



PELVIC ORGAN  
PROLAPSE  
&  
URINARY  
INCONTINENCE

**Allografts**  
A Patient Guide



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Let's talk about it.

Pelvic Organ Prolapse and  
Urinary incontinence

**Pelvic Organ Prolapse and Stress Urinary Incontinence affect millions<sup>1,2</sup> of women every year.**

As women, we face many challenges. Sometimes, we are so busy caring for others, we put our own medical needs aside, especially when they are embarrassing to discuss. Pelvic Organ Prolapse and Stress Urinary Incontinence affect millions<sup>1,2</sup> of women every year. These conditions can occur alone or in conjunction with one another.

Multiple options, including procedures for the repair, replacement, reconstruction, and augmentation of soft tissue using allografts, are available for both pelvic organ prolapse and incontinence. These procedures can restore your quality of life and bring you back to your natural state.<sup>3</sup>

**Your doctor will be happy to discuss options with you.** Together, you can determine the best options for your specific condition.

# Pelvic Organ Prolapse POP

## It's common and treatable<sup>4</sup>

Pelvic organ prolapse is a disorder in which one or more of the pelvic organs drop from their normal position. Pelvic organs that can drop include the bladder, uterus, rectum, vagina and the small intestine (bowel).<sup>4</sup>

Approximately **3.3 million women** in the U.S. suffer from pelvic organ prolapse<sup>2</sup>

**Half of all women** between ages 50 and 79 say they have symptoms<sup>4</sup>



**1 in 3 women** who have gone through childbirth, menopause, or a hysterectomy **experience POP<sup>6</sup>**

# 300,000

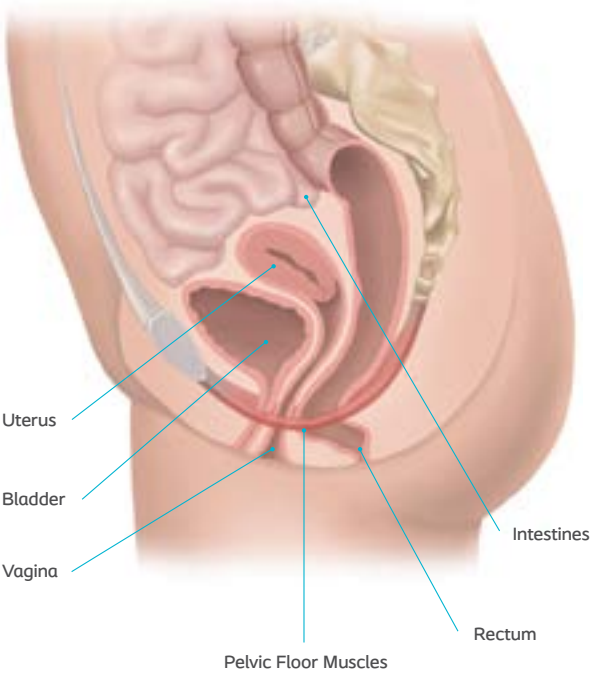
POP surgeries performed  
in the U.S. each year<sup>9</sup>

- Many also have stress urinary incontinence (SUI)<sup>5</sup>
- May be a progressive condition, gradually getting worse and causing more severe symptoms<sup>7</sup>
- May require surgery for relief of symptoms<sup>8</sup>



# The Pelvic Area and What Happens with Prolapse

The pelvic floor is a group of muscles that support the bladder and bowel and helps maintain continence. They are often described as being shaped like a hammock or sling. Normally these muscles and surrounding tissues keep the pelvic organs in place. Sometimes they can become too weak or stretched to continue to support your pelvic organs.<sup>2</sup>





## **Prolapse Causes<sup>5</sup>**

Certain risk factors increase your likelihood of experiencing pelvic organ prolapse:

- Vaginal childbirth
- Menopause
- Obesity
- Chronic cough
- Frequent constipation
- Pelvic organ tumors

## **Prolapse Symptoms<sup>8</sup>**

If you are experiencing prolapse, you may feel:

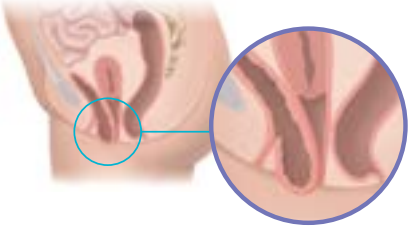
- Heaviness or pressure in the pelvic region
- Vaginal pain and/or pressure
- Pulling or aching feeling in the lower abdomen or pelvis
- Painful or uncomfortable sex
- Difficulty urinating or having a bowel movement



