

# PROACT™

Adjustable Continence Therapy for Men



## Implant Manual

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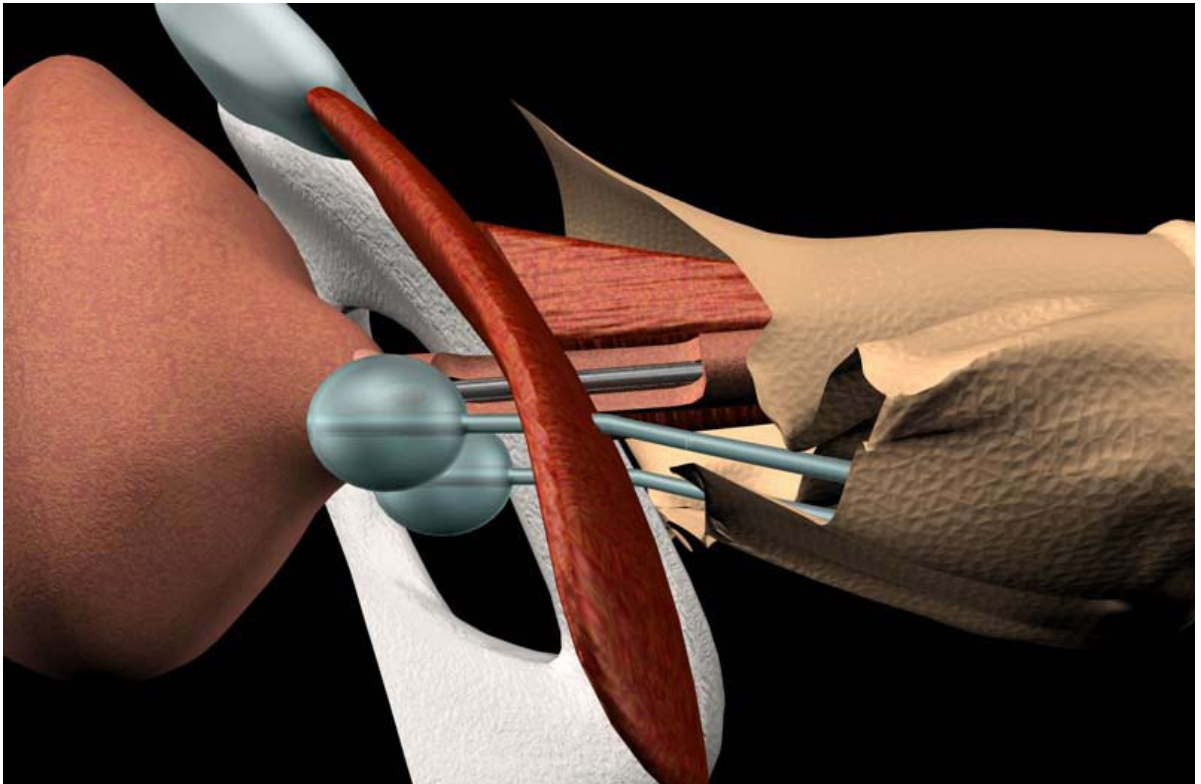
## Section 1 – Patient Selection

### Indications

The ProACT system is a permanent implant designed for the correction of Stress Urinary Incontinence in male patients. It is specifically intended for use in male post-prostatectomy or post-TURP patients suffering from any level of urinary stress incontinence with or without previous surgical treatment for incontinence.

### Patient Selection

- Patients with pharmaceutically controlled detrusor overactivity may be implanted.
- Patients who have undergone prior radiotherapy may be included at the surgeon's discretion; clinical outcomes tend to not be as good as those of non-irradiated patients.
- Patients with a neobladder or who have undergone prior radiation therapy should be counseled about potentially lower success rates in this patient group.



*ProACT*

## Contraindications

- Patients with active systemic or urinary tract infections
- Patients with incontinence due to detrusor instability
- Patients with reduced bladder compliance
- Patients with significant residual volume (>100ml after voiding).
- Patients who have received, are presently receiving or plan to receive radiotherapy.
- Patients suspected of having bladder cancer
- Patients with unsuccessfully treated bladder stones
- Patients with hemophilia or bleeding disorders

**Note:** Balloons and tubing are latex-free, so there is no risk for patients who have a latex allergy.

## Section 2 - Cleaning and Sterilizing the Instruments

Uromedica has developed a set of specific tools to be used when implanting the ProACT balloons. The Uromedica Tissue Expanding Device, trocars and u-sheath are supplied NONSTERILE. These instruments must be cleaned and sterilized prior to use. Also when cleaning, inspect the instruments (especially the TED) for any damage from previous use, particularly to the tip of the instrument.



