Clinical Background

For clinical videos visit smith-nephew.com/education

Statements in this brochure are based upon data sourced from select articles and studies and may not reflect the whole body of evidence available.
Horizontal Cleavage Tears (HCT)

Contact Pressures Increased by HCT
- Based on *in vitro* data, pressure from untreated tear increases contact pressures by 70%.
- Studies have shown unfavorable results in leaflet resection improving contact pressures.
- HCT repair normalizes contact pressures.

Successful HCT Repair is Possible
- 78% clinical success rate of HCT repair upon systematic review, similar to other tear types.
- 91% success rate in broad age range of patients (14-56) confirmed with 2nd look follow up.
- 91% success rate with MRI follow up.

Contact Pressures of HCT Tears

![Graph showing contact pressures of HCT tears](image)

Successful HCT Repair

<table>
<thead>
<tr>
<th>Study</th>
<th>Success Rate</th>
<th>Mean FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kurzweil et. al. Combined Studies</td>
<td>78%</td>
<td>32.2 m</td>
</tr>
<tr>
<td>Ahn et. al. Mean Follow-up (FU)</td>
<td>91%</td>
<td>45.6 m</td>
</tr>
<tr>
<td>Pujol et. al. Mean FU</td>
<td>91%</td>
<td></td>
</tr>
</tbody>
</table>

Note: Clinical success rates were calculated for different techniques including: inside-out (IO), IO with bioabsorbable and Biofix arrow anchors and open procedures. MRI follow-up success rate based on independent surgeon interpretations.

Circumferential Stitches Enable HCT Repair
- Technique articles from leading centers highlight NOVOSTITCH Meniscal Repair System proprietary Circumferential Compression Stitches (CCS) to repair HCTs.
- Use of CCS eliminates posterior incision and minimizes risk of neurovascular injury.

NOVOSTITCH PRO Meniscal Repair System Designed for HCT Repair
- Low profile (1.6mm) and retractable lower jaw facilitate access to peripheral meniscus.
- Curved upper jaw and retractable lower jaw enhance maneuverability for HCT repair vs. other repair methods.

Kurzweil et. al.
Combined Studies
Ahn et. al.
Mean Follow-up (FU)
Pujol et. al.
Mean FU
Root Tears

Meniscectomy for Root Tears Increases Osteoarthritis (OA)

- 35% of meniscectomy patients in root tear study advanced to total knee arthroplasty (TKA) within 5 years\(^\text{10}\)
- Meniscectomy to treat meniscal root avulsions leads to significant joint space narrowing within 5 years\(^\text{11}\)

TKA after Root Tear Treatment\(^\text{10}\)

Successful Root Repair Possible

- 0% of root repair patients advanced to TKA within 5 years, compared to 35% for meniscectomy\(^\text{10}\)
- Root repair patients had greater function, less pain, and greater joint space compared to patients who received meniscectomy\(^\text{11}\)

Stitch Construct Impacts Root Repair Strength

- Most often root repairs fail due to suture pulling through tissue\(^\text{12}\)
- One stitch with cross-fiber purchase and multiple points of fixation is stronger than two stitches without\(^\text{12,13}\)
- Placing stitches 5-7mm from the edge of the meniscus generates stitches that are 38-78% stronger\(^\text{14}\)

Root – Load to Failure\(^\text{13}\)

NOVOSTITCH PRO Meniscal Repair System Enables Strong Root Construct

- Cartridges with size 0 suture enable stitches with two points of fixation to create a double modified locking loop without removing the device from the joint
- Curved upper jaw and retractable lower jaw enhance maneuverability for root repair

Note: Study data based on ex vivo analysis with cadaveric knees
Radial Tears

Meniscectomy of Radial Tears Increases Contact Pressure
- Radial tears increase contact pressures within the knee\(^{15}\), and full-thickness radial tears render the meniscus nonfunctional\(^{16}\).
- Meniscectomy of radial tears increases contact pressures by more than 100% over baseline\(^ {15}\).

### Contact Pressures of Radial Tears\(^ {18}\)

<table>
<thead>
<tr>
<th></th>
<th>Peak Pressure [MPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial Meniscectomy</td>
<td>3.2</td>
</tr>
<tr>
<td>Radial Tear</td>
<td>4.2</td>
</tr>
<tr>
<td>Intact Meniscus</td>
<td>2.1</td>
</tr>
</tbody>
</table>

**Note:** Study data acquired from cadaver knees.

Robust Radial Repairs Possible
- 71-100% radial repair clinical success rates upon systematic review\(^ {17}\) of follow-up results from included studies, similar to other tear patterns\(^ {3}\).
- Outcomes of full-thickness radial repairs comparable to bucket handle repairs\(^ {16}\).

