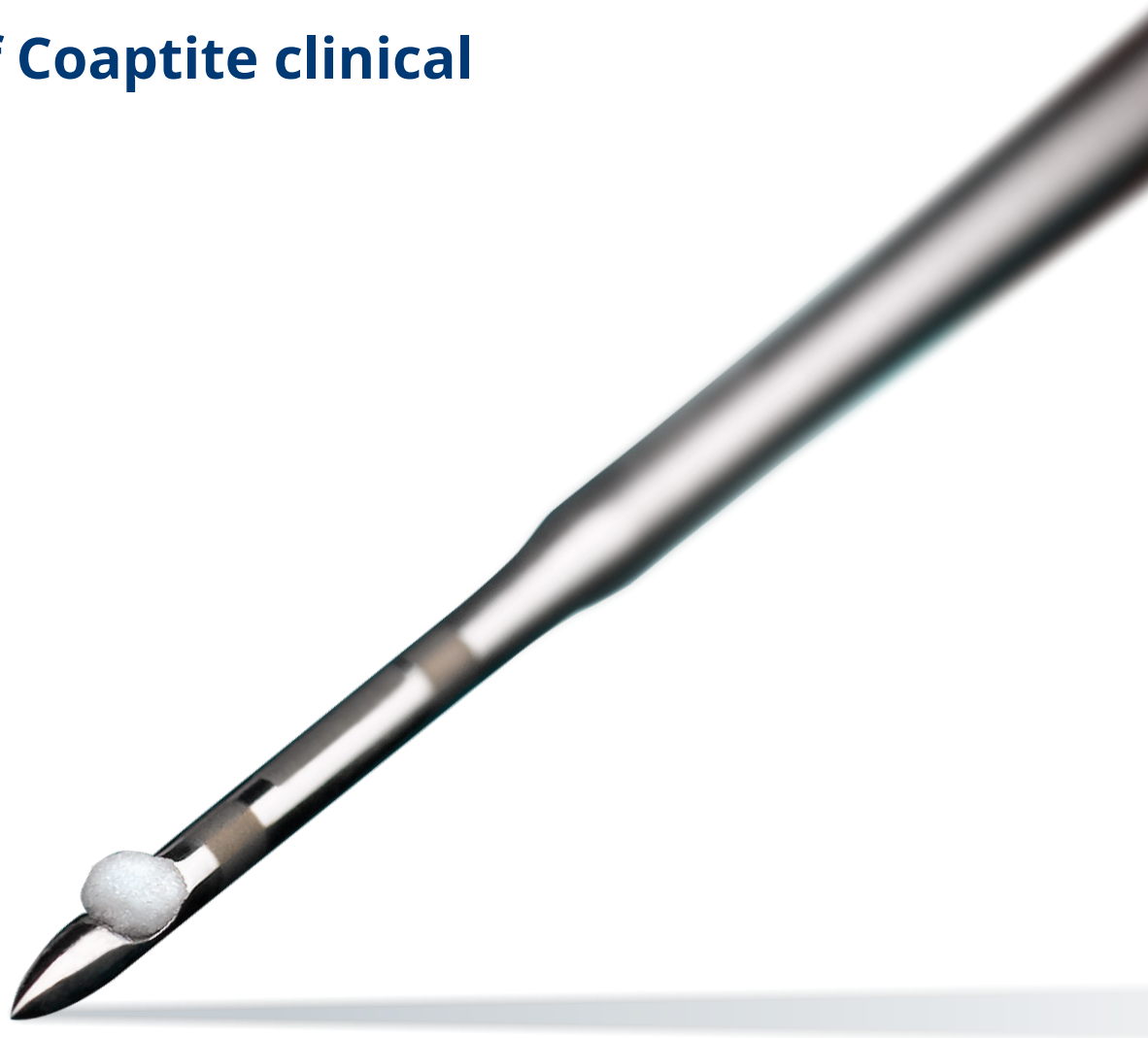
MERZ THERAPEUTICS

Coaptite®

Injectable Implant

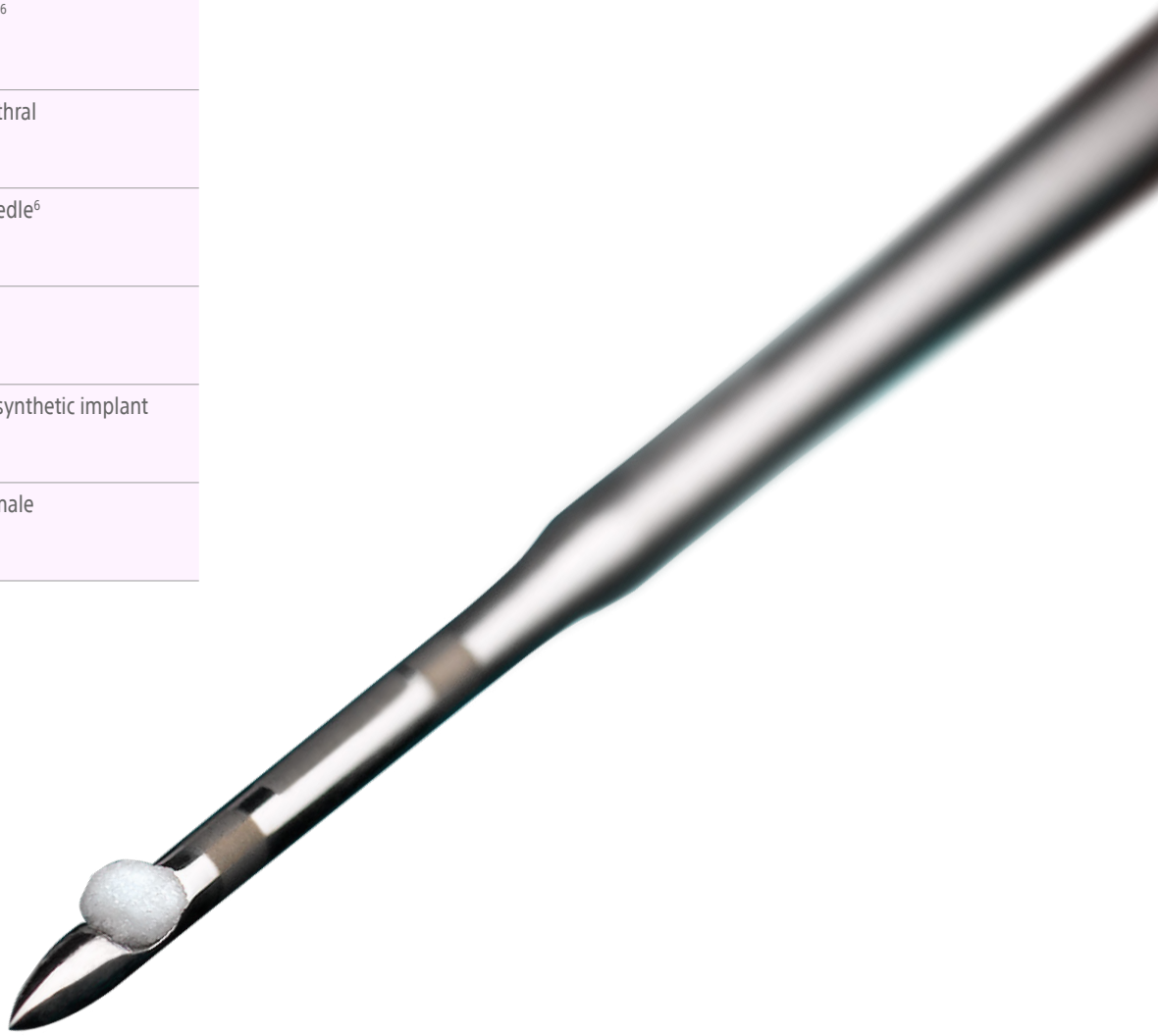
Summary of Coaptite clinical trial



A natural, minimally invasive option for effective SUI relief

Summary of Coaptite Clinical Trial

Product features	Coaptite® Injectable Implant
Agent components	75-125 µm Calcium Hydroxylapatite (CaHA) particles[2]
Carrier gel	Sodium carboxymethyl cellulose (NaCMC), sterile water for injection, and glycerin[2]
Available syringe sizes (injection volume)	1 ml[6]
Needle gauge	21 gauge[6]
Approaches	Transurethral
Needle type	Rigid Needle[6]
Ancillary components	None
Reimbursement path (per ml used)	L8606 – synthetic implant
Patient population (United States)	Adult female



Summary of clinical trials

Clinical study evaluating Coaptite® Injectable Implant[1]

36 months

Study parameter	Coaptite® Injectable Implant
12 month efficacy ≥ 1 Stamey Grade	59.8% (N=234/391)
24 month efficacy ≥ 1 Stamey Grade	63.1% (N=221/350)
36 month efficacy ≥ 1 Stamey Grade	60.5% (N=199/329)
% Receiving 1 treatment	42.8% (N=196/458)
% Receiving > 1 treatment	57.2% (N=262/458)
Initial volume (ml) / patient (mean)	1.8 ml (N=458)
Total volume (ml) / patient (mean)	3.3 ml (N=458)

Treatment and follow-up included patients with at least one observed follow-up.

Clinical study evaluating Coaptite® Injectable Implant[2]

12 months