*Instruments top to bottom: Tissue Expansion Device (TED), sharp trocar, blunt trocar, u-channel sheath*

## Instrument Cleaning and Sterilization

Follow your facility's suggested cleaning and sterilization guidelines, or use the suggested cleaning and sterilization method below:

Cleaning:

1. Soak the instruments in an enzymatic detergent solution, as recommended by the solution manufacturer, to reduce blood, protein and mucous from the instrument.
2. After soaking, rinse thoroughly under running water.
3. Clean the instruments with a neutral pH cleaning solution and a non-abrasive brush. Thoroughly clean all passages of the instruments.
4. Thoroughly rinse the instruments with running water at high pressure.
5. Lubricate the TED with a commercial water-based lubricant in the handle and on the tip, according to standard hospital procedures.

Sterilization:

Steam Sterilization: Pack and steam sterilize the instruments using a pre-vacuum cycle at 132° - 135°C (275°F) for a minimum of three [3] minutes.

## Section 3 - Operating Room Set-up Requirements

### ProACT System

ProACT single-use patient pack (item # 800018-01 – 12cm) or (item # 800018-02 - 14cm), which includes:

- Two (2) ProACT devices pre-mounted on a pushwire
- One (1) 23 gauge, non-coring needle
- One (1) syringe
- One instructions for use insert
- One product label set

**Note:** Typically, there is no need for a back-up set of ProACT devices, but some surgeons like to have a single device pack on hand just in case.



*ACT and ProACT systems differ in length of tubing; otherwise they are the same.*

### Required Equipment

- C-Arm fluoroscopy, sterile cover
- Lead aprons
- Cystoscopy set-up (camera, light source etc.)

### Required Instruments (all sterile)

- Rigid cystoscope
- Regular surgical instrument set
- No. 10 blade and handle
- Debakey forceps
- Rubber shod plain forceps
- Adson forceps
- Cairns tissue forceps
- McIndoe/Metzenbaum scissors
- Dressing scissors
- 7" needleholder

### ProACT Implant tools:

- U-shaped sheath with a sharp trocar (item # 750009)
- Blunt trocar (item # 750022)
- Tissue Expansion Device or TED (item # 750029)



### Accessories

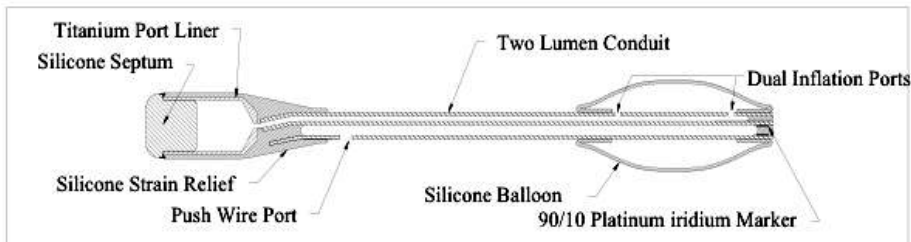
- A Foley catheter to use after the procedure
- Sterile lubricant
- Jug
- Two small bowls
- Two kidney dishes
- Bladder syringe
- 23 gauge non-coring or Huber needle and syringe (10 ml, 20 ml)
- One bag of saline (for cystoscopy irrigation) Solution A
- Contrast and sterile water for filling of the balloons Solution B (see table)
- 200 mls of 0.9% saline for injection with 240 mg Gentomycin for soaking devices (in kidney dish) Solution C
- 250 mls normal saline with 50-100 mls of contrast. 200 mls needed for visualization of bladder and 50 mls for urethrogram. Solution D
- Razor
- Povidone Iodine
- 3/0 Vicryl
- 4/0 Skin suture
- 4x4 sponges, swabs

**Note:** Some OR staff prefer to label the containers to indicate the contents.

## Section 4 - Additional Operating Room Instructions

### Prepare Surgical Gloves

If glove powder, dust or lint enters ProACT tubing, the particles may block the lumen of the ProACT device. Since silicone components actively attract dust and lint, all surgical gloves must be rinsed free of powder and lint before they are used to handle the devices. Position splash basins so surgeons can conveniently clean gloves during the surgical implant procedure.



*ACT/ProACT device*

### Antibiotics

The surgical setup should include a broad-spectrum antibiotic for irrigation (e.g. Gentomycin). The antibiotic solution and the filling solution must be kept separate from each other.

### Assemble Instruments Before Use

It is suggested that the OR staff to try to insert the TED and trocars into the u-channel sheath prior to the surgery (in the sterile field) to ensure that none of the instruments are damaged. The Tissue Expanding Device and the trocars are all intended to lock/unlock into the u-shaped channel sheath.

