



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

## Horizon Scanning Technology Prioritising Summaries

### ProACT™ Therapy for male stress urinary incontinence

September 2006



**ASERNIPs**

**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
College of Surgeons**



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This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).



### Name of Technology:

ProACT™ Therapy for male stress urinary incontinence (Uromedica Inc., Plymouth, MN, USA).

### Purpose and Target Group:

ProACT Therapy is designed for the treatment of male long-term stress urinary incontinence resulting from sphincter deficiency following radical prostatectomy (RP) for prostate cancer or transurethral resection of the prostate (TURP) for benign prostatic hyperplasia (BPH).

### Stage of Development (in Australia):

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

The ProACT Therapy system is registered in the Australian Register of Therapeutic Goods (ARTG number: 104496, Product ID: 181942). Although the device was developed by Uromedica Inc. it is distributed in Australia and New Zealand by Medtronic Australasia Pty Ltd.

### International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely diffused
United States	✓		
Europe		✓	
Australia		✓	

### Impact Summary:

#### *Background*

Urine is produced in the kidneys then flows down the ureters into the bladder where it is stored (National Association for Continence 2005). Urination is controlled by the urinary sphincter, rings of muscles at the base of the bladder and wall of the urethra (tube that connects the bladder to the tip of the penis) (National Association for Continence 2005, UPMC Cancer Centers 2006). When the bladder is full, relaxation of the sphincter in conjunction with contraction of the bladder muscle (detrusor) allows urine to flow out (National Association for Continence 2005). When urination is complete and when the bladder is not full the sphincter contracts and the detrusor relaxes (National Association for Continence 2005).



Urinary incontinence is the inability to hold urine in the bladder and prevent involuntary leaking or dribbling (UPMC Cancer Centers 2006). Urinary incontinence in men can sometimes result from conditions of the prostate (an exocrine gland that surrounds the urethra just below the bladder) and their treatment (UPMC Cancer Centers 2006). In young men, the prostate is approximately the size of a walnut (Agency for Healthcare Research and Quality 2000). As men age the prostate naturally enlarges (US Department of Health and Human Services 2004). Continued growth of the prostate can lead to a non-cancerous prostate enlargement (benign prostatic hypertrophy, BPH), inflammation of the prostate (prostatitis) or prostate cancer (US Department of Health and Human Services 2004). As the prostate becomes larger, it tightens around the bladder outlet and restricts the urethra, creating bladder flow obstruction (US Department of Health and Human Services 2004). In such cases the bladder has to work harder to force out urine and could result in thickening of the bladder wall and potentially cause the bladder to become unstable or over-reactive (US Department of Health and Human Services 2004). The surgery required for the treatment of prostate cancer (radical prostatectomy) or BPH (transurethral resection of the prostate) can sometimes result in sphincteric injury and can lead to postoperative urinary incontinence (Rassweiler *et al.* 2006). In most cases postoperative incontinence is short term and most men regain continence within weeks or months following surgery, however, few men will experience long term or permanent incontinence. Although the mechanism of postoperative incontinence can be through incompetent sphincter mechanism, detrusor instability and bladder neck obstruction, usually long term incontinence is associated with sphincter injury (Palmer *et al.* 2003).

Patients can suffer from different forms of urinary incontinence, including (Palmer *et al.* 2003, National Association for Continence 2005):

- Total incontinence: the complete inability to control leakage of urine.
- Overflow incontinence: occurs when the bladder overflows when it is too full, it can occur when blockage or narrowing of the bladder outlet by cancer or scar tissue (normally resulting from BPH) preventing complete emptying.
- Urge incontinence: urine leakage without warning, resulting from an over reactive bladder.
- Stress incontinence: leakage of urine resulting from activity that strains or stresses the bladder e.g. lifting, sneezing or exercises. Most common form of long term/permanent incontinence following sphincteric damage during surgery.

