



Coaptite® Injectable Implant **Ordering Information**

Order Number	Description
M0068903000	Coaptite Injectable Implant, 1 ml syringe each
M0068903020	Rigid Needle 14.6 inch, 21g

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.**

Manufactured by:

BioForm Medical, Inc.
4133 Courtney Road, Suite 10
Franksville, WI 53126
Toll Free: 866-862-1211

Distributed by:

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com/urology

Ordering Information
1.888.272.1001

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