



Memorandum

APR 11 1997

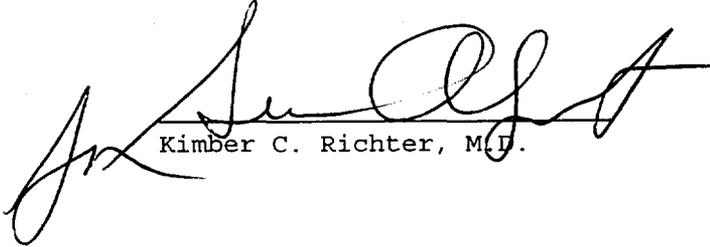
Date .  
From Deputy Director, Clinical and Review Policy, Office of Device Evaluation (HFZ-400), Center for Devices and Radiological Health (CDRH)  
Subject Premarket Approval of American Medical Systems, Inc., Urolume™ Endourethral Prosthesis for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy (BPH) - ACTION  
To Director, CDRH  
ORA \_\_\_\_\_

ISSUE. Publication of a notice announcing approval of the subject PMA supplement.

FACTS. Tab A contains a FEDERAL REGISTER notice announcing:

- (1) a premarket approval order for the above referenced medical device (Tab B); and
- (2) the availability of a summary of safety and effectiveness data for the device (Tab C).

RECOMMENDATION. I recommend that the notice be signed and published.



Kimber C. Richter, M.D.

Attachments  
Tab A - Notice  
Tab B - Order  
Tab C - S & E Summary

DECISION

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_

Prepared by: James Seiler, CDRH, HFZ-470, April 1, 1997, 594-2194

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. \_\_\_\_\_]

American Medical Systems, Inc.; PREMARKET APPROVAL OF UroLume™  
Endourethral Prosthesis for Prostatic Obstruction Secondary to  
Benign Prostatic Hypertrophy (BPH)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by American Medical Systems, Inc., Minnetonka, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the UroLume™ Endourethral Prosthesis for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy (BPH). After reviewing the recommendation of the Gastroenterology/Urology Devices Advisory Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 11, 1997, of the approval of the supplemental application.

DATES: Petitions for administrative review by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

Food and Drug Administration,  
9200 Corporate Blvd.,  
Rockville, MD 20850,  
301-594-2194.

SUPPLEMENTARY INFORMATION: On May 6, 1996, American Medical Systems, Inc., Minnetonka, MN, 55343, submitted to CDRH a supplemental application for premarket approval of the UroLume™ Endourethral Prosthesis for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy (BPH). The device is intended to relieve prostatic obstruction secondary to BPH in men at least 60 years of age, or men under 60 years of age who are poor surgical candidates, and whose prostates are at least 2.5 centimeters in length.

On January 16, 1997, the Gastroenterology/Urology Devices Advisory Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the supplemental application.

On April 11, 1997, CDRH approved the supplemental application by a letter to the applicant from the Deputy Director for Clinical and Review Policy, of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading in this document.

### Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the FEDERAL REGISTER. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER), file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may

be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and re-delegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: \_\_\_\_\_

\_\_\_\_\_



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lisa L. Pritchard  
Senior Regulatory Affairs Specialist  
American Medical Systems, Inc.  
Pfizer Hospital Products Group  
10700 Bren Road West  
Minnetonka, Minnesota 55343

APR 11 1997

Re: P920023/S1  
UroLume™ Endourethral Prosthesis Prostatic Obstruction Secondary to  
Benign Prostatic Hypertrophy (BPH)  
Filed: May 6, 1996  
Amended: October 17, 1996; February 7, March 25 and 26, 1997

Dear Ms. Pritchard:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) supplement for the UroLume™ Endourethral Prosthesis for Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy (BPH). This device is intended to relieve prostatic obstruction secondary to BPH in men at least 60 years of age, or men under 60 years of age who are poor surgical candidates, and whose prostates are at least 2.5cm in length. The PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified upon receipt of this letter.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

In addition to meeting the enclosed post-approval requirements under the authority of 21 CFR 814.44(e), the post approval reports should include annual progress reports on the post-approval study outlined below and recommended by FDA and the Gastroenterology/Urology Devices Advisory Panel during the January 16, 1997, meeting regarding issues not fully addressed by the clinical trial.

The post-approval study should follow at least 100 patients through 10 years to assess long-term hyperplastic tissue growth inside the UroLume™ and device removal rates. At a minimum, these patients should have a cold cup biopsy at 5 and 10 years, and cystoscopy at 1, 2, 5, 7, and 10 years. The long-term data from these studies should be reflected in the labeling (via a supplement) when the post-approval study is completed.

Expiration dating for this device has been established and approved at 3 years.

CDRH will publish a notice of its decision to approve your PMA supplement in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

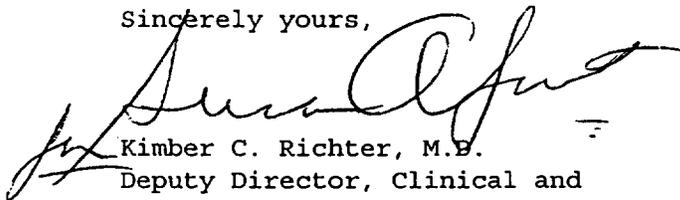
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling affected by this supplement in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. James Seiler at (301) 594-2194.

Sincerely yours,



Kimber C. Richter, M.D.  
Deputy Director, Clinical and  
Review Policy  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

(1) Conditions of Approval

### CONDITIONS OF APPROVAL

**APPROVED LABELING.** As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

**ADVERTISEMENT.** No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

**PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT.** Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
  - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and
  - (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies

of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
  - (a) has not been addressed by the device's labeling or
  - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1350 Piccard Drive, 340  
Rockville, Maryland 20850  
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)  
Center for Devices and Radiological Health  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

**SUMMARY OF SAFETY AND EFFECTIVENESS DATA**

**AMERICAN MEDICAL SYSTEMS'  
UROLUME™ ENDOURETHRAL PROSTHESIS**

**I. GENERAL INFORMATION**

<b>DEVICE GENERIC NAME:</b>	<b>Permanent Urethral Prostatic Stent</b>
<b>DEVICE TRADE NAME:</b>	<b>UroLume™ Endourethral Prosthesis For Prostatic Obstruction Secondary to Benign Prostatic Hypertrophy</b>
<b>APPLICANT NAME:</b>	<b>American Medical Systems, Inc. Pfizer Hospital Products Group 10700 Bren Road West Minnetonka, MN 55343</b>
<b>PREMARKET APPROVAL (PMA) SUPPLEMENTAL APPLICATION NUMBER:</b>	<b>P920023/S1</b>
<b>DATE OF PANEL RECOMMENDATION:</b>	<b>January 16, 1997</b>
<b>DATE OF NOTICE OF APPROVAL TO THE APPLICANT:</b>	<b>April 11, 1997</b>

This device was originally approved on May 6, 1996, for the limited indication for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0 cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction. The UroLume™ is not intended as an initial treatment for bulbar urethral stricture disease nor for the treatment of strictures outside the bulbar urethra. The UroLume™ 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).

The sponsor submitted this supplement to expand the clinical indications. The updated clinical data to support the expanded indication to relieve prostatic obstruction secondary to benign prostatic hyperplasia is provided in this summary. The preclinical test results were presented in the original PMA application. For more information on the data which supported the original indication, the summary of safety and effectiveness data to the original PMA should be referenced. Written requests for copies of the summary of safety and effectiveness data can be obtained from the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Drive, rm. 1-23, Rockville, MD 20857 under Docket #96M-0356.

## II. INDICATIONS FOR USE

The American Medical Systems UroLume™ Endourethral Prosthesis (hereinafter called UroLume™) is intended to relieve prostatic obstruction secondary to benign prostatic hyperplasia (BPH) in men at least 60 years of age, or men under 60 who are poor surgical candidates, and whose prostate glands are at least 2.5 cm in length.

## III. DEVICE DESCRIPTION

The UroLume™ is a braided mesh cylinder designed to radially expand after deployment to hold open sections of the urethra that obstruct the flow of urine. The stent is made from Elgiloy®, a non-ferromagnetic metal alloy composed of cobalt, chromium, nickel, molybdenum, iron, and trace amounts of manganese, carbon, silicon, phosphorous, sulfur, and beryllium. The stent is delivered cystoscopically using a specially designed insertion tool intended to deploy the prosthesis in a controlled manner. Upon deployment, the stent expands in diameter and shortens in length. Its final dimensions are determined by the size and resistance of the urethral lumen. The stent is supplied sterile in 2, 2.5, and 3 cm lengths and opens to a maximum expanded diameter of 14 mm (42 French).

The prosthesis is sterile and packaged pre-loaded in a specialized, disposable delivery tool. The delivery tool consists of two concentric stainless steel tubes with an outer diameter of approximately 7 mm (21 French). The tool includes two security buttons; the first button partially deploys the prosthesis without complete release from the retractable clamp, while the second security button fully retracts the delivery tool's outer shaft, opens the retaining clamp and completely releases the prosthesis. The outer shaft has windows to allow visualization of the urethra and the constrained prosthesis.

#### IV. CONTRAINDICATIONS

The UroLume™ for prostatic obstruction secondary to benign prostatic hyperplasia is contraindicated for patients with:

1. meatal or urethral strictures which cannot be opened to 26 Fr;
2. an active urinary tract infection (UTI);
3. other urethral conditions requiring transurethral manipulations within 8 weeks of potential UroLume™ placement;
4. known or suspected prostate cancer;
5. urethral squamous cell carcinoma;
6. transitional cell carcinoma of the bladder;
7. previous surgical procedures to alleviate symptoms of BPH;
8. median lobe prostatic involvement;
9. a prostatic urethra less than 2.5 cm in length; or
10. bladder stones or neurogenic bladder.

Refer to the UroLume™ for prostatic obstruction secondary to benign prostatic hyperplasia labeling for a list of the warnings and precautions.

#### V. ADVERSE EFFECTS OF THE DEVICE ON HEALTH

There were 27 patient deaths during the study. The primary causes of death were cardiovascular disease, renal failure, hypertension and vascular disease, lung cancer, accident, renal cancer, metastatic prostate cancer, multiple myeloma, liver disease, pneumonia. None of the deaths were considered to be device related.

