Patient Guide to Pelvic Floor Reconstruction

Xenform™ Soft Tissue Repair Matrix
What is the Xenform™ Matrix?

The Xenform Soft Tissue Repair matrix is a porous (sponge-like) material that enables a patients’ cells to populate the implant. The Xenform Soft tissue repair matrix is a biologically-derived graft material consisting of collagen which is intended to assist the body’s natural healing process of damaged or weakened tissues.

How is the Xenform Matrix made?

The Xenform Matrix is derived from the skins of fetal calves. The skins are cleaned and processed to remove cellular components. The biomaterial is then freeze dried, inspected, cut to size, packaged, and sterilized.
When an organ becomes displaced, or slips down in the body, it is referred to as a prolapse. You may have heard women refer to their “dropped bladder” or “fallen uterus.” This problem affects over 3 million women in the United States. You are not alone.
How is the Xenform™ Matrix intended to be used?

The Xenform Matrix is intended to be used to reinforce weakened, damaged or ruptured soft tissue membranes. It is available in a variety of sizes and can be trimmed and sutured by the surgeon during a surgical procedure to meet the patient’s individual needs.

Risks associated with implanting biologic surgical materials like the Xenform Matrix in pelvic organ prolapse procedures may include pain, bleeding, injury to blood vessels or nerves, scarring, inflammation and infection. Also there are risks of urinary incontinence or retention, recurrent prolapse, vaginal narrowing or shortening, fistula formation (abnormal connection between organs and/or vagina), injury to bladder, ureter, or bowel which may require additional surgery to repair; tissue contracture and implant exposure into the vagina or adjacent organs. In some cases implantation has been associated with pain during sexual intercourse (also called dyspareunia). The safety and effectiveness of the Xenform Soft Tissue Repair Matrix has not been studied in a randomized controlled clinical trial. You should consult your physician for a complete understanding of this information and to determine whether this product and procedure is right for you.
What should I expect after surgery?

Most likely, after the procedure you will stay in the hospital for at least one day. Before your discharge from the hospital, you may be given medications such as stool softeners and pain medications. You will be instructed on how to care for your incision area. At the discretion of your physician, most patients resume moderate activities within 6 to 8 weeks, with no strenuous activity for up to 12 weeks.

The FDA has issued a Safety Communication regarding serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Further information on the Safety Communication issued by the FDA can be found online: http://www.fda.gov/medical-devices/safety/alertsandnotices/ucm262435.htm
WHAT CAUSES
Pelvic Organ Prolapse?

Pelvic organ prolapse occurs when muscles and ligaments in the pelvic floor are stretched or become too weak to hold the organs in the correct position in the pelvis. Potential causes include pregnancy and childbirth, aging and menopause, obesity, pelvic tumors, chronic coughing, chronic constipation, heavy lifting, prior pelvic surgeries, neurological conditions, and/or genetic factors.

WHAT ARE some of the symptoms?

Symptoms of Pelvic Prolapse can include:

- Pressure or discomfort in the vaginal or pelvic area, often made worse with physical activities such as prolonged standing, jogging or bicycling.
- Diminished control in the bladder and/or the bowels.
- You may feel or see a bulge/lump in the vaginal area that increases in size with lifting or straining.
- Painful intercourse

You are Not Alone
Apex – The roof, or top of the vagina (also known as vault).

Biologically Derived Graft – Tissue derived from a human or animal source for use in tissue support.

Cystocele – Condition in which weakened pelvic support tissues cause the base of the bladder to drop from its usual position down into the vagina.

Enterocoele – Condition in which weakened pelvic support tissues cause the intestines to bulge downward into the vagina.

Laparoscopic Surgery – A minimally invasive technique in which procedures are performed through small incisions in the abdomen through which a camera and instruments are inserted.

Minimally Invasive Surgery – A procedure that is less invasive (smaller incisions) than open surgery used for the same purpose.

Open Surgery – A procedure which requires an incision through the skin large enough for the surgeon to gain access to the structures they are operating upon.

Pelvic Floor – The muscles and ligaments at the base of the pelvis that support the uterus, bladder, urethra, and rectum.

Pelvic Floor Reconstruction – The surgical repair of prolapse and incontinence.

Pessary – A removable plastic device that is placed in the vagina to hold prolapsed organs in place.

Prolapse – When one of the pelvic organs descends abnormally. Types of prolapse include: cystocele, enterocele, rectocele, uterine prolapse and vaginal vault prolapse.
Rectocele – Condition in which weakened pelvic support tissues cause the rectum to bulge into the vagina.

Robotic Surgery – Surgery facilitated by robotic arms controlled by a physician.

Stress Urinary Incontinence – The involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing, or lifting.

Transvaginal Surgery – Surgery that is approached through an incision in the vagina.

Uterine Prolapse – Condition in which weakened pelvic support tissues and/or ligaments cause the uterus to drop from its usual position out through the vaginal opening.

Vaginal Vault Prolapse – Condition in which weakened pelvic support tissues and/or ligaments cause the vaginal vault (apex) to drop towards or through the vaginal opening.

Vault – The internal end of the vagina (also known as the apex).
Rectocele – A rectocele forms when the back wall of the vagina loses its support, allowing the rectum to bulge into the vagina. This creates a pocket just above the anus where stool can trap. Larger rectoceles can bulge beyond the vaginal opening. Rectoceles may cause difficulty with bowel movements—including the need to strain more forcefully, a feeling of rectal fullness even after a bowel movement, increased fecal soiling and incontinence of stool or gas. Some patients have to push on the back of the vagina to have a bowel movement.

