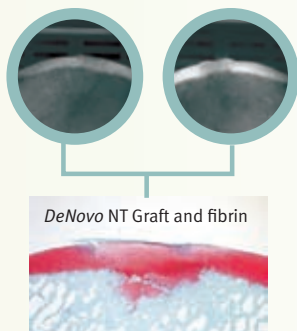
## Single-stage Procedure with Fibrin Adhesive

- Simplified surgical technique, unlike ACI.
- No need to harvest and sew a periosteal flap.
- No donor site morbidity, unlike autologous osteochondral transplant.

## Pre-Clinical Evidence\*

### Demonstrated in Equine Trochlea Model at 6 Months Explantation: <sup>2</sup>

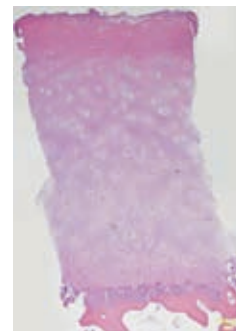
- *DeNovo* NT Graft provided for full-thickness, continuous layer of cartilage repair tissue.
- *DeNovo* NT Graft resulted in minimal subchondral bone resorption.
- Repair tissue integrated into subchondral bone.



## Clinical Experience

- Human clinical experience to date includes 2 years of implant history
- *DeNovo* NT Graft has been used to treat focal articular defects in a wide range of anatomical applications, including:
  - Knee (i.e., condyle, trochlea, patella, tibial plateau)
  - Foot and Ankle (i.e., talus, MPJ)
  - Elbow
  - Shoulder (i.e., humeral head, glenoid)
  - Hip (i.e., acetabulum, femoral head)

H&E staining, human biopsy 8 months post-op in 16 year old female trochlear defect.



\* Animal Study results are not necessarily predictive of human results.

## Comparison of Cartilage Treatment Alternatives

Cartilage Defect Treatment Options	Surgery	Treatment of Defect Area	Tissue Characteristics
<b>DeNovo NT Graft</b>	Single stage	Up to 5cm <sup>2</sup> (and greater at surgeon's discretion)	Juvenile hyaline cartilage implanted (up to 13 yrs old)
<b>ACI</b>	Two-stage	Routinely 5-10cm <sup>2</sup>	Adult chondrocytes implanted Equivalent clinical outcome to microfracture <sup>3</sup>
<b>OATS</b>	Single stage	Limited; 1-3cm <sup>2</sup>	NOT juvenile cartilage Donor site morbidity
<b>Microfracture</b>	Single stage	Limited; 1-2cm <sup>2</sup>	No tissue implanted Fibrous repair tissue <sup>4</sup>
<b>Debridement</b>	Single stage	Variable	No tissue implanted
<b>Osteochonral Allograft</b>	Single stage	Typically 5-10cm <sup>2</sup>	NOT juvenile cartilage Limited Supply

### References:

1. R. Kang, A. Gomoll, S. Nho, T. Pylawka and B. Cole. Outcomes of mechanical debridement and radiofrequency ablation in the treatment of chondral defects: A prospective randomized study. *Journal of Knee Surgery*. 2008; 21: 116-121.
2. Frisbie et al. Data on file at ISTO Technologies, Inc.
3. G. Knutson, J. Drogset, L. Engebretsen, T. Grontvedt, C. Isaksen et al. A randomized trial comparing autologous chondrocyte implantation with microfracture: Findings at five years. *Journal of Bone and Joint Surgery Am*. 2007, 89: 2105-2112.
4. M. Asik, F. Ciftci, C. Sen, M. Erdil and A. Atalar. The microfracture technique for the treatment of full-thickness articular cartilage lesions of the knee: Midterm results. *Arthroscopy: The Journal of Arthroscopic and Related Research*. 2008, 24; 11: 1214-1220.

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