UroLume®
Endoprosthesis
Instructions for Use

For Recurrent Bulbar Urethral Stricture, Prostatic Obstruction Secondary to Benign Prostatic Hyperplasia, and Detrusor External Sphincter Dyssynergia
UroLume Endoprosthesis

Contents
Device Description .........................................................................................................................................................2
Detailed Description .......................................................................................................................................................2
The Prosthesis ........................................................................................................................................................2
The Disposable Delivery System ...........................................................................................................................2
Components ....................................................................................................................................................................2
Prosthesis Specifications ........................................................................................................................................2
Delivery Instrument Specifications ........................................................................................................................2

For Recurrent Bulbar Urethral Stricture
Indications For Use ........................................................................................................................................................5
Contraindications ........................................................................................................................................................5
Warnings .....................................................................................................................................................................5
Precautions ..................................................................................................................................................................6
Adverse Events ............................................................................................................................................................7
Clinical Results ............................................................................................................................................................7
Instructions For Use .....................................................................................................................................................10

For Prostatic Obstruction Secondary to Benign Prostatic Hyperplasia
Indications For Use ......................................................................................................................................................17
Contraindications .........................................................................................................................................................17
Warnings .....................................................................................................................................................................17
Precautions ................................................................................................................................................................18
Adverse Events ............................................................................................................................................................18
Clinical Results ............................................................................................................................................................19
Instructions For Use .....................................................................................................................................................20

For Detrusor External Sphincter Dyssynergia
Indications For Use ......................................................................................................................................................26
Contraindications .........................................................................................................................................................26
Warnings .....................................................................................................................................................................26
Precautions ................................................................................................................................................................28
Adverse Events ............................................................................................................................................................28
Clinical Results ............................................................................................................................................................29
Instructions For Use .....................................................................................................................................................32

Inventory Returns and Warranty Information ..............................................................................................................40
General

Device Description
The UroLume® Endoprosthesis is a braided mesh cylindrical wire stent made from 24 wire filaments. The stent is designed to expand radially after deployment to hold open sections of the urethra that obstruct the flow of urine. The self-expanding properties of the stent press it against the wall of the urethra with radial force, helping to prevent migration of the prosthesis and allowing the urothelium to cover the wire mesh. The UroLume prosthesis is provided sterile preloaded in a disposable delivery instrument. This instrument serves three purposes: 1) it constrains the prosthesis to allow it to be inserted into the urethra; 2) it permits direct visualization of the prosthesis throughout the procedure; and 3) it permits the physician to deploy the prosthesis accurately in the urethra.

Detailed Description
The Prosthesis
The UroLume Endoprosthe sis is a braided mesh cylinder made of high strength, implant grade, superalloy wire. The braided mesh is designed to expand radially after deployment to hold open sections of the urethra that obstruct the flow of urine.

For use in the bulb to prostatic urethra, the UroLume prosthesis is available in the following sizes:

Reference lengths: 1.5cm, 2.0cm, 2.5cm, and 3.0cm
Reference diameter: 14mm

The self-expanding properties of the mesh press it against the wall of the urethra with radial force, helping to prevent migration of the prosthesis and allowing the urothelium to cover the wire mesh.

The Disposable Delivery System
The UroLume prosthesis is provided preloaded in a sterile, disposable delivery instrument. This instrument serves three purposes: 1) it constrains the prosthesis to a diameter small enough to allow it to be inserted into the urethra; 2) it permits direct visualization of the prosthesis throughout the implant procedure; and 3) it permits the physician to deploy the prosthesis accurately in the urethra. Each part of the delivery instrument is described in Figure 1.

Components
The UroLume prosthesis is provided in a kit including the components needed to place one prosthesis in the urethra. All components are sterile. UroLume prosthesis kits contain the following items:

- one UroLume prosthesis (1.5cm, 2.0cm, 2.5cm, or 3.0cm)
- one disposable delivery instrument
- one telescope stabilizer

Caution: All UroLume prosthesis kits are provided sterile. Do not resterilize any components. Resterilization causes damage to the components, and reuse may cause trauma to the urethra.

Prosthesis Specifications

<table>
<thead>
<tr>
<th>Diameter (24 wire filaments)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressed diameter</td>
<td>6mm</td>
</tr>
<tr>
<td>Reference diameter</td>
<td>14mm</td>
</tr>
</tbody>
</table>

Product Number

- For 1.5cm prosthesis: 72402015
- For 2.0cm prosthesis: 72402010
- For 2.5cm prosthesis: 72402011
- For 3.0cm prosthesis: 72402012

Delivery Instrument Specifications

<table>
<thead>
<tr>
<th>Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retractable sheath</td>
</tr>
<tr>
<td>Inner lumen</td>
</tr>
<tr>
<td>Rounded Collars</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Useable Shaft Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>For 1.5cm prosthesis</td>
</tr>
<tr>
<td>For 2.0cm prosthesis</td>
</tr>
<tr>
<td>For 2.5cm prosthesis</td>
</tr>
<tr>
<td>For 3.0cm prosthesis</td>
</tr>
</tbody>
</table>

General
Figure 1: The UroLume prosthesis is preloaded in a disposable delivery instrument.

1. Outer Shaft
2. Retractable sheath (intermediate shaft)
3. Inner shaft and holding mechanism
4. Prosthesis
5. Window For Illustration Purposes Only
6. Rounded collar

A. Front finger grip
B. Back finger grip
C. Front security button
D. Rear security button
E. Water irrigation port
F. Telescope port 12Fr
G. Telescope stabilizer port
The forward end of the delivery instrument has the following features (Figure 1):

1. **Outer Shaft**  
The outer shaft stabilizes the instrument during deployment of the prosthesis.

2. **Retractable Sheath (Intermediate Shaft)**  
By manipulating the finger grips, the physician is able to draw back and advance the retractable sheath to alternately expose and cover the prosthesis until the optimum position for deployment of the prosthesis is found.

3. **Inner Shaft and Prosthesis Holding Mechanism**  
The inner shaft has an open lumen which accommodates a 12Fr telescope. At the tip of the inner shaft is a holding mechanism which holds the prosthesis in the delivery instrument until it is released.

4. **Prosthesis**  
Each delivery instrument is preloaded with a prosthesis. Preloaded in the delivery instrument, the prosthesis assumes a compressed and elongated form. When the prosthesis is released from the delivery instrument, it spontaneously expands from its constrained shape. Unconstrained, the prosthesis assumes a shorter length and larger diameter form.

5. **Windows for Illustration Purposes Only**

6. **Rounded Collar**  
The rounded collar at the tip of the delivery tool and at the end of the stationary outer shaft eases insertion into the urethra.

The handle end of the delivery instrument has the following features (Figure 1):

A. **Front Finger Grip**  
1) Pulling the front finger grip towards the back finger grip causes the retractable sheath to draw back, exposing the prosthesis. 2) Pushing the front finger grip away from the back finger grip causes the retractable sheath to slide forward, covering the prosthesis.

B. **Back Finger Grip**  
The back finger grip is stationary. It is used to stabilize the delivery instrument during prosthesis deployment.

C. **Front Security Button**  
The front security button enables the physician to partially deploy the prosthesis, without releasing it from the delivery instrument. As the prosthesis is uncovered, it partially opens, but does not release.

D. **Rear Security Button**  
Pressing down on the rear security button permits release of the prosthesis. Once the rear security button is pressed, the prosthesis must be released.

E. **Water Irrigation Port**  
The delivery instrument’s luer lock irrigation port permits a constant washing of the urethra and telescope.

F. **Telescope Port**  
The telescope port accommodates a 12Fr telescope. The telescope can be moved in and out to view the implant procedure.

G. **Telescope Stabilizer Port**  
The telescope stabilizer port accommodates the telescope stabilizer (Figure 1a) provided with the UroLume prosthesis.

---

**General**

“C” Position  
Olympus (1.5-3.0 cm stents)

“A” Position  
ACMI (1.5-3.0 cm stents)  
Storz (1.5-3.0 cm stents)  
Wolf (1.5-3.0 cm stents)

Insert and remove the telescope from the scope stabilizer, by grasping the scope stabilizer as shown.
Recurrent Bulbar Urethral Stricture

Indications For Use
The UroLume Endoprosthesis is intended for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction (Figure 2).

The UroLume prosthesis is not intended as a temporary stent. The UroLume prosthesis is not intended as an initial treatment for bulbar urethral strictures nor for the treatment of strictures outside the bulbar urethra. The UroLume prosthesis is an alternative treatment for the patient in whom previous treatment methods (dilation, urethrotomy or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease or there has been recurrence of stricture formation necessitating further treatment).

Figure 2: UroLume prosthesis in the bulbar urethra.

Contraindications
The following conditions contraindicate use of the UroLume prosthesis for the treatment of urethral strictures:

1. Meatal or urethral strictures which cannot be opened to 24Fr by dilation, urethrotomy or meatotomy.
2. Strictures involving the external sphincter.
3. Patients with an active urinary tract infection.
4. Patients with other urethral conditions requiring transurethral manipulations within eight weeks of UroLume prosthesis placement.
5. Infected, suppurating strictures.
6. Presence of a fistula at the proposed prosthesis location.
7. Patients with urethral squamous cell carcinoma.
8. Patients with a perineal urethrostomy.
9. Strictures secondary to fracture distraction defects of the posterior urethra.

Warnings
1. The prosthesis should not be used in patients in whom bleeding may seriously impede the visualization process. If bleeding impairs visualization, a catheter may be placed for 15-20 minutes until bleeding slows, allowing adequate visualization. Alternately, a catheter may be placed and the patient may return in 4-6 days for UroLume prosthesis placement.
2. The prosthesis should not be used in patients with bladder stones, urethral lesions distal to the bulbar-scrotal junction, or strictures caused by traumatic rupture.
3. Patients should be advised to expect mild discomfort, post void dribbling, hematuria, urgency or nocturia during the first few weeks after prosthesis placement. In most cases, these symptoms resolve or diminish spontaneously.
4. Prior to utilizing the UroLume prosthesis in patients who suffer from thrombocytopenia or hemophilia and/or patients who have received blood products for the treatment of a bleeding disorder, other alternative treatment options that would put the patient at less risk of bleeding than that associated with the UroLume prosthesis should be considered.
5. Ensure that the prosthesis does not extend into the external sphincter. Placing the prosthesis in the external sphincter may cause the patient to be incontinent.
Stricture

6. Infection could occur at the prosthesis site. Infection may be treated using bactericidal antibiotic therapy or device removal.

7. Longitudinal compression of the prosthesis by instrumentation could cause trauma to the urethra or could dislodge the prosthesis. Transurethral instrumentation should be avoided prior to urothelial ingrowth.

8. The prosthesis may migrate and/or shorten resulting in incomplete coverage of the stricture. If this occurs, additional prostheses may be placed or the prosthesis position may be adjusted to assure complete stricture coverage.

9. Encrustation of the prosthesis may occur on wires that do not become covered by urothelium. If encrustation develops which causes obstruction, or is associated with repeated infection or intermittent hematuria, it should be removed using electrohydraulic lithotripsy.

10. Tissue ingrowth may obstruct the passage of urine. If obstruction occurs, tissue ingrowth may be removed using resection, dilation or fulguration or an additional prosthesis may be placed.

11. Removal of the prosthesis for any reason after urothelial ingrowth could result in significant trauma to the urethra. After urothelial tissue has grown over the prosthesis, it must be resected before the prosthesis is removed or the prosthesis may unravel.

12. The use of the prosthesis in patients who have had previous external or internal gamma radiation therapy for prostate or proximal urethral cancer should be evaluated carefully, due to complications that may be caused by tissue damaged by irradiation.

Precautions

1. The UroLume prosthesis kit (prosthesis, delivery instrument, telescope stabilizer) is provided sterile. Do not resterilize any components. Resterilization causes damage to the components and reuse may cause trauma to the urethra.

2. This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume prosthesis. Each physician should view an instructional video prior to attempting a UroLume prosthesis insertion.

3. Limited data are available for patients younger than 30 years of age, therefore, safety and effectiveness of the UroLume prosthesis in this population has not been fully established.

4. The prosthesis should not be used for the treatment of strictures longer than 3cm. Safety and effectiveness of the device in strictures longer than 3cm has not been fully established.

5. Squamous cell carcinoma may be an underlying cause of unexplained urethral stricture disease. Patients should be carefully evaluated prior to use of this device.

6. The long term safety and effectiveness of the UroLume prosthesis has not been demonstrated, therefore continuing follow-up is recommended.

7. Safety and effectiveness of prosthesis removal and subsequent replacement has not been established.

8. Verify that the prosthesis extends beyond the stricture by at least 5mm at each end.

9. Failure to resheath the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the urethra.

10. Passing a cystoscope through the prosthesis may displace the prosthesis.

11. Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis.

12. Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter until the prosthesis is stabilized by urothelial ingrowth. Inserting a catheter into the urethra before urothelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the urethra.

13. Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.

