SHAH PENILE PROSTHESIS

(Product Brochure and Instructions for use)

Sterile, EO Sterilized

The *Shah Penile Prosthesis* is a solid silicone, semi rigid, flexible implant for the management of erectile dysfunction. The penile implant is used in pairs. The implants are placed within the corpora cavernosa imparting stiffness sufficient for intercourse.

Unique features of the Shah Penile Prosthesis are the presence of two removable sleeves to adjust the diameter (this helps minimize inventory) and availability of a 15 mm diameter implant (which helps ensure a good fit in a large penis). The Shah Penile Prosthesis is available in 2 models:

1. With Hinge

2. Without hinge

Shah Penile Prosthesis with hinge has a flexible central area, which acts as a hinge. This allows the penis to be bent for concealment when not in use. Due to the hinge the penis would need support at the time of entry. Once inside the vagina, intercourse can proceed without any hindrance.

Shah Penile Prosthesis without hinge is a semi rigid implant with uniform stiffness that is adequate for intercourse while being flexible enough to permit concealment. It can be trimmed from the proximal end so that a single implant can be adjusted to any penile length. It is easy to implant and most durable. It is better suited for shorter penises.

DESCRIPTION

With Hinge

It is a rod-shaped, solid silicone elastomer device. The tip is made of soft silicone. The distal one-third is made of firm silicone with a soft silicone covering. The middle 6-7 cm is made of soft silicone to provide a hinge effect. Proximal one-third is slender and is made of medium hard silicone. This portion can be cut to adjust the total length of the implant.

SHAH PENILE PROSTHESIS WITHOUT HINGE

SHAH PENILE PROSTHESIS WITH HINGE

Without Hinge

From tip to tip, it is made of one type of silicone elastomer. The proximal slender part can be trimmed to adjust the total length of the implant. It is available in two grades of firmness (hardness). The medium firm implant is called REGULAR while the softer one is called SOFT. For high risk patients or difficult cases it is advisable to use the SOFT PROSTHESIS to minimize risk of extrusion.

Rear Tip Extenders

Three pairs of caps are supplied with each set of implants. These fit on the proximal end to facilitate adjustment of length.

To fit an unusually long penis, the length can be further extended by 2.5 cm using the extra large cap and by 3.5 cm using the super large cap, available separately.

Sleeves

Both types and all sizes of prostheses are covered with two sleeves of silicone elastomer, which can be removed to adjust the diameter of the prosthesis.

PRESENTATION

Each set of penile prosthesis contains one pair of penile prostheses, three pairs of caps (0.5 cm, 1 cm and 1.5 cm) and one plastic adapter (to help trimming of proximal part). These are supplied in double peel-open packaging, sterilized by Ethylene Oxide. Reusable sizer (made of stainless steel, code no. PI 11) is also manufactured by Surgiwear.

INDICATIONS

The Shah Penile Prosthesis is indicated for the management of organic erectile impotence due to neurological or vascular causes. It may also be used for penile reconstruction and in cases of impotence due to penile fibrosis,

CONTRAINDICATIONS

The implantation of a penile prosthesis should be avoided in presence of infection anywhere in the body and especially if urinary tract or genital infection is present.

Penile prosthesis implantation is also contraindicated in patients with elevated residual urine due to bladder neck obstruction, prostatic enlargement or neurogenic bladder, or with stricture urethra requiring active management. In some cases of severe corporal fibrosis, it may not be possible to place the implant. Implantation should be avoided in poorly controlled diabetics.

PRECAUTIONS

Prior to surgery, prospective patients and or their representative should be informed of the possible complications associated with the use of this product.

Silicone is easy to cut and torn. Instruments should not be used to handle it. Check the implant before isertion for any physical damage, cuts and nicks.

SELECTION OF TYPE OF SHAH PENILE PROSTHESIS

In most cases the Shah Penile Prosthesis with hinge gives the best results.

For shorter penile lengths (streched length<8 cm), Shah Penile Prosthesis without hinge is more suitable.

