Titan® Touch Inflatable Penile Prosthesis Device Preparation

Cylinders and Pump Preparation

Prior to handling the device, clamp the cylinder tubing with a single click, using a rubber shod mosquito clamp. Pour soaking solution of choice into the packaging tray over the device, pump, and tubing.

**STEP 1** Connect the 60 cc syringe of saline solution to the pump’s black tubing. Ensure that a tight connection is made.

**STEP 2** Hold the cylinders with one hand and unclamp the cylinder tubing, and push 20 cc’s of saline into the pump.

**STEP 3** With both hands, tightly squeeze pump bulb to release the valve bulb to close the deflate valve. A noticeable “pop” will be heard or felt.

**STEP 4** Hold the cylinders with one hand an squeeze the cylinders to expel air. Once the air is removed, re-clamp the cylinder tubing with a rubber shod mosquito clamp, one click only.

**STEP 5** Disconnect the 60 cc syringe of saline solution from the pump’s black tubing and expell all air from the syringe. Re-connect the 60 cc syringe of saline solution to the pump’s black tubing, ensure that a tight connection is made.

**STEP 6** Squeeze pump bulb to pull the saline solution into the pump and cylinders.

**STEP 7** While holding the cylinder’s proximal ends up, gently depress the deflate button once. (Note the deflate button does not need to be continuously pressed to open deflate valve.)

**STEP 8** Aspirate all saline solution from cylinders using syringe. Clamp the tube using a shodded mosquito clamp, single click into the pump tubing.

**STEP 9** Place cylinders and pump into soaking solution until ready to implant.

CL Reservoir Preparation

Prior to handling the reservoir, clamp the reservoir tubing with a single click using a rubber shod mosquito clamp. Pour soaking solution of choice into the packaging tray.

**STEP 1** Connect a 60 cc syringe to the tubing and fill with 15 cc’s of saline.

**STEP 2** Using the syringe, aspirate all the air and saline from the reservoir. Once completed, clamp the tubing with rubber shod mosquito clamp, single click.

**STEP 3** Ensure Lock-out valve is facing up and pull laterally on the lobes to allow dorsal lobe to flatten and crease at the top of the reservoir.

**STEP 4** Place the prepared reservoir into soaking solution until ready to implant.
Titan® OTR Inflatable Penile Prosthesis Device Preparation

Cylinders and Pump Preparation
Prior to handling the device, clamp the cylinder tubing with a single click, using a rubber shod mosquito clamp. Pour soaking solution of choice into the packaging tray over the device, pump, and tubing.

**STEP 1** Connect the 60 cc syringe of saline solution to the pump’s black tubing. Ensure that a tight connection is made.

**STEP 2** Hold the cylinders with one hand and unclamp the cylinder tubing, and push 20cc’s of saline into the pump.

**STEP 3** With both hands, tightly squeeze pump bulb to release the valve bulb to close the deflate valve. A noticeable "pop" will be heard or felt.

**STEP 4** Hold the cylinders with one hand and squeeze the cylinders to expel air. Once the air is removed, re-clamp the cylinder tubing with a rubber shod mosquito clamp, one click only.

**STEP 5** Disconnect the 60 cc syringe of saline solution from the pump’s black tubing and expell all air from the syringe. Re-connect the 60 cc syringe of saline solution to the pump’s black tubing, ensure that a tight connection is made.

**STEP 6** Squeeze pump bulb to pull the saline solution into the pump and cylinders.

**STEP 7** While holding the cylinder’s proximal ends up, gently depress the deflate the Touch Pads once. (Note the deflate Touch Pads do not need to be continuously pressed to open deflate valve.)

**STEP 8** Aspirate all saline solution from cylinders using syringe. Clamp the tube using a shodded mosquito clamp, single click into the pump tubing.

**STEP 9** Place cylinders and pump into soaking solution until ready to implant.

CL Reservoir Preparation
Prior to handling the reservoir, clamp the reservoir tubing with a single click using a rubber shod mosquito clamp. Pour soaking solution of choice into the packaging tray.

**STEP 1** Connect a 60 cc syringe to the tubing and fill with 15 cc’s of saline.

**STEP 2** Using the syringe, aspirate all the air and saline from the reservoir. Once completed, clamp the tubing with rubber shod mosquito clamp, single click.

**STEP 3** Ensure Lock-out valve is facing up and pull laterally on the lobes to allow dorsal lobe to flatten and crease at the top of the reservoir.

**STEP 4** Place the prepared reservoir into soaking solution until ready to implant.
TITAN® BRIEF STATEMENT

Indications
The Titan family of 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 Titan device 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. 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 eliminates natural erections, as well as other related 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. The risks and benefits of implanting this device in patients with lupus, scleroderma, myasthenia gravis, or documented sensitivity to silicone should be carefully considered.

Precautions
A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits.

Potential Complications
Scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction/deflation, pain, difficulty with ejaculation, transient urinary retention, fever, migration, patient dissatisfaction, infection, hematoma wound leakage, bleeding, delayed wound healing, phimosis, sensory loss cylinder aneurysm, fibrous capsule formation, over/under inflation, erosion, scrotal erythema, genital change, inguinal hernia

See the device manual for detailed information regarding the implant procedure, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Coloplast Corp. at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

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