One durable tissue +
Three natural components

Umbilical tissue for surgical applications composed of native viable cells, growth factors, and extracellular matrix

Smith+Nephew

Stravix
Cryopreserved Umbilical Tissue
Stravix°: Umbilical tissue for surgical applications

- Composed of umbilical amnion and Wharton’s jelly of human umbilical cord
- Blood vessels removed to prevent immune response
- Can be used as a wound cover or surgical wrap
- Cryopreserved and stored at -75° to -85° C

Native components are preserved

<table>
<thead>
<tr>
<th>Fresh umbilical tissue</th>
<th>Stravix</th>
<th>Fresh umbilical tissue</th>
<th>Stravix</th>
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<tbody>
<tr>
<td>Epithelial cells</td>
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<td>Fibroblasts</td>
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<td>Mesenchymal stem cells</td>
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Endogenous cells remain viable

Fluorescent cell staining of Wharton’s jelly

H&E tissue staining

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<tr>
<td>Live/dead cell staining</td>
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</table>

3D matrix remains intact

LIVE and DEAD cell staining

Durable
- Easily sutured at 1mm to 3mm thick

Strong
- 10x tensile strength compared to amnion alone

Conforming
- Intimately adapts to injured tissue to form adhesion barrier
Stravix™ in the management of soft tissue defects in patients with gas gangrene

Study overview
- Retrospective, single-center study of Stravix in the surgical management of large soft tissue defects in patients with gas gangrene (n=10)
- Medical histories include coronary artery disease, congestive heart failure, anemia, hypertension, and peripheral arterial disease
- Inclusion criteria:
  - Lower extremity gas gangrene
  - History of diabetes
  - Surgical intervention resulting in large, open defect with exposed bone/tendon/soft tissue
  - Inadequate surrounding soft tissue or skin for surgical wound closure
  - Not candidates for autologous skin grafting/flaps

Patient demographics & wound characteristics

| Patients | 10 |
| Age (mean) | 59.8 years |
| BMI (mean) | 28.6 kg/m² |
| NPWT used | 9/10 patients |
| Wound size (mean) | 45.9 cm² |

Results

All patients achieved complete wound closure following a single Stravix application.

- **13.4 weeks** for wound closure (mean)
- **9 days hospital stay** (mean) vs. 31.1 days hospital stay (mean) in a database review of 11,666 patients with gas gangrene in the foot
- **68.4%** percent area reduction at 4 weeks (mean)
- Minimal scarring
- Restoration of natural pigmentation
Case study 1: complex wound

**Patient information**
- 65-year-old male
- History of uncontrolled type II diabetes, coronary artery disease, congestive heart failure, peripheral artery disease and hypertension
- Presented to the emergency department with black fourth digit and dorsal aspect of right foot

**Procedure**
- All non-viable soft tissue and bone debrided
- 4th digit and 4th metatarsal head amputated
- Liquefactive necrosis noted
- Wound measured 8.5 x 6 cm
- Wound irrigated with Pulsavac
- Stravix™ applied and sutured with 4-0 absorbable sutures
- ADAPTIC non-adhering dressing and vacuum therapy applied

**Results**
- Wound granular at 1 month post-op
- Wound epithelialized at 4 months post-op
- The wound remained closed without complications at 17 months follow-up

*Results may not represent typical surgical outcomes. Every surgery and each patient undergoing an operation represents a unique set of circumstances and, therefore, results will vary.*
Case study 2: complex wound

Patient information

- 45-year-old male
- History of type II diabetes and hyperlipidemia
- Presented with foul smelling, red, hot, swollen 4th digit accompanied by fever and ascending lymphangitis
- X-ray revealed subcutaneous emphysema
- Taken to OR emergently

Procedure

- All non-viable soft tissue and bone debrided
- 4th digit and 4th metatarsal head amputated
- Wound measured 4.5 x 7.5 x 1 cm
- Stravix™ applied and sutured with absorbable sutures
- ADAPTIC non-adhering dressing and dry sterile dressing applied

Results*

- Wound measured 1.5 x 0.5 cm at 3.7 months post-op
- Wound closed by 4.4 months post-op

Dare to be different: In this case series of 10 patients, all patients achieved complete wound closure following a single Stravix application

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Case study 3: complex wound

Patient information

- 76-year-old male
- History of type II diabetes, coronary artery disease, hypertension, and peripheral artery disease
- Presented with an infected right heel

Procedure

- Immediate I&D and a partial right calcaneectomy were performed after all of the necrotic and infected tissue was debrided
- Negative pressure wound therapy was applied intermittently for 4 days at 125 mm Hg during hospitalization
- Fenestrated Stravix™ was placed into the wound bed and sutured to the edges

Results*

- The patient was discharged from the hospital on day 12
- At 4 weeks, percent area reduction was 52%
- Wound closed by 12 weeks post-op

Dare to be different: In this case series of 10 patients, all patients achieved complete wound closure following a single Stravix application

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Case study 4: complex wound

**Patient information**
- 47-year-old male
- History of type II diabetes
- Presented with an open wound of the dorsum of the left foot after previously undergoing I&D for gas gangrene by another surgeon
- Exposed bone and tendon with necrotic tissue were present 2 weeks after surgical debridement

