



Deflux[®]

VUR Overview
for Caregivers

VUR Overview

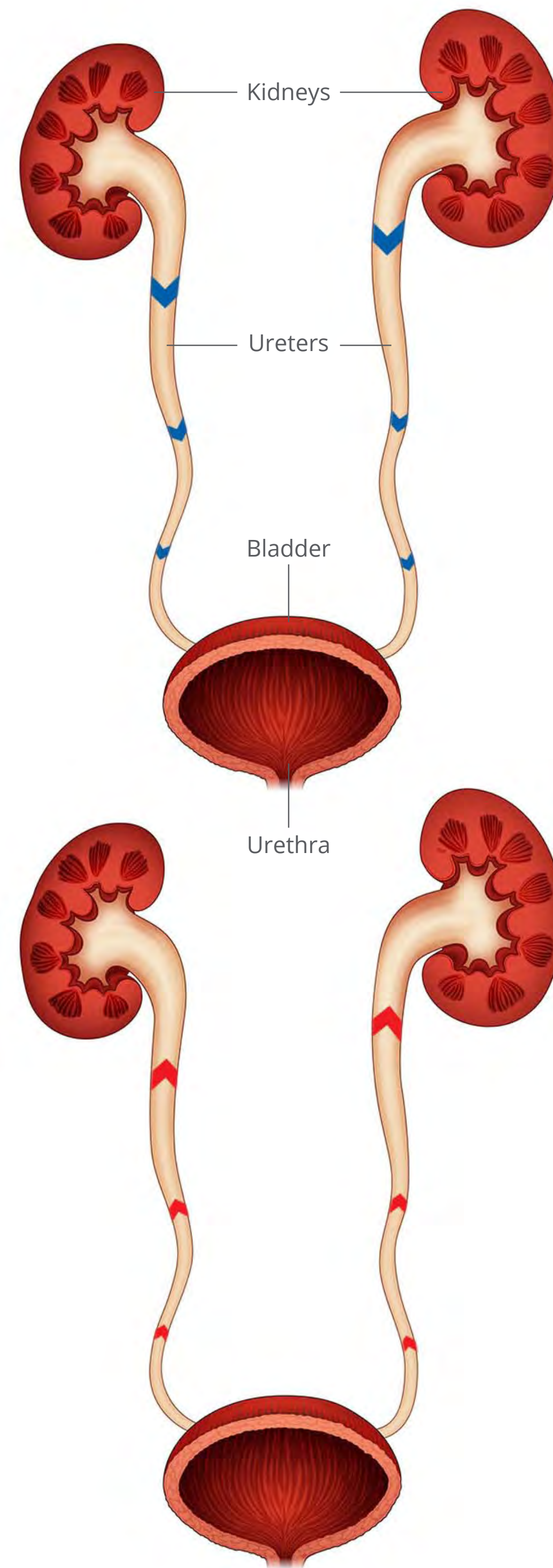
What is VUR?

Most common congenital urinary defect in children, affecting 1% of children worldwide¹

Vesicoureteral reflux (ves-ih-koe-yoo-REE-tur-ul re-flux), commonly known as VUR, is a condition in which urine flows backward from the bladder through the ureters. This backed-up urine can carry bacteria which can cause urinary tract infections (UTIs), kidney infections and potentially long-term kidney damage.

If your child experiences frequent urinary tract infections with fever (called “febrile UTIs”), you may want to talk to your child’s doctor about the possibility of VUR, and a referral to a pediatric urologist.

1. Hensle TW, Grogg AL. Vesicoureteral reflux treatment: the past, present and future. In: Hensle TW. Challenges surrounding vesicoureteral reflux: fuel for a paradigm shift in treatment. *Curr Med Res Opin.* 2007;23(Suppl 4):S1-S6.



NORMAL FLOW

Urine flowing down to the bladder

VUR

Defect allows urine to flow the wrong way, from the bladder to the kidneys.

What kind of doctor should you see for VUR?

