A Minimally Invasive, First-Line Treatment for Vesicoureteral Reflux (VUR)[1]

Deflux® is a viscous gel easily injected in or around the ureteral opening to create a valve function and stop urine from flowing back up from the bladder in children with VUR.[2,3] The gel is made from two polysaccharides that have been in medical use for over two decades: Non-Animal Stabilised Hyaluronic Acid (NASHA®) and dextranomer (Dx) microspheres. The NASHA in Deflux has been used in more than 40 million procedures worldwide.[4]

Deflux is injected submucosally in the urinary bladder in proximity to the ureteral orifice or in the distal ureter. The injection of Deflux creates increased tissue bulk thereby providing coaptation of the distal ureter during filling and contraction of the bladder. The dextranomer microspheres are gradually surrounded by host connective tissue at the implant site.[5]

Benefits

- Indicated for VUR
- Offers an immediate cure, independent of patient compliance[1]
- Minimally invasive, outpatient procedure that takes approximately 15 minutes[6]
- Requires short-acting general anaesthesia[2]
- Children can return to normal activity the next day[1]
- Deflux is the only injectable agent with Australian, European and United States approval for the treatment of VUR*

Long-Term Durability and Clinical Success of Deflux

- Deflux has been used for the treatment of VUR for over two decades with no reported persistent adverse events that are attributable to its use. The procedure itself is well tolerated with a low risk of associated complications[7,8]
- Treatment was shown durable and effective in grade IV VUR during a follow-up period of 15-25 years[9]
- One-time treatment with Deflux has been proven effective in up to 93% of children with VUR grades II-IV[10]
- Less than 4% of patients experienced mild pain in their flank immediately after treatment[6]
- Over time, the gel combines with fibroblasts and collagen which stabilise the position and size of the implant[3]
- Long-term follow up revealed 94% of parents were highly satisfied with Deflux[7]

Deflux®

Product Information

PRODUCT DESCRIPTION	Deflux Hyaluronic Acid and Dextranomer Pre-filled Syringe 1ml	Deflux Metal Needle 3.7FR x 23G x 350mm
PRODUCT TYPE	Deflux vesicoureteral reflux prosthesis	

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Deflux is indicated in the European Union for treatment of vesicoureteral reflux.

Important Information About Deflux Deflux® is indicated for vesicoureteral reflux in children. Deflux (hyaluronic acid/dextranomer) is contraindicated in patients with any of the following conditions: primary refluxing megaureters with distal stenosis, uncontrolled voiding dysfunction. Do not inject more than 6 mL of Deflux in children at the same treatment session. Safety and efficacy of Deflux in pregnant or lactating women has not been established. Please see complete Prescribing Information for DEFLUX at deflux.com.

Clinical References

1. Sung J, Skoog S. Surgical management of vesicoureteral reflux in children. *Pediatr Nephrol.* 2012;27:551-561.
2. Stenberg A, Läckgren G. Treatment of vesicoureteral reflux in children using stabilized non-animal hyaluronic acid/dextranomer gel (NASHA/DX): a long-term observational study. *J Pediatr Urol.* 2007;3(2):80-85.
3. Stenberg A, Larsson E, Läckgren G. Endoscopic treatment with dextranomer-hyaluronic acid for vesicoureteral reflux: histological findings. *J Urol.* 2003;169(3):1109-1113.
4. Data on File. Palette Life Sciences, Inc.
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6. Cerwinka WH, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux with dextranomer/hyaluronic acid in children. *Adv Urol.* 2008;513854. doi:10.1155/2008/513854.
7. Lightfoot MA, Bilgutay AN, Tollin N, et al. Long-term clinical outcomes and parental satisfaction after dextranomer/hyaluronic acid injection for primary vesicoureteral reflux. *Front Pediatr.* 2019;7:Article 392.
8. Puri P, Chertin B, Velayudham M, et al. Treatment of vesicoureteral reflux by endoscopic injection of dextranomer/hyaluronic acid copolymer: preliminary results. *J Urol.* 2003; 170:1541-4.
9. Stenbäck A, Olafsdottir T, Skoldenberg E, Barker G, Läckgren G. Non-animal hyaluronic acid/dextranomer gel (Deflux®) endoscopic treatment in grade IV VUR results after 15-25 years: durable and effective. *Section of Urology, University Children's Hospital.* Uppsala, Sweden. 2019.
10. Kalisvaart JF. Intermediate to long-term follow-up indicates low risk of recurrence after double hit endoscopic treatment for primary vesicoureteral reflux. *J Ped Urol.* 2012;8(4):359-365.
11. Kirsch AJ, Arlen AM, Lackgren G. Current trends in dextranomer hyaluronic acid copolymer (Deflux) injection technique for endoscopic treatment of vesicoureteral reflux. *J Pediatr Urol.* 2014; 84: 462-468.
12. Molitierno JA, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux using dextranomer hyaluronic acid copolymer. *J Pediatr Urol.* 2008;4:221-228.

