



Macroplastique[®]

TREATMENT OF FEMALE
URINARY STRESS INCONTINENCE



Innovation for Health

PREDICTABLE PRODUCT. PROVEN PERFORMANCE.

The use of Macroplastique in the treatment of stress urinary incontinence (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.

MACROPLASTIQUE® URETHRAL BULKING AGENT TREATMENT OF FEMALE SUI

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

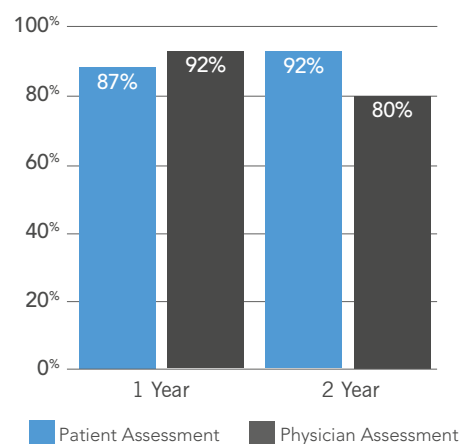
SUSTAINED RESULTS AT 5 YEARS³

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

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 (Suppl 2), 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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CLINICAL IMPROVEMENT Physician and Patient Assessment⁵



“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

“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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