# Types of Pelvic Organ Prolapse<sup>8</sup>

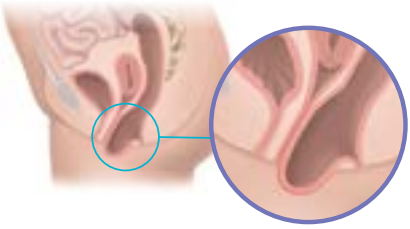
## Cystocele

Bulging of the bladder into the vagina



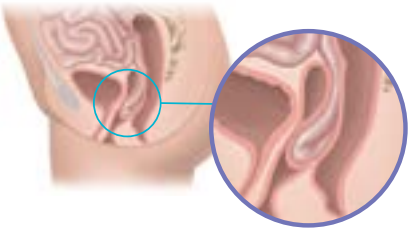
## Rectocele

Bulging of the rectum into the vaginal wall



## Enterocoele

Bulging of the intestine into the upper part of the vagina



## Vaginal Vault

The top of the vagina loses its support and drops into or out of the vagina



## Uterine

The uterus loses its support and drops into the vagina



## Treatment Options<sup>8</sup>

There are different treatment options available and your doctor will be able to help you find the best solution for you. Treatment will depend on the type and cause of your prolapse as well as your plans for the future, such as whether you are planning to become pregnant.

### Non-Surgical

Pelvic organ prolapse may be managed with vaginal pessaries, Kegel exercises, biofeedback and lifestyle changes. These options may involve long-term treatment, on-going maintenance, continued expenses and may not address the underlying condition.

### Surgical

Surgery reconstructs the pelvic floor with the goal of restoring the organs to their original position. Surgical repair can be done through the vagina or through the abdomen.

- **Anterior or posterior colporrhaphy** – A procedure in which the wall of the vagina is strengthened with sutures so that it once again supports the pelvic organs.
- **Allograft** – A procedure can be performed which places an allograft (human tissue graft) through an incision in the vagina intended to reinforce and support fascial structures in the pelvic floor in pelvic organ prolapse procedures.
- **Transabdominal mesh** – Sacrocolpopexy and sacrohysteropexy are done through the abdomen to repair vaginal vault prolapse and uterine prolapse with surgical mesh.

*For more information on allografts, see page 18*

# Urinary Incontinence UI

**It's common and treatable<sup>1</sup>**

Urinary incontinence (UI) is the involuntary loss of urine from the body. It can be frequent or occasional, a few dribbles to a total loss of control. It can be triggered by certain activities, or the result of certain risk factors. Most importantly, *it can be treated!*

Approximately **18 million women** in the U.S. suffer from urinary incontinence<sup>1</sup>

Bladder leakage occurs in **25% of women** over age 18<sup>1</sup>

**80%** of those affected **can be cured or improved<sup>1</sup>**

**2x**

more common  
in women than men<sup>10</sup>

**25%**

of women ages 40-64  
report daily leakage<sup>11</sup>

**65%**

of women ages 40-64  
report occasional  
leakage<sup>11</sup>

**~6.5 years**

the average time  
women will wait to  
talk to their doctor  
about their UI<sup>12</sup>



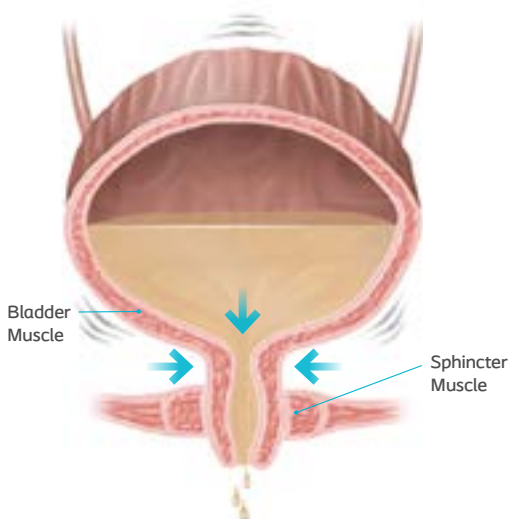
# The Urinary System and How It Works<sup>1</sup>



1. Bladder fills from the kidney.
2. Full bladder contracts and squeezes the urinary sphincter.
3. Empty bladder relaxes, stops contracting, and urinary sphincter closes.

## What goes wrong with UI?<sup>1</sup>

Urinary incontinence may be triggered by activities that cause extra pressure on the bladder like lifting, running, coughing, or even laughing.



It may also occur if the bladder muscles suddenly contract and the sphincter muscles aren't strong enough to prevent urine from leaking.