Of the 146 patients in the combined study cohort 76% (111/146) experienced incontinence, 71% (104/146) experienced hyperplasia (tissue ingrowth), 54% (79/146) experienced urethral pain, 56% (82/146) experienced post void dribbling, 55% (81/146) experienced urge incontinence, 27% (39/146) experienced inadequate prostate coverage, and 23% (34/146) experienced hematuria. These numbers reflect the total number of patients reporting a complication, regardless of severity or pretreatment status of these complaints. The majority of patients who reported incontinence rated their condition on a subjective scale as mild or moderate.

Urinary tract infections (UTI) noted by positive urine cultures occurred in 17% (25/146) of patients during or after UroLume™ implantation compared to only 5% (8/146) at pre-insertion. Reported as part of the baseline data was the fact that approximately 17% of the patients had some history of UTI prior to enrollment in the investigations.

Migration occurred in 5% (8/146) of the patients, five of which required removal. Encrustation of the UroLume™ occurred in 18% (26/146) of the patients, five of whom required electrohydraulic lithotripsy treatment to remove the encrustation. Retention occurred in 16% (23/146) of patients.

Removals of the stent were required in 16% (23/146) of the patients for the following reasons: migrations (5), encrustations (3), hyperplasia (3), obstructions with irritation and pain (3), enlarged prostates (2), and (1) removal each for improper placement, total incontinence, hyperplasia with pain, irritation, incomplete epithelialization and encrustation, frequency with urgency and hematuria, and prostate cancer. Removals occurred nearly as frequently prior to 12 months (n=13) as after 12 months (n=10).

Refer to the Summary of Clinical Investigations (Section IX) for additional details on the adverse events.

## VI. ALTERNATE PRACTICES AND PROCEDURES

A variety of procedures are used in the treatment of benign prostatic hypertrophy (BPH). The most commonly used surgical procedure is transurethral resection of the prostate (TURP). Other options for treatment include prostatectomy, transurethral incision of the prostate, transurethral dilation of the prostate, indwelling catheterization, stenting, therapies that use microwave, laser, or radio frequency energy, watchful waiting, alpha adrenergic antagonists (alpha blockers), and 5-alpha reductase inhibitors.

## VII. MARKETING HISTORY

The UroLume™ device is available throughout most of Europe, Canada, the Middle East, Africa, Latin America, Australia, and the Pacific Rim. The UroLume™ has been available in the United States since May 6, 1996, for the treatment of recurrent, benign bulbar urethral strictures. To date, the UroLume™ has not been withdrawn from any market for any reason related to the safety or effectiveness of the device.

## VIII. SUMMARY OF PRECLINICAL STUDIES

The preclinical studies were identical to those performed for the previously approved bulbar urethral stricture indication of the UroLume™. The following information was provided under the original PMA.

## A. Biocompatibility

The materials used in the UroLume™ were not changed since the original application of the device to treat another disease, therefore, the biocompatibility data are the same. Biocompatibility tests (USP Class VI) as provided in the application were conducted in accordance with standard methodologies, and included: muscle implantation in rabbits (7, 32, 90, and 180 days), hemolysis, cytotoxicity, acute systemic toxicity in mice, intracutaneous irritation in rabbits, pyrogenicity, and chemical analysis. The results showed no significant toxicity.

The UroLume™ was also implanted in the urethra of four male dogs which were sacrificed and examined: two dogs at 6 months, one at 9 months, and one at 16 months. There were no significant systemic or local toxic effects. Interstitial nephritis, chronic prostatitis, and bronchial adenocarcinoma were observed but not attributed to the UroLume™.

Another study involved device implantation in the urethra of 10 female sheep. The sheep were sacrificed: two at 3 months, four at 6 months, and four at 12 months. No significant pathological changes were observed in the sheep at 3 months, but histological analysis did show mild sub-acute inflammation, hemorrhage, and pressure necrosis adjacent to the stent. The 6 and 12 month results included angiogenesis in the submucosa, acute to chronic inflammation, hemorrhage, and hyperplasia of the transitional epithelium in addition to pressure necrosis, fibrous tissue, and thick mineral deposits. It was concluded that the effects observed were not attributable to the toxicity of the materials used in the UroLume™, but may be due to the chronic irritation, pressure, and trauma caused by its presence.

## B. Laboratory Studies

The design of the UroLume™ was not changed since the original application of the device to treat bulbar urethral stricture disease, therefore, the mechanical tests are the same as those evaluated under the original PMA. Mechanical tests were performed on sterilized samples of the UroLume™ to evaluate the effects of constriction, elongation, severe elongation, and corrosion. The constriction test indicated that the device could withstand constriction to 25% of its original diameter. The elongation test demonstrated the device could be stretched and compressed by 25% of its original length for 2.8 million cycles. The severe elongation test demonstrated that the UroLume™ could withstand stretching and compression by 50% of its original length through 5.1 million cycles. The corrosion test demonstrated that no appreciable corrosion to the surface of the UroLume™ occurs when exposed to saline, artificial urine, or air.

## IX. SUMMARY OF CLINICAL INVESTIGATIONS

### Study Design

The UroLume™ clinical investigation was conducted in accordance with an approved investigational device exemptions (IDE) application (G900019). This original study was a baseline controlled study (i.e., it was not controlled against any another treatment for BPH) and is referred to as the “nonrandomized study” in this summary. The investigation began on April 12, 1990, and active patient enrollment under the protocol ceased on July 9, 1992. The maximum enrollment permitted 14 institutions and 130 subjects in the original study. The total study enrollment that resulted was 137 patients at nine United States investigational sites and seven patients at two Canadian investigational sites. Only 126 of these 144 patients were used in the data analyses since 18 patients were excluded because they either did not meet the inclusion criteria or were dropped from the study during unsuccessful insertion of the stent. Approximately 79.3% (100/126) of the insertion procedures under the nonrandomized study were performed at five investigational sites.

FDA recommended that the sponsor of the investigation conduct a separate study which randomly assigned patients to TURP or the UroLume™ device. The randomized study protocol began on September 12, 1991, and active patient enrollment ceased on April 11, 1995. The randomized investigation allowed for enrollment of 240 subjects at 14 institutions. Total enrollment at seven investigational sites in the United States for this randomized study protocol was 36 patients, 20 who received the UroLume™ and 16 who received a TURP. Low patient enrollment was due to patients who chose not to undergo a TURP surgical procedure when many other non-surgical options were available. Approximately 77.7% (28/36) of the insertion procedures under the randomized study were performed at two investigational sites. Due to the small number of patients enrolled in the randomized study who received the UroLume™ (n=20), these patients were combined with the nonrandomized patients (n=126). These two data sets are referred to in this summary as the combined data (n=146).

#### A. Objectives

The objectives of the UroLume™ clinical investigation were to assess: 1) the ease and reliability of endoscopically inserting and positioning the stent in the prostatic urethra; 2) the effectiveness of the stent as manifested by improved voiding function and symptoms; 3) the epithelialization of the stent and the effect on the stent and the prostatic urethra; and 4) any unanticipated adverse events, their incidence, and management.

The hypotheses of the study were that insertion of the prosthesis will: 1) increase peak flow rate and this increase will be sustained for at least 12 months; 2) decrease total symptom score and this decrease will be sustained for at least 12 months; and 3) decrease residual urine volume and this decrease will be sustained for at least 12 months.

## B. Inclusion and Exclusion Criteria

### Inclusion Criteria - Nonrandomized

The inclusion criteria for the nonrandomized study were: males  $\geq$  45 years old, obstructive urinary symptoms that required medical intervention, acceptable anesthesia and surgical risks.

### Exclusion Criteria - Nonrandomized

Specifically excluded from participation in the nonrandomized study were patients with: active UTI, bladder cancer, bladder stones, neurogenic bladders (atonic or hyper reflexive), known or suspected prostate cancer, large median lobe, strictures that prevent passage of a 24 Fr endoscope, previous TURP patient, patients on medication for symptoms of BPH. Additional exclusion criteria added after the study began include: prostate shorter than 2.5 cm, thrombocytopenia, hemophilia and/or patients receiving blood products for a bleeding disorder, unwilling or unable to sign consent, unwilling to return for follow-up, or a participant in another clinical trial.

## C. Protocol

Prior to the UroLume™ implantation the length of the prostatic urethra is measured during a cystourethroscopy using a specially marked measuring catheter. Under visual guidance the UroLume™ is then implanted in the prostatic urethra sometimes using multiple/overlapping stents, if needed to bridge the obstructed region of the prostatic urethra between the verumontanum and the bladder neck.

The nonrandomized study assessed peak and mean urinary flow rates, total and individual symptom scores on the Madsen-Iverson scale, urine cultures to determine UTI status, residual urine volumes, and adverse events. The stent was observed by cystourethroscopy at each follow-up starting at 3 months; this permitted the determination of any evidence of migration, encrustation, erosion, mechanical problems, obstruction, chronic irritation, and extent of epithelialization. Also assessed were the patient assessment of pain/discomfort, sexual function changes, and overall satisfaction.

## D. Critiques of Study and Analysis

Pre-insertion data were not available from patients whose BPH completely blocked the prostate. These patients were evaluated separately as a “retentive” patient group, while all other patients were grouped into a “non-retentive” patient group. Based on the study results, too few patients were available for follow-up beyond 3 months from which to separately analyze the retentive patients (n=31).

A large number of protocol deviations were reported during the clinical investigation. The deviations included alterations in the patient selection criteria, missing or late follow-up visits, and alterations in the methods of device insertion or evaluation.

To evaluate the effects of these deficiencies on the study population, two specific patient cohorts were derived from the non-retentive patients in the nonrandomized study. These cohorts reflect (1) patients with complete prospective study data through 1 year of follow-up (n=51) and (2) patients with complete prospective study data through 2 years of follow-up (n=33). Patients in these cohorts had all data available for analysis, met the patient selection criteria, had no deviations from the implantation procedure specified in the protocol, and met their follow-up visits within 60 days of the scheduled date. Examined for effectiveness results only, the results indicate that the two cohorts, as well as those patients with procedural deviations, experienced similar results as the overall patient population.

Although the effectiveness data did suggest similar results for both UroLume™ and TURP, patient enrollment in the randomized study was insufficient to yield data from which substantial safety and effectiveness results could be drawn. Hence, the data from the randomized patients who received the UroLume™ is combined with the non-retentive patient data from the nonrandomized trial for a “combined data” analysis. In this respect, the patient serves as his own control. The data discussed in this summary are limited to this combined patient population, unless otherwise noted.

