Prospective Registry of Outcomes with Penile Prostheses for Erectile Restoration (PROPPER) ER1005

BSC Study U0552 (also known as AMS Study ER1005)* Version #: 3
Version Date: March 17, 2016

Version Number	Date of Version
1 (Initial Release)	March 16, 2011
2 (Amended)	May 12, 2014
3 (Amended)	March 17, 2016

Registry Sponsor
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Ethical Conduct
This registry will be conducted in compliance with this document, the principles of Good Clinical Practices and other applicable regulatory requirements or standards.

**AMS was acquired by Boston Scientific in August 2015. Due to the fact that the PROPPER Registry was ongoing at time of acquisition, study documents may refer to the study as BSC Study U0552 and/or AMS Study ER1005.*

Protocol Signature Page

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I have read this protocol and agree to conduct the investigation in accordance with the above named protocol, Data Registry Agreement, the principles of Good Clinical Practices, any conditions of approval imposed by the Institutional Review Board/Ethics Committee (IRB/EC), and any other applicable regulatory requirements or standards. I will provide copies of this protocol and all pertinent information to the study personnel under my supervision and to my IRB/EC. I will ensure they are fully informed regarding the conduct of the study according to this protocol and applicable laws and regulatory requirements.

_____

Clinical Site Name

_____ _____

Site Principal Investigator Signature Date

_____

Site Principal Investigator Printed Name

Please complete this page and return to the Registry sponsor:

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1 PROPPER REGISTRY STUDY SYNOPSIS

Sponsor:	Boston Scientific Corporation (BSC)
Protocol Title (BSC Study Number):	Prospective Registry of Outcomes with Penile Prostheses for Erectile Restoration (PROPPER) (ER1005)
Clinical Phase and Regulatory Status	Post-Market Registry
Study Sites:	Up to 16 sites throughout the USA and Canada
Principal Investigators:	Anthony J. Bella, MD, FRCSC University of Ottawa Ontario, Ontario, Canada Rafael E. Carrion, MD University of South Florida, Tampa, FL, USA Brian S. Christine, MD Urology Centers of Alabama, Birmingham, AL, USA Gerard D. Henry, MD Regional Urology; Shreveport, LA, USA Additional investigators are expected. The names and addresses of all participating Principal Investigators will be maintained in a separate document.
Objectives:	To understand "real-world" outcomes for men implanted with BSC penile prostheses, including the following: ▪ Safety ▪ Durability ▪ Patient satisfaction ▪ Effectiveness/Quality of Life
Study Design:	Prospective, multi-center, post-market, observational registry, up to 5 year follow-up
Planned Sample Size:	Approximately 500-1500
Inclusion Criteria:	Men diagnosed with erectile dysfunction (ED) for whom a BSC penile prosthesis is recommended by their physician are eligible for inclusion. Potentially eligible men should also meet the following inclusion criteria for study enrollment: ▪ Willing and able to provide written informed consent prior to enrollment (if applicable).

- Willing to be seen or contacted by phone by the investigator and answer at least 2 questions related to treatment satisfaction and device use 1 year following implantation of an BSC penile prosthesis

Exclusion Criteria: Men who are deemed by their physician to be not suitable for a penile implant are excluded from eligibility.

Device Description(s): Men to be enrolled and followed in this study include those implanted with one of the following marketed BSC penile prostheses:

- 3-piece inflatable penile prosthesis (e.g., AMS 700®)
- 2-piece inflatable penile prosthesis (e.g., AMS Ambicor®)
- Malleable or concealable penile prosthesis (e.g., Spectra™)

Implantation Description: BSC recommends that all devices are implanted according to the device specific Instruction for Use (IFU) and/or Operating Room (OR) manual and the site or investigator's standard of care.

Concomitant Surgical Procedures: Concomitant urological procedures are allowed and will be captured; however, outcomes data on these procedures will not be collected, unless an AMS 800 artificial urinary sphincter or AdVance male sling is implanted concomitantly with the BSC penile prostheses. Optional questionnaires will be available to use for assessment.

Implantation Success Measures: Success will be measured post-operatively by querying patients about treatment satisfaction and device use. Any reported intra-operative and post-treatment complications will be collected in the registry database.

Event Schedule: Patient data will be collected from the baseline/pre-operative visit, the implantation procedure, and follow-up evaluations which will occur according to each physician's standard of care, up to 5 years post-implantation. A 1-year follow-up evaluation will be required, and a 2-year follow-up evaluation will be strongly encouraged.

Duration of Study: 1-2 year enrollment period
Up to 5 year patient follow-up

Measurements: The registry database will include required measures for all participating investigators to complete and *optional*

measures (listed below in italics) for investigators to complete if they coincide with their standard of care.

Each investigator will be asked basic practice information including:

- Practice type (private, academic)
- Main setting for procedures (Hospital or ASC)
- Do you provide standard device cycling instructions to patients receiving IPPs? If yes, please describe your protocol

Data for each patient for whom a BSC penile implant is recommended will be entered into the registry database at baseline/procedure and at post-implant follow-ups to occur at a minimum 1 year after implantation, and through up to 5 years after implantation.

The baseline/pre-operative data will include:

- Age
- Race/Ethnicity
- Primary etiology of ED
    - Organic
        - Diabetes
        - Cardiovascular disease
        - Neurologic disorder
        - Peyronie's disease
        - Other organic (specify)
    - Acute
        - Radical prostatectomy (RP) (robotic, open or laparoscopic)
        - Radical pelvic surgery (other than RP)
        - Pelvic radiation therapy
        - Pelvic trauma or injury
        - Spinal cord injury
        - Venous Leak
        - Priapism
        - Other acute (specify)
- Relevant concomitant medical conditions and concomitant medications that might impact ED (premature or rapid ejaculation/PE, climacturia, cardiovascular disease, diabetes, Peyronie's disease, stress urinary incontinence/SUI, steroid use, anticoagulant use, anti-depressant use, venous leak, and Other, please specify) – with the following sub-

assessments if SUI checked:
    - *Etiology of incontinence (radical prostatectomy, pelvic irradiation, and other – please specify)*
    - *Previous treatment(s) for incontinence (behavior modification, pelvic floor muscle training, transobturator male sling - specify model and implant date, artificial urinary sphincter/AUS – specify implant model date, other - specify)*
    - *Number of pads used daily*
    - *Pad weight (24-hour test)*
    - *Urodynamics: Post-void residual (PVR) volume (ml), maximum flow rate (ml/sec), any detrusor overactivity (DO) or detruser sphincter dyssynergia (DSD)*
    - *Cystoscopy findings (bladder neck contracture, other – specify)*
- *Pre-op flaccid penile length (measured from suprapubic fat pad to tip)*
- *Pre-op stretched penile length (measure from suprapubic fat pad to tip)*
- *Pre-op flaccid girth (circumference measured 1cm proximal to the proximal end of the corona)*
- *Duration of ED (years or months)*
- *Previous ED Treatments [PDE-5 inhibitors (PDE-5s), vacuum erection device (VED), intracavernosal injection (ICI), Combination therapies, previous/failed penile implants), other, specify]*
- *Patient query - any office visits in past year for treatment of depression Y/N*
    - *If Yes: approximately how many visits*
    - *If Yes: taking any depression medication*
- *Was VED and/or penile traction therapy prescribed pre-operatively? (*Y/N)
    - *If Yes: specify Duration (weeks) and Frequency (times/day)*
- *Baseline effectiveness/quality of life assessments*

Implantation surgery data will include:
- Date of procedure
- Original (virgin), revision, salvage or replacement implant
    - If revision or salvage, washout (Y/N)

- Surgical approach (Penoscrotal (PS), Infrapubic (IP), Subcoronal (SC) or “Other, please specify”)
- Implant model type:
    - Spectra™ Concealable Penile Prosthesis
        - Cylinder diameter (9.5, 12, 14 mm)
        - Cylinder length (12, 16, 20 cm)
        - Total number of RTEs per cylinder (0, 1, 2)
        - Total length of RTEs per cylinder (specify: 0.5 to 7.5 cm)
    - AMS Ambicor® Penile Prosthesis (2-piece inflatable)
        - Cylinder diameter (12.5, 14, 15.5 mm)
        - Cylinder length (14, 16, 18, 20, 22 cm)
        - Total number of RTEs per cylinder (0, 1, 2, 3, 4)
        - Total length of RTEs per cylinder (specify: 0.5 to 6.5 cm)
    - AMS 700® Penile Prosthesis (3–piece inflatable)
        - InhibiZone®-impregnated (Y/N)
        - Cylinder type (CX, LGX, CXR, Ultrex, CXM)
        - Cylinder length (10, 12, 14, 15, 16, 18, 21, 24 cm)
        - Total number of RTEs per cylinder (0, 1, 2, 3, 4)
        - Total length of RTEs per cylinder (specify: 0.5 to 7.5 cm)
        - Pump type (MS Pump, Tactile pump, Inflate/Deflate)
        - Preconnect (Y/N)
        - Reservoir (Spherical 65 ml, Spherical 100 ml, Conceal 100 ml)
        - Reservoir placement (space of Retzius, Sub-muscular, Sub-Scarpa’s fascia, other – specify)
        - Reservoir separate incision (Y/N)
- Drain (Y/N)
    - If Yes, Type
- Dressing
    - None, compression/mummy wrap, non-compressive dressing
- Concurrent procedures (Y/N)
    - If Yes, specify procedure(s): ventral

phalloplasty, ligament release, circumcision, suprapubic fat pad reduction, spermatic cord/testicular procedure, AMS 800 (single or multiple incision), sling (specify sling type and single or multiple incision), other - specify

