A person wearing a green jacket, black leggings, and pink sneakers is jumping rope on a wooden pier. The pier has a metal railing and overlooks a blue ocean under a clear sky. The person is holding the handle of the jump rope with their right hand, and the rope is looping around their feet.

A simple, safe and natural
treatment for an improved
quality of life.¹

Deflux[®] Inject Control

Deflux[®] for Stress Urinary
Incontinence (SUI).

Injection Control

Stress urinary incontinence (SUI) is characterised by the involuntary leakage of urine, typically upon exercise, coughing or sneezing. It is a common condition that may affect up to 25% of adult women.² Prevalence of SUI increases with age, affecting up to 40% of elderly women.³

SUI can have a significant impact on the quality of life for people with the condition, which can include social isolation and poor self-esteem. Many women just accept the condition as part of the aging process and rely on pads and changes to their lifestyle to manage SUI.⁴

There are a number of treatment options for SUI. Urethral bulking is a minimally invasive option and offers an effective and safe alternative to open surgery.⁵ Studies show that quality of life improvements after urethral injection are comparable to those obtained with surgery.⁶ Another study reported patients describing their final result as markedly improved, and suggests Deflux as an ideal first line of treatment option for mild SUI.⁷

NASHA® - The Natural Solution

Deflux gel is a viscous substance consisting of two components: Non-Animal Stabilised Hyaluronic Acid (NASHA) and dextranomer (Dx) microspheres.

The NASHA in Deflux has been in medical use for over two decades in more than 40 million procedures worldwide.⁸

In the treatment of SUI, Deflux is injected into the urethra endoscopically to obtain a bulking effect. The NASHA acts mainly as a carrier, leaving the Dx microspheres at the implant site. Over time, the gel combines with the fibroblasts and collagen, which stabilises the position and size of the implant.⁹

When you choose Deflux, you can rely on safety, efficacy and durability.¹⁰

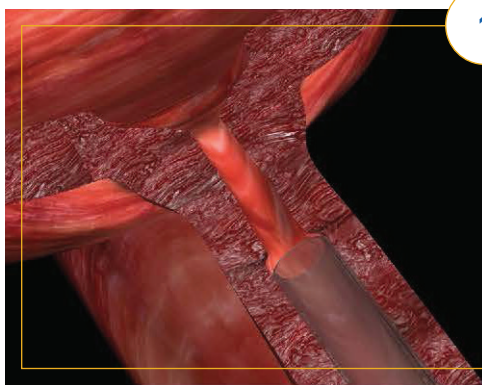
Benefits

- Ability to be administered under local anaesthesia¹¹
- Minimally invasive procedure
- Proven to have minimal side effects⁷
- There is a return to normal activity within 24 – 48 hours¹⁰
- Studies demonstrate a success rate of 74%¹¹
- Does not affect major surgery at a later stage, if required⁷
- Most marked improvements were in incontinence impact, physical limitations, social limitations and personal relationship¹

Deflux is a good compromise among acceptable efficacy, negligible intra- and post-operative complications, and high subjective satisfaction rate.¹²

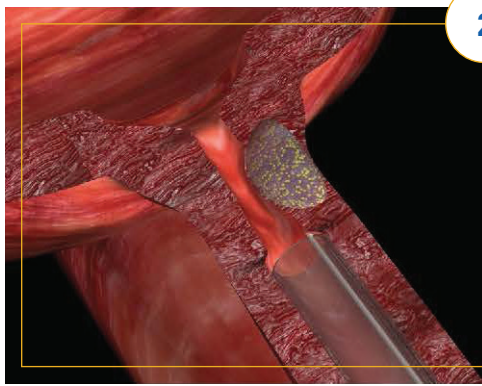
DE / +49 0 800 1813 334
ES / +34 900 993 304
FR / +33 (0) 800 000 013
IT / +39 800 785 440
UK / +44 080 823 4628
Email / palettemc@dlss.com

Treatment Procedure⁹



1

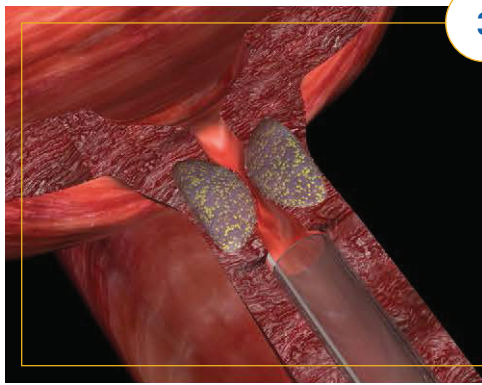
A standard urethro-cystoscope with a working channel is inserted into the urethra.



2

Deflux is injected submucosally at the level of the proximal urethra.

