

Coaptite™
Urethral Bulking Injection



Frequently asked questions about the **Coaptite™** Urethral Bulking Injection

How does the Coaptite Urethral Bulking Injection work?

The Coaptite Urethral Bulking Injection bulks 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 until 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, as well as treatment with other bulking agents, can help. Surgical procedures can repair and reposition organs, restore support to weakened pelvic muscles, or implant an artificial urinary sphincter. You should discuss these treatment options with your doctor.

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

Studies show that 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?

In the post-market clinical study, 458 patients were treated with Coaptite Urethral Bulking Injection and followed for 36 months after initial treatment.¹ The treatment-related adverse events reported included:

- Urinary retention (13.1%)
- Urinary tract infections (2.8%)
- Urge incontinence (1.7%)
- Micturition urgency (0.9%)

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 (38.1%) 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 calcium hydroxylapatite (CaHA) 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 benefit you because it may help you become dry or lessen the amount of urinary leakage.

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, 199 (60.5%) of 329 patients who completed the study were improved at 36 months following treatment with the Coaptite Urethral Bulking Injection. All patients improved in quality 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 – Sack-like 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 material used to bulk or fill out the tissues surrounding the urethra to provide additional support during physical activity. The Coaptite Urethral Bulking Injection is made of round particles of calcium hydroxylapatite.

Contraindications – A statement in the product information that, if the product is used for a certain condition, you may be harmed. For example, the Coaptite Urethral Bulking Injection is contraindicated for patients who have urinary tract infection at the time of treatment.

Cystoscope – An optical instrument placed in the urethra to enable the physician to examine directly inside the urethra and bladder.

Erode/Erosion – The breakdown of the tissue that covers the Coaptite Injection material.

Exposed Bulking Material – When the Coaptite Injection leaks out of your tissue.

Frequent Urination – Condition where you need to go to the bathroom to urinate many times during the day and night, more than 8 to 12 times a day.

Hysterectomy – Removal of your uterus.

Micturition Urgency – Condition where you have a sudden, compelling urge to urinate.

Peripheral Vascular Disease – Damage to your blood vessels that are not in your heart and brain from diabetes, high blood pressure, high cholesterol and smoking.

Risk – Complication that may result from the procedure.

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 problem in younger and middle-aged 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 leakage. Urethral bulking does not close the urethra totally; the urethra can still open normally to allow for urination.

Urethral Sphincter – A circular muscle around the urethra that opens it when you want to urinate but keeps it closed at other times.

Urethral Stricture – An abnormal narrowing or “kink” in the urethra that may prevent normal urination. The Coaptite Urethral Bulking Injection should not be used if a urethral stricture is not corrected.

Urgency – A strong desire to urinate but does not result in accidental leakage or an episode of incontinence.

Urinary Retention – Condition where you are unable to urinate because your urethra is blocked.

Urinary Tract Infection – Condition where the presence of bacteria in 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.

Contraindication

You should not have the procedure at this time if you have inflammation of the bladder (cystitis) or the urethra (urethritis) or other infections. Tell your doctor if you have pain when you urinate or if you urinate often because these may be signs of a urinary tract infection. After your infection is treated, the Coaptite Urethral Bulking Injection treatment can be considered.

Warnings

- Narrowing of the bladder neck or urethra is called a urethral stricture. Your urethra could be blocked and you may not be able to pass urine if you are treated when you have these strictures. Tell your doctor if you have to strain in order to start urinating. This may be a symptom of a stricture. Your doctor will be able to discuss the treatment options for urethral strictures.
- Safety and effectiveness of the Coaptite Urethral Bulking Injection in pregnant women is unknown. It is unknown whether the Coaptite Injection treatment will harm you or your baby if you are pregnant. It is unknown whether the Coaptite Injection treatment will relieve your stress urinary incontinence if you are pregnant.
- If your doctor injects too much of the Coaptite Injection, you may not be able to urinate. If this happens, the doctor may have to put a catheter in you until you can urinate normally.
- The Coaptite Injection may not stay in place where it is injected and this can lead to complications.
- The Coaptite Injection may erode through your tissue. 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.
- Women with peripheral vascular disease and prior pelvic surgery, e.g., hysterectomy or surgery for urinary incontinence, may be at increased risk for tissue erosion.
- Contact your doctor if you have any problem that bothers you or lasts longer than 24 hours after your Coaptite Injection bulking procedure. If you do not contact your doctor, your problem may get worse and harm you.