14. Do not attempt to remount the prosthesis onto the delivery instrument. Attempting to insert a remounted prosthesis into the urethra can cause the delivery instrument to function incorrectly and cause trauma to the urethra.

15. Patients with hypospadias may experience complications after UroLume placement. One publication reported two patients with hypospadias developed pan-urethral strictures after UroLume placement for bulbar stricture disease. Physicians are advised to consider this clinical evidence prior to UroLume placement in patients with hypospadias.

1 Rodriguez, E. and J. Gelman. Pan-urethral strictures can develop as a complication of UroLume placement for bulbar stricture disease in patients with hypospadias.
**Adverse Events**

Adverse events noted throughout the study included: post-void dribbling (88%), pain (71%), incontinence (57%), tissue ingrowth/narrowing (53%), hematuria (44%), positive urine culture (41%), new stricture (32%), erection pain (27%), sexual activity pain (14%), additional insertion procedures (11%), ejaculation pain (9%), pads used for incontinence (8%), resection (8%), catheterization (8%), deaths unrelated to device (6%), retention (5%), migration (5%), urine leak with ejaculation (5%), decreasing stream (4%), dilation within stent area (3%), retrograde ejaculation (3%), hematospermia (3%), white ring of tissue at the end of the stented region (3%), erection ability change from full to partial (3%), squamous metaplasia (3%), encrustation related to stent (3%). Other complications/side effects noted in 2% or less of the patient population include self intermittent catheterization inside stent area, polyps on urethral wall, pooling of urine, testicular pain, drug therapy used for incontinence, itching, thinner semen, blood following ejaculation, odor in urine, curvature of penis, sphincter impaired by stent, superficial abrasion to anterior urethra during stent removal, urinary stream spraying, erection time shortened, stent end did not expand, wires broken during repositioning, bloody discharge while walking, wire ends protruding into lumen, difficulty emptying bladder, progressively worsening erections, inflammation of urethral tissue, urgency, clot retention, medication given for urethral discomfort, soreness noted after ejaculation, urination only while sitting, irregular lumen in distal urethra, stent minimally elevated from mucosa circumferentially, bleeding due to exposed stent with febrility of mucosa, delayed ejaculation with intercourse, odor in semen, gap between stents, pressure in the scrotum with erections, stent wire exposed, exercises for incontinence, excessive mucosa, erectile dysfunction, bulbous edema, proliferative changes at ends of stent and narrowing of urethra.

No deaths during the clinical study were attributed to device use. Refer to the Clinical Results section for further information about the adverse events.

**Clinical Results**

In clinical studies, 86% (149/173) of patients were considered retreatment successes (no further treatments were required for treatment of the urethral stricture within the first twelve months following insertion). A total of 97% (167/173) of the patients were considered successes based upon the device not requiring removal within the first twelve months following insertion. When evaluating success based upon improvement in urinary flow rate, 86% (110/128) of the patients were considered a success (success defined as the patients being brought into the 95th percentile of their age adjusted peak flow range as defined by the Liverpool Nomograms at twelve months following insertion). Using a combined measure of success including: devices did not require removal within the first twelve months following insertion, no further treatments were required for treatment of the urethral stricture within the first twelve months following insertion, and the patient was brought into the 95th percentile of their age adjusted peak flow range (as indicated by the Liverpool Nomogram) at twelve months following insertion, 68% (93/137) of patients were considered to be successes.

Conditions which have required removal of the device in 7 patients include discomfort, stent migration, restricting, urethral discharge/inflammation and urethral catheterization required due to an unrelated surgical procedure prior to urothelialization. Additional reasons for removal may be indicated if additional data becomes available.

A total of 173 patients (mean age 52 years) have been studied in the U.S. and Canada. Outcome effectiveness variables identified in these patients included peak urinary flow rate and total symptom score. (Total symptom score was determined by scoring 10 individual symptoms: hesitancy, poor flow, incomplete emptying, frequency, nocturia, painful urination, hematuria, two stage voiding, post void dribbling and prolonged voiding time). Total symptom score could range from 0 (no symptoms) to 30 (all marked severity symptoms).

Mean peak urinary flow rate prior to insertion was 9.8cc/sec in 149 patients with available data. Six weeks following insertion, mean peak flow rate was 24.4cc/sec in 150 patients with available data. The mean peak urinary flow rate more than doubled following insertion of the UroLume prosthesis. One year following insertion, mean peak flow rate was 22.7cc/sec in 128 patients with available data. Evaluation of clinical data indicated a significant
increase in both peak and average flow results for the majority of patients following UroLume prosthesis insertion. Substantial improvements in flow rates were maintained throughout the study. Six weeks following insertion, 90% of the patients with peak flow data (135 out of 150 patients) met the 95th percentile of the age adjusted flow range defined by the Liverpool Nomogram. One year after insertion, 86% (110 out of 128 patients) were brought into the 95th percentile.

Mean total symptom score prior to insertion was 12.7 in 157 patients with available data. Six weeks following insertion, mean total symptom score had improved to 3.6 in 161 patients with available data. One year following insertion, the mean total symptom score was still significantly improved at 2.2 in 140 patients with available data.

The rate of retreatment in the years following UroLume prosthesis insertion was dramatically reduced from that experienced in the years preceding UroLume prosthesis insertion. In the one year period before UroLume prosthesis insertion, 74.5% of 106 patients required treatment for their urethral stricture. In contrast, only 12.3% of these same patients required treatment for their urethral stricture in the year following UroLume prosthesis insertion. These results may change as further data becomes available.

During clinical evaluation, most patients demonstrated complete (90-100%) coverage by urothelial tissue by six months following stent insertion. Patients whose devices did not become completely covered were found to have no apparent increased propensity for urinary tract infection, stent migration, encrustation or other complications. These patients experienced similarly substantial relief of obstructive symptoms as those patients whose devices became completely covered in urothelial tissue. Many of the complications/side effects noted throughout the study were also noted by patients prior to insertion of the UroLume prosthesis.

There were 10 reported deaths during the clinical evaluation. No deaths were indicated to be related to the device. Causes of the deaths include: intraventricular cerebral hemorrhage possibly secondary to mycotic aneurysm, myocardial infarction (2 patients), cerebral vascular accident (4 patients), congestive heart failure, malignant fibrous histiocytoma and urethral squamous cell carcinoma. Abnormal tissue (cauliflower appearance) was noted within the urethra of one patient before UroLume prosthesis insertion. The prosthesis was removed nine months after insertion. The patient died of squamous cell carcinoma 20 months after insertion.

Squamous metaplasia was identified in five patients throughout the clinical study. Four of these five patients previously underwent skin graft urethroplasty. As such, squamous cells would be anticipated in these patients. The remaining patient was the patient who was also diagnosed with squamous cell carcinoma.

Pain/discomfort was noted by 40% of the patients at pre-evaluation (25% mild, 11% moderate and 4% marked). Up to six weeks following insertion, 61% of the patients noted some degree of pain/discomfort (40% mild, 15% moderate and 6% severe). Six months after insertion of the UroLume prosthesis, the incidence of pain/discomfort had dropped to 28.6% of the patients (21.3% mild and 7.3% moderate). One year after insertion, 18% of patients reported some pain/discomfort (14% mild, 2% moderate and 2% severe). Only 3 patients had their devices removed due to pain/discomfort throughout the duration of this study.

Incontinence was experienced by 40% of the patients six weeks after insertion (26% mild, 10% moderate and 4% marked). Six months after insertion, 33% of patients noted some incontinence (24% mild, 6% moderate and 3% marked). After one year, 28% of the patients were experiencing some incontinence (19% mild, 8% moderate and 1% marked in severity). No devices were removed due to incontinence during this study. These results may change as additional data becomes available.

Post void dribbling was noted by 66% of the patients at pre-insertion (31% mild, 21% moderate and 14% marked). Six weeks after insertion, 81% of the patients were experiencing post void dribbling (52% mild, 21% moderate and 8% severe). Six months after the UroLume prosthesis insertion, 61% of patients experienced post void dribbling (48% mild, 10% moderate and 3% marked in severity). Post void dribbling was noted in 54% of patients one year after insertion (41% were mild, 10% moderate and 3%
marked in severity). No devices were removed due to post void dribbling during this study.

Tissue ingrowth was noted in 40% of the patients six months after insertion (32% mild, 8% moderate in severity). One year following insertion, 33.8% of the patients were experiencing tissue ingrowth (24.3% mild, 8.1% moderate and 1.4% marked in severity). Eighty-four percent of the patients who experienced tissue ingrowth required no treatment. One device was removed due to tissue ingrowth during this study.

Positive urine cultures were noted by 9% of patients at pre-insertion. Six weeks following insertion, 7% of the patients had a positive urine culture. Six months after the insertion procedure, 11% of the patients reported a positive urine culture. One year following insertion, 21% of the patients reported a positive urine culture. The incidence of positive urine culture was reduced two years following insertion, such that 12% of the patients reported a positive urine culture. Forty-eight percent of the patients in this study were noted to have a history of positive urine cultures. No devices were removed due to positive urine cultures during this study.

New strictures were identified proximal to the location of the UroLume prosthesis in 23 patients. New strictures distal to the location of the UroLume prosthesis were noted in 24 patients. New strictures were noted both proximal and distal to the location of the UroLume prosthesis in 9 patients. Eleven patients required treatment for a new stricture.

Hematuria was experienced by 11% of the patients prior to insertion (8% were mild, 1% were moderate and 2% were marked in severity). Up to six weeks following insertion, 31% of patients were experiencing hematuria (27% mild and 4% moderate). Six months following insertion, 12.1% of patients experienced hematuria (10.7% were mild, 0.7% were moderate and 0.7% were marked). One year following insertion, 9% were experiencing hematuria (7% mild and 2% moderate).

An increase in pain with erections was noted after stent insertion which appears to subside or diminish over time. Erection pain was noted in 64% of patients up to six weeks following insertion (39% mild, 14% moderate and 11% severe). At six months following insertion, only 19% of the patients noted erection pain (14% mild and 5% moderate in severity). Twelve months following insertion, 14% of patients were experiencing erection pain, all mild in severity. No change was noted in ejaculation ability following insertion. In patients with pre-insertion data, reports of pain during ejaculation decreased after stent insertion. Sexual function effects may change if further data becomes available.

Additional insertion procedures were required by 11% of the patients involved in this study. Nine percent required two insertion procedures and 2% underwent three insertion procedures.

There were five reported incidents of stone formation in connection with the prosthesis, three requiring treatment to remove the stones. One patient had granulation noted within the stent at two years post-insertion. One patient had tiny stones apparent in the stent which were flushed away during cystoscopy. Of the three patients requiring removal, one patient was reported at one year to have a small calculi removed without difficulty. One other patient had stones adhered to the exposed wires of the stent three years following insertion. The stones were crushed and removed with grasping forceps without difficulty. The stent completely epithelialized after the stones were removed. The third patient had stones adhered to the urethral mucosa 18 months after stent insertion. The stent wires were completely covered with epithelium. The stones were removed using a basket extractor. A bladder stone was also removed from this patient 3.5 years after insertion. This patient had a pre-insertion history of bladder calculi formation.

Other complications/side effects noted throughout the study included: sexual activity pain (14%), ejaculation pain (8%), pads used for incontinence (8%), resection (8%), catheterization (8%), retention (5%), migration (5%), urine leak with ejaculation (5%), decreasing stream (4%), dilation within stent area (3%), retrograde ejaculation (3%), hematospermia (3%), white ring of tissue at the end of the stented region (3%), and erection ability change from full to partial (3%). Other complications/side effects noted in 2% or less of the patient population include: self intermittent catheterization inside stent area, polyps on urethral wall, pooling of urine, testicular pain, drug therapy used for incontinence, itching, thinner semen, blood following ejaculation, odor in urine, curvature of penis,
sphincter impaired by stent, superficial abrasion to anterior urethra during stent removal, urinary stream spraying, erection time shortened, stent end did not expand, wires broken during repositioning, bloody discharge while walking, wire ends protruding into lumen, difficulty emptying bladder, progressively worsening erections, inflammation of urethral tissue, UTI requiring hospitalization, necrotic tissue, urgency, clot retention, medication given for urethral discomfort, soreness noted after ejaculation, urination only while sitting, irregular lumen in distal urethra, stent minimally elevated from mucosa circumferentially, bleeding due to exposed stent with febrility of mucosa, delayed ejaculation with intercourse, odor in semen, gap between stents, pressure in scrotum with erections, stent wire exposed, exercises for incontinence, excessive mucosa, erectile dysfunction, bulbous edema, proliferative changes at ends of stent and narrowing of urethra.

Instructions For Use

Caution: This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume prosthesis. Physicians should view an instructional video, which demonstrates insertion and removal, prior to attempting a UroLume prosthesis insertion.

Patient Communication

To prepare a patient to make an informed decision regarding implantation of the UroLume prosthesis, the physician should communicate several items to the patient, and provide a patient information brochure to each patient.

1. The patient should be advised that post void dribbling may be experienced in the weeks following UroLume prosthesis insertion. Methods for managing post void dribbling should be discussed with the patient.

