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Coaptite™

Urethral Bulking Injection

Best Practices

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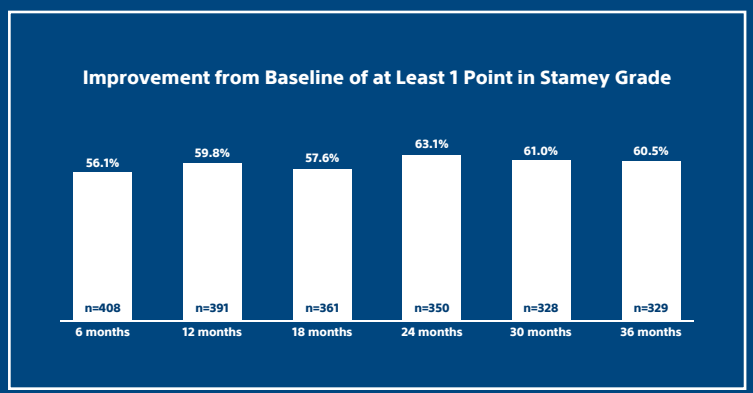
These tips were developed with input from three physician experts. This piece is intended to describe common clinical considerations and procedural steps for the on-label use of referenced technologies as well as current standards of care for certain conditions. Of course, patients and their medical circumstances vary, so the clinical considerations and procedural steps described may not be appropriate for every patient or case. As always, decisions surrounding patient care depend on the physician's professional judgment in light of all available information for the case at hand.

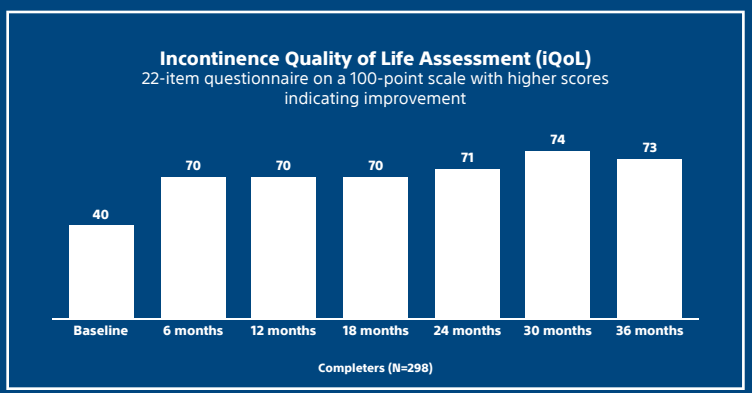
Best Practices in Coaptite™ Urethral Bulking Injection

Urethral bulking provides a minimally invasive option for effective relief of stress urinary incontinence (SUI). Coaptite Urethral Bulking Injection is a natural, well-studied option that offers both procedural ease-of-use and durability. In clinical studies, Coaptite has maintained high success rates through three years.[1]

Drs. Tara Allen, Roger Goldberg and Edward Levy have more than 50 years of combined experience using Coaptite. This best practice guide was developed based on their experience performing the procedure in the office, ambulatory surgery center and hospital.

Coaptite Urethral Bulking Injection Maintains High Success Rates and Improved Quality of Life Through 3 Years[1]





Patient Considerations

Patient Selection

Women who suffer from SUI caused at least in part by intrinsic sphincter deficiency (ISD) may benefit from Coaptite. For some, it is a bridge procedure until they can get a sling. For others, it may be their only option given concomitant medical conditions or other issues that make them ineligible for more invasive procedures.

Consider these factors when identifying possible candidates for bulking:

Mesh-averse

Of childbearing age and looking for non-surgical options

Has a fixed urethra for which there are minimal therapeutic alternatives

High surgical risk, such as those who cannot stop anticoagulant medication for surgery

Has atrophy or has had previous pelvic floor surgery resulting in the vagina being too narrow for a sling

Unwilling to have surgery but desires symptom relief

Of geriatric age and has had unsuccessful prior attempts to achieve continence

Has residual stress incontinence following a sling or bladder neck suspension procedure

Unable to adhere to post-surgical restrictions of more invasive procedures

There are also some populations for whom urethral bulking may not be ideal, such as patients with non-viable tissue (history of significant pelvic irradiation, multiple pelvic surgeries, etc.). Scar tissue and significantly compromised tissue will not coapt appropriately.

Patient Workup

- A history and physical should be documented in each patient's chart.
- Confirming the SUI diagnosis and that the patient is an appropriate candidate for urethral bulking can be done using a stress test to verify leakage and a post-void residual to ensure they are emptying well.
- Urodynamic testing is helpful in ruling out the contraindication of retention and for identifying concurrent overactive bladder, which may decrease success.
- A urinalysis and urine culture are also recommended since patients with an active urinary tract infection should be treated before injection.