If your child has VUR or symptoms similar to those of VUR such as recurrent UTIs with fever, a specialist can help. The specialist for VUR is a pediatric urologist.

What is a pediatric urologist?

Pediatric urologists are doctors who provide specialty care to diagnose, treat and manage children's conditions affecting the kidneys, bladder, urethra or genital tract. He or she has completed a residency in an approved urology training program, a formal fellowship in pediatric urology and is board-certified or board-eligible in urology. VUR is a common condition that pediatric urologists treat. They use equipment specially designed for children, creating a comfortable and non-threatening environment for your child. These VUR specialists are best equipped to answer your questions about VUR.

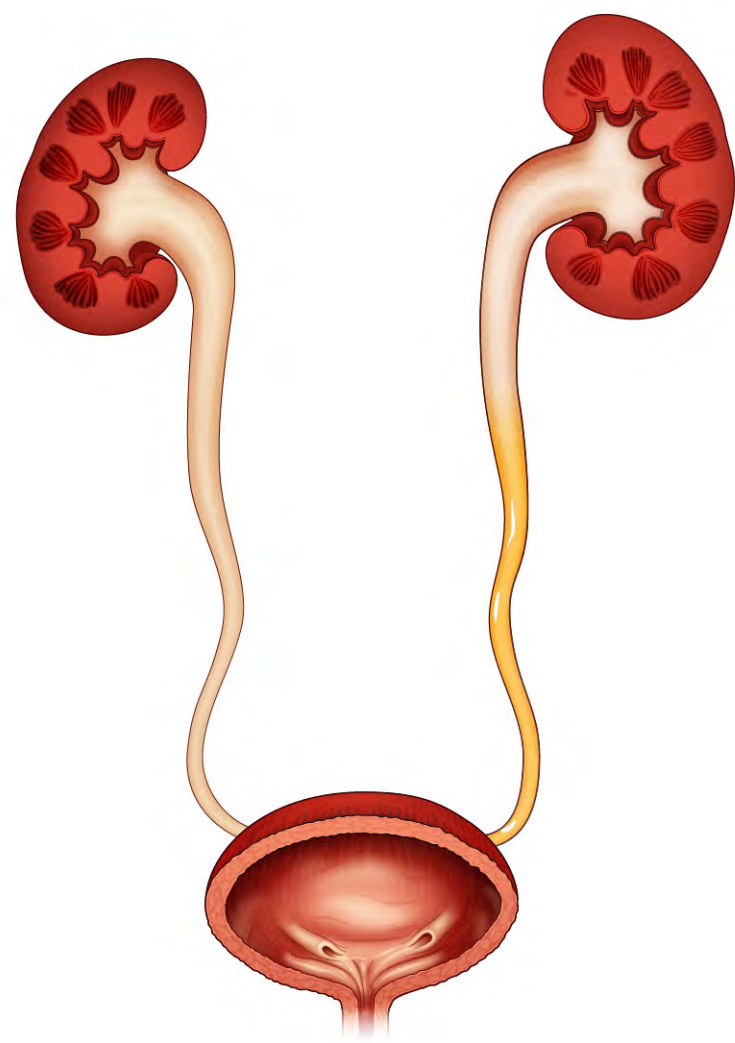
The last page of this ebook has information for locating a pediatric urologist near you.



