



INJECTABLE SUI TREATMENT  
**Opsys**

A NEW STANDARD IN SUI TREATMENT.

**Promedon**  
— People + Innovation



A NEW STANDARD IN SUI TREATMENT.

Women suffering from stress urinary incontinence are seeking for less invasive treatments with low complication rates to improve their quality of life.

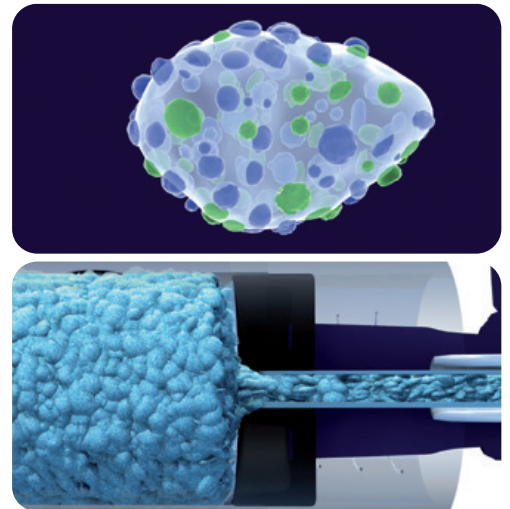
Bulking agent injection for SUI treatment has progressively gained a privileged position among other treatment options.

**Opsys Injectable SUI Treatment** is a new standard for SUI endoscopic treatment.

Opsys is a manually injectable, non-absorbable, synthetic tissue-bulking agent for the endoscopic treatment of Female Stress Urinary incontinence.

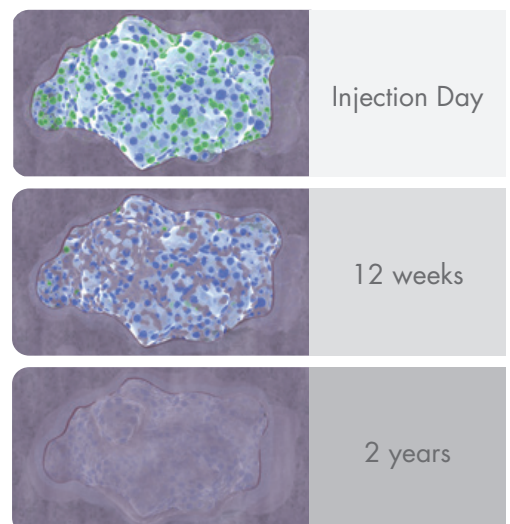
## STATE-OF-THE-ART CHEMICAL ENGINEERING

- As a hydrogel, Opsys Injectable SUI Treatment is comprised of polyacrylate/polyalcohol copolymer (PPC) particles immersed in a carrier that contains a 40% glycerol solution.
- The PPC particles are electrically negative charged; therefore, there is no interaction with the surrounding cells and tissues.
- Opsys particles are amorphous and highly deformable by compression. These features ensure the hydrogel fluidity.
- The material can be extruded through 21-gauge needles, allowing precise and easy injection.
- PPC chemical family is widely used in medical implants.



## RELIABLE AND SAFE: LOW COMPLICATION RATE

- The biological testing of the polyacrylate/polyalcohol copolymer hydrogel has proven the absence of particle migration<sup>(1)</sup>. This is mainly due to the size of its macroparticles, 300 microns average.
- The particles increase the tissue volume, generating a minimum fibrotic growth around them, 70 microns thick.
- Long lasting bulk effect: shape and size remains the same over time.
- Opsys is comprised of biocompatible material that is non-immunogenic and non-antigenic. Additionally, its non-animal origin greatly reduces the risk of an allergic reaction.



## PROVEN LONG-TERM EFFICACY STANDARD: 73% CURE RATE

### HIGH CURE RATE:

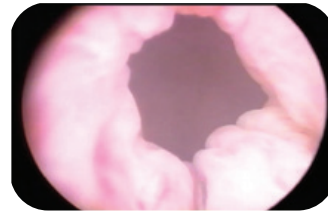
73 % Overall Success rate<sup>2,3</sup>:

46 % Dry

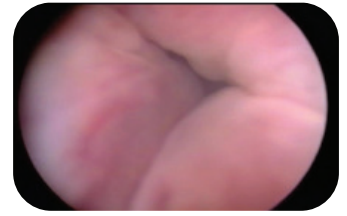
27 % Improved

N:38

**60-MONTH FOLLOW UP**



Cystoscopy evaluation before the implant procedure.



