MENTOR

Product Insert
Data Sheet

-----Alpha I® Inflatable Penile Prosthesis

90-190083-001 PMA DRAFT

CAUTION: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

NOTE: Refer to the "Surgical Protocol" and "Table and Instrument Set-Up" manuals for further information on the Alpha I Inflatable Penile Prosthesis and its implantation.

DEVICE DESCRIPTION

The Alpha I® Inflatable Penile Prosthesis (IPP) is a hydraulic system designed to be surgically implanted into the penis for the management of erectile dysfunction (also known as impotence). This implant provides the patient with voluntary control over the erect and flaccid states of the penis.

Penile prostheses have been used in the management of impotence stemming from a variety of causes, including spinal cord injury or disease, prostatectomy, multiple sclerosis, diabetes mellitus, arteriosclerosis, psychogenic etiologies, and hypertensive vascular disease.The implant consists of two inflatable Bioflex® penile cylinders that are implanted in the corpora cavernosa of the penis. The cylinders are attached to a pump which is placed in the patient's scrotum, and the pump is connected to a fluid reservoir (available with or without a lockout valve) that is implanted underneath the abdominal muscles. The fluid reservoir is filled with a sterile saline solution. Repetitive squeezing of the pump transfers fluid from the reservoir to the cylinders in the penis. As the penile cylinders fill with fluid, the penis enlarges and becomes erect, thereby facilitating intercourse. Fluid pressure in the cylinders is released when the patient squeezes the Release Bar Valve on the top of the pump, returning the penis to the flaccid state. Cylinders are provided pre-attached to the pump or as separate components.

INDICATIONS FOR USE

The Alpha I Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are considered to be candidates for implantation of a penile prosthesis..

CONTRAINDICATIONS

The Alpha I Inflatable Penile Prosthesis is contraindicated in patients who have one or more of the following conditions:

- Patients with an active infection present anywhere in the body, especially urinary tract or genital infection.

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- Patients with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder.
- Patients unwilling to undergo any further surgery for device revision

WARNINGS

- **Implantation of the device may make latent natural erections, as well as other interventional treatment options, impossible.**
- Men with diabetes or spinal cord injuries, as well as immunocompromised patients, may have an increased risk of infection associated with a prosthesis.
- Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue.
- Implantation of a penile prosthesis may result in penile shortening, curvature or scarring.
- Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.
- This device contains solid silicone elastomer. The risks and benefits of implanting this device in patients with lupus (e.g., SLE and DLE), scleroderma (e.g., progressive systemic sclerosis), myasthenia gravis, or documented sensitivity to silicone should be carefully considered. The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been and continues to be the subject of great scientific and medical debate.

PRECAUTIONS

Surgery-Related

- Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery.
- Prostheses of incorrect length may result in voiding difficulties, inflammation, pressure necrosis and erosion into the urethra or through the tunica albuginea of the corpus cavernosum, SST deformity, buckling of the cylinders, or malposition of the pump in the scrotum.
- Do not use narrow cylinders in patients with normal anatomies. Narrow cylinders should only be used in patients with compromised corpora and smaller anatomies. The use of an improper cylinder size increases the risk of an unsuccessful outcome.
- Improper surgical implantation of the prosthesis could result in unsatisfactory performance or require corrective surgery. Careful technique will minimize the possibility of erosion or perforation of the corpora cavernosa and urethra, and aid in preventing kinked tubing.

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- Improper reservoir placement or filling technique can result in spontaneous unintended inflation or deflation of the cylinders.
- Each device should be carefully examined prior to surgery and continuously monitored throughout the surgical procedure to ensure the structural integrity of the device is not compromised in any way. A prosthesis which has been damaged or on which repairs have been attempted should not be implanted.
- The prosthesis should not be handled with pointed, toothed or sharp-cornered instruments, as any nick can be the focus for subsequent failure of the implant. Extreme care should be taken in manipulating the prosthesis with blunt instruments to avoid tearing, warping or nicking.
- Lint, fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants. Any nick or split in the device is a potential mechanical failure site and can serve as a collection point for debris. Such debris could cause foreign body reactions or be a locus for infection.
- Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.
- Utmost care must be used with cautery-type devices in or near the area of the implant, as damage to and subsequent leakage of the implant could occur.

Device-Related

- Use sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. Solution for Injection to fill the implant.
- The components of this implant are manufactured and tested for assembly/use with their specified Mentor devices. The use of Mentor components with other manufacturers' components has not been tested and is not recommended.
- Do not use product that has damaged or opened packaging, as sterility may be compromised.
- This device is sold sterile for single use only, and should never be resterilized. In the event the product becomes contaminated prior to use, the device should be returned to Mentor for replacement.

Patient-Related

- A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits.
- Reports in the literature suggest that prophylactic antibiotic treatment for dental procedures may be indicated for patients with a penile prosthesis.
- Health conditions which hamper sexual activity, such as severe angina, may prevent successful use of this device.

- The prosthesis should not be implanted in patients who lack the manual dexterity necessary to operate the device.
- Psychological characteristics, such as inappropriate attitude or motivation, may inhibit the patient's successful use of the device.
- Trauma to the pelvic or abdominal areas, such as impact injuries associated with sports (e.g., bicycle riding), can result in damage of the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction, including replacement of the device.
- The implantation of this device should only be considered in patients whom the physician determines are adequate surgical risks.

ADVERSE EVENTS

A clinical trial was conducted to determine the safety and effectiveness of the Mentor Alpha I Inflatable Penile Prosthesis. A total of 343 patients were enrolled, 164 of whom had been followed for at least 18 months. The following adverse device effects (complications) were noted during the clinical trial:

Alpha I Inflatable Penile Prosthesis Clinical Trial Adverse Device Effects (n=343 enrolled patients)