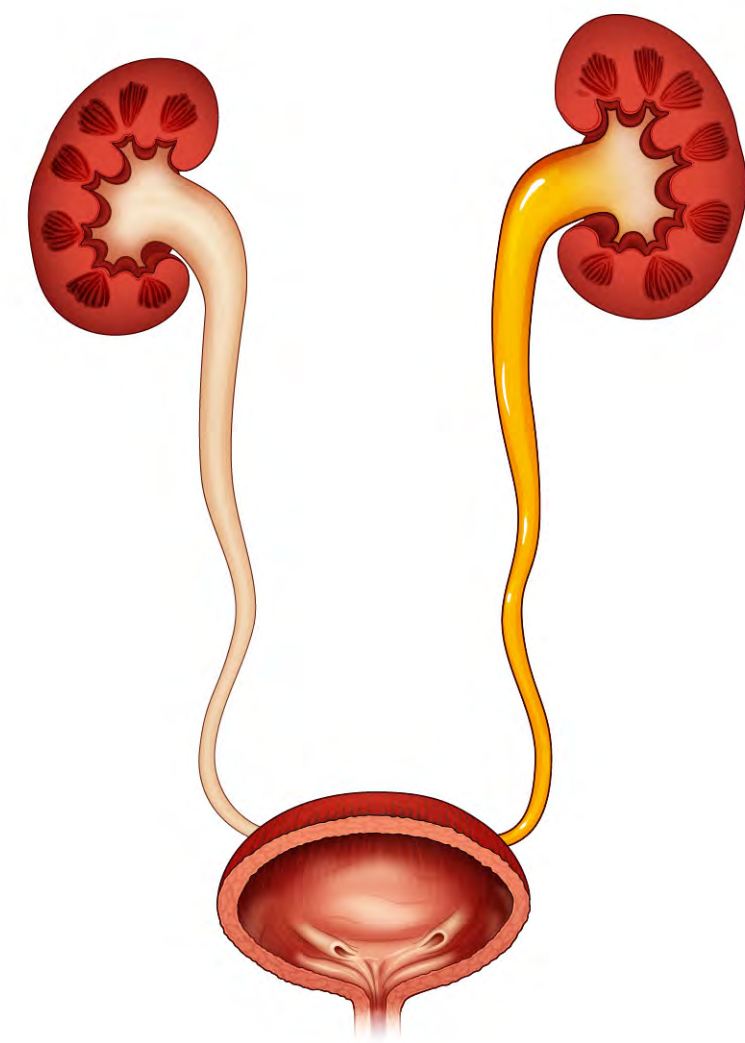
Testing for VUR

Your doctor will diagnose your child based on an evaluation that may include a test called a voiding cystourethrogram, or VCUG. The VCUG will help your doctor determine how serious your child's VUR is with a grading scale.

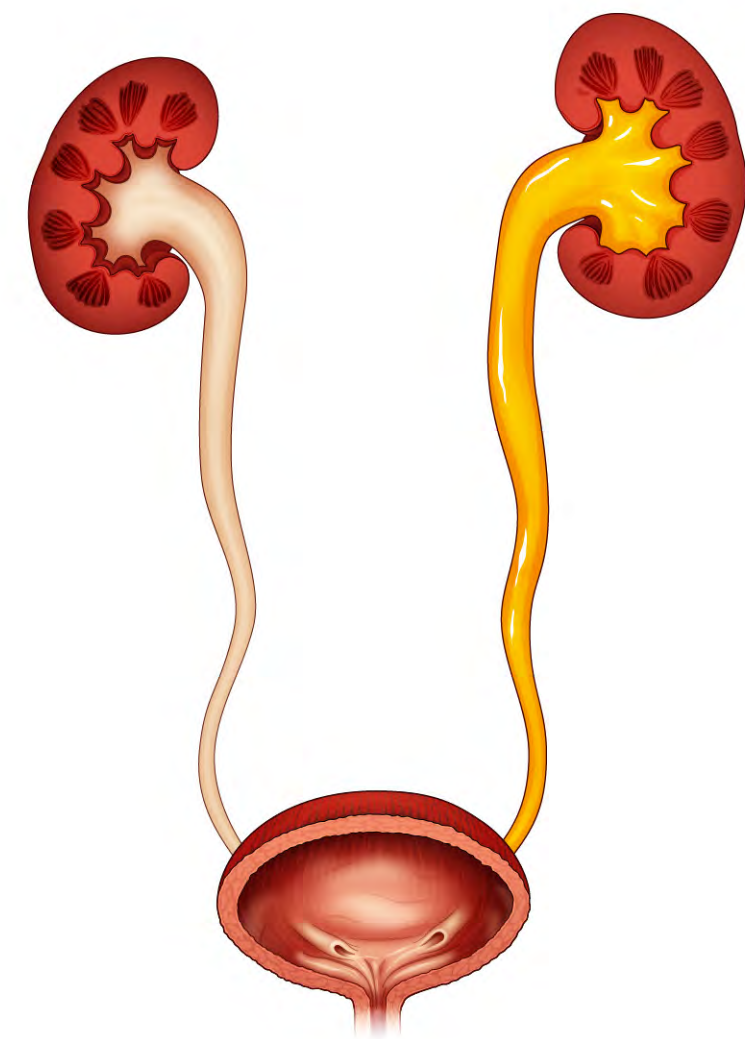
VUR is graded 1-5, with 5 being the most severe. The higher the grade of VUR, the greater the chance that kidney damage will result—and the less likely your child is to outgrow it.¹



