Macroplastique®

Urethral Bulking Agent

Predictable Product. Proven Performance.

- » Injectable bulking agent for adult female SUI
- » Ready to use
- » Non-degradable, non-resorbable
- » Over 20 years of clinical history

Cogentix Medical

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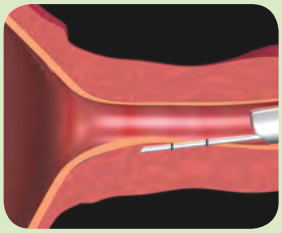
Predictable Product. Proven Performance.

Macroplastique® is an injectable soft-tissue bulking agent used to treat adult female stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency (ISD).

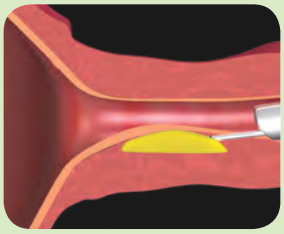
The soft, textured Macroplastique implants are made of solid silicone elastomer and suspended in a water-soluble, bio-excretable carrier gel.

Predictable Product

- Non-degradable, non-resorbable
- Uniquely designed to create an excellent open matrix for collagen deposition
- Average implant size is 140 µm with the majority of implants between 120 – 600 µm
- No evidence of migration in clinical studies or in histological examination of tissue explants
- Size of initial bolus is maintained even after carrier gel is excreted
- Administration Device ensures a controlled and precise implantation procedure
- Suspension of implants in carrier gel makes Macroplastique easy to inject
- Ready to use – no mixing or special storage



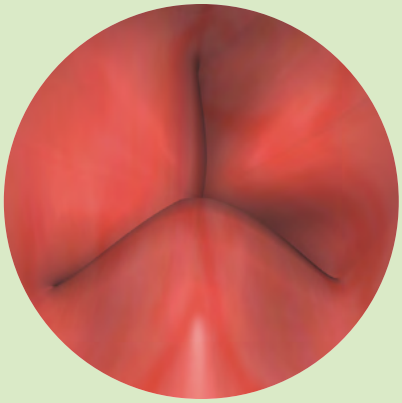
A tunnelling technique is used to inject Macroplastique at the mid-urethral position



The Administration Device ensures a controlled and precise procedure

Urethral Coaptation

Macroplastique is injected in 2-3 locations to achieve urethral coaptation.



Proven Performance

In a multi-center clinical trial, Macroplastique demonstrated excellent clinical efficacy.

Patient outcomes with Macroplastique[1]

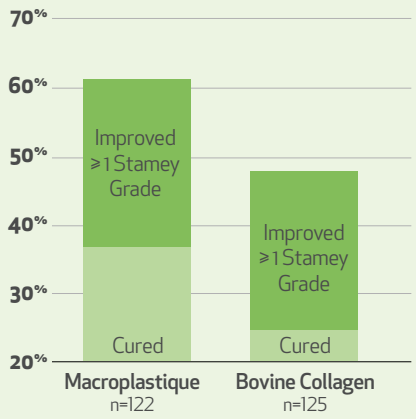
At 12 Months

- 62% of patients had an improvement ≥1 Stamey Grade*
- 37% of patients were dry*
- Physicians considered 80% of the patients dry or markedly improved**
- 60% improvement from baseline in Incontinence Quality of Life surveys (IQOL)**

At 24 Months

- 75% of patients had an improvement ≥1 Stamey grade***
- 33% of patients were dry***
- No serious treatment-related adverse events associated with Macroplastique

12 Month Objective Improvement[1]
Intent to treat per protocol analysis;
patients withdrawn or lost to follow-up considered failures.



"Macroplastique is a safe, efficacious, minimally invasive injectable silicone [elastomer] material that can be administered on an out-patient basis."

Patient Considerations for Macroplastique

- Adult females with stress urinary incontinence, primarly due to intrinsic sphincter deficiency
- Don't want invasive surgery
- Have not met their treatment goals after SUI surgery
- Elderly or frail
- In child-bearing years and desire more children
- Want a short recovery

* 122 patients received Macroplastique treatment.
Subjects who were lost to follow-up or withdrawn are considered failures.
** Of 102 subjects attending 12 month follow-up.
*** Of 84 subjects attending 24 month follow-up.

Product Information

Catalog Number	Product Description	Procedure Requirements
MPQ-2.5	**Macroplastique Implants** One 2.5 ml unit	2 units
AD-US	**Reusable Administration Device** Includes syringe adapter	1 device
MRN-420	**Uroplasty Rigid Endoscopic Needle** 3.8 Fr. shaft x 14.5" (370 mm) long with 20 gauge tip x 0.54" (14 mm) long	1 needle
MRN-518	**Uroplasty Rigid Endoscopic Needle** 5 Fr. shaft x 15" (380 mm) long with 18 gauge tip x 0.54" (14 mm) long	1 needle

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1. Ghoniem, G., Corcos, J., Comiter, C., Bernhard, P., Westney, O.L. & Herschorn, S. (2009). Cross-linked polydimethysiloxane injection for female stress urinary incontinence: Results of a multicenter, randomized, controlled, single-blind study. *J Urol, 181*, 204-210.

Macroplastique is indicated for transurethral injection in the treatment of adult women diagnosed with SUI primarily due to ISD. CONTRAINDICATIONS: Not to be used in patients with acute urogenital tract inflammation/infection or fragile urethral mucosal lining. WARNINGS: Do not use in patients with obstructive conditions until such conditions have been corrected. Overcorrection may lead to urinary obstruction. Adverse events associated with Macroplastique are typically non-serious and transient. Potential genitourinary adverse effects that may occur include: post-operative catheterization, UTI, urinary retention, dysuria, hematuria, pain at implantation site, frequency, urgency. While not reported in the clinical study, other potential events include erythema, embolic phenomena, granuloma, migration and vascular occlusion. CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician trained in diagnostic and therapeutic cystoscopy. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each Macroplastique product or online at www.cogentixmedical.com.