2. The patient should be informed that hematuria and/or pain may be experienced in the weeks following insertion.

3. Patients should be advised not to attempt any manipulation of the stent (applying unnecessary pressure to the area of the prosthesis). Manipulation of the stent can cause the stent to migrate and can cause pain.

4. Patients should be advised that transurethral catheterization or other transurethral procedures should not be used in the weeks following UroLume prosthesis insertion, until urothelium covers the UroLume prosthesis. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability.

5. Patients should be advised to abstain from sexual intercourse and sexual activities for at least four weeks following insertion of the UroLume prosthesis.

6. Patients should be advised that bleeding may occur during the insertion procedure which would necessitate catheterization, and possible hospitalization. The patient would then need to return for stent placement.

7. Patients should be advised that occasionally there may be an unrecognized infection present at insertion.

8. Patients should be advised that there may be situations where a suprapubic tap for urinary drainage proximal to the stent would be advised.

9. Patients should be informed of actions to take in case of an emergency, i.e., when to consult a physician following insertion of the UroLume prosthesis.

10. Patients should be informed of the importance of always carrying their Medical Information Card.

Pre-operative Set-up

Materials

The following materials are required for the placement procedure:

- Urethral sounds or filiform followers
- Urethrotomy equipment
- 12Fr, 0˚ to 12˚ telescope
- Water flushing set-up; typically 1 to 5 liters of sterile water on I.V. pole, 5mm tubing
- 17Fr or 21Fr cystoscope
- AMS Urethral Measuring Catheter, or a graduated ureteric catheter
- UroLume Endoprosthesis kits (two of each size recommended)
**Note:** A selection of at least two UroLume prosthesis kits in each size is advised. This inventory ensures that the correct size is available when the stricture is measured.

**Premedication**
Prior to implantation with the UroLume prosthesis, patients should be given prophylactic broad-spectrum antibiotic coverage according to the protocols commonly used by the hospital.

**Patient Preparation**
Place the patient in the lithotomy position, prep with aseptic solution and drape.

**Anesthesia**
Clinical investigators found that the anesthesia required for urethrotomy or dilation is generally sufficient for prosthesis placement.

**Preparation for Prosthesis Placement**
1. Perform a diagnostic cystourethroscopy.

   **Note:** *If it is not possible to pass a cystoscope through the strictured portion of the urethra, dilate, or perform urethrotomy to allow the instrument to pass.*

2. Measure the length of the stricture. To determine the length of the stricture, apply the same principles used for determining the extent of a substitution procedure. The normal urethra appears pink with normal mucosal tissue and a normal vascular pattern. When it is opened, the vascular spongy tissue is seen through its immediately overlying translucent uro-epithelial cover. A strictured area in the urethra is grey, noting pale mucosa, an irregularity in the mucosal wall and intrusiveness into the urethral lumen. It is essential to stent the entire spongiosfibrosis region (grey area) to decrease the occurrence of restricting proximal and distal to the narrowed region within the urethra as shown in Figure 3.

3. Select a prosthesis that is **1.0cm** longer than the measured length of the stricture.

4. Open the selected prosthesis package. Peel open the plastic tray and remove the sterile contents. Inspect the delivery instrument carefully.

   **Note:** *No wire filaments should protrude from the rounded collar of the delivery instrument. Should filaments be seen protruding from the delivery instrument, return the entire system to your AMS representative and use a new UroLume prosthesis.*

---

**Figure 3**

**STENTED REGION**
**EXTENSIVE Spongiosfibrosis**
**STRicture**

Measure the stricture length using an AMS Urethral Measuring Catheter, following the instructions included with that product, or a graduated ureteric catheter. Instructions for measuring the urethra with a graduated ureteric catheter are as follows: Place the graduated ureteric catheter alongside the telescope into the bladder. Hold the catheter firmly and gently withdraw the telescope while counting the centimeter markings on the catheter to determine the length of the strictured area.
Stricture

Prepare the selected UroLume deployment system for the procedure as follows:

- Attach the light source to the telescope.
- Attach the water source to the irrigation port on the delivery instrument with the water bag approximately 1 meter above the patient. If desired, a three-way tap may be connected to the luer lock of the irrigation port before attaching the water source.

**Note:** A three-way tap will reduce the cross-section of the irrigation port and, therefore, the water flow will also be reduced.

- Insert the 0 degree telescope into the telescope stabilizer and advance the telescope into the desired lock position. Squeezing sides of stabilizer while inserting telescope will impede attachment (see page 4 for telescope compatibility). Insert the telescope stabilizer into the delivery tool. A light push may be required to do so. During the placement procedure, the position of the prosthesis can be monitored by sliding the telescope back and forth in the delivery instrument.
- Apply a small amount of sterile lubricant over the retractable sheath to facilitate passage into the urethra.

During the procedure, the delivery instrument may be manipulated with one hand (Figure 4), while the other hand stabilizes the penis. With these preparatory steps completed, the physician is ready to proceed with the five step placement procedure (Figure 5, 6).

Figure 4: The front finger grip draws back the sheath to expose the prosthesis, while the rear security button prevents its inadvertent release. Reference “Placement Procedure” for complete placement instructions.

**Insertion**

Both security buttons are in the locked position; finger grips are immobile. Hold the grips with thumb and middle finger.

**Partial Deployment**

1) Press the front security button down with the index finger. Note: Do not deploy prior to insertion.
2) Using the middle finger, pull the front finger grip back to retract the sheath.

**Release**

1) Using the index finger press, then release, the rear security button.
2) Using the middle finger, pull the front finger grip back.
3) Gently pull back on the delivery instrument to distance it from the prosthesis.
Placement Procedure

1. **Insertion** (Figure 5)
   
   Open the stricture using dilation and/or urethrotomy. (One incision at the 12 o’clock position or 2 incisions at 4 and 8 o’clock positions recommended. If incisions made at 4 and 8 o’clock, use care not to carry incision beyond the area of fibrosis in the spongiosum tissue to avoid extending the incision to the corpus cavernosum, which may result in shunting of blood and impotence.) The stricture must be opened to a minimum of 26Fr prior to placement of the prosthesis. This allows the UroLume prosthesis to assume the maximum diameter the urethra will allow.

   Introduce the delivery instrument into the urethra, advancing it gently under direct vision. Hold the delivery instrument stable and manipulate the telescope in and out to assess landmarks for prosthesis placement.

2. **Position Confirmation** (Figure 5)
   
   Position the delivery instrument so that its rounded collar is approximately 5mm proximal to the stricture.

   If the stricture is close to the external sphincter, it may be necessary to position the prosthesis by inserting the delivery instrument through the external sphincter and then withdrawing it so that the rounded collar rests just inside the sphincter. Although it may be useful to initiate deployment within the sphincter, use care not to release the prosthesis in the external sphincter. After release, the prosthesis should be distal to the external sphincter. It should be placed in such a way that it will not impinge on the external sphincter.

   **Note:** During deployment, hold the delivery instrument upright as close as possible to the 12:00 o’clock position and try not to rotate the tool beyond the 11:00 and 1:00 o’clock positions. The 12:00 o’clock position is in the vertical direction.

3. **Partial Deployment** (Figure 5)
   
   When the rounded collar of the delivery instrument is positioned appropriately proximal to the stricture, depress the front security button first. While holding down the front security button, gently pull the front finger grip toward the back finger grip until front finger grip has passed the front security button position. This unlocks the sliding mechanism and permits the retractable sheath to slide back, exposing, but not releasing, the prosthesis. It is not necessary to continue
to hold down the security button after the front finger grip has passed the front security button position.

Keep the back finger grip steady and pull the front grip gently toward the back finger grip. This action causes the retractable sheath to draw back in a controlled, gradual manner. As the retractable sheath slides back, the prosthesis is exposed. The prosthesis expands in diameter and shortens in length as it emerges.

When the front finger grip reaches the back security button, the prosthesis is exposed, but not released from the holding mechanism. This offers the opportunity to move the telescope and to make a final check of the position of the prosthesis. It is important to keep the partially deployed prosthesis aligned with the delivery instrument. Moving the delivery instrument at an angle that puts traction on the exposed prosthesis may cause the prosthesis to release prematurely.

Visualize the entire length of the urethral stricture to ensure that the prosthesis is situated in the intended position. The prosthesis should cover the entire length of the urethral stricture. The implanted prosthesis should not cover the external sphincter.

**Warning:** Ensure that the prosthesis does not extend into the external sphincter. Placing the prosthesis in the external sphincter may cause the patient to be incontinent.

If the prosthesis is not in the intended position, resheathe the prosthesis by advancing the delivery instrument’s retractable sheath forward until it completely covers the prosthesis. To do this, withdraw the delivery instrument slightly while gently pushing the front finger grip away from the back finger grip until the first security button re-engages with an audible click. As this is done, the retractable sliding sheath encompasses the prosthesis. With the prosthesis securely inside the delivery instrument shaft, the physician may move the instrument to the intended position in the urethra.

**Caution:** Failure to resheathe the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the urethra.

4. **Release (Figure 6)**

Before releasing the prosthesis, position the telescope to view the prosthesis at the proximal end of the stricture. Confirm with direct vision that the prosthesis overlaps the stricture by at least 5mm and that the prosthesis does not impinge on the external sphincter.

Release the prosthesis from the holding mechanism by pressing down the rear security button first. While holding down the rear security button, completely draw the front finger grip all the way back to the rear finger grip. Use the middle finger to move the front finger grip. The index finger presses the rear security button. The front finger grip locks after the prosthesis is released, and the prosthesis cannot be resheathed or remounted into the delivery instrument.

**Caution:** Do not attempt to remount the prosthesis onto the deployment instrument. Attempting to insert a remounted prosthesis into the urethra can cause improper function of the deployment instrument and result in trauma to the urethra.

5. **Withdrawal of the Delivery Instrument (Figure 6)**

Before beginning to withdraw the delivery instrument, move the telescope back to ensure the delivery instrument is aligned with the distal end of the prosthesis and verify that the prosthesis is off each hook.

If the prosthesis is still attached to a hook(s) as shown below, rotate the delivery instrument lightly between 11:00 and 1:00 o’clock while viewing the prosthesis through the telescope. This rotational movement will ensure that the prosthesis is completely free of the delivery instrument.

Retract the telescope into the delivery instrument, taking care not to let it touch the prosthesis.

Gently withdraw the delivery instrument from the urethra, ensuring the prosthesis is off the hook(s) and using care not to displace the prosthesis. Proceeding with care, perform normal endoscopy using a 17Fr or smaller cystoscope. Manipulate the cystoscope carefully and avoid contact with the prosthesis. Observe carefully to ensure that the prosthesis does not move out of position. Ensure that the prosthesis completely covers the stricture. The prosthesis should overlap the stricture by 5mm or more at each end.

**Caution:** Passing a cystoscope through the prosthesis may displace the prosthesis.
Placing Multiple Stents

If more than one stent is required to adequately cover the strictured area, the first stent placed should cover the most proximal (nearest the external sphincter) end of the stricture. Additional stents may then be placed following steps 1-5 above. The additional stent(s) should overlap the previously placed stent by at least 5mm.

**Caution:** Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis.

Adjusting the Position of a Released Prosthesis

**Caution:** Any repositioning of a released prosthesis must be performed with care in order not to cause trauma to the urethra.

1. **Repositioning a Prosthesis Placed Too Far Proximally**

   If the released prosthesis appears to extend too far into the external sphincter or too far proximal from the urethral stricture, it is possible to reposition the prosthesis using the following procedure:

   Grasp several rows of wire with a biopsy forceps, not less than 2mm from the distal end of the prosthesis. Gently pull the prosthesis into the intended position. Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. Confirm position endoscopically by visualizing some distance between the external sphincter and prosthesis.

2. **Repositioning a Prosthesis Placed Too Far Distally**

   If the released prosthesis appears to be positioned in the bulbar scrotal junction or if it does not extend far enough within the urethral stricture, it is possible to reposition the prosthesis using the following procedure:

   With urologic forceps, grasp several rows of wire near the end of the prosthesis closest to the proximal end of the urethral stricture. Push the prosthesis until it extends at least 5mm proximal to the urethral stricture.

Postoperative Procedures

Prescribe prophylactic antibiotics to the dose and duration typically prescribed for urethrotomy or dilation. If the patient is unable to void, place a suprapubic tube for drainage.

Caution: Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter until the prosthesis is stabilized by urothelial ingrowth. Inserting a catheter into the urethra before urothelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the urethra. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability. If possible, patients should be seen by a physician familiar with the UroLume prosthesis when the implanting physician is not available, until tissue coverage has occurred.

Removing a Released Prosthesis

With a urologic alligator forceps, grasp three to five diamonds of wire at the distal end of the prosthesis. If more than one prosthesis is to be removed, begin with the most recently placed prosthesis. Gently pull the prosthesis. As the prosthesis is drawn out, it elongates and narrows allowing the physician to withdraw it from the urethra.

Note: Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. In this instance, each wire must be removed individually. Each prosthesis consists of 24 wire filaments. Confirm with endoscopy and fluoroscopy that all wire filaments are retrieved.