#### E. Analyses

**Table 1 - Patient Accountability - Randomized and Nonrandomized Study Cohorts**

Category	Nonrandomized Data Analysis		Category	Randomized Data Analysis	
Total Enrolled	144		Total Enrolled	36	
Off Protocol or Dropped at Insertion	18		Deviations (included in analyses)	6	
# of Patients Evaluated	126		# of Patients Evaluated	36	
“Separated Data” Subgroups	31 Retentive	95 Non-retentive	“Separated Data” Subgroups	20 UroLume™	16 TURP

**Table 2 - Patient Accountability - Additional Patient Cohorts Analyzed**

	“Separated Data” 1 Year Cohort	“Separated Data” 2 Year Cohort	“Combined Data” Patient Cohorts
Subgroup Component	--	--	31 - Retentive Patients (Nonrandomized Study)
Subgroup Component	--	--	20 UroLume™ - All Non-retentive Patients (Randomized Study )
Subgroup Component	95 Non-retentive	95 Non-retentive	95 Non-retentive Patients (Nonrandomized Study)
Patient did not attend follow-up	19	37	--
Out of range ( ±60 days)	15	20	--
Missing Effectiveness Data	10	5	--
Total	51	33	115 for Effectiveness Analysis (95+20) 146 for Safety Analysis (95+20+31)

The independent analyses of the nonrandomized study data and the randomized study data used the “separated data” analyses in the table above. The 1 year and 2 year cohorts mentioned earlier in this summary were part of the separated data analyses drawn from non-retentive patients in the nonrandomized study.

The combined data analyses include only those patients who received the UroLume™ regardless of their enrollment in the nonrandomized or randomized study. This summary of safety and effectiveness focuses on the combined analysis with effectiveness and safety analyses through 12 month follow-up and extended follow-up examinations as noted.

Both the combined and separated data analyses have results based on “comparative analyses” of some study variables. These comparative analyses use patients at pre-insertion and a particular follow-up and compares mean data from the identical group of patients. This type of analysis minimizes the impact of the missing data due to poor patient compliance with the follow-up schedule. These comparative results mainly indicate the change in the patient’s condition (e.g., better, same, worse) and the statistical significance (i.e., p-values).

The effectiveness analyses of the combined data cohort includes only non-retentive patients drawn from both the randomized and nonrandomized studies. The safety analyses include all patients who received the UroLume™ treatment regardless of their classification.

“Extended data” reflecting up to 4 years of experience with the UroLume™ for prostatic obstruction are available and are based on the separated analyses of the

nonrandomized study data. Since there are only a few patients at the 3 and 4 year intervals, these extended data only have limited value in estimating long term trends.

#### F. Statistical Tests

Depending on the type of data, different statistical tests were used. Analysis of variance (ANOVA) and paired t-tests were used for the continuous variables of peak and mean flow (including flows adjusted by the square root of the volume voided to adjust for large bladder output), and total symptom score. The Pearson's Chi-square ( $\chi^2$ ) statistic was used for categorical variables such as etiology or previous UTI. The Kruskal-Wallis test was used for independent patient groups with less than 5 occurrences. The Wilcoxon sign rank test was used to compare pre-insertion and post-insertion individual symptom scores. The Kruskal-Wallis statistical test was used to evaluate independent groups, the Wilcoxon signed rank test was used for related samples, and McNemar's test was used for dichotomous variables. Logistic regression was used to evaluate the significance of study variables on safety and effectiveness. Finally, multiple regression was used to determine which factors were related to continuous effectiveness variables.

#### G. Pretreatment Characteristics

The non-retentive patients evaluated from the nonrandomized study had a mean age of 68.2 years (range 48-88) and retentive patients had a mean age of 76.3 (range 55-90). Historical data on the patients concerning UTI revealed that 17% (16/95) of the non-retention patients and 16% (5/31) of the retentive patients had a UTI at any time before the study began and under 10% of either group had positive urine cultures at insertion. The average prostate size was under 40 grams for 78% (74/95) of the non-retentive patients and for 55% (17/31) of the retentive patients. The mean prostate length was 2.9 cm for both patient groups. The mean levels of prostate specific antigen (PSA) were 3.6 ng/ml for non-retentive patients and 5.7 ng/ml for retentive patients. Over 80% of patients from both groups also lacked the following complicating conditions: urethral strictures, median lobe involvement, and bladder stones.

Major prostate obstruction was present for 40% (37/93) of the non-retentive patients compared to 90% (28/31) of the retentive patients. Partial prostate obstruction was present for 60% (56/93) of the non-retentive patients, but only 6% (2/31) of the retentive patients. Marked bladder trabeculation also distinguished the retentive patients (57% (16/28) ) from the non-retentive patients (25% (23/93) ).

Using the combined data from non-retentive patients from both studies, the effectiveness measures prior to stent implantation were 9.06 cc/sec mean peak urinary flow rate and 14.44 mean total symptom score out of a possible maximum score of 30. The mean total symptom score split into obstructive and irritative categories resulted in a mean obstructive symptom score of 10.05 and mean irritative symptom score of 4.39 at pre-insertion. Intermittency and incontinence symptoms were reported for more than 60% of patients.

A total of 179 devices were used to treat the 146 patients, but malpositioned and withdrawn stents resulted in only 154 devices deployed. More 2 cm stents (n=99) were used than 3 cm stents (n=48), and only seven 2.5 cm stents were used. The obstruction was completely covered at the end of the initial insertion procedure in all but 10 patients. Five percent (8/146) of the patients needed additional stents inserted post initial insertion.

#### H. Effectiveness Analysis

Based on the combined data, the UroLume™ increased mean peak urinary flow rates 2 years after insertion in 36% (52/146) of patients. The mean peak flow rate increased from 9.1 cc/sec at baseline (113 patients), to 14.0 cc/sec at 12 months (86 patients), and 13.2 cc/sec at 24 months (52 patients). The results were statistically significant at follow-up through 2 years ( $p < 0.001$ ). Separately analyzed data on retentive patients demonstrated improvement of 10.5 cc/s at 12 months (16 patients).

The adjusted peak flow rate, calculated by dividing peak flow by the square root of the volume voided, also demonstrated statistically significant and clinically meaningful improvements. Adjusted peak flow rate is calculated to adjust the peak flow measurement for the amount of urine volume voided.

Longer term results for non-retentive patients from the nonrandomized study demonstrated comparable mean peak flow at 3 years (14.21 cc/sec, 43 patients) and 4 years (14.87 cc/sec, 24 patients). These follow-up results were still statistically improved compared to baseline ( $p < 0.001$  and  $p = 0.004$ ).

The Madsen-Iversen symptom score used during the clinical study. The score assessed the following obstructive symptoms: stream (estimated strength of urine stream), voiding (estimated need to strain while urinating), hesitancy (waiting prior to voiding), bladder emptying (perceived bladder capacity), intermittency (more than two stops and starts during voiding), incontinence (presence or absence). The following irritative symptoms were also evaluated: urge (immediacy of need to urinate), nocturia (urination frequency at night), and diuria (urination frequency during the day). The total symptom score is the sum of all symptom scores, both obstructive and irritative.

The mean total symptom score improved (decreased) by 58% from an average of 14.4 at baseline (115 patients) to 6.0 at 12 months (87 patients) and 6.2 at 24 months (55 patients) ( $p < 0.001$ ). Similar improvement in the obstructive symptom score was also evident with 69% improvement (decreased) from an average of 10.1 at pre-insertion to an average of 3.1 at 12 months. Irritative symptom score improved (decreased) by 33% from 4.4 at pre-insertion to 2.9 by 12 months. The validity of the irritative symptom score improvement is diminished by the large error of the measurements.

Longer term results from the separated data analyses using non-retentive patients in the nonrandomized study demonstrated comparable improvement in total symptom score,

7.1 at 3 years ( $p < 0.001$ ) based on 44 patients and 6.7 at 4 years ( $p = 0.001$ ) based on 24 patients. These results were still statistically improved compared to baseline.

Individual symptom components of the symptom score indicated that symptomatic improvement was statistically significant ( $p < 0.001$ ) for all individual symptoms (except incontinence) at nearly every follow-up interval. The results indicated that the patient could not expect improvement in incontinence and diuria symptoms. The pre-insertion incidence of incontinence, based on 115 non-retentive patients, was 60% (69/115) compared to 52.9% (46/87) at 12 months follow-up. The distribution of diuria symptoms, similarly did not significantly change from pre-insertion levels through the 12 month follow-up, however urgency and nocturia slightly improved over the same period. The remaining categories of symptoms (stream, voiding, hesitancy, bladder emptying, intermittency) did improve after treatment with the device. Results at 24 months were similar to the results at 12 months.

The average residual urine volume at 12 months follow-up was 42.0 cc (decreased) compared to 82.2 cc at pre-insertion, however, large errors ( $> 75\%$ ) of the measured value make it impossible to draw any conclusions.

In addition to the above, success was also based on 25% increments of improvement during the first 2 years (Table 3). One lenient success criterion is to only consider the improvement in total symptom score when considering success. More strict success criteria considers the total symptom score, the peak uroflow, and the residual urine volume. Note that if one adds in all patients without the data at the follow-up (i.e.,  $n < 146$ ) the success results are considerably lower.

**Table 3 - Success Results**

Success Criteria	All Patients Through N Years	Percentage of Improvement (Quartiles)		
		$\geq 25\%$	$\geq 50\%$	$\geq 75\%$
Total Symptom Score	1 year	80.5% (70/87)	67.8% (59/87)	37.9% (33/87)
	2 years	76.4% (42/55)	54.5% (30/55)	29.1% (16/55)
Total Symptom, Peak Flow, & Residual Urine	1 year	36.7% (29/79)	22.9% (18/79)	11.4% (9/79)
	2 years	22.9% (11/48)	12.5% (6/48)	2.1% (1/48)

Subjective physician assessment of the UroLume™ cited that the majority of physicians 87.6% (85/97) believed the device was a successful treatment for BPH at 12 months. At 24 months this figure rose to 97.3% (72/74).

