

INFORMED CONSENT FOR INSERTION OF PENILE PROSTHESIS

1) I hereby request and authorize Dr. Harold M. Reed assisted by his designated urological associates and surgical technicians, to perform the urological operation entitled Implantation of Penile Prosthesis in an effort to restore lost penile organ function, that is the ability to achieve and sustain an erection. I am well motivated to relate sexually and have a similarly motivated spouse or mate. I am aware of the commonly used types of penile prostheses available: a) semi-rigid rod with or without malleable braided wire insert); b) hydraulic rod; or c) inflatable penile prosthesis with reservoir. I have considered psychotherapy, behavioral (alternate means of sexual expression), vacuuming, pharmacological erection (injection of a vaso-active drug into the base of the penis), and penile revascularization. After careful consideration of these alternatives and as a result of prior discussion with Dr. Reed, I opt for

2) Dr. Reed has displayed to me in his office the various prosthetic models available and has shown me how they operate. He has apprised me of statistics emanating from major urological centers as well as cited his own experience and has revealed statistically the choices made by his other patients.

Furthermore, he has given me an opportunity should I so desire, to confer with other patients that he has implanted, to learn more about their personal reactions and prosthesis use.

3) The "3 piece" inflatable penile prosthesis is produced by 2 major manufacturers: American Medical Systems with their 3 piece hydraulic AMS-700, and the Mentor Corporation with their Alpha-I "3 piece" (Titan upgraded version with Inhibi Zone). The AMS 2 piece is called the Ambicor; and the Mentor 2 piece is called the Excel. The 3 piece is really a 4 piece, 2 cylinders, a reservoir, and a pump. The 2 piece is really a 3 piece. The AMS offers LGX cylinders which expand in length and girth. There are advantages of each product and truly the patient must make the decision. An inflatable prosthesis being a mechanical device is not guaranteed to function indefinitely. Average survival rates before revision and/or replacement could be 6 to 8 years.

Bear in mind the Mentor **products** are guaranteed 100% (replacement) for 10 years whereas the AMS product is warranted on a prorated reimbursement schedule based on the original purchase price. This is to say if there is a defect with the AMS product and the patient requires revision in the first year, the company will simply provide a new implant. After that, the patient will pay the make-up difference between current market price and what was paid originally. Neither company pays for surgical, facility or anesthesia fees. This may concern those who are no longer covered by an insurance.

Traditionally, patients who have had the AMS 700 product in general prefer to stay with that product in the event that a revision is necessary. They appreciated the ease of a pump release operation and the presence of the reservoir which provides for, in their opinion, a firmer erection. Those patients who have the newer Mentor Alpha-I will enjoy a similar ease of operation.

A. semi-rigid rod will not provide for any enhancement of girth. All models are typically installed by a 1 inch incision made horizontally in the mid scrotum.

The AMS 700 prosthesis, and the Mentor Alpha-I contain a fluid transfer pump, a reservoir placed in the anterior pelvis, and 2 expansile cylinders. Connections for the AMS 700 and Mentor Alpha-I are made in the operating room. In either case, squeezing a pump produces cylinder inflation and squeezing the release valve attached to the pump produces flaccidity.

Spontaneous Erections. All inflatable models may be associated with a phenomenon called "spontaneous or auto-erection". The causes of this may include normal residual erectile activity that the patient may have had prior to surgery, a contraction of the capsule around the fluid reservoir or resi-pump, or in the case of active patient movement several incremental compressions of the reservoir that ultimately results in some noticeable erection. Aside from residual erectile activity, the management of the latter includes: 1) always being sure the cylinders are completely deflated after use, and 2) simply being prepared to deflate the prosthesis when spontaneous erection does occur.

Flexibility. All erections produced by an inflatable prosthesis will flex some, as opposed to a natural "rock hard" erection.

Loss of Length. No urologist can guarantee that the length of the erect penis with prosthesis will be exactly as long as before impairment. One reason is that the prosthesis although going into the head of the penis does not produce significant swelling of the head. Using the AMS LGX cylinders certainly helps some.

4) I understand that if I select the Semi-rigid Rod type of prosthesis, I will have a permanent erection and as such there may be difficulties with concealment which cause certain embarrassment. Dr. Reed has discussed ways to place the erection upwards against the lower abdominal wall, retained by the waistband of underwear, or downwards against the inside of the thigh. Complications of semi-rigid rod implantation include migration of the rod, fracture of the rod or malleable filaments, infection, and obstruction of the urinary tract. On occasion continuous pressure of the prosthesis against the head of the penis may lead to prosthesis extrusion. Should cystoscopy or transurethral surgery be required to reach the bladder, a perineal urethrostomy may be required.