### Success of Radial Repairs\(^ {17}\)

<table>
<thead>
<tr>
<th></th>
<th>Success Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haklar</td>
<td>100</td>
</tr>
<tr>
<td>Choi</td>
<td>60</td>
</tr>
<tr>
<td>Ra</td>
<td>77(^ {3})</td>
</tr>
<tr>
<td>Song</td>
<td>20</td>
</tr>
</tbody>
</table>

Strong Radial Repair with Circumferential Compression
- Based on *in vitro* data, Circumferential Compression Stitches (CCS) stronger than inside-out for radial repairs\(^ {18}\).
- CCSs have less gap formation than inside-out repair for radial tears\(^ {18}\).
- The CCS improves repair vectors for radial repairs by creating a stitch straight across the radial tear.

### Radial – Load to Failure\(^ {18}\)

<table>
<thead>
<tr>
<th></th>
<th>Failure Load [N]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circumferential Stitch</td>
<td>140 (p = 0.03)</td>
</tr>
<tr>
<td>Inside-Out</td>
<td>80</td>
</tr>
<tr>
<td>Capsule-Dependent Fixator</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NOVOSTITCH PRO Meniscal Repair System Designed for Radial Repair
- Low profile (1.6mm) and retractable lower jaw facilitate access to peripheral meniscus\(^ {9}\).
- Curved upper jaw and retractable lower jaw enhance maneuverability for radial repair vs. other repair methods\(^ {9}\).
- Cartridges enable placement of complete stitches without removing the device from the joint.
Repair of Avascular Tears Possible

- 87% of repaired tears extending into avascular zone were asymptomatic upon follow-up.\(^9\)
- Patients in the Noyes study were all 40+ years of age.\(^9\)

Outcome in Avascular Tears\(^9\)

<table>
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<tr>
<th>Age Group</th>
<th>Success Rate (%)</th>
</tr>
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<tr>
<td>&gt;40 years old</td>
<td>95%</td>
</tr>
<tr>
<td>&lt;40 years old</td>
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</table>

Age Doesn’t Matter

- Two systematic reviews found no difference in repair success between patients over and under 40 years of age.\(^20,21\)
- Case review showed no difference in repair success in patients over and under 40 years of age.\(^22\)
- Steadman also demonstrated a 94.7% success rate of repair in patients over 40.\(^22\)

Revision Repairs

Successful Revision Repair Possible

- 79% of revision meniscus repairs were pain-free at a mean of 6 years follow-up.\(^23\)
- Failure of repair still resulted in more tissue preservation and less tissue removal during secondary meniscectomy procedures.\(^23,24\)

Repair Success in Revision Surgery\(^23\)

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<th>Revision Repair</th>
<th>Success Rate (%)</th>
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<tr>
<td></td>
<td>79%</td>
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Outcomes in Avascular Tears\(^9\)

Successful Revision Repair Possible

- 79% of revision meniscus repairs were pain-free at a mean of 6 years follow-up.\(^23\)
- Failure of repair still resulted in more tissue preservation and less tissue removal during secondary meniscectomy procedures.\(^23,24\)
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<tr>
<td>CTX-A003</td>
<td>NOVOSTITCH™ PRO Meniscal Repair System (2-0)</td>
</tr>
<tr>
<td>CTX-A004</td>
<td>NOVOSTITCH PRO Meniscal Repair System (0)</td>
</tr>
<tr>
<td>CTX-R001</td>
<td>NOVOSTITCH Cartridge (2-0)</td>
</tr>
<tr>
<td>CTX-R002</td>
<td>NOVOSTITCH Cartridge (0)</td>
</tr>
<tr>
<td>CTX-C001</td>
<td>NOVOCUT Suture Manager</td>
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Refer to the instructions for use for device-specific indications, adverse effects, warnings and precautions.

NOVOSTITCH PRO Meniscal Repair System is 510(k) cleared and available in US only

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### References

8. Brooks K. The NOVOSTITCH PRO Meniscal Repair System is manufactured by Ceterix Orthopaedics, Inc., 6500 Kaiser Drive, Suite 120, Fremont, CA 94535, USA.

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