Adverse Event Category	Number (%) of Patients	Mean (Range) Onset Time in Days
Scrotal swelling	42 (12.2%)	27 (0-543)
Autoinflation	38 (11.1%)	112 (4-584)
Discomfort	37 (10.8%)	32 (0-322)
Angulation/curvature	19 (5.5%)	87 (0-329)
Edema	17 (5.0%)	36 (0-239)
Device malfunction	15 (4.4%)	214 (7-1096)
Chronic pain	11 (3.2%)	69 (1-248)
Difficulty with ejaculation	11 (3.2%)	274 (8-743)
Transient urinary retention	11 (3.2%)	1 (0-6)
Fever	10 (2.9%)	22 (0-167)
Migration	10 (2.9%)	140 (24-365)
Patient dissatisfaction	10 (2.9%)	174 (38-789)
Infection - site	10 (2.9%)	112 (38-248)
Deflation	9 (2.6%)	157 (29-431)
Hematoma/seroma	8 (2.3%)	3 (0-11)
Wound leakage	7 (2.0%)	37 (0-167)
Bleeding	5 (1.5%)	221 (0-608)
Delayed wound healing	5 (1.5%)	59 (6-184)
Phimosis	5 (1.5%)	197 (2-635)
Sensory loss	5 (1.5%)	221 (34-557)
Cylinder aneurysm	4 (1.2%)	339 (101-667)
Fibrous capsule formation	4 (1.2%)	103 (28-169)
Over/under inflation	4 (1.2%)	91 (41-183)
Erosion	3 (0.9%)	39 (6-59)
Scrotal erythema	3 (0.9%)	67 (5-183)
Genital change	2 (0.6%)	272 (89-454)
Infection – wound	2 (0.6%)	106 (28-184)
Inguinal hernia	2 (0.6%)	458 (370-546)
Other device-related events	55 (16.0%)	N/A

The following "Other device-related events" were reported during the study, each of which occurred in ≤ 1.5% of patients: adhesion at pump, allergic reaction to contract medium, corporal rupture, cylinder buckling, cystitis, deformity, difficulty working pump, difficulty voiding, difficulty working prosthesis, drainage from incision, drug reaction, dysuria, extrusion, fluid loss, hematospermia, hematuria, iliac vein injury, incontinence, induration, inflamed glans, lymphadenopathy, mild redness, nausea, pain with intercourse, popped suture, pump hardness, pump stuck in scrotum, rash, reduced penile length, scar tissue formation, scrotal abscess, scrotal discomfort/redness, scrotal heaviness, slow urinary stream, SST deformity, suture sticking out, testicular pain, ulceration, urethroscrotal fistula, urge incontinence, urgency, urinary frequency, UTI, and ventral chordee.

With the exception of the complications that led to revision surgery (summarized in the "Clinical Studies" section), all device-related complications either resolved (with or without non-surgical intervention) or were judged by the patient not to require further treatment.

The following events occurred during the clinical study but were judged by the investigators not to be related to the device or the implantation surgery:

n=18 patients (5.2%): cardiovascular disease/surgery;

n=11 patients (3.2%): cancer;

n=7 patients (2.0%): arthritis/joint pain, hypertension, incontinence;

n=6 patients (1.7%): angina/chest pain, flu/cold;

n≤5 patients (≤ 1.5%): abdominal pain, allergy to drug, anemia, anxiety, asthma, back pain/injury, back surgery, bladder injury, bladder lesion, bladder neck contracture, bladder stones, blood clot, BPH, breast mass, bronchitis, chest congestion, cholecystectomy, chondyloma, constipation, cyst on back, cyst at joint, dermatophyte, depression, detached retina, diabetes, diabetic toe infection, diarrhea, difficult/slow urination, dissatisfaction, diverticulitis, dry skin, dyspnea, epididymitis, enlarged spleen, esophageal reflux, extended hospitalization, fatigue, folliculitis, foot muscle tear, foot pain, GI infection, GI ulcer, gout, growth in mouth, growth on eyelid, hematuria, herpes, hydrocele, indigestion, ingrown toenail, knee surgery, leg injury, leg/foot edema, lipoma, low platelet count, lump on neck, nausea, nocturia, ophthalmic surgery, orchitis, paralysis, Parkinson's disease, penile warts, peripheral neuropathy, peripheral vascular surgery, phlebitis in arm, pneumonia, prostatectomy, prostatitis, pulled muscle, rash, renal cyst, respiratory difficulty, rising PSA, sickle cell complications, sinus infection, shoulder injury, skin lesion, sleep apnea, snoring, sore throat, stomach problems, stroke, suprapubic pain, swollen joint, tendonitis, tetanus, tonsillectomy, TURP, upper respiratory infection, urethral stricture, urgency, urinary frequency, urosepsis, UTI, vertigo, and wrist surgery.

The following risks of inflatable penile implants or their materials have been reported in the medical literature but did not occur during the prospective study: adhesions requiring lysis, gangrene, granuloma formation, immune-related connective tissue disorders, ischemia, necrosis, perforation, vascular compromise, and ventral band formation.

There were five patient deaths during the course of the study period. None of these deaths were attributed to the device or the implantation surgery.

A total of 34 patients underwent revision surgeries during the study period. Information on device revisions is described in the "Clinical Studies" section.

CLINICAL STUDIES

Study Design:
A prospective, multicenter, baseline-controlled clinical trial was undertaken to demonstrate that the Alpha I Inflatable Penile Prosthesis provides an erection suitable for intercourse and has acceptable rates of surgical revision and explantation. This trial was also designed to assess the potential impact of device implantation upon patient sexual function and quality of life.

Three hundred and forty-three male patients, 25 to 86 years of age, were enrolled in this study. All patients diagnosed with erectile dysfunction were eligible for enrollment, provided they did not present with an abscess or infection, a prior silicone or urogenital implant, a history of connective tissue diseases, a history of poorly-controlled diabetes, or any other condition that would prevent the successful use of an inflatable penile prosthesis. Follow-up examinations were performed at 3-6 weeks, 6, 12, and 18 months following implantation.

Device effectiveness was evaluated at the follow-up visits by assessing penile rigidity at a load of 550 grams, after compensating for soft tissue compressibility using a load of 100 grams. The primary effectiveness endpoint was the proportion of patients experiencing less than a 1.5 cm decrease in penile length between the 100 gram and 550 gram loads. Secondary measures of effectiveness included the following standardized, validated quality of life and sexual function scales: the Rosenberg Self-Esteem scale, the Medical Outcomes Study instrument, and selected subscales of the Extended Satisfaction with Life instrument and the Derogatis Sexual Functioning Inventory. The assessment of device safety involved the collection of information about complications, including the rates of explantation and revision surgery.

This clinical trial provided the following results through the 18-month follow-up evaluation:

Assessment of Penile Rigidity:
Sufficient penile rigidity, as defined by the primary effectiveness endpoint, was achieved in 99.0% of the patients evaluated at the 18-month follow-up visit. Patients who had their device explanted or repaired prior to the 18-month exam, which included two cases of split tubing/fluid loss, two cases of cylinder aneurysm, and one case of inability to inflate, were not included in this analysis.

