Package Insert / Instructions for Use

DEVICE DESCRIPTION

The UroLume® Endoprosthesis 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. 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 UroLume® Endoprosthesis is designed to hold open the external sphincter mechanism from the verumontanum to the bulbar urethra and is intended as a long-term (not temporary) stent (Picture 1). The UroLume® Endoprosthesis 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.

INDICATIONS FOR USE

The UroLume® Endoprosthesis is intended for use in men to relieve urinary obstruction due to detrusor-external sphincter dyssynergia (DESD).

INSERT PICTURE 1

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.

9. Patients with untreated obstructive benign prostatic hyperplasia.

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. 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 follow-up 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.

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 ± 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.

Table 1 Open Label Study Device Related Adverse Events			
Adverse Event	**# of Events**	**# of Patients**	**Patient Rate (n=160)**
Urinary Tract Infections (Symptomatic and Asymptomatic)	563	113	70.6%
Autonomic Dysreflexia	109	55	34.4%
Hematuria	73	53	33.1%
Migration	49	38	23.8%
Bladder Neck Obstruction*	41	36	22.5%
Inadequate Stent Coverage of External Sphincter	40	33	20.6%
Urosepsis	28	20	12.5%
Encrustation	23	19	11.9%
Temporary Retention	18	16	10.0%
Difficulty Emptying Bladder	13	8	5.0%
Inadequate Urothelialization	9	9	5.6%
Inflammation of Urethral Tissue	9	8	5.0%
Fever, Post-Operative	6	6	3.8%
Perineal Pain	5	5	3.1%
Squamous Metaplasia	4	4	2.5%
False Passage	4	4	2.5%
Inflammation / Granulation of Urethral Tissue	3	3	1.9%
Urethral Polyps	3	3	1.9%
Hyperplasia within Stent	3	3	1.9%
Wire Protruding into Lumen	2	2	1.3%
Urethral Abrasion	2	2	1.3%
Penile Discomfort	2	2	1.3%
Urinary Fistula	1	1	0.6%
Bladder Stones	1	1	0.6%
Covered Ejaculatory Duct	1	1	0.6%
Stent Compromises Catheterization	1	1	0.6%
Compressed Stent	1	1	0.6%
Urethral Pain	1	1	0.6%
Urethral Perforation	1	1	0.6%
Dysuria	1	1	0.6%
Reflux of Urine into Vas Deferens	1	1	0.6%
Extravasation of Urine	1	1	0.6%
Groin Pain	1	1	0.6%
Abdominal/Penile Pain	1	1	0.6%
Soreness with Sitting	1	1	0.6%

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

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UroLume®/TUS Randomized Study

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.

Table 2 UroLume®/TUS Randomized Study Treatment Related Adverse Events						
Adverse Event	UroLume Patients			TUS Patients		
	# of Events	# of Patients	Patient Rate (n=31)	# of Events	# of Patients	Patient Rate (n=26)
Urinary Tract Infections (Symptomatic and Asymptomatic)	103	20	64.5%	49	15	57.7%
Tissue Response	22	19	61.3%	NA	NA	NA
Hematuria	15	12	38.7%	12	12	46.2%
Autonomic Dysreflexia	14	14	45.2%	14	14	53.8%
Bladder Neck Obstruction*	11	11	35.5%	4	4	15.4%
Inadequate Coverage	9	9	29.0%	NA	NA	NA
Temporary Retention	7	5	16.1%	5	5	19.2%
Bladder Stones	6	4	12.9%	2	2	7.7%
Migration	5	5	16.1%	NA	NA	NA
Fever, Post-Operative	5	5	16.1%	4	4	15.4%
Cystitis	4	4	12.9%	0	0	0.0%
False Passage	3	3	9.7%	0	0	0.0%
Urethral Polyps/Follicular Cysts	2	2	6.5%	NA	NA	NA
Hyperplasia within Stent	2	2	6.5%	NA	NA	NA
Urosepsis	1	1	3.2%	3	3	11.5%
Inadequate Urothelialization	1	1	3.2%	NA	NA	NA
Perineal Pain	1	1	3.2%	0	0	0.0%
Urethral Abrasion	1	1	3.2%	0	0	0.0%
Penile Discomfort	1	1	3.2%	0	0	0.0%
Urethral Pain	1	1	3.2%	0	0	0.0%
Dysuria	1	1	3.2%	0	0	0.0%
Reflux of Urine into Vas Deferens	1	1	3.2%	0	0	0.0%
Extravasation of Urine	1	1	3.2%	0	0	0.0%
Incontinence during Intercourse	0	0	0.0%	1	1	3.8%
Abdominal Pain	1	1	3.2%	0	0	0.0%
Soreness with Sitting	1	1	3.2%	0	0	0.0%
Additional procedures	6	6	19.4%	1	1	3.8%
Penile Prosthesis Complication	0	0	0.0%	1	1	0.0%
Difficulty Emptying Bladder	0	0	0.0%	3	3	11.5%
Hydronephrosis	0	0	0.0%	1	1	3.8%

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

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.