Quality of life data drawn from the separated nonrandomized, non-retentive patients demonstrated that at 24 months, 45.1% (23/51) of patients were very satisfied, and 33.3% (17/51) were moderately satisfied with their UroLume™ treatment. A change in

urination was noted for 96.1% (49/51) of patients with 97.9% (47/48) experiencing an improved urinary flow rate.

## I. Safety Analysis

Safety was assessed through physical examination and by questioning of all 146 patients by the investigators. Assessment measures included cystoscopy, urine culture, patient assessment of pain, patient assessment of sexual function, and overall patient and physician assessment of the treatment.

Growth of the epithelium over the stent was rapid with 86.9% (106/122) of patients achieving over 90% stent coverage within the first 6 months. This increased to 90.4% (66/73) at 2 years. The retentive patients achieved similar results.

The 4 year extended follow-up data demonstrated over 90% stent coverage in 93.6% (29/31) of patients which indicates that long term epithelization of the stent was maintained. Stent removal occurred in three patients, due in part to incomplete epithelialization.

The adverse event listings include many varieties of complications that occurred during the clinical trial. Analyses of complications were performed for 13 separate adverse events: hyperplasia, encrustation, stent migration, inadequate coverage of the prostate, retention, positive urine cultures, incontinence, urgency, urethral pain/discomfort, pain during sexual function, retrograde ejaculation, hematuria, and stent removal. Additional analyses of items such as Quality of Life Assessment, PSA level, and miscellaneous complications were also highlighted.

The incidence of hyperplasia (tissue ingrowth) was approximately 50% through the 3 year follow-up. The severity of tissue ingrowth was 71.2% (42/59) mild severity and 20.3% (12/59) moderate severity at 12 months. Moderate severity of tissue ingrowth increased by 17% between 12 months and 2 years. Since there were less than 10 retentive patients from which to draw hyperplasia information, no similar results concerning the retentive patients can be made.

Encrustation or stone formation on the stent occurred in 11.3% (12/106) of patients at the 12 month follow-up. Extended incidence of encrustation was 16.7% (8/48) at 3 years and 26.7% (8/30) at 4 years. A total of 26 patients (2 retentive patients, 24 non-retentive) experienced 43 separate encrustations. The encrustations were located at the bladder neck in 35 patients. Encrustations were mildly severe for 30 patients, and stone removal by electrohydraulic lithotripsy was necessary for 5 encrustations. Four patients had stone formation that was sufficiently severe to require stent removal. The sponsor modified the placement instructions after the first 70 patients which advised against placement of the UroLume™ such that the stent prongs protruded into the bladder.

UroLume™ migration occurred in 8 patients (2 retentive, 6 non-retentive), 6 of which occurred prior to 3 months. Migrations were associated with catheterization complications in 2 patients, unknown reasons in 2 patients, and 1 each of the following: prostate growth, medial lobe obstruction, insertion tool difficulties, and encrustation. Correctly placed stents covered the prostatic urethra in 85.8% (91/106) of patients at 12 months and the results were approximately the same at the 3 and 4 year follow-up.

Acute retention after placement of the UroLume™ occurred in 23 patients (16 non-retentive and 7 retentive patients). A suprapubic tube was placed, usually within the first month, in 13 patients until the retention subsided. Retention occurred within 1 month of device insertion for 60.9% (14/23) of the patients who experienced retention.

Positive urine cultures, dropped from 5.7% (8/140) patients at pre-insertion to 2.8% (3/106) at the 12 month follow-up. Similar results were reported during extended follow-up through 4 years. Note that a history of UTI pre-insertion was present in 17.9% (17/95) of the non-retentive patients and 16.1% (5/31) of the retentive patients.

Incontinence was not significantly improved by the device. Based on all patients with incontinence data available, 60% (75/125) of patients experienced incontinence prior to insertion compared to 45.8% (54/118) of patients 12 months post-insertion. Similar incontinence results occurred during the extended follow-up exams. Post void dribbling and urge incontinence improved (lower severity) but stress incontinence and incontinence of non-resistance did not change at 12 months, nor at extended follow-up compared to the pre-insertion levels.

The number of patients experiencing a sensation of urgency did not change significantly during the clinical trial, however, the level of severity (absent, mild, moderate, severe) decreased by approximately 20%. The retentive patients experienced similar shifts to lower severity categories. Medications used in 16 patients (3 retentive, 13 non-retentive) to relieve symptoms of urgency included Hytrin, Bethanecol, Minipress, Ditropan, and Probanthine.

The presence of urethral pain did not significantly change: 19.5% (23/118) at pre-insertion compared to 19.7% (23/117) at 12 months. No meaningful results could be obtained for type of pain (bladder, prostate, distal urethra, urethral meatus), pain frequency, or pain severity.

There were a large number of patients with missing sexual function data but there was sufficient data to draw conclusions concerning the effects of the UroLume™ on sexual function. Those with "worse" sexual function at 12 months post-insertion compared to pre-insertion were: 18.8% (6/32) intercourse pain, 25.0% (8/32) ejaculation type (i.e., antegrade or retrograde), 22.3% (21/94) erection type (i.e., none, partial, full), and 12.8% (6/47) erection pain. No greater than 12% of patients were "better" in each sexual function category 12 months post-insertion compared to pre-insertion. Of note is the fact that the retrograde ejaculation rose from 0% at pre-insertion to 28.1%

(18/64) by 12 months and increased to 34.6% (9/26) at 3 years. Other sexual function data on frequency of erections and presence of an ejaculate did not change at any follow-up exam. If evaluated for all follow-up, difficulty with erections occurred in 79% (115/146) of patients before use of the device and in 91% (133/146) of patients after implantation.

Hematuria occurred in 6 patients during the insertion procedure. Ten patients experienced 11 incidents of hematuria during the first 3 months post-insertion. After 3 months and through 2 years, 13 patients experienced 16 incidents of hematuria. Of all occurrences throughout the course of the trial only 2 hematuria episodes in 2 patients required treatment.

The PSA results were unchanged from a mean value of 3.76 (n=134) at pre-insertion to a mean value of 3.20 at the 12 month follow-up (n=37). At 24 months, the mean value increased to 3.26 (n=60). The comparative data did not show a statistically significant difference between the pre-insertion and the 1 and 2 year follow-up exams.

A total of 23 removals (21 non-retentive, 2 retentive) occurred during the investigations of the UroLume™ which represents 15.8% (23/146) of all patients who received the device. Removals occurred more frequently during the first year follow-up (n = 13) than during all follow-up after it (n = 10). The reasons for removal were migrations (5), obstruction/irritative/pain (3), encrustations (3), hyperplasia (3), enlarged prostate (2), and (1) each of the following: hyperplasia/pain, improper placement, total incontinence, irritation, incomplete epithelialization or encrustation, frequency/urgency/hematuria, and prostate cancer. Histopathological analysis of the removed stents did note papillary proliferation of the urethral mucosa from one device that was explanted and analyzed.

The overall death rate under the combined analysis is 18.5% (27/146). The causes of death were not device related and were associated with pre-existing conditions.

## X. CONCLUSIONS DRAWN FROM THE STUDIES

The laboratory, animal, and clinical data provide reasonable assurance of the safety and effectiveness of the UroLume™ device for the treatment of benign prostatic hyperplasia when used as indicated, in accordance with the label.

## XI. PANEL RECOMMENDATION

The Gastroenterology and Urology Devices Advisory Panel met to discuss the application on January 16, 1997. The Panel voted and concluded that (1) the labeling should indicate the device for use in men who are older than 60 years (or have a medical condition precluding standard surgery) and contraindicate the device in patients with large median lobes and in patients who have urothelial or prostatic cancer; and (2) the physician and patient labeling should be rewritten for clarity.

The Panel also recommended a post approval study to include follow-up on all patients for life with a cystoscopy and cold-cut biopsy of the prostatic urethral epithelium at 5 and 10 years on a sample size to be worked out between the sponsor and FDA.

## XII. CDRH DECISION

In consultation with CDRH, the sponsor modified the labeling to address the concerns of the Panel.

As provided in an amendment to the PMA, a modified version of the post approval study recommended by the Panel will be conducted to follow at least 100 patients through 10 years follow-up to assess long-term hyperplastic tissue growth inside the UroLume™ and device removal rates. The patients will have a cold cup biopsy at 5 and 10 years, and a cystoscopy performed at 1, 2, 5, 7, and 10 years. This will provide long-term follow-up recommended by the Panel to address the potential long-term effects associated with use of the device to treat BPH.

CDRH determined that, based on the modified labeling and the proposed post approval study, the application was approvable without further conditions.

FDA determined that the applicant's manufacturing facilities complied with the Good Manufacturing Practices Regulation.

CDRH issued an approval order for the application on April 11, 1997.

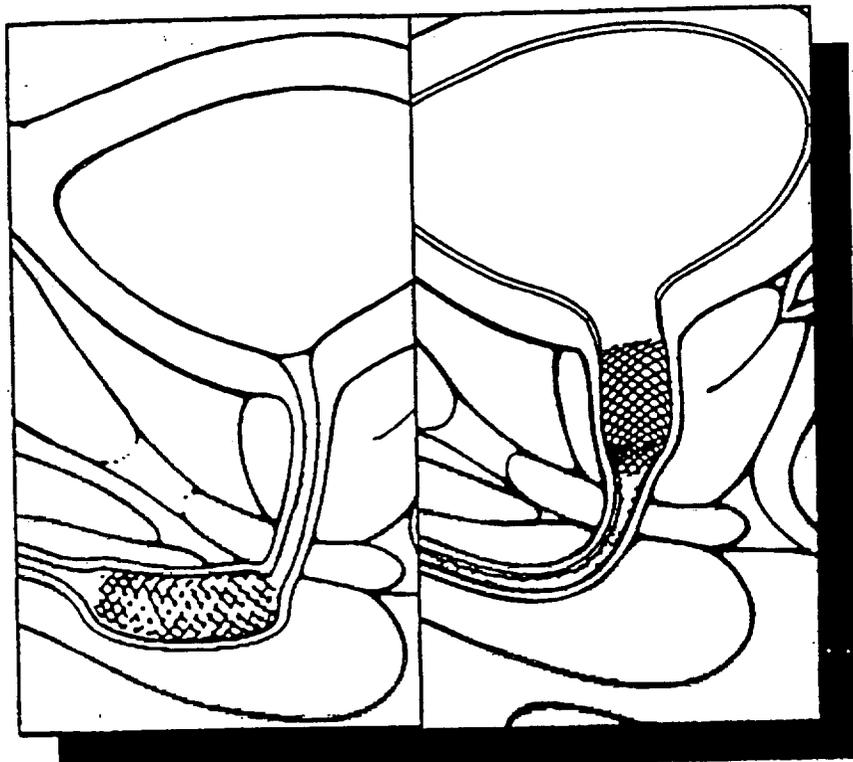
### XIII. APPROVAL SPECIFICATIONS

Directions for Use: See labeling.

