Coloplast

Professional Education

Axis™ Dermis & Suspend® Fascia Lata

Tutoplast® Processed Allografts

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Professional Education

Axis™ Dermis and Suspend® Fascia Lata

Distinguished faculty

Faculty Name

MD, FACOG, FACS

Account affiliation

City, ST

Coloplast

Physician presentation disclaimer_

The following materials are presented for general information purposes only. Coloplast is compensating me for this professional education [or training] presentation.

There are certain segments that I may personalize, based upon my own experience in performing this procedure. These will be distinguished as such during the presentation. To the extent they go beyond Coloplast's written materials, these should be recognized as my individual medical opinions and not the opinions or endorsements of the company.

It is obvious with this, and every other surgical procedure, that you use your own independent judgment that you have received sufficient information and training to proficiently perform the procedure. This lecture and demonstration is intended as a supplement to your own education and training and is not a substitute for your own medical judgment.

I have provided substantial time for questions in this presentation and encourage and welcome any questions that you have.

Note: Clinical cases in this presentation are unique and individual results may vary

Objectives

Communicate the **History of Grafts and Associated Clinical Data**

Convey the importance of **Recovery and Processing**

Analyze the fundamentals of the Allograft procedure

Agenda

01. History of transvaginal (TV) grafts
02. Processing & safety
03. Clinical data
04. Patient selection
05. Patient snapshots
06. Procedural video: anterior
07. Procedural video: posterior

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01

History of TV grafts

Type of grafts, FDA communications & orders

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History of grafts

2003

Porcine
E.g.
Pelvicol/Pelvisoft, SurgiSIS, InteXen, Acell MatriStem

2003

Synthetic mesh
E.g. Avaulta, Elevate, Restorelle, Uphold

2005

Bovine
E.g.
Xenform

2007

Allograft
Axis™ Dermis, Suspend®
Fascia Lata, Repliform

The only type of graft left on the market for homologous uses

FDA orders

The FDA communications regarding TV grafts did not apply to allografts

	Synthetic mesh	Xenograft	Allograft
FDA 522 order applies	X	X	N/A
Removed from market per FDA order in 2019	X	X	N/A

Biologic grafts

xen·o·graft

[ˈzenəˌgraft, ˈzēnəˌgraft]

Noun

A tissue graft or organ transplant from a donor of a different species from the recipient.

al·lo·graft

[ˈaləˌgraft]

Noun

A tissue graft from a donor of the same species as the recipient but not genetically identical.

Allografts ***are not*** xenografts

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Tutoplast® Processed Allografts

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Allografts:
Pelvic Organ Prolapse & Stress Urinary Incontinence

Long term high efficacy rates[1]
- Compare favorably to native tissue repair
- Similar to sacrocolpopexy in 5-year success rates

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

Consistent and easy to use
- Uniform thickness and shape
- Quickly rehydrates*

* See labeling for complete instructions for use

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.

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02

Processing & safety

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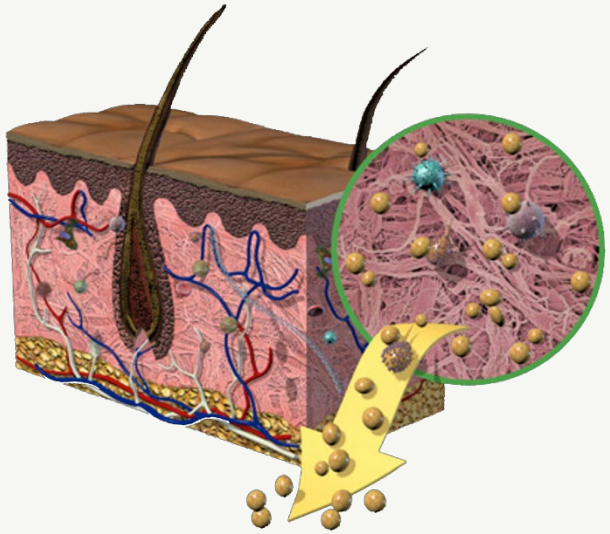
Tutoplast® tissue sterilization process

Osmotic, oxidative and alkaline treatments
break down cell walls, inactivate pathogens, and **remove bacteria**