For high risk cases and difficult cases, it is safer to use the soft prosthesis, although the stiffness may be slightly compromised.

SELECTION OF SIZE OF PENILE PROSTHESIS WITH HINGE

Measure the stretched length of the flaccid penis from symphysis pubis (compress the fat) to mid glans. Refer to table-1 to select the recommended implant code no.. Thus if the stretched length is 9 cm select code WH 09. This will

result in 3 cm of hinge protruding beyond the symphysis, which should provide satisfactory flexibility for concealment. If the stretched penile length is 10 cm. One may select code WH 09 or WH 11. WH 09 will result in 4 cm of hinge protruding beyond the symphysis, while WH 011 will result in 2 cm of hinge protruding beyond the symphysis. Use of longer hinged area favors concealment over stability, while a shorter hinged area favors stability over concealment.

- if a patient wants more flexibility with sacrifice of some rigidity, select a lower code number, if possible.

- if a patient wants more rigidity and less flexibility, select a higher code number, if possible.

- for an unusual patient, SURGIWEAR can supply a customized size and type of implant.

- for high risk patients, it is advisable to use the soft prosthesis (code no. OH S2).

PREOPERATIVE PREPARATION
Apart from routine pre-operative studies (including coagulation profile), urine culture should be done. In elderly men, uroflow-metry, USG for residual urine and prostatic hypertrophy, and PSA assay to screen for prostatic malignancy may be indicated.

Preoperative counseling is very important. The patient must clearly understand that while the implant will restore an erection sufficient for intercourse, **this will be less than his previous best erection in terms of length, girth and rigidity.** Penile prosthesis implantation does not guarantee partner satisfaction, acceptance or a better inter-personal relationship.

The patient must be free of any infective focus anywhere in the body. Oral hygiene should be ensured. If the patient is diabetic, sustained normalization of blood sugar must be achieved. Glycosylated Hb should be <10%.

The patient is instructed to bathe himself with an antiseptic soap solution during the two days prior to surgery. Shaving of the operative site should be done outside the operation theater just prior to surgery. Peri-operative antibiotic cover is essential.

Like any other implant procedure, penile prosthesis implantation should be done as the first procedure in the operation theater to minimize the risk of infection. Laminar flow hood over the operative area is desirable.

SPECIAL INSTRUMENTS
Some special instruments are required for the implantation of penile prosthesis. The following list is not exhaustive or mandatory but a suggestive one only.

1. Hegar dilators
2. Sizer to measure length
3. A 30 cm scale to facilitate adjustment of length
4. Insertion tool (occasionally required for difficult cases)

FIGURES SHOWING STRUCTURE OF DIFFERENT SIZES OF HINGED PENILE IMPLANTS

OPERATIVE PROCEDURE
Surgical Procedure
The implantation of penile prosthesis may be accomplished through variety of procedures. The choice depends upon the training of surgeon, customs in that hospital, country. Therefore the surgeon is best advised to use method, which his/her own practice and training dictate to be best for the patient. Procedure described below may be taken as guidelines only.

There are varieties of approaches for implantation of a penile prosthesis.

a. *Peno-scrotal approach*

b. Infra pubic approach

c. Sub coronal (not recommended for the Shah Penile Prosthesis)

d. Perinea*/ (not recommended) e. Shah lateral approach*

The penoscrotal approach is described below in detail.

PENO- SCROTAL TECHNIQUE
It is the most common technique in use.
A Foley catheter may be introduced to facilitate identification of the urethra and avoid postoperative voiding problems. However, it is preferable to avoid use of a catheter to reduce chances o of infection.

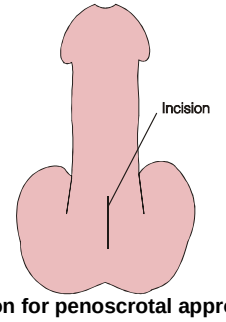

Fig 2: Incision for penoscrotal approach

1. *Incision*: A longitudinal incision is placed at the peno-scrotal junction along median raphe (fig2). This is deepened to expose the corpus spongiosum.

