

Surgical Protocol

Malleable Penile Prosthesis



Genesis® Penile Protheses

This surgical protocol is intended for general information purposes only and is not intended to provide complete surgical instructions. Each physician is individually responsible for his or her own surgical technique. The information described in this protocol is for the following techniques:

- penoscrotal
- infrapubic/suprapubic
- subcoronal
- perineal
- dorsal

Coloplast gratefully acknowledges the assistance provided in the preparation of this protocol by Dr. Marvin Brooks, M.D.

The Following Items Should Be Available

- Size 9.5 mm diameter
- Size 11 mm diameter
- Size 13 mm diameter
- Coloplast Malleable Sizer or equivalent

You should have a backup of each item. All prosthesis components needed are packaged within the set. The Coloplast Malleable Sizer is sold separately.

Table and Instrument Set-up

INSTRUMENTS NEEDED

- One Pelfrey or Furlow Insertion tool or Coloplast Malleable Sizer.
- One set of Brooks or Hegar dilators, 7 mm - 14 mm.
- One #10 or #15 blade and handle to trim the device.
- Two separate basins of antibiotic solution, one to soak prosthesis and its components only, and another one for irrigation only.

SET-UP

- Set up a separate Mayo stand with a sterile sheet for penile prosthesis.
- Have antibiotic solution prepared and appropriate sutures available (surgeon's preference).
- Sterilize Coloplast Malleable Sizer per instructions on page 5.

Penoscrotal Technique

Preparation

After appropriate prepping and draping of the patient in a supine position, the penis is bent back convexly on the lower abdomen.

INCISION

A 1.5 to 2 inch incision is made in the skin of the midline raphe.

The areola tissue of the urethra including Buck's fascia is divided in the midline. The areola tissue is dissected off the tunica albuginea bilaterally giving the corpora clear exposure. Bleeders are cauterized. The surgical area may be irrigated with an antibiotic solution, as determined by the physician, a procedure which may be repeated throughout the operation.

Stay sutures are placed medially and laterally to the long axis of the penis. With stay sutures on traction, the right tunica albuginea is incised and the sinusoidal tissue is cleaned away from the cut edges to facilitate closing. Repeat procedure for left tunica albuginea.

(See Figure A)

Metzenbaum scissors are passed distally to the glans and proximally into the crural space with the pointed end oriented away from the urethra to determine the plane of dilation.

Dilate distally, then proximally, with Hegar or Brooks dilators up to one size larger than the cylinder diameter you will implant. It is important that dilation extends to limits of the corporal space, and completely under the glans. (See Figure B)

Genesis® Malleable Penile Prosthesis

Catalog No.	Diameter Size	Description
519250	9.5 mm	One pair penile prostheses and three pairs tail caps with connectors (standard, +.5 cm and +1 cm). The implanted length can vary from 14 cm to 23 cm (when the +1 cm tail cap is used).
519260	11.0 mm	One pair penile prostheses and three pairs tail caps with connectors (standard, +.5 cm and +1 cm). The implanted length can vary from 16 cm to 25 cm (when the +1 cm tail cap is used).
519270	13.0 mm	One pair penile prostheses and three pairs tail caps with connectors (standard, +.5 cm and +1 cm). The implanted length can vary from 18 cm to 27 cm (when the +1 cm tail cap is used).

Size Selection

Insert the Coloplast Malleable Sizer distally to determine the length of the corporal space; then proximally into the crus (See Figure C). Be sure to take both measurements from the same reference point in your corporotomy. Add the distal and proximal dimensions to determine the approximate length required for the Genesis® Penile Prosthesis. Refer to SIZING information (p. 4) provided in this protocol for complete details.

Once the size is selected, the Genesis should be soaked prior to implantation according to the physician's standard antibiotic practice.

Placement of the Prosthesis

Cut prosthesis to the proper measured length by pressing down firmly with a clean scalpel. The standard cap should be inserted into the trimmed end. Refer to information provided under SIZING (p. 4).