## Potential Causes of UI<sup>13</sup>

Risk of UI gradually increases each decade of life. However, age itself may not be the cause but rather other factors that are more likely present with increasing age:

- Obesity
- Childbirth
- Pelvic surgery

### Other Causes of UI

- Co-morbidities such as diabetes, urinary tract infections, depression and heart disease
- Socioeconomic status
- High impact-exercise
- Menopausal replacement therapy/medications such as estrogen
- Caffeine or alcohol consumption



# Types of Urinary Incontinence and Their Symptoms<sup>13</sup>

## **Stress**

Bladder leaks during physical exertion such as coughing, sneezing, laughing, running and/or jumping.

## **Urge/OAB**

Involuntary leaks resulting from urgency and/or a strong desire to urinate.

## **Mixed**

Combination of stress and urge incontinence resulting from weakened pelvic floor muscles and involuntary actions by bladder muscles.

## **Overflow**

Dribbling of urine due to the inability to completely empty the bladder.

## **Functional**

Mental or physical impairments limits ability to access and/or use the bathroom.





## Treatment Options:

### Urge Incontinence<sup>14,15</sup>

#### Non-Surgical

- Protective undergarments (pads)
- Medications
- Botox bladder injection

#### Surgical

- Implantable neuro-stimulation

### Stress Incontinence<sup>13</sup>

#### Non-Surgical

- Drinking less fluid
- Limiting caffeine
- Stopping smoking
- Losing weight
- Kegel exercises
- Physical therapy and Biofeedback
- Pessary
- Bulking agents

#### Surgical<sup>1</sup>

- **Sling** – A piece of strong material (mesh or allograft) is placed beneath the urethra as a supporting “hammock” with the goal of correcting the poor anatomic support of the urethra and may additionally provide a degree of compression to the urethra.

*For more information on allografts, see page 18*

# Surgical Option Using Allografts

In cases of more advanced prolapse or incontinence, minimally invasive surgery can provide treatment and support.

While synthetic transabdominal mesh grafts and suburethral slings are available, many women work with their doctors to pursue an allograft as an alternative to synthetic implants. Coloplast Axis<sup>®</sup> dermis and Suspend<sup>®</sup> fascia lata grafts are safe and reliable options for the repair, replacement, reconstruction, or augmentation of soft tissue in pelvic organ prolapse repair and stress urinary incontinence procedures.

Axis and Suspend grafts consist of donated human tissue placed through the unique and rigorous Tutoplast<sup>®</sup> process creating a biologically compatible “blank slate” when implanted in the body.



**Axis<sup>®</sup>** dermis graft



**Suspend<sup>®</sup>** fascia lata graft

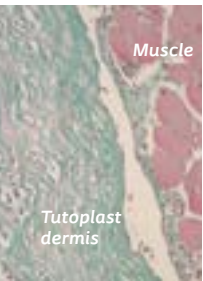
# Biocompatibility

The implanted graft is intended to provide strength as a temporary scaffold with a recognized cell structure, and works in conjunction with your body's natural regenerative healing process. Your body can incorporate its own tissue into the graft in an effort to help correct the prolapse or restore continence and improve quality of life.

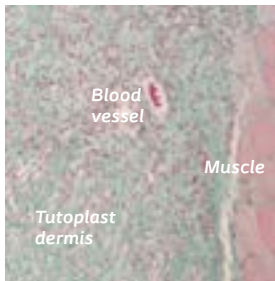
Tutoplast<sup>®</sup> processed implants have a long, proven history and have been successfully implanted in more than 5 million patients with zero confirmed incidence of implant-associated infection.<sup>16</sup>

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In an animal study\*, The Tutoplast<sup>®</sup>-processed grafts were biocompatible, functioned successfully as scaffolds, and were well tolerated and completely remodeled by the hosts.

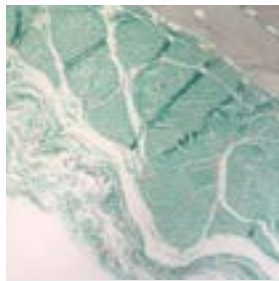


**DAY 1**



**1 WEEK**

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



**16 WEEKS**

post-implantation, nearly complete remodeling has occurred.

Masson's Trichrome Stain, 100x

\* Performance data from animal models may not be representative of performance in humans.

# Surgery

## Before Surgery

Discuss with your physician the correct preparation to take prior to your procedure. These surgeries are minimally invasive procedures. An overnight stay at the hospital may be required, but you can often go home the same day.

## During Surgery

The length of the procedure will vary depending on whether it is performed alone or in conjunction with another procedure. You will require regional or general anesthesia.

