

Physician Equipment Guide

A minimally invasive treatment for Vesicoureteral Reflux (VUR)

Deflux is an easily injectable, viscous gel 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.^{1,2} 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.³

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.⁴

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 years⁹
- One-time treatment with Deflux has been proven effective in up to 93% of children with VUR grades II-IV¹⁰
- Optimal placement and higher injection volumes are associated with improved success⁹
- Less than 4% of patients experienced mild pain in their flank immediately after treatment⁵
- Over time, the gel combines with fibroblasts and collagen, which stabilize the position and size of the implant⁴
- Long-term follow up revealed 94% of parents were highly satisfied with Deflux⁷

Benefits

- Indicated for vesicoureteral reflux (VUR) in children⁴
- Minimally invasive, outpatient procedure that takes approximately 15 minutes⁵
- Requires short-acting general anaesthesia¹
- Children can return to normal activity the next day⁶
- Deflux is the only injectable agent with Australian, European and FDA approval for the treatment of VUR

Clinical Support

Product support will be provided through our sales team, with enquiries to [1800 794 401](tel:1800794401).

Ordering Information

PRODUCT CODE	PLS102408	PLS102409
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	
REBATE CODE	RW001	N/A

Team Medical Supplies' Customer Service: [1300 224 450](tel:1300224450)
Email: palette@teammed.com.au

Deflux is indicated in Australia for treatment of children with vesicoureteral reflux.



Clinical References

- 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.
- Stenberg A, Larsson E, Läckgren G. Endoscopic treatment with dextranomer-hyaluronic acid for vesicoureteral reflux: histological findings. *J Urol.* 2003;169(3):1109-1113.
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Administering Deflux

There are three common techniques for administering Deflux:

STING Technique

Subureteric injection in which the needle is placed directly below the ureteral orifice at the 6'oclock position.¹¹ [see Figure 1]

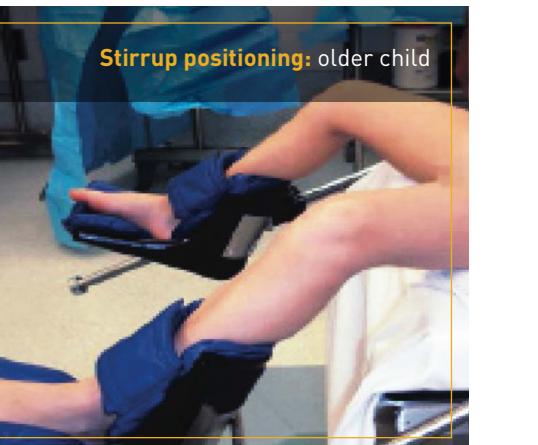
HIT Technique

Single intra-ureteric injection technique that is a modification of STING.¹¹ [see Figure 2]

Double HIT Technique

A refinement of the STING and HIT procedures and includes both proximal and distal intra-ureteric injections.¹¹ A 2014 study shows, the Double HIT technique is the most commonly performed technique for correction of VUR by paediatric urologists in the US.¹² In that study 92% of Deflux procedures use the Double HIT technique which has demonstrated higher efficacy rates.¹² [see Figure 3]

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 taped under the knees or paediatric stirrups set in a low position as the physician sees fit.

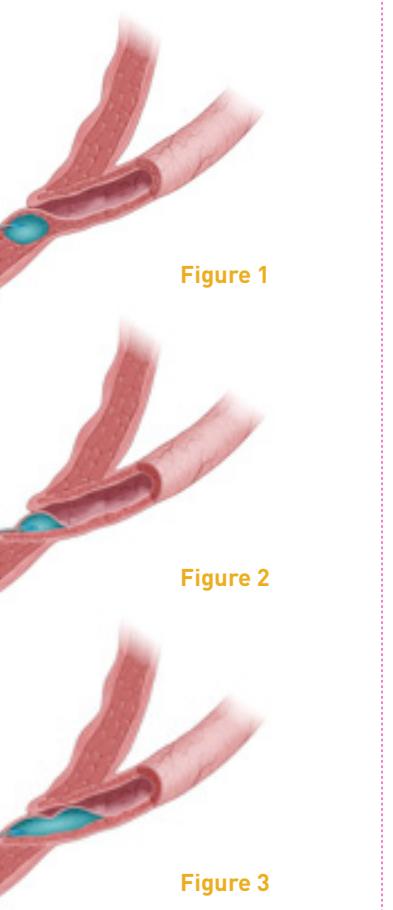


Figure 1

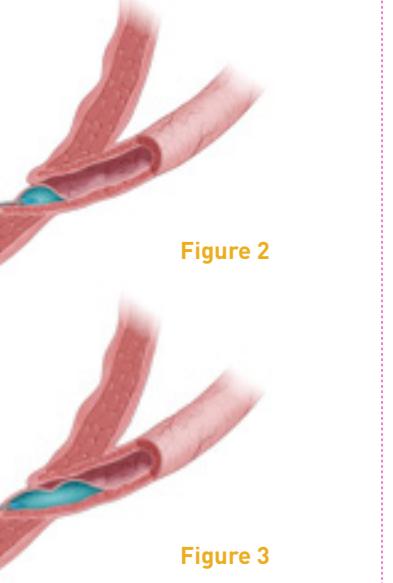


Figure 2

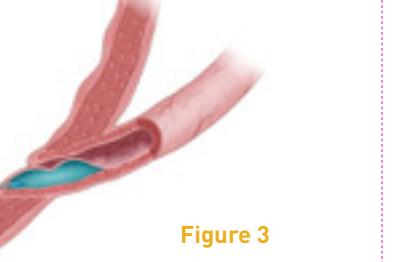


Figure 3

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.

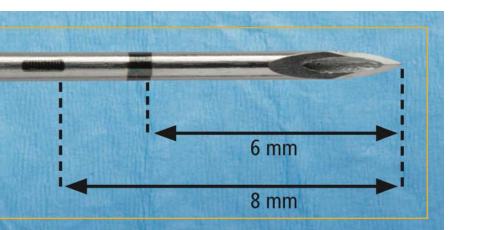
Some manufacturers of offset pediatric scopes are Richard Wolf, KARL STORZ and Olympus.

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



Figure 4



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

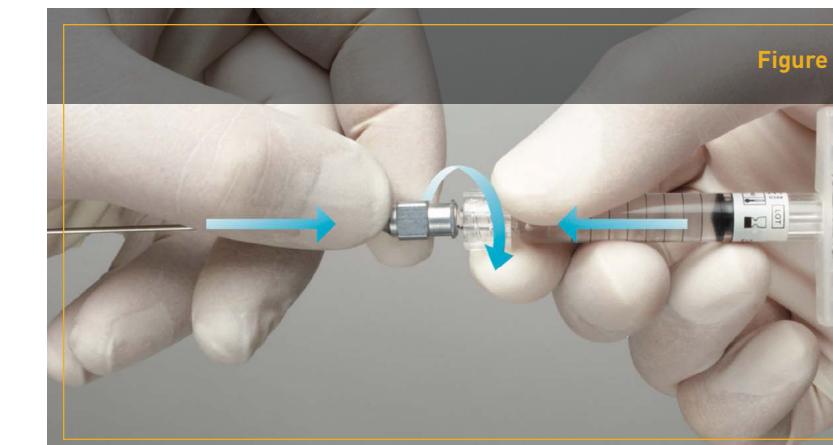


Figure 4

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. It can rotate freely or be pulled off should enough force be applied. 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, please both push and rotate them firmly together (see Figure 4).

Latex-free statement

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