There are also various management and treatment options for sufferers of urinary incontinence. These options range from the use of sanitary pads and disposable underwear to the surgical option of an Artificial Urinary Sphincter (AUS), which is the current standard treatment for stress urinary incontinence (Palmer *et al.* 2003, Hubner and Schlarp 2006, Trigo-Rocha *et al.* 2006). Although treatment may be effective, the implantation of an AUS presents the possible complications of mechanical failure, infections and erosions (Peyromaure *et al.* 2002). Furthermore, complete continence over the long term is rarely



achieved and revision surgery is often required after some years, exposing the patient to further risk (Peyromaure *et al.* 2002).

The ProACT Therapy system consists of a set of two post-operatively adjustable balloons attached to a titanium port via a short length of tubing (Uromedica 2006). They are inserted via a perineal approach bilaterally in a peri-urethral position at the bladder neck or at the apex of the prostatic remnant (Uromedica 2006). The titanium ports, which are sited in the scrotum allow for future percutaneous volume adjustments of the balloons using a fine gauge needle. The implant is designed to increase coaption of the urethra and lift the bladder neck, helping to improve continence (Uromedica 2006). The required implantation procedure is minimally invasive and is able to be performed with general or spinal anaesthesia (Uromedica 2006).

### ***Clinical Need and Burden of Disease***

For men who undergo prostate surgery urinary incontinence is a significant problem, which can have a serious impact on their lives (Palmer *et al.* 2003). The effects of urinary incontinence can be profound and affect a person's social, emotional and physical well being (National Association for Continence 2005).

Unfortunately due to inconsistent definitions of the term 'urinary incontinence', varying data collection methods (subjective versus objective reporting), and lack of a reliable source of information, it is difficult to accurately report the incidence or prevalence of urinary incontinence (Palmer *et al.* 2003, Sacco *et al.* 2006). A recent study, however, reported that following prostate surgery 30% to 40% of patients suffer early incontinence (usually urge incontinence) whereas less than 0.5% of patients suffer late stress incontinence (Rassweiler *et al.* 2006). In another study of radical prostatectomy patients, 8.4% of men were reported incontinent 18 months after surgery (nature of the incontinence was not specified) (Stanford *et al.* 2006). Similarly, Peyromaure and colleagues reported in 2002 that post-operative urinary incontinence following radical prostatectomy affects approximately 5% to 30% of patients (Peyromaure *et al.* 2002).

Most patients who suffer early incontinence following radical prostatectomy will regain continence within 2 years (Sacco *et al.* 2006). This is because early incontinence is usually caused by bladder instability and is successfully treated with physiotherapy and anticholinergic medication (Peyromaure *et al.* 2002). Persistent, long term incontinence, however, is usually stress incontinence in nature and more difficult to treat (Peyromaure *et al.* 2002). It is in these cases where surgical implantation of an Artificial Urinary Sphincter (AUS) may be required (Peyromaure *et al.* 2002). Patients with incontinence due to intrinsic sphincter deficiency, and those with intrinsic sphincter deficiency associated with bladder over reactivity make up the majority of patients suffering from long term post radical prostatectomy urinary incontinence (Trio-Rocha *et al.* 2006).



Although there are no official figures for the prevalence of male urinary incontinence in Australia, estimates have been put at 2.2% or 216,000 men suffering some degree of urinary incontinence (Chiarelli *et al.* 2005). A smaller fraction than this will experience long term stress urinary incontinence as a result of prostate surgery. However, as the Australian population ages and the detection of prostate diseases improve, there is the potential for greater numbers of men being affected by post-surgery urinary incontinence, both long and short term.

### ***Estimated Speed, Geographic and Practitioner Use, Patterns of Diffusion in the Health System***

At the time of writing, the ProACT Therapy system is restricted to investigational use only in the United States (Uromedica Inc. 2006). Outside of the United States however, the ProACT Therapy system is being evaluated for safety and effectiveness in the clinical trial 'Clinical Investigation of the ProACT Adjustable Continence Therapy for Treatment of Post-Prostatectomy Stress Urinary Incontinence' (ClinicalTrials.gov 2006). Currently, the investigators are recruiting patients across several centres in the United States, Canada and New Zealand; the study is expected to be completed in January 2009 (ClinicalTrials.gov 2006).