- Significant corporal fibrosis or scarring noted (Y/N)
- Curvature correction procedure(s) (e.g., for Peyronie's Disease)(Y/N)
    - *If Yes: Initial intraoperative curvature measurement (angle of curvature with inflated device using a goniometer or protractor)*
    - *If Yes: Correction technique (Wilson/Delk remodeling, tunical incision, incision and grafting, or plication)*
    - *Curvature measurement after correction*
    - *Second correction? If Yes, same set of questions as above.*
- Patient status post-op: Admitted/inpatient/≥24 hours or same day discharge/outpatient/<24 hours
    - *If admitted/inpatient/≥24 hours is chosen, include: number of days in the hospital*
- *Length of procedure (measured from time of first incision to time of closure)*
- *Intra-operative penile length measurement with device inflated (measured from suprapubic fat pad to tip)*
- *Intra-op penile girth measurement with device inflated (circumference measured 1cm proximal to the proximal end of the corona)*
- *Intra-op stretched penile length measurement with device deflated (measured from suprapubic fat pad to tip)*
- *Foley in place at discharge? (Y/N)*

Follow-up is required 1 year post-operatively. *Additional follow-ups will be determined per the physician's standard practice up to 5 years.* Follow-up data will include:

- Query for any device related complications and their outcomes by asking patients if they have had any surgery on their penis or problems with the device since their penile prosthesis was implanted (Y/N)
- Patients will be asked:
    - How satisfied they are with the device(s) (using a 5-point scale)

  - If they are using the device (Y/N)
    - If yes, how often they are using the device (less than once per month or more than once per month)
      - *How many times per month?*
    - *If no, why aren't you using the device (loss of partner, partner disinterest, device problem, device dissatisfaction, health decline, other – describe, other device use reason).*
    - *If yes, and not using the device as often as desired, or if dissatisfied with the device, indicate why ((loss of partner, partner disinterest, device problem, device dissatisfaction, health decline, other – describe, other device use reason).*
- *Number of pads used daily (if incontinence indicated pre-operatively)*
- *Pad weight (24-hour test) (if incontinence indicated pre-operatively)*
- *Penile length measurement with device fully inflated (measured from suprapubic fat pad to tip)*
- *Penile girth measurement with device fully inflated (circumference measured 1cm proximal to the proximal end of the corona)*
- *Stretched penile length measurement with device deflated (measured from suprapubic fat pad to tip)*
- *Patient query - any office visits in past year for treatment of depression Y/N*
  - *If Yes: approximately how many visits*
  - *If Yes: taking any depression medication*

- *Effectiveness/quality of life assessments*

Effectiveness Assessments:

Patient questionnaires to measure effectiveness will be optional at baseline and at all follow-up visits. Included are the following validated, patient-reported outcome questionnaires:

Strongly recommended for all:

- *IIEF-5/SHIM erectile function questionnaire*
- *EHS erection hardness questionnaire*
- *SF-12 health-related quality of life questionnaire*

Recommended for all patients with post-prostatectomy ED or incontinence:

- *AUA-SI/IPSS urinary symptom questionnaire*
- *UCLA-PCI urinary, sexual and bowel function and bother questionnaire*

Safety/Device Malfunction Assessments:

Any reported intra-operative or post-operative device or surgery related complications will be recorded throughout study follow-up (for BSC products only). This information will include:

- Complication
- Treatment
- Location of treatment
- Resolution (Resolved or Continuing)

Potential device or surgery related complications are described in the device specific IFU and OR manuals.

Statistical Analyses, Including Determination of Sample Size:

Up to 1500 patients with erectile dysfunction (ED) electing to receive a BSC penile prosthesis implant will be included in this registry.

Analyses of multi-center data for initial publication(s) may be performed after approximately 500 patients complete 1 year follow-up. Additional individual and multi-center data analyses may be performed as warranted throughout the study for publication(s). Analysis for multi-center publication(s) is planned after the study enrollment is complete and all the enrolled patients have completed their one-year and five-year follow-up evaluations, consistent with each physician's standard of care.

Continuous variables will be presented as mean +/- SD; ordinal variables will be summarized using median with interquartile ranges; categorical variables will be presented as count and proportion.

Kaplan-Meier method will be used to estimate the event rate over time by device type for major complications.

For within-patient change at 1 year follow up compared to the baseline visit, signed rank test or paired t-test may be used for continuous variables and McNemar's test may be used for binary variables when applicable. Mixed effects model or Generalized Estimating Equation model may be used to estimate the change from baseline across follow up

visits when appropriate.

The data to be collected in electronic data forms will include the following:

Table 1: Electronic data collection schedule

Data	Baseline/ Procedure	Interim Follow-Up*	1 Year Follow-Up*	2 - 5 Year (Annual) Follow-Up*
Date of Informed Consent/first data record	R			
Demographics and Characteristics	R			
ED History	R			
Depression History	O	N/A	O	O
Implantation Procedure Details	R			
Device Use and Satisfaction	N/A	O	R	SE
Penile Measurements	O	O	O	O
Incontinence Data	O	O	O	O
Patient Questionnaires	SE	SE	SE	SE
Clinical Study Events/Complications	R†	R†	R†	R†

* The same assessments, evaluations, questionnaires that were completed at baseline should be completed at follow-up

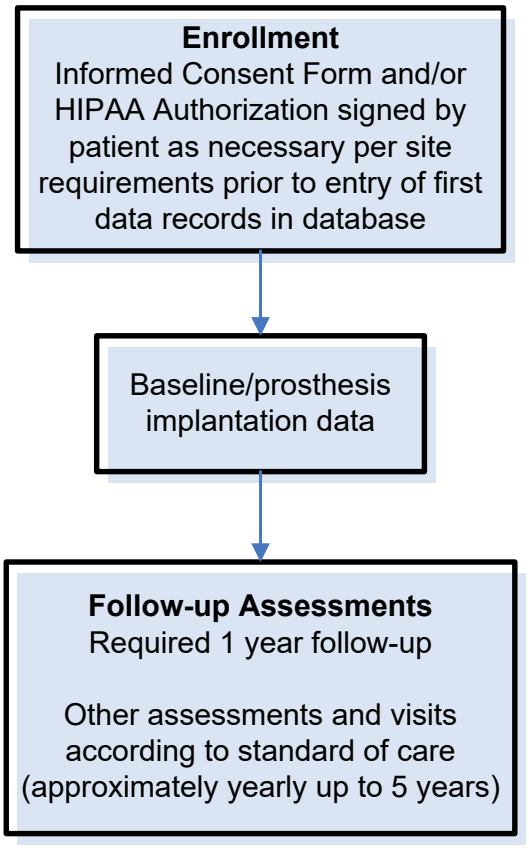
R = Required, O = Optional, SE = Strongly Encouraged, N/A = Not Applicable.

† = if applicable

- Demographics and Characteristics – age, race/ethnicity, concomitant medical conditions and medications
- ED History – primary etiology of ED, previous ED treatments (optional)
- Depression History – query for any treatment of depression in past year – optional at baseline and at annual follow-up
- Implantation Procedure Details – surgical procedure details and implant model information, patient status post-op
- Device Use and Satisfaction – query for device use and device satisfaction
- Penile Measurements – pre-op flaccid and stretched length and girth, intra-op inflated penile length and girth and deflated stretched length, and post-operative inflated length and girth measurements, by physician
- Incontinence Data – Daily pad use, pad weight tests, urodynamics, post-void residual (PVR) volume maximum flow rate

- Patient Questionnaires – IIEF-5/SHIM erectile function questionnaire; EHS erection hardness question; SF-12 health-related quality of life questionnaire; AUA-SI symptom questionnaire; UCLA-PCI urinary, sexual and bowel function and bother questionnaire
- Clinical study events – device or procedure related complications (adverse device effects/events), device malfunctions, revision procedures related to the device or implantation procedure

Figure 1: Study Flow Diagram



2 BACKGROUND AND REGISTRY RATIONALE

2.1 BACKGROUND

Erectile dysfunction (ED), or impotence, is defined as a persistent failure to develop and maintain erections sufficient for penetrative sexual intercourse.[1] The total prevalence of erectile dysfunction of varying degrees in the United States is estimated to be approximately 30 million. According to the Massachusetts Male Aging Study, an estimated 52% of men over 40 are affected by ED.[2] Prevalence is expected to increase by one-third due to the aging of the population and factors such as increases in weight, dietary changes, smoking behavior, and an emerging increase in diabetes by 2020.[3] Erectile dysfunction is associated with many risk factors or precursors including surgical trauma, diabetes, hypertension, dyslipidemia, and smoking, and has been associated with depression, as well as increased mortality primarily through its association with cardiovascular disease.[4-8] Following a radical prostatectomy or other acute pelvic surgery or trauma, vascular, neurologic and other tissue injury contributes to ED that is often persistent.[9]

Every man undergoing surgery for prostate cancer will experience some impact on sexual function after prostatectomy, even if erectile function is eventually restored.[10-15] Erectile dysfunction also occurs in up to 86% of patients after androgen deprivation therapy, as well as after external beam radiation therapy for prostate cancer.[16-18] Restoration of the same degree of potency enjoyed prior to radical prostatectomy (RP) occurs only rarely, and older men and those with decreased pre-operative function generally recover erections less fully than pre-potent and younger men. Nerve sparing surgeries have increased the recovery of post-prostatectomy erectile function by approximately 20% 1-2 years after surgery to over 50% for unilateral and over 75% for bilateral nerve sparing procedures performed by some specialists. However, even with early penile rehabilitation using PDE-5 drug therapy or vacuum erection devices to aid in the restoration of function, only approximately 50-60% of patients will have unassisted functional erections restored by 2 years after prostate cancer treatment.[19-23] With almost 200,000 new prostate cancer diagnoses forecast each year in the United States alone, the impact of persistent, prostatectomy-associated ED is great.[24]

Regardless of the cause of ED, the surgical implantation of a penile prosthesis can provide a high level of satisfaction along with durable and reliable restoration of erectile function.[25-37] Restoration of erectile function and rigidity can be related to or predictive of improvement in other areas of health that impact quality of life and psychosocial status, as sexual health is integral to overall well-being.[38, 39]

Although there is a large body of scientific literature describing outcomes associated with penile implants, articles reporting prospectively collected, validated outcomes in large numbers of patients implanted with modern BSC penile implant models are limited.

