

## A Minimally Invasive, First-Line Treatment for Vesicoureteral Reflux (VUR)<sup>1-3</sup>

Deflux™ injectable gel is 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.<sup>3</sup> The gel is made from two polysaccharides that have been in medical use for over two decades: Non-Animal Stabilized Hyaluronic Acid (NASHA) and dextranomer (Dx) microspheres. Deflux gel is proven with 500,000+ successful procedures over 25 years.<sup>5</sup> NASHA has been used in more than 50 million procedures worldwide.<sup>4</sup>

Deflux gel is injected submucosally in the urinary bladder in proximity to the ureteral orifice or in the distal ureter. The injection 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.<sup>6</sup>

### Benefits

- Indicated for VUR grade II-IV<sup>7</sup>
- Offers an immediate cure, independent of patient compliance<sup>2</sup>
- Minimally invasive, outpatient procedure that takes approximately 15 minutes<sup>8</sup>
- Requires short-acting general anesthesia<sup>9</sup>
- Children can return to normal activity the next day<sup>8</sup>
- The only injectable agent for VUR approved in the United States<sup>5,7</sup>

### Long-Term Durability and Clinical Success of Deflux Injectable Gel

- Deflux gel has been used for the treatment of VUR for over two decades. The procedure itself is well tolerated with a low risk of associated complications<sup>2,4</sup>
- Treatment was shown durable and effective in grade IV VUR during a follow-up period of 15-25 years<sup>10</sup>
- One-time treatment with Deflux has been proven effective in up to 93% of children with VUR grades II-IV<sup>2</sup>
- Less than 4% of patients experienced mild pain in their flank immediately after treatment<sup>8</sup>
- Long-term follow up revealed 94% of parents were satisfied<sup>11</sup>

### Clinical References

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2. Kirsch, Cooper, Lackgren Non-Animal Stabilized Hyaluronic Acid/ Dextranomer Gel (NASHA/Dx, Deflux) for Endoscopic Treatment of Vesicoureteral Reflux: What Have We Learned Over the Last 20 Years? *Jurolog.* 2021;157: P15-28.
3. 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.
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7. Deflux prescribing information. Santa Barbara, CA: Palette Life Sciences, Inc.; 2019.
8. Cerwinka WH, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux with dextranomer/hyaluronic acid in children. *Adv Urol.* 2008;51:3854.
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10. Stenbäck A, Olafsdóttir T, Sköldenberg E, Barker G, Läckgren G. Proprietary non-animal hyaluronic acid/dextranomer gel (NASHA/Dx) for endoscopic treatment of grade IV vesicoureteral reflux: Long-term observational study. *J Pediatr Urol.* 2020;S1477-5131(20)3017-8.
11. 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.
12. Kirsch AJ, Arlen AM, Lackgren G. Current trends in dextranomer hyaluronic acid copolymer (Deflux) injection technique for endoscopic treatment of vesicoureteral reflux. *J*
13. Moliterno JA, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux using dextranomer hyaluronic acid copolymer. *J Pediatr Urol.* 2008;4:221-228.

### Product Information

PRODUCT CODE	011504	DX1201
PRODUCT DESCRIPTION	Deflux Hyaluronic Acid and Dextranomer Pre-filled Syringe 1ml	Deflux Metal Needle 3.7FR x 23G x 350mm

### CONTACT

#### Medical Information Department

For product complaints and adverse event reports, contact our Medical Information Department:

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Deflux™ injectable gel is indicated for treatment of children with vesicoureteral reflux (VUR) grades II-IV. As with any medical procedure, individual results may vary. The following adverse events were associated with the use of Deflux gel from spontaneous post-marketing surveillance reporting or from clinical studies (occurring >2%) and include but are not limited to: ureteral obstruction with or without hydronephrosis (some cases requiring temporary placement of a ureteric stent, and rare cases of ureteral re-implant procedures), hematuria, urgency, frequency, pyelonephritis, foreign body reaction, calcification, pyrexia, hypertonic bladder, bladder irritation, Henoch-Schonlein purpura, delayed ureteral obstruction; impact on renal function; newly detected contralateral VUR; and pelvic, lateral or flank pain. More information on indications, contraindications, warnings and instructions for use can be found in the Instructions For Use at <https://www.deflux.com/important-safety-information/>

**U.S CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

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## Equipment Guide

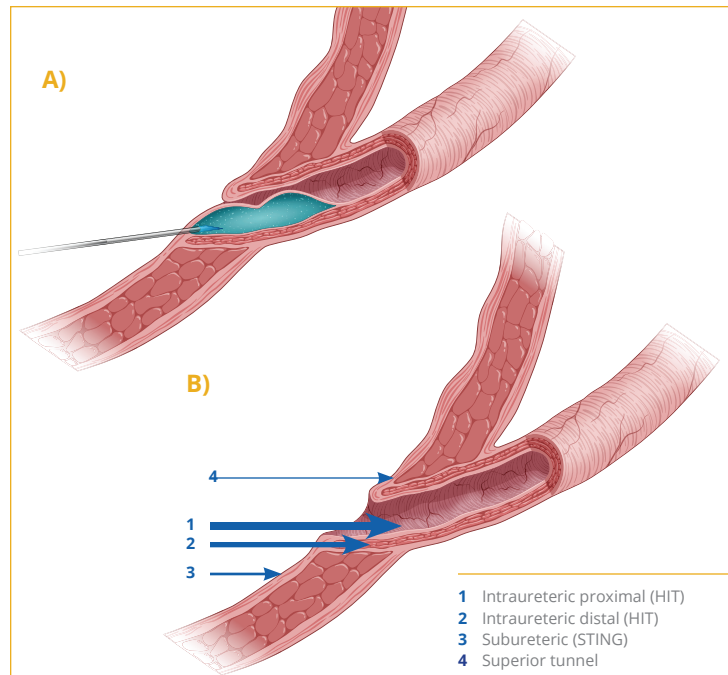
A minimally invasive treatment with immediate results<sup>1</sup>

