Axis™ Dermis
Suspend® Fascia Lata

Allograft implants have been used for both:

- Pelvic floor restoration
- Urethral sling procedures

Ordering Information

Axis™ Dermis and Suspend® Fascia Lata Tissue are available in multiple sizes. Please contact our Customer Service department at 1-800-258-3476 and ask to speak to a Urology Care customer service representative.

Order Number	Description
939227	Axis Dermis 2x7cm
939212	Axis Dermis 2x12cm
939234	Axis Dermis 3x4cm
939247	Axis Dermis 4x7cm
939412	Axis Dermis 4x12cm
939258	Axis Dermis 5x8cm
939268	Axis Dermis 6x8cm
939612	Axis Dermis 6x12cm
939812	Axis Dermis 8x12cm

Order Number	Description
937200	Suspend Fascia Lata 2x4cm
937227	Suspend Fascia Lata 2x7cm
937212	Suspend Fascia Lata 2x12cm
937202	Suspend Fascia Lata 2x18cm
937224	Suspend Fascia Lata 2x24cm
937201	Suspend Fascia Lata 4x7cm
937412	Suspend Fascia Lata 4x12cm
937268	Suspend Fascia Lata 6x8cm
937712	Suspend Fascia Lata 7x12cm

SUSPEND FASCIA LATA AND AXIS DERMIS BRIEF STATEMENT

Indications:
Suspend Tutoplast Processed Fascia Lata and Axis Tutoplast Processed Dermis are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional. This includes suburethral placement for stress urinary incontinence procedures and for pelvic floor reconstruction.

Donor Screening and Tissue Processing:
Axis and Suspend grafts are processed by RTI Surgical using the Tutoplast process. The donated human tissue utilized was recovered from a donor screened for risk factors associated with infection diseases and medical conditions that rule out donation. Trace amounts of manufacturing residuals may remain after processing. Low dose gamma irradiation is applied terminally to the product to achieve a sterility assurance level of 10-6.

Warnings/Precautions:
Axis and Suspend should only be used by appropriately qualified and properly trained medical practitioners. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients. Patients should be counseled that there are alternative prolapse and stress urinary incontinence surgical and non-surgical treatments, and the reason for choosing a cadaveric graft procedure should be explained. Physician should also obtain patient consent to surgery with an understanding of the postoperative risks and potential complications of the planned surgery. As with any human tissue implant, it is not possible to guarantee freedom from transmission of infection agents or other adverse reactions.

Adverse Reactions:
Possible adverse reactions include hypersensitivity, allergic or immune response. Other possible reactions include pain, infection, erosion, extrusion, exposure, contracture and procedure failure may occur. Serious adverse tissue responses or infection may require removal of implant.

See the Instructions for Use for detailed information regarding the implant procedure. Warnings /precautions, adverse reactions, prior to using this product.

For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

CAUTION: Federal (USA) law restricts this device to sale by, or on, the order of a physician.

Coloplast Corp., 1601 West River Road North, Minneapolis, MN 55411 USA. Customer Service: 800.258.3476