### Filling Solutions

The fluid used to fill ProACT implants must be sterile and completely free of particulate matter that could clog its valves. The solution must also be isotonic to minimize the transfer of fluid across the silicone tubing and balloons. If contrast media is preferred, one of the tested solutions listed in the following chart may be used. ***Do not use sterile saline or lactated Ringer's solution to dilute the contrast solutions.***

***If the patient is allergic to contrast solutions, normal saline can also be used as isotonic filling solution (in which case the radiopaque marker at the tip of the device would be the lone landmark on the fluoroscopic image).***

### Mixing Table for Isotonic Fluids (Balloon Filling)

Contrast Medium	Amount/ml	+	Sterile H <sub>2</sub> O/ml
Cysto-Conray	8	+	17
Cysto-Conray II	19	+	6
Cystografin 14%	13	+	12
Dip Conray 30%	12	+	13
Hypaque 25%	11	+	14
Iomeron 150	25	+	0
Iomeron 200	19	+	6
Iomeron 250	18	+	7
Iomeron 300	16	+	9
Iomeron 350	14	+	11
Iomeron 400	13	+	12
Isopaque Cysto	17	+	8
Isovue 200	19	+	6
Isovue 250	15	+	10
Isovue 300	14	+	11
Isovue 370	12	+	13
Omnipaque 140	23	+	2
Omnipaque 180	19	+	6
Omnipaque 210	17	+	8
Omnipaque 240	16	+	9
Omnipaque 300	13	+	12
Omnipaque 350	11	+	14
Solutrast 200	18	+	7
Telebrix 12	13	+	12
Ultravist 150	23	+	2
Ultravist 240	17	+	8
Ultravist 300	14	+	11
Ultravist 370	12	+	13
Visipaque 150	25	+	0
Visipaque 270	25	+	0
Visipaque 320	25	+	0

Note: Isovue (iopamidol) is also sold under the brand name "Solutrast"

## Selection of Implants

- 12 cm implants (800018-01) are mostly used with patients who are incontinent after TURP (balloon placement at the apex of the prostatic remnant).
- 14 cm implants (800018-02) are typically used in patients who are incontinent after Radical Prostatectomy (balloon placement at the location of the removed prostate).

### *TIP*

Use caution when removing the plastic lid from the tray. Occasionally balloons will stick to the lid and can fall outside of the sterile field.

## Implant Preparation (priming devices)

- Fill balloons through port with about 2 ml contrast/saline (**Solution B**) using a 23 gauge non-coring or Huber needle. Hold the syringe with the plunger pointing towards the ceiling and withdraw the solution as well as any air bubbles. Do this until balloon collapses and three “wings” form in the balloon.
- Remove the needle from the port and place the implant in the antibiotic solution **Solution C**.

## Cautions

- At implant, 1.0 -1.5ml of solution is added to each balloon, and more solution may be added during adjustments. However, **total volume should not exceed 8 ml**.
- Use caution with surgical sutures and staples from previous procedures, since these can damage the implant.
- Use the correct isotonic mixture of sterile water and contrast fluid (Solution B) to fill the balloons. **Do not use sterile saline or lactated Ringer’s solution to dilute the contrast solutions.**

If incorrect mix is used, liquid may disappear as a result of osmosis (hypertonicity) Alternatively, the balloon may attract fluids and will increase in size (hypotonicity).

## Contact Uromedica

Please notify your ProACT Sales Representative if you encounter problems with ProACT, especially if an explant is required. Please complete the Field Experience Report (FER), which your ProACT Sales Representative will supply and also ensure that the explant is returned for analysis. Based on the analysis a replacement device may be provided free of charge.

## Section 5 -ProACT Implantation

### Preparing the Patient

- Start oral antibiotic therapy with gyrase inhibitor (e.g. ciproflavin 500 mg) during anesthesia.
- Position patient in lithotomy position.
- Shave and prep groin and perineal area with an iodophor (if the patient is not allergic) or equivalent surgical preparation.
- Drape.
- Perform cystourethroscopy. Drain bladder and fill with 100-200 ml of contrast/saline mix **Solution D**. Cystoscope stays in position during procedure to visualize and palpate the urethra and to serve as landmark indicating the bladder neck.

### Selecting Anesthesia

Physicians and anesthesiologists should use their best judgment regarding anesthesia. However, here are some considerations:

- Many physicians prefer spinal or general anesthesia.
- If a spinal or general anesthetic is used instead of a local anesthetic, then 20cc of 0.9% saline may be infiltrated along the path of the dilator up to the tip of the bladder neck on both sides. The addition of the fluid (whether local anesthetic or normal saline) will assist in separating the tissue layers for easier dilation.