2.2 Registry Design Rationale

The selection of specific effectiveness data measurements in this Registry study was based on outcomes reported in published literature for a range of current ED treatment options, to allow for generalized comparisons between modern, prospective penile prosthesis outcomes and historical data for a variety of ED treatments.

Current recommendations for ED diagnosis, management and research from international evidence-based consensus panels were also consulted to determine which patient-reported outcomes (PROs) are measured as part of the standard of care for clinical evaluation and treatment of ED.[40-43]

In both clinical practice and research, it has been recommended that ED severity be categorized using the International Index for Erectile Function EF domain (IIEF-EF). The IIEF-5 (also identified as the Sexual Health Inventory for Men or SHIM) is a validated and well established erectile function measure comprised of 5 of the 15 IIEF items, including 4 of the 6 IIEF-EF questions and one question from the intercourse satisfaction domain. [44-49] A single-item, validated erection hardness scale/score (EHS) is also commonly recommended and used. [50- 53] These tools have been successfully employed to measure baseline and post-treatment erectile function and penile rigidity in many clinical trials of ED pharmacotherapy and devices as well as in clinical practice.

For patients with ED due to treatment of prostate cancer, the UCLA Prostate Cancer Index (UCLA-PCI) is a validated 20-item tool for measurement of health-related quality of life specific to sexual, urinary, and bowel function and bother; and has been employed in numerous published studies to demonstrate serial improvements or declines in the six domains commonly affected by prostate cancer treatment. [49, 54-58] Each UCLA-PCI domain scale is scored on a scale of 0–100 points with higher values representing better outcomes. A difference of 5–10 points has been considered a clinically important change in a given domain. [59]

Incontinence or urinary leakage and obstruction often accompanies ED after prostate cancer treatment, at least transiently, and is measured in clinical practice and research using pad counts and weights and validated PROs. [47-48, 60-63] The American Urological Association Symptom Index (AUA-SI) is comprised of 7 of the 8 items of the International Prostate Symptom Score (IPSS), and has been widely used to report baseline and post-treatment clinical urinary symptom outcomes. [56, 64-67]

General health-related quality of life (HRQOL) has been evaluated in many different disease state settings with serial assessments using the Short Form Health Survey (SF-12), which is a 12-item adaptation of the RAND 36-Item Health Survey (SF-36) that takes only two to three minutes to complete. The SF-12 (v2) is a practical, reliable, and valid measure of physical and mental health widely used in large population applications. The SF-12v2 is available in multiple modes of administration and in both standard four week and acute one week recall periods. The SF-12 quantifies HRQOL into two composite scores: the Physical Component Summary (PCS) and Mental

Component Summary (MCS) scales. This survey also quantifies HRQOL into the same eight multi-item subscale domains used in the SF-36 with one or two questions in each domain: physical functioning, emotional well-being, general health, pain, energy, social functioning, and role limitations (problems with work or other daily activities) as a result of physical or emotional health.[49, 57-58, 67- 71] Because this survey uses norm-based scoring, comparisons can be made between published outcomes from the broader SF-36 survey.

Additional measurements were identified for required and optional data collection in the Registry database based on interviews with physician Principal Investigators and their standard of care for management of patients with ED before and after implantation of a penile prosthesis. The two, simple, individual questions about device use and satisfaction with the device were selected based on this feedback and the published studies using similar single-item assessments, since there is no validated tool available at present to measure the outcomes associated with penile implants as a treatment for ED.

The required 1-year follow-up time frame was chosen based on a large body of literature reporting clinical outcomes of this duration or longer after ED treatment, and the recommendations in the labeling for BSC penile prostheses for evaluating long-term device function [AMS 700® with MS Pump Operating Room Manual, 06/10]. The overall 5-year follow-up time frame is the minimum duration that is generally considered long-term follow-up after penile implantation. [40]

2.3 DEVICE DESCRIPTION

Devices included in this registry are the AMS 700® Series Inflatable Penile Prosthesis, AMS Ambicor® Penile Prosthesis, and the Spectra™ Concealable Penile Prosthesis. These devices have been approved for marketing and are manufactured by Boston Scientific Corporation (Marlborough, MA, USA). The penile prostheses are intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are for men who, after appropriate patient history and diagnostic evaluation as well as discussions with the urologist about other alternative treatment methods, are determined to be suitable candidates for implantation surgery. For specific device descriptions and information about their use and implantation refer to each device's Instructions for Use (IFU) and Operating Room (OR) Manual.

2.4 DEVICE ACCOUNTABILITY

All of the BSC devices for which data are being collected in this registry have been approved for marketing, and will be obtained by participating physician investigators through normal purchasing processes. A BSC Patient Information Form (PIF) related to each surgical implant procedure may be completed as per standard practice in addition to entering implant data into the study database. Individual device unit or lot numbers will not be tracked or accounted for in this study.

3 REGISTRY OBJECTIVES

3.1 MAIN OBJECTIVE

The objective of this registry study is to prospectively collect data prior to and after BSC penile prosthesis implantation in order to document and evaluate 'real-world' penile prosthetic outcomes including safety, durability, patient satisfaction and effectiveness/Quality of Life.

4 REGISTRY DESIGN SUMMARY

The PROPPER Registry is a post-market, multi-center, non-interventional, observational collection of clinical outcomes for patients implanted with a BSC penile prosthesis for the treatment of erectile dysfunction.

As an observational collection, the registry does not dictate patient selection for implantation of BSC devices, and does not direct physicians in the medical and surgical management of patients. Physicians are free to select and manage their patients according to their usual practice. Concomitant urological procedures are allowed and will be recorded. However, outcomes data on these procedures will not be collected, with the exception of select data for any concomitantly implanted AMS 800 Artificial Urinary Sphincters or AdVance slings for the treatment of incontinence.

BSC recommends that all devices are implanted according to the device specific Instruction for Use (IFU) and/or Operating Room (OR) manuals and the site or physician's standard of care.

Patient data will be collected from the baseline/pre-operative visit, the procedure, and follow up evaluations which will occur according to each physician's standard of care, up to 5 years post-operatively. A 1=year follow up evaluation will be required, and a 2-year follow-up evaluation will be strongly encouraged. Follow-up evaluations may occur during visits with the physician and/or by telephone or mail.

Each physician will determine if the device implantation procedure was successful based on his/her standard of care. Any reported intra-operative complications will be collected in the registry database. Success will be measured post-operatively by querying patients about device use.

The PROPPER Registry is designed to obtain post market safety and effectiveness information as well as to serve as an active surveillance system for collecting device related events or complications and malfunctions in patients implanted with BSC penile prostheses and reporting product complaints to BSC. This will provide a robust database of clinical information from which a number of analyses can be performed.

5 PATIENT ELIGIBILITY

The PROPPER Registry is expected to enroll approximately 500 to 1500 patients at up to 16 sites throughout the US and Canada. Enrollment is expected to be over a one to two year period with up to five year patient follow-up.

5.1 INCLUSION CRITERIA

Men diagnosed with erectile dysfunction (ED) for whom a BSC penile prosthesis is recommended by their physician are eligible for inclusion. Potentially eligible men should also meet the following inclusion criteria for study enrollment:

- Willing and able to provide written informed consent prior to enrollment (if applicable)
- Willing to be seen or contacted by phone by the physician and answer at least 2 questions related to satisfaction, device use, and potential issues with the device 1 year following implantation of an BSC penile prosthesis, as well as standard physician assessments throughout the study

5.2 EXCLUSION CRITERIA

Men who are deemed by their physician to be not suitable for a penile implant will be excluded.

6 PATIENT ENROLLMENT

All patients who meet eligibility criteria should be encouraged to enroll in the registry. Patients will be considered enrolled once they have signed an informed consent. If a site has a waiver of informed consent each patient from that site will be considered enrolled once the first data records are entered into the database. A unique patient identifier will be assigned to each patient at enrollment (upon signing an ICF or database entry). The PROPPER Registry is expected to enroll approximately 500 to 1500 patients at up to 16 sites throughout the US and Canada. Enrollment is expected to be over a one to two year period with up to five year patient follow-up. A total of more than 500 patients are anticipated to be implanted and entered into the registry database per year of enrollment. Based on historical estimates and assuming 10 to 15 participating physicians, the following number of each BSC penile prosthesis type will be implanted each year of enrollment: 500 AMS 700® Inflatable Penile Prostheses, 15 AMS Ambicor® Penile Prostheses, and 20Spectra™ Concealable Penile Prostheses.

7 DATA COLLECTION

Data will be collected via internet-based electronic data capture (EDC) with paper based questionnaires for collection of patient-reported outcomes (PRO) data. The PRO data will be entered into the registry database by the physician, physician staff or BSC staff. The EDC module will be developed and maintained by BSC.

Physicians are not required to complete all data fields in the database. Each will be asked to enter the required data at baseline/procedure and one-year follow-up for each

patient and optional data based on the information that they collect per their own standard of care.

Additional outcomes will be collected at whatever time frames are deemed appropriate by the physician, based on their standard of care for treatment of ED.

