

# Macroplastique<sup>®</sup>

Urethral Bulking Agent

UROLOGY & UROGYNECOLOGY

A minimally invasive alternative  
for the treatment of Stress Urinary  
Incontinence.

Predictable.  
Permanent.  
Proven.



**Macroplastique<sup>®</sup>**  
Urethral Bulking Agent

# Predictable Product

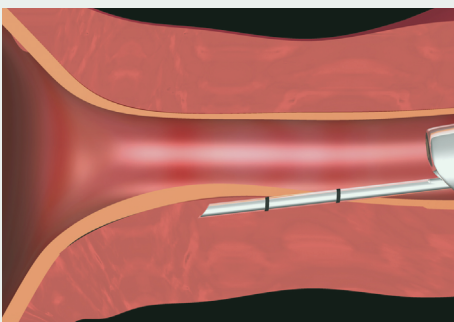
Macroplastique® is an injectable soft-tissue bulking agent used to treat adult female stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency (ISD). The soft, textured Macroplastique implants are made of solid silicone elastomer and suspended in a water-soluble, bio-excretable carrier gel.

- 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

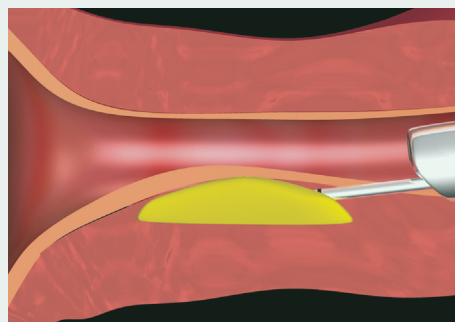


## Patient Considerations for Macroplastique

- Adult females with stress urinary incontinence, primarily 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



- ▲ 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

Macroplastique has demonstrated excellent and long-term clinical efficacy in multiple studies.\*

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## PATIENT OUTCOMES WITH MACROPLASTIQUE:

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### Greater than 18 months from a systematic review and meta-analysis<sup>1</sup>

- 64% of patients improved
- 36% were dry
- No reports of patient erosion

### At 3 years from a single site study<sup>2</sup>

- 47% were objectively cured, absence of urine leakage during a stress test
- 51% were subjectively cured and satisfied (PGI-I score < 2 and a patient satisfaction score > 8)
- No reports of patient erosion

### At 5 years from a multi-center study<sup>3</sup>

- 53% were Stamey Grade 1
- 22% were dry/Stamey Grade 0
- Four patients (1.4%) experienced erosion

### At 7.4 years from a single site study<sup>4</sup>

- 43% success if their most recent subjective UDI-6 Q3 score on stress urinary incontinence was 0 or 1
- Across all groups, patients had improvement in Quality of Life and IIQ-7 Question 7 (frustration)
- Eight patients (7.5%) had an MPQ erosion with 6 of these patients having a history of prior incontinence surgery
- The study included women with a history of previous SUI treatment such as prior collagen ± fascial sling, a fascial sling, or MUS. Only 38% were treatment-naïve, and 30% of them received more than one injection<sup>5</sup>

### At 10 years from a study of five urogynecology departments<sup>5</sup>

- 56% were objectively cured using urodynamically proven cough stress incontinence (USI)
- 71% were subjectively cured and satisfied (PGI-I score < 2 and a patient satisfaction score > 8)
- Long-term data in this prospective study revealed no significant decline in subjective or objective cure rates
- No reports of patient erosion

**Most complications were minor and transient.**

\*These studies had unique methodologies such as different inclusion factors and success metrics. Please refer to each study for specifics.



# Predictable Product. Proven Performance.

## MACROPLASTIQUE® BULKING AGENT

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

“Macroplastique is a safe, efficacious, minimally invasive injectable silicone [elastomer] material that can be administered on an out-patient basis.”<sup>6</sup>

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



Macroplastique  
Animation Video



Macroplastique Model  
Procedure Video



Macroplastique Set-up  
Video

1. Ghoniem GM, Miller CJ. A systematic review and meta-analysis of Macroplastique® for treating female stress urinary incontinence. Int Urogynecol J. 2013 Jan;24(1):27-36. doi: 10.1007/s00192-012-1825-9. Epub 2012 Jun 15. PMID: 22699885; PMCID: PMC3536958.

2. Serati M, Soligo M, Braga A, et al. Efficacy and safety of polydimethylsiloxane injection (Macroplastique®) for the treatment of female stress urinary incontinence: results of a series of 85 patients with at least 3 years of follow-up. BJU Int 019;123:353-9.

3. Ghoniem G, Lane, Felicia, Couri, Bruna. 5-Year follow-up study on safety and efficacy of Macroplastique® in female patients with stress urinary incontinence. SUFU. 2022. Feb 22-26 Presentation

4. Kusin SB, Carroll TF, Alhalabi F, Christie AL, Zimmern PE. Long-term Outcomes With Macroplastique in Women With Stress Urinary Incontinence Secondary to Intrinsic Sphincter Deficiency. Urology. 2024 Mar;185:36-43. Epub 2024 Jan 8. PMID: 38199277;DOI: 10.1016/j.urology.2023.12.019

5. M. Serati, C. Scancarello, G. Mesiano et al., Macroplastique Is a Safe and Effective Long-term Surgical Treatment for Stress Urinary Incontinence: Prospective Study with 10-Year Follow-up, Eur Urol Focus (2024). <https://doi.org/10.1016/j.euf.2024.07.010>

6. Ghoniem G, Corcos J, Comiter C, Bernhard P, Westney OL, Herschorn S. Cross-linked polydimethylsiloxane injection for female stress urinary incontinence: results of a multicenter, randomized, controlled, single-blind study. J Urol. 2009 Jan;181(1):204-10. doi: 10.1016/j.juro.2008.09.032. Epub 2008 Nov 14. PMID: 19013613.

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. Other post-treatment complications associated with the implant, and the patient's general tolerance to any injected material, may occur, such as erosion, implant exposure and potential stone formation on the surface of the implant material (if exposed). 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. Macroplastique is a registered trademark. Macroplastique is manufactured by Uroplasty LLC. Models are for illustrative purpose only. ©2024 Laborie. All rights reserved.

Laborie<sup>1</sup>

### USA

Pease International Tradeport T +1 802 857 1300  
180 International Drive, F +1 802 878 1122  
Portsmouth, NH 03801, USA W laborie.com  
E usmarketing@laborie.com



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