*Note: Some physicians create pockets for the ports before placing the balloons. See p. 14 for details.*

### Creating Path with Trocar

- Make a 3-4 cm long transverse perineal incision (or two 1 cm long incisions on either side of the midline), posterior to the base of the scrotum, immediately posterior to the urethra.
- Metzenbaum/McIndoe scissors can be used to dissect adipose tissue and muscle layers on each side of the midline, creating a channel or path for each balloon. Avoid making the channels too wide, since this can increase the likelihood of balloon migration.
- The implantation set (trocar inserted and locked in the u-channel sheath) is guided under fluoroscopic control through the incision. Identify the tip of the fascial triangle created between the urethra and interior pubic rami. Use the trocar in the u-channel sheath to push through the pelvic diaphragm at this point, creating a space for the implantation set to pass through (a pair of artery forceps can also be used).
- Under fluoroscopic control, use controlled force and a twisting motion to move the instrument set proximally towards the bladder neck. Ensure that the instrument does not get too medial (more than 5mm) or too close to the urethra (risk of perforation).
- Close to the bladder neck, replace the sharp trocar with the blunt trocar. Use lateral motion of the blunt trocar towards the urethra (containing the cystoscope) to assess correct anatomic plane (“tapping the urethra”).



***TIP***

**Difficult to Penetrate**

If scar tissue from an earlier surgery makes it difficult to penetrate the pelvic floor, use a twisting motion with the trocar, rather than a pushing motion. Use one hand for the twisting motion and use the other hand as “brake.” Hydro-dissection could also be tried. Use a needle and syringe with saline or lidocaine w/adrenaline and progress the needle while instilling 20cc of fluid each side.

***TIP***

**If Trocar Entry is Too Lateral to Urethra**

If the trocar entry is too lateral to the urethra, it needs to be repositioned. Instead of angling the fully inserted trocar tip toward the bladder neck, which moves the distal end of the trocar outward, withdraw it and create a new channel that is closer to the urethra. Creating a new channel assures that the tip and full length of the u-channel sheath are in alignment with the urethra and not at an angle to it. Misalignment of the balloon may cause wear leakage, because the balloon may rub against the tubing. Angling the trocar also enlarges the channel so the balloon and tubing may slip from their intended position and become misaligned.

## Enlarge Space with TED

- After reaching the preferred location, remove the trocar, but leave the u-channel sheath and push the u-channel sheath proximally to occupy the space initially occupied by the trocar tip.
- Insert the Tissue Expansion Device (TED) and create a space for the balloon at the bladder neck. This space will allow the balloon to expand, which will help anchor the implant.
- Ensure that the dilator never opens towards urethra (right side: only 12, 3 and 6 o'clock positions, left side: only 12, 9 and 6 o'clock positions).
- Remove the TED and check that no fluid is coming down the u-channel. This would indicate bladder perforation.
- Using the TED is especially helpful if the patient has a great deal of scar tissue.

## Insert Balloon

- Lubricate the u-channel. Remove the first implant from the antibiotic solution and ensure that the pushwire is fully pushed into the balloon.
- Hold the implant like a dart and slide the balloon down the u-channel with one of the wings in the six o'clock position.
- Push on the pushwire until the balloon reaches the bladder neck.
- Check the placement of the radiopaque marker at the end of the balloon with fluoroscopy.
- Pull the sheath back about 2 cm to allow the balloon to expand evenly. Be sure the balloon is not pulled back as well. Use a 23 gauge non-coring needle and syringe to inject 0.5-1.0 ml of the contrast and sterile water mixture through the port under fluoroscopic control. Leave the pushwire in place.
- Repeat the procedure at the contralateral side.



### **TIP**

#### **If the balloon isn't circular on x-ray**

Sometimes the balloon may not appear perfectly round. Usually the balloon shape will become spherical with time as scar tissue adjusts to the balloon. However, if the balloon has an hourglass shape, it may not be completely through the pelvic floor. In this case, remove the balloon and try to advance the trocar a little further, try placing the balloon again, and recheck its shape.



*Retrograde urethrogram showing co-aptation of urethra*

### **Check Balloon Position**

- Because of the patient's position during surgery, the fluoroscopic image of balloon placement is only two-dimensional. Consequently, it's possible to see if one balloon is higher or lower on a horizontal plane, but it is difficult to see if the balloons are equally anterior/shallow or posterior/deep (i.e. in the same plane). Good clinical outcomes can be achieved if one balloon is slightly higher. However, outcomes will be affected if one balloon is more anterior and the other balloon is more posterior.

Placement at the urethrovesical junction can be checked in the following ways:

- Use the cystoscope to observe the impact of the balloons on the urethra. Typically, the urethra will appear closed (or at least narrowed).
- When the balloons are placed correctly, they will both move on the fluoroscopic image. To check balloon placement, pull the cystoscope back 1 - 1.5 cm and then push it forward 1 - 1.5 cm to see if the balloons move a little as well. When the balloons are placed correctly, one will notice a flattening of the side of the balloon which is facing the urethra/cystoscope.
- Check the urethral closure effect with a retrograde Urethrogram (you want to observe an obstructive effect).
- If the position of one of the balloons is not correct, empty the balloon, remove the device, soak in antibiotics and create a new track or re-dilate the existing track and place the balloon again.

- If the location is correct, remove the pushwires from both ProACT devices after balloon inflation. Hold the balloon while pulling the push wire so as not to change the balloon position.
- Take a fluoroscopic image of the balloon placement for the patient file.