2. *Dissection*: The dissection is extended laterally to expose tunica albuginea of the two corpora cavernosa on either side of the urethra (fig 3).

3. *Incision into corpora cavernosa*: Two stay sutures are placed in each corpus and a longitudinal corporotomy is made between these stay sutures (fig 3). Additional stay sutures may then be placed to hold open the edges of the incision (fig 4).

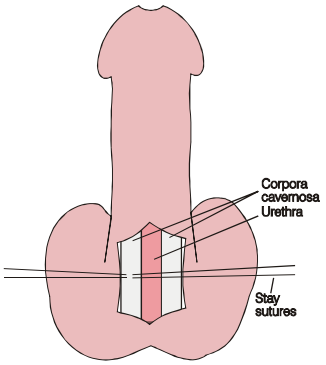

Fig 3: Relationship of three structures after dissection

4. *Dilatation of corpora cavernosa:* The corpora cavernosa need to be dilated to create space for implanting the prosthesis. For dilatation, either Hegar or Brooks dilators (9-15 mm) can be used. (fig 5)
It is very important that gentle dilatation be carried out to the distal-most extent of the corpora so that the prosthesis is satisfactorily seated and the glans is stabilized over the ends of the prosthesis. However, care must be exercised during dilatation, since distal or proximal perforation can occur.

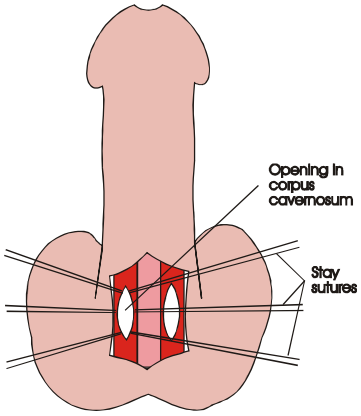

Fig 4: Showing openings in corpora cavernosa

5. *Selection of diameter of prosthesis :* The diameter of the prosthesis is decided on the basis of maximum size of dilator that can be easily inserted. The diameter of the Shah Prosthesis can be adjusted by removing the sleeves. There are two sleeves on each Shah Prosthesis. Removal of each sleeve will reduce the diameter by almost 2 mm. The regular implants have diameters of 13 mm, 11 mm and 9.5 mm. The large implants provide diameters of 15 mm, 13 mm and 11 mm.

6. *Measurement of length of the corpora cavernosa :* Intra-corporal length of each corpus cavernosum is measured proximally and distally after dilatation. Proximal and distal measurements are added to obtain the final length. Measurement of length can be done easily using the sizer made by SURGIWEAR.

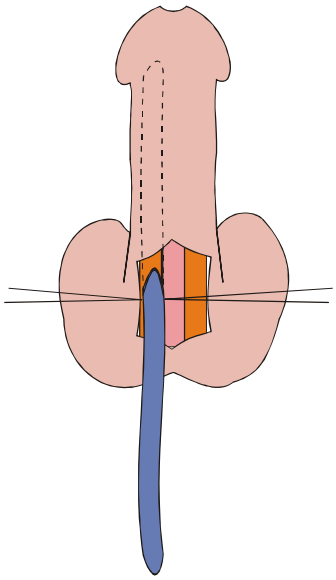

Fig 5: Dilatation of Corpus cavernosum

Usually the length should be the same on both sides, though small differences are not uncommon. A difference of more than 1 cm between the two sides should suggest the possibility of inadequate dilatation or perforation, with or without crossover.

7. *Adjustment of length of the Shah Prosthesis :* The length of Shah Penile Prosthesis can be adjusted by trimming the proximal slender end. While trimming, deduct the size of the cap going to be used (at first, only the smallest cap 0.5 cm, is used to keep margin for an unexpected requirement for a longer prosthesis). For e.g., if the distal measurement is 7 cm and the proximal measurement is 8 cm the total length required will be 15 cm. The prosthesis is trimmed to 14.5 cm and the 0.5 cm cap is fitted on. Use the plastic adapter provided to achieve a perpendicular cut while trimming (fig 6).