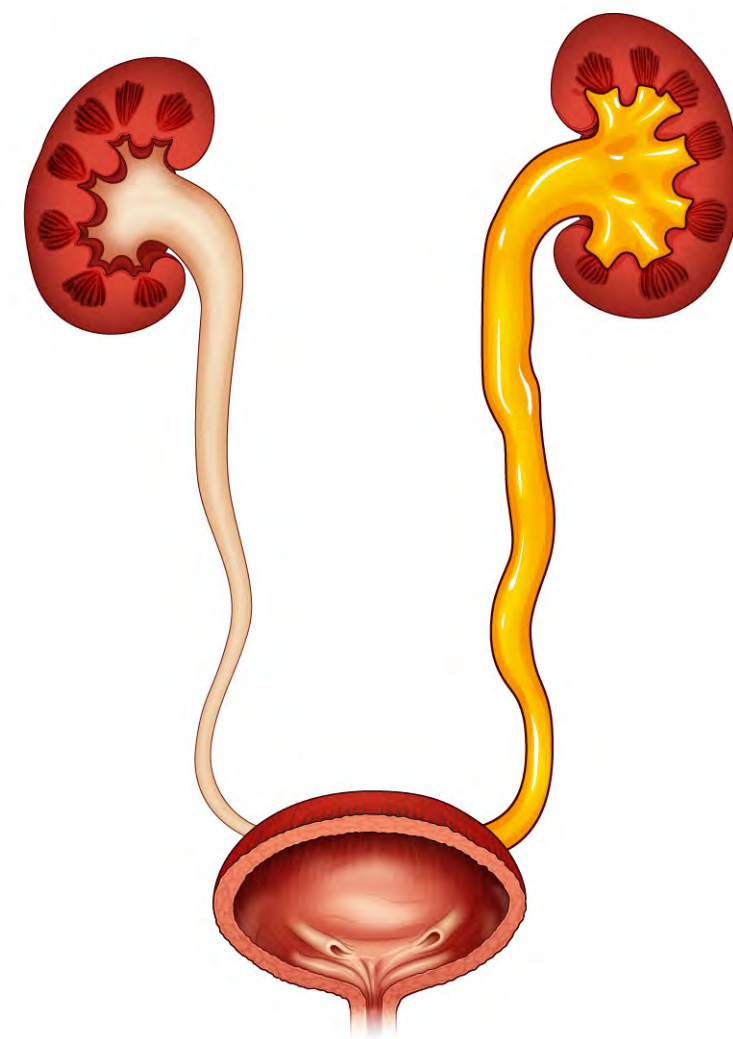
GRADE 1



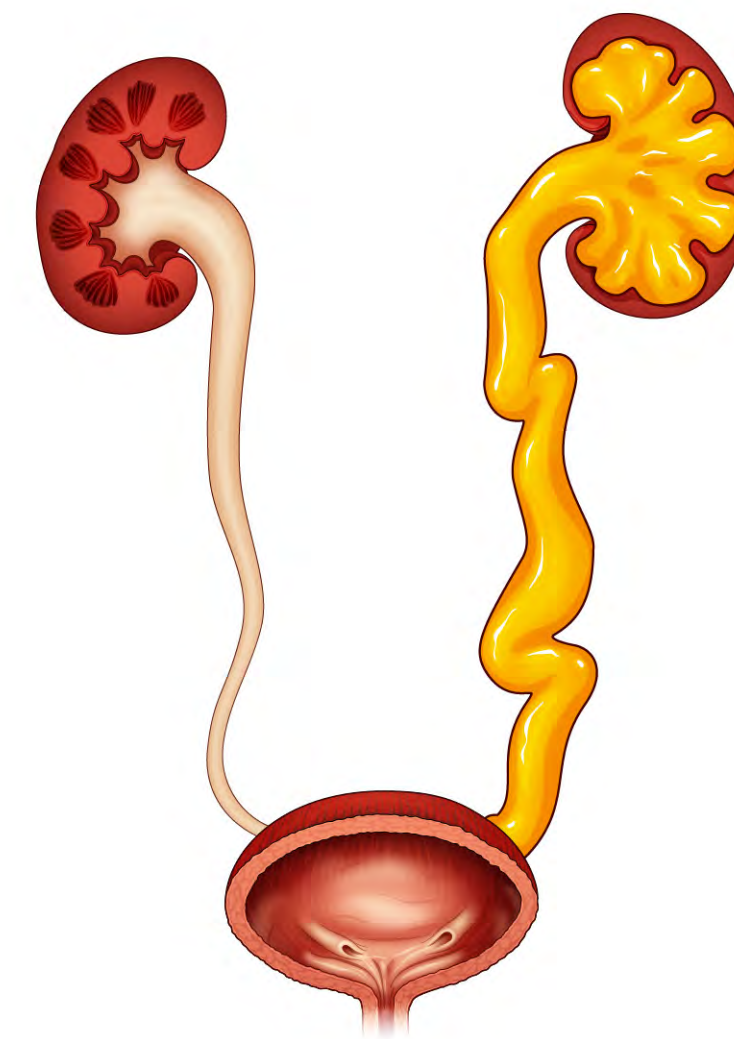
GRADE 2



GRADE 3



GRADE 4



GRADE 5

1. Elder JS, Peters CA, Arant BS, et al. AUA pediatric vesicoureteral reflux clinical guidelines panel: The management of primary vesicoureteral reflux in children. American Urological Association Education and Research, Inc. 1997.

There Is Help for VUR

It is critical to assess your child's VUR, and treat febrile UTIs to prevent possible infection and long-term kidney damage. There are four ways your child's pediatric urologist or doctor may suggest treating the VUR, depending on the severity, to help you determine what's right for your child.



WATCHFUL WAITING

may be an option if your child has a milder case of VUR (grade 1). If a breakthrough febrile UTI (UTI with fever) occurs, a pediatric urologist can help determine next steps.



ANTIBIOTICS

are prescribed to treat UTIs associated with VUR. Antibiotics are used until the child outgrows VUR. Outgrowing VUR is dependent on many factors, and may not occur. Waiting for resolution may take several years and require long periods of antibiotic prescriptions.



ENDOSCOPIC TREATMENT,

Deflux is a treatment option for children with VUR grades 2-4. The treatment is a 15-minute, minimally invasive same day procedure with no cuts or incisions, and your child can return to normal activities the next day.¹



SURGICAL REPAIR

is suitable for the most severe cases. Since an incision is made, your child will likely need to stay in the hospital for a few days to recover.

1. Cerwinka WH, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux with dextranomer/hyaluronic acid in children. *Advances in Urology*. 2008; 1-7.

What is Deflux?