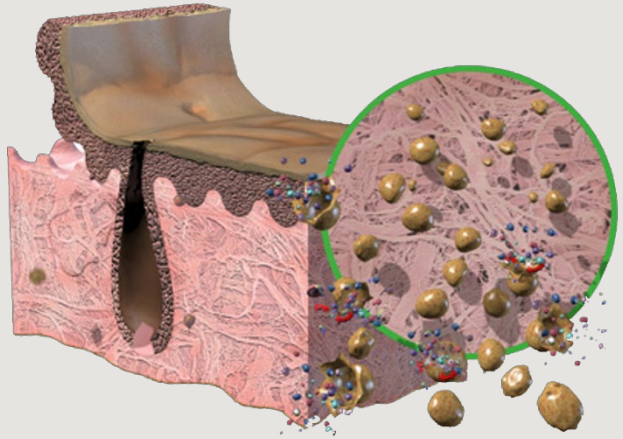
1 Alkaline treatment

Removes cells and lipids which interfere with healing *(If indicated)*



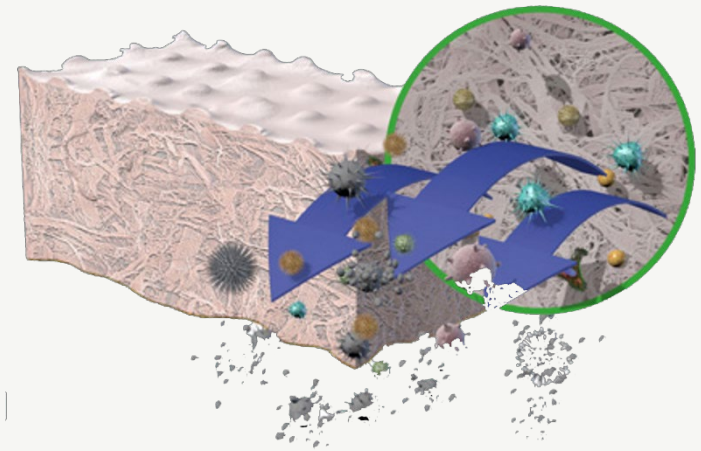
2 Osmotic treatment

Disrupts cell membranes to allow easier removal of cellular components



3 Oxidative treatment

Removes immunogenic structures, enveloped and non-enveloped viruses



Images depict dermal processing.

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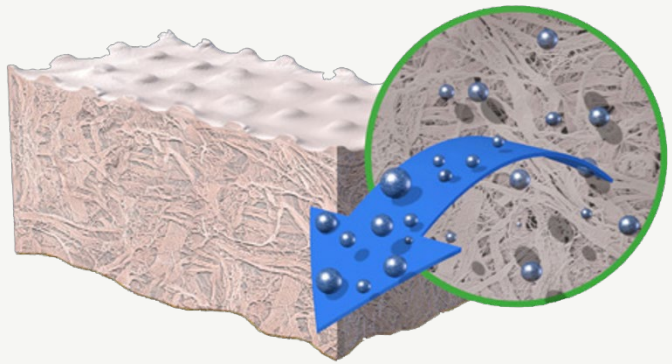
Tutoplast® tissue sterilization process

Solvent dehydration allows for room-temperature storage of tissue without damaging the native tissue structure. Low-dose gamma irradiation ensures a **sterility assurance level (SAL) of 10-6 of the final packaged graft.**

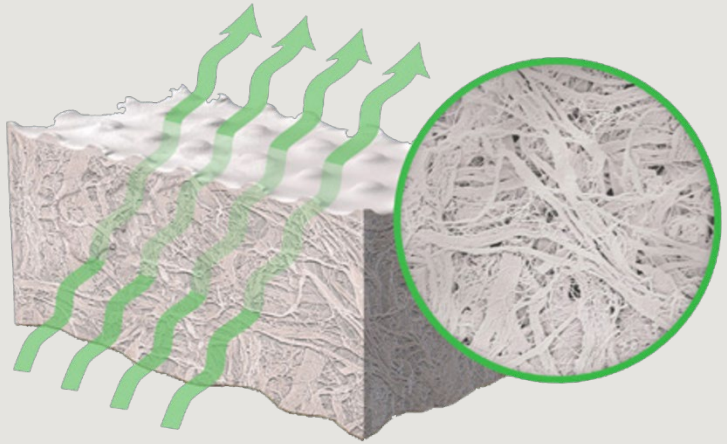
4 Solvent treatment

Removes water from tissue, preserves the natural tissue matrix and allows for a five-year shelf life



5 Irradiation

Low-dose irradiation produces a terminally sterilized graft, while preserving structural integrity



Images depict dermal processing.

Infection incidence rate

Over

7 million

Tutoplast processed grafts have been distributed with...