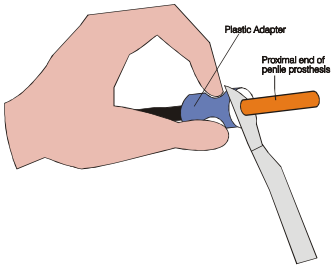

Fig 6 : Adjusting length of prosthesis

Special attention is required when using the hinged prosthesis. The stretched penile length from symphysis pubis to mid - glans, is measured. The model number of implant selected is based on this measurement, as described earlier. The proximal end will then be trimmed to achieve the desired total length. This will ensure that 3-4 cm of the hinge portion will protrude beyond the symphysis. For example, if the total corporal length is 18 cm and the external stretched length (symphysis to mid-glans) is 11 cm, select model WH 011; trim the rear end to achieve a total length of 17.5 cm and add the 0.5 cm cap.

The implant should not come in contact with talc or lint. Wash the gloves with sterile water before handling the implants. The duration of environmental exposure should be minimized. Hence open the prosthesis packaging only when ready for actual implantation. The operative site should be irrigated with antibiotic solution. Longer implantation times are associated with greater risk of infection.

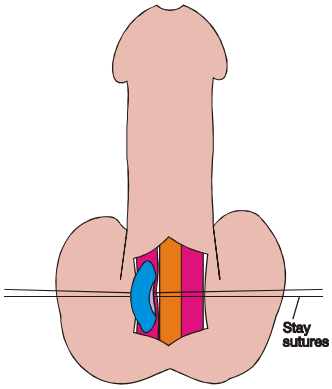

Fig 7 : Insertion of prosthesis

8. *Insertion of prosthesis* : The prosthesis is first inserted into the distal end of the corpus. It is then flexed on itself and the proximal end is guided through the cor-porotomy into the crus of the penis (fig 7). If the distal placement is not satisfactory, a stitch may be placed through the prosthesis and the Furlow introducer be used to guide the prosthesis into place.

9. *Readjustment of length :* The erection is checked for proper cylinder fit. Distal ends should be at same level (in some cases this may not be possible) and the glans should be stable ; the proximal ends should be securely seated in the crura. There should be no lateral bending or buckling of the prosthesis. In case it is discovered that length of the prosthesis is more than required, it can be taken out and further trimmed after removal of the cap. If it is found to be too short, a bigger cap is applied after removing the prosthesis from the corpus cavernosum.

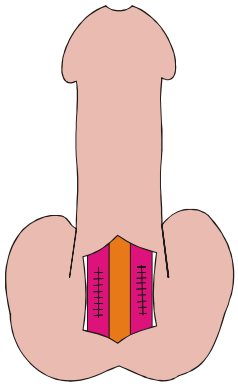

Fig 8 : Closure of Tunica Albuginia

10: *Closure:* The tunica albuginia is closed with Vicryl or PDS (fig 8), Cremastric & subcutaneous layers are approximated and skin is closed with suitable suture material. A drain is usually not required.

SHAH LATERAL APPROACH

1. A 2 cm transverse incision is made on the lateral aspect of the base of the penis through the scrotal skin. The incision is deepened to expose the corpus caverno-sum.

2. Two retractors are used to stretch the incision longitudinally. The stay sutures are now placed and the further steps proceed as described earlier.
3. To expose the other corpus cavernosum a similar incision is made on the other side of the shaft.

This approach has the advantage of a rapid direct exposure of the corpus cavernosum with minimal dissection and no need for any special retractors.

POSTOPERATIVE MANAGEMENT

Intra venous antibiotics are used for first 48 hours. Oral antibiotics are then given for ten days. Foley catheter, if introduced, is removed on the 1st or 2nd post-operative day. Adequate analgesics must be prescribed. Intercourse is permitted after 45 days.
With either implant, some patients need to wear an athletic supporter to achieve good concealment..