Prosthesis Removal After Urothelial Coverage

**Warning:** A prosthesis that has covered with urothelial tissue must have the tissue resected before it can be removed.

The first step in the UroLume removal technique is to remove as much tissue as possible from the inner stent surfaces. This is done by thoroughly resecting the overlying tissue from the inner surfaces of the stent using a 24 French electrosurgical loop. Use the lowest possible current setting, beginning at 40 watts and increasing by 10 watt increments if necessary. Do not exceed 70 watts, as this may damage or destroy the wire filaments of the stent.
Stricture

Using smooth, even cutting motions, completely remove all tissue within the stent. Pay particular attention to removing all tissue overlaying the proximal and distal stent edges.

The second step is to create a loop access space to provide an access point for the electrosurgical loop to engage the stent edge. This is done by cauterizing an access space around each stent edge using an electrosurgical loop in cauterization mode.

The third step involves separating the stent from the urethral wall. During this step make sure that the electrosurgical loop is in the “off” position.

Engage the proximal edge of the stent with the electrosurgical loop and pull the edge towards you, distal to the bladder. This motion compresses the stent, longitudinally loosening the outer stent surfaces from the urethral wall. Repeat this compression at 4 different positions around the stent edge at the twelve, three, six and nine o’clock positions.

Repeat the same step at the distal stent edge. At this point use the electrosurgical loop to push the stent proximal, or towards the bladder, at 4 different positions around the stent edge. Again, the twelve, three, six and nine o’clock positions may be used. Once this step is completed, the stent should be loose in the urethra and ready to be removed.

Replace the resectoscope with a cystoscope. Select a long urologic grasping forcep to pass through the working channel of the cystoscope. Firmly grasp three or four rows of stent diamonds and pull the stent through the sheath to retrieve it.

Once the UroLume stent has passed through the sheath, inspect it to ensure that all 24 wires are intact.

Caution: Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.

Should a UroLume prosthesis ever be extracted after placement, the prosthesis must be returned to AMS. Contact your AMS representative for returned goods and warranty information.

If the prosthesis is inadvertently deployed, do not attempt to reassemble it into the delivery instrument. In this instance, contact your AMS representative to return the prosthesis and delivery instrument.

Caution: Do not attempt to remount the prosthesis into the delivery instrument. Attempting to remount the prosthesis into the delivery instrument can cause the delivery instrument to function incorrectly and cause trauma to the urethra.

Imaging of the Prosthesis

The UroLume prosthesis may be imaged using ultrasound, magnetic resonance imaging (MRI) and plain film radiogram.
**Prostate Obstruction Secondary to Benign Prostatic Hyperplasia**

**Indications For Use**

The UroLume Endoprosthesis is intended to relieve prostatic obstruction secondary to benign prostatic hyperplasia (BPH) in men at least 60 years of age, or men under age 60 who are poor surgical candidates, and whose prostate glands are at least 2.0 cm in length (Figure 1). The UroLume prosthesis is not intended as a temporary stent.

**Contraindications**

The following conditions contraindicate use of the UroLume prosthesis for the treatment of prostatic obstruction secondary to benign prostatic hyperplasia:

1. Meatal or urethral strictures which cannot be opened to 24Fr.
2. Patients with an active urinary tract infection.
3. Patients with other urethral conditions requiring transurethral manipulations within eight weeks of potential UroLume prosthesis placement.
4. Patients with known or suspected prostate cancer.
5. Patients with urethral squamous cell carcinoma.
6. Patients with transitional cell carcinoma of the bladder.
7. Patients with previous surgical procedures to alleviate symptoms of BPH.
8. Patients with median prostatic lobe involvement.
9. Patients with a prostatic urethra less than 2.0 cm in length.
10. Patients with bladder stones or neurogenic bladder.

**Warnings**

1. Accurate placement of the stent is crucial. Ensure that the prosthesis does not extend into the external sphincter which may cause the patient to be incontinent. Also ensure that the prosthesis does not extend into the bladder which could cause stone formation.

2. Patients should be advised to expect mild discomfort, post void dribbling, hematuria, urgency and/or nocturia during the first few weeks after prosthesis placement. In most cases, these symptoms resolve or diminish spontaneously.

3. Patients should be advised to abstain from sexual intercourse and sexual activities for at least four weeks following insertion.

4. Prior to utilizing the UroLume prosthesis in patients who suffer from thrombocytopenia or hemophilia and/or patients who have received blood products for the treatment of a bleeding disorder, other alternative treatment options that would put the patient at less risk of bleeding than that associated with the UroLume prosthesis should be considered.

5. Bleeding may seriously impede visualization and proper placement of the prosthesis. If bleeding impairs visualization, a catheter may be placed for 15-20 minutes until bleeding slows, allowing adequate visualization. Alternately, a catheter may be placed and the patient may return in 4-6 days for UroLume Endoprosthesis placement.

6. The prosthesis may migrate and/or shorten resulting in incomplete coverage of the prostatic urethra. If this occurs, additional prostheses may be placed or the prosthesis position may be adjusted to assure complete coverage.

7. Infection could occur at the prosthesis site. Infection may be treated using bactericidal antibiotic therapy or device removal.

8. Transurethral catheterization or other transurethral procedures should not be used in the weeks following UroLume prosthesis insertion, until urothelium has covered the UroLume prosthesis. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability.
9. Encrustation of the prosthesis may occur on wires that do not touch tissue and do not become covered with urothelium. If encrustation develops which causes obstruction, or is associated with repeated infection or intermittent hematuria, it should be removed during cystoscopy or using electrohydraulic lithotripsy.

10. Tissue ingrowth may obstruct the passage of urine. If obstruction occurs, tissue may be removed using resection or fulguration, or dilation may be required, or an additional prosthesis may be placed.

11. Removal of the prosthesis for any reason after urothelial ingrowth could result in significant trauma to the urethra. After urothelial tissue has grown over the prosthesis, it must be resected before the prosthesis is removed or the prosthesis may unravel.

12. The use of the prosthesis in patients who have had previous external or internal gamma radiation therapy for prostate or proximal urethral cancer should be evaluated carefully, due to complications that may be caused by tissue damaged by irradiation.

Precautions

1. The UroLume prosthesis kit (prosthesis, delivery instrument, telescope stabilizer), is provided sterile. Do not resterilize any components. Resterilization causes damage to the components and reuse may cause trauma to the urethra.

2. This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume prosthesis. Each physician should view an instructional video prior to attempting a UroLume prosthesis insertion.

3. The long term safety and effectiveness of the UroLume prosthesis has not been demonstrated, therefore continuing follow-up is recommended.

4. Failure to resheath the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the urethra.

5. Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis.

6. Passing a cystoscope through the prosthesis may displace the prosthesis.

7. The safety and effectiveness of prosthesis removal and subsequent replacement has not been established.

8. Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.

9. Do not attempt to remount the prosthesis onto the delivery instrument. Attempting to insert a remounted prosthesis into the urethra can cause the delivery instrument to function incorrectly and cause trauma to the urethra.

Adverse Events

There were 146 patients evaluated in this study. There were 27 reported deaths during the clinical evaluation. No deaths were related to use of the UroLume prosthesis. Conditions which have required removal of the device in 23 patients include migration, improper placement, incomplete urothelialization, encrustation, obstruction, incontinence, irritative symptoms, hematuria, pain and prostate cancer.

The following significant adverse events occurred during the clinical trial: tissue ingrowth (71%; stent removal in 3%), post-void dribbling (56%; mostly occasionally or rare), urge incontinence (55%; mostly occasionally or rare), urethral pain (54%; stent removal in 2%), stent removal (16%), urinary retention (16%; urinary retention prior to insertion in 8%), and migration (5%).

Other adverse events that occurred in at least 3% of patients in the clinical trial include: difficulty with erections (91%; difficulty with erections prior to insertion in 79%), incontinence (76%; incontinence prior to insertion in 51%), suprapubic tube placement at insertion (47%), inadequate coverage (27%), hematuria (23%; stent removal in 0.7%), intercourse pain (21%), retrograde ejaculation (20%), incontinence of non-resistance (19%), stress incontinence (19%), encrustation (18%; stent removal in 3%), positive urine culture (17%), erection pain (15%), drug therapy for urge/incontinence (12%), drug therapy for BPH (8%), pain with ejaculation (8%), irritative symptoms at insertion (4%), indwelling catheter (3%), removal of encrustation (3%), and stent extending into bladder (3%).
Other complications/side effects noted in 2% or less of the patient population include bulbous urethral strictures, soreness with sitting, papillary tumor, prostatic edema, penile strictures, urosepsis, bladder neck closed, groin pain, wire exposed, irritable bladder syndrome, bladder pain, blood clot passed, prostate growth causing stent displacement, detrusor instability, dysuria, wears pads for incontinence, inflammation of urethral tissue, proliferative changes at stent ends, stent elevated, pain with intercourse, laser ablation of BPH tissue, hyperplasia outside stent, perineal pain, delayed ejaculation, necrotic tissue, external sphincter impairment, urine leak after intercourse, urgency after intercourse, dilation of meatal stenosis, passed stone from encrustation, ureteroscopy unsuccessful, hematospermia, semen thinner/diminished, erythema of the prostatic urethra, prostatic hypoechoic nodules, decreased sensation with ejaculation, erections progressively worsened, transurethral resection of the bladder neck, stent repositioned, erection duration reduced, stent compromises catheterization, pain, urethrotomy, wires broken at insertion, hypotension at insertion, pulmonary edema at insertion, clots evacuated, blood in urine after ejaculation, TURP, narrowing in non-stented region, membranous urethral stricture, blood loss, confusion, post-operative bleeding.

Many of the adverse events noted throughout the study were also noted by patients prior to insertion of the UroLume prosthesis. The incidence of adverse events at any particular point in time was less than the cumulative incidence of adverse events for the duration of the study reported above.

Clinical Results

A total of 146 patients (115 non-retention, 31 retention) have been studied in the U.S. and Canada. The average age in the non-retention group was 68 years, the average age in the retention group 76 years. Outcome effectiveness variables identified in these patients included total symptom score (Madsen-Iversen) and peak urinary flow rate.

In clinical studies, 81% (70/87) of patients were considered symptom score successes (at least 25% improvement in total symptom score one year after insertion). When evaluating success based upon improvement in urinary flow rate, 60% (50/84) of the patients were considered a success (success defined as a 25% improvement in peak flow rate one year after insertion).

Mean peak urinary flow rate prior to insertion was 9.1cc/sec in 113 non-retention patients with available data. One month following insertion, mean peak flow rate was 16.0cc/sec in 96 patients with available data. One year following insertion, mean peak flow rate was 14.0cc/sec in 86 patients with available data.

Evaluation of clinical data indicated a significant increase in peak flow rate for the majority of patients following UroLume Endoprosthesis insertion. Substantial improvement in flow rate was maintained throughout the study.

Mean total symptom score prior to insertion was 14.4 in 115 non-retention patients with available data. One month following insertion, mean total symptom score had improved to 6.2 in 100 patients with available data. One year following insertion, the mean total symptom score was still significantly improved at 6.0 in 87 patients with available data. Irritative symptoms did not show as much improvement as obstructive symptoms.

During clinical evaluation, most patients demonstrated complete (90-100%) coverage by urothelial tissue by six months following stent insertion. Patients whose devices did not become completely covered were found to have no apparent increased propensity for urinary tract infection.

Caution: For high risk patients with an expected high mortality rate, the 10-year explant rate due to tissue response prior to death is estimated at 3.7% with 1-sided 95% upper confidence limit of 11.5%. For healthier patients with an expected moderate mortality rate, the rate is expected to be higher.
Instructions For Use

Caution: This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume prosthesis. Physicians should view an instructional video, which demonstrates insertion and removal within the prostatic urethra, prior to attempting a UroLume prosthesis insertion.

Patient Communication

To prepare a patient to make an informed decision regarding implantation of the UroLume prosthesis, the physician should communicate several items to the patient, and provide a Patient Information Brochure to each patient.

1. The patient should be advised that post void dribbling may be experienced in the weeks following UroLume prosthesis insertion. Methods for managing post void dribbling should be discussed with the patient.

2. The patient should be informed that hematuria and/or pain may be experienced in the weeks following insertion.

3. Patients should be advised that transurethral catheterization or other transurethral procedures should not be used in the weeks following UroLume prosthesis insertion, until urothelium covers the UroLume prosthesis. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability.

4. Patients should be advised that urgency and/or nocturia may be experienced in the weeks following insertion.

5. Patients should be advised to abstain from sexual intercourse and sexual activities for at least four weeks following insertion of the UroLume prosthesis. Retrograde ejaculation or pain with erections may be noted after insertion.

6. Patients should be advised that bleeding may occur during the insertion procedure which may hinder device placement, necessitate catheterization, and possible hospitalization. The patient would then need to return for stent placement once the bleeding subsides.

7. Patients should be advised that there may be situations where a suprapubic tap for urinary drainage proximal to the stent would be advised.