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

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.

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 hydroxylapatite, 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.

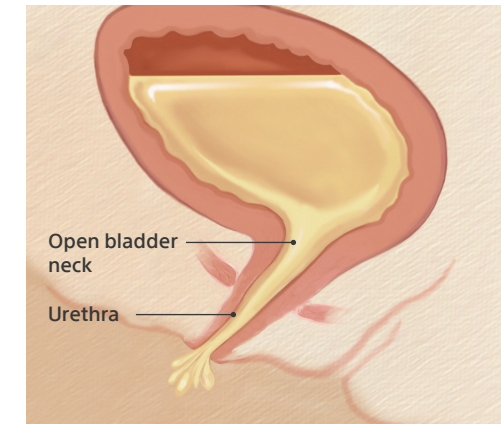


Figure 1: Before Coaptite treatment, the sphincter muscle in the urethra is weak, causing urine leakage from the bladder

Source: Marcia Williams, MWM

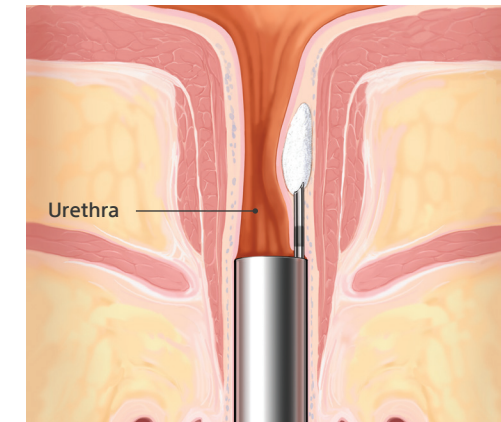


Figure 2: During Coaptite treatment, bulking material is injected into the urethra

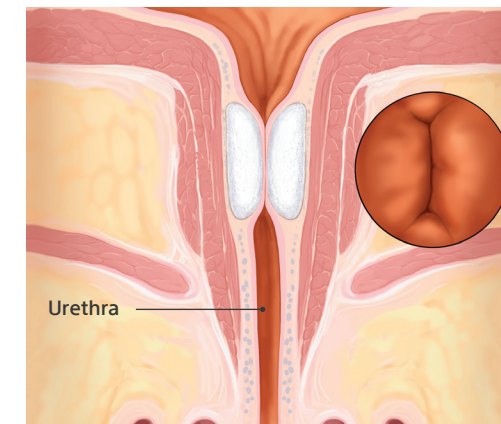
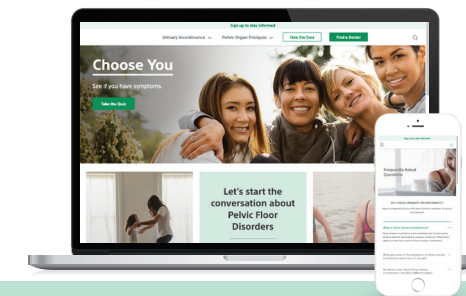


Figure 3: After Coaptite treatment, urethral tissue is “filled out,” preventing urine leakage

1. ClinicalTrials.gov Identifier: NCT00996489

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in diagnostic and therapeutic cystoscopy.

All images are the property of Boston Scientific. All trademarks are the property of their respective owners.



Learn more about stress urinary incontinence (SUI) and watch patient stories at [chooseyou.com](https://www.chooseyou.com)

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

© 2020 Boston Scientific Corporation
or its affiliates. All rights reserved.

WH-505519-AB JAN 2020

Boston Scientific
Advancing science for life™

CONTENT IS PROVIDED BY BOSTON SCIENTIFIC. BOSTON SCIENTIFIC IS DEDICATED TO TRANSFORMING LIVES THROUGH INNOVATIVE MEDICAL SOLUTIONS THAT IMPROVE THE HEALTH OF PATIENTS AROUND THE WORLD.