5) Should I select a fluid rod "2 piece" implant (Ambicor or Excel) penile prosthesis (example Dynaflex), I realize while this prosthesis still provides me with the opportunity to achieve both a controllable erection and a degree of flaccidity at other times, the quality of that erection is not as rigid nor is the flaccidity as soft as that produced by the "true" inflatable penile prosthesis (AMS 700, Mentor Alpha-I).

I understand that when the fluid rod prosthesis is not in use, it should be completely deflated to prevent spontaneous erection.

6) Implantation of any type of penile prosthesis results in a displacement and some loss of natural spongy erectile tissue. The prosthesis typically protrudes halfway into the glans but the glans itself will not necessarily become turgid during sexual activity.

7) Implantation of any type of penile prosthesis may result in some degree of urethral compression which can reduce the caliber of urinary flow. This effect may be exaggerated by postoperative edema and usually subsides within a few days to a week. On occasion the Foley catheter, may have to be reinstated for a few days to permit optimal urine output while the swelling subsides. In my personal experience, in only one patient out of a hundred has a prostate operation been necessary because of urinary retention. All other patients re-establish their typical preoperative voiding abilities and note no appreciable change in the caliber of their urinary stream.

Some patients may notice some degree of post-voiding dribbling. This can be managed by standing over the commode for a few extra seconds to allow the urine to drain from the urethra and by compressing the underside of the urethra if necessary to help expel any residual urine.

8) Following implantation of the Inflatable Penile Prosthesis with scrotal pump, the pump may have a tendency to rise in the scrotum towards the base of the penis. The patient is expected to keep the pump in a dependent scrotal position by gently pulling down on the pump daily for 1 minute twice a day for six weeks following surgery.

9) I am aware that there may be a significant tenderness in the surgical area that can last anywhere from a few days to several weeks and is gradually reduced by the formation of fibrous capsule which surrounds the prosthesis. I agree to wear the penis in an upright position for 2 weeks following surgery to ensure the straightest possible erection.

I agree not to use the prosthesis for penetration until all inflammation from the surgical process has substantially subsided and Dr. Reed has given me adequate instruction in its use. I agree to confer frequently with Dr. Reed as necessary regarding any questions I may have about the prosthesis and keep my appointments with Dr. Reed as necessary regarding any questions I may have about the prosthesis and keep my appointments with Dr. Reed so that he may follow my post-operative progress.

10) Complications that may occur with any prosthetic surgery include but are not limited to: infection, extrusion of the implant from the skin or urinary opening, bleeding and or hematoma, wound separation, herniation of the cylinders, mechanical failure, fluid loss resulting in malfunction, redundant connecting tubing, and prolonged tenderness.

11) PENILE CURVATURE NOTED IN THE OPERATING ROOM AFTER INSTALLATION OF AN IMPLANT. On occasion this is noted and may be related to prior scarring or fibrosis of the erectile bodies, a pre-existing condition.

Dr. Reed's primary approach is to use manual molding to correct the bending or curvature as this often works after one or two applications for about 45 seconds. If not, Dr. Reed is then authorized by the patient to make a circumanular incision similar to a circumcision, and to deglove the skin of the penis and try to correct the curvature by firstly making a simple release (incision) of the tethering area which may require lifting of the neuro-vascular bundle or freeing of the urethra (urinary channel) on the underside, or if this requires too extensive an incision which would cause the implant to be unstable, filling the released area in with a Tutoplast Pericardial cadaveric graft (taken from a deceased donor). Doing this adds more time to the operation and although with every added step, the possibility of wound infection or complication is always somewhat heightened, correction of the curvature is still advisable, as this will be done in the same setting and the prosthesis will be checked before and after closure for proper function.

12) I understand that Dr. Reed, during the operative procedure, will be occupied totally with surgery and that administration of anesthesia is an independent function. Although discussion of choice of anesthesia and anesthetic risks should be addressed to the anesthesiologist, some common complications that may occur include use of supplementary anesthetic, post anesthetic headache or backache.

13) I understand the maintenance of personal hygiene, especially genital cleanliness is extremely important in preventing postoperative infection and promise only to operate the prosthesis with clean hands and well-trimmed fingernails. As this is also applicable to your sexual partner in managing of the prosthesis.

14) I have had an opportunity to discuss the informed consent contained herein with Dr. Reed, and question him about any unfamiliar medical terminology.

15) The information presented above by Dr. Reed although intended to be comprehensive and detailed, is not purported to represent the full scope of collective urological experience with penile prosthesis. I recognize that there are inherent risks in all surgical procedures and can appreciate the possibility of side effects and complications stemming both from the procedure and recovery therefrom.

16) There is no unfamiliar medical terminology.

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On _____ day of _____, 20____ in the
presence of witness whose signature appears below.

PATIENT

WITNESS

I have personally discussed with the patient the above described proposed surgery, its risks and potential complications, as well as the alternatives available.

HAROLD M. REED, M.D.

(=con_penile_implant, 01/18/2010)