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 $\pm$ 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 H_2O) placed 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 H_2O $\pm$ 28.2 cm H_2O in the study population. Following stent insertion, DLPP mean was 37.4 $\pm$ 23.9 cm H_2O 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 $\pm$ 150.1 cc at baseline to a mean of 113 $\pm$ 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 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 $\pm$ 39.2 minutes) than for TUS (47.9 $\pm$ 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_2O 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_2O, 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.

The Prosthesis

The UroLume® Endoprosthesis 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 the external sphincter.

For use in the external sphincter, the UroLume® Endoprosthesis is available in the following sizes:

Reference lengths: 2.0cm, 2.5cm, and 3.0cm

Reference diameter: 14mm

The self expanding properties of the mesh press it against the wall of the external sphincter 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® Endoprosthesis 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 in to 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 Picture 2.

Insert Picture 2

The forward end of the delivery instrument has the following features (Figure 2):

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 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*
Window openings in the retractable sheath permit endoscopic visualization of the urethra and the prosthesis throughout the placement procedure.

6. *Rounded Collar*
The rounded collar at the end of the outer shaft eases insertion into the urethra.

7. *End Ring*
The end ring at the end of the delivery instrument eases insertion into the urethra.

The handle end of the delivery instrument has the following features (Figure 2):

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

B. *Rear Finger Grip*
The rear 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 urologist to partially deploy the prosthesis, without releasing it form 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 irrigation port, with its luer lock, permits a constant washing of 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 through the windows and at the delivery instrument tip.

G. *Telescope Stabilizer Port*
The telescope stabilizer port accommodates the telescope stabilizer (Figure 2a) provided with the UroLume® Endoprosthesis. The telescope stabilizer has three functions: 1) It enables the delivery instrument to accommodate the major telescopes. The 30cm Storz, Wolf and ACMI (M-2) telescopes can be positioned in lock A, and the 28cm Olympus telescope can be positioned in lock B. 2) It stabilizes the telescope on the delivery instrument, preventing rotation and keeping the light source upright. 3) It enables the telescope to slide freely within the delivery instrument.

An ACMI adapter ring is provided for use with the ACMI telescope. The ACMI adapter ring enables the ACMI telescope to be positioned into lock A of the telescope stabilizer.

Components

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

- one (1) UroLume® Endoprosthesis (2.0cm,. 2.5cm, or 3.0cm)
- one (1) disposable delivery instrument
- one (1) ACMI adapter ring
- one (1) telescope stabilizer

Caution: All UroLume® Endoprosthesis 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		*Delivery Instrument Specifications*	
Diameter		*Diameter*	
Compressed diameter	6mm	Retractable sheath	21.0Fr
Reference diameter	14mm	Inner lumen	12.0Fr
		End ring	24.0Fr
Product Number		*Usable Shaft Length*	
For 2.0cm prosthesis	72402010	For 2.0cm prosthesis	20.7cm
For 2.5cm prosthesis	72402011	For 2.5cm prosthesis	19.5cm
For 3.0cm prosthesis	72402012	For 3.0cm prosthesis	18.5cm

3.1 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 maybe 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 3.0cm stents, two 2.5cm stents and two 2.0cm stents is advised, to ensure the correct stent lengths will be available.

Premedication

Prior to implantation with the UroLume® Endoprosthesis, patients may 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 catheters 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.

14. 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 3.0cm prosthesis for the initial insertion. To ensure that the entire external sphincter is covered, an additional stent or stents (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, checking that the prosthesis is visible in the windows.

Note: No wire filaments should protrude either from the rounded collar of the delivery instrument or through the windows of the retractable shaft. 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 then place into the delivery instrument. 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.

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

Placement Procedure

1. Insertion
Dilate the meatus to 24 Fr 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.

3. Partial Deployment
When the rounded collar of the delivery instrument is positioned proximal to the external sphincter at the apex of the prostate, depress the front security button. 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.

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

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. 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 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 holding mechanism by pressing the rear security button and completely withdrawing the retractable sliding sheath. Use the middle finger to move the front finger grip. The index finger presses the rear security button.

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 fully released.

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.

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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.

Withdraw the delivery instrument from the urethra, 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 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 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.

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.

To resect urethral tissue from a prosthesis that has covered with urothelium, use a low current setting and employ the resectoscope loop with continuous movement. High current and/or prolonged contact between the loop and the prosthesis may cause wires to melt. If necessary, the current can be increased slowly until the desired power is attained. Gently resect with a scraping motion until all tissue covering the interior lumen of the stent has been removed.

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

After the resected tissue is removed, grasp three to five diamonds of wire at the distal end of the prosthesis using a urologic alligator forceps of sufficient length. Manipulate the device gently, rotating it until it is freed up from the urethral bed. The explant procedure can then be carried out as described above under "Removing a Released 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[1]

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 stent is subject to approval under the terms of the AMS Return Goods Policy and the AMS Limited Warranty Policy. 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.

Reference

1. Tay HP, Juma S: Magnetic resonance imaging of the UroLume® urethral stent. *Journal of Urology.* **153(4)**: 1225-1226, Apr 1995.