### Add Contrast Fluid and Check Bladder and Urethra

- When the balloons are in the right location, add an additional 0.5 ml of contrast/saline mix (for a total of no more than 1.0-1.5 ml in each balloon).
- Check the inside of the bladder and urethra for potential injury, using the cystoscope.

### Place Ports

- Using an artery forceps, create a pocket passing from the initial incision into each postero-lateral wall of the scrotum in order to place the ports.
- Place the ports so they will cause no discomfort to the patient but can still be easily accessed for further adjustments.
- It is advisable to use rubber shod forceps when handling the ports, so as not to damage the silicone coating.



*Placing the port in the scrotal area*

### Closing and Post-Operative Care

- Rinse with antibiotics before closing the incision.
- Close incision in two layers.
- Appropriately sized catheter is placed overnight.
- The patient should take oral antibiotics for the next three days.
- Schedule patient to return in 4-6 weeks for assessment and further filling (if needed).
- **Complete two copies of the ProACT Implant Card. The physician should keep one implant card with the patient's records. The other ProACT Implant Card should be given to the patient.**

<i>Patient Information</i>	<i>Implant Information</i>	<i>Balloon Adjustments</i>		
_____	_____	<b>Date</b>	<b>left (ml)</b>	<b>right (ml)</b>
_____	_____	<small>(typical adjustment 0.5-1.0 ml)</small>		
Last Name	Implantation date	Initial: _____	_____	_____
_____	_____	1. Adjust. _____	_____	_____
First name	Hospital	2. Adjust. _____	_____	_____
_____	_____	3. Adjust. _____	_____	_____
D.O.B.	_____	4. Adjust. _____	_____	_____
_____	_____	5. Adjust. _____	_____	_____
Address	_____	6. Adjust. _____	_____	_____
_____	_____	7. Adjust. _____	_____	_____
City, Post code	Physician	Contrast : _____ ml	_____ ml	sterile water
_____	_____			
Tel Nr	Tel. Nr.			

*ProACT Implant Card provided by your ProACT Sales Representative.*

## ProACT Implantation in Patients after TURP

TURP patients present several differences from the Radical Prostatectomy patients, not the least being the presence of the prostatic remnant:

- TURP patients typically have no scar tissue (no need to use the TED)
- In TURP patients, the x-ray provides less support, as it does not visualize the size nor shape of the prostatic remnant.

Follow the same procedure as for radical prostatectomy patients, except:

- In these cases, the balloon is placed at the apex of the prostatic remnant.
- Prior to the procedure one should review a TRUS to fully understand the anatomy.
- Prior to making the first incision, retract the cystoscope until it is at the level of the verumontanum, which will serve as the landmark for placement of the balloons. Take a fluoro shot of this location and move this to the spare screen. This will serve as the benchmark during the procedure.
- In these cases, a 12 cm implant is typically used.

## Section 6 – Adjustments (Increases in Balloon Volume)

### 0-4 Weeks Post-op

- 1.0 to 1.5 cc of fluid were added to each balloon at implant.
- To avoid device migration, allow a pseudo capsule to form. **Do not perform adjustments during first 4 weeks.**
- Should patient become obstructed, reduce balloon fluid volume.

## Initial Adjustment at 4-6 weeks

- Adjustments are often done without anesthesia. If needed, apply EMLA<sup>®</sup> cream 20 minutes prior to adjustments or use freezing spray.
- Use a 23 gauge non-coring needle for adjustments, because a smaller gauge needle could pass through the port and puncture the tubing, causing a leak.
- Some physicians find it helpful to use a smaller size syringe (1 or 2 ml) for adjustments as the gradation makes it easier to measure the quantities more precisely.
- Use the same mix of contrast solution and sterile water for the adjustment as was used for the initial filling.
- If the patient experiences discomfort at filling, reduce the amount of the intended adjustment (e.g. 0.25 -0.5 cc instead of 1.0 cc).
- Do a visual stress test after every adjustment. If patient cannot void after the adjustment, remove a small quantity of the contrast solution.

### TIP

When a non-coring needle is not available, one can also use a Becton Dickinson 23 gauge Thin Wall needle (BD#305194). This is known as a general use “regular bevel needle.” It is also possible to use a Terumo 23g x 1 1/4” Needle (Code: NN\*2332R).

## Subsequent Adjustments

- Several adjustments may be required.
- After every few adjustments, check to see that balloons are still in same location.
- If several adjustments do not result in any improvement, consider doing an imaging study (CT or MRI scan).
- **Never fill the balloons over 8 ml.**

When	Amount
1st adjustment 4-6 weeks post-implant	Up to 1 cc per balloon can be added Use same mixture of contrast and sterile water used at time of implant.
2nd adjustment 2-4 weeks after first adjustment	Up to 1 cc per balloon can be added
After 2 adjustments	Add 1.5 cc – 2 cc per adjustment until continence is achieved or patient is satisfied
<b>Maximum fill</b>	<b>8 cc</b>

## Troubleshooting for ProACT

**Note:** Please notify your ProACT Sales Representative or Uromedica directly <http://www.uromedica-inc.com/contact> if you encounter problems with ProACT, especially if an explant is required.