Assessment of Quality of Life/Sexual Function:
There were significant increases from baseline in mean follow-up scores for all instruments directly related to sexual functioning: the Sex Life subscale of the Extended Satisfaction with Life instrument, and the Sexual Drive, Sexual Satisfaction, and Total Score of the Derogatis Sexual Functioning Inventory.

There was no decline in self-esteem and quality of life as assessed using the Rosenberg Self-Esteem scale and the Medical Outcomes Study instrument.

Surgical Revisions:
A surgical revision is defined as any urogenital surgical intervention after the device implantation procedure. Of the 343 study patients, a total of 34 experienced a revision surgery. The reasons for these 34 revisions can be stratified as follows: 17 were device explantations, 5 were device repair surgeries, and 12 were "other surgeries" that did not involve explantation or repair of the device (e.g., circumcision, inguinal hernia repair). Using a Kaplan-Meier Survival Analysis, the probability of a patient being free of a revision at 18 months was 88.5% (lower bound of 95% confidence interval = 84.5%). Similarly, the probability of a patient being free of device explantation at 18 months was 94.6% (lower bound of 95% confidence interval = 91.9%).

Half of the 34 revision surgeries occurred within the first 6 months post-implantation. The specific reasons reported for the 17 explantation surgeries were: infection (n=6), autoinflation (n=3), cylinder aneurysm (n=2), chronic pain (n=2), split tubing/fluid loss (n=2), cylinder erosion (n=1), and inability to inflate (n=1). The reasons for the five device repair surgeries were: erosion with or without Gortex sock placement (n=2), autoinflation (n=1), split tubing (n=1), and excessive scar tissue formation (n=1). The reasons for the 12 "other surgeries" were unrelated to device function.

PATIENT EDUCATION AND INFORMED CONSENT

Implantation of a penile prosthesis for the management of erectile impotence is not without potential complications and risks. The use of this prosthesis is an elective procedure; the patient should be counseled prior to surgery regarding the benefits and possible risks associated with implantation of an inflatable penile prosthesis. The safety, use and effectiveness of other procedures, devices and other alternatives available should be discussed with the patient.

Patients should be advised that penile implants should not be considered lifetime implants due to the inherent nature of mechanical devices, implant procedures and potential physiological reactions. Implantation of the prosthesis may damage or destroy dormant, natural or spontaneous erectile capability, and erections achieved with penile implants may not be of equal length as to what was previously experienced with normal erections.

Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications should be discussed with and understood by the patient prior to surgery. It is the responsibility of the surgeon, and Mentor relies on the surgeon, to advise the

patient of all potential risks and complications associated with the proposed surgical procedure and device, including providing a comparison of the risks and complications of alternative procedures and devices. Patients should be advised that penile implants should not be considered lifetime implants due to the inherent nature of penile implants, implant procedures and potential individual physiological reactions. Implantation of the prosthesis may damage or destroy dormant, natural, or spontaneous erectile capability.

Excessive stresses or manipulations that may occur during daily routines such as vigorous exercise, athletics, manual massage and intimate physical contact could cause damage/separation to the implant and/or components (penile cylinders, pump/reservoir, tubing).

Patients must be warned that any movements or activities that put pressure directly on the pump or release mechanism can cause involuntary erection or deflation. This includes, but is not limited, to straddle seating, such as on motorcycles, bicycles, horses, etc. Obesity may also be a contributing factor for stresses and pressure.

The natural capsule that forms around the pump may activate the inflate/deflate mechanism and cause involuntary inflation or deflation. This is a physiological reaction to the device.

Intra-abdominal pressure can cause fluid to be spontaneously transferred to the cylinders causing auto-inflation. The potential for auto-inflation of the device can be reduced by creating a large enough pocket for the reservoir and verifying that the correct amount of fluid is placed in the device.

Should surgical, physical, psychological, or mechanical problems occur, removal of the prosthesis may be indicated.

Osmotic imbalance of the fill solution to body fluids in-vivo can result in gradual fluid transfer and subsequent overinflation or deflation of the device.

Complications which may result from the use of this prosthesis include the risks associated with the medication and methods utilized in the surgical procedure, as well as the patient's reaction, response or degree of tolerance to any foreign object implanted in the body. Some complications may necessitate removal of the prosthesis.

This is a mechanical prosthesis which, like any mechanical device, can wear out, be subject to user misuse, malfunction and require replacement. Mechanical complications may include malfunction of the pump component, cylinders or tubing; or separation of components due to elastomer fatigue, repeated stresses, prolonged buckling or folding of the components, or abrasion. Inability to inflate or deflate the device may be experienced. Inflatable penile implants may lose some or all of the fill solution over indefinite periods of time as the result of tubing, connector, or cylinder leaks. Patients should be informed prior to surgery that a replacement surgery may be necessary to restore function of the device.

This device requires user familiarity and education. Some users, however, may never develop an adequate level of familiarity with the prosthesis and may, therefore, be unable to use the device successfully.

If the normal capsule forms around a deflated reservoir component in the 3 to 4 weeks postoperatively, subsequent inflation of the reservoir and deflation of the cylinders may be difficult or impossible. Cylinders must remain deflated and the reservoir totally inflated until the third or fourth week after surgery.

The contracture of fibrous tissue around the pump component can cause unnatural firmness, discomfort, and an involuntary erection or deflation.

Deflation of the device may be slow or difficult for some patients.

Gentle squeezing of the penis while squeezing the pump release valve will allow the cylinders to deflate more quickly. Squeezing the penis without simultaneously squeezing the release valve can result in damage to the penis and/or damage and subsequent malfunction of the pump.

Autoinflation of inflatable penile implants can occur, generally as a result of:

- an implant having been left in an inflated state during the postoperative healing period, resulting in the formation of a capsule around the deflated reservoir component;
- placement of pump or reservoir components in an inadequate pocket;
- heavy capsule formation around the pump or reservoir components; or
- excess fluid in the system.

A revision surgery may be required.

Patients should be made aware that erections achieved with an inflatable penile implant may not be of equal length compared to what was previously experienced with normal erections and there may be a slight twisting or bending of the erection.

Some patients may experience pain in the glans or the scrotum during the initial postoperative period.

It is up to the individual surgeon to decide upon the best method by which to counsel a patient prior to surgery. Mentor relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of the Alpha I Inflatable Penile Prosthesis.