COMPLICATIONS

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

The medical literature is full of hazards and complications associated with use of Penile Prosthesis. It is implied & understood that since user is highly trained super-specialist. He has experience of implantation of Penile Prosthesis. He is fully aware of all the hazards associated with use of Penile Prosthesis and he has studied the medical literature well before use.

Complications due to use of penile prosthesis include infection, erosion, migration, mechanical failure, insufficient stability and persistent post-operative pain.

The incidence of infection in various series varies from 0.4% to 5.0%. Acute infection is usually acquired at the time of surgery. If it is superficial, it may respond to antibiotics. If it involves the corpora, the implants will have to be removed. This can be followed by (depending on the circumstances) immediate replacement, delayed salvage after 3 to 5 days, or later re-implantation after 6 months. Irrigation and drainage of the corpora and the use of appropriate parenteral antibiotics is important. Low grade infection may manifest as persistent pain. Late infection may occur following hematogenous spread at any time. Hence an antibiotic cover is necessary during a dental extraction, other surgical procedures or whenever the patient acquires a focus of infection.

Mechanical failure is uncommon with the semi rigid implants. It manifests as loss of rigidity.

Penile instability will result if the implant is undersized. Too short an implant will result in an "SST deformity".(i.e. an unstable, tilted glans). Too narrow an implant will result in wobbling of the prosthesis within the corpora.

Persistent post-operative pain may be due to an oversized implant or due to low grade infection.

External erosion or proximal migration is usually due to intra-operative damage to the corpus cavernosum during the dilatation process. If such damage is recognized it should be immediately repaired or bypassed. Additionally, the prosthesis may be fixed to the tunica using a thick suture. Delayed erosion may occur if the prosthesis is too long. Patients with impaired sensations or those requiring repeated catheterisation, have a much higher incidence of erosion. In men with spinal cord injury the infection/ erosion rate is 15% to 25%.

Though penile prosthesis implantation carries the risk of a variety of potential complications with which the implanting surgeon must be familiar, a carefully performed implantation in a correctly selected patient should have a total complication rate of less than 2% to 5%.
A video cassette demonstrating the operative technique and how to prevent, identify and treat complications is available from SURGIWEAR.

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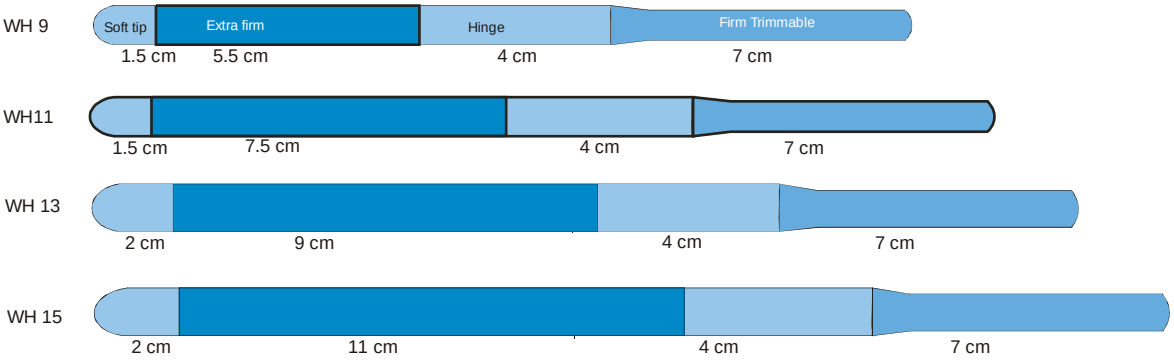
PRODUCT INFORMATION DISCLOSURE

FIGURES SHOWING STRUCTURE OF DIFFERENT SIZES OF HINGED PENILE IMPLANTS



FIGURES BELOW SHOW HOW PLACEMENT OF IMPLANT CHANGES THE FUNCTIONAL HINGE LENGTH