



Macroplastique[®]

URETHRAL BULKING AGENT

**A minimally invasive alternative
for the treatment of Stress
Urinary Incontinence**



Macroplastique®

URETHRAL BULKING AGENT

Predictable. Permanent. Proven.

This brochure is designed to help you decide whether or not to have a Macroplastique urethral bulking procedure for the treatment of stress urinary incontinence. Please read this entire brochure and discuss it with your doctor. Your doctor will answer any questions you have prior to your making a decision about treatment.

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Glossary

If you see a term in bold, it will be defined in the glossary.

Adverse Event: Complication that may result from a procedure.

Bladder: Balloon-like organ in the lower abdomen where urine is stored.

Bulking Agent(s): Natural or man-made material injected into the body to support tissues.

Catheter: A small tube placed into the body through which fluids pass.

Catheterization: The use of or insertion of a catheter.

Contraindication: A statement in the product information that the product should not be used when a certain condition exists. For example, Macroplastique is contraindicated for patients who currently have a urinary tract infection.

Clinical Trial: Cogentix Medical's research study of women with incontinence and treated with Macroplastique or control bulking agent.

Cross-linked Polydimethylsiloxane (PDMS): The solid, medical grade silicone elastomer material used to make Macroplastique Implants.

Cystoscope: A small optical instrument used by the doctor to view the urinary organs (the urethra and bladder).

Incontinence: A condition where a person is unable to control the release of bodily fluids.

Intrinsic Sphincter Deficiency (ISD): A condition where the group of circular muscles surrounding the bladder neck weakens and can no longer close properly to hold urine.

Macroplastique Implants: Urethral bulking agent made with silicone elastomer implants.

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

Saline: Salt water.

Silicone Elastomer: A rubber-like material.

Stamey Grade: A diagnostic measure used by physicians to rate the severity of stress urinary incontinence.

Stress Urinary Incontinence (SUI): The accidental leakage of urine during exercise, or during normal, everyday activities such as coughing, sneezing, laughing, or during 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.

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 urine leakage. Urethral bulking does not close the urethra totally; the urethra can still open normally to allow for urination.

Urethral Hypermobility: A condition where the urethra is not sufficiently supported by the pelvic floor muscles resulting in stress urinary incontinence.

Urinary Incontinence: The accidental leakage of urine.

Urinary/Urethral Sphincter: A ring of muscles in the urethra that help keep the urethra closed and can be opened voluntarily to allow urination. In one type of SUI, the urethral sphincter does not close adequately, and allows urine to leak accidentally during physical activities.

Urinary Tract: The organs and pathways involved in the passing of urine.

Voiding: Eliminating urine from the body.

Water-soluble gel, Polyvinylpyrrolidone (PVP): The liquid that can be absorbed by the body in which Macroplastique Implants are mixed.

Introduction

If you worry about occasional **bladder** leakage, a condition called **urinary incontinence**, you are not alone. Millions of women worry about bladder leakage -- a frustrating and often embarrassing condition that can affect a woman's lifestyle, relationships, and emotional well-being.

This brochure is provided as an overview of **Macroplastique Implants** and **stress urinary incontinence**. It is not intended to replace discussions with your doctor. Please be sure to discuss this information and any questions you may have with your doctor.

Approximately 13 million people in the United States are affected by **stress urinary incontinence (SUI)**. Of the 13 million, 85% are women. While SUI occurs more frequently in older women, SUI affects women of all ages and is not necessarily a result of getting older. More importantly, **incontinence** is treatable and is usually curable. You don't have to live with the effects of **incontinence**.

Frequently Asked Questions

What is stress urinary incontinence?

Stress urinary incontinence (SUI) is the most common type of **urinary incontinence**. SUI is the sudden, accidental loss of urine that occurs during normal, everyday activities. You may have SUI if you leak urine when you sneeze, cough or laugh, when you stand up, when you exercise, or when you lift items.

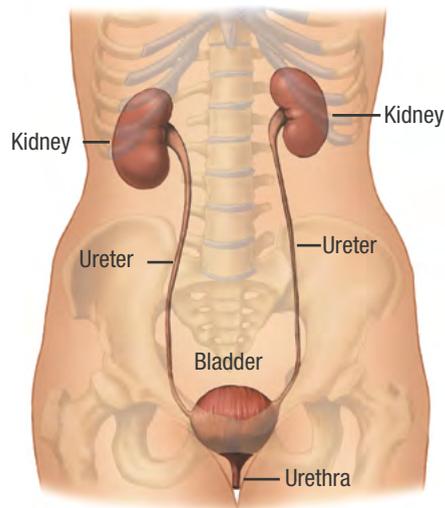
There are other types of **urinary incontinence**. Your doctor will be able to determine if your leakage problems are the result of SUI after learning your medical history and conducting a physical examination. Your doctor may perform special tests to evaluate your **bladder** and urethral function.

