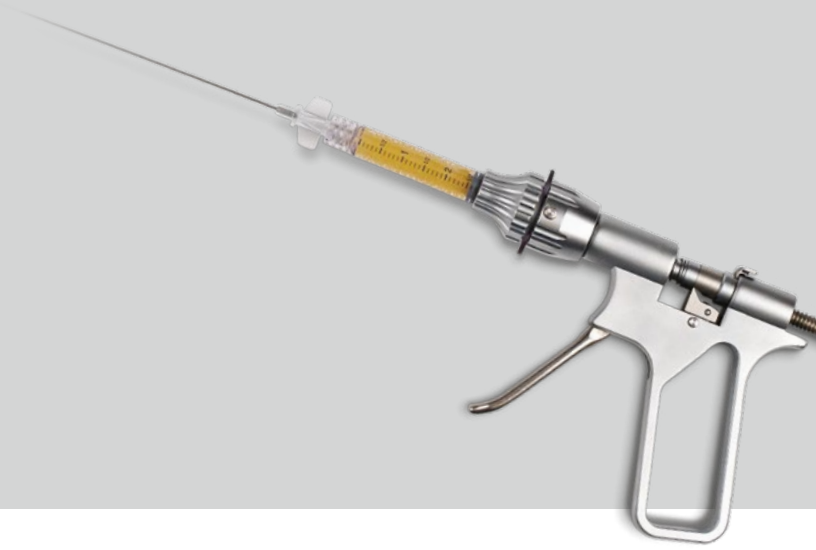
Macroplastique®

PRODUCT EFFICACY AND SAFETY

Macroplastique is a safe and effective soft tissue bulking agent used as a treatment for adult women diagnosed with stress urinary incontinence (SUI) primarily due to intrinsic sphincter deficiency (ISD).

Since 1991 Macroplastique technology has been used successfully outside the United States for SUI, fecal incontinence, vocal cord rehabilitation and soft tissue augmentation/plastic surgery.



CLINICALLY EFFECTIVE

Macroplastique received FDA PMA-approval in October 2006. In the clinical trial, 122 patients received Macroplastique and 125 patients received the Control, an absorbable bulking agent. There were no serious product-related adverse events associated with Macroplastique.

At 12 months:

- 62% of patients improved by > 1 Stamey Grade[1]
- 37% of patients were dry[2]

At 24 months:

- 75% of patients improved by > 1 Stamey Grade[3]
- 33% of patients were dry[4]

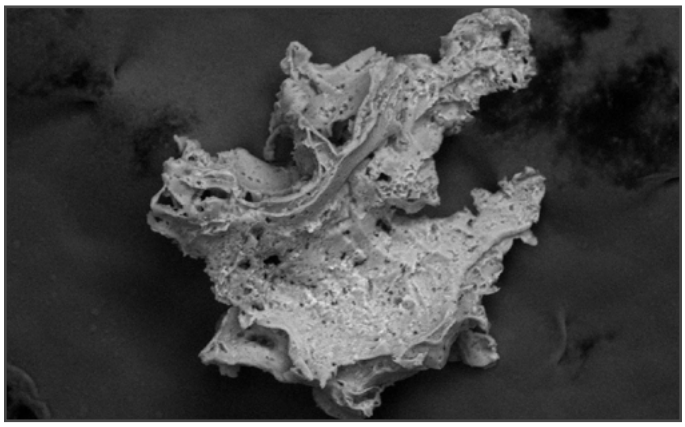


Figure 1
Scanning Electron Microscope (SEM) image of Macroplastique implant

INERT AND STABLE

Macroplastique is comprised of nonresorbable, flexible, biocompatible, highly-textured implants of cross-linked, silicone elastomer polydimethylsiloxane (PDMS) suspended in a bio-excretable polyvinylpyrrolidone (PVP) carrier gel. The textured surface geometry of the implants is conducive to tissue ingrowth (Figure 1).

Macroplastique is made of silicone elastomer. This stable and inert form of silicone consists of highly cross-linked polymer molecules. This property distinguishes silicone elastomer from silicone gels and silicone oils, which contain few cross-linked molecules.

Silicone elastomer is a preferred material for medical devices such as pacemaker leads, catheters, shunts, artificial hips, and subdermal implants for controlled release of pharmaceuticals.

NO EVIDENCE OF MIGRATION

In a long term porcine study, following injection, the carrier gel was exchanged for tissue fluids containing host fibroblasts that subsequently deposited a collagen matrix around the individual implants. There was no evidence of silicone implant migration in local tissues surrounding the encapsulated implant site or major visceral organs (Figures 2 - 4).

BIOCOMPATIBLE

In an extensive battery of biocompatibility tests,[5] including cytotoxicity, mucosal irritation, sensitization and genotoxicity, no adverse effects or toxicity was observed with Macroplastique implants.

CONCLUSION

Macroplastique is an exceptionally safe and effective product as demonstrated by clinical experience, product composition and biocompatibility testing. The safety of this technology is further reinforced by more than 25 years of global experience in a wide variety of applications.

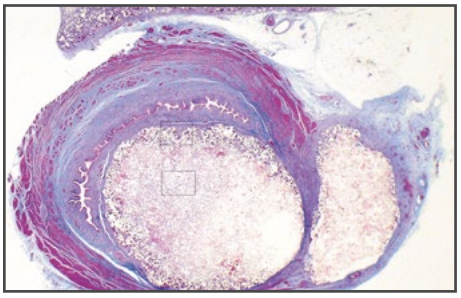


Figure 2
1 week post-implant

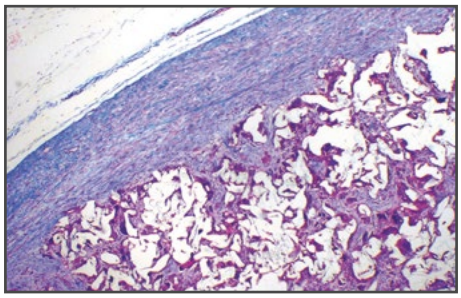


Figure 3
1 month post-implant

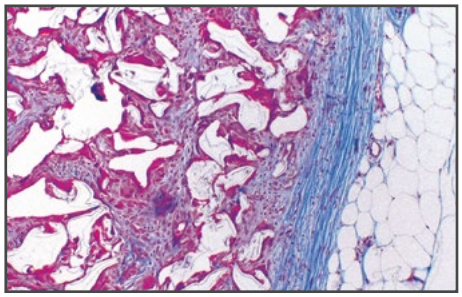


Figure 4
1 year post-implant

1. PMA clinical study. 75 out of 122 implanted patients. Subjects lost to follow-up or withdrawn are considered failures
2. PMA clinical study. 45 out of 122 implanted patients. Subjects lost to follow-up or withdrawn are considered failures
3. PMA clinical study. 63 out of 84 subjects attending 24 month follow-up
4. PMA clinical study. 28 out of 84 subjects attending 24 month follow-up
5. Per ISO 10993 – Biological Evaluation of Medical Devices

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. While not reported in the clinical study, other potential events include erythema, embolic phenomena, granuloma, migration and vascular occlusion. 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.

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