How does the Coaptite Urethral Bulking Injection work?

The Coaptite Urethral Bulking Injection bulk the area around the urethra and increases the resistance of the urethra to leak urine.

What can I expect during my procedure with the Coaptite Urethral Bulking Injection?

The procedure will take place in a doctor’s office, an outpatient surgery center or in an operating room. The procedure takes approximately 15 to 20 minutes. Your doctor will determine what type of anesthesia is best for you.

During the procedure, a needle is placed into the urethra (see Figure 2) using a cystoscope and the Coaptite Injection is injected into the tissues surrounding your urethra providing a bulking effect. The doctor removes the needle and the procedure is completed. After the procedure, you will stay in the office or recovery room for 30 minutes to make sure you are able to pass urine on your own, usually within a few hours.

Your doctor will talk to you so you know what to expect from your treatment.

Are there other options?

There are also other ways to treat your problem. They can be non-surgical, including strengthening exercises for the pelvic muscles to improve support of the bladder and urethra, and biofeedback to assist in retraining the pelvic muscles. Drugs, such asalpha blockers, may help improve retention of urine or prevent the need for storage at night. In some cases, it is helpful to work with a physical therapist to do exercises to strengthen the pelvic muscles.

How long do the benefits of the Coaptite Urethral Bulking Injection last?

Studies show that the effects of the treatment can last between one and three years.

Can I go back to my normal activity after I go home?

Your physician will give you specific instructions regarding your activity level after your procedure. Most people return to normal activity within one to two days.

What are the risks of Coaptite Injections?

The Coaptite Urethral Bulking Injection is contraindicated for patients who have an allergy to calcium hydroxylapatite. If you are pregnant, you should not have the injection.

• Narrowing of the bladder neck or urethra is called a urethral stricture. If that happens, surgery may be needed to repair the damaged tissue. In the post-market clinical study, two out of 158 patients developed this problem and had to have surgery to correct the problem.

• Contact your doctor if you have any problem that bothers you or lasts longer than 24 hours after your Coaptite Urethral Bulking Injection procedure. If you do not contact your doctor, your problem may get worse and harm you.

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What are the risks of Coaptite Injections?

In the post-market clinical study, 458 patients were treated with Coaptite Urethral Bulking Injection and followed for 36 months after initial treatment. The treatment-related adverse events reported included:

• Urinary retention (13.3%)
• Urinary tract infections (2.8%)
• Urge incontinence (1.7%)
• Micittance urgency (0.5%) Most of the adverse events listed above happened within 24 hours and went away within 30 days. Most of the adverse events were either mild (58.6%) or moderate (20%). You may require more than one treatment to achieve dryness or satisfactory improvement, or the Coaptite injection may not help at all.

So far, the Coaptite treatment has been shown to last up to 36 months. Over time, the particles should break down and be taken up by the body. Everyone is different, and it may not last as long for you.

What are the benefits of the Coaptite Urethral Bulking Injection?

The Coaptite Urethral Bulking Injection may help you if it may help you become dry or lessen the amount of urine leakages.

The Coaptite Injection is made of round particles of CaHA in a water-based gel. The body takes up the gel. The particles remain to act as a space-filling bulk, causing the closing of the urethra.

In the post-market clinical study, 198 (60.5%) of 329 patients who completed the study were improved at 16 months following treatment with the Coaptite Urethral Bulking Injection. All patients showed improvement of life scores. More than 80% of patients received only one or two injections during the three years studied. Thirty-six of 458 patients (7%) got worse after one year.

Glossary

Bladder - The organ in the lower abdomen where urine is stored for elimination from the body.
Calcium hydroxylapatite (CaHA) - A natural occurring material that is found in bones and teeth.
Coaptite Urethral Bulking Injection - A medical solution bulk that is injected into the tissues surrounding the urethra providing a bulking effect.
Contraindications - A statement in the product information that alerts you to a potentially harmful condition in which you should contact your physician.
Cystoscope - An optical instrument placed in the urethra to enable the physician to examine the bladder.
Erode/Erosion - The breakdown of the tissue that covers the Coaptite Injection material.
Exposed Bulking Material - When the Coaptite Injection leaks out of position.
Frequent Urgench - Condition where you need to go to the bathroom to urinate more than 8 or 10 times a day.
Hysterectomy - Removal of your uterus.
Micittance Urgency - Condition where you have a sudden, compelling urge to pass urine.
Periodical Vascular Disease - Damage to your blood vessels that are not in your heart and brain from diabetes, high blood pressure, high cholesterol or smoking.
Risk - Complication that may result from a procedure.
Stress urinary incontinence - A condition where you need to go to the bathroom to urinate. This may be a symptom of a stricture. Your doctor will be able to discuss the treatment options for urethral strictures.
Urethral Bulking - The injection of material (bulking agent) into the tissues surrounding the urethra to help the urethra close and avoid accidental urine leakage.
Urethral Sphincter Erode/Erosion - The breakdown of the tissue that covers the Coaptite Injection material.
Urinary Retention - Condition where you are unable to urinate because you are not able to open yoururethra.
Urinary Tract Infection - Condition where the presence of bacteria in your urine causes frequent urination and pain during urination.
Warnings - A statement in the product information that alerts you to a potentially harmful condition in which you should contact your physician.
The Coaptite™ Urethral Bulking Injection: A Natural, Non-Surgical Option for SUI Relief

The Coaptite Urethral Bulking Injection is a material that is used to bulk or “fill out” the tissues surrounding the urethra to provide additional support during physical activity in order to prevent or minimize urine leakage caused by stress urinary incontinence (Figures 2 and 3). Coaptite is made of round particles of calcium hydroxyapatite, a natural component of your teeth and bones, in a water-based gel.

This brochure will help you make a decision as to whether or not to have a urethral bulking procedure with the Coaptite Urethral Bulking Injection. Coaptite treatment is only one way to treat stress urinary incontinence. Your doctor will provide you with recommended options for treating your incontinence and help you make the right treatment decision.

Stress Urinary Incontinence (SUI)

SUI is the involuntary loss of urine during physical activity such as coughing, laughing or sneezing. The round muscle (sphincter) used to keep urine in the bladder can become weak, and urine leaks out during these activities (Figure 1). SUI can be treated both surgically and non-surgically.

More than 13 million adults have stress urinary incontinence in the United States, 85% of which are women.