POSSIBLE REACTIONS TO SILICONE AND THERMOPLASTIC ELASTOMER

Introduction

This text contains a brief summary of information from the medical literature. The following information is mainly derived from literature and studies based on mammary implants, but may also be relevant to other implants, prostheses and devices composed of like materials.

Mentor recognizes that the information contained within this text is highly technical. However, medical ethics and practice dictate that the physician must be an intervening party between the manufacturer of prescriptive medical devices and the patient. In light of the foregoing, Mentor provides this text as an overview of current information to assist the physician in obtaining informed consent from the patient.

The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been the subject of significant scientific debate. Three prestigious multi-specialty scientific expert panels, however, have now exhaustively reviewed the published literature on this topic, specifically as it relates to silicone breast implants, and have issued lengthy reports of their findings, in many cases after several years of investigation. These expert panels include the Independent Review Group (commissioned by the Chief Medical Officer of the U.K.), the National Science Panel (appointed by Judge Pointer for MDL 926), and the Institute of Medicine. These three panels have uniformly concluded that there was no discernable evidence of causal association or positive relative risk ratio between exposure to silicone breast implants and recognized or new autoimmune or connective tissue diseases.

Articles continue to be published on a regular basis on this subject. Because of the dynamic nature of this issue, and because product information supplied by Mentor can only reflect a summary of information as of a specific point in time, Mentor reminds surgeons of their independent responsibility to keep abreast of scientific developments relating to devices they are prescribing and to provide prospective patients with the most up-to-date information.

The association between silicone and other thermoplastic elastomers (hereafter "silicone") and the following complications has not been verified by controlled scientific studies. However, there have been case reports in the medical literature associating these complications with silicone implants and devices. Toxicity studies have and continue to be conducted by various research facilities, universities, government agencies, the medical community and the medical device industry. Some of these studies are conducted in animal models to determine potential immunotoxicity and autoimmune issues related to silicone materials. There is a potential that in the animal models being studied, immunotoxicity may result. The clinical significance of some of these studies has not been determined.

Immunological and Neurological Response

The medical literature has raised the possibility that there may be an association between certain immunological-based diseases and silicone implants. The diseases most commonly mentioned include scleroderma, rheumatoid arthritis and syndromes which mimic systemic lupus erythematosus. Available information does not permit precise quantification of risk. Neurological problems have been reported in a small number of breast implant patients who also exhibit immunological symptoms. These reports do not prove a link between the implants and immunological neurological problems.

NOTE: If an immunological response is suspected, the physician must evaluate the necessity of removing the implant. Limited observations suggest that removal of silicone breast implants may alleviate symptoms in some patients who have developed rheumatic disease; however, this is not predictable (American College of Rheumatology 3/91). The long-term eff3ects of silicone in terms of immunological responses are currently unknown.

Connective Tissue Disorders

The term, Connective Tissue Disorders, has been used to describe a variety of symptoms thought to be related to silicone breast implants. Symptoms include, but are not limited to, skin lesions, alopecia, pyrexia, rash, swelling of joints, weight loss, chronic arthropathy, morphea, arthritis, general malaise and keratonconjunctivitis. Some cases of these disorders have been reported in women with breast implants, and some of these women have reported a reduction in symptoms after their implants were removed. Manufacturers have sponsored large-scale scientific studies to explore whether a possible link exists between silicone breast implants and connective tissue disorders. To date, there is no evidence to suggest that the prevalence of these disorders is greater among women who have received silicone implants than among the general age-matched female population.

Based on their exhaustive reviews of clinical and epidemiological literature, the Institute of Medicine, the National Science Panel, and the Independent Review Group concluded that there was no convincing evidence associating silicone breast implants and increased risk of autoimmune, connective tissue, or neurological disease.

Biocompatibility

Reports in the medical literature suggest that host biocompatibility responses may be affected by different biomedical polymers by altering fibroblast production and function, and selectively modulating monocyte/macrophage activity and induction of Interleukin 1 (IL1).

Degradation/Toxicity

The medical literature suggests that in vivo degradation and particle shedding of silicone elastomers may occur in the fibrous capsule and draining lymph nodes. Further research is being undertaken to determine the effects of enzymatic degradation and the possibility of extract toxicity.

Tumorogenicity/Carcinogenicity

Case reports in the medical literature have associated tumors with the presence of silicone mammary implants. During the past two decades of clinical use, the medical literature generally indicates silicone mammary prostheses are not carcinogenic. However, the full range of long-term biological effects of silicone are currently unknown.

Reproductive and Teratogenic Effects

Animal studies show no evidence that birth defects are caused by silicone implants. Further scientific studies may be necessary to show an association in humans between silicone implants and birth defects.

Mentor requests physicians to notify the company of complications which occur with the use of this device.

Mentor relies on the surgeon to advise the patient of all potential risks and complications associated with a proposed surgical procedure and device, including a comparison of the risks and complications of alternative procedures and implants.

INSTRUCTIONS FOR USE

A variety of surgical techniques normally used with inflatable penile implants may be employed in the placement of the Alpha 1 Inflatable Penile Prosthesis. The placement technique and location of incision is at the discretion of the physician. Any surgeon implanting penile prostheses should be familiar with currently available techniques for measuring the patient, determining implant size, and performing the surgery. Mentor reminds the surgeons of their responsibility to keep current with scientific and medical developments relating to the devices they are prescribing. Copies of related reference materials and surgical protocols are available from the company, and should be reviewed prior to surgery. The following suggested instructions are provided as a general guide only.

SUGGESTED PREOPERATIVE INSTRUCTIONS

All patients should undergo a complete physical and urological examination. Patients may also profit from undergoing an evaluation with a nocturnal penile tumescence monitor and/or hormone studies, as well as psychological counseling prior to surgery.

After careful psychological or psychiatric evaluation, and in certain cases, nocturnal tumescence studies, the implanting physician may decide patients with psychogenic impotence may receive the prosthesis after it has been clearly established that psychological or psychiatric counseling cannot help the patient.

If the patient has elevated residual urine, symptoms suggestive of bladder outlet obstruction, neurogenic bladder, or other urinary difficulties, these problems should be resolved prior to implantation of the penile prosthesis.

Prior to surgery, the patient should be shown the penile prosthesis and have its function and use demonstrated and be informed of the possible complications associated with use of this prosthesis.