Patient Counseling

- Urethral bulking often requires multiple procedures over time to maintain satisfactory long-term results. It is important to set expectations that a re-injection may be needed.
- Patients should be informed of the importance of balancing the desire for improvement with the risk of urinary retention from over-injection.

For more information to share with patients, download the Boston Scientific Coaptite patient brochure.

Supplies, Room Setup and Scope Selection

Scope Selection

Coaptite consists of a simple delivery system and is compatible with many scopes. Specialized injection scopes minimize the technical challenges associated with the procedure and facilitate reproducible results.

However, experienced scope operators can achieve similar results with cystoscopes that have a working channel all the way down the length of the scope.

Injection scope

An injection scope provides the greatest precision and stability. It is recommended for physicians purchasing new equipment to perform urethral bulking procedures. This scope also can be used for other types of in-office injections.

Cystoscope

Allows for ease when directing and controlling the needle. The following specifications are recommended:

- 17 Fr., but larger sizes can be used. It is best to try the needle on the scope prior to the case to ensure proper fit.
- 5 – 7 Fr. working channel to accommodate the Sidekick™ Injection Needle

(14.6 inch, 21 gauge).

- 30° telescope allows better visualization of the needle point (most commonly used). Some physicians also use 0° and 12° telescopes.
- Short beak preferable.

Scope Best Practices

Working element with a full-length bridge provides more needle stability/control than working element without a full-length bridge.

If you do not have an injection scope or full-length bridge, you may want to consider using an Albarran Deflector (Bridge). It can help stabilize the needle.

For more information to share with patients, download the Boston Scientific Scope Compatibility Guide.

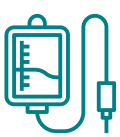
Bulking Procedure Fundamentals

Training & First Procedures

- If you are new to urethral bulking, it is recommended to do your first 5–10 procedures with the patient sedated. This will allow you to become comfortable with the procedure and the flexibility to take it slow without the pressure of the patient being awake, moving or in discomfort.
- You may want to consider practicing with urethral bulking models to help shorten the learning curve.
- Having someone proctor the first few cases can also help in providing guidance and support, as it may take some time to get comfortable with the technique and variations in urethral anatomy.

Anesthesia

- Some physicians prefer to perform urethral bulking using general anesthesia for patient comfort and ease of doing the procedure without patient movement.
- The majority of Coaptite injections can be done with local anesthesia in the office or outpatient setting. In those cases, you can use URO-Jet lidocaine to numb the peri-urethral area, depending on physician discretion; give ample time for the anesthesia to take effect.
- You can also apply local anesthetic prior to the lidocaine injection to improve the patient experience.
- Patient distraction during this time is also helpful to minimize pain and movement.



IV Fluids

- You should empty the bladder before injecting Coaptite.
- Saline should be used to get enough flow through the urethra to open it a little. One liter of saline should be more than enough without over-distending the bladder.

Troubleshooting: Clogged Needle

- In rare instances, the needle may clog. Clogging usually occurs either because the needle was primed too early, leading to solidification of the bulking material, or the material is being injected too rapidly, which causes the diluent to be injected ahead of the bulking material.
- If you experience clogging, you may find simply changing the needle is all you need, and the remaining Coaptite in the syringe can still be used. In some cases, you may need to start over with a new needle and syringe.
- Don't try to force it, as this could lead to injecting more Coaptite than intended.

Room Setup/OR Prep

Always be sure to follow your office's or institution's room setup and sterile procedures. The following items are typically needed for a Coaptite procedure:

- ☐ **2 – 4 Coaptite syringes in room (leave cap on end until ready to use); extra in stock**
- ☐ **URO-Jet lidocaine or BLT (benzocaine, lidocaine, tetracaine) cream**
- ☐ **Coaptite Sidekick™ Injection Needle (1 open, 1 on standby)**
- ☐ **Chuck pads for under buttocks to soak up fluid**
- ☐ **Lubricant for end of scope**
- ☐ **Cysto tubing and stopcock**
- ☐ **PPE and gown/apron (optional)**
- ☐ **1–2 1L bags of sterile water**
- ☐ **Cidex™ solution for cleanup**
- ☐ **Sterile 4x4 gauze pads**
- ☐ **Video setup**
- ☐ **Light source**
- ☐ **Drain pan**
- ☐ **Sterile gloves**
- ☐ **Stirrups on table**
- ☐ **IV pole**

Concomitant Procedures

- It is not recommended that you do other procedures simultaneously. In the event there are complications, you want to be able to trace back to the cause.

