

STRICTURE

*Information and Instructions for*  
**Patients Considering a**

**UroLume<sup>®</sup>**

*Endoprosthesis*



American Medical  
Systems

You are currently evaluating the treatment alternatives for your recurrent bulbar urethral stricture disease. After discussing all your options (including dilation, urethrotomy, urethroplasty, or a urethral stent) with your physician, you are now considering having a UroLume® Endoprosthesis inserted in your urethra.

This brochure will answer many of your questions about the UroLume prosthesis, as well as the insertion procedure. It is intended to supplement the discussions you have with your urologist. Additionally, you will learn more about the risks and benefits of the UroLume prosthesis. A glossary of medical terms is provided at the end of this brochure.

All of this information will help you make an informed decision about your treatment to relieve the symptoms of your recurrent bulbar urethral stricture disease. If you have any additional questions about your stricture disease or the information provided in this brochure, be sure to ask your physician.

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# 1 ABOUT THE UROLUME® ENDOPROSTHESIS

The UroLume® Endoprosthesis is a braided, wire mesh tube that is placed in the urine canal to hold it open (Figure 1). It is used to treat men with urinary obstruction due to recurrent benign urethral stricture disease. The device stays in the body permanently.

The UroLume prosthesis is an alternative treatment for patients in whom other treatment methods including dilation, urethrotomy, and/or urethroplasty, have been unsuccessful - the treatment did not initially relieve the stricture disease or the stricture has returned, needing another treatment.

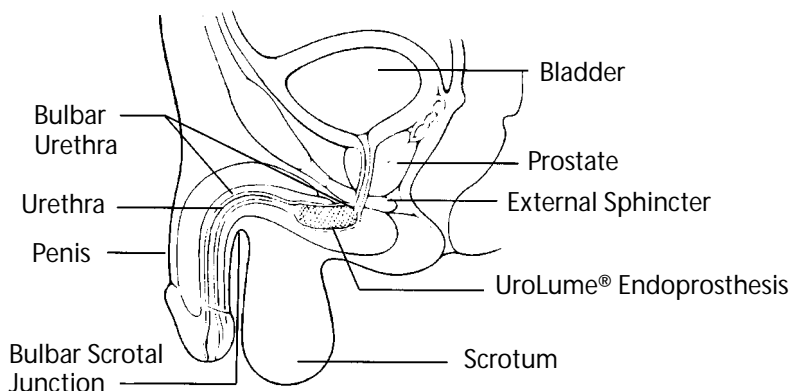


Figure 1: Urethral Stricture Treated with the UroLume Endoprosthesis

As your physician has already explained, you have a urinary obstruction called a stricture. The stricture causes your urethra to become narrower and makes it more difficult for your urine to get through. The UroLume prosthesis is designed to treat men, like you, who have recurrent bulbar urethral strictures (strictures between the external sphincter and the bulbar scrotal junction) that are shorter than 3.0cm.

## 2 HOW THE PROSTHESIS WORKS

The UroLume prosthesis has two parts: the prosthesis itself and the tool your physician uses to place it in your urethra. As mentioned previously, the prosthesis is a braided mesh tube that is made of a high strength metal wire (Figure 2). The braided mesh design allows the tube to expand in width once it is inserted in the bulbar urethra so that it will hold the area of the stricture open. This allows urine to easily flow from the bladder to the outside of the body.

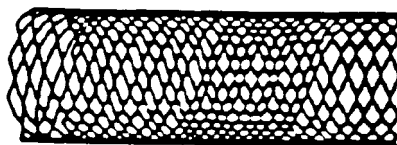


Figure 2: The UroLume Endoprosthesis

Because the UroLume prosthesis expands in width, it presses against the wall of the urethra and prevents the prosthesis from moving within the urethra. This also allows your urethral tissue to grow and, eventually, cover the wire mesh. Urethral tissue growth over the prosthesis is expected over time. If, however, the tissue does not completely cover the wire mesh, stones may develop on the prosthesis. If stones do develop, an endourethral procedure may be necessary to remove them.

The second part of the UroLume prosthesis, the insertion tool (Figure 3), is used to place the prosthesis inside your urethra. This tool compresses the wire mesh prosthesis to make it smaller than your urethra so that it is easier to insert. The tool's hollow inner tube allows your physician to use a telescope to see inside your urethra and to see the exact location of your stricture. Mounted on the tool's inner tube, the prosthesis is exposed and released when your physician pulls the finger grips together. Once the UroLume prosthesis is released in your urethra, it is designed to expand in width to hold the stricture open.