Situation	Suggestions for Resolution	Comments/Suggestions for Prevention
<b>ADJUSTMENT</b>		
The exact isotonic mixture in the balloons is unknown.	<ul style="list-style-type: none"> <li>Withdraw all fluid from balloon and note volume removed.</li> <li>Inject and remove contents repeatedly to remove contents.</li> <li>Mix new contrast from approved list printed on p. 8 and in the IFU.</li> <li>Determine desired volume to be inserted.</li> <li>Re-inflate with contrast.</li> <li>Note contrast/mixture/volume/date on ProACT Implant Card.</li> </ul>	<ul style="list-style-type: none"> <li>Thorough recordkeeping at implant or adjustments in nursing/surgical notes.</li> <li>Document the solution used on ProACT Implant Cards. Physician keeps one with patient records. The other is given to patient.</li> <li>If hospital has a contrast solution not on the Uromedica, Inc. approved list, contact Uromedica, Inc. for isotonic formula.</li> </ul>
Finding/accessing port for adjustment is painful.	<ul style="list-style-type: none"> <li>Numb the area around port with topical analgesic like lidocaine (e.g., EMLA® cream or freezing spray) prior to adjustment. If analgesic injection is used, care should be taken to avoid puncturing the port, septum or lumen of device.</li> <li>If port cannot be located, suggest imaging to determine location.</li> <li>Check skin for erythema or tenderness. Treat as necessary.</li> </ul>	<ul style="list-style-type: none"> <li>Ensure proper location at implant.</li> <li>Prepare patient for procedure.</li> <li>Hold port at the base (septum) to stabilize port for needle penetration and minimize patient pain.</li> </ul>
Patient complains about pain during adjustment	<ul style="list-style-type: none"> <li>Adjusted balloon may be stretching the capsule around the implant.</li> <li>If mild, consider analgesic.</li> <li>If severe, consider reducing balloon fill until pain disappears.</li> </ul>	Different patients have different tolerances to pain.
<b>ARTIFICIAL URINARY SPHINCTER in place.</b>	<ul style="list-style-type: none"> <li>If ProACT is being considered because of poor results with AUS, usual view is that there is no need to remove AUS.</li> <li>AUS (Cuff placed at bulbar urethra) should not interfere with ProACT placement.</li> <li>If there is infection or erosion, AUS should be removed first.</li> </ul>	<ul style="list-style-type: none"> <li>Check for notes in patient's records that document earlier implant and clinical success with AUS.</li> </ul>
<b>BALLOON</b>		
Balloons not spherical at implant.	<ul style="list-style-type: none"> <li>Ensure that balloon is located in proper position i.e. completely through the pelvic floor.</li> <li>Balloon shape will most likely become spherical with time as scar tissue adjusts to balloon.</li> <li>If damage to the balloon is suspected, an explant may be in order.</li> </ul>	<ul style="list-style-type: none"> <li>Balloons need not be spherical at implant to achieve continence. Scar tissue will distort the shape of the balloon.</li> <li>Consider using the TED implantation tool.</li> </ul>
Balloons are not in proper location at implant.	<ul style="list-style-type: none"> <li>Remove balloons while in surgery.</li> <li>Dilate area once again, correcting angle of trocar from original placement.</li> <li>Insert TED and create a "pocket."</li> <li>Re-insert original balloon (if undamaged) and inflate.</li> <li>Repeat if necessary.</li> </ul>	<ul style="list-style-type: none"> <li>Fluoroscopy, cystoscopy and surgical experience will provide valuable information to the implanting physician.</li> <li><b>NOTE:</b> Consider delaying implant for 60 days if dilation becomes difficult or if repeated attempts to dilate may create too many "paths" in the endopelvic fascia, thus compromising muscle integrity and increasing the risk of migration.</li> </ul>
Balloon is difficult to insert.	<ul style="list-style-type: none"> <li>Use liberal quantity of lubricant in u-channel sheath.</li> <li>Pull balloon back out.</li> <li>Check to be sure pushwire is pushed to tip of balloon and not kinked.</li> <li>Re-insert.</li> <li>Twist the sheath either on the right or left. Gently push the sheath down when inserting the balloon again to create a little more space.</li> </ul>	<ul style="list-style-type: none"> <li>Before inserting, make sure pushwire is pushed to tip of balloon.</li> <li>Consider using the pushwire from the second balloon if the first pushwire is warped.</li> <li>Take care to ensure that the second wire can be used for both balloons.</li> </ul>

