



For the Treatment of
Stress Urinary Incontinence
in Women

Information For Patients

This brochure is designed to help you decide whether or not to have a Tegress™ Urethral Implant 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 Tegress™ Urethral Implant procedure for the treatment of stress urinary incontinence in adult women, or the condition of accidental leakage of urine during physical activity. There are many options for treating incontinence, including both non-surgical and surgical. Injectable bulking agent therapies such as Tegress™ Implant may also be used to treat incontinence.

Please read this brochure carefully and discuss the information with your physician. Your physician can determine whether you are a suitable candidate for injectable bulking agent therapy such as Tegress™ Implant. You should discuss your options with your physician and make sure that all of your questions have been answered to your satisfaction before deciding whether to proceed with the procedure.

GLOSSARY OF TERMS

The following are key terms and definitions you should review prior to reading this brochure.

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 (see illustration below).

Contraindication: statement in the product information that the product should not be used when a certain condition exists. For example, Tegress™ Implant 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.

Dimethyl sulfoxide (DMSO): one of the chemicals used to make Tegress™ Implant.

Erosion: the breakdown of the urethral tissue that covers the Tegress™ Implant material which may result in migration of the implant into the urethra, bladder or vagina.

Ethylene vinyl alcohol copolymer (EVOH): one of the chemicals used to make Tegress™ Implant.

Exposed bulking material: the breakdown of the tissue that covers the Tegress™ Implant material.

Extrusion of urethral implant through tissue: the inability of the urethral tissue to hold the implant in place at the time of the injection which may result in separation of the tissue.

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

Necrosis: the death of the urethral tissue that covers the Tegress™ Implant.

Non-pyrogenic: describes a healthcare product that does not cause a fever

Pelvis: the lower part of the trunk of the body

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). Tegress™ Implant is a synthetic polymer.

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

Sterile: free from germs

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 (see illustration below).

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. Tegress™ Implant 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: Tegress™ Implant should not be used in patients with urethral strictures until the strictures have been corrected.

OVERVIEW OF URINARY INCONTINENCE

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

Urinary incontinence is the accidental or unintentional leakage of urine. 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.

OVERVIEW OF TEGRESS™ IMPLANT

What Is Tegress™ Implant?

Tegress™ Implant is a sterile, non-pyrogenic implant composed of ethylene vinyl alcohol copolymer dissolved in dimethyl sulfoxide. When Tegress™ Implant is injected with a needle into the area around the urethra; it changes from a liquid to a spongy material. The additional material bulk in the urethra will assist in holding the urine in the bladder until urination is desired. Tegress™ Implant remains permanently implanted at that location.

Am I a Good Candidate for the Tegress™ Implant Bulking Procedure?

Tegress™ Implant is specifically indicated for the treatment of adult women who have stress urinary incontinence due to a poorly functioning urethral sphincter.

You should provide your physician with a complete medical history of any known condition or previous medical procedure that may affect your urethra such as radiation treatment or surgery. This will assist in determining whether or not you are a candidate for Tegress™ Implant.

Who Should Not Be Treated with Tegress™ Implant?

Tegress™ Implant should not be used in patients with the following conditions:

- Redness, heat, swelling or pain in the urethra, bladder or ureters.
- Infection in the sexual or urinary organs.
- Weak or fragile urethral tissue, which your physician can determine when he/she examines your urethra through the cystoscope.

Warnings

- Tegress™ Implant should not be used if you have abnormal narrowing (strictures) or obstruction of the urethra until the narrowing or obstruction has been corrected. Such use may block your urethra.
- The safety and effectiveness of Tegress™ Implant have not been established for males. Therefore, it is unknown what harm or benefit males may have from Tegress™ Implant.
- The safety and effectiveness of Tegress™ Implant have not been established for patients who are pregnant or lactating. Therefore, it is unknown what harm or benefit women who are lactating or pregnant or their developing fetuses or children may have from Tegress™ Implant.
- The effect of Tegress™ Implant on pregnancy and delivery occurring after treatment is unknown.
- Tegress™ Implant should only be used by a doctor properly trained in the use of the product.

What are the Risks and Benefits Associated with Tegress™ Implant?

There are risks associated with a 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 Tegress™ Implant injection. The Tegress™ Implant material may leak back out of the injection site. As a result, you may experience no benefit from the bulking procedure. If the Tegress™ Implant is injected too deeply in the tissues around the urethra there may be inadequate bulking, and you may experience no benefit from the treatment.

Another risk of the Tegress™ Implant bulking procedure is exposed bulking material, which is a breakdown of the tissue that covers the Tegress™ Implant material. Exposed material is more likely to occur if the Tegress™ Implant is injected improperly (too shallow, too much at one site, too close to the bladder) or if your urethral tissue is weakened or damaged. 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 should resolve.