Cystocele – A cystocele forms when the front wall of the vagina loses its support and sags down towards the vaginal opening. This allows the bladder, which is located above the vagina, to drop. When a cystocele becomes advanced, the bulge may extend outside the vaginal opening. The visible tissue is the weakened vaginal wall; the bladder is right behind the vaginal lining but cannot be seen. The symptoms caused by cystoceles can include pressure, slowing of the urinary stream, overactive bladder, leaking urine during intercourse, painful intercourse, and difficulties of emptying the bladder.

Your physician will be able to assess which type of pelvic organ prolapse you may have and review potential treatment options.
Vaginal Vault Prolapse – Vaginal vault prolapse occurs when the support structures holding the upper part of the vagina are weakened. If the uterus has been removed and the upper part of the vagina is dropping down it is usually referred to as apical or vaginal vault prolapse. When the uterus is present this is called uterine prolapse. When the apical prolapse becomes advanced, the bulge may become visible outside of the vaginal opening. The symptoms may include: pressure, pain, bladder infections and difficulty urinating.

Enterocele – An enterocele typically forms when the intestine bulges through the top of the vagina after a hysterectomy. In some women the intestine may slide between the back of the vagina and the rectum as shown in this picture with a uterus. The symptoms can be vague, including a bearing down pressure in the pelvis and vagina, and perhaps a lower backache.
You don’t have to live like this. Vaginal wall prolapse can be treated in several ways, depending on the exact nature of the prolapse and its severity. The goal of these treatments is to restore prolapsed organs to a normal anatomical position and function.

You have Options
You and your physician may discuss:

**Non-Surgical Options:**

- Changes to your **diet** and fitness routine.
- Use of a **“Pessary”**, a rubber or plastic device, inserted vaginally and designed to relieve symptoms when in place.
- **Physical therapy** such as Kegel exercises designed to increase strength and maintain muscle tone in the pelvis.

**Surgical Options:**

- **Transvaginal graft** – Place a piece of **biologically derived** or **synthetic** material over the weakened connective tissue. These grafts may also be attached to a ligament or similar structure to provide support. This kind of graft is placed through an incision in the vagina.
- **Sacrocolpopexy / Sacrocolposuspension** with an open, laparoscopic or robotic approach. Involves abdominal incisions for the attachment of a graft between the vaginal apex and tailbone. May require hysterectomy dependent on technique.
- **Native tissue repair** – A type of repair where suture(s) are used to sew weakened vaginal wall tissue back together. Sutures may also be used to suspend the apex of the vagina to support structures like ligaments.

Many surgical procedures have been developed for the correction of pelvic prolapse. Please consult your physician to discuss the treatment options including the potential adverse reactions/complications and postoperative care.
There are several surgical materials which could be used to facilitate your repair. In a transvaginal biologically derived graft procedure, a thin graft of tissue may be used. This material will be used to reinforce the vaginal wall back into place and stabilize your pelvic support structures. Risks associated with implanting biologic mesh in pelvic organ prolapse procedures include those associated with anesthesia and other risks generally associated with any transvaginal graft procedure.

As with all surgical procedures, certain risk factors are known to impact patient outcomes including, but not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. These processes should be understood and should not be ignored when considering if you are an appropriate candidate.

What types of biologic or collagen tissue grafts are available?

**Allografts:** This tissue comes from human donors and is screened and processed for surgical use.

**Xenografts:** This tissue is derived from animal sources and is screened and processed for surgical use.

**Autologous Tissue:** This tissue is harvested from elsewhere on the patient’s own body.
INTENDED USE
The Xenform™ Soft Tissue Repair Matrix is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of colon, rectal, urethral, and vaginal prolapse; reconstruction of the pelvic floor; and procedures such as sacrocolposuspension and urethral sling.

CONTRAINDICATIONS
The Xenform Soft Tissue Repair Matrix is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients include those with:

- Pathology of the soft tissue into which the Xenform Soft Tissue Repair Matrix is to be placed.
- Known history of hypersensitivity to collagen or bovine products.
- Any pathology which would compromise implant placement.
- Any pathology that would limit blood supply and compromise healing.
- Patients diagnosed with autoimmune connective tissue disease.
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before using Xenform Soft Tissue Repair Matrix.

WARNINGS
Patients should avoid heavy lifting, exercise, and intercourse for a minimum of six (6) weeks after the procedure. Your physician should determine when it is suitable for you to return to each of these activities. You should consult your doctor if you experience heavy vaginal bleeding, burning with urination, a fever, or other such problems after surgery.

ADVERSE EVENTS
Potential adverse reactions that may be associated with surgically implanted materials include: Erosion/extrusion/exposure; Pain, discomfort, irritation; Infection/sepsis potentiation/abscess formation; Bleeding (bruising, hematoma, hemorrhage, post-operative bleeding); Dyspareunia; Organ perforation/fistula formation; Ureteral injury/obstruction; Urinary incontinence and/or fecal incontinence; Urinary retention; Foreign body reaction; Vaginal shortening or stenosis; Recurrent prolapse; Allergy, hypersensitivity or other immune reaction; Adhesion formation; Vessel/Nerve injury; Acute or chronic inflammation; Vaginal discharge; Dehiscence and/or necrosis; Constipation/defecatory dysfunction; Granulation tissue formation.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of pelvic organ prolapse. Refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events.