Zero

Confirmed incidence of implant-associated infection

Data on file with RTI Surgical

03

Clinical data

Native tissue repair vs augmentation

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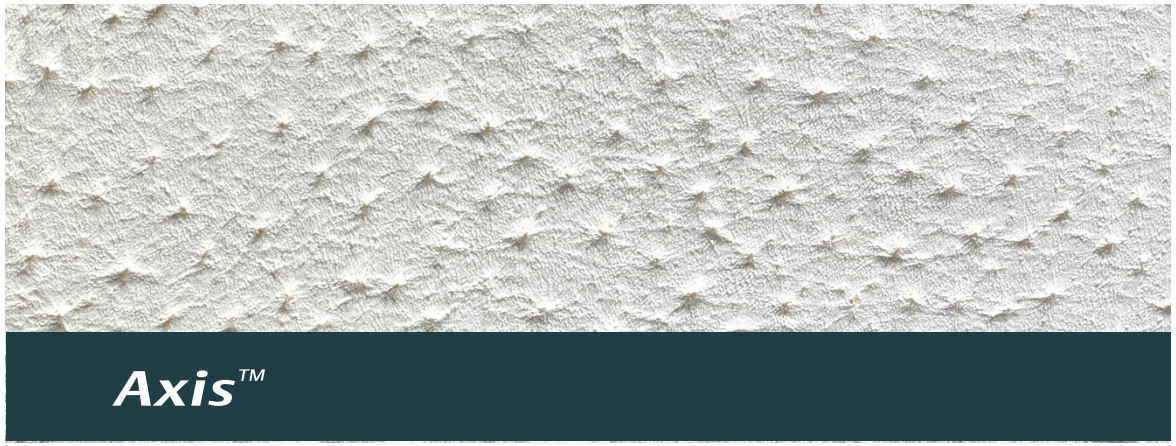
The **most studied allografts** for soft tissue repair and support in POP and SUI procedures



Juma and Raheem 2015[1]
51 patients

Juma and Raheem 2017[2]
184 patients

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

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

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.

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

Leach and Rogers 2013[1]
510 patients

4-year average follow-up:

92.4%

had no significant cystocele recurrence

1. Leach and Rogers 2013 - 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.
* Distributed by market leader

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Long-term high efficacy rates compared to native tissue pelvic floor repair procedures

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%[3]		Apical: 29.7%[5]	Apical: 38.5%[5]

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.
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3. 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.
4. Daniel Altman et al, "Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic-Organ Prolapse" *N Engl J Med* 2011;364:1826-36.
5. 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.

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04

Patient selection

Transvaginal procedure

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Physician POP repair goals

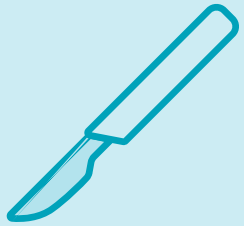
Function and structure

- Correct the prolapse[1]
- Put pelvic organs back in place[1]

Improve symptoms

- Reduce discomfort

Uterine preservation vs. hysterectomy



1. Pelvic organ prolapse – Diagnosis and treatment – Mayo Clinic

Patient selection: transvaginal repair

Medical history

- High-risk patients
- Previous surgeries
- Age

Patient desires

- Preference for vaginal surgery
- Aversion to mesh

Prolapse structure

- Location
- Stage of prolapse
- Presence of uterus

05

Patient snapshots

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1 Patient snapshot

Age 60

Sexually active

Physically active

Generally good health

Supportive family environment

Lives in the Midwest

Medical history

- Previous hysterectomy
- Diabetes
- High-risk

Prolapse details

- **Level 3** prolapse
- 2nd prolapse reoccurrence
- Weak native tissue
- Posterior prolapse

Desires

- Wants at least 10 years of durability
- Anti mesh
- Minimally invasive approach with shorter recovery time

2 Patient snapshot

Age 50

Inactive lifestyle
Poor health
Overweight
Lives in the South

Medical history

- Previous hysterectomy
- History of abdominal surgeries

Prolapse details

- **Level 3** prolapse
- Anterior and posterior prolapse
- 1st prolapse repair

Desires

- Wants durability
- Wants a better quality of life

3 Patient snapshot

Age 35

Sexually active
Physically active: triathlete
Good health
Child-bearing stage
Lives in the NE

Medical history

- No hysterectomy
- Diabetes

Prolapse details

- **Level 2-3** prolapse
- No prior repairs
- Weak native tissue
- Uterine descent into vaginal canal

