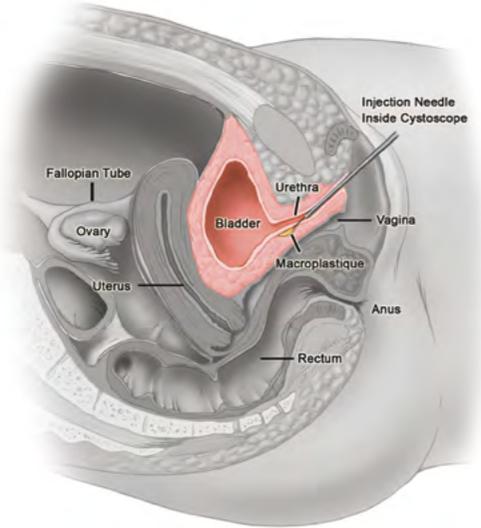
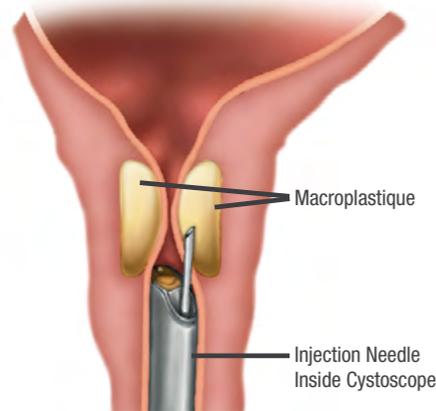


How does Macroplastique work?

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 to see where Macroplastique is injected.



Macroplastique injection site



Macroplastique injection site (close-up)

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.

Macroplastique has been available to treat stress urinary incontinence 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 hospital or clinic. A successful treatment is a decrease in the amount and frequency of urine leakage due to stress urinary incontinence.



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.

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Macroplastique[®]

BULKING AGENT

A minimally invasive alternative for the treatment of Stress Urinary Incontinence

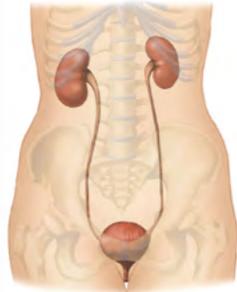


What is stress urinary incontinence?

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, laugh, when you stand up, when you exercise, or when you lift items.

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:



Female urinary anatomy

- » 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).
- » 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.



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.

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 is the Macroplastique treatment performed?

The procedure to inject Macroplastique can be performed in an outpatient clinic or hospital in approximately 30 minutes. Prior to the procedure, the doctor may give you an antibiotic to reduce the risk of infection. Upon the start of the procedure, the doctor may give you local anesthetic in the tissues near your bladder to reduce discomfort. At the beginning of the procedure, your doctor will fill your bladder to halfway with water or saline.

What can I expect after the procedure?

Most women can expect:

- » To stay at the clinic 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.

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.

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.

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. If your doctor thinks that it is necessary for you to receive anesthesia during the treatment, there is also a potential risk related to this.

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.