

Macroplastique®

BULKING AGENT

Treatment of Female Stress Urinary Incontinence

The use of Macroplastique in the treatment of SUI is a simple procedure that avoids the degree of complications and the post-procedure convalescence associated with alternative treatments. In correctly diagnosed and selected patients, this procedure provides a simple outpatient day case solution in both primary and secondary indications.



Superior Performance at 1 Year¹

In a randomised, controlled multi-centre trial (RCT), the Macroplastique group (n=122) outperformed the collagen control group (n=125)

- » 80% of patients were dry or markedly improved based on physician evaluation
- » 62% of patients improved by at least 1 Stamey Grade; statistically superior results compared to 48% of collagen group ($p < 0.05$)

Improved Outcomes at 2 Years²

In the RCT, Macroplastique patients followed to 2 years (n= 84) maintained excellent outcomes

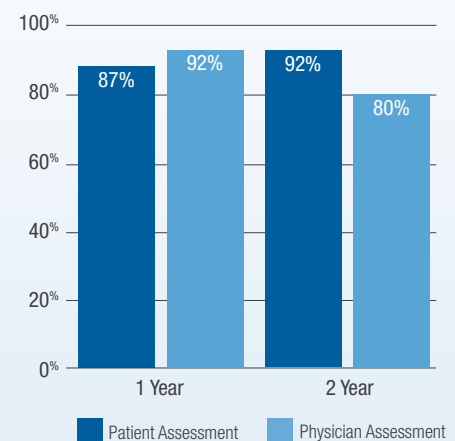
- » 75% of patients had an improvement of at least 1 Stamey Grade

Sustained Results at 5 Years³

- » 83.3% success for Type I
- » 80% success for Type III

“Urethral injection therapy has been shown to provide statistically significant and clinically meaningful improvements in QoL. Indeed, the QoL improvement is similar to that with surgery.”⁵

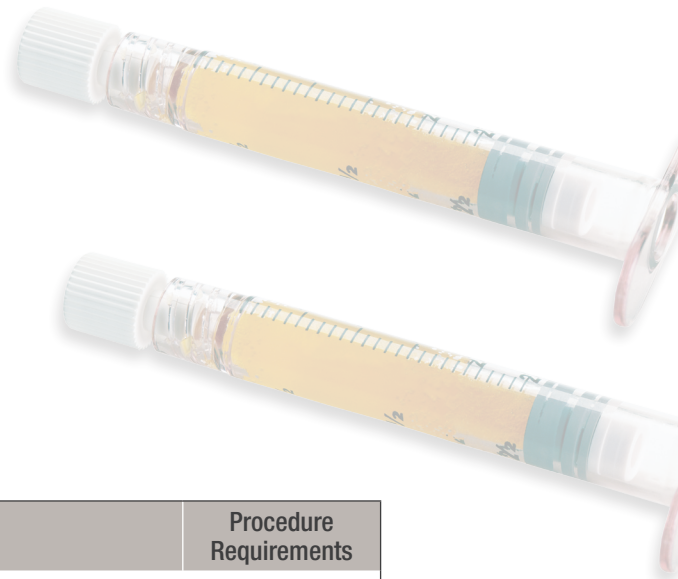
Clinical Improvement Physician and Patient Assessment⁵



“Macroplastique has been shown to be a safe and effective treatment for female stress urinary incontinence, with sustained results through two years.”⁴

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Product Information

Catalog Number	Product Description	Procedure Requirements
MPQ-2.5	Macroplastique Implants 2.5 ml unit	2 units
AD	Reusable Control Flow Administration Device Includes syringe adapter	1 device
MRN-018	Rigid Endoscopic Needle - Adult 5 Fr. shaft x 380 mm long with 18 gauge tip x 14 mm long	1 needle
MFN-718	Flexible Endoscopic Needle - Adult 7 Fr. shaft x 400 mm long with 18 gauge tip x 10 mm long	1 needle

1. Ghoniem, G., Corcos, J., Comiter, C., Bernhard, P., Westney, O.L. & Herschorn, S. (2009). Cross-linked polydimethylsiloxane injection for female stress urinary incontinence: Results of a multicenter, randomized, controlled, single-blind study. *JUrol*, 181, 204-210.
2. Uroplasty, Inc. (2006). Macroplastique Premarket Approval Study.
3. Zafirakis, H.G., Nathan, S., & Shah, J. (2002). Long-term efficacy of submucosal urethral injection for genuine stress incontinence in women. *AUA abstract*, Florida, USA.
4. Ghoniem, G., Bernhard, P., Corcos, J., Comiter, C., Tomera, K., Westney, O., et al. (2005). Multicenter randomized controlled trial to evaluate Macroplastique urethral bulking agent for the treatment of female stress urinary incontinence. *Int Urogynec J*, 16(Suppl2), S129-S130.
5. Chapple, C., Brubaker, L., Haab, F., Van Kerrebroeck, P., & Robinson, D. (2007). Patient-perceived outcomes in the treatment of stress urinary incontinence: Focus on urethral injection therapy. *Int Urogynecol J Pelvic Floor Dysfunct*, 18(2), 199-205.

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