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

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Deflux®

Physician Equipment Guide

A minimally invasive treatment for Vesicoureteral Reflux (VUR)

Administering Deflux

Optimal placement and higher injection volumes are associated with improved success[9,11]

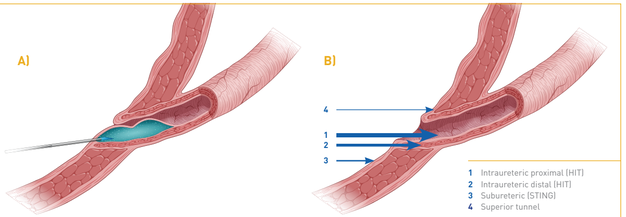
Double HIT Technique (Figure 1)

Although there are three common techniques for administering Deflux; STING, HIT and Double HIT, the Double HIT technique has increasingly become the most commonly performed technique for correction of VUR by paediatric urologists in the US. In 2014, a study showed 92% of Deflux procedures use the Double HIT technique which has demonstrated higher efficacy rates. [11]

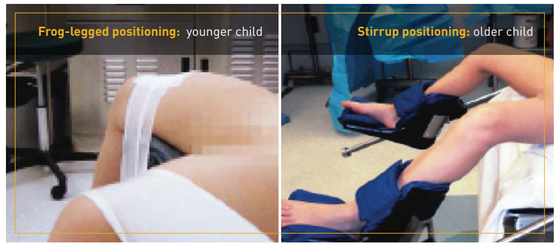
Figure 1.

A) Double HIT

B) Endoscopic injection needle placement algorithm. Numbers indicate the order of the injection sites. Sites 1 and 2 represent Double HIT method. Site 3 is uncommonly used and site 4, is only used in complex cases.[12]



Some Options for Patient Positioning



It is important to position the patient in a way that allows the thighs and abdomen to be in a flat plane. This allows the surgeon to pass the cystoscope over the leg while viewing the contralateral ureter that is laterally displaced. This may be achieved by using towel rolls or ankle support gel pads taped under the knees or paediatric stirrups set in a low position as the physician sees fit.

Equipment for Endoscopic Injection with Deflux Gel

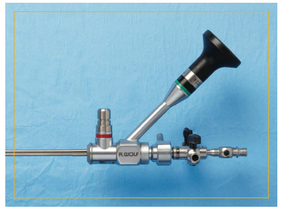
Offset Paediatric Scopes

Visualisation is the most important aspect of any endoscopic injection technique. A common cysto-urethroscope used for Deflux injection has a rigid rod lens optic. The scope should be compatible with commonly used OR camera systems and couplers.

Some manufacturers of offset paediatric scopes are Richard Wolf, KARL STORZ and Olympus.

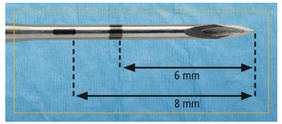
SUGGESTED EQUIPMENT

- Compact universal 9.5 Fr cysto-urethroscope with a straight 5 Fr working channel and 5 degree angle of view
- Rigid Cystoscopy Setup

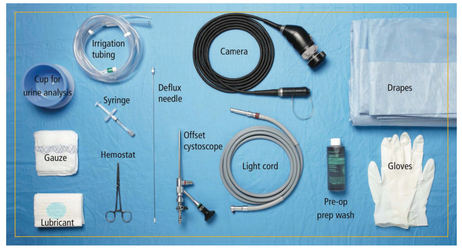


The Deflux Needle (Product Code: PLS102409)

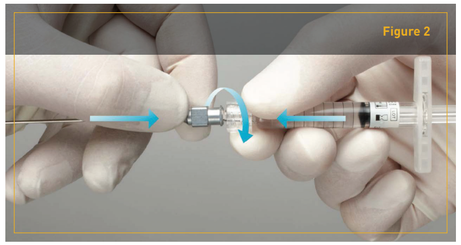
Deflux gel is injected using the Deflux metal needle, a 3.7 F x 23 G x 350 mm needle. Two reference marks have been placed on the needle to guide proper placement during the procedure.



Back Table Setup Example



Luer Lock Adapter



When fastening the needle to the syringe, please note that the Luer lock adapter is snapped onto the syringe and held in place with friction only. If too much force is applied, the Luer lock may rotate freely or come off all together causing an improper seal with the needle. Because of this, it is recommended that the thumb and forefinger are held firmly around both the glass syringe barrel and the Luer lock adapter when assembling the needle and syringe. To facilitate proper threading/fastening of needle hub and Luer lock adapter, push and rotate them firmly together (see Figure 2).

Latex-free statement

The components used for the manufacturing of Deflux Injectable Gel are free from Latex.

Deflux®