The ProACT Therapy system has already being approved for clinical use in the European market and is distributed throughout Europe, Canada, Brazil, Malaysia and Australasia through a variety of distributors (Trigo-Rocha *et al.* 2006, Uromedica 2006).

### ***Existing Comparators***

- Medications (UPMC Cancer Centers 2006):
  - Decongestants
  - Anticholinergic medication nerves to prevent bladder spasms, sometimes used for urge incontinence
- Biofeedback (UPMC Cancer Centers 2006)
- Injection therapy (Peyromaure *et al.* 2002): retrograde or antegrade injection of substances (e.g. autologous fat, Teflon, silicone, collagen) in region of external sphincter
- Surgical (Hubner and Schlarp 2006, Trigo-Rocha *et al.* 2006):
  - Male sling: supports the bulbar urethra, helps to achieve effective adynamic urethral resistance
  - Artificial urinary sphincter: Considered the gold standard treatment option for men with stress incontinence caused in intrinsic sphincter deficiency.

### ***Estimated Cost Impact***

Specific costs for the ProACT device or the implantation procedure were not revealed in the searches conducted. However, the manufacturer has suggested that due to the simpler



mechanism of the ProACT device compared to the AUS, ProACT Therapy would offer significant cost reductions (Trigo-Rocha *et al.* 2006).

The Medicare Benefits Schedule item numbers, reimbursements and number of claims between July 2005 and June 2006 for treatments of male urinary incontinence are outlined in Table 1.

**Table 1 Year 2006 Medical Benefits Schedule of Fees for Treatment of Male Urinary Incontinence**

Category	Item Number	Benefit	Number of Claims July 2005 to June 2006
Periurethral or transurethral injection of materials for the treatment of urinary incontinence.*	37339	\$207.60	652
Sling operation for stress incontinence, with or without mesh or tape.*	35599	\$583.75	5016
Division or removal or urethral sling for urethral obstruction or erosion, following previous surgery for urinary incontinence.	37341	\$788.70	76
Sling procedure for bladder stress incontinence, using autologous fascial sling, including harvesting, with or without mesh.*	37042	\$788.70	226

\* Indicates combined number of claims for men and women.

### ***Efficacy and Safety Issues***

#### **List of Studies Found**

Total number of studies	5
Case series studies	5

The studies included in this summary are highlighted in bold in the reference list.

Safety and efficacy data from 5 case series studies have been selected for inclusion in this summary. Two studies were presented as peer reviewed publications while the remaining three studies were conference abstracts therefore more data may become available when studies are fully reported.

### ***Safety***

Hubner and Schlarp (2005) evaluated the safety and efficacy of the ProACT Therapy system in 117 consecutive men (median age 70 years). The study begun using first generation balloons of the implant (implanted in the first 50 patients) but later switched to the use of second generation re-engineered balloons (remainder of patients) following concerns about fluid leakages. Of the 117 men, 110 had post-RP incontinence, 6 post-TURP incontinence



and 1 post-radical cystectomy and orthotopic neobladder. The median period of incontinence was 33 months (range: 3 to 180 months) and 87% of men had been incontinent for over a year prior to implantation of the device.

The implantation procedure was uneventful in 96 men, however, 15 suffered urethral or bladder perforations and the outcome of 6 men was not reported. In the 15 men who suffered complications, the ProACT device was implanted contra laterally to the perforation. The affected side was later implanted 1 to 4 months later.

Post-operatively, seven men (6%) experienced urinary retention on the day following implantation, which was successfully resolved through the withdrawal of a small amount of the balloon filling fluid via the injection ports. Twenty-one patients experienced 24 balloon ruptures (20 first generation balloons and four second generation balloons), all of which were successfully replaced one to two months later. No further complications from the rupture of the balloons were reported. Seventeen implant migrations (16 unilateral, one bilateral) were also reported in 16 patients but were successfully repositioned. Erosion of the urethra and bladder was also reported in 13 patients (11 unilateral, two bilateral). In these patients removal of the implants was required followed by re-implantation six weeks later. Additionally, 31 more explantations due to non-response were performed without any complications.