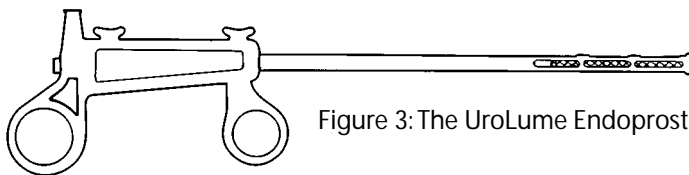


Figure 3: The UroLume Endoprosthesis Insertion Tool

### **3 ABOUT THE PROCEDURE**

Before the procedure, your physician may decide to give you local anesthesia so that you remain awake during the insertion of the UroLume prosthesis. Or, you may receive a general anesthesia so that you are asleep for the procedure. The telescope that your physician will use is the same kind used during a routine urethroscopy procedure that you have already had in the past. To you, the insertion procedure may seem very similar to a urethroscopy.

Your physician starts the procedure by inserting a small urethroscope through the end of your penis. The urethroscope helps the physician see and measure the stricture to determine what size UroLume prosthesis you will need. The physician will also dilate the strictured area and/or perform a urethrotomy to make it easier to insert the prosthesis.

Next your physician places the UroLume prosthesis' insertion tool into your urethra through the end of your penis. Using a telescope inserted through the tool's hollow inner tube, the physician looks inside your urethra and moves the tool to where your stricture is located.

When everything is positioned correctly, the physician releases the UroLume prosthesis from the insertion tool. Once released, the device expands and presses against the walls of your urethra. The insertion tool is removed, but the UroLume prosthesis stays inside you to hold your urethra open. If one prosthesis does not completely cover your stricture, your physician may insert additional UroLume prostheses to provide complete coverage.

## 4 WHAT TO EXPECT AFTER INSERTION

Your physician will give you a medical information card after the insertion procedure. This card contains important information about the UroLume prosthesis that was just inserted. Remember to always carry this card with you.

After the insertion procedure, your physician will want you to take antibiotic drugs to reduce your risk of infection. It is very important for you to take all the medicine as prescribed. Your physician will probably also advise you to wait at least four weeks before resuming sexual intercourse or other sexual activities. The exact period of time will depend on your medical condition and history. This is important because it minimizes the possibility of pain, infection or bleeding, and prevents the UroLume prosthesis from moving out of position. Be sure to follow all of your physician's instructions carefully.

In the weeks following the insertion procedure, you may dribble urine after going to the bathroom. If this dribbling is a concern for you, your physician may be able to provide advice about how to remove urine from your urine canal more completely.

Some men also have blood in their urine or pain during the first few weeks after insertion of the UroLume prosthesis. If you have bleeding or pain that seems to get worse over time, be sure to contact your physician.

Men who frequently ride bicycles or horses or who participate in other activities that put similar stresses on the urethra, may experience some mild discomfort during these activities after insertion of the UroLume prosthesis. Many cyclists have eased their discomfort by using a large bicycle saddle.

Because physical manipulation of the UroLume prosthesis may cause pain or movement of the prosthesis, you should avoid applying unnecessary pressure to the area where the prosthesis is located.

Catheters or other instruments should not be placed into the urethra until the UroLume prosthesis has been stabilized by the growth of urethral tissue. If instrumentation is needed to empty your bladder, your physician may decide to use a suprapubic catheter. You should inform treating physicians that you have a UroLume prosthesis implanted in your urethra and show them your medical information card.

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

## 5 REMOVING THE UROLUME ENDOPROSTHESIS

If necessary, the UroLume prosthesis can be removed. For example, if your physician determines during the insertion procedure that the prosthesis is not in the correct position, it can be removed using forceps. To do this, your physician will use forceps to grasp the prosthesis' wire mesh and pull the forceps and the UroLume prosthesis out of your urethra. As the prosthesis is pulled, it becomes longer and narrower, making removal from your urethra possible. If, however, the physician does not grasp enough of the prosthesis with the forceps, the wire mesh can come apart or break. If this occurs, your doctor will remove the mesh tube one wire at a time using forceps.

If the UroLume prosthesis needs to be removed after your urethral tissue has covered the prosthesis, your physician will need to remove this tissue before removing the prosthesis. After loosening the prosthesis from the tissue, the UroLume prosthesis can be removed using forceps as described above.

Urethral trauma may occur during the removal process. During the clinical studies, however, the trauma experienced during prosthesis removal was mild. Additionally, there has been no known increase in the formation of strictures for patients who had the UroLume prosthesis removed. Typically, the stricture returns in the area of the urethra that was covered by the prosthesis - the condition that was present before the UroLume prosthesis was ever inserted.

## 6 BENEFITS OF UROLUME ENDOPROSTHESIS

### *Improved Flow of Urine*

Clinical studies show that the UroLume prosthesis is effective and significantly improves the flow of urine out of the body.

### *Reduced Symptoms of Stricture Disease*

Most men notice a significant improvement in the symptoms associated with their stricture disease including hesitancy, poor flow, incomplete emptying, frequency, getting up to go to the bathroom at night, painful urination, two stage voiding (starting urine flow and then stopping and starting again), and increased voiding time.