8. Patients should be informed of actions to take in case of an emergency, i.e., when to consult a physician following insertion of the UroLume prosthesis.

9. Patients should be informed of the importance of always carrying their Medical Information Card.

Pre-operative Set-up

Materials
The following materials are required for the placement procedure:

- Urethral sounds
- 12Fr, 0° to 12° telescope
- Water flushing set-up: typically 1 to 5 liters of sterile water on I.V. pole, 5mm tubing
- 17Fr or 21Fr cystoscope
- AMS Urethral Measuring Catheter or a graduated ureteric catheter
- UroLume® Endoprosthesis kits (two of each size recommended)

Note: A selection of at least two UroLume prosthesis kits in each size is advised. This inventory ensures that the correct size is available when the prostatic urethra is measured.

Note: 12° telescopes cannot be used with a telescope stabilizer as they must be rotated to view the anterior bladder neck during prosthesis placement.

Premedication
Prior to implantation with the UroLume prosthesis, patients should be given prophylactic broad-spectrum antibiotic coverage according to the protocols commonly used by the hospital.

Patient Preparation
Place the patient in the lithotomy position, prep with aseptic solution and drape.

Anesthesia
Clinical investigators found that the anesthesia required for cystoscopy is generally sufficient for prosthesis placement.
Preparation for Prosthesis Placement

To employ the appropriate size UroLume prosthesis kit, select a prosthesis that is 0.5 cm shorter than the measured length of the prostatic urethra.

1. Perform a diagnostic cystourethroscopy.

2. Measure the length of the prostatic urethra, from mid verumontanum to bladder neck (Figure 8). This may be accomplished by using an AMS Urethral Measuring Catheter, following the instructions included with that product, or a graduated ureteric catheter. Instructions for measuring the urethra with a graduated ureteric catheter are as follows: With the bladder full, place a graduated ureteric catheter alongside the telescope into the bladder. Hold the catheter firmly and gently withdraw the telescope while counting the centimeter markings on the catheter to determine the length of the prostatic urethra. Empty the bladder before withdrawing the cystoscope.

3. Select a prosthesis that is 0.5 cm shorter than the measured length of the prostatic urethra.

4. Open the selected prosthesis package. Peel open the plastic tray and remove the sterile contents. Inspect the delivery instrument carefully.

**Note:** No wire filaments should protrude from the rounded collar of the delivery instrument. Should filaments be seen protruding from the delivery instrument, return the entire system to your AMS representative and use a new UroLume prosthesis.

Prepare the selected UroLume deployment system for the procedure, as follows:

- Attach the light source to the telescope.

- Attach the water source to the irrigation port on the delivery instrument, with the water bag approximately one meter above the patient. If desired, a three-way tap may be connected to the luer lock of the irrigation port before attaching the water source.

**Note:** A three-way tap will reduce the cross-section of the irrigation port and, therefore, the water flow will also be reduced.

- Insert the 0 degree telescope into the telescope stabilizer and advance the telescope into the desired lock position. Squeezing sides of stabilizer while inserting telescope will impede attachment (see page 4 for telescope compatibility). Insert the telescope stabilizer into the delivery tool. A light push may be required to do so. During the placement procedure, the position of the prosthesis can be monitored by sliding the telescope and stabilizer back and forth in the delivery instrument.

- Apply a small amount of sterile lubricant over the outer shaft to facilitate passage into the urethra.

During the procedure the delivery instrument may be manipulated with one hand (Figure 9), while the other hand stabilizes the penis. With these preparatory steps completed, the physician is ready to proceed with the five step placement procedure (Figures 10, 11).
Figure 9: The front finger grip draws back the sheath to expose the prosthesis, while the rear security button prevents its inadvertent release. Reference “Placement Procedure” for complete placement instructions.

**Insertion**

Both security buttons are in the locked position; finger grips are immobile. Hold the grips with thumb and middle finger.

**Partial Deployment**

1) Press the front security button down with the index finger.
   *Note:* Do not deploy prior to insertion.

2) Using the middle finger, pull the front finger grip back to retract the sheath.

**Release**

1) Using the index finger press, then release, the rear security button.
2) Using the middle finger, pull the front finger grip back. Verify that the prosthesis has been completely released by pulling back on the telescope.
3) Gently pull back on the delivery instrument to distance it from the prosthesis.

Figures 10, 11: Placing the UroLume prosthesis.

Figure 10

1. Insertion
2. Confirmation
3. Partial deployment

Figure 11

4. Release
5. Withdrawal
Placement Procedure

1. Insertion (Figure 10)
   - Dilate the meatus if required. The minimum dilation required for the insertion and placement of the prosthesis is 26Fr.
   - Introduce the delivery instrument into the urethra, advancing it gently under direct vision. Hold the delivery instrument stable and manipulate the telescope in and out to assess landmarks for prosthesis placement.

2. Position Confirmation (Figure 10)
   - Position the delivery instrument so that its rounded collar is proximal to the bladder neck.
   - Note: During deployment hold the delivery instrument upright as close as possible to the 12:00 o'clock position and try not to rotate the tool beyond the 11:00 and 1:00 o'clock positions. The 12 o'clock position is in the vertical direction.

3. Partial Deployment (Figure 10)
   - When the rounded collar of the delivery instrument is positioned proximal to the bladder neck, depress the front security button first. While holding down the front security button, gently pull the front finger grip toward the back finger grip until the front finger grip has passed the front security button position. This unlocks the sliding mechanism, and permits the retractable sheath to slide back, exposing, but not releasing, the prosthesis. It is not necessary to continue to hold down the security button after the front finger grip has passed the front security button position.
   - Hold the delivery instrument as close to the 12 o'clock position as possible. Keep the back finger grip steady, and pull the front grip gently toward the back finger grip. This action causes the retractable sheath to draw back in a controlled, gradual manner. As the retractable sheath slides back, the prosthesis is exposed. The prosthesis expands in diameter and shortens in length as it emerges. Observe this shortening in relation to the urethra.
   - Note: Clinical investigators recommend keeping the telescope at the level of the bladder neck while deploying the prosthesis to observe this shortening in relation to the bladder neck. When properly positioned, the prosthesis should not protrude into the bladder.
   - Note: If using a 12° telescope, without stabilizer, the telescope should be rotated within the delivery instrument to view the entire bladder neck. Do not rotate the delivery instrument.

When the front finger grip reaches the back security button, the prosthesis is exposed, but not released from the holding mechanism. This offers the opportunity to move the telescope and to make a final check of the position of the prosthesis. It is important to keep the partially deployed prosthesis aligned with the delivery instrument. Moving the delivery instrument at an angle that puts traction on the exposed prosthesis may cause the prosthesis to release prematurely.

Visualize the entire length of the prostatic urethra to ensure that the prosthesis is situated in the intended position. The prosthesis should cover the prostatic urethra from the bladder neck to the verumontanum.

- Warning: Ensure that the prosthesis does not protrude into the bladder, or encrustation could occur.
- Warning: Ensure that the prosthesis does not extend into the external sphincter. Placing the prosthesis in the external sphincter may cause the patient to be incontinent.

If the prosthesis is not in the intended position, resheathe the prosthesis by advancing the delivery instrument’s retractable sheath forward until it completely covers the prosthesis. To do this, withdraw the delivery instrument slightly while gently pushing the front finger grip away from the back finger grip until the first security button re-engages with an audible click. As this is done, the retractable sliding sheath encompasses the prosthesis. With the prosthesis securely inside the delivery instrument shaft, the physician may move the instrument to the intended position in the prostatic urethra. The bladder should be empty before releasing the prosthesis.

- Caution: Failure to resheathe the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the prostatic urethra.

4. Release (Figure 11)
   - Confirm with direct vision that the prosthesis is in the intended position, with distal end of prosthesis at verumontanum or mid verumontanum. Then, before releasing the prosthesis from the holding mechanism, position the telescope to view the prosthesis at the bladder neck.
Release the prosthesis from the delivery instrument by pressing down the rear security button first. While holding down the rear security button, completely draw the front finger grip all the way back to the rear finger grip. Use the middle finger to move the front finger grip. The index finger presses the rear security button. The front finger grip locks after the prosthesis is released and the prosthesis cannot be resheathed or remounted into the delivery instrument.

**Caution:** Do not attempt to remount the prosthesis onto the deployment instrument. Attempting to insert a remounted prosthesis into the prostatic urethra can cause improper function of the deployment instrument and result in trauma to the urethra.

5. **Withdrawal of the Delivery Instrument** (Figure 11)

Before beginning to withdraw the delivery instrument, move the telescope back to ensure the delivery instrument is aligned with the distal end of the prosthesis, and verify that the prosthesis is off each hook.

If the prosthesis is still attached to a hook(s) as shown below, rotate the delivery instrument lightly between 11:00 and 1:00 o'clock while viewing the prosthesis through a telescope. This rotational movement will ensure that the prosthesis is completely free of the delivery instrument.

Pull gently on both finger grips to distance the delivery instrument shaft from the released prosthesis. Observe that the prosthesis does not move out of position as the delivery instrument pulls away from it. Using the back finger grip as a stabilizer, pull the delivery instrument away from the correctly placed prosthesis just enough to ensure that the prosthesis is completely free of the holding mechanism. Some physicians rotate the delivery instrument slightly, while viewing the prosthesis through the telescope. In this way they ensure that the prosthesis is completely free of the delivery instrument.

Retract the telescope into the delivery instrument, taking care not to let it touch the prosthesis.

Gently withdraw the delivery instrument from the urethra, while ensuring the prosthesis is off the hook(s) and using care not to displace the prosthesis.

Proceeding with care, perform normal endoscopy using a 17Fr or smaller cystoscope. Manipulate the cystoscope carefully, and avoid contact with the prosthesis. Observe carefully to ensure that the prosthesis does not move out of position. Ensure that the prosthesis completely covers the prostatic urethra.

**Caution:** Passing a cystoscope through the prosthesis may displace the prosthesis.

### Placing Multiple Stents

If more than one prosthesis is required to adequately cover the prostatic urethra, the first stent placed should cover the most proximal (nearest the bladder neck) end of the prostatic urethra. Additional stents may then be placed following steps 1-5 above. The additional stent(s) should overlap the previously placed stent by at least 5mm (approximately 5 diamonds).

**Caution:** Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis.

### Adjusting the Position of a Released Prosthesis

**Caution:** Any repositioning of a released prosthesis must be performed with care in order not to cause trauma to the prostatic urethra.

1. **Repositioning a Prosthesis Placed Too Far Proximally**

   If the released prosthesis appears to extend into the bladder, it is possible to reposition the prosthesis using the following procedure:

   Grasp several rows of wire with a biopsy forceps, not less than 2mm from the distal end of the prosthesis (closest to the external sphincter). Gently pull the prosthesis into the intended position. Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break or bend wires, necessitating removal. Confirm position endoscopically by visualizing no wires protruding into the bladder.

2. **Repositioning a Prosthesis Placed Too Far Distally**

   If the released prosthesis appears to be positioned too near the external sphincter, use forceps to push the end of the prosthesis closest to the external sphincter over the verumontanum. If the released prosthesis does not extend to the bladder neck, use urologic forceps to grasp several
rows of wire near the end of the prosthesis closest to the bladder neck and pull the prosthesis to the bladder neck.

**Postoperative Procedures**

Prescribe prophylactic antibiotics to the dose and duration typically prescribed for cystoscopy or endoscopic procedures. If the patient is unable to void, place a suprapubic tube for drainage.

*Caution:* Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter until the prosthesis is stabilized by urothelial ingrowth. Inserting a catheter into the prostatic urethra before urothelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the prostatic urethra. In emergency situations, suprapubic urinary catheterization may be used, however, no transurethral instruments should be used until a physician familiar with the UroLume prosthesis can check its stability. If possible, patients should be seen by a physician familiar with the UroLume prosthesis when the implanting physician is not available, until tissue coverage has occurred.

**Removing a Released Prosthesis**

With a urologic alligator forceps, grasp three to five diamonds of wire at the distal end of the prosthesis. If more than one prosthesis is to be removed, begin with the most recently placed prosthesis. Gently pull the prosthesis. As the prosthesis is drawn out, it elongates and narrows allowing the physician to withdraw it from the urethra.

*Note:* Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. In this instance, each wire must be removed individually. Each prosthesis consists of 24 wire filaments. Confirm with endoscopy and fluoroscopy that all wire filaments are retrieved.

**Prosthesis Removal After Urothelial Coverage**

*Warning:* A prosthesis that has covered with urothelial tissue must have the tissue resected before it can be removed.

The first step in the UroLume removal technique is to remove as much tissue as possible from the inner stent surfaces. This is done by thoroughly resecting the overlying tissue from the inner surfaces of the stent using a 24 french electrosurgical loop. Use the lowest possible current setting, beginning at 40 watts and increasing by 10 watt increments if necessary. Do not exceed 70 watts, as this may damage or destroy the wire filaments of the stent.

Using smooth, even cutting motions, completely remove all tissue within the stent. Pay particular attention to removing all tissue overlaying the proximal and distal stent edges.