HOW SUPPLIED

The Alpha I Inflatable Penile Prosthesis contains a pre-attached pump with cylinders. Reservoirs and assembly kits, which contain the rear tip extenders, are available separately. All components of the system are supplied sterile and nonpyrogenic in a double-wrap packaging system.

Components of the Alpha I Inflatable Penile Prosthesis System are sterilized by the following methods:

PRODUCT	STERILIZATION METHOD	SYMBOL
Alpha I® Penile Prostheses	Ethylene Oxide	STERILE EO
Alpha I® Assembly Kits	Gamma Radiation	STERILE R
Reservoir	Ethylene Oxide	STERILE EO

CLEANING AND STERILIZATION

The Alpha I Inflatable Penile Prosthesis is supplied sterile and is for single use only.

Caution: This device may not be steam autoclaved. In the event the product becomes contaminated, it is recommended that the device be returned to Mentor for replacement.

FILLING SOLUTION

Caution: Use sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. Solution for Injection to fill the implant.

TRUE-LOCK® CONNECTORS

The True-Lock® connector system consists of straight connectors with clamps. The connector holder is utilized to facilitate placement of the tubing into the cage of the connector.

CHECKING THE SYSTEM

Care must be taken throughout implantation of this device to avoid inadvertent damage to the implant.

Caution should be used during the positioning of connector tubing to prevent kinking, folding, or twisting, and to prevent the possibility of tubing abrading against itself or other tubing/components of the implant. Abrasion of the tubing may result in weakening of the material and subsequent separation. If the tubing connection is not carefully and properly made, damage to the tubing and subsequent fluid loss can occur, resulting in a revision surgery.

The use of the provided rear tip extenders should be considered to allow for proper positioning of the cylinders and pump and minimize the potential for stress to components.

Overpressurizing the system (too much fluid fill volume) beyond what is necessary to achieve an adequate erection for penetration during intercourse can result in the inability to achieve desired flaccidity and/or result in the malfunction of the pump component and/or system failure.

Insufficient pressurizing (too little fluid fill volume) of the implant may prevent the penis from obtaining sufficient rigidity to permit vaginal penetration. A surgical procedure may be required to adjust the fluid volume.

After the pump and reservoir connection has been completed, the functioning of the prosthesis is tested. All shod clamps are removed and the penile cylinders are inflated by repetitive squeezing of the scrotal pump. The cylinders are deflated by steadily squeezing the pump release valve with a light pressure until enough fluid has transferred back to the reservoir to allow cylinder deflation (10-30 seconds).

INSTRUCTIONS FOR RESERVOIR WITH LOCKOUT VALVE

Placement Considerations:

The following placement points should be considered:

- Ensure the reservoir cap is not bent or distorted.
- Ensure the reservoir is positioned so that only the reservoir tubing transverses the muscle and fascial layers.
  - The complete reservoir, bladder, cap with Lock-out valve and strain relief (tapered reinforcement) should reside within the space of Retzius/perivesicle space.
- It is recommended that the entire reservoir be placed behind the pubic bone.

Fluid Adjustment Procedures:

1. Instilling (Filling) the Reservoir
   - The valve is designed to allow flow into the reservoir without any special considerations.

2. Removing Air or Fluid from the Reservoir
   - The lockout valve will inhibit the expulsion of air or fluid from the reservoir when the reservoir bladder is squeezed.
   - To accomplish removal or adjustment, use one of the methods described below

   a. Syringe Method
      - Connect an empty syringe with a green blunt needle to the reservoir tubing.
      - Pull the plunger out to withdraw fluid or air.
      - Clamp the open tube with a rubber shod mosquito (one click).

   b. Manual Method
      - Gently squeeze the Lock-Out valve portion of the reservoir cap with a fingertip on the diaphragm (the flat disc portion of the valve).
      - This will open the valve and allow fluid or air to be removed by squeezing the bladder of the reservoir.

- Clamp the open tube with a rubber shod mosquito (one click) and place in antibiotic solution.

Lock-Out Valve Functional Testing Procedure:

NOTE: Perform this test in the OR, only if sterility of the assembly will not be compromised. The prepping nurse or physician should perform these activities while in the sterile field.

1. Evacuating Reservoir
   - Connect an empty syringe with a blunt needle to the tubing.
   - Withdraw the plunger to evacuate any air.
   - Clamp the open tube with a rubber shod mosquito (one click).

2. Filling the Reservoir
   - Instill approximately 50% of the reservoir of saline solution by means of a syringe with a blunt needle.
   - Remove the syringe and needle from the tubing.
   - <u>It is acceptable for some fluid to trickle.</u>
     - There is no internal pressure to seat the valve.

3. Lock-Out Verification
   - Lift the assembly off of the table by the tubing.
   - Grasp the suspended bladder and squeeze while monitoring the end of the tubing for leakage.
   - A few drops may be expelled.
     - <u>No continuous leakage should occur.</u>

In Situ (in the body) Lock-Out Verification (not recommended for routine execution)

NOTE: In-situ Lock-Out verification outcome can vary even when the components are functioning properly. If there is any tissue in contact with the diaphragm of the device, some leakage may be observed.

1. Prior to performing this test, ensure the following:
   - The reservoir is positioned so that only the reservoir tubing transverses the muscle and fascial layers.
   - The complete reservoir, bladder, cap with Lock-out valve and strain relief (tapered reinforcement) should reside within the space of Retzius/perivesicle space.

2. Filling the Reservoir
   - Fill the reservoir to capacity PLUS an additional 10cc's.

3. Lock-out Verification
   - Disconnect the syringe and monitor the tubing for leakage.
   - If leakage occurs the orientation of the reservoir may be changed to reduce or possibly eliminate the leakage.

Due to some fluid trickle and to ensure accurate filling, the reservoir should be evacuated completely and refilled within the appropriate fill range.

POSTOPERATIVE CARE

Postoperative care is determined by the treating physician. In general, antibiotics are administered intravenously for 48 hours and oral antibiotics are given for 5 days after discharge from the hospital. The prosthesis cylinders are left partially inflated at the time of surgery. The cylinders are then completely deflated the day after surgery and left deflated as this fills the reservoirs and prevents the normal capsule from forming around a deflated reservoir. The device is not further activated until scrotal edema and pain have subsided. Most patients begin inflation and deflation of the device in the third or fourth week after surgery. In patients with prolonged scrotal edema or tenderness, this maneuver has been delayed indefinitely without adverse functional or cosmetic results.

