



## The prosthetic urology opportunity

Erectile Dysfunction (ED) is a common male sexual health problem affecting many men and poses a significant quality of life burden on men and their partners.<sup>1</sup> This burden can extend to work too, with men experiencing up to 35 days of work impairment per year resulting in \$7,224 in lost productivity per man.<sup>2</sup> Despite these detrimental effects, there are **over 1.7 million insured men in the United States with ED** that could benefit from a penile implant, yet, **approximately 23,000 or only 1.3% of these patients undergo a penile implant procedure annually.**<sup>3,4</sup> This undertreatment provides a significant opportunity to extend much-needed care to this patient population and grow the urology service line.

In addition, male stress urinary incontinence (SUI) is a significant quality of life issue for men as it can rob them of their freedom to live a normal life.<sup>5</sup> Male SUI is often a side effect of prostate cancer treatment, specifically radical prostatectomy (RP).<sup>5</sup> It is reported that 14% to 32% of men had some level of SUI one year after robot-assisted radical prostatectomy (RARP).<sup>6</sup> There are over 89,000 RPs performed annually in the U.S. which can lead to **12,460 to 28,480 new patients each year in the U.S. that may need SUI treatment.**<sup>4,7\*</sup> Treating SUI provides prostate cancer survivors an opportunity to live a more normal and fulfilling life.

Though there are several potential causes for undertreatment for these conditions, lack of awareness around treatment options, apprehension to discuss, and the limited number of prosthetic urologists in many geographies are three fundamental factors that contribute to the struggle that men face when trying to navigate through these emotionally and physically distressing disease states.

To accelerate the treatment journey and connect this growing population of men who suffer from ED and SUI to the care they need, healthcare providers have an opportunity to prioritize proven surgical options to address this community's unique needs, concerns, and goals of adding life back to their years.

Boston Scientific's commitment to innovation delivers solutions that are purposefully designed to provide both patients and providers with optimized outcomes, an enhanced experience, and positive economic benefits.

\* Calculated using 14-32% of 89,000; the majority of RP cases in the US are RARP (70-85% in 2015)

# Challenges

Research indicates that on average it takes a patient up to 6.2 years from ED diagnosis to undergo their penile implant procedure.<sup>4</sup> This prosthetic urology journey is too long and can be frustrating for patients.

➤ **Lack of awareness around viable treatment options beyond first-line medications and other coping mechanisms**



- Both ED and SUI are very personal matters that can lead patients to search the internet for treatment options, which can result in information overload that can be difficult to navigate and lead to more confusion
- Men can start to withdraw from friendships, fall into depression, and lose their purpose and self-identity<sup>8</sup>
- The rise of accessible retail medicine e.g., Men's Health Clinics and/or GetRoman.com is rapidly emerging as a key competitor to traditional urology for men who may see this option as quick, easy, and discrete<sup>9</sup>

➤ **A 2013 research report commissioned by Boston Scientific assessed the satisfaction and dissatisfaction of patients with ED who did and did not receive an implant. The following were the dissatisfaction rates of patients who did not receive an implant:\*\***



**Orals**  
**57%**  
Dissatisfied or very dissatisfied  
**Primary reasons for discontinuation:**

- No efficacy
- Inconsistent
- Declining efficacy

**Vacuum device**  
**74%**  
Dissatisfied or very dissatisfied  
**Primary reasons for discontinuation:**

- Lack of spontaneity
- Difficult administration of the device
- Inconvenient

**Injectables**  
**61%**  
Dissatisfied or very dissatisfied  
**Primary reasons for discontinuation:**

- Pain with administration
- Declining efficacy
- Lack of spontaneity

**Urethral suppository**  
**83%**  
Dissatisfied or very dissatisfied  
**Primary reasons for discontinuation:**

- Difficult administration of the device
- Declining efficacy
- Inconsistent

**30% to 50% of patients who have tried sexually assistive aides after RP discontinue use after a year.<sup>10</sup>**

➤ **Projected decreasing supply of urologists, with only a small subset of urologists performing the majority of penile implant procedures<sup>4</sup>**

- Only 3 in 100 practicing urologists have completed an ED fellowship in 2021<sup>11</sup>
- For every 1 new urologist, an estimated 10 urologists are of retirement age<sup>4</sup>
- By 2025, the U.S. will have 29% fewer urologists than projected needs. There will be a shortage of 3,630 urologists<sup>4</sup>



**Approximately 1% of the 12,145 practicing urologists perform 50% of the prosthetic urology volume.<sup>4</sup>**

\*\* Boston Scientific Qualitative Research Report, Behaviors, Attitudes and Opinions of Penile Implant Candidates, June 2013: Relevant to satisfaction/dissatisfaction rates, the referenced data is based on questionnaires answered by 30 patients who have had erectile dysfunction for > 1 year and who have tried and discontinued a prior treatment due to ineffectiveness. Patients were asked to rate their satisfaction level on a five-point scale whether they were Very Dissatisfied or Dissatisfied. Patients were also asked to identify the reason they discontinued a particular therapy option.

# Opportunity for institutions and urologists

Growing patient demand and a favorable reimbursement landscape suggest that prosthetic urology, within the urology service line, is a source of procedural volume and new patients.