The second step is to create a loop access space to provide an access point for the electrosurgical loop to engage the stent edge. This is done by cauterizing an access space around each stent edge using an electrosurgical loop in cauterization mode.

The third step involves separating the stent from the urethral wall. During this step make sure that the electrosurgical loop is in the “off” position.

Engage the proximal edge of the stent with the electrosurgical loop and pull the edge towards you, distal to the bladder. This motion compresses the stent, longitudinally loosening the outer stent surfaces from the urethral wall. Repeat this compression at 4 different positions around the stent edge at the twelve, three, six and nine o’clock positions.

Repeat the same step at the distal stent edge. At this point use the electrosurgical loop to push the stent proximal, or towards the bladder, at 4 different positions around the stent edge. Again, the twelve, three, six and nine o’clock positions may be used. Once this step is completed, the stent should be loose in the urethra and ready to be removed.

Replace the resectoscope with a cystoscope. Select a long urologic grasping forceps to pass through the working channel of the cystoscope. Firmly grasp three or four rows of stent diamonds and pull the stent through the sheath to retrieve it. Once the UroLume stent has passed through the sheath, inspect it to ensure that all 24 wires are intact.

*Caution:* Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.

*Should a UroLume prosthesis ever be extracted after placement, the prosthesis must be returned to AMS. Contact your AMS representative for returned goods and warranty information.*

If the prosthesis is inadvertently deployed, do not attempt to reassemble it into the delivery instrument. In this instance, contact your AMS representative to return the prosthesis and delivery instrument.

*Caution:* Do not attempt to remount the prosthesis into the delivery instrument. Attempting to remount the prosthesis into the delivery instrument can cause the delivery instrument to function incorrectly and cause trauma to the urethra.

**Imaging of the Prosthesis**

The UroLume prosthesis may be imaged using ultrasound, magnetic resonance imaging (MRI) and plain film radiogram.
DESD

Detrusor External Sphincter Dyssynergia

Indications For Use
The UroLume® Endoprosthesis is intended for use in men to relieve urinary obstruction due to detrusor-external sphincter dyssynergia. (DESD). The UroLume® Endoprosthesis is designed to hold open the external sphincter mechanism from the verumontanum to the bulbar urethra and is intended as a longterm (not temporary) stent (Figure 12).

Contraindications
The following conditions contraindicate use of the UroLume® Endoprosthesis for the treatment of DESD.

1. Meatal or urethral strictures which cannot be opened to at least 24Fr by dilation, urethrotomy or meatotomy.

2. Patients with an active urinary tract infection.

3. Patients with other urinary conditions requiring transurethral manipulation within eight weeks of UroLume® Endoprosthesis placement.

4. Patients with known or suspected prostate cancer.

5. Presence of urethral squamous cell carcinoma.

6. Patients with bladder cancer.

7. Patients with untreated bladder stones.

8. Patients with untreated bladder neck obstruction.


10. Presence of fistula at the proposed prosthesis location.

Warnings
1. The prosthesis should not be used in patients in whom bleeding may seriously impede the visualization process. If bleeding impedes visualization, a catheter may be placed for 15 - 20 minutes until bleeding slows, allowing adequate visualization. Alternately, a catheter may be placed and the patient may return in 4 - 6 days for UroLume® Endoprosthesis placement.

2. The prosthesis is not intended to be used to treat the conditions of inadequate detrusor contractions or poor bladder compliance. The role of the UroLume® for treatment of DESD in patients with areflexia or hyperreflexia has not been evaluated.
3. Prior to utilizing the UroLume® Endoprosthesis in patients who suffer from thrombocytopenia or hemophilia and/or patients who have received blood products for the treatment of a bleeding disorder, alternative treatment options should be considered that would put the patient at less risk of bleeding than that associated with the UroLume® Endoprosthesis.

4. The use of the prosthesis in patients who have had previous external or internal gamma radiation therapy for prostate or proximal urethral cancer should be evaluated carefully, due to complications that may be caused by tissue damaged by irradiation.

5. Longitudinal compression of the prosthesis by instrumentation could cause trauma to the urethra or could dislodge the prosthesis. Transurethral instrumentation should be avoided prior to urothelial ingrowth.

6. The prosthesis may migrate and/or shorten resulting in incomplete coverage of the external sphincter. If this occurs, additional prostheses may be placed or the prosthesis position may be adjusted to assure complete sphincter coverage. Some patients who have experienced shortening of the stent do not require further treatment, if detrusor leak point pressures remain low and if the patient remains improved with regard to autonomic dysreflexia, hydronephrosis and/or symptomatic urinary infection.

7. Infection could occur at the prosthesis site. Infection may be treated using antimicrobial therapy or device removal.

8. Encrustation of the prosthesis may occur on wires that do not touch tissue and do not become covered by urothelium. If obstruction, repeated urinary tract infection or intermittent hematuria occur as a result of encrustation, the encrustations should be removed. Investigators have reported removal of encrustation by gently brushing the encrustations off with the beak of the cystoscope or by using electrohydraulic lithotripsy.

9. Tissue ingrowth may obstruct the passage of urine. If obstruction occurs, tissue ingrowth may be removed using resection, coagulation or fulguration, or an additional prosthesis may be placed.

10. Erosion through the external sphincter could occur. If this occurs, the UroLume® Endoprosthesis should be removed.

11. Removal of the prosthesis for any reason after urothelial ingrowth could result in significant trauma to the urethra. After urothelial tissue has grown over the prosthesis, it must be completely resected before the prosthesis is removed, or the prosthesis may unravel.

12. Patients should be advised to expect mild discomfort or hematuria during the first few weeks after prosthesis placement. In most cases these symptoms resolve or diminish spontaneously.

13. Care must be taken when transferring or transporting the patient during the first eight weeks post-stent insertion to avoid putting pressure on the perineal area. This will allow adequate urothelialization and help avoid dislodging the prosthesis.

14. Patients who require assistance with bowel evacuation must follow a modified bowel evacuation program carefully, for at least eight weeks after stent insertion, to avoid dislodging the prosthesis prior to complete urothelialization.

15. Patients should not engage in rehabilitation or physical therapy for the first three weeks following stent insertion. This will allow adequate urothelialization and help avoid dislodging the prosthesis.

16. Patients should be advised to abstain from sexual intercourse and sexual activities for at least four weeks following insertion.

17. Patients with both a penile implant and a stent should be advised that development of an infection or fistula at the site of either implant may necessitate removal of both implants.

18. Patients should be advised if they have a stent and currently or subsequently have another genitourinary prosthesis placed in the vicinity of the stent, that in the event of a complication with either prosthesis (i.e., infection, erosion, etc.) both implants may have to be removed.
Precautions

1. The UroLume® Endoprosthesis kit (prosthesis, delivery instrument, telescope stabilizer, ACMI adapter ring) is provided sterile. Do not resterilize any components. Resterilization causes damage to the components and re-use may cause trauma to the urethra.

2. This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume® Endoprosthesis for treatment of DESD. Each physician should view an instructional video prior to attempting a UroLume® Endoprosthesis insertion.

3. Ensure that the UroLume® Endoprosthesis adequately covers the external sphincter.

4. Failure to resheathe the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and may cause trauma to the urethra.

5. Moving the delivery instrument at an angle that puts traction on a partially deployed prosthesis may cause the prosthesis to release prematurely.

6. Exercise care with instrumentation to ensure that the first prosthesis is not dislodged while placing a second prosthesis. Whenever possible, place the more proximal prosthesis first.

7. Passing an endoscope through the prosthesis prior to urothelialization may displace the prosthesis.

8. Use care in handling an explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.

9. The stent is accurately placed when the proximal end of the prosthesis is approximately 2mm distal to the distal end of the verumontanum and the distal end of the stent is fully deployed against the walls of the external sphincter. The distal end of the stent may extend into the bulbar urethral region if necessary.

10. Do not attempt to remount the prosthesis onto the delivery instrument. Attempting to insert a remounted prosthesis into the urethra may cause the delivery instrument to function incorrectly and may cause trauma to the urethra.

11. Safety and effectiveness of stent replacement that occurs a significant amount of time after prosthesis removal has not been established.

12. The long term safety and effectiveness of the UroLume® prosthesis has not been demonstrated, therefore continuing followup is recommended.

13. Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter for at least eight weeks after stent insertion, until the prosthesis is stabilized by urothelial ingrowth. Inserting a catheter into the urethra before urothelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the urethra.

Adverse Events

American Medical Systems conducted two studies, the Open Label UroLume™ Study and the UroLume™/TUS Randomized Study, to assess the performance of the UroLume® Endoprosthesis when used for relief of urinary obstruction secondary to Detrusor-External Sphincter Dyssynergia (DESD). All adverse effects which occurred during or as a result of participation in the studies were prospectively reported. Results from each of the studies are reported below.
Clinical Results

American Medical Systems conducted clinical evaluations of the UroLume® Endoprosthesis to assess the performance of the device for use in relieving urinary obstruction secondary to Detrusor-External Sphincter Dyssynergia (DESD). Two separate studies were conducted, the Open Label UroLume® Study and the UroLume®/TUS (transurethral sphincterotomy) Randomized Study.

Bladder neck obstruction is a separate condition from DESD, which often only becomes apparent only after DESD is resolved.

<table>
<thead>
<tr>
<th>Open Label Study / Device Related Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Event</strong></td>
</tr>
<tr>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Urinary Tract Infections (Symptomatic and Asymptomatic)</td>
</tr>
<tr>
<td>Autonomic Dysreflexia</td>
</tr>
<tr>
<td>Hematuria</td>
</tr>
<tr>
<td>Migration</td>
</tr>
<tr>
<td>Bladder Neck Obstruction*</td>
</tr>
<tr>
<td>Inadequate Stent Coverage of External Sphincter</td>
</tr>
<tr>
<td>Urosepsis</td>
</tr>
<tr>
<td>Encrustation</td>
</tr>
<tr>
<td>Temporary Retention</td>
</tr>
<tr>
<td>Difficulty Emptying Bladder</td>
</tr>
<tr>
<td>Inadequate Urothelialization</td>
</tr>
<tr>
<td>Inflammation of Urethral Tissue</td>
</tr>
<tr>
<td>Fever, Post-Operative</td>
</tr>
<tr>
<td>Perineal Pain</td>
</tr>
<tr>
<td>Squamous Metaplasia</td>
</tr>
<tr>
<td>False Passage</td>
</tr>
<tr>
<td>Inflammation / Granulation of Urethral Tissue</td>
</tr>
<tr>
<td>Urethral Polyps</td>
</tr>
<tr>
<td>Hyperplasia within Stent</td>
</tr>
<tr>
<td>Wire Protruding into Lumen</td>
</tr>
<tr>
<td>Urethral Abrasion</td>
</tr>
<tr>
<td>Penile Discomfort</td>
</tr>
<tr>
<td>Urinary Fistula</td>
</tr>
<tr>
<td>Bladder Stones</td>
</tr>
<tr>
<td>Covered Ejaculatory Duct</td>
</tr>
<tr>
<td>Stent Compromises Catheterization</td>
</tr>
<tr>
<td>Compressed Stent</td>
</tr>
<tr>
<td>Urethral Pain</td>
</tr>
<tr>
<td>Urethral Perforation</td>
</tr>
<tr>
<td>Dysuria</td>
</tr>
<tr>
<td>Reflux of Urine into Vas Deferens</td>
</tr>
<tr>
<td>Extravasation of Urine</td>
</tr>
<tr>
<td>Groin Pain</td>
</tr>
<tr>
<td>Abdominal/penile Pain</td>
</tr>
<tr>
<td>Soreness with Sitting</td>
</tr>
</tbody>
</table>

Open Label Study

During the study, 279 stents were inserted in 160 patients. Some patients required more than one device to adequately cover the external sphincter.

Patients were followed on average $3.6 \pm 2.0$ patient years. Table 1 lists the adverse effects reported in the study that were reasonably associated with use of the device.

Six patient deaths were reported during the study. No deaths were related to the insertion or use of the UroLume® Endoprosthesis.
Sixty-one patients were enrolled in the study. Following baseline evaluation, 32 patients were randomly assigned to undergo insertion of a UroLume® Endoprosthesis and 29 patients were assigned to undergo transurethral sphincterotomy (TUS). Three of the TUS patients refused the assigned treatment, therefore only 26 patients received TUS. Of the 32 patients assigned to the UroLume® treatment group, 31 patients went on to receive 51 devices. UroLume® patients were followed on average 2.0 + 1.2 patient years.

Table 2 summarizes the experience of both the UroLume® and TUS treatment groups. Listed are the events that were reasonably associated with use of the device. During the study, no deaths were reported in the UroLume® treatment group, however, one patient in the TUS treatment group died due to causes unrelated to the study treatment.

* Bladder neck obstruction is a separate condition from DESD, which often only becomes apparent only after DESD is resolved.
Open Label Study

A total of 160 male patients with DESD were enrolled at fifteen investigational sites in the US and Canada. Patient age ranged from 16 to 74 years (mean = 36.3 ± 12.1). The majority of patients (150 of 160) developed DESD following spinal cord injury. DESD was attributed to multiple sclerosis or vascular accident in the remaining 10 patients.

