**RETROPUBIC SLING**

*Please read and sign the following consent form when you feel that you completely understand the surgical procedure that is to be performed and after you have asked all of your questions. If you have any further questions or concerns, please contact our office prior to your procedure so that we may clarify any pertinent issues.*

**Definition:** Retropubic Sling (SPARC) is a surgical procedure that uses a narrow strip of permanent mesh to correct stress urinary incontinence (SUI). This procedure is completed through the vagina and two small incisions on the lower abdomen just above the pubic symphysis; it creates stabilization and support for the urethra, the tube carrying urine from the bladder to the outside of the body. Once placed, the sling creates a V-shape that supports the urethra, therefore preventing urinary leakage during episodes of increased abdominal pressures, such as coughing, sneezing, or lifting.

**Procedure:** After sedation from general anesthesia is achieved, a catheter is placed in the bladder. The surgeon will begin by making a small incision in the vagina under the urethra and two small incisions on the lower abdominal wall just above the pubic symphysis. Next, a specially designed instrument (narrow mesh carrier) is passed through the abdominal incision, guided through the retropubic space (internal area behind the pubic symphysis and in front of the bladder), and into the vaginal incision. This step is then repeated on the other side of the pelvis. The surgeon will then perform a cystoscopy. During a cystoscopy, a small telescope is placed into the bladder to confirm that no injury to the bladder, ureters, or urethra has occurred during surgery. One end of the sling is then attached to each of the mesh carrier instruments. The instruments are then withdrawn which pulls the mesh back through the retropubic area and out through the abdominal incisions. The instruments are then removed completely, the mesh is adjusted under the urethra, and the excess mesh is trimmed off at the surface of the skin. The mesh is held in place by the friction between the mesh and the tissues and muscles in the retropubic space. Scar tissue later develops, which secures the mesh and prevents migration. Sometimes the surgeon will also place absorbable sutures in the mesh to help with tensioning. When placement is complete the mesh creates a V shape that supports the urethra. The procedure is then completed by closing the vaginal and abdominal incisions.

**Diagnosis:** The reason to have a retropubic bladder sling is *stress urinary incontinence* (SUI). SUI is the involuntary leakage of urine during episodes of increased intra-abdominal pressures, including exertion such as coughing, sneezing, laughing, exercising and/or intercourse. SUI occurs when the pelvic support tissues and muscles have been weakened by pregnancy/childbirth, trauma, radiation, prior surgery, muscle damage or hormonal changes, causing the bladder and the urethra to relax from their normal positions. The increased mobility and laxity allows the pressure in the bladder to exceed the pressure in the urethra, causing leakage to occur. Another reason to have a retropubic sling is *Intrinsic Sphincter Defect* (ISD). ISD is the weakening of the smooth muscle in the urethra; weakness of the urethral muscle/sphincter prevents the urethra from staying closed and thus allowing incontinence episodes. A retropubic bladder sling allows the surgeon to place more tension and support on the urethra in a patient with ISD; thus increasing the probability that the surgery will fix the incontinence.

**Expectations of Outcome:** This bladder sling procedure takes about 30 minutes to complete. When you awake from surgery you will have an IV and possibly a bladder catheter in place. Patients who have just the sling procedure performed will go home the same day as surgery. There will be lifting, exercise, and intercourse restrictions for 4-6 weeks. Normal voiding patterns may be delayed for several weeks due to swelling and operative manipulation to the bladder. This can happen in up to 30% of patients who have a retropubic sling. Therefore, some patients will be required to wear a foley catheter or utilize self catheters for a short time. Studies show 80-90% of women will report cure or improvement of incontinence following the surgery. However, behavioral changes need to be incorporated into your lifestyle to insure lasting results. Some of these are: fluid management, bladder training/retraining, pelvic floor exercises, maintaining appropriate body weight, and diet changes.

**Possible Complications of the Procedure:** All surgical procedures, regardless of complexity or time, can be associated with unforeseen problems. They may be immediate or even quite delayed in presentation. While we have discussed these and possibly
others in your consultation, we would like you to have a list of some specific complications so that you may ask questions if you are still concerned. Aside from anesthesia complications, a list of possible complications, would include, but are not limited to:

- **Organ Injury:** During any part of the procedure, any organ in the pelvis can be inadvertently injured. Damage to the bladder, urethra, ureter, vagina, or bowel is the most common type of surgical injury during a retropubic bladder sling procedure. Often the injury is minor and can be treated with relative ease; however if the injury is major or the repair is complicated, more extensive surgery may be necessary. This may prolong the hospital stay and recovery and might also necessitate additional surgical procedures in the future. If injury to the bladder occurs, it may be necessary to wear a Foley catheter for 2-4 weeks while the bladder heals.

- **Infections:** Although prophylactic antibiotics are given through your IV prior to surgery, post operative infections can still occur. The most common type of infection is a bladder infection (UTI). A UTI can cause burning with urination, increased urinary frequency, blood in the urine, pelvic or back pain, fever and or chills. The incision sites can also become infected. If a wound infection is present the patient may have a fever more than 100 degrees, increasing pain in the vagina or pelvic region, redness around the incisions, and/or foul odor vaginal discharge. While this typically resolves with antibiotics and local wound care, occasionally part or all of the incision may open and require revision. Pneumonia is an infection involving the lungs. Pneumonia may occur from lack of deep breathing after surgery due to pain from the incision sites. Early ambulation and deep breathing helps to reduce the risk of pneumonia. While rare, sepsis is another infection that can occur. Sepsis is when the infection enters the bloodstream and can make you very ill. Sepsis symptoms usually include: fever, chills, weakness, nausea, vomiting and or confusion. *If any of the above symptoms of infection occur, call our office.*

- **Vascular Injury:** While rate, inadvertent injury to a blood vessel can occur as instruments are introduced into the pelvis, during the placement and adjustment of the sling, or from electrical injury to the vessel wall. Most of these injuries are recognized and resolved at the time of surgery. Major vessel injury or delayed bleeding may require additional surgery, interventional radiologic procedures, prolonged hospital stay and recovery, readmission to the hospital, and blood transfusion.