Measuring Success of the Procedure

- As with most urinary incontinence procedures, the typical measure of whether the bulking procedure is successful is symptom relief and patient satisfaction. Some patients may not achieve complete dryness, but they might still feel very satisfied with their improvement.

Discharge Instructions

- After the procedure, ask the patient to void, with the goal of having a strong flow and at least 200 cc emptied.
- To detect possible retention issues, a bladder scan may be used to determine post-void residual volume. The residual should be half the void volume and preferably 100 cc or less.
- If the patient is unable to void, straight catheterize and empty the bladder, and then have the patient void prior to discharge. It is common that the initial void after the procedure may be difficult if the bladder is very full and local anesthesia has been used. Typically, patients who fail to void initially will be able to void after the bladder is emptied once.
- If transient urinary retention persists, you can either teach the patient intermittent self-catheterization (usually needed less than 24 hours), or you can send the patient home with an indwelling 12 Fr. foley catheter and have her come back to the office the next day for removal and evaluation.

Discharge instructions should review:

- Possibility of retention and how to manage. Patients should be instructed to call the office first, but if they have to go to the ER, they should get an in and out catheterization.
- Risk of UTIs is low (2.8% in three-year data).
- Activity restrictions, such as not straining the pelvic area for a few days after the procedure.
- Likelihood of Coaptite floating in the urine and some bleeding for a couple of days.

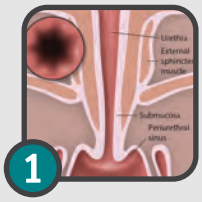
Follow-up Procedures

- It is up to the physician's discretion on when a patient should return for follow-up; however, it is recommended between two and four weeks. At this time, you can assess how the patient is doing using subjective measures and check post-void residual with a bladder scan to make sure the patient isn't retaining urine.
- If the patient is still leaking, you also can do a cough stress test in the office to try to visualize it.
- If the patient has at least some improvement, this shows proof of concept that urethral bulking is effective and a reinjection may be done.
- At the second injection, you might try different things to improve results; if the first injection was at the urethrovesical junction, then the second time you might want to go distal to that first one and inject more at the level of the mid-urethra rather than inject right at the site of the previous injection.
- If you've done two procedures and the patient does not show any improvement, it is unlikely that future injections would be effective.
- Even though you usually know right away if the patient needs an additional injection, when you can reinject may vary depending on the patient's insurance coverage.

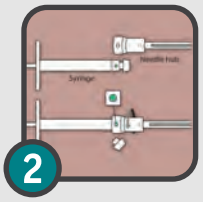
Reimbursement

- Due to unique reimbursement scenarios at practices and hospitals, certain considerations may need to be taken into account. Topics for consideration include need for pre-authorization, language that needs to be noted in the chart (e.g., failed non-surgical, physical and behavioral therapy) in order for insurance to be approved, and when patients are eligible to return for subsequent injections from an insurance provider's perspective.

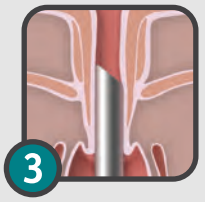
Coaptite Urethral Bulking Injection Step-by-Step Instructions



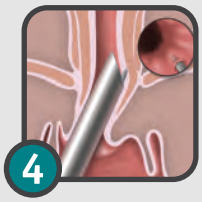
The objective of the Coaptite Urethral Bulking Injection procedure is to obtain closure at the bladder neck to mid-urethra by injecting Coaptite until the tissue of the bladder neck and/or urethra coapts.



Using standard procedure, prepare the patient for cystoscopy. Connect the Coaptite Injection syringe to the needle by turning the needle hub 1-1/2 turns ensuring that one green dot on the syringe is visible through the window on the needle hub. Prime the needle as the last step immediately before inserting needle into scope.

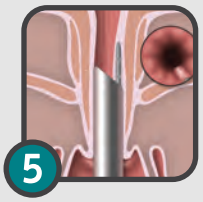


Insert the primed needle into the port of the scope. Insert the scope into the urethra.

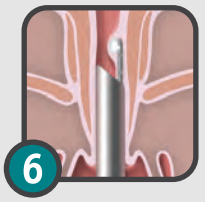


At the mid-urethra, position the needle bevel towards the urethral lumen at a 4 o'clock position.

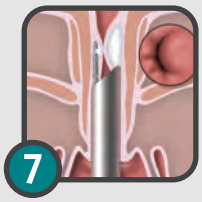
Puncture the tissue at a 45° angle until the bevel of the needle is covered in tissue and advance until the first circumferential marking.



