Axis™ Dermis and Suspend® Fascia Lata

Tutoplast® Processed Allografts for Pelvic Organ Prolapse and Stress Urinary Incontinence

Coloplast

The only allografts with the inclusion of POP repair and SUI in their Instructions for Use*

The most studied allografts for use in the pelvic floor on the market

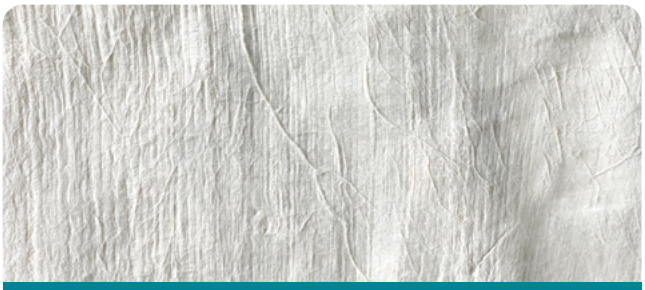
Axis™

Juma & Raheem 2015[1,**]
51 patients

5-year follow-up:
86.3%
were grade 1 or 0

Juma & Raheem 2017[2,**]
184 patients

12-month follow-up:
79.9%
were grade 1 or 0



Suspend®

Leach & Rogers 2013[3,**]
510 patients

4-year average follow-up:
92.4%
had no significant cystocele recurrence

Long-term high efficacy rates compared to native tissue repair

POP Repair Success Rate**

Time Frame	Graft Augmented		Native Tissue		
	Axis Dermis Allografts Augmentation	Sacrocolpopexy	Colporrhaphy	Sacrospinous Ligament Fixation	Uterosacral Ligament Suspension
1-year success rate	Anterior: 79.9%[2]		Anterior: 47.5%[4]		
5-year success rate	Apical: 86.3%[1]	Apical: 89.3%[5]		Apical: 29.7%[6]	Apical: 38.5%[6]

*Distributed by a market leader

**Clinical cases are unique and individual results may vary

Safe and trusted: Tutoplast processed

The only allografts used for soft tissue repair in pelvic floor repair procedures that are processed using the trusted Tutoplast Tissue Sterilization Process.

Over
7 million
Tutoplast processed grafts have been distributed with

Zero
confirmed incidence of implant-associated infection

Consistent and easy to use

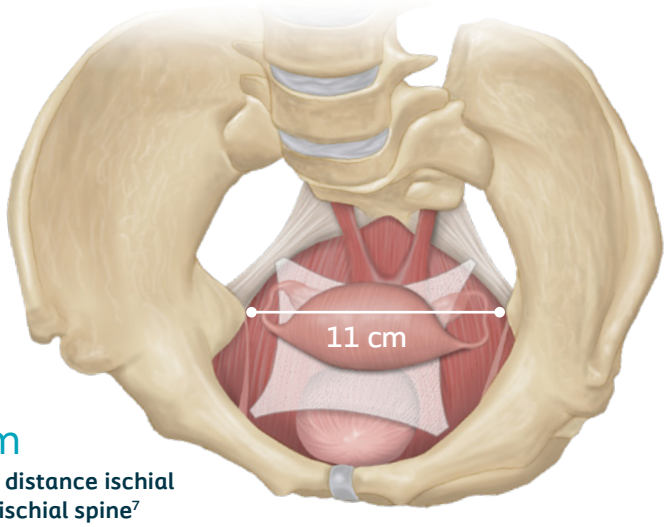
- Uniform thickness and shape
- No specific orientation required
- Quick 2-minute soak
- Shelf stable for 5 years+

+Data on file RTI Surgical

Range of sizes for complete coverage

- Options large enough to cross the full pelvic anatomy
- Customizable in the OR

Axis Dermis	Suspend Fascia Lata
4 cm x 7 cm	2 cm x 7 cm
6 cm x 8 cm	2 cm x 12 cm
6 cm x 12 cm	2 cm x 24 cm
6 cm x 16 cm	4 cm x 7 cm
8 cm x 12 cm	6 cm x 8 cm



11 cm

Average distance ischial spine to ischial spine[7]

Ordering Information

Axis Dermis
Tutoplast Processed Omni-directional Allografts

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
4 x 7	EA	1	**939247**
6 x 8	EA	1	**939268**
6 x 12	EA	1	**939612**
6 x 16	EA	1	**939616**
8 x 12	EA	1	**939812**

Suspend Fascia Lata
Tutoplast Processed Uni-directional Allografts

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
2 x 7	EA	1	**937227**
2 x 12	EA	1	**937212**
2 x 24	EA	1	**937224**
4 x 7	EA	1	**937201**
6 x 8	EA	1	**937268**

Axis™/Suspend® Brief Statement

Description

Axis Tutoplast® Processed Dermis and Suspend Tutoplast® Processed Fascia Lata are regulated as 361 human and cell tissue products and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional. This includes supplemental support and reinforcement of soft tissue, such as suburethral graft placement in stress urinary incontinence procedures, and support and reinforcement of fascial structures in the pelvic floor in pelvic organ prolapse procedures.

Warnings

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function.

Precautions

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant, as such conditions may compromise outcomes. The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determined that the clinical circumstances require implantation in a site that is contaminated, or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to success of the surgical procedure. The Suspend implant should be used with caution in sites where it is placed perpendicular to native tissue.

PM-11535 08/20

References

1. Saad Juma and Omer Raheem, "MP81-17 solvent dehydrated dermal allograft (Axis™) augmented cystocele repair: longitudinal long-term results," *J of Urol* 2015 April; 193(1): e1035, doi: 10.1016/juro.2015.02.2895.
2. Saad Juma and Omer Raheem, "Solvent-dehydrated dermal allograft (AXIS™) augmented cystocele repair: longitudinal results," *Int Urogynecol J* 2017 Aug; 28(8):1159-1164, doi: 10.1007/s00192-016-3245-8.
3. Alexandra Rogers et al, "Prolapse repair with non-frozen cadaveric fascia lata: long-term results," *J of Urol* 2013 Apr; (189)4s: e881, https://doi.org/10.1016/j.juro.2013.02.2060.
4. Daniel Altman et al, "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse" *N Engl J Med* 2011;364:1826-36.
5. Patrick J Culligan et al, "Long-term outcomes of robotic-assisted laparoscopic sacrocolpopexy using lightweight Y-mesh," *Female Pelvic Med Recontr Surg* 2020 Mar; 26(3):202-206, doi: 10.1097/SPV.0000000000000788.
6. Eric Jelovsek et al, "Effect of uterosacral ligament suspension vs sacrospinous ligament fixation with or without perioperative behavioral therapy for pelvic organ vaginal prolapse on surgical outcomes and prolapse symptoms at 5 Years in the OPTIMAL randomized clinical trial," *JAMA* 2018 Apr 17; 319(15): 1554-1565, doi: 10.1001/jama.2018.2827.
7. Stein TA, Kaur G, Summers A, Larson KA, DeLancey JO. Comparison of bony dimensions at the level of the pelvic floor in women with and without pelvic organ prolapse. *Am J Obstet Gynecol.* 2009 Mar;200(3):241.e1-5. doi: 10.1016/j.ajog.2008.10.040. PMID: 19254580; PMCID: PMC2866149.

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