174 women were treated with Tegress™ Implant in a clinical study. These women had follow-up examinations for one year after their treatments. 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 Tegress™ Implant 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%)
- Infection/tenderness of the sexual or urinary organs – 20 patients (11%)
- Blood in the urine – 19 patients (11%)
- Urinary incontinence when the urge to urinate is felt – 16 patients (9%)
- Worsening of urinary incontinence – 14 patients (8%)
- Blockage of the urethra – 13 patients (7%)
- Pain at the injection site – 13 patients (7%)
- Pain in the pelvis – 13 patients (7%)
- Yeast infection – 12 patients (7%)
- Leakage of urine – 9 patients (5%)
- Bulking material injected into the bladder – 7 patients (4%)
- Tiredness – 3 patients (2%)
- Unusual urine test – 3 patients (2%)
- Bladder fullness – 3 patients (2%)
- Excessive nighttime urination – 3 patients (2%)
- A feeling of heaviness in the pelvis – 3 patients (2%)
- Noncancerous tumor on the uterus – 3 patients (2%)

After FDA approval, the following events have been observed occasionally in the use of Tegress™ Implant and have been noted immediately after the injection or in the period of days to months after injection.

- Erosion of the urethral tissue
- Death of the urethral tissue that covers the implant (necrosis)
- Extrusion of urethral implant through the tissue

More than one treatment with Tegress™ Implant may be required to achieve dryness or a satisfactory level of improvement in incontinence. Patients receiving repeat Tegress™ Implant 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 Tegress™ Implant have not been proven, and it is not known what effect pregnancy may have on the results you experienced after Tegress™ Implant treatment.

The benefit of treating with Tegress™ Implant is that it may help you become dry or lessen the number of times you experience urinary leakage. Tegress™ Implant 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.

What are the Alternative Practices and Procedures for Treating SUI?

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.

In addition to Tegress™ Implant, other injectable bulking agent therapies are available.

Surgical procedures are designed to repair and reposition the bladder or urethra, restore support to weakened pelvic muscles, or implant an artificial urinary sphincter.

You should discuss these treatment options with your physician.

THE TEGRESS™ IMPLANT PROCEDURE

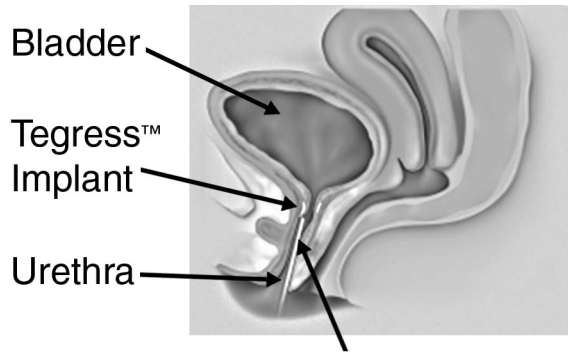
What Can I Expect from the Procedure?

The objective of the Tegress™ Implant 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 Tegress™ Implant, 76 out of every 100 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 evaluated these patients by assessing the physical stress level of activities at which they leaked compared with those activities prior to treatment with Tegress™ Implant. 49 out of every 100 patients showed improvement in incontinence, which included 18 out of every 100 who were dry, one year after completion of treatments. 47 patients out of every 100 showed no improvement in incontinence while 4 out of every 100 experienced a worsening of their incontinence.

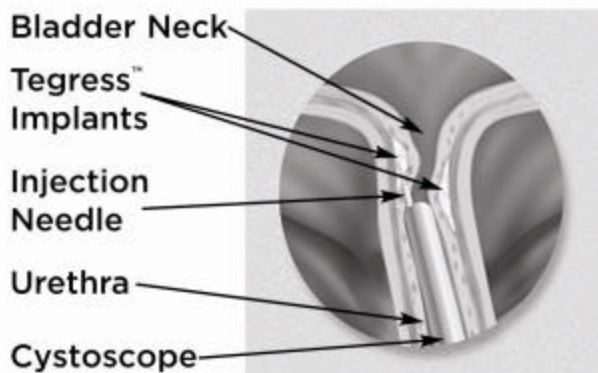
What Is the Tegress™ Urethral Implant Bulking Procedure?

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. Tegress™ Implant will then be injected, usually on both sides of your urethra. One to three injections of Tegress™ Implant may be performed in a single treatment.



Injection needle inside the cystoscope

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 Tegress™ Implant injections, one on each side of the urethra.

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 should I do if I experience pain, discomfort or have a concern after the procedure?

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

What should I do if I have further questions after reading this brochure?

Your physician will be able to best answer any additional questions you may have after reading this brochure. You may also contact Bard Urological Division Medical Services and Support at 1-800-227-3357 for information about Tegress™ Urethral Implant.

C. R. Bard, Inc. Covington, GA 30014 800.526.4455
www.bardurological.com

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