The cylinders must remain deflated and the reservoir component totally inflated until the third or fourth week after surgery. This helps prevent the normal capsule formation from hindering reservoir inflation and cylinder deflation when the prosthesis is operated, and helps prevent autoinflation caused by the capsule. Postoperative care and instructions should be discussed with and understood by the patient prior to surgery.

Release Bar Valve Instructions

To Inflate: Repeatedly squeeze the pump (Figure A) (located in the scrotum) to fill the penile cylinders with fluid from the reservoir, causing the penis to enlarge and become erect, thereby facilitating intercourse.

To Deflate: Place thumb and forefinger on pump, and move them up towards the narrow top of the pump until the protruding bars are felt. Position thumb and finger on the release bars above the pump. Place thumb on one bar and finger on the opposite bar (Figure B). Squeeze release bars with a firm and steady pressure. Continuous pressure is necessary. Gently squeezing the penis at the same time will help move fluid back into the reservoir.

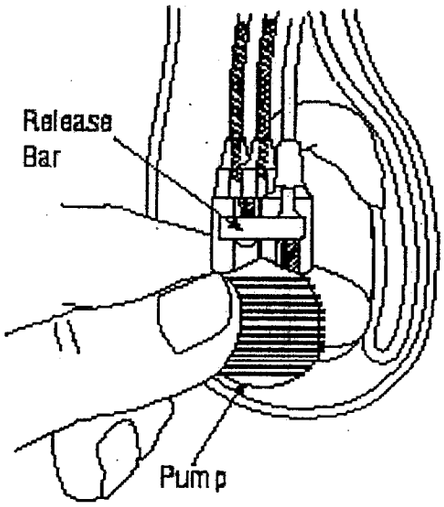


Figure 1

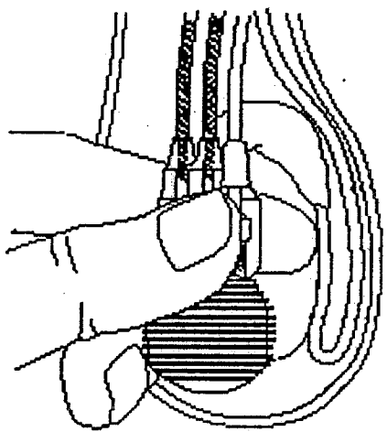


Figure 2

PRODUCT EVALUATION

Mentor requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any explanted components. For safe handling during shipment and upon receipt, Mentor requests that devices/components be decontaminated prior to shipment. This is requested even though Mentor will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If explantation is necessary, Mentor may analyze the explanted device, and the patient and physician may be asked to allow Mentor to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to the immediate attention of: Quality Assurance, Product Evaluations Department, Mentor, 1601 West River Road North, Minneapolis, MN 55411; Toll free (800) 338-7908 in USA, or outside USA call (612) 588-4685.

RETURNED GOODS POLICY

U.S. Customers

Authorization must be received from Mentor prior to the return of merchandise. Merchandise returned must have all manufacturers' seals intact and be received within 30 days from date of invoice to be eligible for full credit or replacement. Please contact the Mentor Urology Products Customer Service Department for details. To obtain a Return Authorization Number, call (800) 235-5731. Returned products may be subject to restocking charges. Mentor does not accept returns on Special Order Devices.

International Customers

Authorization for return of merchandise should be obtained from your respective Mentor dealer. Other conditions noted previously also apply.

LIFETIME REPLACEMENT POLICY

Mentor's replacement policy provides that the Alpha I Inflatable Penile Prosthesis or its components will be replaced by Mentor upon request of the purchaser for any reason. The replacement policy does not cover surgical or hospital costs, and is limited to replacement of the prosthesis or its components.

PRODUCT INFORMATION DISCLOSURE

Mentor excludes all warranties (except the Replacement Policy above), whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. Mentor shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by Mentor for any purpose. Mentor neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

PRODUCT ORDER INFORMATION

U.S. Customers

To order directly in the USA or for information on Special Order Devices, please contact the Mentor Urology Products Customer Service Department, 201 Mentor Drive, Santa Barbara, CA 93111, toll free telephone (800) 235-5731.

International Customers

For product information or to order directly, contact your local Mentor distributor or the International Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA. Telephone (805) 879-6000; FAX (805) 967-7108.

REFERENCES

Literature references are available upon request from:

Mentor
Literature Services Department

201 Mentor Drive
Santa Barbara, CA 93111
Toll free (800) 525-0245

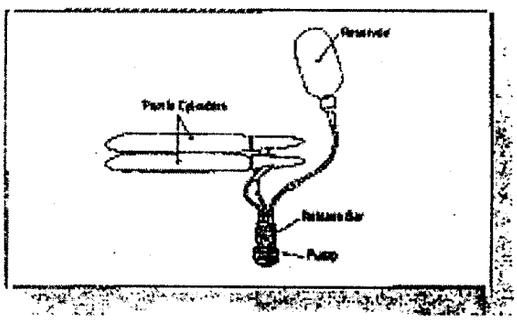
Covered by one or more of the following U.S. Patents: 4,566,446; 4,890,866; 5,851,176.

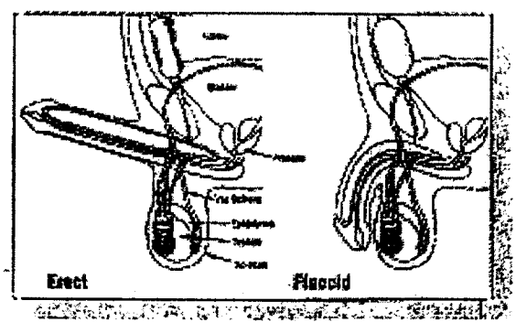
Patient Guide for Alpha 1 Inflatable Penile Implant

Note: The patient should read the sections titled "What to expect during recovery from implant surgery" and "Problems that may develop after surgery" prior to surgery for information on the potential risks of the Alpha I Inflatable Penile Implant.

INTRODUCTION

The Alpha I Inflatable Penile Implant is a self-contained fluid-filled system made from Bioflex® and silicone. Bioflex is a supple, yet durable, biopolymer material. There are four parts: two penile cylinders, a pump and a reservoir. Silicone tubing interconnects each part.





The Alpha I Inflatable Penile Implant offers a dependable method of restoring sexual function. It is the result of advanced engineering and medical research designed with the needs of its user in mind. It brings a new dimension to the reliability and control of the inflatable implant, offering new hope to the many sufferers of impotence.