Insert proximal end of the prosthesis first: the distal end is then pushed to the glans. (See Figure D)

The erection is checked for proper cylinder fit: distal ends at same level and the proximal ends securely seated in the crus. To check for proper malleability, bend penis completely down. There should be no buckling or lateral bowing of the cylinders. (See Figure E)

Closing

Close the tunica albuginea incision with a watertight closure. Close Colles' and Buck's fascia in single layer with running suture. Remove all stay sutures and close skin using the preferred method of the physician.

Operating field is washed, incision dressed, and your routine postoperative protocols instituted.

Allow 4-6 weeks post-op recovery
before use of the implant.

Figure A

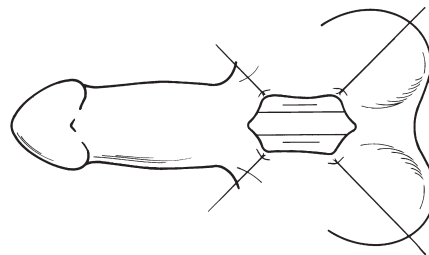


Figure B

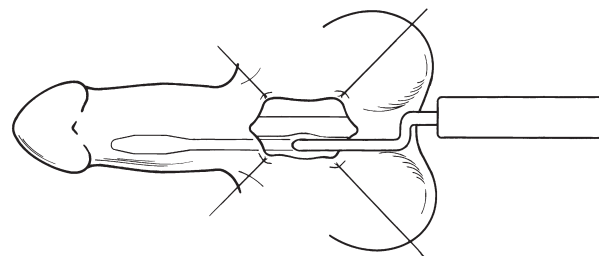


Figure C

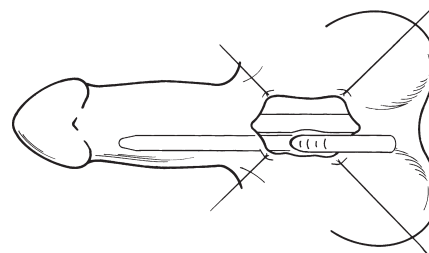


Figure D

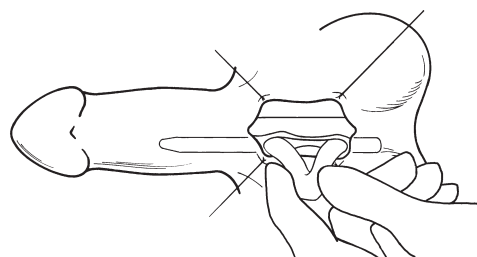
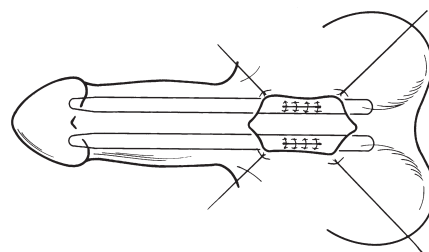


Figure E



Other Techniques

Infrapubic / Suprapubic Incision

A 5-6 cm transverse incision is made 1 to 1.5 cm above penile-abdominal junction. Dissection is carried through to the tunica albuginea. Place two stay sutures (markers) in each tunica lateral to dorsal penile nerves. Incise the corpora laterally between the stay sutures and dilate with Hegar or Brooks dilators up to 10-14 mm, distally and proximally. Measure the corpora (distally and proximally) with the Coloplast Malleable Sizer and add the two measurements to determine overall length. Cut the Genesis® Penile Prosthesis to proper length; add standard tail cap to cut end. Insert prosthesis proximally, then distally. Check cylinder sizing and close tunica and skin in separate layers using the preferred method of the physician.