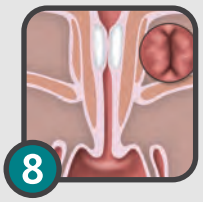
Re-angle the scope back parallel to the urethra. Tunnel the needle tip in the direction of the bladder neck until the second circumferential marking on the needle. After tunneling, the needle tip should lie at the proximal urethra.



Begin injecting Coaptite using slow, consistent, and moderate thumb pressure on the syringe plunger to dispense the particles and gel evenly into the tissue. The submucosal lining should begin to rise at the site of the injection unilaterally. Continue to inject Coaptite into this site until the bleb has crossed the midline of the urethra. Pause for a minimum of 10 seconds to reduce extravasation, and then remove the needle.



Repeat steps 2-6 on the contralateral side at the eight o'clock position.



Continue to inject Coaptite until the tissue of the bladder neck and/or urethra coapts. The bladder neck/or urethra should be closed when viewed with cystoscopic irrigation on.

The combination of Coaptite (CaHA) and the carrier gel Sodium Carboxymethylcellulose (NaCMC) helps to establish an even distribution of particles with a degree of interstitial space that provides coaptation at the mid-urethra. The carrier gel is gradually absorbed and replaced by the surrounding cells.

Injection Tips:

Do not open the syringe or prime your injection needle until right before you start.

It is important to **secure the syringe tightly to the needle** in order to prevent air from entering the system, which can cause clogging.

You have the **option to orient the bevel of the needle toward or away from the urethral lumen**, depending on what works best for you.

In cases of **reinjection, it may be appropriate to place the needle and implant at a spot where there is relative "underbulking"** seen cystoscopically rather than in the same location as original injection.

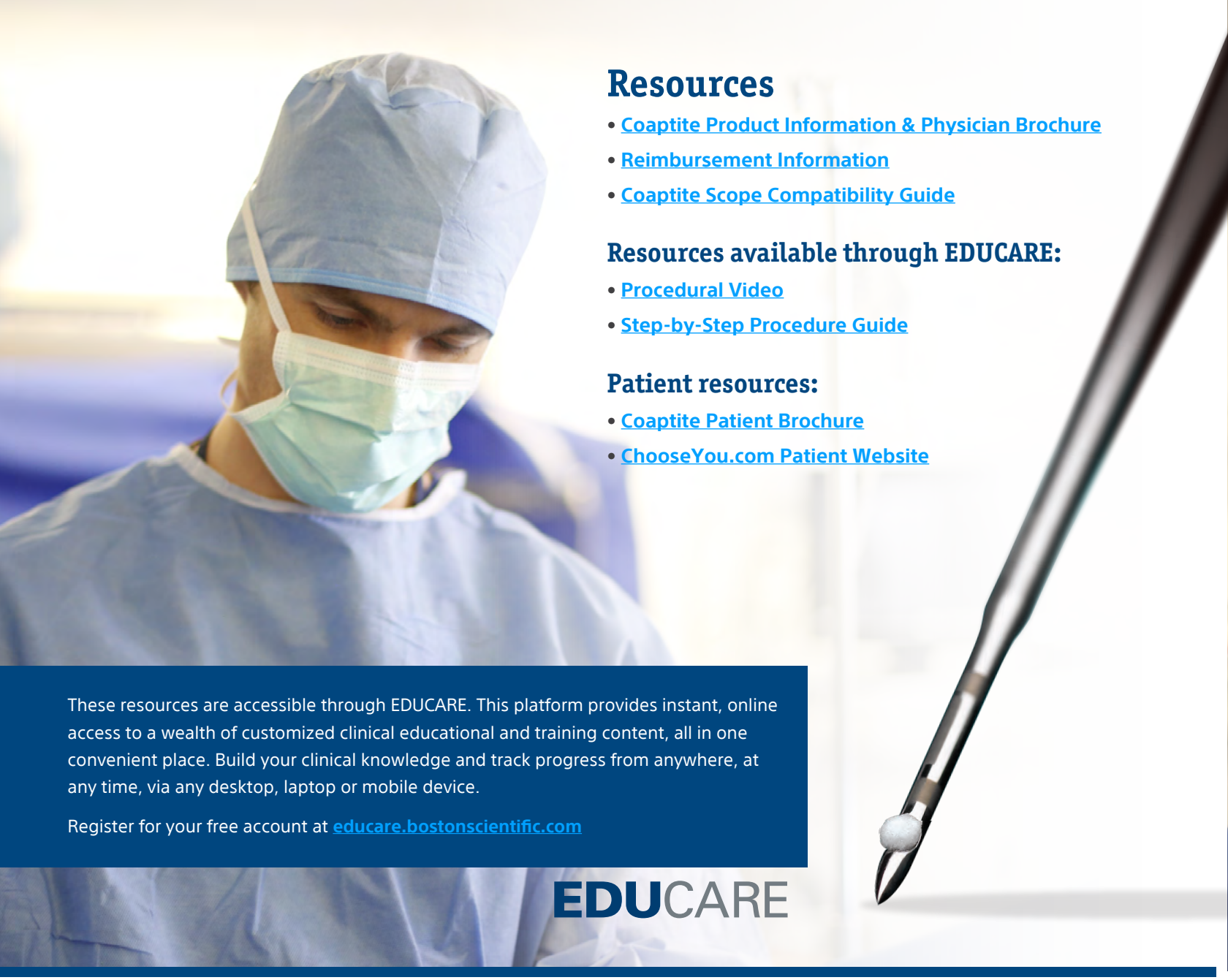
Usually two separate injections are performed, but this may vary from 1-4 depending on the patient's anatomy.