Hazards to Health from Use of the Device: see indications, contraindications, warnings, precautions and adverse events in the labeling.

Post Approval Requirements and Restrictions: see approval order.

# UROLUME® ENDOPROSTHESIS



**For Recurrent Bulbar Urethral Stricture  
and Prostatic Obstruction Secondary to  
Benign Prostatic Hyperplasia**



Instructions For Use

**UroLume Endoprosthesis for Recurrent Bulbar Urethral Stricture..... 2 to 18**

**UroLume Endoprosthesis for Prostatic Obstruction Secondary  
to BPH.....20 to 35**

**UroLume Endoprosthesis for Recurrent Bulbar Urethral Stricture**

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## Device Description

The UroLume prosthesis 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 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.

## 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 1).

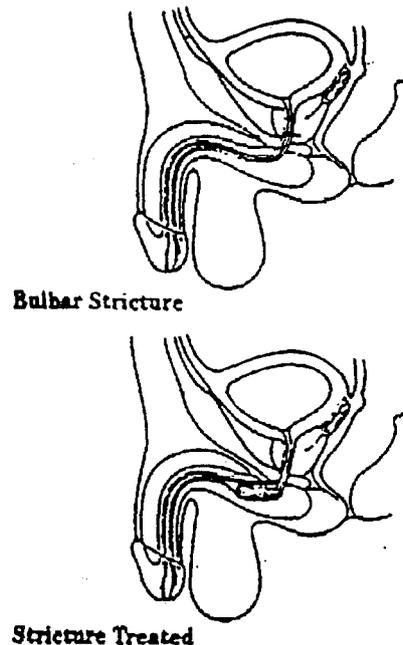


Figure 1: The UroLume prosthesis holds open the portion of the bulbar urethra obstructed by urethral stricture.

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).

## 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 26Fr 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.

## 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 Endoprosthesis 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.
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.

### **Precautions**

1. The UroLume prosthesis kit (prosthesis, delivery instrument, telescope stabilizer, ACMI adaptor ring) 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 epithelial 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.

### **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 (1%), 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%), 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 the stent (3%). Other complications/side effects noted in 2% or less of the patient population include self intermittent catheterization inside the stent area, polyps of 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 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 the device. 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<sup>1</sup> 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<sup>1</sup>) 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, restructing, urethral discharge/inflammation and urethral catheterization required due to an unrelated surgical procedure prior to epithelialization. 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 Endoprosthesis. 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 Endoprosthesis 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 Endoprosthesis insertion was dramatically reduced from that experienced in the years preceding UroLume Endoprosthesis insertion. In the one year period before UroLume Endoprosthesis 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 Endoprosthesis 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 epithelial 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 Endoprosthesis insertion. The prosthesis was removed nine months after insertion. The patient died of squamous cell carcinoma.

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™ Endoprosthesis, 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 in severity). 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™ Endoprosthesis 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 Endoprosthesis in 23 patients. New strictures distal to the location of the UroLume Endoprosthesis were noted in 24 patients. New strictures were noted both proximal and distal to the location of the UroLume Endoprosthesis 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: ejaculation pain (8%), pads used for incontinence (8%), resection (8%), catheterization (8%), sexual activity pain (7%), 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.

## **Detailed Description**

### **The Prosthesis:**

The UroLume prosthesis 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 bulbar urethra, the UroLume prosthesis 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 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 2.

Figure 2: 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. Windows
6. Rounded collar
7. End Ring

- A. Front finger grip
- B. Rear finger grip
- C. Front security button
- D. Rear security button
- E. Water irrigation port
- F. Telescope port
- G. Telescope stabilizer port

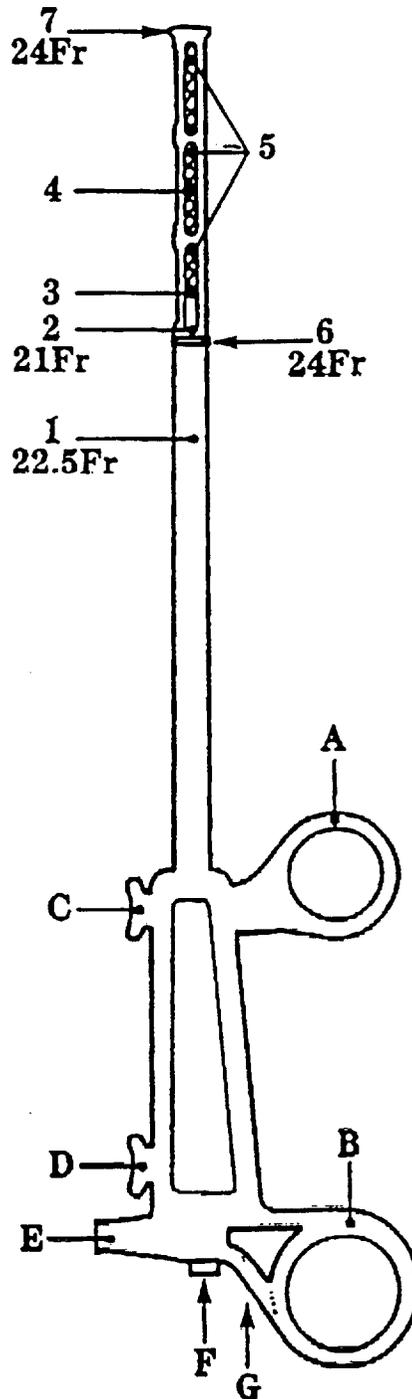
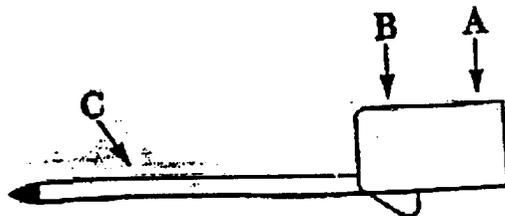


Figure 2a: The telescope stabilizer facilitates telescope movement within the delivery instrument, while preventing telescope rotation.

- A. Storz/Wolf/ACMI telescope lock
- B. Olympus telescope lock
- C. Stabilizing pin

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 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*  
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 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. *Rear 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 irrigation port, with its luer lock, 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 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 prosthesis. 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 adaptor ring is provided for use with the ACMI telescope. The ACMI adaptor ring enables the ACMI telescope to be positioned into lock A of the telescope stabilizer.

## Components

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

- one (1) UroLume prosthesis (2.0cm, 2.5cm, or 3.0cm)
- one (1) disposable delivery instrument
- one (1) telescope stabilizer
- one (1) ACMI adaptor ring

**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**

Diameter

Compressed diameter 6mm  
 Reference diameter 14mm

Product Number

For 2.0cm prosthesis 72402010  
 For 2.5cm prosthesis 72402011  
 For 3.0cm prosthesis 72402012

**Delivery Instrument Specifications**

Diameter

Retractable sheath 21.0 Fr  
 Inner Lumen 12.0 Fr  
 End Ring 24.0 Fr

Useable shaft length

For 2.0cm prosthesis 20.7cm  
 For 2.5cm prosthesis 19.5cm  
 For 3.0cm prosthesis 18.5cm

UroLume Delivery Instrument / Telescope Compatibility	
Telescope Model	Stabilizer Position
Olympus 28 cm	B
ACMI Storz Wolf 30 cm	A

## 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 epithelialization of the UroLume prosthesis has occurred. 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 spongiofibrosis region (grey area) to decrease the occurrence of restructuring proximal and distal to the narrowed region within the urethra as shown in Figure 3 below.

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.

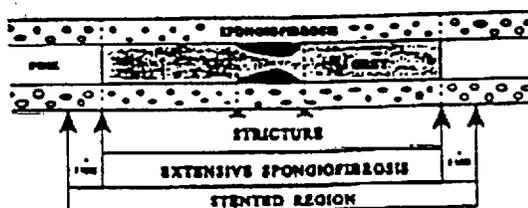


Figure 3

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, 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 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 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 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 4). During the procedure, the delivery instrument may be manipulated with one hand (Figure 5), while the other hand stabilizes the penis.

**Overview**

Figure 4: Placing the UroLume prosthesis requires five procedural steps: insertion, confirmation, partial deployment, release and withdrawal.