What causes stress urinary incontinence?

SUI occurs when the **urethra**, the tube that carries urine from the **bladder** to outside the body, does not remain closed until it is time to urinate. Even an activity such as standing up may result in accidental loss of urine. There are two main causes of SUI:

1. The **urinary sphincter**, a group of muscles surrounding the **urethra**, weakens and can no longer close properly to hold urine. This condition is called **Intrinsic Sphincter Deficiency** (also known as **ISD**). Approximately 2 million people have SUI due to **ISD**. **Macroplastique** is used to treat SUI primarily due to **ISD**.
2. The pelvic floor muscles weaken and are unable to provide sufficient support to the **urethra**. In this case, any increased pressure to the **bladder**, such as coughing, may cause the **urethra** to lose its seal and allow urine to escape.

Various factors may contribute to the weakening of the pelvic floor muscles including: pregnancy and childbirth, chronic heavy lifting or straining, obesity, menopause, or estrogen deficiency.



Female urinary anatomy

What are common treatment options?

Pelvic muscle strengthening: Pelvic floor exercises, commonly referred to as Kegel exercises, will most likely be one of the first treatment options recommended by your doctor. Depending on the severity of your SUI, Kegel exercises may not be sufficient to improve your symptoms. Kegel exercises may be combined with:

- » **Pelvic muscle stimulation** – mild electrical stimulation to help automate the process of performing Kegel exercises. Stimulation is generally applied using a home-use device.
- » **Biofeedback** – a process using signals of sight or sound to assist targeting the right muscle during pelvic muscle exercises.

Medications: Some types of **urinary incontinence** may be treated with drugs that affect the **bladder** and **urethra** muscles, and help prevent leakage. Hormone therapy, such as estrogen creams, may also be effective in helping to improve pelvic floor muscle function.

Bulking agents: **Bulking agents**, like **Macroplastique Implants**, may be used to treat SUI, specifically when the cause is **intrinsic sphincter deficiency**. Treatment with a **bulking agent** involves injecting a material into the tissues surrounding the **urethra** to help increase the thickness (the “bulk”) of the **urethra**, thereby improving urethral closure to avoid accidental leakage. Urethral bulking does not close the **urethra** totally; the **urethra** can still open normally to allow for urination.

Surgery: Surgery is often used to treat SUI, especially when the cause is a weakened pelvic floor. A common surgery to provide support for the **urethra** is a sling procedure. During this surgery, a narrow strip of a permanent material, a “sling,” is placed below the **urethra** to support the urethra and to maintain its seal.

All treatment options are associated with **contraindications**, **precautions**, and **adverse events**. You can discuss the variety of treatments available with your doctor.

What is Macroplastique?

Macroplastique is an injectable soft-tissue **urethral bulking agent** for treating **stress urinary incontinence** primarily due to **intrinsic sphincter deficiency**. **Macroplastique** is made up of two parts – the **water-soluble gel (polyvinylpyrrolidone)** that is absorbed and removed from the body in urine and the man-made, rubber-like, **silicone elastomer** implant material (**cross-linked polydimethylsiloxane**) that is permanent and not absorbed by the body. It is this permanent material that causes the bulking effect around the **urethra** after implantation.



Macroplastique bulking agent

Is Macroplastique right for me?

Your doctor will perform tests to determine what type of **incontinence** you have and the cause for your **incontinence**. You and your doctor will then decide on the treatment that is most suitable for you.

Macroplastique may be right for you, even if other **incontinence** treatments such as a sling procedure have failed.

How does Macroplastique work?

Macroplastique is injected into the tissues surrounding the **urethra**. The increased “bulk” allows the **urethra** to close more effectively and prevents urine from leaking. Refer to the drawings on the next page to see where **Macroplastique** is injected.

How is the Macroplastique treatment performed?

The procedure to inject **Macroplastique** can be performed in your doctor’s office or in an outpatient clinic or hospital in approximately 30 minutes. Prior to the procedure, the doctor will give you an antibiotic to reduce the risk of infection. Upon the start of the procedure, the doctor will give you local anesthetic in the tissues near your **bladder** to reduce discomfort.

