

**DRAFT 5**

**INFORMATION FOR PATIENTS**

**URYX® Urethral Bulking Agent**

**For the Treatment of Stress Urinary Incontinence in Women**

This brochure is designed to help you decide whether or not to have a URYX Urethral Bulking Procedure for the treatment of stress urinary incontinence in women. Please read this entire brochure and discuss it thoroughly with your physician, so that all of your questions have been answered before you decide about your treatment.

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## Introduction

This brochure provides information to help you decide whether to have the URYX Urethral Bulking procedure for the treatment of your ***stress urinary incontinence***, or the condition of accidental leakage of urine during physical activity. Studies show that many women with stress urinary incontinence have less or no leakage one year after treatment with ***urethral bulking***. However, there are many options for treating incontinence, including surgery. One advantage of URYX is that it is a minimally invasive alternative to surgery that may be performed on an outpatient basis. URYX may be an option if you wish to avoid or are not a candidate for surgery.

Please read this brochure carefully and discuss the information with your physician. Your physician can determine whether you are a suitable candidate for the URYX procedure. However, you are the only one who can decide whether this procedure is right for you. The information in this brochure should help you make your decision. You should discuss your decision with your physician and make sure that all of your questions have been answered to your satisfaction before proceeding with the procedure.

## What are Urinary Incontinence and Stress Urinary Incontinence (SUI)?

- ***Urinary incontinence*** is the accidental or unintentional leakage of urine. It is a very common condition affecting over 13 million people in the United States, 85% of whom are women. Although incontinence is often considered a part of aging, incontinence may be brought on early in life, even in very active people. Incontinence should not be considered a normal part of life; something that one must endure without treatment.
- There are several types of incontinence. The most common is called ***stress urinary incontinence*** or SUI. The term comes from the physical actions – or stresses on the ***bladder*** – that cause accidental leakage of urine. With increased physical activity and some abrupt actions, such as coughing, laughing or sneezing, pressure may be exerted on the bladder. This pressure can cause involuntary leakage.

Leakage can also occur with more strenuous activities such as aerobics, jogging, dancing or lifting heavy objects.

### **What causes SUI?**

SUI is a sign of an underlying condition often caused by a poorly functioning **urethral sphincter**, a muscle in the **urethra** (the tube that carries urine out of the bladder) that helps to hold the urine in the bladder. In normal circumstances, this muscle can withstand abrupt pressures and hold the urine back until you desire to urinate. SUI may also be caused by excessive movement of the urethra, or by weakened muscles in the pelvic floor that can no longer support the bladder and other organs.

For women, SUI may be related to factors such as pregnancy and/or natural childbirth, strenuous exercise, loss of pelvic muscle tone, and previous gynecologic surgery.

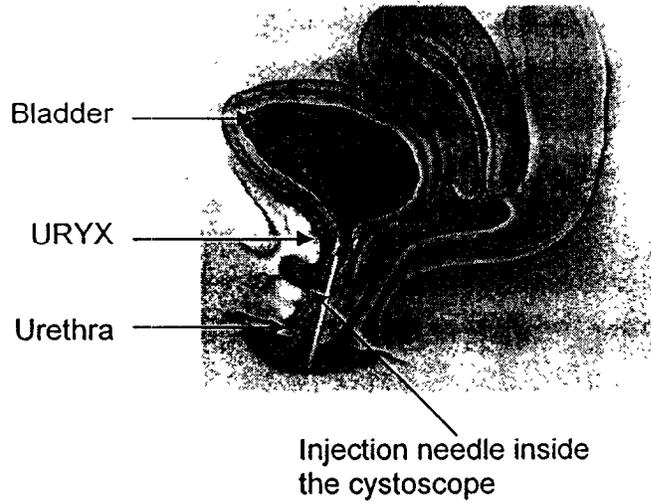
### **What is URYX?**

URYX is a synthetic **polymer** dissolved in a liquid. When URYX is injected with a needle into the area around the urethra, it changes from a liquid to a spongy material. URYX remains permanently implanted at that location.