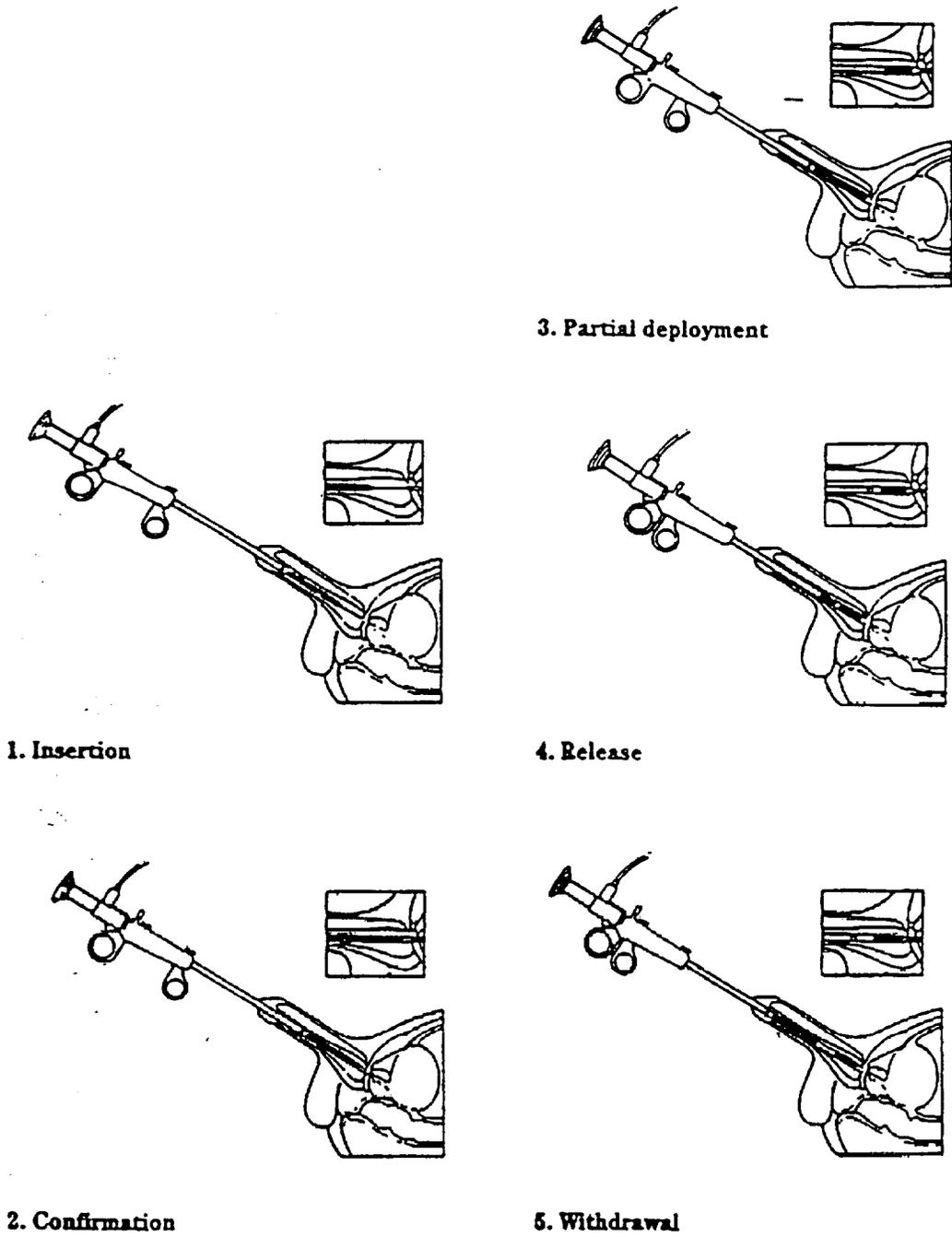
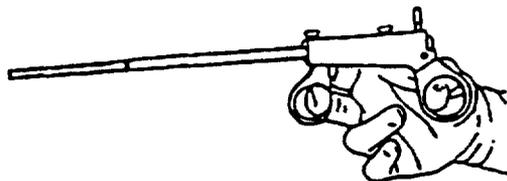


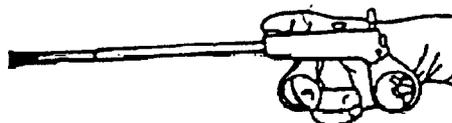
Figure 4

Figure 5: 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.
- 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.

Figure 5

## Placement Procedure

### 1. *Insertion*

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*

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.

### 3. *Partial Deployment*

When the rounded collar of the delivery instrument is positioned appropriately proximal to the stricture, 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.

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, resheath 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 resheath 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 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 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.

**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.

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.

Withdraw the delivery instrument from the urethra, 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 epithelial ingrowth. Inserting a catheter into the urethra before epithelium 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 epithelialization has occurred.

## Removing a Released Prosthesis

With a urologic alligator forceps, grasp three to four 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.

To resect urethral tissue from a prosthesis that has epithelialized, use a low current setting and employ the resectoscope loop with a continuous movement. Prolonged contact between the loop

and the prosthesis may cause wires to melt. After the resected tissue is removed, the procedure described above is used to remove the prosthesis from the urethra.

**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.

### **Inventory Returns 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.

### **Reference**

1. Haylen, B.T., Ashby, D., Sutherst, J.R., Frazer, M.I., West, C.R.: MAXIMUM AND AVERAGE URINE FLOW RATES IN NORMAL MALE AND FEMALE POPULATIONS - THE LIVERPOOL NOMOGRAMS; British Journal of Urology; July 1989, Vol. 64, No. 1, pp. 30-38.

This document is written for professional medical audiences.

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

**UroLume Endoprosthesis for Prostatic Obstruction Secondary to Benign Prostatic Hyperplasia**

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## Device Description

The UroLume prosthesis 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 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.

## 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 2.5 cm in length (Figure 1).

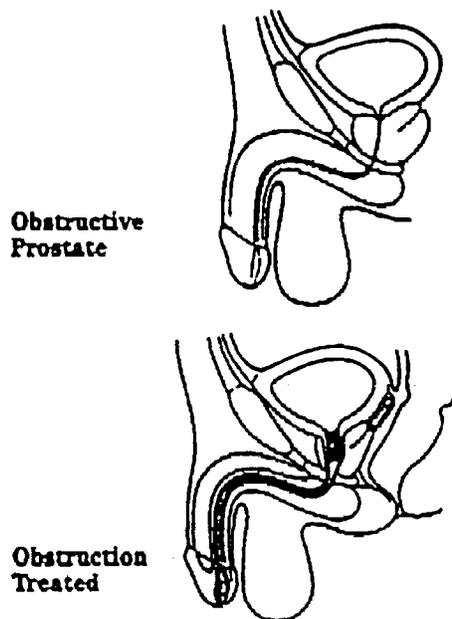


Figure 1: The UroLume prosthesis is intended to hold open the portion of the prostatic urethra obstructed by BPH.

## 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 26Fr.
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 2.5 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.

### **Precautions**

1. The UroLume prosthesis kit (prosthesis, delivery instrument, telescope stabilizer, ACMI adaptor ring) 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 resheathe 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.

## **Detailed Description**

### **The Prosthesis:**

The UroLume prosthesis 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 prostate.

The UroLume prosthesis 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 prostatic 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 prostatic urethra. Each part of the delivery instrument is described in Figure 2.

Figure 2: 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. Windows
6. Rounded collar
7. End Ring

- A. Front finger grip
- B. Rear finger grip
- C. Front security button
- D. Rear security button
- E. Water irrigation port
- F. Telescope port
- G. Telescope stabilizer port

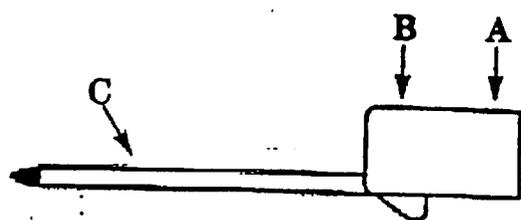
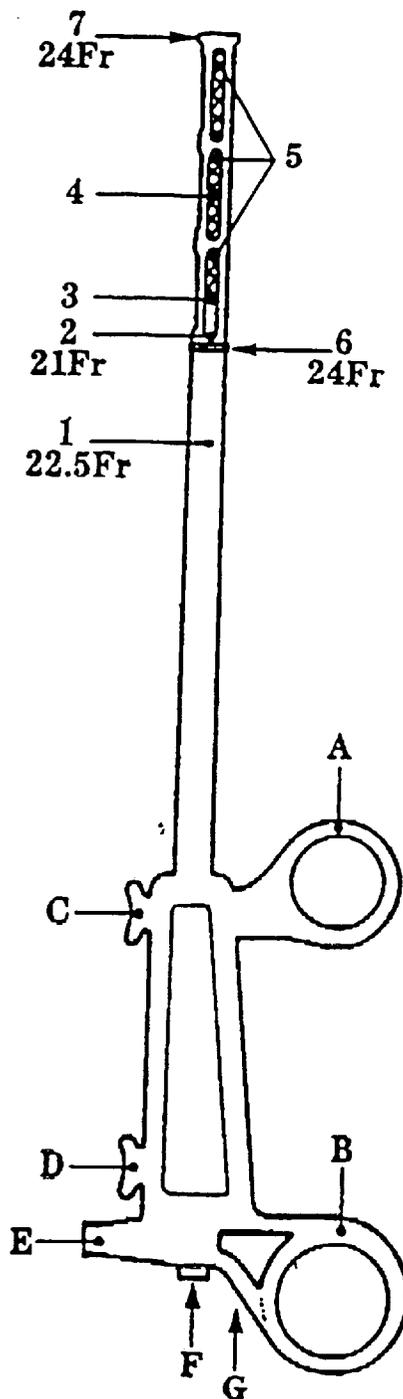


Figure 2a: The telescope stabilizer facilitates telescope movement within the delivery instrument, while preventing telescope rotation.

- A. Storz/Wolf/ACMI telescope lock
- B. Olympus telescope lock
- C. Stabilizing pin

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 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*  
Window openings in the retractable sheath permit endoscopic visualization of the prostatic 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 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. *Rear 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 irrigation port, with its luer lock, 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 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 prosthesis. 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 adaptor ring is provided for use with the ACMI telescope. The ACMI adaptor ring enables the ACMI telescope to be positioned into lock A of the telescope stabilizer.

## Components

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

- one (1) UroLume prosthesis (2.0cm, 2.5cm, or 3.0cm)
- one (1) disposable delivery instrument
- one (1) telescope stabilizer
- one (1) ACMI adaptor ring

**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**

Diameter

Compressed diameter 6mm  
 Reference diameter 14mm

Product Number

For 2.0cm prosthesis 72402010  
 For 2.5cm prosthesis 72402011  
 For 3.0cm prosthesis 72402012

**Delivery Instrument Specifications**

Diameter

Retractable sheath 21.0 Fr  
 Inner Lumen 12.0 Fr  
 End Ring 24.0 Fr

Useable shaft length

For 2.0cm prosthesis 20.7cm  
 For 2.5cm prosthesis 19.5cm  
 For 3.0cm prosthesis 18.5cm

UroLume Delivery Instrument / Telescope Compatibility	
Telescope Model	Stabilizer Position
Olympus 28 cm	B
ACMI Storz Wolf  30cm	A

## 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 the following 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 0.5cm 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. This may be accomplished by using an AMS Urethral Measuring Catheter, following the instructions included with that product, or a graduated ureteric catheter (Figure 3). 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.