Deflux has been used safely for over two decades in children with VUR. Deflux is an injectable gel made from two tissue-friendly polysaccharides (types of sugar molecules) – hyaluronic acid (HA) and dextranomer. Hyaluronic acid is a naturally-occurring material, and the HA in Deflux has been used in more than 40 million procedures worldwide, often as a dermal filler for wrinkle correction.¹

NASHA - The Natural, Safe Solution

The HA in Deflux is Non-Animal Stabilized Hyaluronic Acid (NASHA®) and is naturally broken down (biodegraded) over a short time while the dextranomer remains in place longer, and is gradually surrounded and replaced by the body's own material. NASHA is a patented technology and is designed for optimal biocompatibility and stability.

1. Galderma. Restylane. Available at: <https://www.galderma.com/uk/restylane>. Accessed September 1, 2020.



The Deflux Advantage

Deflux works well to stop VUR in children. Most children have success after one injection. A 2019 study shows Deflux was proven effective in up to 93% of children, with no febrile UTIs after one injection.¹

In a study involving children with moderate VUR, 80% of parents preferred endoscopic treatment (Deflux) over antibiotics or open surgery.² The treatment takes about 15 minutes and allows children to go back to normal activities the next day.

PROVEN EFFECTIVE
IN UP TO

93%

OF CHILDREN ¹

1. Kalisvaart JF. Intermediate to long-term follow-up indicated low risk of recurrence after double hit endoscopic treatment for primary vesicoureteral reflux. *J Ped Urol.* 2012;8(4):359-365.
2. Capozza N, Lais A, Matarazzo E, et al. Treatment of vesicoureteric reflux: a new algorithm based on parental preference. *BJU International.* 2003; 92:285-288.



The Deflux Procedure

First, the pediatric urologist examines the bladder with a lighted camera, called a cystoscope, which is inserted into the urethra. Deflux gel is injected at the spot where the ureters connect to the bladder. This will help keep urine from flowing back into the ureters and kidneys. Eventually, new tissue grows around the gel providing long-term results for many children.

There is usually no pain after the procedure, but some children may feel a little stinging during the first few times they urinate. Typically, they can return to normal activities by the next day.

94% OF PARENTS REPORTED
HIGH SATISFACTION WITH
DEFLUX TREATMENT ¹

1. Lightfoot MA, Bilgutay AN, Tollin N, et al. Long-term clinical outcomes and parental satisfaction after dextranomer/ hyaluronic acid injection for primary vesicoureteral reflux. *FrontPediatr.* 2019;7:Article 392.

Deflux – Safe & Effective

Deflux has been studied worldwide for over 25 years, and has been used safely and effectively for over 20 years in the United States to treat VUR grades 2-4 in children.^{1,2}

Treatment with Deflux has a small risk of infection and bleeding from the procedure. Although rare, the gel might block the ureter and cause the urine to back up in the kidney. You should ask your pediatric urologist about these potential side effects.

Find a VUR doctor
(Pediatric Urologist)
near you.

FIND A DOCTOR

1. Cerwinka WH, Scherz HC, Kirsch AJ. Endoscopic treatment of vesicoureteral reflux with dextranomer/hyaluronic acid in children. *Adv Urol.* 2008;1-7.
2. Stenbäck A, Olafsdottir 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. DOI: 10.1016/j.jpuro.2020.04.008.

Learn more
about Deflux at
deflux.com

Important Safety Information about DEFLUX

Deflux® is indicated for treatment of children with vesicoureteral reflux (VUR) grades 2-4. Children with certain medical conditions should not be treated with Deflux: non-functional kidney(s), hutch diverticulum, ureterocele, active voiding dysfunction, and ongoing urinary tract infection. Discuss these conditions with your healthcare provider. There is a small risk of infection and bleeding from the procedure. There are adverse effects that can happen. These include urinary tract infection. Discuss these adverse effects with your healthcare provider. Safety and effectiveness of treatment of duplex systems, use of more than 6 mL of Deflux (3 mL at each ureteral orifice) at the same treatment session, and treatment of children under 1 year of age have not been established. For more information about Deflux, please visit deflux.com.

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



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For more information about Deflux, please visit deflux.com.

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