The results from this study showed a decrease in the rate of revision surgery as greater numbers of patients were treated, which as argued by the authors reflects the development of the device and the short learning curve associated with the use of the device.

In a smaller study, Trigo-Rocha and colleagues (2006) observed similar intra-operative and post-operative complications as Hubner and Schlarp (2005). The patient sample included 25 men (mean age 68.6 years) suffering severe stress urinary incontinence for a mean of 40 months post prostatectomy, who received implantation of the ProACT device. Intra-operative perforation of the bladder occurred on two occasions during implantation, resulting in unilateral implantation on the non-affected side (second balloon was later implanted). Despite this, patients were able to be discharged on the first post-operative day. Post-operative follow-up for a mean of 22.4 months (range: six to 48 months) was performed for 23 patients (one lost to follow-up and one death). The death was a result of myocardial infarction and considered unrelated to treatment, but no details are given. Urinary retention during the early post-operative period was observed in one patient and was successfully corrected by removal of 0.5ml of filling solution from each balloon without the need for anaesthesia. Four revision surgeries were also required. It was not stated whether generation I or generation II balloons were used. Finally, two patients presented with detrusor over activity which was successfully treated within six months with anticholinergic medication.



An abstract from Gilling *et al.* 2005 of 203 patients in seven international centres evaluated the effects of ProACT Therapy implantation on Incontinence Quality of Life (IQoL) and daily pad usage over a period of 24 months. Although specific rates of intra-operative or post-operative complications were not reported, revision surgery was required in 36 out of 172 patients (20.9%) resulting from a combination of erosion, device migration or non-response to initial surgery.

A further study presented as an abstract by Kastler *et al.* (2006) of a multi-centre evaluation of 58 patients (51 post RP, four post TURP and two post 'other' prostatectomies) evaluated the effect of ProACT Therapy implantation on the mean urethral closure pressure, daily pad usage and mean IQoL for a median follow-up of 14 months. The time since surgery was highly variable: 0.5 - 20.6 years. In this study, a total of 16 patients required explantation throughout the study period (two for infection, one for urinary retention, one for pain, one for urethral erosion, two for defective balloons, eight for non-response and one not specified). Four patients required re-implantation (reasons not reported) which proceeded uneventfully.

The final abstract detailing a study of 30 post-RP and seven post-benign surgery patients followed up for a mean of 18.9 months in the RP group and 27.8 months in the post-benign group (Gilling *et al.* 2006). In this sample of patients infection and balloon migrations occurred in three and two occasions respectively. In all cases however successful management of the events was achieved by outpatient removal of the device and later re-implantation.

The current available literature on the ProACT system suggests that the device is safe for implantation. However as the studies presented suggest there are recurring safety issues with the device, namely post-operative complications such as the migration of the device and erosion of the urethra or the bladder. Though these complications were able to be corrected through removal and later re-implantation of the device in most cases this presents an added risk to the patient as a result of the re-implantation procedure. Intra-operatively, implantation of the device is not reported as overly difficult and successful implantation may increase as surgeons familiarise themselves with the procedure (Hubner *et al.* 2005). Further studies investigating the long term (more than two year) effects of the ProACT Therapy system are required to determine any long term advantage of the ProACT Therapy system over other treatment options. Additionally, RCT or comparative studies are required to compare differences in rates of complications between ProACT Therapy and other treatment options.

## ***Efficacy***



Efficacy of the ProACT Therapy system was primarily evaluated through the attainment of continence, improvement in IQoL and uro-dynamic evaluation. However, a lack of definition of the term 'continent' by some of the studies presented prevents any combination of results to form a conclusion regarding the efficacy of the ProACT Therapy system.

The case series study by Hubner and colleagues (2005) of 117 patients (110 post-RP, six post-TURP, one after radical cystectomy and neobladder) reported implantation time of the device to range from 14 to 56 minutes for all patients. However the authors noted that as experienced was gained by the surgeons implantation time decreased to less than 20 minutes for the last 20 patients. Post-operatively, just over one third (36 of 117) patients did not experience satisfactory (definition for 'satisfactory' was not stated) results and in these the device was successfully removed. Patients then either received an AUS (28 patients), declined further treatment (three patients) or were lost to follow-up (five patients).

