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Titan[®]

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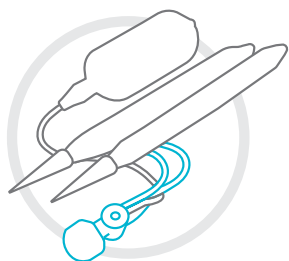
Tips & Tricks to Ensure Success

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Introduction and Disclaimer

Coloplast (Mentor) inflatable penile prosthesis (IPP) has been available since 1983. Over the almost four decades, the device has undergone many improvements and enhancements to facilitate both durability and patient satisfaction. What has resulted is a medical device that is among the least likely of all medical devices to require a revision operation.⁸ Nevertheless, occasionally challenges occur with both the device and the manner of implantation. Physicians and patients recognize difficulties with the device and contemplate a revision operation. This guide is designed to help the company's representatives provide guidance to the physician on appropriate responses in the face of perceived challenges. *The opinions of this guide are those of the author, Steven K. Wilson, who was compensated to write the publication.



IPP Pump Tips & Tricks to Ensure Success

Back Table Preparation

Pump compresses but does not “pop” during preparation (Titan Touch):

The Challenge: The pump valve is not properly lubricated or pumping is not forceful enough.

FIRST SOLUTION:

Squeeze harder on the bulb or rapidly compress the pump bulb and deflate several times. When it “pops,” you are OK to finish device preparation. Cycle several times after implanting the IPP to be sure of pump lubrication. After cycling, always press the pump bulb once to engage the valve so upon next usage, the first pump does not require a lot of pressure.

SECOND SOLUTION:

During device preparation, forcibly inject 20 cc's of sterile saline in the reservoir tubing of the pump and watch the pump “jump” or make a “pop” noise. If it does not jump, inject another 20 cc's of saline. This method of pump lubrication is a simple method for obtaining a properly lubricated valve. Again, cycle the IPP several times and pump the bulb once after full deflation.

Intraoperative Challenges (during surgical implantation)

Pump bulb is hard and cannot be activated (Titan Touch):

The Challenge: The pump valve was insufficiently lubricated during preparation. The pump must be manipulated until fluid is transferred upon pumping.

FIRST SOLUTION:

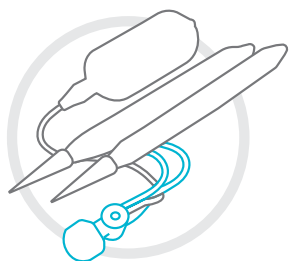
Ask the surgeon to make certain all rubber shod clamps have been removed from the tubing. Cycle the device a couple of times to make sure the pump is functioning properly.

SECOND SOLUTION:

Ask the surgeon to alternately squeeze pump and deflate valve until pump begins to work. Cycle the device a couple of times to make sure the pump is functioning properly.

THIRD SOLUTION:

Ask the surgeon to squeeze as hard as they can on pump bulb. Make sure they feel a pop and not just a soft depression of the pump bulb. Cycle the device a couple of times to make sure the pump is functioning properly.



IPP Pump Tips & Tricks to Ensure Success

Post-operative Patient Care

Pump bulb is hard and cannot be activated by the patient (Titan Touch):

The Challenge: This is the “Sticky Pump Syndrome.”¹ It is caused by lack of lubrication of the valve. If early in the postoperative course (perhaps, the first patient teaching visit), the reason may be insufficient initial preparation of the pump. If several months after implantation, it may be caused by lack of use of the implant by the patient for an extended time. Ask the patient if he suffered a medical condition that required discontinuation of sexual relations for an extended period of time.

VERY IMPORTANT:

After the prosthesis has been deflated, for each new inflation, the first pump may require more pressure than subsequent pumps. It is recommended after full deflation of the IPP to teach the patient to inflate one pump to make the next usage easier.

FIRST SOLUTION:

Using one hand, press both tubings where they enter the corpora in effect straightening the tubing angle of insertion. With the other hand pull downward on the pump and softly press the pump bulb. It should activate immediately and without excessive pressure. This solution, if done properly, straightens the tubing angle and will activate the pump with minimal discomfort to the patient according to its originator, Robert Valenzuela, MD.

SECOND SOLUTION:

Use two hands. One to stabilize and press the deflate button above pump bulb and the other to press the pump bulb. Rapidly squeeze the bulb (not particularly hard,) and while squeezing deflate area 10 times in succession. If it does not activate, press as hard as you can on the pump. It should activate, but the latter maneuver may be painful for the patient. If it is only 4-6 weeks since the surgery and you are unsuccessful, give the patient another 2 weeks, encouraging hot baths twice daily to decrease scrotal edema and inflammation around the pump. When the patient returns for their follow up visit, arrange for some oral sedation one hour in advance of the appointment (e.g. Valium®, Xanax® &/or NSAID.) At this return visit with the patient having less edema and sedated for some discomfort, institute the two solutions above. If unsuccessful at this visit, wait another two weeks and prescribe more Sitz baths for optimum edema resolution.

THIRD SOLUTION:

Use conscious sedation or anesthesia and press hard on the pump. Cycle the pump several times after you have “popped” the valve.

VERY IMPORTANT:

All patients with a “sticky” pump should be advised to cycle their device daily to prevent recurrence. They should also be instructed to pump the device once after full deflation to ensure the valve has transferred after usage.

*"Dilution is
the solution to
pollution."⁴*

Post-operative Patient Care

Pump makes noise when squeezed but device does not inflate (Titan & Titan Touch):

The Challenge: The IPP device has a leak. It has lost fluid and there is air in the system creating turbulence that is audible upon pumping the device.