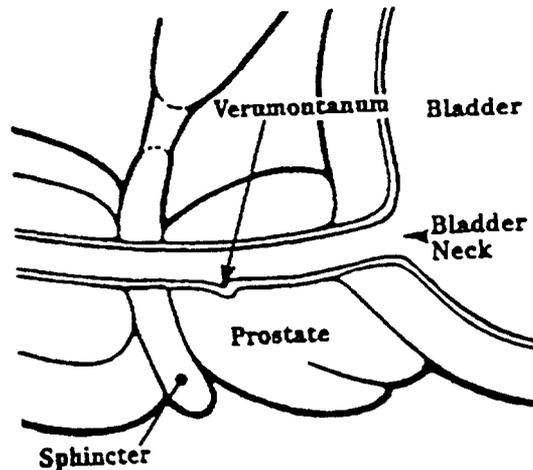


Figure 3: Careful measurement of the prostatic urethra helps ensure that the selected UroLume prosthesis fits the prostatic urethra from verumontanum to bladder neck.

3. Select a prosthesis that is 0.5cm 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, 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 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 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 then place into the delivery instrument. 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 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 4). During the procedure, the delivery instrument may be manipulated with one hand (Figure 5), while the other hand stabilizes the penis.

**Overview**

Figure 4: Placing the UroLume prosthesis requires five procedural steps: insertion, confirmation, partial deployment, release and withdrawal.

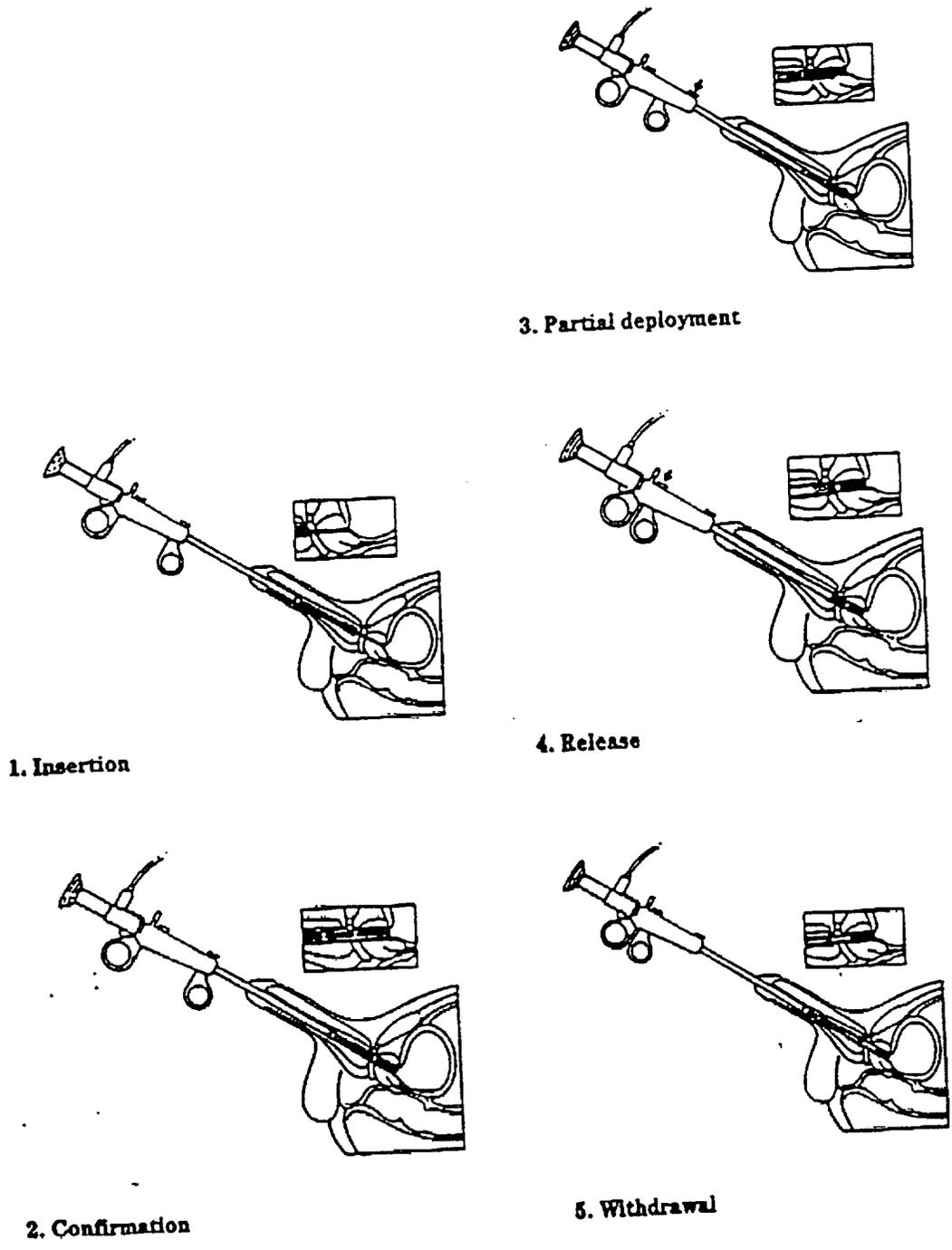
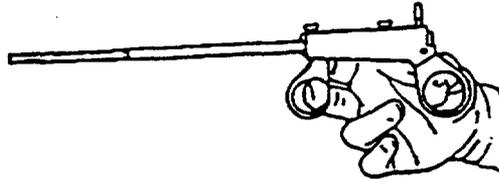


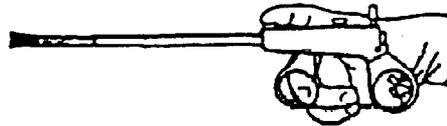
Figure 4

Figure 5: 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.



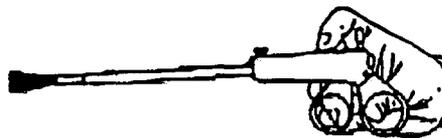
#### Insertion

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.
- 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 the prosthesis has completely released by pulling back on the telescope.
- 3) Gently pull back on the delivery instrument to distance it from the prosthesis once it has completely released.

Figure 5

## Placement Procedure

### 1. *Insertion*

Dilate the meatus if required. The minimum dilation required for the insertion and placement of the prosthesis is 26 Fr.

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*

Position the delivery instrument so that its rounded collar is proximal to the bladder neck.

### 3. *Partial Deployment*

When the rounded collar of the delivery instrument is positioned proximal to the bladder neck, 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.

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.

**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 bladder neck to 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 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*

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 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.

**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*

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.

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.

Withdraw the delivery instrument from the urethra, 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 may 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.

To resect urethral tissue from a prosthesis that has covered with urothelium, use a low current setting and employ the resectoscope loop with a continuous movement. Prolonged contact between the loop and the prosthesis may cause wires to melt. After the resected tissue is removed, the procedure described above is used to remove the prosthesis from the prostatic urethra.

**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.

### **Inventory Returns 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 updates product literature. If you have any questions regarding the currency of this information, please contact American Medical Systems.

**American Medical Systems, Inc.**  
Pfizer Hospital Products Group  
10700 Bren Road West  
Minnetonka, MN 55343 U.S.A.  
U.S. Toll free: (1) 800-328-3881  
Telephone: (1) 612-933-4666  
Telex: 4994119 (AMERMEDSYS MTKA)  
FAX: (1) 612-930-6592

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**IMPORTANT INFORMATION**

**FOR PATIENTS CONSIDERING AN**

**AMS UROLUME<sup>®</sup> ENDOPROSTHESIS**

You are now thinking about ways your doctor can treat your urinary problem due to your enlarged prostate. After discussing all of your options with your physician, you are now thinking about having a UroLume Endoprosthesis inserted in your prostatic urine canal (urethra). There are other options for treating your enlarged prostate. The main treatment options include getting regular exams to see if your prostate enlargement is getting worse (watchful waiting), taking drugs to relax the prostate (alpha blockers), taking drugs to shrink the prostate (Finasteride), or surgery to remove or reduce the enlarged prostate tissue.

This booklet will tell you about the UroLume prosthesis, and how it can help you. You will learn about the risks and benefits of the prosthesis. A glossary of medical terms is provided at the end of this brochure.

This will help you decide about your treatment to relieve your urinary problem. Ask your doctor any questions that this booklet does not answer for you.

## About the AMS UroLume Endoprosthesis

As your doctor has already explained, you have an enlarged prostate. This causes your urine canal to become narrower. This makes it harder for you to urinate. The UroLume prosthesis is designed for men like you.

The AMS UroLume Endoprosthesis is a braided, wire mesh tube. See Figure 1. Doctors use it to treat men whose prostates have partly blocked their urine canals. It is placed in the urine canal to hold it open (Figure 2). The mesh tube pushes on the walls of the urine canal to hold them apart. This allows urine to more easily pass through and out of your penis. As the mesh tube pushes on the walls of your urine canal, it tends to stay put. In time, tissue grows over the mesh tube. The device stays in the body.

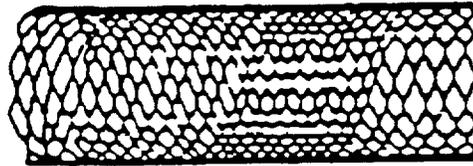


Figure 1: The UroLume Endoprosthesis

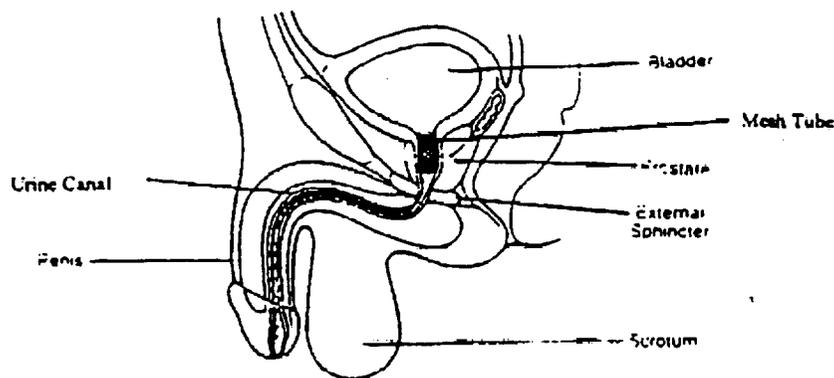


Figure 2: Prostatic Obstruction Treated with the UroLume Endoprosthesis

## About the Procedure

Your doctor may give you local anesthesia so you stay awake during the insertion. Or, your doctor may give you general anesthesia so you sleep during the procedure. Your doctor will use a small telescope to help put the mesh tube (prosthesis) in the right place. The telescope is the same kind used before to look in your urine canal (routine urethroscopy). Your doctor will use the tool shown in Figure 3 to put the mesh tube in your urine canal through the end of your penis. This tool holds the mesh tube so your doctor can put it in your urine canal.