To correct pelvic organ prolapse, a procedure can be performed that includes placing the graft material, vaginally, through one small incision to restore the pelvic floor to its natural state (Figure A). To correct incontinence, a procedure can be performed that includes placing a small strip of graft material as a sling to support the urethra using 3 small incisions. (Figure B).



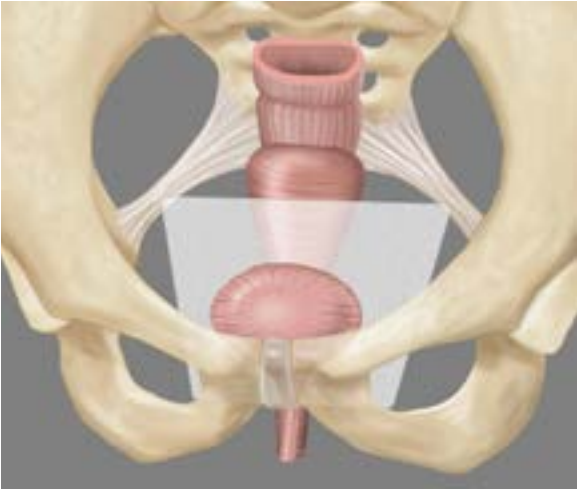


Figure A: Pelvic Organ Prolapse



Figure B: Incontinence

## Recovery

Although every patient's recovery process is different, there are general guidelines that apply to most pelvic floor or sling procedures.

- You may be required to take an antibiotic.
- You may be required to stay in the hospital overnight.
- You may experience some minor discomfort and fatigue during the first 24-48 hours after your surgery.
- You should be able to return to work and resume most of your regular activities within four to six weeks.
- During your recovery, it is important to avoid heavy lifting and sexual intercourse.

Your physician will provide you with more specific details about your individual recovery process, and he or she may have other recommendations based on your individual needs.

Should any problems occur after your surgery, contact your physician immediately. This is especially important if you have a high temperature, or if your surgical area becomes excessively swollen, painful, red or inflamed.



## Next Steps

Do not delay in seeking treatment, you do not have to live with these symptoms you feel every day. Contact your Gynecologist, Urologist or Urogynecologist today and ask questions and seek treatment for correcting pelvic organ prolapse and incontinence.

Visit [FemalePelvicSolutions.com](https://www.femalepelvicsolutions.com) to review treatment options and find a physician who specializes in treating pelvic organ prolapse or female urinary incontinence.

### 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.

Tutoplast is a registered trademark of Tutogen Medical GmbH.

**Feel confident again.  
You have options and you  
can take back control.**

#### References

1. <https://www.nafc.org/urinary.incontinence>. Downloaded 10.17.
2. <https://www.nichd.nih.gov/newsroom/resources/spotlight/051313-PFD>. Downloaded 07.20.
3. KE Whitmore, Axis® Allograft Dermis for female pelvic organ prolapse repair: a post market study, SUFU 2020 poster presentation
4. <https://www.health.harvard.edu/womens-health/pelvic-organ-prolapse-youre-not-alone>. Downloaded 07.20.
5. <https://www.webmd.com/women/guide/vaginal-prolapse#1>. Downloaded 7.20.
6. <https://www.bch.org> Pelvic Organ Prolapse: A Disease of Silence. Downloaded 07.20.
7. <https://health.usnews.com/health-care/for-better/articles/2018-02-09/understanding-female-pelvic-prolapse>. Downloaded 7.20.
8. <https://www.acog.org/patient-resources/faqs/gynecologic-problems/pelvic-support-problems>. Downloaded 7.20.
9. US Gynecological Market Data Report 2017 DRG Millenium Research.pdf.
10. <https://www.womenshealth.gov/a-z-topics/urinary-incontinence>. Downloaded 8.17.
11. <https://aeroflowurology.com/incontinence-middle-age-women-scorecard/>. Downloaded 07.20.
12. <https://www.health.com/condition/incontinence/12-myths-and-facts-about-incontinence#the-truth-about-bladdercontrol-0>August. Downloaded 7.20.
13. Abrams,P, Cardozo, L, Wagg, A, Wein, A. (Eds) Incontinence 6th Edition (2017). ICI-ICS. International Continence Society, Bristol UK, ISBN: 978-0956960733.
14. <https://medlineplus.gov/ency/patientinstructions/000146.htm>. Downloaded 8.18.
15. <https://medlineplus.gov/ency/article/001270.htm>. Downloaded 1.18.
16. RTI 50 Years of The Tutoplast Sterilization.

Clinical cases are unique and individual results may vary.



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