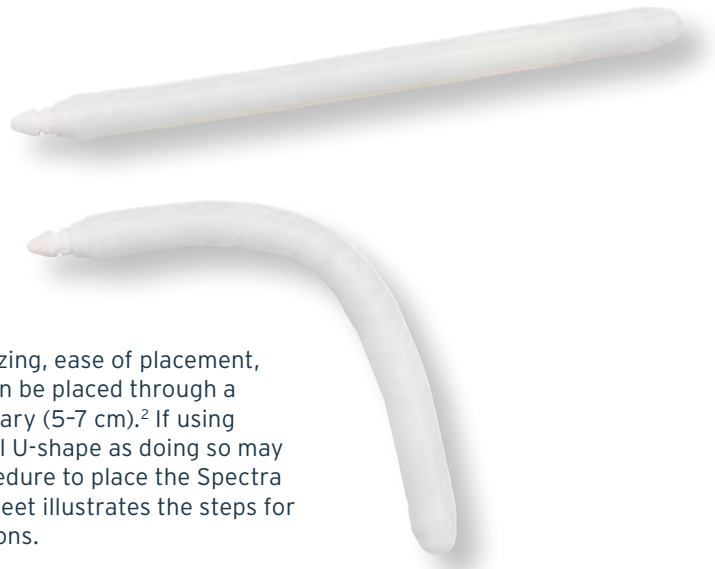


Spectra™

Concealable Penile Prosthesis



Subcoronal approach

The Spectra Concealable Penile Prosthesis offers simplified sizing, ease of placement, excellent concealment and rigidity.¹ The Spectra Prosthesis can be placed through a penoscrotal incision, yet a longer corporotomy may be necessary (5-7 cm).² If using this approach, do not over bend cylinders beyond their natural U-shape as doing so may damage the prosthesis and shorten its product life.² The procedure to place the Spectra Prosthesis is straightforward, via subcoronal incisions. This sheet illustrates the steps for placement of the Spectra Prosthesis via two subcoronal incisions.

Step 1: Incision

Circumcised patient:

Suture through the glans to allow traction and stretching of penis. For circumcised male, make a 3 cm distal subcoronal incision.

For an uncircumcised male, consider an alternate incision to avoid compromising the foreskin.



Suture in glans, mark skin

Incise skin and Buck's fascia

Step 2: Dissection and stay sutures²

Dissect through Buck's fascia to expose the tunica albuginea and make appropriate corporotomies in each corpus cavernosum.



Step 3: Corporal dilation²

Using a series of progressively larger dilators, dilate both corpora proximally and distally to accommodate the prosthesis diameter.

Note: It is recommended to dilate approximately 1 mm beyond the diameter of the device to be implanted. Use care to avoid crossover through the intracavernosal septum during corporal dilation.

AMS Disposable Dilators are also available and allow for dilating and measuring in one step.



Dilators available in sizes (9-16 mm)



The Spectra cylinders are available in 3 diameter sizes; 9.5, 12 or 14 mm.



Step 4: Repeat incision and dilate²



Repeat incision and dilatation on other side

Step 5: Evaluate fit²



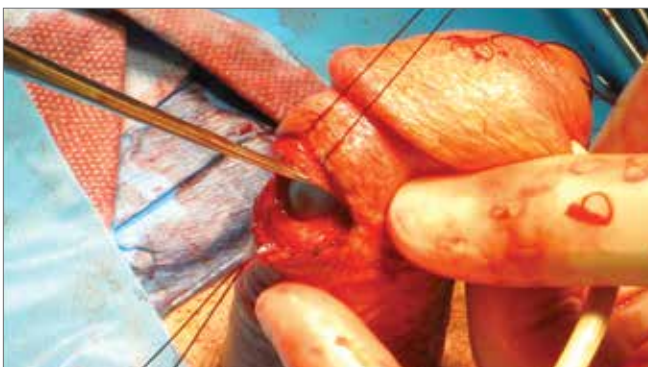
After dilating the corpora, select two dilators whose total diameter equals the total diameter of the cylinders to be implanted. Simultaneously insert the dilators side by side into the proximal ends of the corpora cavernosa to evaluate the overall fit.

Note: If you cross over through the intracavernosal septum to the contralateral side, remove and place the dilator into the contralateral side and reposition the cylinder on the ipsilateral side.

Repeat this step for the distal ends of the corpora.

Step 7: Closure²

Advance glans over the Spectra Prosthesis. Close the corporotomies and incision using an acceptable surgical technique.



Step 6: Sizing and placement²

Stretch the penis to approximate an erection. Use the AMS sizers or disposable dilators to measure the proximal and distal corporal lengths and add them together to attain the total intracorporal length.

The implant should be sized such that there is not excessive pressure on the glans of the penis which could lead to pain and potential for erosion.



Insert proximal end of Spectra Prosthesis into proximal corpus.



Insert distal tip under the glans by lifting and retracting the corpus distally. Press the distal tip of the Spectra Prosthesis under the glans.

Step 8: Results²



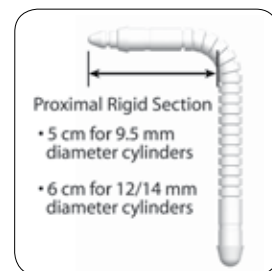
Concealed within the body



Solid erection

- ▶ The device gives the best, long-term result if the widest width possible is utilized
- ▶ For subcoronal dilation, use long dilators or the AMS Disposable Dilators to facilitate dilation necessary to achieve placement of the Spectra Prosthesis
- ▶ Rear tip extenders (RTE) should be chosen remembering that the proximal 5 cm of the 9.5 mm cylinder and the proximal 6 cm of the 12 and 14 mm cylinders need to be within the plane of the body since this portion of the implant does not bend. RTEs available in sizes of 0.5–6 cm. For the 12 and 14 mm cylinders, a 1.5 cm stackable RTE is also available.

Thus, if the proximal measurement is 10 cm and the width chosen is 14 mm, the surgeon should choose a length of rod with a RTE no longer than 4 cm to ensure that the proximal 6 cm of the cylinder is positioned proximal to the body plane. Since the length of the rods are 12, 16 and 20 cm, the surgeon would need to choose the cylinder and/or RTE based on the total intracorporal length, keeping in mind the RTE should be no longer than 4 cm.



Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

The AMS Spectra™ Concealable Penile Prosthesis is intended for use in the treatment of male erectile dysfunction (impotence). Implanting a penile prosthesis will damage or destroy any remaining natural ability to have a natural erection, as well as make other treatment options impossible.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Implantation may result in penile shortening, curvature or scarring.

Potential adverse events may include device malfunction/failure leading to additional surgery, device/tissue erosion, infection, and pain/soresness.

1. Data on file with Boston Scientific.

2. Spectra™ Concealable Penile Prosthesis Instructions for Use. American Medical Systems, Inc. 2017.