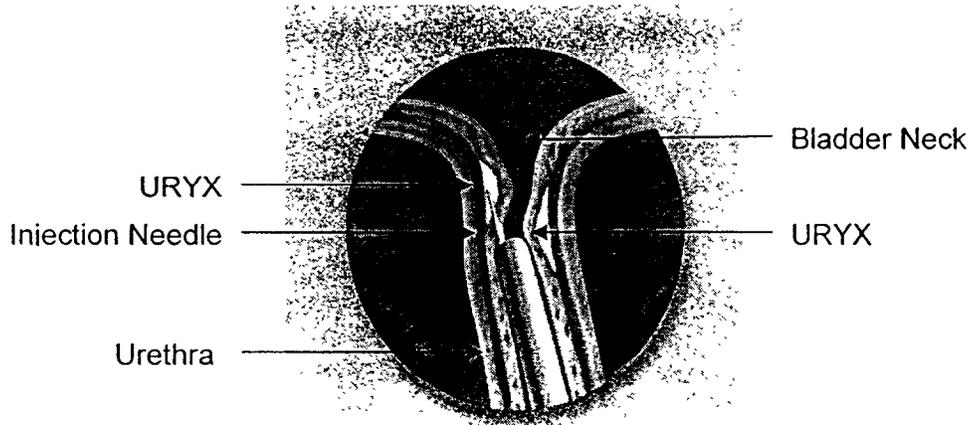
### **What is the URYX Urethral Bulking Procedure?**

This procedure to implant URYX in the urethral tissues is called **urethral bulking**. The additional material bulk in the urethra will assist in holding the urine in the bladder until urination is desired.

Your physician will place a small **cystoscope** into your urethra. While viewing the injection site, the physician will place the needle into the urethral tissue. URYX will then be injected, usually on both sides of your urethra. One to three injections of URYX may be performed in a single treatment.



The picture above shows the cystoscope inside the urethra, with the tip of the needle inserted into the tissue surrounding the urethra.



The picture above is a close-up view of the needle tip in the tissue and two URYX injections, one on each side of the urethra.

**Am I a good candidate for the URYX bulking procedure?**

URYX is specifically *indicated* for the treatment of adult women who have stress urinary incontinence due to a poorly functioning urethral sphincter. This treatment is not for other causes of SUI, such as excessive movement of the urethra or weakened pelvic floor muscles.

You and your doctor should be aware of the following *warnings* about treatment with URYX:

- URYX should not be used if you are experiencing any of the following conditions:
  - Bladder infection.
  - Infection of the *ureters* (the tubes carrying urine from the kidneys to the bladder).
  - Other acute or chronic urinary or genital infection.
- URYX should not be used if your urethral tissue is not strong, which your physician can determine when he examines your urethra through the cystoscope.
- You should provide your physician with a complete medical history of any known condition.
- URYX should not be used if you have untreated *urethral strictures* or obstructive conditions. Such use may make you unable to urinate normally.
- The safety and effectiveness of URYX has not been established for patients who are pregnant or lactating. The effect of URYX on pregnancy and delivery occurring after treatment is unknown.

**What are the benefits and risks associated with URYX?**

The benefit of treating with URYX is that it may help you become dry or lessen the number of times you experience urinary leakage. URYX is a synthetic material that is considered safe to the tissues and is not known to cause any allergic reactions. Because it is synthetic, the body does not break down the material after it has been implanted.

You should also understand that there are potential risks and discomfort that may be associated with any urethral bulking procedure. You may experience some discomfort from the injection of anesthetic into the tissues around your urethra. There is a risk of infection or

bleeding as a result of the URYX injection. The URYX material may leak back out of the injection site. As a result, you may experience no benefit from the bulking procedure. If the URYX is injected too deeply in the tissues around the urethra there may be inadequate bulking, and you may experience no benefit from the treatment.

One possible side effect of the URYX bulking procedure is ***exposed bulking material***, which is a breakdown of the tissue that covers the URYX material. If the URYX is injected improperly (too shallow, too much at one site, too close to the bladder), exposed material is more likely to occur. The occurrence of exposed material usually leads to pain on urination, blood in the urine, frequency of urination, infection and other complications. Once the urethra heals, these complications will resolve. If you experience any of these symptoms several days after treatment, you should contact your physician.

174 women were treated with URYX in a clinical study. Their physicians followed them for one year after their last treatment. Many of the ***adverse events*** or complications that occurred during the clinical study occurred shortly after the procedure and were brief (lasting less than 24 hours) in duration. Events related to URYX treatment occurred in 7 out of 10 patients. The following were the most common adverse events reported in the clinical study:

- Urinary tract infection – 50 patients (29%)
- Delayed voiding – 32 patients (18%)
- Painful urination – 31 patients (18%)
- Exposed bulking material – 28 patients (16%)
- Urgency to urinate – 24 patients (14%)
- Frequent urination – 22 patients (13%)
- Blood in the urine – 19 patients (11%)

You should contact your physician if you experience any complication that bothers you or lasts more than 24 hours.