Only five men experienced full continence and required no adjustment of balloon volume on the first day after surgery. The remaining 112 (96%) required a median of three (range: one to 15) volume adjustments to achieve satisfactory results. At implantation the median balloon volume was 2 ml (range: 0.5 to 7.5 ml) while the final mean volume after all adjustments in patients who were deemed to have experienced success was 3.5 ml (range: 1 to 10 ml). Patients were followed up for a mean of 13 months (range: three to 54 months) with time points at baseline, one, three, six, 12 and 24 months. During this period there was a significant ( $p < 0.001$ ) improvement in all time points for the number of pads used daily compared with baseline. At baseline, a mean of 5.6 pads per day (range: one to 24 pads per day) in 117 patients improved to a mean of 2.5 pads per day (range: zero to 15 pads per day) in 117 patients at three months, 1.9 pads per day (range: zero to seven pads per day) in 92 patients at six months, 1.4 pads per day (range: zero to six pads per day) in 63 patients at 12 months, and 1.2 pads per day (range: zero to six pads per day) in 40 patients at 24 months after surgery.

The Stamey Incontinence grading system was used as subjective assessment tool to confirm the effects of a reduction in daily pad usage. At baseline 37 patients were considered grade 1 (leakage with stressful activities e.g. coughing or sneezing), 33 as grade 2 (leakage with minimally stressful activities e.g. walking) and 47 as grade 3 (leakage at all times with any activity). At 12 months post-implantation the proportion of patients considered as grade 2 or 3 fell to 13% from a baseline of 68%. Similarly the proportion of patients classified as grade 0 or 1 increased from 32% at baseline to 88% at 12 months post-implantation. In both cases the improvements were statistically significant at the  $P < 0.001$  level.

Similarly significant ( $p < 0.001$ ) improvements at all time points for quality of life were observed in these patients. Scores in the IQoL questionnaire (maximum score 100) improved from a baseline mean of 34.7 in 117 men to 64.8 at six months in 92 men, 64.9 at 12 months in 63 men and 66.3 at 24 months in 42 men.



Trigo-Rocha and colleagues in their smaller study were able to provide support for the effects of ProACT Therapy implantation in a sample of 25 patients, of which 23 were followed up for a mean of 22.4 months (range: 6 to 48 months) (Trigo-Rocha *et al.* 2006). In this study, the mean operative time was 35.4 minutes (range: 22 to 58 minutes), a figure similar to Hubner and colleagues (2005). On average, 4.6 adjustments (range: one to seven adjustments) were required to achieve and maintain continence.

Daily pad usage also significantly ( $p < 0.05$ ) improved from a mean of  $4.8 \pm 1.7$  pads per day to a mean of  $1.8 \pm 1.6$  pads per day at last follow-up. This translated to 15 men (65%) being considered continent (using zero to one pad daily) and satisfied, three men (13%) considered as having some improvement and being unsatisfied and five men (22%) remaining the same. However no details were provided as to how satisfaction levels were determined.

Not surprisingly this was coupled with a significant increase in IQoL scores which significantly ( $P < 0.05$ ) improved from a baseline of  $63.0 \pm 20.4$  to  $82.6 \pm 15.2$  at the last follow-up.

The study also conducted uro-dynamic evaluation (Valsalva leak point pressure, VLPP) to measure the effect that the implant has on urethral resistance and post-void residual urine volume to determine the ability of a patient to empty his bladder. At baseline, the VLPP was  $48.76 \pm 25.4$  cm H<sub>2</sub>O, which improved significantly ( $P < 0.05$ ) to  $84.10 \pm 33.5$  cm H<sub>2</sub>O.

There were eight unsatisfied patients, two of which opted for a successful removal of the implants and implantation of an AUS, three awaiting revision surgery to correct balloon migration and a further three considering alternative forms of treatment.

Further work by Gilling *et al.* (2005) detailed in abstract form reports a positive impact of ProACT Therapy implantation on daily pad use and IQoL in 203 patients. The abstract reports a drop in daily pad use from a mean of 4.3 pads per day in 199 men at baseline to 1.8 pads per day in 163 men at six months, 1.5 pads per day in 123 men at 12 months and 1.6 in 52 men at 24 months. This translates to 63% of patients considered dry, using zero to one pad daily at the two year follow-up.