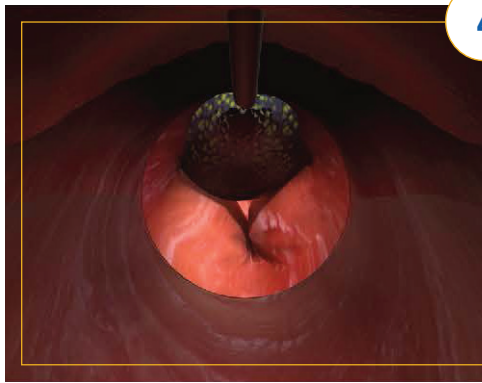
Deflux should be injected slowly to allow the tissue to accommodate the material until the bulge under the mucosa is seen to protrude to the midline of the urethra.



3

Inject Deflux at 2-4 sites (e.g. 3, 6, 9 and 12 o'clock positions).

3-6 mL has proved sufficient in the majority of patients - but the volume and number of injections to achieve successful results can vary significantly, depending on the visible bulking effect.



4

The needle should be held in place for 15-30 seconds at each injection to allow the gel to settle.

The open urethra is closed with swelling towards the midline observed after injection.

After The Procedure

- Patients may experience dysuria, urinary tract infection, hematuria and pain at the injection site for a few days⁹
- The most common complications immediately after the injection procedure are urinary retention and voiding dysfunction¹⁰
- Most patients return to normal activities within 48 hours¹¹
- 83% of adverse events were mild or moderate intensity, with a median of 7 days¹

Contact Us

For product information, adverse event reports, and product complaint reports, contact:

Palette Life Sciences Medical Information Department- EU

DE: +49 0 800 1813 334
ES: +34 900 993 304
FR: +33 (0) 800 000 013
IT: +39 800 785 440
UK: +44 080 823 4628

Email: palettemc@dlss.com



Deflux is indicated in the European Union for treatment of stress urinary incontinence due to urethral sphincter incompetence. Preliminary clinical data suggest that Deflux may be also effective for stress urinary incontinence due to urethral hypermobility

Q-Med AB is the current legal manufacturer and holds the CE Mark.

© 2020 Palette Life Sciences, Inc.
All rights reserved. Deflux® and NASHA® are registered trademarks.

Clinical References

1. Chapple CR, Haab F, Cervigni M, et al. An open, multicenter study of NASHA/Dx Gel (Zuidex) for the treatment of stress urinary incontinence. *Eur Urol.* 2005;48(3):488-494.
2. Hannestad YS, Rortveit G, Hunskaar S. Help-seeking and associated factors in female urinary incontinence. The norwegian EPINCONT study. *Epidemiology of incontinence in the county of Nord-Trondelag. Scand J Prim Health Care.* 2002;20(2):102-107.
3. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: The Norwegian EPINCONT study. *Epidemiology of Incontinence in the County of Nord-Trondelag. J Clin Epidemiol.* 2000;53(11):1150-1157.
4. Andersson G, Johansson JE, Garpenholt O, Nilsson K. Urinary incontinence - prevalence, impact on daily living and desire for treatment: A population-based study. *Scan J Urol Nephrol.* 2004;38(2):125-130.
5. Herschorn S. Current role of injectable agents for female stress urinary incontinence. *Can J Urol.* 2006;13(1): 5-12.
6. Chapple CR, Brubaker L, Haab F, van Kerrebroeck P, Robinson D. Patient-perceived outcomes in the treatment of stress urinary incontinence: Focus on urethral injection therapy. *Int Urogynecol J Pelvic Floor Dysfunct.* 2007;18(2):199-205.
7. Kaba R, Kaba R, Birnie A, Turney B, Foley S. The use of Deflux® to treat stress urinary incontinence: 3 year results. *International Continence Society 2011 Poster Presentation.* Abstract #856.
8. Galderma. Available at: <https://www.galderma.com/uk/restylane>. Accessed May 13, 2020.
9. Deflux [prescribing information]. Santa Barbara, CA: Palette Life Sciences, Inc.; 2019.
10. Bent AE. Sling and bulking agent placement procedures. *Rev Urol.* 2004;6(5):S26-S46.
11. Blick C, Marsh H, Muneer A, Tokaca N, Foley SJ. NASHA/Dx gel (Zuidex™) for stress urinary incontinence: Results from a single-centre study of 150 patients. *Curr Urol.* 2008;2:194-199.
12. Serati M, Mancini V, Balzarro M. Urethral bulking agents for the treatment of female stress urinary incontinence. *Int Urogynecol J.* 2020. DOI: <https://doi.org/10.1007/s00192-019-04221-3>.

A simple, safe and natural treatment
for an improved quality of life.