For background information on how an erection occurs, causes of impotence, and the available treatment options, you can read "Impotence: You Can Do Something About It!" Additionally you should talk with your doctor if you have any questions.

IMPLANTING THE ALPHA 1 INFLATABLE PENILE IMPLANT

Once the device is implanted, it is entirely within the body and is not visible. The penis appears relaxed and normal.

The operation to implant any prostheses is considered major surgery. You may be fully anesthetized (puts you to sleep for the surgery), or you may be given a local anesthetic (numb the area where the surgery occurs). Surgical incisions will be made to give your doctor access to the corpus cavernosa, which are the two spaces in the penis, which fill with blood and produce an erection. The cylinders will be properly sized to fit you, and inserted into the

corpus cavernosa. Since you are being implanted with an inflatable device, the pump, which you will use to inflate the implant, will be placed in the scrotum and the fluid reservoir will be placed in the abdominal cavity. The implant is surgically placed into the genitalia through a small incision made slightly above the base of the penis or through an incision on the undersurface of the penis where it joins the scrotum. The surgery typically lasts between 30 minutes to 2 hours.

WHAT HAPPENS AFTER YOUR SURGERY?

After surgery, your doctor will deflate the implant, and tape your penis against the skin for a week or longer to promote healing. Your doctor may insert a catheter (hollow tube) into your penis to drain urine from your bladder. The catheter will be removed before you leave the hospital.

In a typical operation, you will be discharged from the hospital 1 to 3 days after the operation. Some pain medication may be necessary following your surgery. Your doctor may place you on antibiotics after surgery. Your doctor will detail the post-operative course of treatment.

WHAT TO EXPECT DURING RECOVERY FROM IMPLANT SURGERY

Placement of a penile implant requires an operation under anesthesia. Therefore, the risk and discomfort of this procedure is similar to that with any major surgery. The medication given to you, the surgical procedure, as well as your body's reaction to the implant may cause complications (problems).

The cylinders should remain deflated until the third or fourth week after surgery in order to help prevent autoinflation (inadvertent and unwanted inflation of the device). Additionally you should avoid wearing tight fitting underwear. This helps to prevent curving of your penis during healing. Anytime you have to void, retape your penis in the same straight position that it was in prior to untaping.

You may be asked to come in for a check-up at about 5-14 days after surgery, as well as have other appointments with your doctor during the recovery time to be sure you are healing properly. Check with your doctor as to when you can return to everyday activities, including intercourse.

Once you leave the hospital, you will be able to do everyday activities, those that you were able to do before your surgery (work, exercise, gardening), at the discretion of your doctor. Ask your doctor for instructions on bathing during the healing time.

Many doctors recommend that you wait four to six weeks before having intercourse. This time allows your incision site to heal. If you attempt intercourse before the incision has healed completely, you risk the possibility of infection, pain, or surgical complications.

During the recovery period and after, avoid activities that could cause trauma to the pelvic or

abdominal area, or device malfunctions. Always keep in mind that you have an implant. Examples of trauma that can cause injury or device malfunction may include a seat belt jolt from a car accident, being tackled in contact sports, or falling on ice. Trauma may damage the implant or surrounding tissues.

Take precautions to avoid trauma to your pelvic and abdominal areas such as might occur during contact sports, slipping on ice, etc.

You may experience discomfort, pain, and swelling at the operative site(s) during the early time after surgery and when you first use your implant. In most cases the pain goes away within a few weeks of surgery. However, if pain or swelling continues, see your doctor.

PROBLEMS THAT MAY DEVELOP AFTER SURGERY

Implant surgery carries the same types of risks as other surgical procedure, including infection and anesthesia complications (problems). Some other complications that may occur are discussed below.

Your implant can fail over time, and should not be considered a lifetime implant. If your implant must be removed because of a complication, the removal may leave scars inside your penis. This may also make implanting a new implant difficult. Implantation of a penile implant may destroy any remaining natural erectly capability, and may result in anatomical changes that can make some of the alternative therapies for impotence ineffective.

Infection

Infection can happen after any kind of surgery. Your doctor will work to lower your risk by giving you antibiotics before and after your operation and by irrigating (washing out) the surgical site with antibiotics during surgery.

Some conditions that may increase the risk of getting an infection are:

- diabetes
- spinal cord injury
- existing infection anywhere in your body, such as incision site or in your urinary tract.

Contact your doctor immediately if you notice any redness, swelling, and/or heat around the incision area or drainage from the incision. These symptoms may indicate an infection.

If you get an infection your doctor may treat it with antibiotics. If the infection cannot be treated successfully with antibiotics, your doctor may have to remove the implant.

Only 2.9% of patients in the clinical trial reported having an infection. Over half the patients

who experienced infection had their implant surgically removed.

Erosion
Erosion is when the tissue next to any part of the device is "worn away." Erosion involving the cylinders most often involves: the glans (the tip of the penis), the urethra (the tube inside the penis that carries urine out of the body), and the skin of the penis. The pump may erode through the skin of the scrotum, and the reservoir can erode into the bowel or bladder

Some conditions that may cause erosion include:
- Infection
- tissue damage
- pressure on the tissue
- misplacing cylinders, reservoir, or inflate/deflate pump
- improper sizing

Symptoms of erosion into the scrotum or penis may include:
- pain
- redness of skin
- changes in skin texture
- drainage
- tenderness in the operative areas
- being able to see the implant through the skin

Symptoms of erosion into the bladder may include:
- pain
- tenderness in bladder area
- change in your ability to urinate
- change in the color of urine

Contact your doctor immediately if you notice any pain, tenderness over the surgical area, change in skin texture, drainage, or if you can see the implant through your skin. These symptoms may indicate erosion. Failure to treat the erosion can make it worse and lead to infection and loss of tissue.

Your doctor must evaluate any possible erosion. Sometimes the tissue can be repaired and only part of the implant replaced. Other times the entire device must be removed.
Less than 1% of patients in the clinical trial experienced erosion of any part of the device.

Migration
Migration is the movement of one or both cylinders, pump, or reservoir within the body space where they were originally placed.

Conditions that may cause migration include:
- improperly-sized cylinders
- improper positioning of the reservoir or pump

- incorrect tubing length

Contact your doctor immediately if you notice any pain, tenderness over the surgical area, or failure of the implant. These symptoms may indicate migration. Failure to treat the migration can make it worse and may lead to erosion and loss of implant function.