<b>BLEEDING</b>		
Excessive bleeding occurs as trocar is introduced.	<ul style="list-style-type: none"> <li>• If bleeding is within normal limits, continue with implant. Bleeding may diminish with implant in location.</li> <li>• Apply perineal pressure until bleeding stops.</li> <li>• Use electrocautery.</li> </ul>	<ul style="list-style-type: none"> <li>• Check for notes in patient's records that may alert to possible surgical complications.</li> <li>• Bleeding should not exceed 100 ml.</li> <li>• Patient on anticoagulant or with bleeding disorder will need to be monitored during procedure.</li> </ul>
<b>CONTRAST ALLERGY</b>	<ul style="list-style-type: none"> <li>• Repeatedly inject and remove fluid in balloon.</li> <li>• Inject 0.9% normal saline into balloons if allergic.</li> </ul>	<ul style="list-style-type: none"> <li>• If contrast causes an allergic reaction, 0.9% normal saline may be used in balloons. This will leave the radiopaque marker as the only part of the balloon visible under fluoroscopy.</li> <li>• Document the solution used on ACT Implant Cards. Physician keeps one with patient records. The other is given to patient.</li> </ul>
<b>INFECTION</b>		
Infection is noted at site of incision.	<ul style="list-style-type: none"> <li>• Examine wound and port site to determine if tissue has eroded.</li> <li>• If wound has dehisced, infection is likely to include device and may need to be explanted.</li> <li>• If port has eroded through the tissue, anesthetize and irrigate area with antibiotic solution. Re-suture in two layers.</li> <li>• Aggressive oral antibiotic regime per physician's order.</li> <li>• If port erosion through tissue has led to balloon migration, explant.</li> </ul>	<ul style="list-style-type: none"> <li>• Soak implant in antibiotic solution prior to implant.</li> <li>• Properly irrigate area at implant with antibiotic solution.</li> <li>• Remind patient of postoperative restrictions and care.</li> <li>• May want to use waterproof dressing.</li> <li>• Pre-operative Betadine® scrub and perioperative shave.</li> </ul>
Patient is suspected of urinary tract infection on the day of surgery	<ul style="list-style-type: none"> <li>• Perform urinalysis to determine results.</li> <li>• Postpone implant if positive.</li> </ul>	Note: Pre-operative urinalysis must be performed within 2 weeks prior to implant.
<b>LOSS OF CONTINENCE</b>		
Patient remains incontinent at initial or subsequent follow-up visits.	<ul style="list-style-type: none"> <li>• Once 4-6 week healing period has passed, adjustments may be made in 0.5 ml- 1.0 ml increments.</li> <li>• If the balloon volume after adjustments exceeds approximately 3.5-4.0 ml (women) and 4.5- 5.0 ml (men) without improvement, image the balloon to determine its location.</li> <li>• If balloon has migrated, consider explanting one or both devices.</li> <li>• Consider re-implant after healing.</li> <li>• Do not exceed maximum balloon filling level of 8 ml.</li> </ul>	<ul style="list-style-type: none"> <li>• Achieving continence may involve one or more postoperative adjustments that may be performed in an office setting.</li> <li>• Physicians are encouraged to proceed conservatively in adjustments to continence.</li> <li>• When physician reaches desired volume of adjustment into balloon, maintain pressure on syringe (to prevent balloon volume from returning to the syringe) while withdrawing needle from port.</li> </ul>
Patient was continent and is now incontinent.	<ul style="list-style-type: none"> <li>• Image balloons to determine location and filling.</li> <li>• If balloon has migrated or eroded through tissue, explant device.</li> <li>• Consider re-implant after healing.</li> <li>• If balloon is empty, refill with appropriate solution. If balloon empties again, it may be leaking and should be replaced.</li> </ul>	
Patient complains about worsening incontinence	<ul style="list-style-type: none"> <li>• Some patients will develop temporary de-novo OAB. If this is the case, consider a temporary course of anticholinergics.</li> <li>• Sometimes the worsening is in the patient's mind and it is more an issue of the expected improvement taking longer than desired.</li> <li>• Explain nature of Adjustable Continence Therapy and continue with adjustments.</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure that patient understands that improvement is not immediate and that improvement may only be after several balloon adjustments.</li> </ul>