**Procedure**
- Following revisional I&D with a 2nd metatarsal resection, the initial wound measured 105 cm²
- Amputation of the hallux which was ischemic was advised, but the patient refused
- Stravix™ was applied to the dorsal wound over the exposed bone and tendon
- Negative pressure wound therapy was applied intermittently for 7 days at 125 mm Hg during hospitalization

**Results**
- The patient was discharged from the hospital on day 10
- At 4 weeks post-op, the wound area had reduced by 61%
- The wound achieved epithelialization at 18 weeks
- Unrelated to the application of Stravix, the patient did ultimately undergo amputation of the hallux

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Stravix™ in the repair of ruptured Achilles tendons

Study overview
- Retrospective, single-center analysis of four patients (avg. age 59) with acute partial or complete Achilles tendon injuries surgically treated with Stravix
- Four patients (avg. age 60) from the same institution with similar degrees of Achilles tendon rupture and similar surgical procedures without treatment with Stravix were used as a control group for comparison
- Stravix and control patient histories include diabetes, hypertension, cancer, hypercholesterolemia, osteoporosis, rheumatoid arthritis, and smoking

Procedure
- End-to-end repair, autograft repair or cadaveric tendon graft for structural repair of rupture
- Repair augmented with Stravix sutured over the tendon ends with absorbable sutures (not performed on control patients)
- Non-weight bearing postoperative for 4-6 weeks

Results
When Achilles tendon repair was augmented with Stravix, patients returned to pre-injury activities sooner
- Time to return to normal shoe gear (mean): 6.25 weeks for Stravix vs. 11.5 weeks for control
- All Stravix-treated patients:
  - Maintained durable skin closure
  - Returned to pre-injury activity levels without loss of function

![Graph showing time to return to normal shoe gear](image)
Case study: Achilles tendon

Patient information
- 54-year-old female smoker
- Acute/complete Achilles tendon rupture with palpable defect
- Hospitalized for intravenous steroid treatment prior to surgery to decrease edema/inflammation

Procedure
- Intraoperative repair of 8 cm Achilles tendon defect using split Achilles autograft and 2 end-to-end repairs with sutures
- Stravix™ was placed over the repaired Achilles tendon at both juncture sites and sutured into place

Results*
- The patient was able to ambulate in normal shoes and actively plantar flex at postoperative week 6

*Results may not represent typical surgical outcomes. Every surgery and each patient undergoing an operation represents a unique set of circumstances and, therefore, results will vary.
Stravix® in the repair of ruptured tendons

Study overview

- Retrospective, single-center study on Stravix as an adjunct surgical wrap in the repair of ruptured tendons in five patients (avg. age 41)
- Ruptured tendons included 2 peroneus brevis tendons, 2 Achilles tendons, and 1 tibialis posterior tendon
- All patients had failed 6 months of conservative therapy

Procedure

- End-to-end structural repair of the tendon rupture
- Stravix wrapped circumferentially around the tendon and secured with absorbable sutures
- Second piece of Stravix laid along incision site before skin closure
- Non-weight bearing postoperative for 3 weeks

Results

The findings demonstrated favorable outcomes over historically observed controls.

- No postoperative erythema, tenderness, drainage, heat, or swelling at surgical site at 1 week
- Time to return to normal shoe gear (mean): 5.6 weeks
- No infection or dehiscence in 24 months (mean) follow-up
Case study: Peroneal tendon

<table>
<thead>
<tr>
<th>Patient information</th>
<th>Procedure</th>
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</thead>
<tbody>
<tr>
<td>• 19-year-old male</td>
<td>• Modified Brostrom and excision of low-lying muscle belly</td>
</tr>
<tr>
<td>• Partial tear of the left peroneus brevis tendon</td>
<td>• Stravix™ wrapped around the tendon</td>
</tr>
<tr>
<td>• Anterior talofibular ligament injury in the left ankle</td>
<td>• Additional Stravix graft laid over Brostrom repair prior to closure</td>
</tr>
</tbody>
</table>

Results*

- At **4 weeks**, the patient was removed from the cast, placed into a **controlled ankle motion (CAM) boot**, and physical therapy was initiated
- **Ambulating** in a shoe at **6 weeks**
- The patient recovered **faster with fewer complications** than previous procedures

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Stravix™:
Easy to apply in complex surgical procedures

Stravix requires minimal preparation and is easy to maneuver and apply, making it an ideal solution for surgical soft tissue repair.

Stravix in action – thaw with sterile saline and apply

This series of studies is provided for informational and educational purposes only. These cases may not represent typical surgical outcomes. Every surgery and each patient undergoing an operation represents a unique set of circumstances and, therefore, results may vary. Smith & Nephew does not provide medical advice. The information presented is not, and is not intended to serve as, medical advice. It is the responsibility of the treating physician to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients.

References:
2. Data on file at Osiris Therapeutics, Inc.

Placental tissue source | Product description | Part #
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Cryopreserved umbilical amnion and Wharton’s jelly | Stravix 2 cm x 2 cm (4 cm²) | PS60006
| Stravix 2 cm x 4 cm (8 cm²) | PS60005
| Stravix 3 cm x 6 cm (18 cm²) | PS60008

Actual sizes shown

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Advanced Wound Management Smith & Nephew Inc. | www.smith-nephew.com | STPE1-22546-1219