## Demand for prosthetic urology is increasing, while the supply of urologists is decreasing



**Affordable solution for patients:** Medicare out-of-pocket cost for a penile implant is equivalent to buying 27 Viagra.<sup>4,12</sup>



Severe SUI is 7x less tolerable than even severe erectile dysfunction, **motivating patients to seek a proven treatment.**<sup>13\*\*\*</sup>



There are **over 1.7 million insured men in the U.S.** with moderate to severe ED who could benefit from a penile implant.<sup>3</sup>

2023 Medicare deductible cap:  
**\$1,600**

Per benefit period for patients having an outpatient procedure

**\$1774.94** for Walmart quantity 30 or **\$59.16/pill**

Based on the lowest listed cost from GoodRx (Accessed 12/22/2022)

**= 27.05 Viagra equivalent**

## Favorable procedural economics



**Inflatable penile prosthesis (IPP) procedures generate a margin on par with other outpatient implant procedures such as total knee arthroplasty (TKA)<sup>4</sup>**

- Given the national average payor mix weighted reimbursement, less national average implant cost, an IPP generates a margin comparable to other well-established implant procedures, such as outpatient TKA<sup>4</sup>
- CMS reported intraoperative time (minutes) divided by work RVUs for IPP vs. TKA remains favorable – with 18.8 working minutes to generate 1 RVU for IPP compared to 19.1 working minutes to generate 1 RVU for TKA<sup>4</sup>



**Commercial model maximizes contribution margin**

- No capital outlay is required
- Short-term consignment “loaner kit” program saves over \$500K in total inventory carrying cost, based on the value of the most commonly used erectile restoration and male continence loaner kits to complete a procedure

Medicare national average hospital outpatient department reimbursement for prosthetic urology has increased over the last 6 years from 2017 to 2023:<sup>4</sup>

IPP	↗ <b>34%</b>
Male Sling	↗ <b>61%</b>
AUS	↗ <b>34%</b>

## ED patients may also be candidates for other treatments as ED is often connected to other comorbidities



**ED is a predictor for future cardiovascular events<sup>14</sup>**

- On average, ED precedes a cardiovascular disease (CVD) event by 3 years
- The severity of ED is associated with the severity of heart disease
- In value-based systems, screening men who have symptoms of ED for CVD may lead to cost-savings by preventing future complications related to both conditions



**Satisfied prosthetic urology patients can lead to return patients for future procedures**

A meta-analysis of 14 studies with a mean follow-up of 6.1 years found men with ED have a 25% increased risk of all-cause mortality compared to men without ED as well as a significantly increased risk of:<sup>14,15</sup>

Cardiovascular disease events by	<b>44%</b>
Myocardial infarction by	<b>62%</b>

\*\*\* In one study of 1381 cancer prostate cancer patients, almost 28 months of additional life are needed to compensate for severe urinary leakage vs. 4 months for severe impotence.

# Suite of support services and resources

Boston Scientific offers a differentiated portfolio of technologies supported by services for patients, urologists and institutions including:



## Clinical education

- Specialized Resident courses designed to instill the fundamentals of prosthetic urology surgical procedures and patient communication skills
- Grants to support fellowship programs for emerging implanters that provide in-depth specialized training on all aspects of being a future thought leader and expert in prosthetic urology
- Continuing training for established urologists through preceptorships, proctorships, and other educational opportunities to hone prosthetic urology surgical and communication skills
- Advanced Practice Provider training on pre- and post-operative management of prosthetic urology patients



## Case support

- Dedicated Territory Managers who provide education to offices and clinical support in the operating room during cases



## Health economics and market access resources

- Education on reimbursement and coding for prosthetic urology procedures
- Benefits verification including patient support around insurance coverage authorization, denials, and exclusions
- Local market insights on opportunities that inform investment decisions
- Procedure access assistance program to aid patient navigation through employer exclusions



## Patient education and support

- Patient-focused websites to guide men and their partners through the treatment journey ([FixIncontinence.com](https://www.fixincontinence.com) and [EDCure.org](https://www.edcure.org))
- In-person and virtual educational seminars on the disease state and treatment options
- Patient Education Coordinators who provide one-on-one patient education and facilitate the connection to care
- Field Marketing Teams that partner with local providers to raise awareness of the disease state and treatment options in their community
- Patient Services Specialist supports the post-procedure experience by providing education, guidance, and an empathetic ear

### ➤ **AMS 700™** Inflatable Penile Prosthesis

Long-term treatment with **95% patient and 90% partner satisfaction**<sup>16</sup>

### ➤ **AdVance™ XP** Male Sling System

Cured and improved rates ranging from **63% to 83% at 5 years in patients with mild to moderate incontinence**<sup>18,19</sup>

### ➤ **AMS 800™** Artificial Urinary Sphincter

90% long-term patient satisfaction (>10 years)<sup>17</sup>  
40 years of clinical use, with over **235,000 systems implanted worldwide**<sup>4</sup>

### ➤ **InhibiZone™** Antibiotic Surface Treatment

**56% reduction** (from 2.5% to 1.1%) **in revisions** due to infection in first-time AMS 700™ implant patients<sup>20</sup>  
20 years of clinical use<sup>4</sup>

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EDCure.org and FixIncontinence.com are websites sponsored by Boston Scientific.

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