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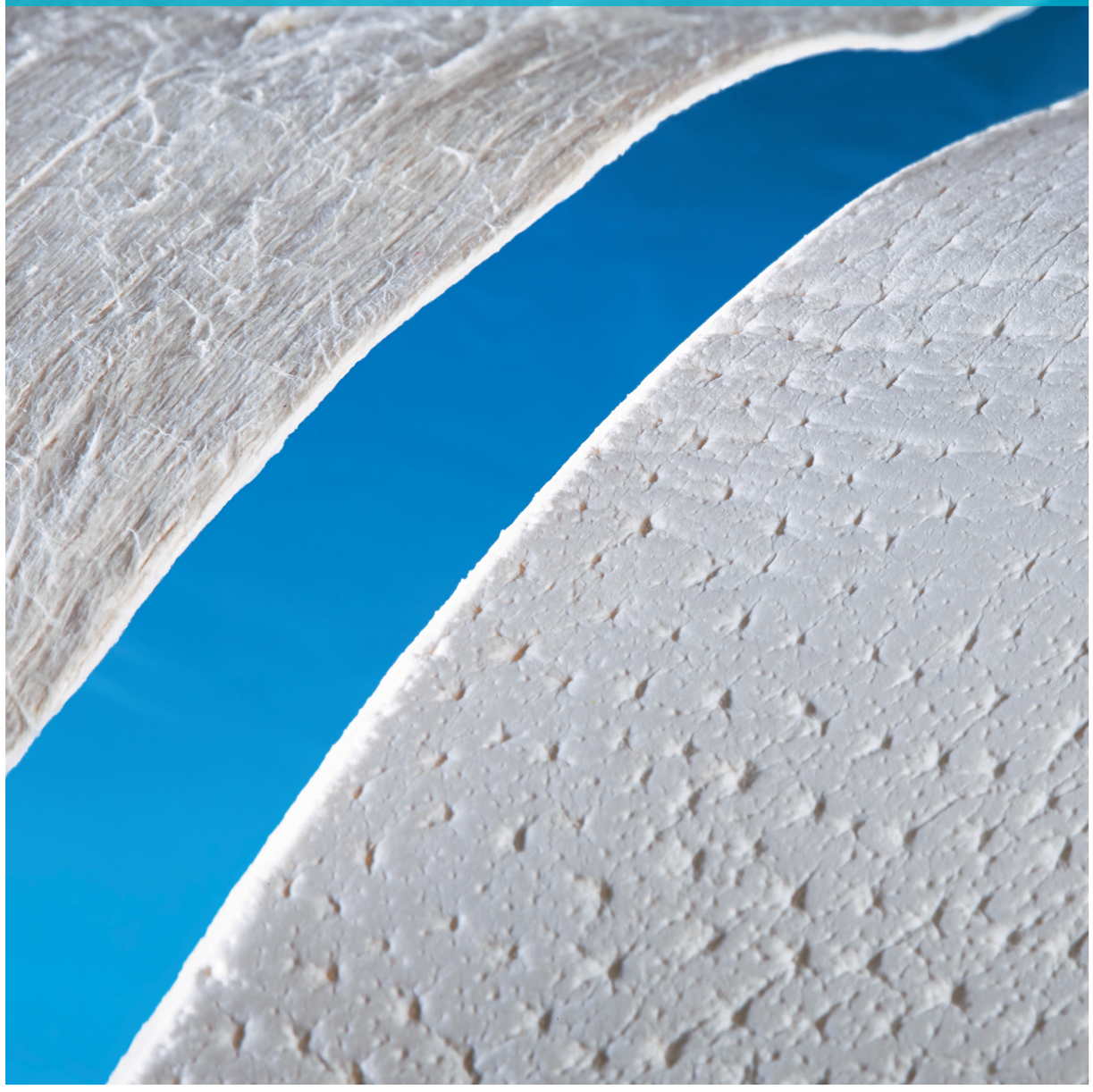
Coloplast

Soft tissue augmentation



The Axis™ Dermis and Suspend® Fascia Lata are allografts rendered through the Tutoplast® Tissue Sterilization Process. These allografts conform easily to irregular surfaces and provide a strong scaffold to support the body's natural regenerative process.

Data Snapshot

Suspend Fascia Lata

- >13 year follow up, 624 women
- 80 % had no significant cystocele reoccurence
- High patient satisfaction, low morbidity
- Complication rate 4%

CYSTOCELE REPAIR WITH NON-FROZEN CADAVERIC FASCIA LATA: LONG-TERM RESULTS. Jennifer Sung MD, Kulwant Singh DO, Sharron L Mee MD, Gary E Leach MD. Abstract presented at the Western Section AUA 2015.

Axis Dermis

- >5 year follow-up (60-141 months)
- 86.3% had better than grade 0 or 1 cystocele post repair.
- No dyspaerunia, extrusion, visceral, neural or vascular injury.

SOLVENT DEHYDRATED DERMAL ALLOGRAFT (AXIS DERMIS) AUGMENTED CYSTOCELE REPAIR: FIVE YEARS FOLLOW-UP. Saad Juma, MD and Omer Raheem, MD. Abstract presented at SUFU 2015.