Primary outcome variables assessed during the study were detrusor leak point pressure (DLPP) and post-void residual urine volume (PVR). Secondary outcome variables evaluated in the study included: indwelling catheter usage, incidence and severity of upper tract deterioration, occurrence of autonomic dysreflexia, and urothelialization of the device.

Elevated detrusor leak point pressures (>60 cm H₂O) place the patient at risk for upper urinary tract damage which can lead to renal failure. Detrusor leak point pressures measured at baseline averaged 75.1 cm H₂O + 28.2 cm H₂O in the study population. Following stent insertion, DLPP mean was 37.4 + 23.9 cm H₂O at 1 year based on a paired data analysis. Therefore the risk for upper urinary tract damage was reduced, as determined by upper tract imaging.

Similarly, PVR was reduced from a mean of 204.9 cc + 150.1 cc at baseline to a mean of 113 + 125 cc at 1 year based on a paired data analysis.

Evaluation of the secondary effectiveness variables demonstrated the following:

- Catheter use was reduced from 53.8% of patients at baseline to 10% at one year following stent insertion.
- The incidence of hydronephrosis was reduced from 18.8% at baseline, to 3.4% at one year following stent insertion.
- The occurrence of autonomic dysreflexia was reduced from 72% of patients at baseline to 30% through one year period following stent insertion.

During clinical evaluation, most patients demonstrated complete (90%-100%) urothelial covering of the stent by six months following insertion.

During the open label study a total of 279 stents were inserted and 81 stents taken out. The stents taken out include: 37 explants (taking out all stents from a patient), 24 retrievals (taking out a stent at an insertion procedure), 12 insertion difficulties (based only on those stents that were not released from the insertion tool), 6 replacements (taking a stent out and immediately replacing it with another stent), and 2 removals (taking out a stent where other stents remain). Based on the number of stent insertions attempted, 29% (81/279) of the stents were either taken out or had insertion difficulties. Based on the number of patients in the open label study, 33% (52/160) of patients had stents taken out.

Reported reasons for stent removal included: stent migration, inadequate urothelialization, encrustation, urinary tract infection, inadequate coverage of the external sphincter, urethral bleeding, fistula, squamous metaplasia, autonomic dysreflexia, benign prostatic hyperplasia, inability to use a condom catheter due to displacement causing penile skin breakdown, hyperplasia, pain, spasticity, and penile implant infection.

Under the open label study 58 additional stents were inserted into 41 patients, or 26% (41/160) of patients.

The adverse events reasonably associated with the UroLume® Endoprosthesis are listed in the Adverse Event Section.

UroLume®/TUS Randomized Study

A total of 61 male patients with DESD were enrolled at three investigational sites in the US. A total of 57 patients, 31 UroLume® and 26 TUS, received treatment under the randomized study because three TUS patients and one UroLume® patient elected not to undergo treatment after randomization.

Based on the baseline characteristics of the two treatment groups, there were no clinically or statistically significant differences between patients receiving a UroLume® Endoprosthesis and patients undergoing TUS Evaluation of the procedure and postoperative care demonstrated the following:
The average procedure length was shorter for the UroLume® (34.1+39.2 minutes) than for TUS (47.9+39.0 minutes).

Perioperative bleeding was similar for stent insertion and TUS as quantified by comparison of preoperative hemoglobin levels to hemoglobin levels obtained the first postoperative day.

Significantly less postoperative bleeding was noted following stent insertion as compared to TUS.

Nineteen of 31 UroLume® patients did not have an indwelling or suprapubic catheter placed in the postoperative period. All TUS patients had a catheter placed immediately following treatment.

Incidence of postoperative episodes of autonomic dysreflexia was similar for UroLume® patients and TUS patients.

A higher percentage of UroLume® patients required only a one day hospital stay following treatment as compared to TUS patients, who often required two or more days of hospitalization following sphincterotomy.

During follow-up, the primary and secondary outcome variables assessed were the same as those variables evaluated under the open label study.

The DLPP measured at baseline was not significantly different between treatment groups. At baseline, 90% or more patients in both treatment groups had DLPP over 60 cm H\textsubscript{2}O but after the randomized intervention, at least 60% of the UroLume® group and at least 76% of the TUS patients had DLPP under that value. Using a DLPP criterion of 40 cm H\textsubscript{2}O, at least 20% of the UroLume® patients and at least 29% of the TUS patients had mean DLPP under this level after treatment. No statistically significant difference between treatment groups was noted at three months, six months, one year and three years following treatment. At two years, the TUS group demonstrated a slightly higher reduction in DLPP than the UroLume® group.

The PVR measured at baseline was not statistically different between treatment groups. Measurements through 2 years of follow-up demonstrated no significant differences in PVR as compared to baseline for either treatment group. Likewise, no significant difference was noted between treatment groups.

Evaluation of the secondary effectiveness variables demonstrated the following:

- Both treatment groups demonstrated similar reductions in the use of indwelling catheters from >50% at baseline to 4.3% of UroLume® patients and 11.8% of TUS patients one year following treatment.
- No difference in incidence or severity of hydronephrosis or autonomic dysreflexia was noted between treatment groups or compared to baseline values.

One TUS patient died during the study. The death was attributed to sequelae of quadriplegia and was not related to the patient’s participation in the study.

A total of 423 events were reported for both treatment groups during the study.

During the randomized study, a total of 51 stents were inserted and 18 stents taken out for the following reasons: 8 explants, 8 retrievals, 1 insertion difficulty, and 1 replacement. Based on the number of stent insertions attempted, 35% (18/51) of the stents were either taken out or had insertion difficulties.

There were 5 additional stents that were needed in 5 patients.

**Instructions For Use**

*Caution: This device is to be used only by physicians who have received appropriate training regarding the use of the UroLume® Endoprosthesis. Physicians should view an instructional video, which demonstrates insertion and removal, prior to attempting a UroLume® Endoprosthesis insertion.*

**Patient Communication**

To prepare a patient to make an informed decision regarding implantation of the UroLume® Endoprosthesis, the physician should communicate several items to the patient, and provide a patient information brochure to each patient.

1. Patients should be advised that bleeding may occur during the insertion procedure which would necessitate catheterization and possible hospitalization. The patient would then need to return for stent placement.
2. Patients should be advised that there may be situations where a suprapubic catheter for urinary drainage proximal to the stent would be advised.

3. Patients should be advised that occasionally there may be an unrecognized infection present at insertion.

4. Patients should be informed that hematuria and/or pain may be experienced in the weeks following insertion.

5. Patients should be advised to avoid positions that place undue pressure or strain on the perineum until the prosthesis has stabilized. Increased pressure to the perineum may cause movement of the prosthesis away from the external sphincter. For quadriplegic and paraplegic patients, rehabilitation and physical therapy should be discontinued for at least three weeks following insertion. Personnel providing patient care should be advised to exercise care when moving the patient.

6. Patients should be advised that transurethral catheterization or other transurethral procedures should not be used for at least eight weeks following UroLume® Endoprosthesis insertion, until urothelium covers the UroLume® Endoprosthesis. Suprapubic urinary catheterization may be used. However, no transurethral instruments should be used until a physician familiar with the UroLume® Endoprosthesis can check its stability.

7. Patients should be advised to abstain from sexual intercourse and sexual activities for at least four weeks following insertion of the UroLume® Endoprosthesis.

8. Patients following bowel evacuation programs should be advised to employ stool softeners and to avoid digital touch in the vicinity of the external sphincter for at least eight weeks following stent insertion, until urothelium covers the UroLume® Endoprosthesis.

9. Patients who suffer spastic muscle contractions should be advised that antispasmodics may be used to control spasticity until the prosthesis stabilizes.

10. Patients with both a penile implant and a stent should be advised that development of an infection or fistula at the site of either implant may necessitate removal of both.

11. Patients should be advised that stent removal, if necessary, could necessitate an open surgical procedure.

12. Patients should be informed of actions to take in case of emergency, i.e., when to consult a physician following insertion of the UroLume® Endoprosthesis.

13. Patients should be informed of the importance of always carrying their Medical Identification Card.

Pre-operative Set-up

Materials
The following materials are required for the placement procedure:

- Urethral sounds
- 12Fr, 0° to 30° telescope
- Water flushing set-up; typically 1 to 5 liters of sterile water on I.V. pole, 5mm tubing
- 17 Fr flexible or rigid cystoscope (for inspection of stent, post-placement)
- 21 Fr rigid cystoscope and grasping forceps (for use in the event that the stent required repositioning or retrieval)
- AMS Urethral Measuring Catheter, or a graduated ureteric catheter
- UroLume® Endoprosthesis kits

Note: An inventory of at least three 3.0 cm stents, two 2.5 cm stents and two 2.0 cm stents is advised, to ensure the correct stent lengths will be available.

Premedication
Prior to implantation with the UroLume® Endoprosthesis, patients should be given prophylactic broad-spectrum antibiotic coverage according to the protocols commonly used by the hospital.

Patient Preparation
A urine culture should be obtained just prior to the procedure. Place the patient in the lithotomy position, prep with aseptic solution and drape. For patients with a small bladder capacity, a small temporary suprapubic tube may be used to facilitate bladder drainage during the procedure. Other considerations for use of a suprapubic tube include improved visualization and ability to check residual urine perioperatively and postoperatively.
**Note:** Not all patients require catheterization. In our series, fewer than 50% of patients required perioperative or postoperative catheterization. Of those procedures requiring temporary catheterization, approximately one third of catheteres were placed as a precaution, the remaining two thirds were due to the patients’ inability to void immediately post-procedure.

**Anesthesia**

Although patients with spinal cord lesions are often insensitive to pain, clinical investigators often used anesthesia (spinal or general) to prevent penile erections or autonomic dysreflexia during bladder infusion. Alternately, lidocaine jelly may be used for patients who are not susceptible to autonomic dysreflexia, or who do not desire to use anesthesia.

**Preparation for Prosthesis Placement**

1. Perform a diagnostic cystourethroscopy.

2. Measure the length of the external sphincter.

   This may be accomplished by using an AMS Urethral Measuring Catheter, following the instructions included with that product, or a graduated ureteric catheter. Instructions for measuring the urethra with a graduated ureteric catheter are as follows: Place the graduated ureteric catheter alongside the telescope into the bladder. Hold the catheter firmly and gently withdraw the telescope while counting the centimeter markings on the catheter to determine the length of the external sphincter.

3. Select a prosthesis that is 0.5 cm longer than the measured length of the external sphincter.

   **Note:** Physicians generally use a 3.0 cm prosthesis for the initial insertion. To ensure that the entire external sphincter is covered, an additional stent or stents (1.5 cm, 2.0 cm, 2.5 cm, 3.0 cm) may be used in combination.

4. Open the selected prosthesis package. Peel open the plastic tray and remove the sterile contents. Inspect the delivery instrument carefully.

   **Note:** No wire filaments should protrude from the rounded collar. Should filaments be seen protruding from the delivery instrument, return the entire system to your AMS representative and use a new UroLume® Endoprosthesis.

Prepare the selected UroLume® deployment system for the procedure as follows:

- Attach the light source to the telescope.
- Attach the water source to the irrigation port on the delivery instrument with the water bag approximately 1 meter above the patient. If desired, a three-way tap may be connected to the luer lock of the irrigation port before attaching the water source.

   **Note:** A three-way tap will reduce the cross-section of the irrigation port and, therefore, the water flow will be reduced.

- Insert the telescope into the telescope stabilizer and advance the telescope into the desired lock position. Squeezing sides of stabilizer while inserting telescope will impede attachment (see page 4 for telescope compatibility). Insert the telescope stabilizer into the delivery tool. A light push may be required to do so. During the placement procedure, the position of the prosthesis can be monitored by sliding the telescope back and forth in the delivery instrument.

- Apply a small amount of sterile lubricant over the retractable sheath to facilitate passage into the urethra.

During the procedure, the delivery instrument may be manipulated with one hand (Figure 13), while the other hand stabilizes the penis. With these preparatory steps completed, the physician is ready to proceed with the five step placement procedure (Figure 14,15).
Figure 13: The front finger grip draws back the sheath to expose the prosthesis, while the rear security button prevents its inadvertent release. Reference “Placement Procedure” for complete placement instructions.

Insertion
Both security buttons are in the locked position; finger grips are immobile. Hold the grips with thumb and middle finger.

Partial Deployment
1) Press the front security button down with the index finger.  
Note: Do not deploy prior to insertion.
2) Using the middle finger, pull the front finger grip back to retract the sheath.

Release
1) Using the index finger press, then release, the rear security button.  
2) Using the middle finger, pull the front finger grip back. Verify that the prosthesis has been completely released by pulling back on the telescope.  
3) Gently pull back on the delivery instrument to distance it from the prosthesis.

Figures 14, 15: Placing the UroLume prosthesis.