THE SOLUTION:

Revision surgery will be necessary. There is a leak in the prosthesis. To help the physician plan his surgery, inquire the time frame since the implantation. If early (several months) from the implantation, it will be a leak at the connection or an inadvertent needle puncture. If considerable time has passed (years) it usually will be a break in the tubing where it exits the pump.

Pump depresses but does not spring back (Titan & Titan Touch):

The Challenge: Most of the saline has leaked out of the system through a small opening ... usually a needle puncture of a cylinder. Needle puncture takes a long time to exhaust the system of fluid because the puncture only leaks when the prosthesis is inflated. The patient will typically give the history of progressive diminution of the quality of his erection which may present itself many months or even a few years after the surgery.

THE SOLUTION:

Revision surgery will be necessary to get the device working again. It is optimum to plan replacement of all components accompanied by washout with antiseptic solutions to minimize the risk of subsequent device infection (see below).

VERY IMPORTANT:

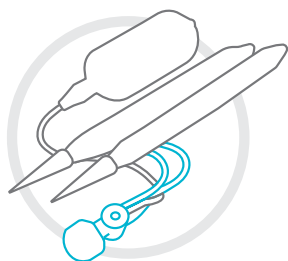
Device infections after revision operations occur much more often than with the original implantation. It is best to remove and replace all components – not just the broken one – because leaving components from the original implantation behind increases the possibility of subsequent infection.²

VERY IMPORTANT:

This increased incidence of revision infection can also be significantly diminished (from 10% to <2%) by washing out the implant spaces. Before replacing the components, the surgeon irrigates the implant spaces with antiseptic solutions.³ This lavage of the implant spaces cleanses the implant spaces removing bacteria and their products (biofilm) left behind from the original implantation. Dr. Wilson's textbook quotes Dr. Mulcahy indicating, "**Dilution is the solution to pollution.**"⁴

IMPORTANT VARIANCE:

While the literature proves the importance of removing all components during revisions for reasons other than infection, many physicians prefer to disconnect the old reservoir but leave it indwelling in the patient. This avoids the possibility of complications removing reservoirs whose location may be challenging ... including those placed by a different surgeon. Physicians "drain & retain" the old reservoir, placing a new, sterile reservoir in a different location. This practice has been verified to be safe by literature support.⁵ In the rare occasion that the old reservoir causes mischief in the future, it can be removed without impacting the function of the new system.⁶



IPP Pump Tips & Tricks to Ensure Success

Post-operative Patient Care

Malposition of pump: migration into the groin (“high riding”) or perineum (Titan & Titan Touch):

The Challenge: The perineal migration is caused by postoperative edema &/or hematoma in pumps placed through a scrotal incision. The “high riding pump” is more frequent with infrapubic or subcoronal placed pumps.

THE SOLUTION:

Patience is counseled; it may take 3 months but eventually the pump will be usable. During the 3 months the patient may improve the position by daily attempts to modify the pump location – pulling on the pump. The important advantage of conservative watchful waiting is that the pump will have stimulated a capsule. If revision surgery is necessary, this tough fibrous membrane will be useful in positioning the pump in a new location that is easy to find and use.

VERY IMPORTANT:

There is very little that can happen post-operatively to require a rapid or emergency return to the operating room. The only two conditions are wound dehiscence with drainage of old blood clots or pus. These conditions can be treated with 3 months of observation.

- Cylinder malposition
- Reservoir hernia
- Visible reservoir
- Autoinflation
- Pump is perineal, or high riding – difficult to find &/or use
- Corporal perforation – proximal or distal

The physician should be counseled to wait 3 months for the capsule to be fully formed as the capsule is very useful for repairing components in improper places. In addition, with “tincture of time,” many patients will not be so concerned about the less than perfect result and a revision operation will not be necessary.



Suggestions for Optimum Outcomes

It is a good idea for the patient to cycle his device daily in order to keep the pump lubricated and avoid sticky pump syndrome. He doesn't have to cycle completely; just pump it a few times, deflate it and then pump it one time again. This ensures daily movement of the valve in the pump. It is not necessary to press hard to deflate or to keep your finger on the deflate valve for more than a single push. If the patient is having difficulty depressing the deflate valve, reverse the thumb and forefinger on the deflate portion. Humans have much more power in their thumb than forefinger and elderly patients may not be developing enough pressure with their fingers.

It has also been shown in the literature that the Titan will expand and possibly lengthen & widen the penis if the patient inflates daily for 1-3 hours.⁷ Patients will confirm this expansion as the number of pumps to full inflation will increase over time.

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- 6 Rajpurkar A, Bianco F, Al Omar O, et al. Fate of the retained reservoir after placement of 3-piece penile prosthesis. *J Urol* 2002; 172: 662-664.
- 7 Henry G, Carrión R, Jennermann C, Wang R. Prospective evaluation of postoperative penile rehabilitation: penile length/firth maintenance following Coloplast Titan inflatable penile prosthesis. *J Sex Med* 2015; 12: 1298-304.
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TITAN, TITAN OTR AND TITAN TOUCH BRIEF STATEMENT

Indications: The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are candidates for implantation of a penile prosthesis.

Contraindications: The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients with an active infection present anywhere in the body, especially urinary tract or genital infection; with a documented sensitivity to silicone; with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder; or, 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.

Precautions: Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible.

Potential Complications: Potential complications include scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us.

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