
Informed Consent Form

Advance XP Male Sling

Please carefully read this document, initial each page and sign the last page.
Please bring a signed copy along on the day of your procedure

Patient Name: _____

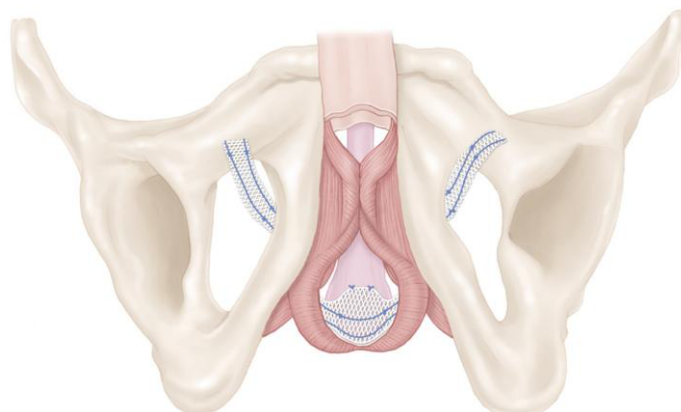
ID Number: _____

Doctor: Dr F van Wijk

Date: _____

What is the Advance XP Male Sling Procedure?

The Advance XP Male Sling is a minimally invasive surgery designed to treat male stress urinary incontinence (SUI). The procedure involves placing a sub-urethral sling inside the body to support the urethra and restore bladder control. The Sling is designed to stop leakage by supporting the sphincter muscle. The sling is a strip of soft mesh placed inside the body. The Sling moves the sphincter back to its natural position to help restore bladder control. The Sling requires no action by the patient to function.



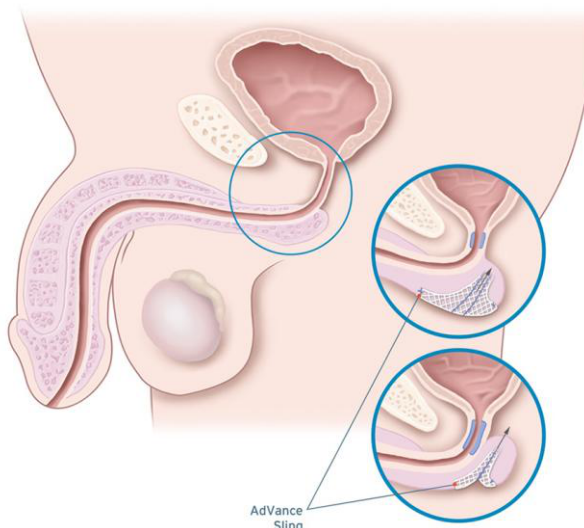
Why is it done?

Your urinary sphincter (SFINK-ter) is a muscle that controls the flow of urine out of your bladder. When your urinary sphincter is contracted (closed), it blocks the opening of your bladder. This stops urine from leaking out. Normally, your urinary sphincter stays closed until you choose to relax (open) it to urinate. When you relax your urinary sphincter, urine leaves your bladder and flows out of your body through your urethra. Your urethra is the tube that carries urine from your bladder out of your body. Some people have trouble controlling their urinary sphincter. This causes them to leak urine. This can happen after surgery to remove the prostate or radiation therapy to the prostate.

How is it done?

- Patients undergo a thorough evaluation to confirm the appropriateness of the Advance XP Male Sling for their condition. Discussion includes medical history, current medications and any further tests or scans required
- Patients may be required to avoid certain medications prior to procedure (ie blood thinners)
- Done under general anaesthetic
- A small incision is made to access the urethra and the urinary sphincter.

- The sling is placed under the urethra and tensioned to reposition the urethra and optimize the sphincter's function. Most patients are continent immediately following the procedure and can resume normal, non-strenuous activities within a few days.
- The surgical site is cleaned and a catheter is placed temporarily.
- Patients are monitored in the recovery room post operatively and pain management is provided as needed.
- Most patients stay in the hospital for 1- 2 days for observation
- Follow up consultations are scheduled to check on the healing process and the function of the AdVance XP Male Sling



Possible Benefits

- Effective leakage prevention.
 - Placed entirely inside the body, it is undetectable to others
 - High success achieved in patients with mild to moderate SUI
 - Most patients are continent immediately following the procedure
 - It operates on its own to restore continence
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Risks and Possible Problems

All surgery has risks. For this procedure, these can include:

- Risk of infection. As with any surgery, there is a risk of infection at the surgical site. This can occur during or after the procedure and may require treatment with antibiotics or additional procedures.
 - Device Failure
 - Urinary retention
 - Bruising, swelling, temporary discomfort
 - Rarely: bleeding, scar tissue, anaesthetic complications.
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After the Operation

- Some swelling and bruising is normal.
- Pain relief medications to manage post operative pain and discomfort. It is essential to communicate with your healthcare providers about any discomfort.
- Most patients stay in the hospital 1-2 days for observation
- Avoid strenuous activities, heavy lifting and vigorous exercise for at least 4-6 weeks post surgery
- Walking is encouraged to promote circulation but should be done at a gentle pace.

- Keep the surgical site clean and dry. Follow specific instructions given by your healthcare provider. Look for signs of infection such as increased redness, swelling or discharge and report any concerns to your healthcare provider.

My Consent

I have read or had this form read to me. I understand:

- What the Advance XP Male Sling procedure is.
- The possible benefits, risks, and alternatives.
- That the outcome cannot be guaranteed.
- I have had the opportunity to ask questions and discuss any concerns regarding the procedure, and I feel prepared to proceed.
- I acknowledge that a representative from Boston Scientific will be present during the procedure for technical support

Patient's Signature: _____ Date: _____

Witness's Signature: _____ Date: _____

Doctor's Signature: _____ Date: _____