

## Informed Consent Form

### AMS 700 Inflatable Penile Prosthesis

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 700 Procedure?

The AMS 700 is an inflatable penile prosthesis designed to treat chronic erectile dysfunction (ED) which is a common condition that can significantly impact a patient's quality of life in men who have not responded to other treatments. This device allows for the restoration of erectile function, enabling the patient to achieve an erection suitable for sexual intercourse



## Why is it done?

Erectile dysfunction is the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. This condition can be caused by physical, psychological, or a combination of both factors

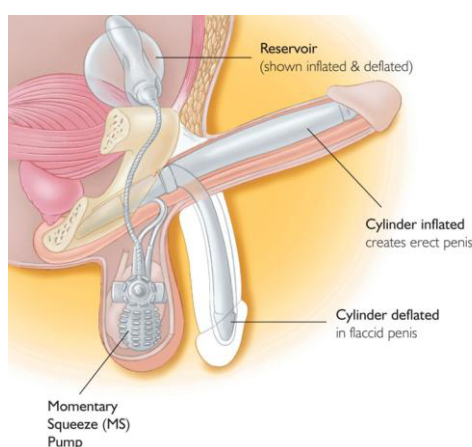
The AMS 700 may be recommended for you if:

- You have been diagnosed with severe erectile dysfunction
- Other treatments have been ineffective or unsuitable for you
- You have conditions such as but not limited to diabetes, vascular disease, prostate cancer treatment, pelvic surgery history, Peyronie's disease, anxiety, depression and or the side effects of certain medications that contribute to ED

## How is it done?

- Patients undergo a thorough evaluation to confirm the appropriateness of the AMS 700 for their condition. Discussion includes medical history, current & past medications and or treatments 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
- An incision is made that will allow access to place all 3 components of the AMS 700 which includes a reservoir, a pump & the cylinders. The reservoir is implanted in the pelvic area and the cylinders are inserted side by side in the shaft of the penis, with the pump located in the scrotum. The pump is used to transfer fluid from the reservoir to the cylinders. This process is controlled by squeezing and releasing the pump bulb. The pump bulb is the rounded part at the bottom of the pump. The deflation button is above the bulb on the firm, rectangular shape of the pump (deflation block).
- 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 700
- It is advised to not have sexual intercourse for 6 weeks post operatively to allow healing and to prevent erosion



## Possible Benefits

- **Effective Treatment for ED.** The AMS 700 allows men to achieve and maintain an erection suitable for sexual intercourse, addressing the core issue of ED
- **Psychological benefits.** Restoring erectile function can significantly boost self esteem and reduce anxiety associated with sexual performance
- **Control and convenience.** The inflatable system allows for an erection to be achieved on demand, providing flexibility and spontaneity in sexual activities
- **Discreet use.** The device can be inflated or deflated discreetly, allowing for sexual activity without the need for advance preparation
- **Long lasting solution.** The AMS 700 is designed to last for many years, often resulting in a permanent solution for ED
- **Realistic Experience.** The inflatable design provides a more natural feel which can enhance comfort and satisfaction

- **Aesthetic Considerations.** The prosthesis is designed to mimic the natural rigidity of an erection, contributing to a more satisfying experience for both partners
- **Preservation of Sensation.** Most patients retain normal penile sensation and can still achieve orgasm, which is an important consideration for sexual health
- **Established Technology.** The AMS700 is a well established device with a long history of successful use backed by clinical research and data

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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 malfunction**
- **Erosion.** In some cases, the implant can erode into surrounding tissue, necessitating further surgical intervention
- **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.

- Your doctor will provide guidance on positioning your penis and the type of undergarment to use during your healing period.
  - After voiding you should carefully reposition your penis per your doctor's guidance.
  - You will be able to return to work and everyday activities at the discretion or direction of your doctor. After three to six weeks your doctor may instruct you to cycle the device for the first time.
  - Your doctor will discuss when you will be able to use your device.
  - During the recovery time and after, take care to avoid trauma to the pelvic or abdominal area.
  - Always keep in mind that you have had a surgical implant and choose your activities wisely.
  - Trauma may damage the implant or surrounding tissues.
  - Use of injection therapy in the pelvic or abdominal area, or additional treatment in that area, may also damage the implant.
  - Always talk to your doctor about medical procedures you may undergo in the future.
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### **Symptoms indicating that you should contact your Healthcare Provider:**

- As with any medical procedure, there is the possibility that complications may develop after the procedure.
- Unusual or prolonged pain
- Redness or rash near the incision or scrotum
- Swelling near the incision, scrotum or penis
- Pus coming from the incision or head of the penis
- Hives
- Fever
- Any problems with urination

## Frequently asked questions:

Below are answers to some of the more frequently asked questions about penile prostheses. Talk to your doctor about any additional questions you may have.