### *Reduced Need for Further Treatment*

After insertion of the UroLume prosthesis, most patients do not require further treatment for their stricture for at least two years. Clinical studies, in fact, indicated a dramatic reduction in the need for further treatment of the strictures in the two years following prosthesis insertion as compared to the need for stricture treatments in the two years prior to insertion.

### *Easy Insertion*

Most UroLume prosthesis insertions have been performed as outpatient procedures, reducing the time spent in a hospital setting. For additional information about the benefits of the UroLume prosthesis, please contact your physician.

## 7 RISKS ASSOCIATED WITH THE UROLUME ENDOPROSTHESIS

### *Urinary Incontinence*

Misplacement of the prosthesis within your external sphincter can cause urinary incontinence.

### *Infection*

Your UroLume prosthesis may need to be removed if an infection develops at the prosthesis site.

### *Trauma Caused by Prosthesis Removal*

Removal of your prosthesis after it is covered in urethral tissue could cause trauma to your urethra.

### *Trauma Caused by Urethral Instruments*

Urethral instruments, such as a urethroscope or a catheter, could cause trauma to your urethra or dislodge your UroLume prosthesis.

### *Bleeding*

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

### *Encrustation*

If your urethral tissue does not grow to cover the UroLume prosthesis over time, your prosthesis may become encrusted. If so, the prosthesis may need to be removed.

### *Migration/Shortening*

The UroLume prosthesis may migrate (move) and/or shorten within your urethra. If this occurs, the prosthesis may not completely bridge the strictured area of your urethra.

### *Obstruction*

Tissue that grows through the UroLume prosthesis may cause an obstruction in your urethra. This may limit the flow of urine from your body. Urethral tissue growth that causes an obstruction may require removal of that tissue and, possibly, the prosthesis itself.

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

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

### *Painful Erections and/or Ejaculation*

You may experience some pain with erections and/or ejaculation after insertion of the UroLume prosthesis. In most cases, these symptoms will end or diminish on their own.

### *Changes in Benign Growth*

Changes of benign growth within the urethra may occur after insertion of the UroLume prosthesis that may require a biopsy - especially for patients who have had a previous skin graft urethroplasty.

### *Suprapubic Catheter*

There may be times when a catheter would be needed.

You should also be aware that, during the clinical study of the UroLume prosthesis, a patient who had an abnormal looking stricture before receiving the prosthesis was found to have urethral cancer several months after the insertion. Although it appears that this patient had the cancer before insertion of the UroLume prosthesis, there may be some risk of developing urethral cancer.

Be sure to discuss any additional possible risks with your physician.

## 8 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.

**BULBAR SCROTAL JUNCTION:** The area of the urethra where the penis meets the body.

**BULBAR URETHRA:** The area of the urethra between the external sphincter and the bulbar scrotal junction.

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

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

**DRIBBLING AFTER URINATION:** The passage of a limited amount of urine after the completion of urination.

**EJACULATION:** The discharge of semen from the urethra.

**ENCRUSTED:** Stone-like formations that attach to the prosthesis.

**ENDOURETHRAL:** Within the urethra.

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

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

**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.

**INCONTINENCE:** The inability to control the flow of urine from the body, resulting in the involuntary passage of urine.

**INSTRUMENTATION:** Using medical tools within the urethra.

**MANIPULATION:** Applying unnecessary pressure to the area where the prosthesis is located.

**OBSTRUCTION:** A blockage of the urethra that restricts the flow of urine out of the body.

**PROSTHESIS:** An artificial replacement (the implanted device) for a body part.

**RECURRENT BULBAR URETHRAL STRICTURE:** A narrowing of the bulbar urethra that keeps returning even after treatment.

**STABILIZED:** When the prosthesis is held in position by urethral tissue.

**STRICTURE:** A narrowing of the urethra that limits the flow of urine.

**SUPRAPUBIC CATHETER:** A catheter placed through your stomach to allow the flow of urine from the bladder.

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

**TWO STAGE VOIDING:** Interrupted urine flow, resulting in urine flow that starts, stops, and starts again.

**URETHRA:** The tube that moves urine from the bladder, through the penis, and outside the body.

**URETHROPLASTY:** A procedure to cut out the strictured area of the urethra and either replace it with a graft or connect the two ends of the urethra where the stricture was removed.

**URETHROSCOPE:** A special telescope used to view the inside of the urethra.

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

**URETHROTOMY:** A procedure to enlarge the diameter of the urethra by making a series of small cuts through the strictured area.

**URGENCY:** A strong desire to urinate immediately.

**VOIDING:** Urination.

**Solutions for Life™** American Medical Systems is a world leader in medical devices and procedures that treat three major diseases: incontinence, erectile dysfunction (ED) and benign prostate hyperplasia (BPH). Any one of these conditions can profoundly diminish a patient's quality of life and significantly impact relationships. Our products provide a cure or reduce the incapacitating effects of these diseases, often through minimally invasive surgery.



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