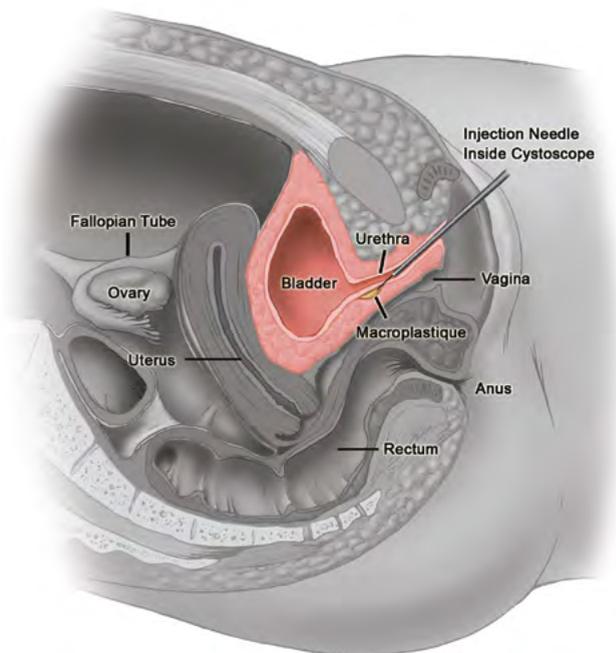
A small optical instrument (**cystoscope**), placed in the **urethra**, is used during the procedure to allow your doctor to view your **urethra** and **bladder** while injecting **Macroplastique** into the surrounding urethral tissue. Your doctor will also fill your **bladder** to halfway with water or **saline** to better view the implantation area. The optical instrument is removed after the injection and your treatment is complete.

What can I expect after the procedure?

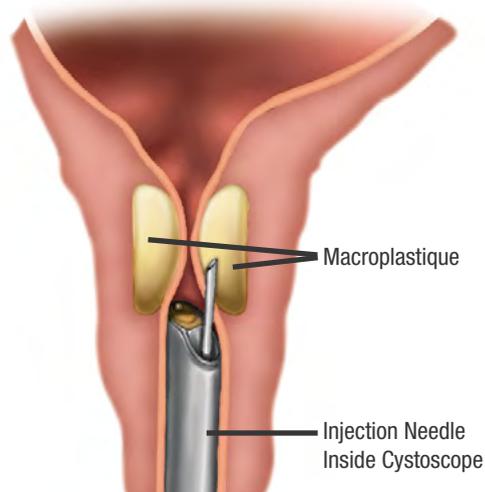
Most women can expect:

- » To stay at the treatment facility until the numbness from the anesthetic is gone and they can urinate on their own. If you have difficulty urinating after the procedure, a catheter may be inserted until you urinate normally.
- » To receive a prescription for antibiotics to prevent infection. It is important to take this antibiotic to reduce the risk of a urinary tract infection.
- » To resume their normal daily activities and return to work within a few days.

Your doctor will provide you with more specific instructions about your own recovery and if any restrictions on normal activities are recommended.



Macroplastique injection site



Macroplastique injection site (close-up)

Are there times when Macroplastique should not be used?

You cannot be treated with **Macroplastique** if you have an infection or inflammation of the kidney, **bladder** or **urinary tract**, or vagina. Your doctor will test your urine to ensure you do not have a **urinary tract** infection because the **Macroplastique** injection cannot be performed until an infection has been treated. Also, **Macroplastique** cannot be injected if the tissue around your **urethra** does not look healthy to the doctor.

This treatment has not been evaluated in pregnant women or women who had a child within the past year.

What are the treatment benefits?

The benefit of **Macroplastique** treatment is that you could be free from unwanted urinary leakage (dry) or have fewer episodes of urinary leakage. Other commercially available **bulking agents** may be absorbed into the body; **Macroplastique** is made of a **water-soluble gel** that is removed from the body leaving behind the permanent **silicone elastomer** implants.

Macroplastique has been available to treat this condition worldwide since 1991. The majority of women treated with **Macroplastique** report a cure or improvement in their symptoms, with many seeing that improvement as soon as they leave the doctor's office, hospital or clinic. A successful treatment is a decrease in the amount and frequency of urine leakage due to **stress urinary incontinence**.

