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Dr. FJ van Wijk
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Informed Consent Form

AMS 800 Artificial Urinary Sphincter

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 AMS 800 Procedure?

The AMS800 is a surgical procedure designed to treat urinary incontinence by implanting an artificial urinary sphincter. This device helps control urination, providing patients with improved quality of life.

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Why is it done?

The primary purpose of the AMS 800 procedure is to treat urinary incontinence. Incontinence is defined as any involuntary leakage of urine. Urinary incontinence is usually caused by a damaged sphincter or an improperly functioning bladder. The sphincter is the circular muscle that controls urine flow out of the bladder. When damaged, this muscle cannot squeeze and close off the urethra, the tube that carries urine from the bladder to the outside of the body. The result is urine leakage. This can significantly impact quality of life. Other causes of SUI may include surgical treatment for enlarged prostate (BPH); TURP — Transurethral resection of the prostate; Conditions such as diabetes, multiple sclerosis, Parkinson's disease, Spina Bifida, or stroke; Pelvic trauma or surgery

The AMS 800 system achieves continence by implanting an artificial urinary sphincter that helps control the flow of urine, allowing the patient to regain better bladder control and improve their overall urinary function

How is it done?

- Patients undergo a thorough evaluation to confirm the appropriateness of the AMS 800 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
- Two incisions are made, one in the lower abdomen (balloon placement) and one in the scrotum (pump and cuff placement)
- The cuff is positioned around the urethra. It is designed to compress the urethra to prevent urine leakage. The cuff is connected to the pressure regulating balloon.
- The pump is inserted into the scrotum. This is a small device that the patient will use to control the cuff. The pump is connected to the cuff, allowing inflation and deflation of the cuff.

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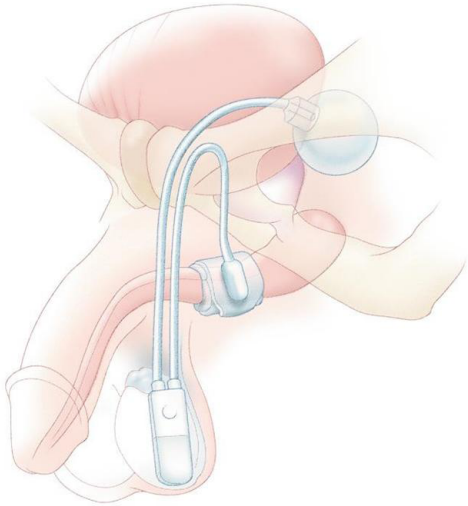
- The balloon is implanted in the abdomen and connected to the cuff and pump. This balloon maintains the pressure necessary for the cuff to function correctly
- After all components are in place and have been tested, the incisions are carefully closed with sutures.
- The surgical site is cleaned and 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 AMS 800
- The device is typically activated 4-6 weeks after surgery to allow healing.



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Possible Benefits

- Effective leakage prevention. The AMS 800 artificial urinary sphincter provides reliable control over urination, significantly reducing or eliminating involuntary leakage
- Restoration of normal urinary function. Many patients regain the ability to manage their urinary function effectively, allowing for more normal daily activities.
- Enhanced quality of life. Improved urinary control allows individuals to engage in social activities and relationships without fear or embarrassment and often report a boost in self esteem and confidence, as they no longer have to worry about accidents
- Minimal impact on daily activities. The AMS 800 is designed for patient control, individuals can activate the device easily when they need to urinate. The device is unobtrusive, allowing for normal clothing and activities without drawing attention.
- Long term solution. The device can function effectively for several years, providing a long term solution for urinary incontinence.

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 malfunction
- Erosion. In some cases, the cuff can erode into surrounding tissue, necessitating further surgical intervention
- 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.
- Final results are seen after activation 4-6 weeks post operative.

Activation of the AMS 800 Device

- The cuff will remain deflated for 4-6 weeks to allow the surgical site to heal properly
- Your surgeon will activate the device in his consulting rooms 4-6 weeks post surgery
- Your surgeon will teach you how to use the pump to inflate and deflate the cuff
- If you require future hospitalisation or any procedures where a catheter will be placed, ensure to inform your healthcare providers that you have an AMS 800 Artificial Urinary Sphincter which will need to be deactivated to allow catheter placement, as failing to do so will cause damage to the cuff

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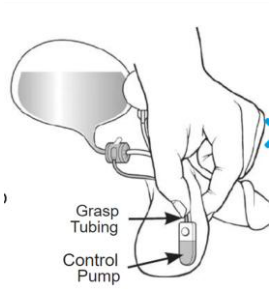
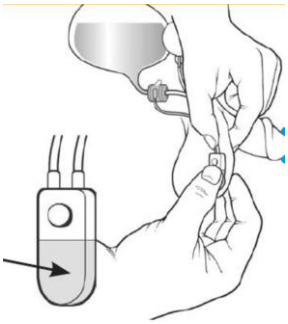
Daily use:



- While the cuff is closed, urine stays inside the bladder.
- To urinate, open the cuff as follows:
- Feel for the control pump in your scrotum.
- Stabilize the control pump in the proper place by grasping the tubing above the control pump



- Use the other hand to squeeze and release the lower, softer part of the pump several times.
- Repeat this step until the pump is flat.
- Once flat, this indicates that the cuff is deflated.
- The urethra is now open and you can urinate
- The cuff will automatically refill in +/- 90sec

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My Consent

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

- What the AMS 800 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: _____

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