

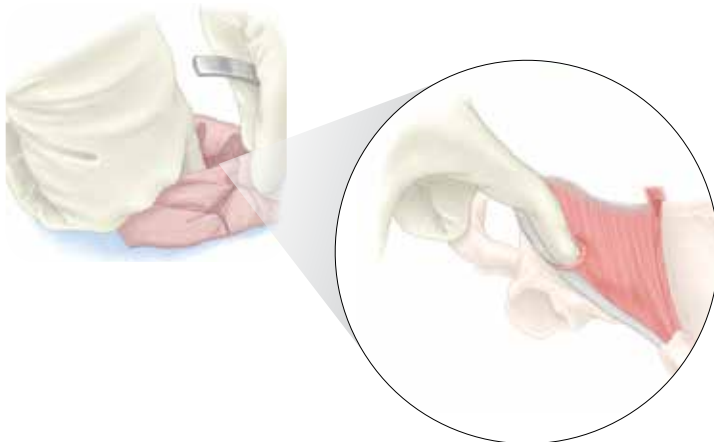


An approach for reservoir placement of the AMS 700™ Implant.
For full instructions, please consult the Operating Manual.



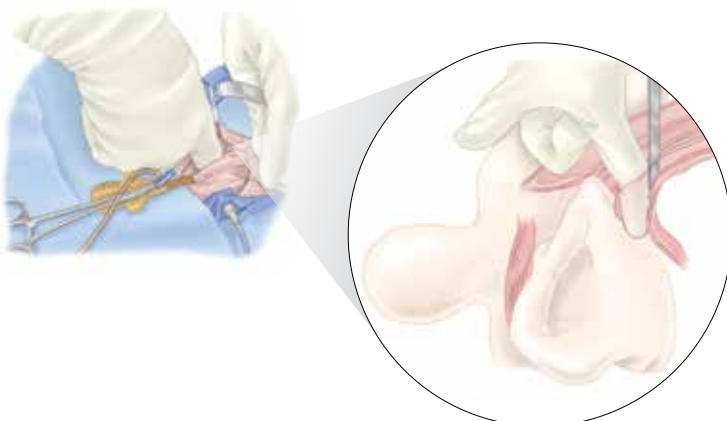
1. POSITION and prepare the patient

- **Understand past medical history**
 - Avoid the side of prior surgery if possible
 - Recline the patient
 - Trendelenburg position takes advantage of gravity and causes the bladder and bowels to “fall away” from the inguinal ring, and moves the abdomen contents and fat cephalad.
- **Empty the bladder.¹**
 - Maintaining the goal of keeping the viscera and vessels away from the inguinal ring, completely empty the bladder, via a Foley catheter.



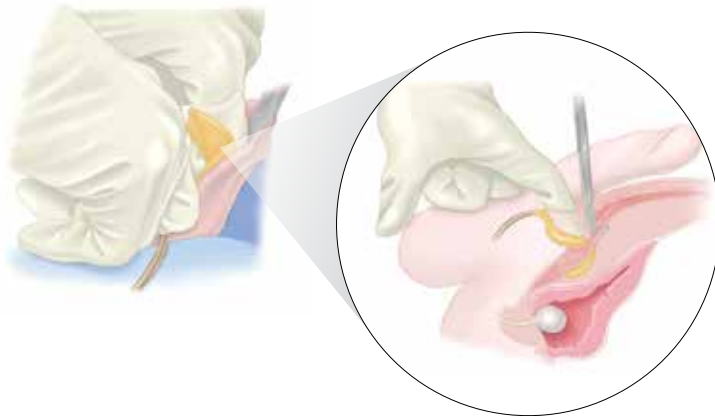
2. RETRACT cephalically once satisfied with the finger's position just over the pubic bone

1. **Keep the palm down** as turning the palm up forces the surgeon's hand lateral towards more dangerous structures, e.g. the external iliac vein.
2. **Retrace the finger sweep window** so there is no tissue between finger and the periosteum of the pubic bone directly next to the penis (typically at the level of the corporotomy).
3. Moving the index finger towards the ipsilateral shoulder stopping just superior to the pubic bone, then slightly laterally and medially, **find a recess in the fascia.**
4. **“Hook the ring”** with a pediatric Deaver retractor, nasal speculum, or surgical instrument of choice.
5. **Position the retractor** to allow comfortable entry into the retroperitoneal space.
 - There are two “fascial” type layers.²
 - The first is the transversalis fascia and this is the only fascia that should be entered.
 - The second is now the peritoneum and entry through this layer is into the peritoneal cavity.



3. ENTER the retroperitoneal space and replace the retractor through the defect created in the fascia

- Enter the retroperitoneal space just above the pubic bone and pierce with an index finger or a tool only an inch or less through the transversalis fascia. Make sure the bladder is empty as stated above.



4. SWAP fingers

- Place the index finger of the non-dominant hand in the space created for the reservoir and make sure there is adequate volume available.
- Use the retractor in the space to pull up cephalically, ensuring access to the space.
- The dominant index finger controlling the prepped reservoir is then closely pushed into the desired space, replacing the non-dominant finger.
 - Typically, the pathway is a curve located behind the pubic bone and not a straight line aimed at the lumbar spine.
- Using alternating index fingers push the reservoir into the space until the entire reservoir is placed into the created space.
- During filling of the reservoir, if it is difficult to inject the normal saline, reevaluate the space created and the placement of the reservoir.
- Leave an index finger on the reservoir for fluid filling; insuring good placement and no herniation of the reservoir.



5. SHORTEN the tubing

- After filling the reservoir, pull gently on the kink resistant tubing to assess for reservoir herniation.
- If the tube retracts during filling, then this usually indicates the placement is accurate.
- Consider leaving the hub of the reservoir superficial to help with removal of the reservoir, if indicated, during future revision surgery.

References:

1. Henry G, Hsiao W, Karpman E, Bella AJ, Carrion R, Jones L, Christine B, Eisenhart E, Cleves MA, Kramer A. <http://www.ncbi.nlm.nih.gov/pubmed/24274160> A Guide for Inflatable Penile Prosthesis Reservoir Placement: Pertinent Anatomical Measurements of the Retropubic Space. J Sex Med. 2014;11(1):273-8
2. Morey AF, Cefalu CA, Hudak SJ. High Submuscular Placement of Urologic Prosthetic Balloons and Reservoirs via Transscrotal Approach. J Sex Med 2013;10:603-10

This document is a summary of the procedural steps associated with implantation of the AMS 700™ Penile Prosthesis and is not intended to replace the instructions included with the products labeling.

The AMS 700™ Series Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700™ with Inhibizone™ Antibiotic Treatment have a known sensitivity or allergy to rifampin, minocycline, or other tetracyclines). Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), urogenital edema, urogenital ecchymosis, urogenital erythema, reservoir encapsulation, patient dissatisfaction, auto-inflation, mechanical malfunction, impaired urination, and infection. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

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