The final two abstracts detailing the impact of the ProACT Therapy system focused on the impact of the implant on attainment of continence and improvement in the IQoL score.

Kestler *et al.* (2006) implanted the ProACT Therapy system in 58 patients (51 post-RP, six post-benign surgery) as part of a multicentre study. Although improvement in the number of daily pads used per patient was not reported, at the median follow-up period of 14 months, 11 patients (19%) were considered dry, 21 patients (36%) improved, 17 patients (29%) unchanged, two patients (3.4%) worse than at baseline and seven patients (12%) had undergone explantation surgery. The mean IQoL score improved from 45 (range: two to 85) to 61 (range: 17 to 100) at the median-follow-up.



Gilling *et al.* (2006) in a smaller sample of patients (30 post-RP and 7 post-benign surgery) reported daily pad use and IQoL scores separately for both groups of patients to reveal any differences between the two groups. The post-RP patients were followed up for a mean period of 18.9 months and experienced a reduction in mean daily pad use from 2.6 pads per day at baseline to 0.7 pads per day at six months, 0.5 pads per day at 12 months, 0.6 pads per day at 24 months and 0.4 pads per day at 36 months. No statistical analysis was reported. In comparison, the daily pad usage in the post-benign group (mean follow-up 27.8 months) decreased in a similar fashion to the post-RP patients although having slightly higher values at each time point. In this group, pad usage was 3.8 pads per day at baseline, 1.2 pads per day at six months, 1.0 pad per day at 12 months, 1.0 pad per day at 24 months and 0.7 pads per day at 36 months. Improvements in the IQoL scores between both groups followed similar pattern to improvements in daily pad use. Post-RP patients improved IQoL scores from a baseline of 49.6 to 71.7 at six months, 74.9 at 12 months, 70.6 at 24 months and 88 at 36 months. Post-benign patients improved from a baseline of 49.7 to 77.9 at 6 months, 78.6 at 12 months, 76.1 at 24 months and 86.5 at 36 months.

### ***Ethical Issues***

No issues were identified from the retrieved literature.

### ***Cultural or Religious Considerations***

No issues were identified from the retrieved literature.

### ***Other Issues***

Various contraindications for the ProACT system are outlined by the manufacturer, including:

- Active systemic or urinary tract infections
- Unmanageable detrusor instability, reduced bladder compliance
- Residual volume greater than 100ml after voiding
- Pelvic region radiotherapy within 6 months of system implantation
- Bladder cancer
- Unsuccessfully treated bladder stones
- Haemophilia or bleeding disorders

In addition, the manufacturer has outlined that prior to any implantation being performed by a physician, appropriate training is required.



## Conclusion:

Although evidence regarding the safety and efficacy of the ProACT Therapy system exists, this evidence is found only in case series studies and abstracts of other studies. One death occurred in one study, which was considered unrelated to treatment. Higher quality studies, preferably randomised controlled trials are required to better evaluate the safety and efficacy of this implant for male stress urinary incontinence. Furthermore in order to accurately compare and combine data from different studies, the terms 'continence' and 'satisfactory' need to be clearly defined in each study so as to avoid confusion. Based on the lack of information from randomised, controlled trials and the potential to be an alternative form of treatment for male post-prostatectomy stress urinary incontinence, it is recommended the following be conducted:

- |  |  |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input checked="" type="checkbox"/> Monitor      | <input type="checkbox"/> Archive                           |

## HealthPACT recommendation:

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#### **Search Criteria:**

A search of MEDLINE, PubMed, *The Cochrane Library*, the Current Controlled Trials metaRegister, the UK National Research Register, the International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in July 2006.

Search terms used were:

'ProACT', 'ProACT Therapy', 'stress urinary incontinence', 'urinary incontinence', 'adjustable continence therapy', 'post-prostatectomy incontinence', 'prostatectomy', 'benign prostatic hyperplasia'.

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