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Coaptite™

Injectable Implant

Summary of bulking agents and their respective clinical trials

A natural, minimally invasive option for effective SUI relief

Summary of bulking agents

Product features	Coaptite™ Injectable Implant	Bulkamid® Injection	Macroplastique® Injection	Durasphere® EXP Injection
Agent components	75-125 µm Calcium Hydroxylapatite (CaHA) particles[2]	Polyacrylamide hydrogel (PAHG; 2.5% polyacrylamide and 97.5% water)[7]	120-600 µm silicone elastomer[8]	212-500 µm pyrolytic carbon-coated zirconium oxide beads[5]
Carrier gel	Sodium carboxymethyl cellulose (NaCMC), sterile water for injection, and glycerin[2]	Water[7]	Polyvinylpyrrolidone (PVP) gel	Beta-glucan and water gel[5]
Available syringe sizes (injection volume)	1 ml[6]	1 ml x 2 syringes per kit[7]	2.5 ml	1 ml and 3 ml[9]
Needle gauge	21 gauge[6]	23 gauge[7]	18 and 20 gauge[8]	18 and 20 gauge[9]
Approaches	Transurethral	Transurethral	Transurethral	Transurethral and Periurethral
Needle type	Sidekick™ Rigid Needle[6]	Rigid needle[7]	Uroplasty Rigid Endoscopic Needle[4]	Pencil Point Tip Needle Bent Spinal Tip Needle[9]
Ancillary components	None	Rotatable sheath, reusable cystoscope (2.7 x 113 mm, 0°) is provided separately[7]	Administration device[4]	None
Reimbursement path (per ml used)	L8606 – synthetic implant	L8606 – synthetic implant	L8606 – synthetic implant	L8606 – synthetic implant
Patient population* (United States)	Adult female	Adult female	Adult female	Adult female

* At time of publication
Data on File at BSC

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	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.

Clinical study evaluating Bulkamid® Injection[3]

12 months

Study parameter	Bulkamid Injection	Control
No. of incontinence episodes/3 consecutive days*	3.3	3.0
12-month efficacy ≥ 50% decrease in pad weight & UI episodes	53.2% (75/141)	55.4% (36/65)
Patients receiving a single treatment	22.7% (52/229)	33.0% (38/115)
Patients receiving more than one treatment	77.3% (177/229)	67.0% (77/115)
Mean initial volume injected per patient	1.6 ml (N=229)	4.7 ml (N=115)
Mean total volume injected per patient	3.3 ml (N=229)	8.6 ml (N=115)

* Baseline pad weight not provided

Clinical study evaluating Macroplastique® Injection[4]

12 months

Study parameter	Macroplastique Injection	Control
Baseline pad weight	28 grams (N=126)	28 grams (N=130)
12-month efficacy ≥ 1 Stamey Grade	61.5% (75/122)	48.8% (60/125)
Patients receiving a single treatment	47.5% (58/122)	41.3% (52/126)
Patients receiving more than one treatment	52.5% (64/122)	58.7% (74/126)
Mean initial volume injected per patient	4.6 ml (N=122)	4.6 ml (N=126)
Mean total volume injected per patient	6.8 ml (N=122)	7.2 ml (N=126)

Treatment and 12-month follow-up for patients in the "Intent-to-Treat" and "Per Protocol" groups.

Summary of clinical trials (continued)

Clinical study evaluating Durasphere® EXP Injection[5]

12 months

Study parameter	Durasphere EXP Injection	Contigen Injection*
Baseline pad weight (mean)	46.4 grams (N=178)	41.5 grams (N=177)
12-month efficacy ≥ 1 Stamey Grade	66.1% (76/115)	65.8% (79/120)
Patients receiving a single treatment	43.0% (49/115)	N/A
Patients receiving more than one treatment	57.4% (66/115)	N/A
Mean initial volume injected per patient	4.8 ml (N=115)	6.2 ml (N=120)
Mean total volume injected per patient	7.6 ml (N=115)	9.6 ml (N=120)

Treatment and follow-up included patients with complete 12-month follow-up.
* Contigen Injection was discontinued in 2011.

Coaptite™ Injectable Implant

Ordering information

Order Number	Description
M006**8903000**	Coaptite Injectable Implant, 1 ml syringe (each)
M006**8903040**	Sidekick™ Needle, 14.6 inch, 21 gauge (each)

Stamey Grade scale

Grade	Description[2]
0	Continent (dry)
1	Urine leakage is associated with vigorous activities such as lifting weights, coughing or sneezing, but never in bed at night.
2	Urine leakage is associated with activities of minimal stress, such as walking or standing.
3	Urine leakage occurs at all times regardless of activity or position.

1. Coaptite Post-Approval Clinical Study
2. Coaptite Summary of Safety and Effectiveness Data
3. Sokol ER, Karram MM, Dmochowski. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: A randomized, prospective, multicenter North American study. *J Urol*. 2014 Sep;19 (3):843-9.
4. Macroplastique Summary of Safety and Effectiveness Data
5. Durasphere Summary of Safety and Effectiveness Data
6. Coaptite Injectable Implant Instructions for Use
7. Bulkamid Summary of Safety and Effectiveness Data
8. https://www.cogentixmedical.com/hubfs/docs/Resource_Center/Macroplastique/Macroplastique_Product_Brochure.pdf Accessed 1/10/2022
9. https://www.coloplast.us/durasphere-exp-en-us.aspx#section=product-variants_4 Accessed 1/10/2022

Results from different clinical investigations are not directly comparable. Information provided for education purposes only.
Short term clinical investigation results are not indicative of long term outcomes. Please refer to product Instructions for Use for updated clinical study data.

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. URO-1641410-AA

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