Cogentix Medical conducted a **clinical trial** with **Macroplastique** at twelve medical centers in the U.S. and Canada. One hundred twenty two (122) female patients received **Macroplastique Implants** and were followed for 12 months after the initial treatment. In the study, 75 out of 122 **Macroplastique** patients (61.5%) were improved at 12 months based on a physician's scoring system (**Stamey Grade**). Of the 75 improved patients, 45 (36.8% of the original 122 patients) were dry using the same scoring system.

For 22 of the 122 **Macroplastique** patients in the trial (18%), their SUI was worse or was unknown after 12 months. When the patient's condition was unknown, data was not available and Cogentix Medical does not know if these patients' symptoms improved, remained the same, or became worse.

What are the risks I should know about?

As with any treatment, there are risks involved. It is important to discuss risks and side effects with your doctor before undergoing any type of medical treatment.

Risks following a **Macroplastique** treatment include pain related to the procedure (which can be controlled with pain medication), a small amount of blood in your urine, having to use the bathroom more often or more urgently, delayed **voiding**, painful urination, and/or **urinary tract** infection. There is also a potential risk related to receiving anesthesia during the treatment.

If after 48 hours you have urination that is difficult, frequent, or painful, or there is blood in your urine, contact your doctor immediately. These may be signs of other more serious problems.

An additional risk is that you may experience no benefit from **Macroplastique** treatment. This could happen if **Macroplastique** is placed too deeply in the tissue, thereby creating poor bulking around the **urethra**. Also, if you have a different type of **incontinence** (i.e., urge **incontinence**) or your **incontinence** condition worsens (i.e., due to **urethral hypermobility**), **Macroplastique** may not be an effective treatment for you.

In the **clinical trial**, 122 patients were treated with **Macroplastique** and followed for 12 months after the last treatment. The most common side effects (**adverse events**) reported are listed below.

Adverse Event	Number of Patients
Post-operative catheterization *	43 in 100
Urinary tract / bladder infection (0 – 365 days post treatment)	25 in 100
Urinary retention	21 in 100
Painful urination (Dysuria)	19 in 100
Blood in urine (Hematuria / Transient hematuria)	19 in 100
Pain at implantation site	16 in 100
Frequency	12 in 100
Strong desire to urinate, but no incontinence episodes (Urgency)	12 in 100
Slowed urine stream	7 in 100
Incomplete bladder emptying	6 in 100
Urge incontinence	6 in 100
Hesitancy	5 in 100

* *Instructions to the doctors allowed them to perform **catheterizations** as a routine part of the procedure.*

Many of the side effects reported in the clinical study occurred within 7 days after treatment and resolved within 30 days. You should talk to your doctor about these side effects and how they can be resolved.

Will I need more than one treatment?

In the **clinical trial**, about half of the patients requested an additional treatment to either further improve or cure their **incontinence**. Cogentix Medical recommends patients wait 12 weeks between treatments to allow healing and accurately see the full effect of the first treatment. Talk to your doctor about an additional treatment if you continue to experience urine leakage.

What are the long-term results?

The long-term results with **Macroplastique** have not been established. Eighty-four women participated in the **Macroplastique clinical trial** for 2 years. Using the same physician’s scoring system reported at 12 months (**Stamey Grade**), 63 out of these 84 women were improved at 2 years. However, too many women did not attend their 2-year exam to assess improvement at 2 years. Therefore, the actual improvement rate beyond 12 months is unknown.

If your symptoms do not improve or if symptoms return after treatment with **Macroplastique**, there are other options available. You may require further treatment for **stress urinary incontinence** or you may have an additional form of **incontinence** or other urology or gynecology problem that needs to be diagnosed and treated. For example, many women have mixed **incontinence**, such as a combination of **SUI** and urge **incontinence**, where urge **incontinence** is a sudden and uncontrollable urge to urinate. If this were the case, your doctor would work with you to determine an appropriate treatment option for your urge **incontinence**. Treatment with **Macroplastique** does not prevent you from receiving other types of **incontinence** treatments – either for **SUI** or another form of **incontinence**.

Ongoing evaluation of safety

After the completion of the clinical study, Cogentix Medical continued to collect safety information from physicians using **Macroplastique**. In the two years following market introduction, over 99% of physician responses reported no **adverse events**. Only two separate cases of temporary urinary retention, a known potential side effect of urethral **bulking agent** treatment, were reported. This program demonstrates **Macroplastique** is being used safely in the field with no new safety issues.



More information about incontinence:

National Association for Continence
1-800-BLADDER or 1-843-377-0900
www.nafc.org

The Simon Foundation for Continence
1-800-23-SIMON or 1-847-864-3913
www.simonfoundation.org

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