This is an observational collection of prospective patient data, with the following data required for each enrolled physician and patient:

- basic practice information for each physician
- baseline/pre-operative patient information: age, race/ethnicity, primary etiology of ED, relevant concomitant medical conditions and concomitant medications that might impact ED
- implantation surgery data: date of procedure, surgical approach, implant model type, drain, dressing, concurrent procedures, significant corporal fibrosis or scarring noted, curvature correction procedure(s) (e.g., for Peyronie's disease), and patient status post-op
- 1-year post-operative follow-up (at a minimum): each patient is asked 3 standardized questions during a visit or by phone to record any potential device related complications and their outcomes, patient satisfaction with implanted device(s) and use of device.

Refer to Table 1 for the study data collection schedule.

7.1 DEVICE USE AND SATISFACTION QUESTIONS

The following two standardized, non-validated questions will be used to assess post-implantation patient satisfaction with the device and use of the device:

- How satisfied are you with the device(s)? (5-point scale)
  1 – Very Dissatisfied
  2 – Dissatisfied
  3 – Neither Satisfied nor Dissatisfied
  4 – Satisfied
  5 – Very Satisfied
- Are you using the device? (Y/N)
  - (If yes) How often are you using the device? (less than once per month, or more than once per month)
  - How many times per month?
  - If no, why aren't you using the device? (Loss of partner, partner disinterest, device problem, device dissatisfaction, health decline, other, other device use reason)
  - If yes, and not using the device as often as desired, or if dissatisfied with the device, indicate why (Loss of partner, partner disinterest, device problem, device dissatisfaction, health decline, other, other device use reason)

7.2 DEPRESSION HISTORY QUESTIONS

The following patient questions used to assess depression will be optional at baseline and at each annual follow-up.

- Have you had any office visits in past year for treatment of depression? (Y/N)
  - If Yes: Approximately how many visits?
  - If Yes: Are you taking any medication for treatment of depression?
    - If Yes: How many months have you taken the medication?

7.3 PATIENT QUESTIONNAIRES

Patient questionnaires to measure effectiveness will be optional at baseline and at all follow-ups. The following validated, patient-reported outcome questionnaires are *strongly recommended* for all patients at baseline and follow-up:

- IIEF-5/SHIM erectile function questionnaire
- EHS erection hardness questionnaire
- SF-12 health-related quality of life (HRQOL) questionnaire

The following validated, patient-reported outcome questionnaires are recommended for all patients with post-prostatectomy ED or incontinence:

- AUA-SI/IPSS urinary symptom questionnaires
- UCLA-PCI urinary, sexual and bowel function and bother questionnaire

The questions for each individual questionnaire are provided in the Appendix.

7.3.1 International Index of Erectile Function-5 / Sexual Health Inventory for Men (IIEF-5/SHIM)

The IIEF-5 (also known as the SHIM) is a validated, self-report questionnaire with a 25-point maximum score, summed from responses to four questions derived from the erectile function domain (items 2, 4, 5, and 15) and one question from the intercourse satisfaction domain (item 7) of the broader validated 15-item IIEF questionnaire used to assess sexual function in multiple domains. Severity of ED is categorized based on the following IIEF-5 domain scores established and validated in previous studies:

Severe—5 to 7
Moderate—8 to 11
Mild-Moderate—12 to16
Mild—17 to 21
No ED—22 to 25

7.3.2 EHS Erection Hardness Questionnaire

Patients will be asked to respond to the Erection Hardness Score (EHS) questionnaire once per year or at each follow-up visit to assess erection hardness based on their most recent sexual encounter(s). The EHS has a range of responses from 0 to 4 with higher scores corresponding to a more firm or rigid erection.

7.3.3 SF-12 Health-related Quality of Life (HRQOL) Questionnaire

The SF-12v.2 Health Survey is a generic measure and does not target a specific age or disease group. It is a shorter version of the SF-36V2 Health Survey that uses 12 questions to measure function health and well-being from the patient's point of view. The SF-12 quantifies HRQOL into two composite scores, the Physical Component Summary (PCS) and Mental Component Summary (MCS) scales. This survey also quantifies HRQOL into the same eight multi-item subscale domains used in the SF-36 with one or two questions in each domain: physical functioning, emotional well-being, general health, pain, energy, social functioning, and role limitations (problems with work or other daily activities) as a result of physical or emotional health. Each individual domain and the component summary scores (PCS and MCS) are calculated and converted to a standardized 0-100 scale, with higher scores indicating better HRQOL.

7.3.4 American Urological Association – Symptom Index (AUA-SI)

THE AUA-SI (comprised of 7 of the 8 questions of the International Prostate Symptom Score, or IPSS) is used to quantify urinary irritative/obstructive symptom frequency and severity and is scored on a scale of 0–35 based on the summary of the values for each item, with higher scores corresponding to worse outcomes. Classification of urinary irritative/obstructive symptoms based on these scores are as follows:

Mild – 0 to 7

Moderate – 8 to 19
Severe – 20 to 35

7.3.5 UCLA-Prostate Cancer Index (UCLA-PCI) Questionnaire

The UCLA-PCI assesses disease-specific, organ targeted health related quality of life (HRQOL) in six scales or domains that are of special concern to men treated for prostate cancer. Each UCLA PCI domain is scored on a scale of 0–100 points with higher values representing better outcomes.

7.4 SAFETY ASSESSMENTS

Prior to enrollment in the study, patients should be informed by the physician of all known potential risks and discomforts that may be associated with the implantation of a BSC penile prosthesis, or with the study evaluations and data collection. The implantation of a BSC penile prosthesis is a standard medical treatment for ED, and no experimental interventions, tests or procedures are included in this observational Registry study. A complete list of potential adverse device effects and surgery or device related complications that may occur during or after the implantation of the BSC devices can be found in the device specific IFU and/or OR and Patient Manuals.

As per the OR Manual for the penile prosthesis, after penile prosthesis implantation, the Principal Physician is responsible for checking with the patient for any signs of complications, and for reporting device complications in compliance with local regulations (e.g. IRB/EC, country) for a market-released device. The physician should continue to have contact with the patient at least on an annual basis to ask if he has noticed any changes in device functioning (e.g., cylinders losing rigidity), and to check for signs of complications such as infection or erosion. Patients should be instructed to discuss any changes noticed in the function of their prosthesis or problems that may develop after implantation surgery with their physician.

7.4.1 CLINICAL STUDY EVENTS

Clinical study events to be collected for assessment of safety include complications (adverse device effects/events), device malfunctions, and revision procedures related to the device or implantation procedure. At follow-up, including the required 1-year post-operative visit or telephone call, the following standardized, non-validated question will be used to determine whether any complications with the device have occurred:

- Have you had any surgery on your penis or problems with the device since your penile prosthesis was implanted? (Y/N)

A clinical study event data form will be provided to record any events that occur during or after surgical implantation of a BSC penile prosthesis device. Any reported intra-operative or post-operative device or surgery related complications should be recorded

at the time of procedure and any follow-up visits (for BSC products only). The information recorded will include the following:

- Complication
- Treatment
- Location of treatment
- Resolution (Resolved or Continuing)

BSC personnel will follow up with the physician to obtain additional available details, if needed, related to any reported complication that results in a serious adverse device effect, or device deficiency that could have led to a serious adverse device effect, or is severe and may pose unreasonable risk, or potential for death, or serious injury to the patient.

7.4.2 DEVICE COMPLAINT REPORTING

Product complaints are any communication relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device, or any report of a failure of a device to meet its performance. Entering a clinical study event into the database during this study will automatically result in an event that might be considered a product complaint associated with a BSC device being reported directly to BSC Consumer Affairs and any appropriate regulatory authority without any additional action required by the physician. If a reportable event is identified, BSC Consumer Affairs will seek to obtain as much of the following information as possible: name of the product, lot series number (if known), source of data/physician, event description, event start date, date of BSC notification, medical action taken, patient outcome (if known), investigation results, corrective action taken (if any), and regulatory reports (if any). These additional details for any device complaint will not be recorded in the Registry study database.

The Principal Physician will be responsible for reporting events to the IRB/EC based on local requirements. The Principal Physician will also be responsible for reporting any device complications that occur after the time of study exit and all updates to device complications that are unresolved at the time of study exit using the usual process applicable to market-released devices.

7.4.3 SAFETY REPORTING

Definitions and Classification

Adverse event definitions are provided in Table 2. Administrative edits were made to combine definitions from ISO 14155-2011 and MEDDEV 2.7/3 (2015).

Table 2: Safety Definitions

Term	Definition
Adverse Event (AE) *Ref: ISO 14155-2011* *Ref: MEDDEV 2.7/3 (2015)*	Any untoward medical occurrence, unintended disease or injury, or any untoward clinical signs (including an abnormal laboratory finding) in subjects, users or other persons, whether or not related to the investigational medical device.
Serious Adverse Device Effect (SADE) *Ref: ISO 14155-2011* *Ref: MEDDEV 2.7/3 (2015)*	Adverse event that: a. Led to death, b. Led to serious deterioration in the health of the subject, that either resulted in as defined by either: 1.a life-threatening illness or injury, or 2.a permanent impairment of a body structure or a body function, or 3.in-patient or prolonged hospitalization, or 4.medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, c. Led to fetal distress, distress death or a congenital abnormality or birth defect. NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the Clinical Investigational Plan, without serious deterioration in health, is not considered a serious adverse event.
Unanticipated Adverse Device Effect (UADE) *Ref: 21 CFR Part 812*	Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
Unanticipated Serious Adverse Device Effect (USADE) *Ref: ISO 14155-2011* *Ref: MEDDEV 2.7/3 (2015)*	Serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report. **NOTE 1**: Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report.