- **Urinary Retention/Bladder Instability:** While there are benefits to the increased tension support that a retropubic sling provides, about 30% of patients will have voiding problems post operatively. If the weakness in your pelvic floor and SUI was present for a long time, you may have become accustomed to the abnormal changes in your anatomy. Therefore, after this bladder sling procedure it may take some time for your bladder and urethra to adjust to the sling and the urethra’s restored support. It is not uncommon to develop urinary frequency/urgency during this adjustment period and some patients may need medications to relax the bladder. It is also possible to have urinary retention (inability to empty bladder completely) following surgery. Patients who develop urinary retention may need to have a Foley catheter placed or use self catheterization for 1-2weeks while the bladder and urethra adjust from surgery. Urinary retention usually resolves with time and observation, but in rare instances a corrective procedure to loosen the sling may be necessary.

- **Mesh Erosion/Rejection:** It is possible for the sling material to erode through the tissues that surround it. If the mesh erodes into the vaginal tissue, a small portion of the sling can be removed with a minor procedure. In some cases of vaginal mesh erosion, the patient will stay continent because scar tissue from the surgery will continue to support the urethra. However, if the back of the sling erodes into the urethra, surgical removal is more involved and the urethra will need to be reconstructed. The sling can also migrate into the bladder. In this situation the sling will need to be surgically removed, the bladder will need to be repaired, and you will need a catheter for several weeks to allow healing of the bladder. While rare, it is also possible for your body to reject the synthetic mesh material. It is very important to follow the post-op lifting restrictions, attend your post-op appointments and abstain from sexual intercourse for at least 6 weeks following surgery. **There is wide variation in the reported incidence of mesh erosion for sling procedures. The most common range reported is 0.6 % to 7.4%**.

- **Blood Loss/Transfusion:** The pelvic region is vascular. Usually the blood loss in this procedure is minimal. In some cases blood loss can be significant enough to necessitate a blood transfusion. If a transfusion is necessary, there is a small risk of blood related infections such as Hepatitis or HIV.

- **Hematoma:** When a small blood vessel continues to bleed after the procedure is over, the area of collected blood is referred to as a hematoma. The body normally re-absorbs this collection over a short period of time but surgical drainage may be necessary, however, this is rare.
• Chronic Pain: With any procedure, a patient can develop chronic pain in an area that has undergone surgery. Typically, the pain disappears over time, although some feeling of numbness may persist.

• Treatment Failure: While a retropubic bladder sling has a good success rate, there is a chance that the procedure can fail to correct incontinence or can fail in the months or years to follow surgery. Stress urinary incontinence or total incontinence may persist or resume after a length of time following surgery. Patients who also suffer from urge incontinence may need medications to help decrease urinary leakage.

• Deep Vein Thrombosis (DVT)/Pulmonary Embolus (PE): In any operation (especially longer operations), you can develop a clot in a vein of your leg (DVT). Typically, this presents two to seven days post op as pain, swelling and tenderness to touch in the lower leg area. Although less likely, this blood clot can move through the veins and block off part of the lung (PE). This presents as shortness of breath and chest pain. If you notice any of these signs, call our office.

• Lower Extremity Weakness/Numbness: While this is rare, it is possible that due to the positioning of your legs in the lithotomy position (legs in the air/stirrup) for a long period of time or direct injury to nerves by surgical instruments, you may develop weakness or numbness in your legs. It is usually self-limited, with a return to baseline.

• Permanent Injury/Death: Permanent injuries from surgery are rare but do occur. Permanent injuries may involve removal of organs not planned during the original surgery, pain that does not resolve with time, or diminished ability to enjoy life. Death is extremely rare from Gynecologic surgery but does occur. The most common reasons are massive blood loss, overwhelming sepsis, heart attack, DVT/Pulmonary embolus, stroke, and anesthesia complications.

Additional Procedures/Consultations: If there are unanticipated findings, difficulty during the surgery, or a situation where your doctor does not believe that he has the expertise to accomplish all of your case then an intra-operative consultation may be necessary. Intra-operative consultation is when another physician or surgeon is asked to give recommendations, assist or take over a surgical case. This occurs at your doctor’s discretion for your safety and without regard to whether the other physician is on your insurance panel. By signing below you give consent to intra-operative consultations if necessary.

Photographs/Recordings: Still photographs and digital recordings of your surgery may occur for documentation of intra-operative findings or for educational purposes.

Consent: I, Dr. __________________________, have counseled __________________________________________ regarding her planned surgery. In my professional opinion I believe that the surgery is reasonable and most likely will result in a beneficial outcome. It is my belief that the patient has considered her options and fully weighed the risks of surgery.

Signed __________________________________________ Date __________________ Time ______________

I, __________________________, believe that the surgical procedure listed above is the best option for me. My situation is not an emergency and I understand that I have other options, including not having surgery. I understand that complications, bad outcomes, and unanticipated events will occur occasionally during surgery and recovery. I understand that my doctor and his surgical team are not perfect and at no point have I been guaranteed any outcomes or results. I have been given the opportunity to ask all my questions and I believe that I have all the information necessary to make a reasonable decision. Therefore, I elect to give my consent and proceed with the above surgery, as witnessed by my signature below.

Patient Signature __________________________________________________________ Date ______________

Witness Signature __________________________________________________________ Date ______________