- **Will I have to take any precautions before undergoing future medical procedures?**  
It is important to tell your healthcare provider that you have a penile implant to prevent damage or injury.
- **Can I have magnetic resonance imaging (MRI)?**  
The device is MR Conditional, meaning that you can be MRI scanned safely within certain limits. Talk to your doctor before undergoing MRI scanning.
- **Can I go through security screening?**  
When you walk through security screening, the metal in your implant may be detectable. Since most inflatable penile implants have minimal metal parts, they should not set off a metal detector; however, if detected, tell the Security Officer that you have an implanted medical device. It is recommended that individuals with an implanted medical device carry a Patient Identification Card that identifies them as a medical device patient. If you do not have a Patient Identification Card or if you have questions about your device as it relates to MRI or security screening, please ask your doctor.

### **What do I do if the cylinders are difficult to inflate, or if they won't inflate?**

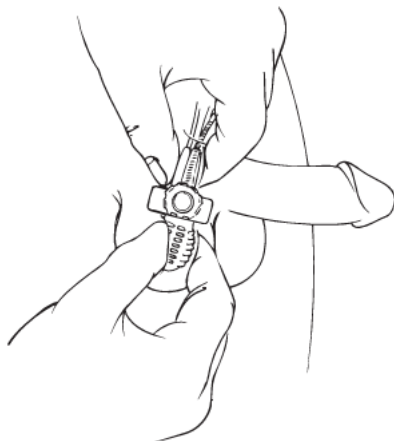
Reset the pump by following these steps:

1. Squeeze the deflation button to refill the pump bulb.
2. Reactivate the pump with a HARD, QUICK squeeze of the pump bulb.
3. Inflate the device normally. If this doesn't resolve the problem ;
  - \* Squeeze the sides of the deflation block to refill the pump bulb.
  - \* Squeeze the deflation button for 2-4 seconds to reset the lock-out mechanism.
  - \* Reactivate the pump with a HARD, QUICK squeeze of the pump bulb.
  - \* Inflate the device normally. DO NOT squeeze the deflation button and pump bulb at the same time. DO NOT squeeze the ends of the deflation block while squeezing the pump bulb at the same time.

## How to use my device:

### Inflating the implant

- When you squeeze and release the pump bulb, the fluid moves from the reservoir, through the pump and into the cylinders.
- When the cylinders fill with fluid, the penis becomes erect.
- Feel for the pump in your scrotum.
- Grasp the tubing above the deflation block with one hand, to hold the pump in place.
- Initially, squeeze the pump bulb quickly and firmly, and then release it to activate the pump
- The remaining pump bulb squeezes can be slower.
- Releasing allows the inflation bulb to refill with fluid.
- Continue to alternate squeezing and releasing until the cylinders fill with fluid and become erect.
- Full erection may take multiple squeezes of the pump bulb. Be sure to talk to your doctor for the optimal number of squeezes.
- **Note: Do not squeeze the deflation button while squeezing the pump bulb.**



### Deflating the implant

- When you squeeze the deflation button for about four seconds the fluid begins to leave the cylinders and return to the reservoir.
- After about four seconds, release the deflation button and the cylinders will return to their deflated position.
- The penis becomes soft (flaccid).
- Feel for the pump in your scrotum.
- Grasp the tubing above the deflation block with one hand, to hold the pump in place.
- With your other hand, locate the raised deflation button on the deflation block.
- To effectively squeeze the deflation button, you must place a thumb and forefinger on opposite sides of the deflation block
- Squeeze the deflation button for about four seconds and then release.
- The cylinders will continue to deflate and your penis will become soft (flaccid).
- **Note: Do not squeeze the deflation button while squeezing the pump bulb. 6**
- After the cylinders have deflated, you may squeeze your penis to make it more flaccid.



The AMS 700 can significantly improve the quality of life for men with Erectile dysfunction.

It is essential for patients to be well informed about the procedure, and the emotional aspects of adjusting to a penile prosthesis.

If you have any concerns, please discuss these with your Healthcare Provider

We understand there may be a learning curve as you get to know your new device. Your best resource is your doctor, they are most familiar with your medical situation and can work with you to make sure you get the best possible results from the penile implant.

Boston Scientific offers additional videos and information about your device

Visit the Boston Scientific website  
([www.bostonscientific.com/en-US/patients/about-your-device/penile-implants/resources.html](http://www.bostonscientific.com/en-US/patients/about-your-device/penile-implants/resources.html))

## 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: \_\_\_\_\_