Subcoronal Incision

A hemicircular incision is made on the dorsal surface of the penis just below the glans. Dissection is carried to the tunica albuginea. Stay sutures are placed in the tunica albuginea and the corpora is incised vertically. Dilate with Hegar or Brooks dilators up to 10-14 mm, distally and proximally. Measure the corpora (distally and proximally) with the Coloplast Malleable Sizer and add the two measurements to determine overall length. Cut the Genesis Penile Prosthesis to proper length; add standard tail cap to cut end. Insert prosthesis proximally then distally into the corpora, check cylinder sizing, and close tunica albuginea and skin in separate layers using the preferred method of the physician.

Perineal Incision

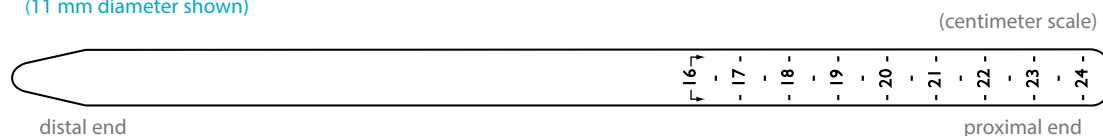
A 1.5 to 2 inch vertical midline incision is made from the base of the scrotum toward the rectum. Dissection is carried through to tunica albuginea. The corpora is opened laterally between two stay sutures and dilated distally to the glans and proximally to crus with Hegar or Brooks dilators (10-14 mm). Measure corpora distally and proximally with Coloplast Malleable Sizer to determine proper length. Cut the Genesis Penile Prosthesis to proper length; add standard tail cap to cut end. Insert prosthesis into corpora proximally then distally. Check cylinder sizing and close tunica albuginea and skin in separate layers using the preferred method of the physician.

Dorsal Incision

A 1.5 to 2 inch vertical midline incision is made on the dorsal surface of the penis just above the penile-abdominal junction. Dissection is carried through to the tunica albuginea. Corpora is incised between 2 stay sutures and dilated with Hegar or Brooks dilators (10-14 mm) distally to glans and proximally to crus. Measure the corpora distally and proximally with the Coloplast Malleable Sizer to determine proper length. Cut the Genesis Penile Prosthesis to proper length; add standard tail cap to cut end. Insert prosthesis proximally, then distally into the corpora. Check cylinder sizing and close tunica albuginea and skin in separate layers using the preferred method of the physician.

Allow 4-6 weeks post-op recovery
before use of the implant.

Genesis Prosthesis
(11 mm diameter shown)



Tail Caps



Standard



+ .5 cm



+ 1.0 cm

Sizing

Measuring the Corpora

Proper sizing of the prosthesis depends on careful and thorough dilation of the corpora cavernosa to determine the length and diameter of prosthesis needed.

Length

After careful dilation of corpora, the distal end of the Coloplast Malleable Sizer is inserted into the distal corpora body and its length noted. The proximal end is then inserted into the proximal corpora body, and the length noted. The Sizer is then removed. All measurements, distal and proximal, must be taken from the same landmark to determine the approximate length required for the Genesis® Penile Prosthesis.

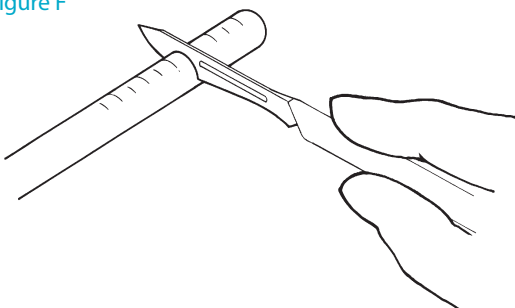
Diameter

The diameter of the prosthesis is determined by the largest diameter dilator that was easily inserted. For example, if the penis is dilated with a 12 mm dilator, then an 11 mm Genesis Penile Prosthesis should be selected.

Trimming the Prosthesis

Using a clean, sterile scalpel with a fresh blade, make a straight, right-angled cut into the proximal end of the prosthesis at the appropriate length calibration (e.g., if measured length is 20 cm, cut on the 20 cm mark. See Figure F.)