Patient not improving after several adjustments	<ul style="list-style-type: none"> <li>• Balloon placement may not be optimal.</li> <li>• Consider doing a 3-D imaging study (CT, MRI or Ultrasound).</li> </ul>	<ul style="list-style-type: none"> <li>• During implant procedure, confirm that balloons are above the pelvic floor and at the urethral level.</li> <li>• Observe flattening of balloons against urethra with Fluoro, or observe co-aptation of urethra with cystoscopy.</li> </ul>
Balloon volume appears reduced upon imaging	<ul style="list-style-type: none"> <li>• Verify initial balloon volume and changes via clinic notes.</li> <li>• Withdraw fluid from balloon and note any difference in volume from recorded amount.</li> <li>• Re-inflate balloon with appropriate volume using new mix of contrast and sterile water solution (see p 8).</li> <li>• Recheck balloon volume in two weeks.</li> <li>• If volume changes significantly, explant balloon and return it to distributor/Uromedica.</li> </ul>	<ul style="list-style-type: none"> <li>• Inspect balloons prior to implant.</li> <li>• Prime balloons prior to implant and note any abnormalities.</li> <li>• Note the presence of other material from previous procedures in surgical area.</li> <li>• Take x-ray image with device in place.</li> </ul>
<b>PERFORATION</b>	<ul style="list-style-type: none"> <li>• Confirm that perforation has occurred.</li> <li>• Cease implant on perforated side.</li> <li>• Continue with implant on contra-lateral side.</li> <li>• Reschedule implant after bladder wall/urethra have healed.</li> </ul>	<ul style="list-style-type: none"> <li>• Use of the blunt-tipped trocar when nearing the bladder may help prevent bladder perforation.</li> <li>• Maintain some distance from bladder neck to avoid postoperative urgency.</li> <li>• Maintain some distance to urethra when dilating space.</li> </ul>
Physician suspects bladder, urethral perforation.		
<b>SCAR TISSUE</b>	<ul style="list-style-type: none"> <li>• Using a controlled, twisting motion gently proceed parallel to the urethra toward bladder neck using the sharp trocar.</li> <li>• If polypropylene mesh material is present, penetrate with same motion.</li> <li>• If scar tissue is present at desired site of balloon placement, use of the TED may improve “pocket” creation.</li> <li>• Use fluoroscopic guidance or digital palpation.</li> </ul>	<ul style="list-style-type: none"> <li>• Proper assessment of patient history to determine previous procedures performed.</li> <li>• Patients may present in surgery with sling material already in the area.</li> <li>• Assess impact on ProACT device placement and procedure.</li> </ul>
Scar tissue making implantation difficult.		
<b>TORTUOUS URETHRA OR URETHRAL POCKETS</b>	<ul style="list-style-type: none"> <li>• Previously eroded injectables or traumatic catheterization can make urethra tortuous.</li> <li>• Perform several urethrograms to map area.</li> <li>• Keep implants away from areas of concern.</li> </ul>	<ul style="list-style-type: none"> <li>• Usually only seen at time of surgery.</li> <li>• Be aware that any history of failed injectables may present this complication.</li> </ul>
<b>VOIDING DIFFICULTY</b>	<ul style="list-style-type: none"> <li>• Leave catheter in place overnight.</li> <li>• Allow anesthesia to subside.</li> <li>• If still unable to void, consider removing 0.5 ml of fluid from each balloon.</li> </ul>	<ul style="list-style-type: none"> <li>• Edema is expected following surgery.</li> <li>• Retention may be addressed through adjustment.</li> </ul>
Patient cannot void after recovery.		
<b>DEVICE REMOVAL</b>	<ul style="list-style-type: none"> <li>• Disinfect the skin surface.</li> <li>• Administer local anesthesia.</li> <li>• Palpate the ports and find the tubing.</li> <li>• Make small incision through the skin of the perineum over the tubing.</li> <li>• Expose tubing and gently pull with a forceps, exposing the ports.</li> <li>• Use a syringe to drain the remaining fluid from the balloons so they deflate completely.</li> <li>• Once the balloons are emptied, pull on the ports to remove the devices from the patient.</li> <li>• Close the incisions.</li> </ul>	<ul style="list-style-type: none"> <li>• If the therapy was discontinued because of possible device defect or patient dissatisfaction with the clinical outcome, please pass the device to your ProACT Sales Representative so it can be returned for analysis.</li> <li>• In addition, please complete the Field Experience Report (FER), which your Sales Representative will supply.</li> </ul>
<b>DEVICE REPLACEMENT</b>	<ul style="list-style-type: none"> <li>• Before replacing a balloon, allow some time to pass so the balloon location (pocket) can “shrink”. This can be done by deflating the balloons 6-8 weeks prior to removal and re-implantation.</li> </ul>	<ul style="list-style-type: none"> <li>• Alternatively, the balloons can be removed in an initial procedure and the patient can return after 6-8 weeks for the re-implantation. However, this approach has the disadvantage of requiring two procedures.</li> </ul>

## **Section 8 - Product List**

### **ProACT**

800018-01 12 CM Patient Pack

800018-02 14 CM Patient Pack

800022-01 14 CM Patient Pack (Single)

800022-02 14 CM Patient Pack (Single)

### **Instruments**

750009 IIS (Sharp Trocar)

750022 Blunt (Trocar)

750029 TED (Tissue Expansion Device)

750033 TED Replacement for removable jaw (for TED II)

750034 TED II (Tissue Expansion Device with removable Jaw for easy cleaning)



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