## Administering Deflux™ Injectable Gel

Optimal placement and higher injection volumes are associated with improved success<sup>10</sup>

### Double HIT Technique (Figure 1)

Although there are three common techniques for administering Deflux gel; STING, HIT and Double HIT, the Double HIT technique has increasingly become the most commonly performed technique for correction of VUR by pediatric urologists in the US. In 2014, a study showed 92% of Deflux procedures use the Double HIT technique which has demonstrated higher efficacy rates.<sup>12</sup>

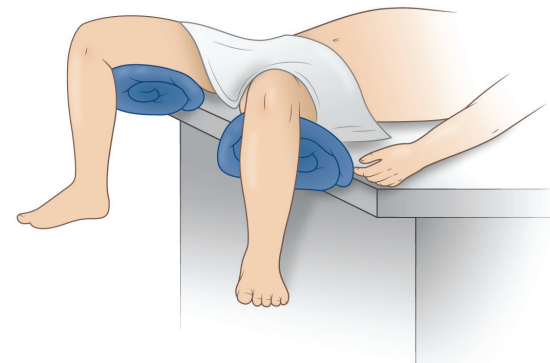


**Figure 1.**

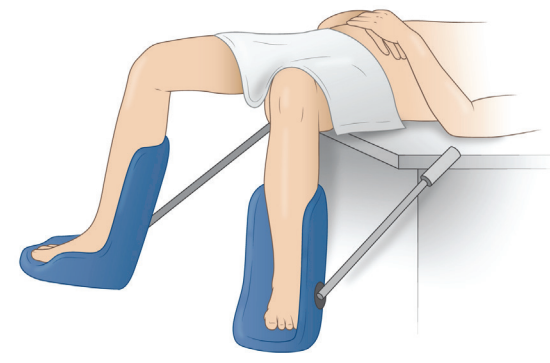
- A)** Double HIT  
**B)** Endoscopic injection needle placement algorithm. Numbers indicate the order of the injection sites. Sites 1 and 2 represent Double HIT method. Site 3 is uncommonly used and site 4, is only used in complex cases.<sup>13</sup>

### Options for Patient Positioning<sup>9</sup>

#### Frog-legged positioning: younger child



#### Stirrup positioning: older child



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 pediatric stirrups set in a low position as the physician sees fit.

## Recommended Equipment for Endoscopic Injection with Deflux Gel

### Offset Pediatric Scopes

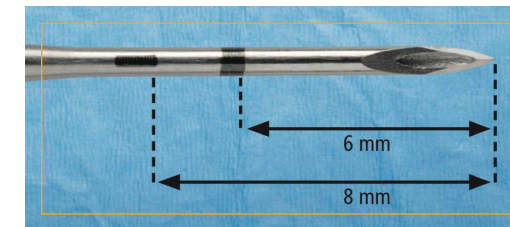
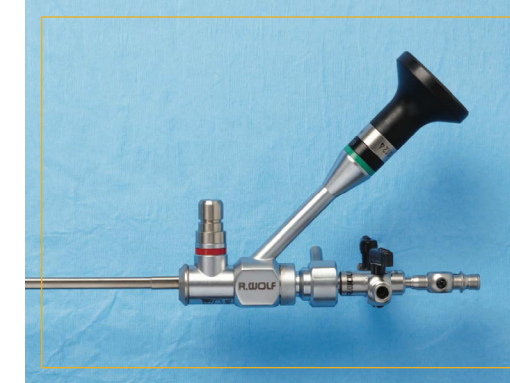
Visualization is the most important aspect of any endoscopic injection technique. A common cysto-urethroscope used for Deflux injection has a rigid rod lens optic. The scope should be compatible with commonly used OR camera systems and couplers.

#### 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: DX1202)

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

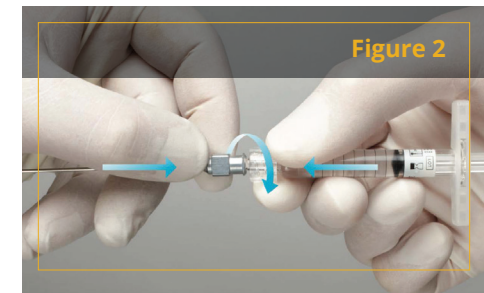
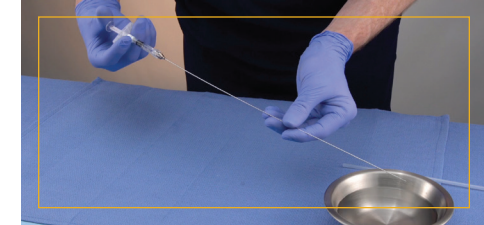


### Needle Preparation

Before injecting with Deflux gel, it is important to prime the needle with saline. Priming the needle has been shown to reduce injection force.<sup>5</sup>

### 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 altogether 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.