Figure F



For a custom fit, the Genesis Penile Prosthesis can be cut to a multiple of lengths within its sizing range (not just in centimeter increments). After cutting the end of the prosthesis, securely connect a standard tail cap (See Figure G). The prosthesis is calibrated so that the trim marks indicate the final length when a standard tail cap is applied. The Genesis Penile Prosthesis is now ready to be inserted into the corpora.

Shortening / Lengthening the Genesis Penile Prosthesis

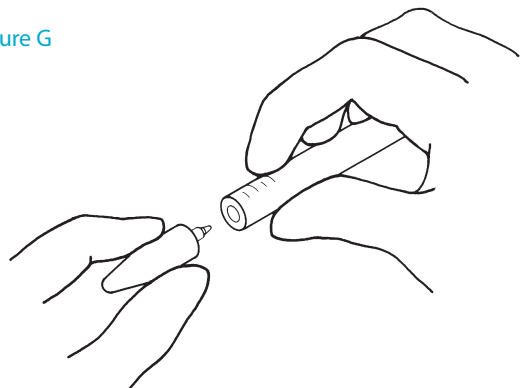
If upon implantation the prosthesis length is incorrect, remove it and detach the tail cap. The prosthesis can be shortened by retrimming and then replacing the standard tail cap. Do not retrim the prosthesis, however, if it has been cut beyond the minimum length calibration mark. To lengthen the prosthesis, remove the tail cap and replace it with either the +.5 cm or the +1.0 cm tail cap, and reinsert into the corpora.

Correcting for “Nonerection” Position

There are three possible causes for the penis, upon implantation, not to bend to the micturition position:

- Prosthesis is too long: remove prosthesis and tail cap, then trim the cylinder
- Prosthesis diameter is too large: remove device and replace with the next smaller size diameter prosthesis.
- The anatomic length of the penis is too short to allow malleability of the prosthesis.

Figure G



Sterilization

Genesis Penile Prosthesis

The Genesis® Penile Prostheses are packaged sterile and pyrogen-free in a double wrap package and are recommended for single use only.

Sizer

The Coloplast Malleable Sizer is supplied non-sterile and is intended for single use only. The following instructions are designed to achieve effective Sizer sterilization, provided the device surface is not pierced, broken or otherwise compromised. Sterility, safety and efficacy cannot be assured for damaged devices.

Sterilization Procedure for Sizer

It is recommended that each institution establish the efficacy of its sterilization procedure by a method which includes the sterilization of an intentionally contaminated product.

The following sterilization technique has been found effective and is provided as a guide only.

CAUTION: DO NOT STERILIZE IN THE PACKAGING SYSTEM PROVIDED.

Autoclaving Procedures

Wrap the Sizer and components in a suitable wrapping material intended for autoclave use.

Place the wrapped unit in an open, clean autoclave tray and autoclave by using one of the following cycles:

Type of Sterilizer	Temperature	Time
Gravity Displacement	132°C (270°F)	10 minutes
Prevacuum	132°C (270°F)	4 minutes

CAUTION: DO NOT USE AN ETHYLENE OXIDE (EtO) STERILIZATION CYCLE.

To dry the wrapped Sizer after the autoclave cycle is complete, open the autoclave door slightly to allow excess steam to escape, close the door, and allow the Sizer to remain in the autoclave until the wrapping is entirely dry.

Use aseptic techniques to handle the Sizer following the sterilization procedure. Leave the sterile unit covered until placement; otherwise airborne contaminants may collect on the surface.

Coloplast – Your partner in Men's Health

Coloplast develops products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. We call this intimate healthcare. Our business includes ostomy care, urology and continence care and wound and skin care. We operate globally and employ more than 7,000 people.

Ostomy Care
Urology & Continence Care
Wound & Skin Care