Desires

- Wants a viable option for uterine preservation
- Anti mesh
- Wants to be able to stay active and lift young children

06

Procedural video

Axis™ Dermis graft for anterior and apical support

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07

Procedural video

Axis™ Dermis graft for posterior and apical support

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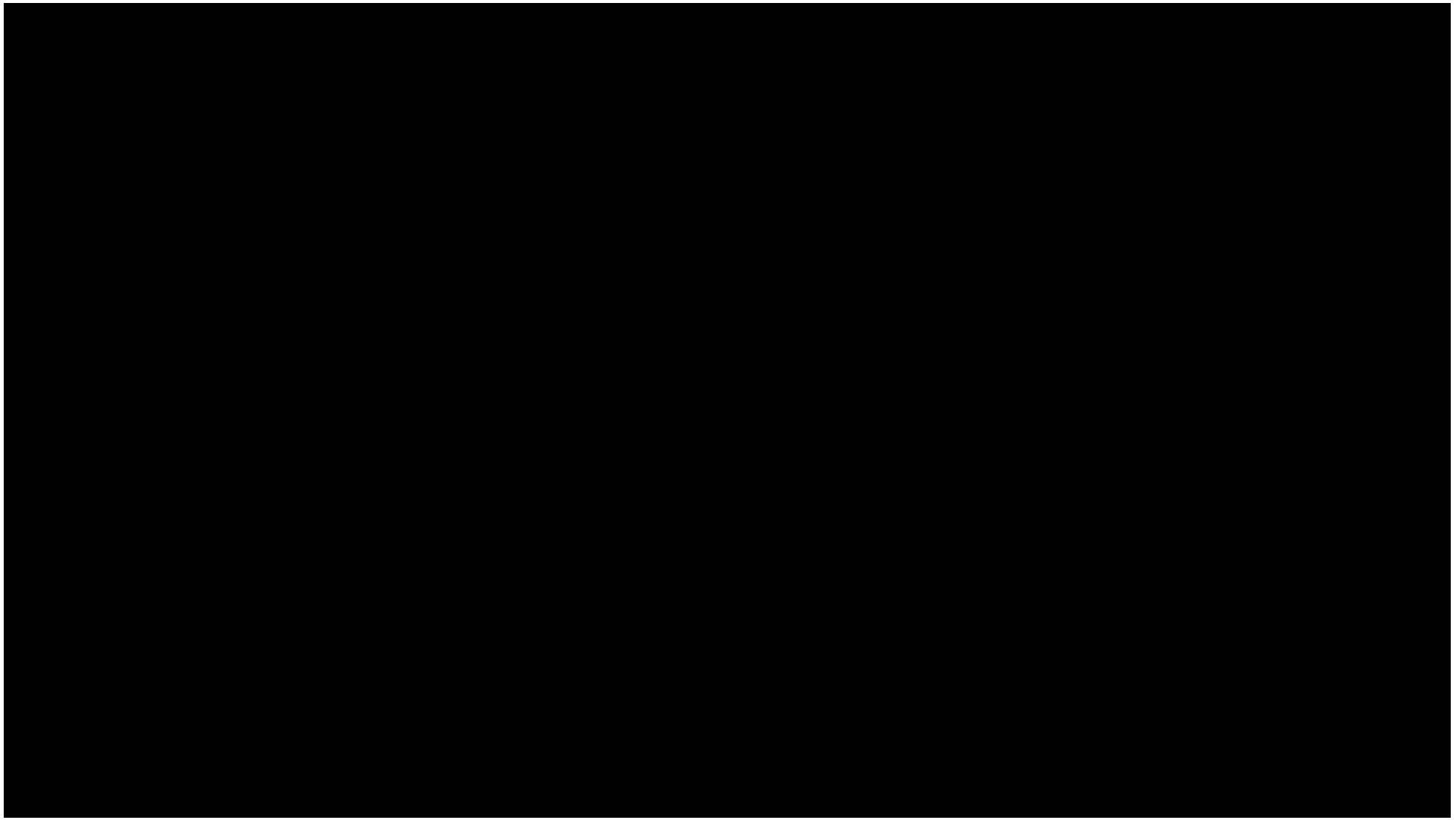

Questions_

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Axis™ Dermis and Suspend™ Fascia Lata 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

Mission

Making life easier for people with intimate healthcare needs

Values

Closeness... to better understand
Passion... to make a difference
Respect and responsibility... to guide us

Vision

Setting the global standard for listening and responding

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