**Coaptite™**

**Injectable Implant**

**Coaptite Injectable Implant** is designed to offer improved procedural ease of use, fewer re-injections, and less material volume versus another approved bulking agent while maintaining the durability characteristics of a synthetic product.

**Ease of Use**
- A 21 gauge needle is designed to reduce product extravasation and surrounding tissue trauma.
- No refrigeration storage is required for the Coaptite Implant.
- No skin test is required.

**Less Material Volume**
- Coaptite Implant patients required 37% less material volume upon first injection. In total injections, Coaptite Implant patients required 41% less material volume during the PMA clinical trial (Fig 2).
- Less material volume means fewer syringe exchanges potentially reducing the risk of needle movement during injections and less time in the procedure.
- Less material volume injected reduces cost to the facility and to the patient.

**For effectiveness, durability and ease of use... it’s a natural**

The combination of calcium hydroxylapatite (CaHA) particles and the sodium carboxymethylcellulose (NaCMC) carrier gel form a scaffold that promotes tissue infiltration. The Coaptite Implant particles are composed of the same components that are found in bone and teeth, and are biocompatible.

**Picrosirius Red Staining for Collagen (Fig. 3)**

The Coaptite Implant promotes tissue ingrowth in the urethra.

Note absence of red stain around particles which indicates lack of new collagen infiltration.

*Note presence of red stain around particles which indicates new collagen infiltration.*

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PMA Clinical Trial. Data on file at Merz Aesthetics, Inc. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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**Commitment to Clinical**

Boston Scientific is committed to providing products that meet the clinical standards of the physician community.

**Effectiveness and Durability**

**Less Material Volume**
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- Less material volume injected reduces cost to the facility and to the patient.
Procedural Steps

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

Using standard procedure, prepare the patient for cystoscopy. Connect the Coaptite Implant 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.

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. Do not insert past the bevel.

Re-angle the scope back parallel to the urethra. Using the circumferential markings on the needle as a guide, tunnel the needle tip towards the bladder neck depending on the approximated length between the mid-urethra and bladder neck. After tunneling, the needle tip should lie at the proximal urethra.

Begin injecting Coaptite Implant using slow, consistent, and moderate thumb pressure on the syringe plunger. The submucosal lining should begin to rise at the site of injection and should flow unilaterally. Continue to inject Coaptite Implant into this site until the bleb has crossed the midline of the urethra.

Repeat steps 2–6 on the contralateral side at the eight o’clock position.

The objective of the procedure is to obtain closure at the bladder neck to mid-urethra. Continue to inject Coaptite Implant until the tissue of the bladder neck and/or urethra coapts. The bladder neck/urethra should be closed when viewed with cystoscopic irrigation on.

The combination of Coaptite (CaHA) Implant and the carrier gel Sodium Carboxymethylcellulose (NaCMC) help to establish an even distribution of particles with a degree of interstitial space that promotes collagen infiltration. The carrier gel is gradually absorbed and replaced by the surrounding cells.