



Macroplastique®

for the 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

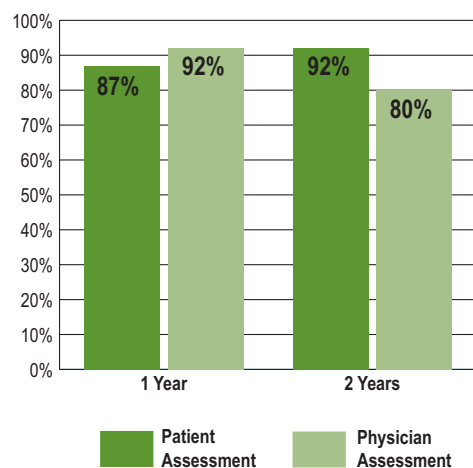
- 75% of patients had an improvement of at least 1 Stamey Grade

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

Physician and Patient Assessment of Clinical Improvement⁵



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

Product Information

Catalog Number	Product Description	Procedure Requirements
MPQ-2.5	Macroplastique Implants <ul style="list-style-type: none"> • 2.5 ml unit 	2 units
AD	Reusable Administration Device <ul style="list-style-type: none"> • Includes syringe adapter 	1 device
MRN-018	Uroplasty Rigid Endoscopic Needle - Adult <ul style="list-style-type: none"> • 5 Fr. shaft x 380 mm long with 18 gauge tip x 10 mm long 	1 needle
MFN-718	Uroplasty Flexible Endoscopic Needle - Adult <ul style="list-style-type: none"> • 7 Fr. shaft x 400 mm long with 18 gauge tip x 10 mm long 	

References

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. *Journal of Urology*, 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. Epub 2006 Jul 18.



Uroplasty

Essential Incontinence Solutions

Uroplasty BV, Hofkamp 2, 6161 DC Geleen, The Netherlands
 Tel: + 31 (0)46 423 79 20, Fax: +31 (0)46 423 79 22
 e-mail: info.holland@uroplasty.com

Uroplasty Ltd., Manchester Business Park, 3000 Aviator Way, Manchester M22 5TG, UK
 Tel: 0800 032 5964, Fax: 0800 032 5965
 e-mail: info.uk@uroplasty.com

www.uroplasty.com

For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions and disclaimer of warranties, please refer to the insert accompanying each Macroplastique. Model is for illustrative purposes. Uroplasty and Macroplastique are registered trademarks.
 © 2007 Uroplasty. All rights reserved. 0555003B 05/09

 0473