Your doctor must evaluate any possible migration. Sometimes the implant can be repositioned. Other times parts of the device or the entire device must be removed.

Only 2.9% of the patients in the clinical trial had migration of device parts.

Malfunction
Malfunction, is a failure of the device to perform as intended according to how it was designed. In the clinical study, 4.4% of the patients had part of the implant malfunction (e.g., undesired inflation, excessive widening/bulging of the cylinder during inflation, fluid loss from the implant, and inability to inflate).

Conditions that can cause malfunction are:
- overpumping the system beyond what is necessary for an adequate erection to achieve penetration during intercourse can result in the malfunction of the pump
- trauma to the pelvic or abdominal areas
- rough or improper use of the device
- scar tissue formation or mechanical failure

Contact your doctor if the device fails to function properly. The device may not be malfunctioning, so your doctor may provide additional training on how to properly use the device. Device malfunction may necessitate surgery to restore device function, including possible device replacement.

Pain
It is normal to have some pain to your penis, scrotum, and around the incisions immediately after surgery. You may also have pain to your penis and scrotum when you are first using the device. In the study, 11% of the patients reported pain after surgery.

Some patients have had chronic (continuing) pain with no known medical cause. Sometimes these patients had their device removed because the pain would not go away. Chronic pain occurred in 3.2% of the study patients. Talk to your doctor if you are experiencing chronic pain.

Swelling
Swelling is when the tissue next to any part of the device is swollen. It is a normal part of postoperative recovery for you to have some swelling

Five percent of the study patients reported tissue swelling and 12.2% reported swelling of the scrotum.

If swelling continues after healing has occurred, see your doctor. Also, if swelling reoccurs, see your doctor, as this may be a symptom of infection.

To relieve the normal swelling which occurs during healing, your doctor may provide medication, or have you apply ice packs.

Trauma
Trauma (injury) to the hip or stomach area can cause damage to either the device or the surrounding tissue in your penis, scrotum or abdomen. This can cause the device to malfunction and could require surgery to replace it.

To decrease the likelihood of trauma:
- take precautions when walking on slippery surfaces, where you might slip and fall
- avoid contact sports where you might be tackled or hit in the hip or stomach area

If you suspect that you may have caused trauma to the device or it is malfunctioning, go see your doctor.

Dissatisfaction
In the study, over 99% of the patients achieved sufficient rigidity to achieve vaginal penetration. If you are dissatisfied with your device's performance, related to rigidity, go see your doctor, who may provide further education about the use of the device. In the clinical study, 2.9% of patients reported that they were unsatisfied with the device, regardless of its mechanical function.

The appearance of your penis and scrotum will be relatively unchanged after surgery. Your doctor will attempt to hide and reduce the scars from the incisions. You should have realistic expectations for the appearance of your erect penis. Your erect penis may be shorter after the surgery. This is to be expected, as the implant does not inflate the glans (the tip of the penis), as would normally occur when your penis is filled with blood. Talk with your doctor regarding this issue if you have questions.

Questions on Other Problems

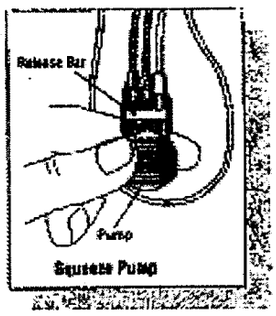
Please ask your doctor for explanations on any of the problems that you do not understand.

USING YOUR IMPLANT

The penile implant is designed to closely mimic the characteristics of a normal erection. Instead of the heart pumping blood into the penis, the scrotal pump, when squeezed repeatedly, transfers its fluid from the reservoir into the penile cylinders. As the cylinders fill, an erection develops which can be maintained as long as desired. By activating the release bar on the pump, the fluid in the cylinders will return to the reservoir where it is again stored. The penis then returns to its normal relaxed position.

To Simulate an Erection

To transfer the fluid to the cylinders, locate the pump in the scrotum. Squeeze the pump firmly a few times between the thumb and fingers until an erection is achieved.

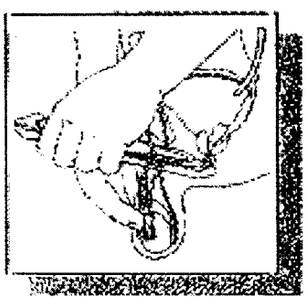


To Return to a Flaccid Slate

To return the fluid balance to the reservoir, follow the tip of the Pump as it narrows until the protruding bars are felt. Position thumb and finger on the release bars above the pump.

Place thumb on one bar and a finger on the opposite bar. Squeeze release bars with firm and steady pressure. Continuous pressure is necessary.

To achieve a flaccid state more quickly, squeeze the penis gently with the other hand while squeezing the release bar. Practice these inflate/deflate procedures in various positions: standing, seated, lying - until they become natural and easy.



If any problems are encountered during the use of this device, or any pain or discomfort is experienced, please contact your doctor immediately.

GLOSSARY

Antibiotics – drugs used to fight infection

Autoinflation - inadvertent and unwanted inflation of the device

Biopolymer – a plastic material that is designed to be implanted in the body

Catheter - hollow tube used to remove urine from the bladder.

Chronic pain – pain that continues beyond the normal recovery period.

Complication – an unwanted problem.

Corpus cavernosa – chambers in the penis that fill with blood during an erection.

Cylinder – a part of an inflatable penile implant. They are filled with fluid to give an erection. The cylinders are implanted in the penis.

Erosion - tissue next to any part of the device which is "worn away."

General anesthesia - puts you to sleep for the surgery.

Glans of the penis - the head of the penis.

Impotence - unable to get or keep an erection that is firm enough for sexual intercourse.

Local anesthesia – numbs the surgical area .

Malfunction - failure of the inflatable penile implant to perform as intended.

Migration - movement of one or both cylinders, pump, or reservoir within the body, from where they were originally placed.

Pump - a part of an inflatable penile implant. Transfers fluid between the reservoir and the cylinders. The pump is implanted in the scrotum.

Reservoir – a part of an inflatable penile implant. Holds the fluid when the penis is not erect. The reservoir is implanted in the abdomen.

Scrotum - the external pouch of skin and muscle containing the testes.

Swelling - when tissue next to any part of the device is swollen.

Trauma - injury

Urinary tract – the system in the human body which stores and gets rid of urine.

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