Coaptite®

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use
The COAPTITE Injectable Implant is injected sub-mucosally at the bladder neck. The injection creates increased tissue bulk and soft tissue augmentation of the bladder neck and/or urethra. The gel carrier suspends the CaHA particles and allows delivery through injection needles and is dissipated in vivo, while the CaHA particles remain at the injection sites and provide the tissue bulking to cause coaptation of the urethra and increase urethral resistance to urine leakage.

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
- In patients with significant history of urinary tract infections without resolution.
- In patients with current or acute conditions of cystitis or urethritis.
- In patients with fragile urethral mucosal lining.

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. (See POST-APPROVAL STUDY section of the directions for use for further information.)
WARNING: Women with peripheral vascular disease and prior pelvic surgery may be at increased risk for tissue erosion following injection of the COAPTITE Injectable Implant. (See POST-APPROVAL STUDY section of the directions for use for further information.)

Warnings
- 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.
- Injections of the COAPTITE Injectable Implant should only be performed by physicians who have experience with diagnostic and therapeutic cystoscopic procedures.

Adverse Events
- Urinary Tract Infection
- Fungal Infection
- Cystitis
- Vulvovaginal Mycotic Infection

- Urinary Retention
- Urge Incontinence
- Micturition Urgency
- Pollakiuria
- Hematuria
- Nocturia
- Urethritis noninfective
- Hemorrhage Urinary Tract
- Cystocele
- Hemorrhage

Precautions

- The long-term safety and effectiveness of the COAPTITE Injectable Implant treatment has not been established.
- Safety and effectiveness of periurethral injection of the COAPTITE Injectable Implant has not been established.
- Safety and effectiveness of the COAPTITE Injectable Implant in men 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.
- Do not re-sterilize. The COAPTITE Injectable Implant is supplied sterile and non-pyrogenic in a sealed foil pouch and is intended for single use only. The foil pouch should be carefully examined to verify that neither the pouch nor the syringe has been damaged during shipment.
- Do not use if the foil pouch is compromised or the syringe has been damaged.
- Do not use if the syringe end cap or syringe plunger are not in place or removed.

Precautions can be found in the product labeling supplied with each device.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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