Table 2: Safety Definitions

Term	Definition
Device Deficiency *Ref: ISO 14155-2011* *Ref: MEDDEV 2.7/3 (2015)*	An inadequacy of an investigational medical device related to its identity, quality, durability, reliability, safety or performance. This may include malfunctions, use error, or inadequacy in the information supplied by the manufacturer.

Relationship to Study Device(s)
The investigator must assess the relationship of the AE to the study device as related or unrelated. See criteria in Table 3:

Table 3: Criteria for Assessing Relationship of Study Device to Adverse Event

Classification	Description
Unrelated	• The adverse event is determined to be due to a concurrent illness or effect of another device/drug and is not related to the investigational product.
Related	• The adverse event is determined to be potentially related to the investigational product, and an alternative etiology is equally or less likely compared to the potential relationship to investigational product, or • There is a strong relationship to investigational product, or recurs on re-challenge, and another etiology is unlikely, or • There is no other reasonable medical explanation for the event.

Relationship to Study Procedure
The investigator must assess the relationship of the AE to the study procedure as unrelated, possibly related, or probably related. See criteria in Table 4:

Table 4: Criteria for Assessing Relationship to Study Procedure

Classification	Description
Unrelated	•No evidence that the timing of the adverse event has a relationship to the procedure performed.
Related	•The adverse event has a timely relationship to procedure performed. However, a potential alternative etiology may be responsible for the adverse event.

8 STATISTICAL METHODS AND DATA ANALYSIS

Analyses of multi-center data for initial publication(s) may be performed after approximately 500 patients complete 1 year follow-up. Additional individual and multi-center data analyses may be performed as warranted throughout the study for publication(s). Analysis for study publications is planned after the study enrollment is complete and all the enrolled patients have completed their 1-year and 5-year follow-up evaluations.

8.1 SAMPLE SIZE

Up to 1500 patients with erectile dysfunction (ED) electing to receive a BSC penile prosthesis implant will be included in this registry over a 1- to 2-year enrollment period. A total of more than 500 patients are anticipated to be implanted and entered into the registry database per year of enrollment, based on the following BSC historical estimates of the number of each BSC penile prosthesis type implanted, and assuming 10 to 15 participating physicians:

- 500 AMS 700®
- 15 AMS Ambicor®
- 20 Spectra™

The minimum sample size for multi-center data analysis will depend on the total number of patients, or the number of patients with each type of penile prosthesis implanted for whom sufficient follow-up data on multiple endpoints of interest are available. Generally, a minimum follow-up of at least one year after implantation is desired for analysis of data for the device subsets with previous clinical outcomes reported in the literature (e.g., AMS 700®, AMS Ambicor®). Because clinical data has been published from multiple studies including more than 100 patients implanted with AMS 700® devices in the past decade (since the introduction of the InhibiZone antibiotic-impregnated devices and the current MS Pump), analysis of less than 100 patients implanted with these devices with at least one1 year of follow-up is not planned. However, an analysis sample size as small as 10 to 25 patients implanted with the newer Spectra™ or AMS 700® Series devices with the Conceal Low Profile reservoir, with 6 to 12 months of post-implant follow-up, may be of value for publication in the scientific literature due to the lack of any prospective clinical outcomes published to date for these products.

8.2 SAFETY OBJECTIVES

Safety will be assessed by collection and review of all reported intra-operative and post-operative device or surgery related clinical study events recorded during the implantation or any follow-up visits (for BSC products only).

<u>Endpoint:</u>

- Complications (adverse device effects/events)
    - Intra-operative device or surgery related complications - reported during Implantation visit (e.g., cylinder crossover)

  - Post-operative device or surgery related complications - reported during follow-up (e.g., mechanical malfunction, infection)
  - Unanticipated and serious adverse device effects (per ISO 14155:2011)
  - Deaths (related to the device or implantation procedure)

- Device Malfunctions
  - Device deficiencies or malfunctions (per ISO 14155:2011)

- Revision procedures related to the device or implantation procedure

Statistical Analysis:
Descriptive statistics (number of events, number and proportion of patients) will be summarized by complication category by device type and for the full group. Kaplan-Meier method will be used to estimate the major complication event rate at 1 year post-operative follow up by device type and overall for all BSC penile prostheses recipients.

Descriptions will also be prepared of the following details associated with device related complications in each category, and will include the following as available for each:
- Treatment for complication
- Location of treatment
- Resolution (resolved or continuing)

Additional analyses may be prepared for other follow-up time such as 6 month, 2, 3, 4, and 5 years.

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3 EFFECTIVENESS OBJECTIVES

Effectiveness of the BSC penile prostheses will be assessed in all patients with data available at the required 1-year (± 4 months) post-operative follow-up, and any of the following additional follow-up time points with data available:
- 3 months (± 1 month)
- 6 months (± 1 month)
- 18 months (± 1 month)
- 2 years (± 4 months)
- 3 years (± 6 months)
- 4 years (± 6 months)
- 5 years(± 6 months)

8.3.1 EFFECTIVENESS OBJECTIVE 1 – DEVICE USE AND SATISFACTION

To assess post-implantation patient satisfaction with the device and use of the device.

Endpoint:

- How satisfied are you with the device(s)? (5-point scale)
  1 – Very Dissatisfied
  2 – Dissatisfied
  3 – Equally Satisfied and Dissatisfied
  4 – Satisfied
  5 – Very Satisfied
- Are you using the device? (Y/N)
  - (If yes) How often are you using the device? (less than once per month, or more than once per month)
  - How many times per month?
  - If no, why aren't you using the device? (Loss of partner, partner disinterest, device problem, device dissatisfaction, health decline, other, other device use reason)
  - If yes, and not using the device as often as desired, or if dissatisfied with the device, indicate why (Loss of partner, partner disinterest, device problem, device dissatisfaction, health decline, other, other device use reason)

Statistical Analysis:
The number and percentage of patients with responses in each category for the satisfaction and the device use questions at 1-year visit and any of the additional follow-up time points with data available will be summarized for each device type and overall for all BSC penile prostheses recipients.

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3.2 EFFECTIVENESS OBJECTIVE 2 – IIEF-5/SHIM QUESTIONNAIRES

To assess sexual function in IIEF-5 scores.

Endpoint:
The endpoint is the change in IIEF-5 total scores from baseline to 1-year post-operative follow-up.

Statistical Analysis:
The IIEF-5 total scores will be computed for each patient at baseline and 1-year follow up, and the change from baseline to 1-year follow up will be calculated. Descriptive summary statistics including mean, median, standard deviation (SD), and range will be generated by each device type and overall for all BSC penile prostheses recipients. For within patient change at 1-year follow up compared to baseline, signed rank sum test or paired t-test may be used when applicable.

Additional analyses may also be used to summarize the values at the other follow-up time points with data available along with changes from baseline for each device type and overall for all BSC penile prostheses recipients. Mixed effects model may be used to estimate the change from baseline across follow up visits when appropriate.

In addition, the number and percentage of patients with IIEF-5 scores meeting the following criteria will be calculated at baseline and at each post-treatment time point for each device type and overall:

- ≤ 7 points (severe ED)
- 8 to 11 points (moderate ED)
- 12 to16 points (mild-moderate ED)
- 17 to 21 points (mild ED)
- ≥ 22 points (no ED)

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3.3 EFFECTIVENESS OBJECTIVE 3 – EHS QUESTIONNAIRES

To assess erection hardness based on patients' most recent sexual encounters.

Endpoint:
The endpoint is the change in the single-item EHS scores from baseline to 1-year post-operative follow-up.

Statistical Analysis:
The EHS scores will be computed for each patient at baseline and 1-year follow up, and the change from baseline to 1-year follow up will be calculated. Descriptive summary statistics including mean, median, SD, and range will be generated by each device type and overall for all BSC penile prostheses recipients. For within patient change at 1-year follow up compared to baseline, signed rank sum test or paired t-test may be used when applicable.

Additional analyses may also be used to summarize the values at the other follow-up time points with data available along with changes from baseline for each device type and overall for all BSC penile prostheses recipients. Mixed effects model may be used to estimate the change from baseline across follow up visits when appropriate.

In addition, the number and percentage of patients who meet the following criteria will be calculated at baseline and each follow up visit for each device type and overall:

- Patients with an EHS score ≥ 3 (penis hard enough for penetration but not completely hard)
- Patients with an EHS score = 4 (penis completely hard and fully rigid)

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3.4 EFFECTIVENESS OBJECTIVE 4 – SF-12 HRQOL QUESTIONNAIRES

To measure function health and well-being from the patient's point of view.

Endpoint:
The endpoint is the change in each of the following SF-12 scales from baseline to 1-year post-operative follow-up.

Two component summary scales:
- PCS (physical component summary)
- MCS (mental component summary)

Eight individual domain scales:
- Physical functioning
- Role physical
- Emotional well-being
- Role emotional
- Social functioning
- Energy
- Pain
- General health

Statistical Analysis:
The PCS, MCS and individual domain scores will be computed for each patient at baseline and 1-year follow up, and the change from baseline to 1-year follow up will be calculated. Descriptive summary statistics including mean, median, SD, and range will be generated for each device type and overall for all BSC penile prostheses recipients. For within patient change at 1-year follow up compared to baseline, signed rank sum test or paired t-test may be used when applicable.

Additional analyses may also be used to summarize the values at the other follow-up time points with data available along with changes from baseline for each device type and overall for all BSC penile prostheses recipients. Mixed effects model may be used to estimate the change from baseline across follow up visits when appropriate.