Cystoscopy evaluation after the implant procedure.

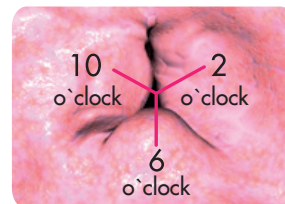
"According to these results, OpsyS offer a remarkable improvement in the quality of life of the women seeking for less invasive treatments for SUI. Indeed, a large group of them (62,5 %) are completely dry".<sup>[2]</sup>

## IMPROVED EFFICIENCY: LOW RE-IMPLANTATION RATE OF 13,2%<sup>3</sup>

### SIMPLIFIED INJECTION PROCEDURE



- OpsyS Injectable SUI Treatment allows a simple and versatile procedure since there is no need for additional accessories for injection.
- It is suitable for commonly used endoscopes with 6 Fr working channel or larger.



OpsyS Injection sites

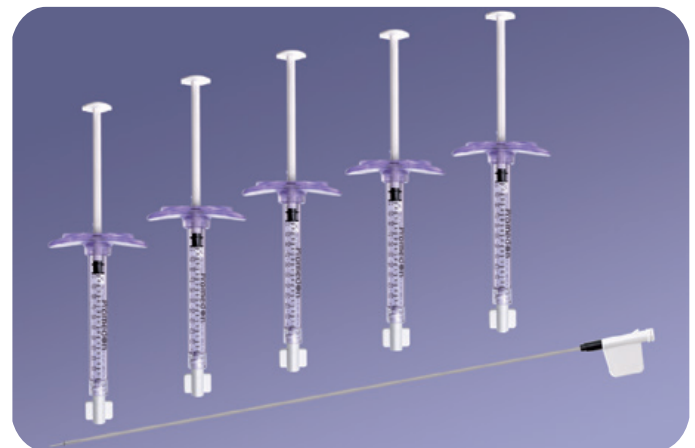
### HOW SUPPLIED

OpsyS Injectable SUI Treatment is supplied in two versions:

- 1 Kit containing 5 syringes of 1 ml Tissue Bulking Agent.
- 1 Reinforcement 1 ml Tissue Bulking Agent syringe.

It is recommended to use the injection needle developed by Promedon, with the following features:

- 1 flexible injection needle (Code 60 F), 6 Fr x 21 G x 350 mm.



1. Ormaechea M, Paladini M, Pisano R, Scagliotti M, Sambuelli R, Lopez S, Guidi A, Muñoz J, Rossetti V, Carnerero M, Beltramo D, Alasino R, Bianco I, Griguel O, Valladares D, De Badiola F. Universidad Católica de Córdoba, School of Medicine, Córdoba, Argentina. Vantris, a biocompatible, synthetic, non-biodegradable, easy-to-inject bulking substance. Evaluation of local tissular reaction, localized migration and long-distance migration. Arch Esp Urol. 2008 Mar;61(2):263-8.

2. Zangone M, Olmedo T, Palma P, Ricetto C, Tamanini T. Hospital Bernardino Rivadavia. Buenos Aires, Argentina. Hospital San José - University of Chile. Santiago, Chile. Hospital Central Unicamp - University of Unicamp. Campinas, Brasil. Hospital Santa Casa. Jau, Brasil. Transurethral Bulking Agent Injection: Promissory results using the new "Opsys" polyacrylate polyalcohol copolymer in the treatment of stress urinary incontinence (SUI). Joint Annual Meeting of the ICS and IUGA 2010. Toronto, Canada. Abstract#772.

3. Data on File



## ORDERING INFORMATION

### *Opsys Injectable SUI Treatment*

Opsys Kit (containing 5 1ml Bulking Agent syringes) - Code: BAI-5J

Opsys Reinforcement syringe - 1 ml Bulking Agent syringe - Code: BAI-1J



[www.promedon.com](http://www.promedon.com)