If **extrusion of Coaptite** around the needle occurs, **choose another injection spot in the urethra**.

Watch how the tissue behaves as you're injecting. If you don't see bulking, you are probably too deep. If you see the beadiness of the bulking material through the skin, you are too shallow. In either of these cases, remove the needle and try again. **Ideally, a bilateral bulking effect is seen**, but complete coaptation is not necessary to achieve a successful result.

If bulking is not seen as the Coaptite is injected, withdraw the needle 1-2mm. Sometimes the needle may extend beyond submucosa causing injection into the periurethral tissue. In such cases, after withdrawing the needle slightly, the bulking effect is usually seen.

For short urethras, as with typical cases, make sure to keep the fluid going so the urethra doesn't close up. It also may be necessary to alter your injection angle to achieve optimal bulking with shorter urethras.



Resources

- Coaptite Product Information & Physician Brochure
- Reimbursement Information
- Coaptite Scope Compatibility Guide

Resources available through EDUCARE:

- Procedural Video
- Step-by-Step Procedure Guide

Patient resources:

- Coaptite Patient Brochure
- ChooseYou.com Patient Website

These resources are accessible through EDUCARE. This platform provides instant, online access to a wealth of customized clinical educational and training content, all in one convenient place. Build your clinical knowledge and track progress from anywhere, at any time, via any desktop, laptop or mobile device.

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IMPORTANT INFORMATION: These materials are intended to describe common clinical considerations and procedural steps for the use of referenced technologies but may not be appropriate for every patient or case. Decisions surrounding patient care depend on the physician's professional judgment in consideration of all available information for the individual case. Boston Scientific (BSC) does not promote or encourage the use of its devices outside their approved labeling. Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

Coaptite Injectable Implant: Refer to Coaptite Injectable Implant Instructions for Use provided with product for complete instructions for use.

INDICATIONS: Coaptite Injectable Implant is indicated for soft tissue augmentation in the treatment of stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in adult females. **CONTRAINDICATIONS:** The Coaptite Injectable Implant is contraindicated for use in a patient: who has significant history of urinary tract infections without resolution; who has current or acute conditions of cystitis or urethritis; who has fragile urethral mucosal lining. **POTENTIAL ADVERSE EFFECTS** that may occur include: genitourinary adverse events (i.e., urinary retention, hematuria, dysuria, UTI, urinary urgency and frequency), erosion, erythema, embolic phenomena, and vascular occlusion. **WARNINGS:** Note: Failure to follow any instructions or to heed any Warnings or Precautions could result in serious patient injury. **WARNING:** Following injection of Coaptite Implant, dissection of the device through tissue may lead to 1) tissue erosion and may require corrective surgery or 2) elevation of the bladder wall causing ureteral obstruction. This may be caused by improper injection technique using Coaptite Implant. (See adverse event section in IFU for further information.) **WARNING:** Women with peripheral vascular disease and prior pelvic surgery may be at increased risk for tissue erosion following injection of Coaptite Implant. (See adverse event section in IFU for further information.) Please refer to complete instructions for use for a complete listing of all warnings and potential adverse effects. **CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in diagnostic and therapeutic cystoscopy.** WH-550709-AA

Reference:
1. Post-approval of Coaptite® in the Treatment of Female Urinary Incontinence Post-market Study. Clinical Study Report Protocol #P1005185. Merz North America, Inc. Coaptite P040047/R027. OSB Lead PMA Post-Approval Study Report. June 14, 2018.

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