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3.5 EFFECTIVENESS OBJECTIVE 5 – AUA-SI/IPSS QUESTIONNAIRES

To quantify urinary irritative/obstructive symptom frequency and severity.

Endpoint:
The endpoint is the change in the AUA-SI total scores from baseline to 1-year post-operative follow-up.

Statistical Analysis:
The AUA-SI total scores will be computed for each patient at baseline and 1-year follow up, and the change from baseline to 1-year follow up will be calculated. Descriptive summary statistics including mean, median, SD, and range will be generated for each device type and overall for all BSC penile prostheses recipients. For within patient change at 1-year follow up compared to baseline, signed rank sum test or paired t-test may be used when applicable.

Additional analyses may also be used to summarize the values at the other follow up time points with data available along with changes from baseline for each device type and overall for all BSC penile prostheses recipients. Mixed effects model may be used to estimate the change from baseline across follow up visits when appropriate.

In addition, the number and percentage of patients who meet the following criteria will be calculated at baseline and each follow up visit:

- Mild (0 to 7)
- Moderate (8 to 19)
- Severe (20 to 35)

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3.6 EFFECTIVENSS OBJECTIVE 6 – UCLA-PCI QUESTIONNAIRES

To assess disease-specific, organ targeted health related quality of life in six scales or domains that are of special concern to men treated for prostate cancer.

Endpoint:
The endpoint is the change in each of the following UCLA-PCI domains from baseline to 1-year post-operative follow up.

- Sexual Function
- Sexual Bother
- Urinary Function
- Urinary Bother
- Bowel Function
- Bowel Bother

Statistical Analysis:

The individual domain scores will be computed for each patient at baseline and 1-year follow up, and the change from baseline to 1-year follow up will be calculated. Descriptive summary statistics including mean, median, SD, and range will be generated for each device type and overall for all BSC penile prostheses recipients. For within patient change at 1-year follow up compared to baseline, signed rank sum test or paired t-test may be used when applicable.

Additional analyses may also be used to summarize the values at the other follow-up time points with data available along with changes from baseline for each device type and overall for all BSC penile prostheses recipients. Mixed effects model may be used to estimate the change from baseline across follow up visits when appropriate.

Determination of Patients for Analysis:
All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.3.7 ADDITIONAL EFFECTIVNESS OBJECTIVES

To assess the penile length and girth, number of pads used daily and pad weight (24-hour test).

Endpoint:
The endpoint is the change in each of the following measurements from baseline to 1 year post-operative follow-up.

- Inflated penile length measurement (measured from suprapubic fat pad to tip)
- Inflated penile girth measurement (circumference measured 1cm proximal to the proximal end of the corona)
- Number of pads used daily (if incontinence indicated pre-operatively)
- Pad weight (24-hour test) (if incontinence indicated pre-operatively)

Statistical Analysis:
Descriptive summary statistics for penile length and girth, number of pads used daily and pad weight at baseline and 1-year follow up, and the change from baseline and 1-year follow up will be calculated and summarized for each device type and overall for all BSC penile prostheses recipients. For within patient change at 1-year follow up compared to baseline, signed rank sum test or paired t-test may be used when applicable.

Additional analyses may also be used to summarize the values at the other follow up time points with data available along with changes from baseline for each device type and overall for all BSC penile prostheses recipients.

Determination of Patients for Analysis:

All enrolled patients that received a BSC penile prosthesis with data available will be included.

8.4 ADDITIONAL DATA ANALYSIS

8.4.1 SUBGROUP ANALYSIS

Subgroups of patients for which analyses of safety and effectiveness outcomes may be performed based on relevant available data include, but are not limited to, the following:

- Implant type and model (AMS 700®, Ambicor®, Spectra™)
  - AMS 700® LGX
  - AMS 700® Series with Conceal
  - AMS 700® MS Pump
  - AMS 700® with InhibiZone
- Original (virgin) and revision implants (if revision – with or without washout)
- Primary etiology of ED (e.g., Diabetes, Cardiovascular disease, Radical prostatectomy, Peyronie's disease)

8.4.2 PHYSICIAN DATA

Recorded data from each practice will be summarized in the following categories:

- Practice type (private or academic)
- Main setting for procedures (Hospital or ASC)
- Standard device cycling instructions to patients receiving IPPs (number and percentage) – a description of each physician's recorded device cycling protocol will also be prepared.

8.4.3 BASELINE/ PRE-OPERATIVE DATA

The following demographic and patient characteristics will be summarized (including mean, median, and standard deviations) for patient groups based on the type of BSC device implanted and overall for all BSC penile prostheses recipients:

- Age
- Duration of ED (years or months)
- Pre-op flaccid penile length (measured from suprapubic fat pad to tip)
- Pre-op stretched penile length (measure from suprapubic fat pad to tip)
- Pre-op flaccid girth (circumference measured 1cm proximal to the proximal end of the corona)
- Number of office visits in past year for treatment of depression
- Duration (weeks) and Frequency (times/day) of VED use prescribed pre-operatively
- Number of pads used daily (for SUI)
- Pad weight (24-hour test) (for SUI)
- Urodynamics (for SUI): Post-void residual (PVR) volume (ml), maximum flow rate (ml/sec)

The number and percentage of patients with recorded baseline data will also be summarized within each device type and the full patient group in the following categories:

- Race/Ethnicity
- Primary etiology of ED
    - Organic
        - Diabetes
        - Cardiovascular disease
        - Neurologic disorder
        - Peyronie's disease
        - Other organic (specify)
    - Acute
        - Radical prostatectomy (RP) (robotic, open or laparoscopic)
        - Radical pelvic surgery (other than RP)
        - Pelvic radiation therapy
        - Pelvic trauma or injury
        - Spinal cord injury
        - Venous Leak
        - Priapism
        - Other acute (specify)

- Concomitant medical conditions and concomitant medications:
    - premature or rapid ejaculation/PE
    - climacturia
    - cardiovascular disease
    - diabetes
    - Peyronie's disease
    - steroid use
    - anticoagulant use
    - anti-depressant use
    - Venous Leak
    - stress urinary incontinence/SUI
        - Etiology of incontinence (radical prostatectomy, pelvic irradiation, and other)
        - Previous treatment(s) for incontinence (behavior modification, pelvic floor muscle training, transobturator male sling, artificial urinary sphincter/AUS, and other)
        - Cystoscopy findings (bladder neck contracture, other) (for SUI)
        - Any detrusor overactivity (DO) or detruser sphincter dyssynergia (DSD) (for SUI)
    - any others recorded
- Previous treatments used for ED (PDE-5 inhibitor, VED, ICI, combination therapies, previous/failed penile implants)
- Patients with any office visits in past year for treatment of depression

- Patients taking any depression medication in past year
- Patients with VED and/or penile traction therapy prescribed pre-operatively

8.5 IMPLANTATION DATA

Descriptive summaries of all available implantation data collected in the registry database will be prepared, to include the number of patients (and percentage or range of values, as applicable) with recorded data within each device type and the full patient group in the following categories:

- Date of procedure (range)
- Original (virgin), revision, salvage, or replacement implant (if revision or salvage, with or without washout)
- Surgical approach (percentage of patients by category: Penoscrotal (PS), Infrapubic (IP), Subcoronal (SC) and Other)
- Implant model type
    - Spectra™ Concealable Penile Prosthesis
        - Cylinder diameter (9.5, 12, 14 mm)
        - Cylinder length (12, 16, 20 cm)
        - Total number of RTEs per cylinder (0, 1, 2)
        - Total length of RTEs per cylinder (specify: 0.5 to 7.5 cm)
    - AMS Ambicor® Penile Prosthesis (2-piece inflatable)
        - Cylinder diameter (12.5, 14, 15.5 mm)
        - Cylinder length (14, 16, 18, 20, 22 cm)
        - Total number of RTEs per cylinder (0, 1, 2, 3, 4)
        - Total length of RTEs per cylinder (specify: 0.5 to 6.5 cm)
    - AMS 700® Penile Prosthesis (3–piece inflatable)
        - InhibiZone-impregnated
        - Cylinder type (CX, LGX, CXR, Ultrex, CXM)
        - Cylinder length (10, 12, 14, 15, 16, 18, 21, 24 cm)
        - Total number of RTEs per cylinder (0, 1, 2, 3, 4)
        - Total length of RTEs per cylinder (specify: 0.5 to 7.5 cm)
        - Pump type (MS Pump, Tactile pump, Inflate/Deflate)
        - Preconnect
        - Reservoir (Spherical 65 ml, Spherical 100 ml, Conceal 100 ml)
        - Reservoir placement (space of Retzius, Sub-muscular, Sub Scarpas's fascia, other)
        - Reservoir separate incision
- Drain (None or Type)
- Dressing (None, compression/mummy wrap, non-compressive dressing)
- Concurrent procedures (ventral phalloplasty, ligament release, circumcision, suprapubic fat pad reduction, spermatic cord/testicular procedure, AUS (including single or multiple incision), sling – (including sling type and single or multiple incision)
- Significant corporal fibrosis or scarring noted
- Peyronie's Disease

    - Initial intraoperative curvature measurement (angle of curvature with inflated device using a goniometer or protractor)
    - Any curvature correction procedure(s) performed (including correction technique (Wilson/Delk remodeling, tunical incision, incision and grafting, or plication)
        - Curvature measurement after correction
        - Second correction procedure(s) (including summary details as above)
- Patient status post-op (Admitted/inpatient/≥24 hours, same day discharge/outpatient/<24 hours)
    - Number of days in the hospital for admitted patients (mean, median, standard deviation)
- Length of procedure (mean, median, standard deviation)
- Intra-operative penile length measurement with device fully inflated (mean, median, standard deviation)
- Intra-op penile girth measurement with device fully inflated (mean, median, standard deviation)
- Intra-op stretched penile length with device deflated (mean, median, standard deviation)
- Foley in place at discharge

9 PROTOCOL DEVIATIONS

All attempts should be made not to deviate from the clinical protocol. If, however, a Protocol Deviation occurs a Protocol Deviation data form should be recorded for each study protocol deviation (e.g., failure to obtain written informed consent if required, enrolling a patient who does not meet inclusion criteria, not obtaining minimum required follow-up data). This form will include a description of the deviation, reason for deviation, and corrective and/or preventative action, if necessary. The Principal Physician is responsible for reporting protocol deviations in compliance with their IRB/EC regulations. BSC will determine and document whether the data obtained from patient(s) with one or more protocol deviations are sufficient to be included in the study outcomes analyses prior to locking the data for the analyses.