1. Insertion
2. Confirmation

Figure 15

3. Partial Deployment
4. Release
5. Withdrawal
Placement Procedure

1. Insertion

Dilate the meatus to 24Fr if necessary to allow passage of the delivery tool.

Introduce the delivery tool into the urethra, advancing it gently under direct vision. Hold the delivery instrument stable and manipulate the telescope in and out to assess landmarks for prosthesis placement.

2. Position Confirmation

Position the delivery instrument so that the rounded collar is positioned at the apex of the prostate.

*Note: During deployment hold the delivery instrument upright as close as possible to the 12:00 o'clock position and try not to rotate the tool beyond the 11:00 and 1:00 o'clock positions. The 12 o'clock position is in the vertical direction.*

3. Partial Deployment

When the rounded collar of the delivery instrument is positioned appropriately proximal to the sphincter, depress the front security button first. While holding down the front security button, gently pull the front finger grip toward the back finger grip until the front finger grip has passed the front security button position. This unlocks the sliding mechanism and permits the retractable sheath to slide back, exposing, but not releasing, the prosthesis. It is not necessary to continue to hold down the security button after the front finger grip has passed the front security button position.

Withdraw the delivery instrument to position the proximal end of the prosthesis at approximately mid-urethra.

While holding the delivery instrument as upright as possible at the 12 o'clock position, keep the back finger grip steady and pull the front grip gently toward the back finger grip. This action causes the retractable sheath to draw back in a controlled, gradual manner. As the retractable sheath slides back, the prosthesis is exposed. The prosthesis expands in diameter and shortens in length as it emerges. Observe this shortening in relation to the urethra. It is possible to observe the deployment of the prosthesis by simultaneously withdrawing the telescope. Care should be taken that the device is deploying fully against the walls of the external sphincter.

*Note: If any resistance is encountered while retracting the sheath, it may be helpful to resheathe the device and re-start the process of partial deployment.*

When the front finger grip reaches the back security button, the prosthesis is exposed, but not released from the holding mechanism. This offers the opportunity to move the telescope and to make a final check of the position of the prosthesis. It is important to keep the partially deployed prosthesis aligned with the delivery instrument. Moving the delivery instrument at an angle that puts traction on the exposed prosthesis may cause the prosthesis to release prematurely.

Visualize the entire length of the external sphincter to ensure that the prosthesis is situated in the intended position. The prosthesis should cover the entire length of the external sphincter. The most proximal end of the prosthesis should be placed at the distal edge of the verumontanum. It is acceptable for the stent to extend into the bulbar urethral region.

*Caution: The implanted prosthesis should not cover the verumontanum or the ejaculatory duct.*

If the prosthesis is not in the intended position, resheathe the prosthesis by advancing the delivery instrument’s retractable sheath forward until it completely covers the prosthesis. To do this, withdraw the delivery instrument slightly while gently pushing the front finger grip away from the back finger grip until the first security button re-engages with an audible click. As this is done, the retractable sliding sheath encompasses the prosthesis. With the prosthesis securely inside the delivery instrument shaft, the physician may move the instrument to the intended position in the urethra.

*Caution: Failure to resheathe the prosthesis before advancing the delivery instrument will result in compression of the prosthesis and possible trauma to the urethra.*

4. Release

Before releasing the prosthesis, position the telescope to view the prosthesis at the proximal end of the external sphincter. Confirm with direct vision that the proximal end of the prosthesis is approximately 2mm from the distal end of the verumontanum.

*Note: If the proximal end of the stent is in good position, the distal end of the stent will also be correctly placed. An additional stent or stents may then be placed, if necessary, to ensure complete coverage of the external sphincter.*

Again, it is important to keep the partially deployed prosthesis aligned with the delivery instrument. Moving the delivery instrument at an angle that puts traction on the exposed prosthesis may cause the prosthesis to release prematurely.
Release the prosthesis from the delivery instrument by pressing down the rear security button first. While holding down the rear security button, completely draw the front finger grip all the way back to the rear finger grip. Use the middle finger to move the front finger grip. The index finger presses the rear security button. The front finger grip locks after the prosthesis is released, and the prosthesis cannot be resheathed or remounted into the delivery instrument.

**Note:** If the prosthesis does not release immediately upon pressing the rear security button, gently push the deployment tool forward slightly and rotate the deployment tool slightly. This will facilitate release of the prosthesis from the deployment tool.

If a prosthesis is inadvertently deployed, do not attempt to reassemble it into the delivery instrument. In this instance, contact your AMS representative to return the prosthesis and delivery instrument.

**Caution:** Do not attempt to remount the prosthesis onto the deployment instrument. Attempting to insert a remounted prosthesis into the urethra can cause improper function of the deployment instrument and result in trauma to the urethra.

5. **Withdrawal of the Delivery Instrument**

Before beginning to withdraw the delivery instrument, move the telescope back to ensure the delivery instrument is aligned with the distal end of the prosthesis and verify that the prosthesis is off each hook.

If the prosthesis is still attached to a hook(s) as shown below, rotate the delivery instrument lightly between 11:00 and 1:00 o'clock while viewing the prosthesis through the telescope. This rotational movement will ensure that the prosthesis is completely free of the delivery instrument.

**Note:** If the prosthesis has not completely released from the deployment tool, gently push the deployment tool forward slightly and rotate the deployment tool slightly. This will facilitate release of the prosthesis from the deployment tool.

Pull gently on both finger grips to distance the delivery shaft from the released prosthesis. Observe that the prosthesis does not move out of position as the delivery instrument pulls away from it. Using the back grip as a stabilizer, pull the delivery instrument away from the correctly placed prosthesis just enough to ensure that the prosthesis is completely free of the holding mechanism. Rotate the delivery instrument slowly, while viewing the prosthesis through the telescope. This will ensure that the prosthesis has fully released from the delivery instrument.

Retract the telescope into the delivery instrument, taking care not to let it touch the prosthesis.

Gently withdraw the delivery instrument from the urethra, while ensuring the prosthesis is off the hook(s) and using care not to displace the prosthesis.

Proceeding with care, some physicians choose to perform normal endoscopy using a 17 Fr or smaller flexible cystoscope. Manipulate the cystoscope carefully to avoid contact with the prosthesis. Observe carefully to ensure that the prosthesis does not move out of position. Ensure that the prosthesis completely covers the external sphincter without covering the verumontanum.

**Caution:** Passing a cystoscope through the prosthesis prior to urothelialization may displace the prosthesis.

**Placing Multiple Stents**

If more than one stent is required to adequately cover the external sphincter, the first stent placed should cover the most proximal (nearest the verumontanum) end of the external sphincter. Additional stents may then be placed following steps 1-5 above. The additional stent(s) should overlap the previously placed stent by at
Adjusting the Position of a Released Prosthesis

Caution: Any repositioning of a released prosthesis must be performed with care in order not to cause trauma to the urethra.

1. Repositioning a Prosthesis Placed Too Far Proximally

If the released prosthesis appears to extend too far proximal from the external sphincter, it is possible to reposition the prosthesis using the following procedure: Grasp several rows (3 to 5 diamonds) of wire with a biopsy forceps. Gently pull the prosthesis into the intended position. Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. Confirm position endoscopically by visualizing some distance between the verumontanum and prosthesis.

2. Repositioning a Prosthesis Placed Too Far Distally

If the released prosthesis does not extend far enough to completely cover the external sphincter, it is possible to reposition the prosthesis using the following procedure:

With urologic forceps, grasp several rows of wire near the end of the prosthesis closest to the proximal end of the external sphincter. Push the prosthesis until it extends to within 2mm of the verumontanum.

An alternate stent repositioning technique involves nudging the stent slightly with the beak of the cystoscope or toothless alligator forceps until the stent is in the desired position.

Postoperative Procedures

Prescribe prophylactic antibiotics to the dose and duration typically prescribed for urethrotomy or dilation. If the patient is unable to void, place a suprapubic tube for drainage.

Caution: Use care to avoid contact that would displace the prosthesis or modify its position. Do not use a urethral catheter until the prosthesis is stabilized by urothelial ingrowth (approximately eight weeks). Inserting a catheter into the urethra before urothelium has grown over the prosthesis may cause the prosthesis to move out of position and may cause trauma to the urethra. No transurethral instruments should be used until a physician familiar with the UroLume® Endoprosthesis can check its stability. If possible, patients should be seen by a physician familiar with the UroLume® Endoprosthesis when the implanting physician is not available, until tissue coverage has occurred.

Prescribe an antispasmodic for at least three weeks following insertion for patients who suffer from spastic pelvic muscle contractions. Untreated, spasm of the pelvic muscles could create forces that would push the prosthesis retrograde.

Removing a Released Prosthesis

With a urologic alligator forceps of sufficient length, grasp three to five diamonds of wire at the distal end of the prosthesis. If more than one prosthesis is to be removed, begin with the most recently placed prosthesis. Gently pull the prosthesis. As the prosthesis is drawn out, it elongates and narrows allowing the physician to withdraw it from the urethra.

Under certain circumstances, it may be desirable to push the stent proximally, into the bladder, rather than pull the prosthesis distally, through the urethra. The stent can then be retrieved with a foreign body extractor tool, or can be secured with a guidewire and pulled into a resectoscope sheath.

Note: Grasping and pulling only a single wire may cause the wire mesh prosthesis to unravel or break. In this instance, each wire must be removed individually. Each prosthesis consists of 24 wire filaments. Confirm with endoscopy and flouroscopy that all wire filaments are retrieved.

If a prosthesis is inadvertently deployed, do not attempt to reassemble it into the delivery instrument. In this instance, contact your AMS representative to return the prosthesis and delivery instrument.

Caution: Do not attempt to remount the prosthesis onto the delivery instrument. Attempting to insert a remounted prosthesis into the urethra may cause the delivery instrument to function incorrectly and may cause trauma to the urethra. Do not attempt to remount the prosthesis onto the deployment instrument. Attempting to insert a remounted prosthesis into the urethra can cause improper function of the deployment instrument and result in trauma to the urethra.

Prosthesis Removal After Urothelial Coverage

Warning: A prosthesis that has covered with urothelial tissue must have the tissue COMPLETELY resected before it can be removed. All urothelial tissue covering the stent must be resected.
The first step in the UroLume removal technique is to remove as much tissue as possible from the inner stent surfaces. This is done by thoroughly resecting the overlying tissue from the inner surfaces of the stent using a 24 french electrosurgical loop. Use the lowest possible current setting, beginning at 40 watts and increasing by 10 watt increments if necessary. Do not exceed 70 watts, as this may damage or destroy the wire filaments of the stent.

Using smooth, even cutting motions, completely remove all tissue within the stent. Pay particular attention to removing all tissue overlaying the proximal and distal stent edges.

The second step is to create a loop access space to provide an access point for the electrosurgical loop to engage the stent edge. This is done by cauterizing an access space around each stent edge using an electrosurgical loop in cauterization mode.

The third step involves separating the stent from the urethral wall. During this step make sure that the electrosurgical loop is in the “off” position.

Engage the proximal edge of the stent with the electrosurgical loop and pull the edge towards you, distal to the bladder. This motion compresses the stent, longitudinally loosening the outer stent surfaces from the urethral wall. Repeat this compression at 4 different positions around the stent edge at the twelve, three, six and nine o’clock positions.

Repeat the same step at the distal stent edge. At this point use the electrosurgical loop to push the stent proximal, or towards the bladder, at 4 different positions around the stent edge. Again, the twelve, three, six and nine o’clock positions may be used. Once this step is completed, the stent should be loose in the urethra and ready to be removed.

Replace the resectoscope with a cystoscope. Select a long urologic grasping forcep to pass through the working channel of the cystoscope. Firmly grasp three or four rows of stent diamonds and pull the stent through the sheath to retrieve it.

Once the UroLume stent has passed through the sheath, inspect it to ensure that all 24 wires are intact.

**Note:** The use of laser or rollerball-type resection devices is not advised for resection of urothelial coverage of the prosthesis.

Visualization during the resection process may be improved with continuous irrigation via a temporary suprapubic catheter.

**Caution:** Use care in handling the explanted prosthesis to prevent the prosthesis from puncturing the protective surgical gloves.

Should a UroLume® Endoprosthesis ever be extracted after placement the prosthesis must be returned to AMS. Contact your AMS representative for returned goods and warranty information.

**Imaging of the Prosthesis**

The UroLume® Endoprosthesis may be imaged using ultrasound, magnetic resonance imaging (MRI) and plain film radiograph.

**Reference**

General

Returning Inventory and Warranty Information

Before returning any stents, whether explanted or unused and sterile, customers must fill out the Return Goods Form located on the last page of the Patient Information Form. Follow all of the instructions on the form carefully and be sure that the stents have been thoroughly cleaned before returning them to American Medical Systems, Inc.

In all cases, obtaining credit or percentage of credit for a returned Urolume stent is subject to approval. For complete information regarding these policies, contact the AMS Customer Service Department.

This document is written for professional medical audiences.

American Medical Systems Inc. periodically updated product literature. If you have any questions regarding the currency of this information, please contact American Medical Systems.