More than one treatment with URYX may be required to achieve dryness or a satisfactory level of improvement in incontinence. Patients receiving repeat URYX treatments were

more likely to report certain complications, particularly **urinary urgency**, delayed ability to urinate, urinary tract infection, and pelvic pain.

The long-term (more than 1 year) safety and effectiveness of URYX have not been proven, and it is not known what effect pregnancy may have on the results you experienced after URYX treatment.

**Will I be awake for the procedure?**

This procedure may be accomplished with local anesthesia, which allows you to be awake. However, in some cases general anesthesia, where you are put to sleep, may be appropriate. You and your physician will decide which is best for you.

**How long will the procedure take?**

The actual procedure usually only takes 10-15 minutes, carried out in your physician's office, or in the hospital's outpatient surgery center or operating room. You will usually stay in the office or in a recovery area until you are able to pass urine on your own. After the procedure, you may be able to return to your normal activities immediately or as soon as you feel up to them. You should ask your physician if you should restrict any of your normal activities.

**What can I expect from the procedure?**

The objective of the URYX procedure is to decrease the amount and frequency of urine leakage. You may require more than one treatment to achieve dryness or a satisfactory level of improvement in incontinence. In a clinical study with URYX, 76% of patients required more than one treatment. In this study, patients received follow-up from their physicians for at least 12-months after their last treatment. The physicians evaluate these patients by assessing the physical stress level of activities at which they leaked compared with those activities prior to treatment with URYX. 49% of patients showed improvement in incontinence, which included 18% who were dry, one year after completion of treatments. You should contact your physician with your questions about your condition.

**What are the alternative practices and procedures for treating SUI?**

URYX is one of many options you have for treatment of your SUI. All of them have *contraindications, precautions* and adverse events (complications) associated with their use.

There are non-surgical therapies, including strengthening exercises for the pelvic muscles to improve support of the bladder and urethra, and biofeedback to assist in retraining the pelvic muscles. There are also drugs that may be used, as well as treatment with other bulking agents.

Surgical procedures have been designed to repair and reposition organs, restore support to weakened pelvic muscles, or implant an artificial urinary sphincter.

You should discuss these treatment options with your physician.

## Glossary of Terms

**Adverse Event:** complication that may result from the procedure.

**Bladder:** sack-like organ in the lower abdomen where urine is stored for elimination from the body.

**Contraindication:** statement in the product information that the product should not be used when a certain condition exists. For example, URYX is contraindicated for patients who have a urinary tract infection at the time of treatment.

**Cystoscope:** an optical instrument that is placed in the urethra and enables the physician to directly examine inside the urethra and bladder.

**Exposed bulking material:** the breakdown of the tissue that covers the URYX material.

**Indicated:** a statement that the product may be used for a specific treatment. URYX is indicated for the treatment of stress urinary incontinence in adult women.

**Polymer:** a type of chemical structure that is made of many smaller units. A polymer may be natural (like a protein) or synthetic (like a plastic). URYX is a synthetic polymer.

**Precaution:** a statement in the product information that alerts the physician to take measures to avoid a problem.

**Stress Urinary Incontinence (SUI):** the accidental leakage of urine during exercise, or physical activities such as coughing, sneezing, laughing, or other body movements that put pressure on the bladder. SUI is the most common type of urinary incontinence in younger and middle-age women. In some cases it is related to childbirth. It may also begin around the time of menopause.

**Ureters:** the tubes that carry urine produced in the kidneys to be stored in the bladder.

**Urethra:** the tube that carries urine from the bladder to outside the body for elimination.

**Urethral Bulking:** the injection of material (bulking agent) into the tissues surrounding the urethra to help the urethra close to avoid accidental leakage. Urethral bulking does not close the urethra totally; the urethra can still open normally to allow for urination.

**Urethral Sphincter:** a muscular structure in the urethra that closes to keep urine in the bladder and opens to allow for urination. In one type of SUI, the urethral sphincter does not close adequately, and allows urine to leak accidentally during physical activities.

**Urethral Stricture:** an abnormal narrowing or “kink” in the urethra that may prevent normal urination. URYX should not be used if a urethral stricture is not corrected.

**Urinary Incontinence:** the accidental leakage of urine, sometimes called a “bladder control problem.”

**Urinary Urgency:** a strong desire to urinate but does not result in accidental leakage or an episode of incontinence.

**Warnings:** a statement in the product information that alerts the physician to a potentially hazardous condition. For example, Warning: URYX should not be used in patients with urethral strictures until the strictures have been corrected.