10 DATA ANALYSIS

Sites will be able to access their own data via ad hoc reporting at any time. Through BSC, sites will also be able to request some summary data. Aggregate data from more than one site will be made available to Principal Physician(s) only upon approval of a request by the PROPPER Publication Review Committee. To preserve anonymity, aggregate data may not be made available until a minimum of 50 patients have been enrolled into the Registry.

11 DATA SECURITY

The EDC system to be used for this study by Boston Scientific Corporation is in full compliance with 21 CFR 11, Guidance on Computerized Systems used in Clinical Trials, and ICH and ISO GCP guidelines for electronic clinical data systems.

Electronic access to the EDC system will be carefully controlled by Boston Scientific Corporation. System entry will be limited via unique usernames and password-protected logon procedures. Physicians will have access only to data from their own sites; they will not have access to data from other sites.

12 DATA QUALITY ASSURANCE

The EDC system will include edit checks that will inform physicians as soon as they enter inappropriate data. There are 2 levels of edit checks: soft and hard. 'Soft' errors result in a pop-up message that notes the nature of the error and a confirmation request of the value in question. 'Hard' errors generate similar error messages, but also prevent the form from further data entry until the error is corrected. An example of a soft error generation is entering an out of range value, for example a dry pad weight value of 20g and a pad weight after test value of 10g, would be outside the expected value of pad weight difference. An example of a hard error is failing to respond 'yes' to the question: 'Was Informed Consent/HIPAA waiver obtained (per your IRB/EC requirements)?'. Validation tests of this edit check system have been performed by BSC and selected physicians.

13 MONITORING PLAN

BSC will conduct pre-study telephone calls, and site initiation visits to ensure appropriate physician training. Interim monitoring visits will be completed by a CRO after patients have been enrolled at each site to ensure that records related to the study and patient informed consent documentation are maintained at each site as needed. Sites are required to grant access to source documentation for the purposes of monitoring visits including patient Informed Consent Forms. All Informed Consent Forms will be monitored, with additional monitoring to be conducted as necessary throughout the study and per the monitoring plan.

14 INSTITUTIONAL REVIEW BOARD (IRB)/ETHICS COMMITTEE (EC) REVIEW

This registry will be performed in accordance with all applicable requirements set forth in the ICH Good Clinical Practices (GCPs), the World Medical Association Declaration of Helsinki, ISO 14155 Good Clinical Practice standards, and any other applicable local laws and regulations.

The PROPPER Registry is an observational collection of data and as such physicians are free to manage their patients according to their usual practices. BSC devices for which clinical outcomes will be collected in the registry have all been cleared for marketing by the FDA or other local responsible regulatory agency. Physicians are

encouraged to use these devices according to the labeled indication and product use instructions. Therefore, participation in the Registry study poses no additional risk to the patient in relation to the device implantation for the treatment of ED or related standard-of-care testing or assessments. BSC will ensure adequate provisions are in place to protect the privacy of patients and to maintain the confidentiality of study data as required by regulations, including limiting electronic database system access to authorized individuals. This study protocol will be subject to an IRB/EC for review and approval if required prior to patient enrollment at each site. All physicians must comply with the requirements of their IRB/EC.

15 INFORMED CONSENT AND PATIENT PRIVACY

BSC will provide a template Informed Consent Form describing this study for physicians at each participating site to submit to their IRB/ECs. All physicians must comply with the requirements of their IRB/EC. If an IRB/EC requires patients to provide informed consent to participate in this study, a site-specific Informed Consent Form will be submitted for IRB/EC review and approval prior to patient enrollment at the site. Because this registry study is non-interventional and physicians are using standard-of-care treatment and assessments in this study, the IRB/EC at some sites may not require written informed consent from patients prior to their participation in this study. If study-specific informed consent is not required at a site, a waiver from informed consent must be documented from the site's IRB/EC prior to study patient enrollment. A site's IRB/EC may require that an approved HIPAA authorization be signed instead of, or in addition to, informed consent prior to enrollment of study patients.

16 STUDY RECORDS AND REPORTS

Data from this study related to the safety or performance of the BSC penile prostheses may be submitted to regulatory authorities. Study records will be maintained by the Principal Physician and by BSC consistent with FDA/ICH and ISO ICH Good Clinical Practice (GCP) guidance and standards [FDA/ICH E6 Guidance, April 1996; ISO 14155:2011(E)]. The physician is responsible for maintaining accurate, complete, and current records and documents relating to the conduct of this study as outlined in the GCP standards, including the following:

- Clinical investigational plan (CIP/protocol) and any amendments
- Signed Investigator agreement and clinical study reimbursement agreement
- Physician curriculum vitae (CV) (current by address)
- Physician medical license (current by date)
- Physician financial disclosure information
- Study personnel training records (BSC to provide)
- IRB/EC composition, approvals, renewals and correspondence (as applicable)
- Delegation of Authority Log (BSC to provide)
- Study related correspondence with another physician, an IRB/EC, BSC, monitors, patients, or responsible regulatory authority, including required reports that relate to this study
- Patient's medical records
- Signed study Informed Consent Form for each patient (ICF, if required)

- Patient questionnaires (if used)

All records pertaining to this clinical study will be maintained for at least 2 years after the conclusion of the study, or until the physician is informed by BSC that the records are no longer required to support a regulatory application, whichever occurs later. These records should be retained for a longer period, however, if required by the applicable regulatory requirements. If records are stored or transferred to a location other than the site where the study was conducted a pointer will be placed in the site file explaining where the records are located and BSC should be notified. If the physician wishes to withdraw from the responsibility of maintaining these study records, a transfer of responsibility to a person willing to accept the responsibility must occur and be reported to BSC not more than 30 days after the transfer occurs.

16.1 PHYSICIAN REPORTS

Physician is responsible for preparation and submission of the following reports as identified in Table 5 below.

Table 5: Description and Submission Requirements of Physician Reports

Report	Submit to	Description
Clinical Study Events	Sponsor/IRB/EC	Unanticipated adverse device Effect (UADE), and Serious Adverse Device Effect (SADE) need to be submitted to the Sponsor and may need to be submitted to the IRB/EC in accordance with the IRB/EC requirements at the study site, as soon as possible but no later than 10 working days after the physician learns of the event
Study Patient Death	Sponsor/IRB/EC	Death must be reported to the sponsor and may need to be submitted to the IRB/EC in accordance with local requirements, no later than 10 working days after the physician learns of the death
Withdrawal of IRB/EC approval	Sponsor	The physician must report a withdrawal of approval by the reviewing EC/ IRB of the physician's part of the study, within 5 working days of the physician learning of the withdrawal of approval
Progress Report	Sponsor/IRB/EC	The physician must submit this report to the sponsor and the IRB/EC at regular intervals in accordance with the IRB/ EC requirements at

		the study site
Study Deviations	Sponsor/IRB/EC	Notice of deviations from the plan will be submitted to the sponsor and may need to be submitted to the IRB/EC in accordance with IRB/EC requirements
Final Report	Sponsor/IRB/EC	Notification of clinical investigation close-out to the IRB/EC by physicians, where required.

16.2 BSC REPORTS

BSC is responsible for preparation and submission of the following reports as identified in Table 6 below.

Table 6: Description and Submission Requirements of BSC Reports

Report	Submit to	Description
Unanticipated Adverse Device Effects	Physicians, FDA/CA, IRB/EC, (where required)	Notification within 10 working days after the Sponsor learns of the event
Withdrawal of IRB/EC approval	Physicians, IRB/EC, (where required)	Notification within 5 working days of the Sponsor learning of the withdrawal of approval
Recall	Physicians, FDA/CA, IRB/EC (where required)	Notification within 30 working days and will include the reasons for any request that a physician return, repair or otherwise dispose of any devices
Final report	IRB/EC, Physicians (if required)	BSC will notify physicians and IRBs/ECs within 6 months after completion or termination of this study.

17 PHYSICIAN NON-COMPLIANCE AND STUDY TERMINATION

Protocol deviations will be closely monitored by BSC and analyzed for trends that may be occurring at each site or more than one site. If excessive deviations or a failure to reduce deviations are noted, BSC reserves the right to suspend study enrollment until a sufficient system is in place at the site to reduce further deviations. BSC may also terminate study activities at the site as required by GCPs or local regulations for issues of non-compliance that cannot be resolved. A physician may elect to withdraw from study participation at any time during the study.

18 PUBLICATION PLAN

Results of this study are intended to be submitted for publication in scientific journals and at scientific meetings. Study data acquisition, analyses and interpretation of aggregate multi-center study data for all enrolled patients after completion of 1-year follow-up and final study follow-up for publication will be overseen by BSC, in collaboration with actively participating physician(s) and study Publication Review Committee members. Additional statistical analysis or aggregate data publications describing study outcomes authored by one or more physicians will be considered by this committee comprised of physicians and BSC representatives.