When your doctor has the mesh tube in the right place inside your urine canal, (s)he will let go of it. The mesh tube will then expand to be wider and push on the walls of your urine canal to spread them apart. Your doctor will then remove the tool (Figure 3).

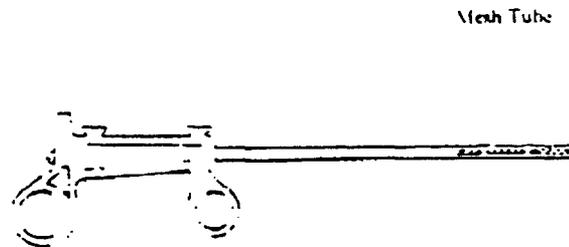


Figure 3: The Tool to Place the Prosthesis

## What to expect after insertion

Your doctor will give you a medical information card after the insertion procedure. This card contains important information about the UroLume prosthesis. Always carry this card with you.

Your doctor will want you to take medicine to reduce your risk of infection after insertion. It is very important for you to take all the medicine as prescribed. Be sure to follow all of your doctor's instructions carefully.

You may notice some pain with erections or sex after insertion. Your doctor will advise you to wait at least four weeks before resuming sexual activities. This is important because it minimizes the possibility of pain, infection or bleeding and prevents the mesh tube from moving out of position. Some men have backward (retrograde) ejaculation after insertion. When this happens, semen does not leave the urine canal at the time of ejaculation. The semen leaves the urine canal during urination.

In the weeks after insertion, you may dribble urine after going to the bathroom. If this dribbling is a concern for you, your doctor may be able to advise you how to remove urine from your urine canal more completely.

Some men also have blood in their urine (hematuria) or pain during the first few weeks after insertion. If you have bleeding or pain that seems to get worse, be sure to contact your doctor.

Men who take part in sports that put stress on the urine canal (like bike or horse riding), may experience some mild discomfort after insertion. Many cyclists have eased their discomfort by using a large bike seat.

Catheters or other instruments should not be placed into the urine canal until the mesh tube is held in place by tissue growth. If help is needed to empty your bladder, a catheter may be placed through your abdomen.

Contact your doctor if you have fever, increased pain, or problems going to the bathroom. Also talk to your doctor about any other questions or concerns you have after the insertion procedure.

## **Removing the UroLume Endoprosthesis**

If necessary, the mesh tube can be removed. If the mesh tube is not in the right place, it can be removed using forceps. To do this, your doctor will grasp the mesh tube and pull it out of your urine canal with forceps. As the mesh tube is pulled, it becomes longer and narrower, to allow removal. The mesh tube may come apart or break. If this occurs, your doctor will remove the mesh tube one wire at a time using forceps. If the mesh tube needs to be removed after tissue has covered it, your doctor may remove this tissue before removing the mesh tube.

Urine canal trauma may occur when the mesh tube is removed. In most men, this trauma will be mild. The blockage, that was present before insertion, usually returns after the mesh tube is removed.

## **Benefits of the UroLume Endoprosthesis**

### *Improved Flow of Urine*

Most men notice an increase in the speed of urination after insertion.

### *Reduced Symptoms*

Most men notice a large decrease in the symptoms associated with their enlarged prostate within a few weeks. These include hesitancy, poor flow, urine still in your bladder (incomplete emptying), frequency, getting up to go to the bathroom at night (nocturia), painful urination, starting urine flow and then stopping and starting again (two stage voiding) and taking longer to urinate (increased voiding time).

### *Easy Insertion*

Most UroLume prosthesis insertions are outpatient procedures. This reduces the time spent in a hospital.

If you have questions about the benefits of the UroLume prosthesis, please contact your doctor.

## **Risks of the UroLume Endoprosthesis**

### *Urinary Incontinence*

If the mesh tube is placed in your external sphincter, urinary incontinence could result.

### *Trauma Caused by Prosthesis Removal*

Removal of the mesh tube after it is covered in tissue could cause trauma to your urine canal.

### *Trauma Caused by Instruments*

Urine canal instruments, such as a urethroscope or a catheter, could cause trauma to your urine canal or dislodge your UroLume prosthesis.

### *Bleeding*

You may experience blood in your urine (hematuria) for the first few weeks after the procedure.

### *Stones*

If tissue does not cover the mesh tube over time, stones may develop on the mesh tube.

### *Movement/Shortening*

The mesh tube may move and/or shorten, if this occurs, the mesh tube may not completely bridge your prostate.

### *Obstruction*

Tissue that grows through the UroLume prosthesis may block your urine canal. This may reduce the flow of urine from your body. This tissue may need to be removed. The mesh tube may also need to be removed. Changes of benign growth within the urine canal may occur after insertion of the mesh tube. A sample of tissue may need to be taken to be looked at more closely.

### *Discomfort and Other Symptoms Following the Procedure*

You can expect mild discomfort, some dribbling, urgency, and/or nocturia for the first few weeks after insertion of the UroLume prosthesis. In most cases, these symptoms will end or decrease on their own.

### *Pain with Erections and/or Sex*

You may experience some pain with erections and/or sex after insertion of the mesh tube. In most cases, these symptoms will end or decrease on their own.

### *Retrograde Ejaculation*

Some patients experience backward (retrograde) ejaculation after insertion. When this happens, semen does not leave the urine canal at the time of ejaculation.

### *Suprapubic Catheter*

There may be times when a catheter would need to be placed through your abdomen (suprapubic catheter).

If you have any questions about the risks of the UroLume prosthesis, please contact your doctor.

## GLOSSARY OF TERMS

**ANESTHESIA:** The loss of all sensation in a specific area of the body (local anesthesia) or throughout the entire body (general anesthesia).

**ANTIBIOTIC:** A medication used to prevent or treat infection.

**BENIGN:** Not caused by cancer.

**CATHETER:** A tube inserted through the urine canal and into the bladder to allow urine to flow out of the body.

**DILATION:** Enlarging the diameter of a narrow area by passing tubes of gradually increasing width through the narrow area.

**DRIBBLING AFTER URINATION:** Passing a small amount of urine after the completion of urination.

**EJACULATION:** The discharge of semen from the urine canal.

**EXTERNAL SPHINCTER:** A muscle around the urine canal that opens and closes to allow the flow of urine.

**FORCEPS:** An instrument resembling tweezers that is used to grasp objects within the urine canal.

**FREQUENCY:** A need to urinate often.

**HESITANCY:** Delayed start of urine flow after the need to urinate is felt and the person wishes to urinate.

**INSTRUMENTATION:** Using medical tools within the urine canal.

**NOCTURIA:** Getting up to go to the bathroom at night.

**PROSTATE:** A gland around the urine canal located between the bladder and external sphincter.

**TELESCOPE:** An instrument used to view the inside of the urine canal.

**URETHROSCOPE:** An instrument used to view the inside of the urine canal.

**URETHROSCOPY:** A procedure to look inside the urine canal using a urethroscope.

**URINARY INCONTINENCE:** The inability to control the flow of urine from the body.

**VOIDING:** Urination.

American Medical Systems, Inc.  
Pfizer Hospital Products Group  
10700 Bren Road West  
Minnetonka, MN 55343 U.S.A.  
U.S. Toll Free: (1) 800-328-3881  
Telephone: (1) 612-933-4666  
Telex: 4994119 (AMERMEDSYS MTKA)  
FAX: (1) 612-930-6592

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## MEDICAL INFORMATION CARD

**This man has a UroLume® Endoprosthesis inserted in his urethra. The prosthesis is located in the:**

- Prostatic Urethra
- Bulbar Urethra

**DO NOT CATHETERIZE OR PLACE AN ENDOSCOPIC TOOL IN THE PATIENT UNTIL A PHYSICIAN HAS EVALUATED THE STABILITY OF THE PROSTHESIS.**

The UroLume Prosthesis is a braided superalloy mesh cylinder which expands in the urethra to hold open sections that obstruct urine flow. In the course of healing after implantation, the prosthesis becomes completely covered with urothelial tissue. If possible, this patient should be seen by a physician familiar with the UroLume prosthesis when the implanting physician is not available, until urothelial tissue has covered the prosthesis.

### **Imaging**

The UroLume can be imaged using ultrasound, plain film radiograms, and magnetic resonance imaging.

### **Precautions**

1. Do not catheterize or perform any endoscopic or transurethral procedures until urothelial tissue has stabilized the prosthesis (usually within the first eight weeks). 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.
2. A cystoscope or catheter may be used only if urothelial tissue has stabilized the prosthesis. Manipulate the instrument gently through the prosthesis to avoid any contact that would modify its position, or trauma to the urethra may result.
3. Do not attempt removal or manipulation of the implanted prosthesis. If the prosthesis must be removed, contact the implanting physician.

**Patient Information**

Name \_\_\_\_\_

Soc. Sec. No \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_ Zip \_\_\_\_\_

Telephone \_\_\_\_\_

Hospital \_\_\_\_\_

Telephone \_\_\_\_\_

Implanting Surgeon \_\_\_\_\_

Implant Date \_\_\_\_\_

Number of Stents Implanted \_\_\_\_\_

Hospital File No. \_\_\_\_\_

Health Insurance \_\_\_\_\_

Policy Number \_\_\_\_\_

**In Case of Emergency Please Notify:**

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_ Zip \_\_\_\_\_

Telephone \_\_\_\_\_

Relationship \_\_\_\_\_

or

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_ Zip Code \_\_\_\_\_

Telephone \_\_\_\_\_

Relationship \_\_\_\_\_

If the patient or relative is unable to provide emergency information regarding the prosthesis,  
please contact:

Dr. \_\_\_\_\_

Telephone \_\_\_\_\_

Hospital \_\_\_\_\_

(Use ballpoint pen, let ink dry)

**A note for U.S. patients:**

American Medical Systems, Inc. (AMS) keeps track of each implanted AMS device. For U.S. patients, we use your social security number as a reference. If you do not want your social security number used, please notify the AMS Customer Service Department at the address printed on this card, or by calling (800) 328-3881.

It is important that your record is accurate and current. Please help us keep your file up-to-date by notifying AMS any time you change your address or if you change your name.

Thank you for your considerate attention to this important part of having an implanted AMS UroLume Endoprosthesis.