Coaptite Brief Summary

Indications for Use: The COAPTITE™ Injectable Implant is indicated for soft tissue augmentation in the treatment of stress urinary incontinence (SUI) due to intrinsic sphincteric 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 EVENTS that may occur include:
Urinary Tract Infection, Cystitis, Vulvovaginal Mycotic Infection, Urinary Retention, Urge Incontinence, Micturition Urgency, Pollakiuria, Hematuria, Nocturia, Urethritis non-infective, Hemorrhage Urinary Tract, dysuria, 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 The COAPTITE Injectable 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 The COAPTITE Injectable Implant. Women with peripheral vascular disease and prior pelvic surgery may be at increased risk for tissue erosion following injection of The COAPTITE Injectable Implant.
- The COAPTITE Injectable Implant in patients with urethral or bladder neck strictures should not be used until the strictures have been corrected.
- Use in patients with strictures may cause injury and/or urethral obstruction.
- Avoid using in patients with non-viable tissue, e.g., history of significant pelvic irradiation, multiple pelvic surgeries, etc. Scar tissue and significantly compromised tissue will not coapt appropriately.
- Avoid using in patients with very short urethras and who have had multiple surgeries for stress incontinence. These patients may experience urethral caruncle formation.
- Over correction using the COAPTITE Injectable Implant may lead to obstruction.
- Avoid injecting in blood vessels. The COAPTITE Injectable Implant injection into blood vessels may cause vascular occlusion

PRECAUTIONS:

- The long-term safety and effectiveness of the COAPTITE Injectable Implant treatment has not been established.
- Safety and effectiveness of the COAPTITE Injectable Implant in patients with the following conditions has not been established - Urinary incontinence due to detrusor

instability, Bladder neuropathy, Nocturnal enuresis (bed wetting), Prolapsed bladder, Overflow incontinence, Functional incontinence.

- Safety and effectiveness of the COAPTITE Injectable Implant in patients that are pregnant, or lactating has not been established.
- The effect of the COAPTITE Injectable Implant on subsequent pregnancy and delivery, and the impact of subsequent pregnancy on the effect of the COAPTITE Injectable Implant, is unknown. Therefore, the risks and benefits of the implant in women of childbearing potential should be carefully assessed.
- Patients should be counseled that one or more repeat injection procedures may be required to achieve dryness or a satisfactory level of improvement in urinary incontinence.

Disclaimers: Please refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in diagnostic and therapeutic cystoscopy.

Coaptite Injectable Implant is commonly referred to as Coaptite Urethral Bulking Injection

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