The PROPPER Publication Review Committee will develop a charter describing its membership and the details of the schedule and procedures for requesting data, analyses or other support related to publications for submission to scientific organizations. This charter will be distributed to all participating physicians by BSC. A BSC Clinical Project Leader or designee will be the coordinator for facilitating the submission of analysis or publication support requests by interested physician authors to the committee for consideration.

Physicians will have access to the data from their own patients throughout the study and may perform independent analyses for publication(s). However, BSC requires that the author furnish a copy of any proposed publication to BSC for Publication Review Committee review prior to submission to the publisher.

Generally accepted criteria for publication authorship will be considered appropriate for all study-related publications[72]:

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2) drafting the manuscript or revising it critically for important intellectual content; and
3) final approval of the version of the manuscript to be submitted for publication.

Each individual author should qualify for authorship, and all authors who qualify should be listed either as individual authors or as part of an authors' group on study publications. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Although BSC representatives may in some cases co-author publications, acquisition of data or general supervision of the study alone does not qualify one for authorship.

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APPENDIX 1 - QUESTIONNAIRES

International Index of Erectile Function-5 / Sexual Health Inventory for Men (IIEF-5/SHIM)

The 5 specific questions comprising the IIEF-5/SHIM are shown below. Each question is preceded by the phrase, “Over the past 6 months,”:

1. How do you rate your confidence that you could get and keep an erection?
    1 - Very low
    2 - Low
    3 - Moderate
    4 - High
    5 - Very high
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?
    1 - Almost never/never
    2 - A few times (much less than half the time)
    3 - Sometimes (about half the time)
    4 - Most times (much more than half the time)
    5 - Almost always/always
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?
    1 - Almost never/never
    2 - A few times (much less than half the time)
    3 - Sometimes (about half the time)
    4 - Most times (much more than half the time)
    5 - Almost always/always
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?
    1 - Extremely difficult
    2 - Very difficult
    3 - Difficult
    4 - Slightly difficult
    5 - Not difficult
5. When you attempted sexual intercourse, how often was it satisfactory for you?
    1 - Almost never/never
    2 - A few times (much less than half the time)
    3 - Sometimes (about half the time)
    4 - Most times (much more than half the time)
    5 - Almost always/always

EHS Erection Hardness Questionnaire

The specific question comprising the EHS is shown below.

EHS: “How would you rate the hardness of your erection?”
- 0: Penis does not enlarge.
- 1: Penis is larger but not hard.
- 2: Penis is hard but not hard enough for penetration.
- 3: Penis is hard enough for penetration but not completely hard.
- 4: Penis is completely hard and fully rigid.

SF-12 Health-related Quality of Life (HRQOL) Questionnaire

The 7 specific questions comprising the SF-12 are shown below.

1. In general, would you say your health is:
   - 1 - Excellent
   - 2 - Very good
   - 3 - Good
   - 4 - Fair
   - 5 - Poor

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

   Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf
   - 1 – Yes, limited a lot
   - 2 – Yes, limited a little
   - 3 – No, not limited at all

   Climbing several flights of stairs
   - 1 – Yes, limited a lot
   - 2 – Yes, limited a little
   - 3 – No, not limited at all

3. During the past 4 weeks how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health

   Accomplished less than you would like
   - 1 – All of the time
   - 2 – Most of the time
   - 3 – Some of the time
   - 4 – A little of the time

5 – None of the time

Were limited in the kind of work or other activities
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time
5 – None of the time

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Accomplished less than you would like
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time
5 – None of the time

Did work or other activities less carefully than usual
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time
5 – None of the time

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
1- Not at all
2 – A little bit
3 – Moderately
4 – Quite a bit
5 – Extremely

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please five the one answer that comes closet to the way you have been feeling. How much of the time during the past 4 weeks…

Have you felt calm and peaceful?
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time

5 – None of the time

Did you have a lot of energy?
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time
5 – None of the time

Have you felt downhearted and depressed?
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time
5 – None of the time

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?
1 – All of the time
2 – Most of the time
3 – Some of the time
4 – A little of the time
5 – None of the time

American Urological Association – Symptom Index (AUA-SI)

The 7 specific questions comprising the AUA-SI are shown below.

Over the past month, how often have you had a sensation of not emptying your bladder completely after you finished urinating?
0 – Not at all
1 – Less than 1 time in 5
2 – Less than half the time
3 – About half the time
4 – More than half the time
5 – Almost always

Over the past month, how often have you had to urinate again less than two hours after you finished urinating?
0 – Not at all
1 – Less than 1 time in 5
2 – Less than half the time
3 – About half the time
4 – More than half the time

5 – Almost always

Over the past month, how often have you found you stopped and started again several times when you urinated?

0 – Not at all
1 – Less than 1 time in 5
2 – Less than half the time
3 – About half the time
4 – More than half the time
5 – Almost always

Over the past month, how often have you found it difficult to postpone urination?

0 – Not at all
1 – Less than 1 time in 5
2 – Less than half the time
3 – About half the time
4 – More than half the time
5 – Almost always

Over the past month, how often have you had a weak urinary stream?

0 – Not at all
1 – Less than 1 time in 5
2 – Less than half the time
3 – About half the time
4 – More than half the time
5 – Almost always

Over the past month, how often have you had to push or strain to begin urination?

0 – Not at all
1 – Less than 1 time in 5
2 – Less than half the time
3 – About half the time
4 – More than half the time
5 – Almost always

Over the past month, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?

0 – None
1 – 1 time
2 – 2 times
3 – 3 times
4 – 4 times
5 – 5 times

UCLA-Prostate Cancer Index (UCLA-PCI) Questionnaire

The 20 specific questions comprising the 6 scales of the UCLA-PCI are shown below.

Sexual Function

How would you rate each of the following during the last 4 weeks?

1. Your level of sexual desire?
   - 1 - Very poor
   - 2 - Poor
   - 3 – Fair
   - 4 – Good
   - 5 - Very Good
2. Your ability to have an erection?
   - 1 - Very poor
   - 2 – Poor
   - 3 – Fair
   - 4 – Good
   - 5 - Very Good
3. Your ability to reach orgasm (climax)?
   - 1- Very poor
   - 2- Poor
   - 3 – Fair
   - 4- Good
   - 5 - Very Good
4. How would you describe the usual QUALITY of your erection?
   - 1 - None at all
   - 2 - Not firm enough for any sexual activity
   - 3 - Firm enough for masturbation and foreplay only
   - 4 - Firm enough for intercourse
5. How would you describe the FREQUENCY of your erections?
   - 1 - I NEVER had an erection when I wanted one
   - 2 - I had an erection LESS THAN HALF the time I wanted one
   - 3 - I had an erection ABOUT HALF the time I wanted one
   - 4 -I had an erection MORE THAN HALF the time I wanted one
   - 5 -I had an erection WHENEVER I wanted one
6. How often have you awakened in the morning or night with an erection?
   - 1 –Never
   - 2 - Seldom (less than 25% of the time)
   - 3 - Not often (less than half the time)
   - 4 - Often (more than half the time)
   - 5 - Very often (more than 75% of the time)
7. During the last 4 weeks, did you have vaginal or anal intercourse?
   - 1 –No
   - 2 - Yes, Once
   - 3 - Yes, More than once

8. Overall, how would you rate your ability to function sexually during the last 4 weeks?
    1 - Very poor
    2 – Poor
    3 - Fair
    4 – Good
    5 - Very Good

Sexual Bother

1. Overall, how big a problem has getting and maintaining an erection been for you during the last 4 weeks?
    1 - No problem
    2 - Very small problem
    3 - Small problem
    4 - Moderate problem
    5 - Big problem

Urinary function

1. Over the past 4 weeks, how often have you leaked urine?
    1 - Every day
    2 - About once a week
    3 - Less than once a week
    4 - Not at all

2. Which of the following best describes your urinary control during the last 4 weeks?
    1 - No control whatsoever
    2 - Frequent dribbling
    3 - Occasional dribbling
    4 - Total control

3. How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks?
    1- 3 or more pads per day
    2 - 1-2 pads per day
    3 - No pads

4. How big a problem, if any, has each of the following been for you during the last 4 weeks?

    Dripping urine or wetting your pants
        0 - No problem
        1 - Very small problem
        2 - Small problem
        3 - Moderate problem
        4 - Big problem
    Urine leakage interfering with your sexual activity

0 - No problem
1 - Very small problem
2 - Small problem
3 - Moderate problem
4 - Big problem

Urinary Bother

1. Overall, how big a problem has your urinary function been for you during the last 4 weeks?
    1- No problem
    2- Very small problem
    3- Small problem
    4- Moderate problem
    5- Big problem

Bowel Function

1. How often have you had rectal urgency (felt like I had to pass stool, but did not) during the last 4 weeks?
    1 - More than once a day
    2 - About once a day
    3 - More than once a week
    4 - About once a week
    5 - Rarely or never
2. How often have you had stools (bowel movements) that were loose or liquid (no form, watery, mushy) during the last 4 weeks?
    1 - Never
    2 - Rarely
    3 - About half the time
    4 - Usually
    5 - Always
3. How much distress have your bowel movements cause you during the last 4 weeks?
    1- Severe distress
    2- Moderate distress
    3- Little distress
    4- No distress
4. How often have you had crampy pain in your abdomen or pelvis during the last 4 weeks?
    1- Several times a day
    2- About once a day
    3- Several times a week
    4- About once a week
    5- About once this month
    6- Rarely or never

Bowel Bother

1. Overall, how big a problem have your bowel habits been for you during the last 4 weeks?
    1- No problem
    2- Very small problem
    3- Small problem
    4- Moderate problem
    5- Big problem