



MIS[®]

SIMPLE. PRECISE. PROVEN.



Innovation for Health

MACROPLASTIQUE® IMPLANTATION SYSTEM (MIS)

Proven performance and unique non-endoscopic delivery make the MIS procedure ideal for the treatment of female stress urinary incontinence (SUI), both as a primary treatment and as a second line therapy when other methods fail.

SIMPLE. PRECISE. PROVEN.

SIMPLY FULFILLS PATIENT EXPECTATIONS

- Consistent with patients' preference for less invasive procedures (Table 1)¹
- Reduced risks compared to more invasive procedures

IDEAL PATIENTS FOR MIS:

- Those not suitable for invasive surgery
- Those not continent after other SUI treatment
- Older or frail patients
- Women in childbearing years who desire more children
- Patients who require a short recovery time

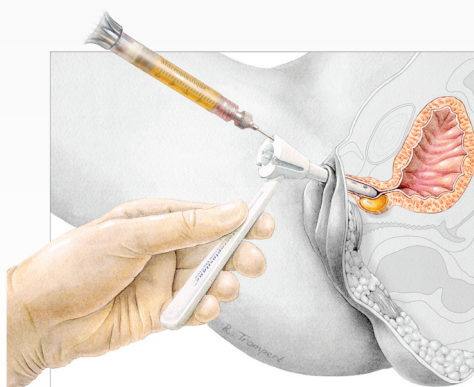
Table 1: Survey of Patients with Urinary Symptoms¹

Treatment acceptability (n=100)	
Clinic (outpatient) procedure	57%
Pelvic floor exercises for life	41%
Minor operation	38%
Major operation	23%
Regular drugs for life	14%
Treatment objective (n=100)	
Good improvement	43%
Complete cure	17%
Being able to cope better	13%
Any improvement	10%

"The improvement in the quality of life is in the same range as with surgical interventions and confirms the trend in patient's preference to have a procedure with a lower risk of complications."⁴

PRECISE, EFFICIENT PROCEDURE

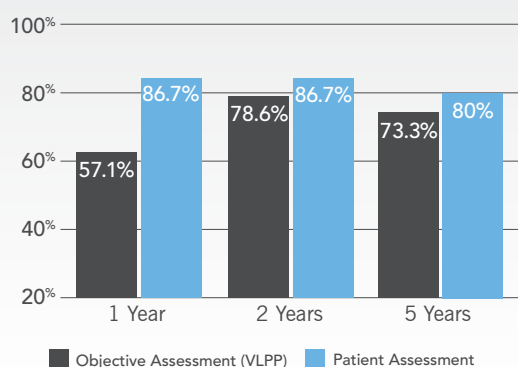
- Central fluid channel locates bladder neck
- Measuring scale and needle entry ports ensure correct location and depth of injection
- Outpatient procedure; local anaesthetic
- Simple set-up and quick (15 minute) procedure



"THE MIS PRODUCED PROMISING LONG-TERM SUBJECTIVE AND OBJECTIVE OUTCOMES, AS WELL AS LONG-LASTING IMPROVEMENTS IN QOL."²

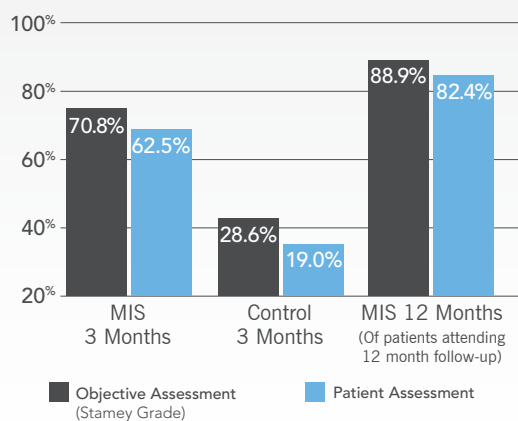
LONG TERM SUCCESS RATES²

In Patients Attending 60-month Follow-up



RANDOMIZED CONTROL TRIAL RESULTS⁴

MIS vs. Pelvic Floor Exercises



PROVEN CLINICAL RESULTS

- Comparable outcomes to endoscopic delivery of Macroplastique implants³
- Statistically superior to pelvic floor exercises:
 - Stamey Grade improvement
 - Decrease in pad use
 - Subjective assessment by physicians ($p=0.029$) and patients ($p=0.002$)⁴
- 74% of patients satisfied with their urinary condition following Macroplastique²
- Side-effects acceptable and mild



SAFE. SIMPLE. RESTORATIVE.

MACROPLASTIQUE® IMPLANTATION SYSTEM

- Non-endoscopic delivery of Macroplastique implants
- For female stress urinary incontinence
- Long-term success up to 80%

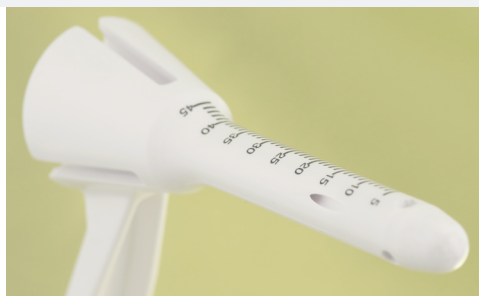


CATALOG NUMBER	DESCRIPTION	
MIS-5.0	MIS Macroplastique Implantation System, 2 Macroplastique Implants, 2.5 ml, 1 Macroplastique Implantation System (MIS-025) – 1 Macroplastique Implantation Device (MID) – 2 MID Implantation Needles	1 system
AD	Reusable Administration Device, Includes syringe adapter	1 device

1. Robinson, D., Anders, K., Cardozo, L., Bidmead, J., Dixon, A., Balmforth, J., et al. (2003). What women want – their interpretation of the concept of cure. *J Pelvic Med Surg*, 9, 273-277.
2. Tamanini, J.T.N., D'Ancona, C.A.L., & Netto, N. R., Jr. (2006). Macroplastique Implantation System for female stress urinary incontinence: Long-term follow-up. *Journal of Endourology*, 20(12), 1082-1086.
3. Zullo, M.A., Plotti, F., Bellati, F., Muzii, L., Angioli, R., & Panici, P.B. (2005). Transurethral polydimethylsiloxane implantation: A valid option for the treatment of stress urinary incontinence due to the intrinsic sphincter deficiency without urethral hypermobility. *J Urol*, 173, 898-902.
4. ter Meulen, P.H., Berghmans, L.C.M., Nieman, F.H.M., & van Kerrebroeck, P.E.V.A. (2009). Effects of Macroplastique® Implantation System for stress urinary incontinence and urethral hypermobility in women. *Int Urogynecol J Pelvic Floor Dysfunct*, 20(2), 177-183.

Only available for sale outside the U.S.

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