Study parameter	Coaptite® Injectable Implant	Control
Baseline pad weight (mean)	74.8 grams (N=158)	85.3 grams (N=138)
12-month efficacy ≥ 1 Stamey Grade	63.4% (83/131)	57.0% (57/100)
Patients receiving a single treatment	37.4% (49/131)	27.0% (27/100)
Patients receiving more than one treatment[3]	62.6% (82/131)	73.0% (73/100)
Mean initial volume injected per patient	2.2 ml (N=131)	3.3 ml (N=100)
Mean total volume injected per patient	4.0 ml (N=131)	6.8 ml (N=100)

Treatment and follow-up included patients with complete 12-month follow-up.

Coaptite® Injectable Implant

Ordering information

Order Number	Description
8005M0	Coaptite Injectable Implant, 1 ml syringe (each)
9012M0	Rigid Needle, 14.6 inch, 21 gauge (each)

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
2. Mayer RD, Dmochowski RR, Appell RA, et al. Multicenter prospective randomized 52-week trial of calcium hydroxylapatite versus bovine dermal collagen for treatment of stress urinary incontinence. Urology. 2007;69(5):876-880.
3. US Food and Drug Administration. Summary of Safety and Effectiveness Data for Coaptite. https://www.accessdata.fda.gov/cdrh_docs/pdf4/p040047b.pdf. Accessed October 9, 2024.

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.

Precaution: 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. 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.

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