SINGLE INCISION 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: Single Incision Sling (also known as the Mini-Sling) is a surgical procedure that uses a narrow strip of permanent mesh to correct stress urinary incontinence (SUI). This procedure is completed through a single vaginal incision and creates stabilization and support for the urethra, the tube carrying urine from the bladder to the outside of the body. Once placed, the sling lies under the urethra and acts as a hammock to provide the needed support to prevent urinary leakage during episodes of increased abdominal pressures, such as coughing, sneezing, or lifting.

Procedure: After appropriate anesthesia is achieved the bladder will be emptied with a catheter. The surgeon will begin by making a small incision in the vagina under the urethra. Through the vaginal incision the surgeon will locate the obturator internus muscle, which is positioned along the pelvic sidewall. The tip of the self-fixating mini mesh is then connected to a specially designed introducing instrument (narrow mesh carrier). The instrument and mesh are inserted through the vagina and the tip of the mesh is placed into the obturator internus muscle. The instrument is then removed and the mesh stays anchored to the muscle. This step is repeated on the other side of the pelvis with the remaining part of the mesh. When placement is complete the mesh lies under the urethra like a hammock and returns the urethra to its proper position. Scar tissue later develops to help secure the mesh and prevent migration. Lastly the surgeon may perform a cystoscopy. During a cystoscopy, a small telescope is placed into the bladder to potentially identify injuries to the bladder, ureters, or urethra that may have occurred during surgery. The procedure is then completed by closing the vaginal incision with absorbable sutures.

Diagnosis: The reason to have a single incision 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.

Expectations of Outcome: This bladder sling procedure takes about 30 minutes to complete. When you awake from surgery you will have an IV. Typically the catheter will have been removed while you were asleep. 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. 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 significant 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 single incision bladder sling. 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 site 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, and/or foul odorous 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 rare, 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:** 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 a bladder sling procedure it may take some time for your bladder and urethra to adjust to the sling and the urethra’s restored position. 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 1-2 weeks 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.

- **Sling/Mesh Erosion:** While the Mini Bladder Sling has the least amount of mesh used in bladder sling procedures, 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 repaired. 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. 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 the single incision bladder sling has a high success rate, there is a chance that the procedure can fail or that in the months to years following the procedure Incontinence may recur. *The single incision bladder sling has a slightly higher risk of recurrent stress urinary incontinence (SUI) due to the fact that less mesh is placed during surgery. However, this is balanced by a lower risk of complications as compared to other slings.* SUI 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________________