Axis Dermis and Suspend Fascia Lata at a glance

Sterile

- Low dose gamma irradiation
- Not freeze-dried
- Validated viral inactivation

Biocompatible

- Well-suited for augmentation of soft tissue repair
- Preserves key components of collagen matrix
- Revascularization evident as early as seven days in animal models *

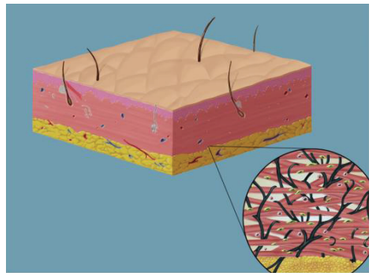
Convenient

- Room temperature storage **
- Five year shelf life
- Simple, single-step rehydration

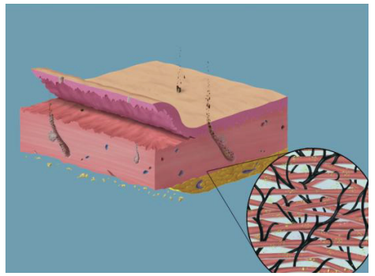
Tutoplast® Tissue Sterilization Process

Osmotic, oxidative, and alkaline treatments break down cell walls, inactivate pathogens, and remove bacteria. Solvent dehydration results in room temperature storage of tissue without damaging the collagen structure. Low-dose gamma irradiation ensures sterility of final packaged products.

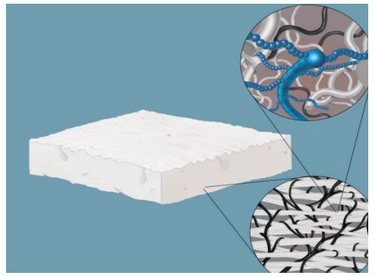
Natural Dermal Matrix



In-Process Dermal Matrix



Implantable Acellular



Treatment Steps:

Delipidization
Removes lipids and red and white blood cells

Osmotic Treatment
Disrupts cell membranes to allow easier removal of cellular components

Oxidative Treatment
Removes immunogenic structures, enveloped and non-enveloped viruses

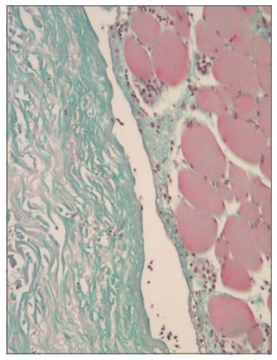
Alkaline Treatment
Inactivates and destroys viruses and DNA/RNA with final pH neutralization

Solvent Treatment
Preserves the natural tissue matrix and allows for five-year shelf life

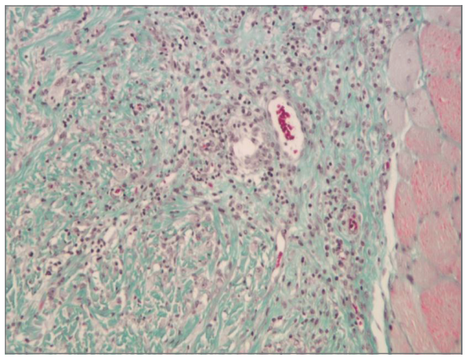
Irradiation
Low dose gamma irradiation produces a terminally sterial graft, while preserving structural integrity

Biocompatiblity

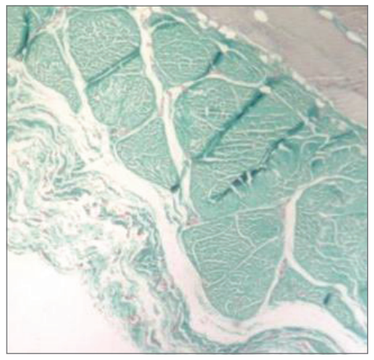
In-vivo Animal Study
Masson's Trichrome Stain, 100x



In-vivo biological response after one day.



By one week post-implantation, neovascularization is evident, along with with cellular invasion of fibroblasts, neutrophils, and other cells normally found in the healing cascade.



By 16 weeks post-implantation, nearly complete remodeling has occurred.

The Tutoplast®-processed grafts were highly biocompatible, functioned successfully as scaffolds, and were well tolerated and completely remodeled by the hosts

* Greenspan DC, Hernandez R, Faleris J. Histology of Surgically Implanted Tutoplast Processed Dermis. Unpublished data, 2008
**see labeling for storage temperature range