Deflux™

Minimally Invasive Treatment for the Immediate Relief of VESICOURETERAL REFLUX (VUR)

Your child has a condition known as **vesicoureteral reflux (VUR)**. Thankfully, there are treatments that can help.

What is VUR?

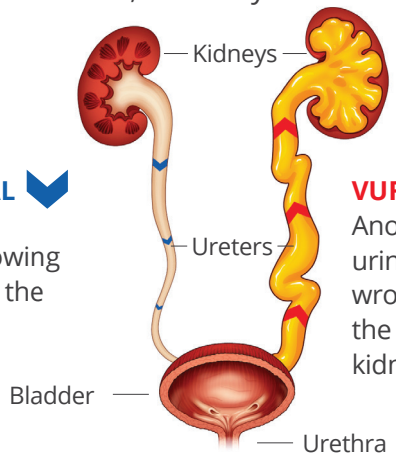
Urine is made in the kidneys. Normally, urine only flows in one direction – from the kidneys down the ureters and into the bladder. VUR is a condition where urine flows backward from the bladder into the ureters and sometimes back up to the kidneys. Since urine from the bladder is no longer sterile, VUR can increase the risk of urinary tract infections and may cause long-term kidney damage if left untreated.

VUR is most commonly diagnosed at a young age and is a condition that affects about 1% of children worldwide.[1]

Read on to **learn more** about VUR and how it can be treated.

More About VUR

VUR occurs when the connection between the bladder and ureter is atypical. The lower part of the ureter tunnels through the muscle of the bladder. If this tunnel is too short or is located too much to one side, VUR may occur.



NORMAL FLOW
Urine flowing down to the bladder

VUR
Anomaly allows urine to flow the wrong way, from the bladder to the kidneys

VUR Symptoms – What to Look For

VUR itself does not show symptoms. However, VUR presents itself most commonly with recurrent urinary tract infections (UTIs) accompanied by a fever, or what your doctor may call febrile urinary tract infections (fUTIs). VUR is the most common underlying cause of fUTIs in children.[2] Among children with a first-time fUTI, up to 40% have VUR.[3] Behaviors such as infrequent or incomplete urination and related constipation are also associated with VUR.

There is Help for VUR

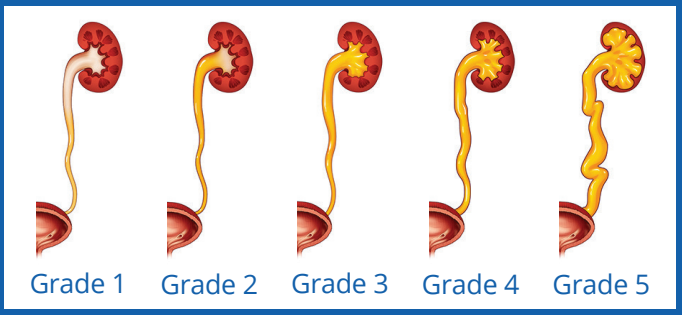
Antibiotics are most suitable for milder grades of VUR and may be used to prevent UTIs from reoccurring until the VUR goes away naturally. This course of treatment requires children to take medicine every day and be tested regularly. Long-term treatment with antibiotics has been proven ineffective in reducing the rate of kidney infections and renal damage/scarring in children under 30 months of age.[4]

Endoscopic Injection Therapy is minimally invasive and can provide an immediate cure through a single procedure.[5] During endoscopic therapy, the doctor injects a gel (bulking agent) into the wall of the ureter creating a little bulge. The bulge makes it harder for the urine to flow back through the ureter to the kidneys. There are no incisions or scars with this procedure. Deflux® gel is not indicated for all types of VUR.

Surgery can repair the ureters to stop VUR. This type of treatment cures most children. However, the operation can be stressful and painful to the child, may require a hospital stay and is associated with a higher risk of complications.[6] Surgery is most suitable for more complex or severe cases.

Is VUR Serious?

There can be serious consequences of VUR. Febrile UTIs can occur when infected urine flows back into the kidneys. This can lead to scarring and damage to the kidneys, which can lead to poor kidney function and high blood pressure later in life. Swift treatment helps minimize the risk of long-term damage. VUR severity is measured using a grading system. Grade 1 is least severe and grade 5 is most severe.



The Deflux Advantage

What is Deflux?

Deflux is an injectable gel used to treat VUR. It is injected at the spot where the ureter connects 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.

The Procedure

Your doctor will use a small camera called a cystoscope (a thin tube used to view the bladder) to properly place Deflux. During the procedure, your child may be under general anesthesia. **The procedure usually takes about 15 minutes and allows children to go back to normal activities the next day.**[7]

Deflux endoscopic treatment is indicated for children with VUR grades 2-4.

Safe Treatment for VUR

Deflux has been used safely for over two decades to treat children with VUR.[8] The two most common side effects include urinary tract infections, typically occurring in patients with persistent reflux, and ureteral dilatation with most cases resolving on their own.[16]

More than

500,000

procedures performed to date[9]

Deflux - Effective Treatment for VUR

Deflux works well to treat VUR with the majority of children having success after one injection.[5] It may be comforting to know that in studies, one-time treatment with Deflux has been proven effective in up to 93% of children with VUR grades 2-4.[5] If the first injection is not successful, a second injection or surgery is still an option.

In long-term studies, **after one injection of Deflux:**

93% had no fUTIs within 19 months[5]

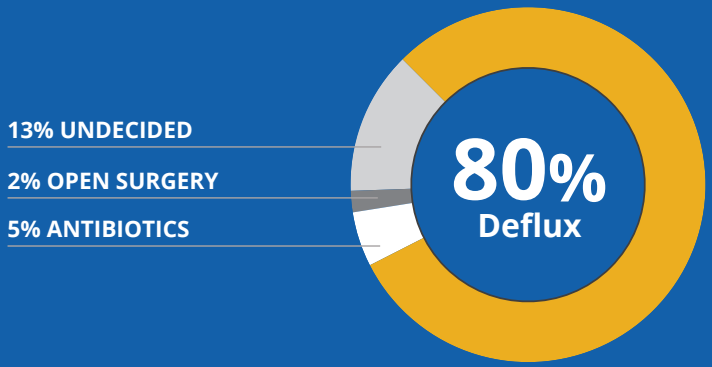
Long-Term Safety Record

20 years after its approval in The United States, Deflux is a well-tolerated procedure with a low risk of associated complications.[5,10]

During 15-25 years of follow up, 97% of patients had no reported safety issues following a Deflux injection.[11]

Deflux success for treating VUR is comparable with open surgery, but without the need for a hospital stay.[3]

In a study involving children with moderate VUR, **80% of parents preferred endoscopic treatment** over antibiotics or open surgery:[12]



Answers to Commonly Asked Questions

Who should be tested?

Repeat urinary tract infections (UTIs) can be a symptom of VUR in an otherwise healthy child. Children with repeat UTIs should be referred to a pediatric urologist.

How do I know if my child has a urinary tract infection?

Common signs include:

- Foul smelling or cloudy urine
- Fever
- Stomachache
- Backache
- Side pain
- Burning or pain when urinating
- Frequent and urgent urination
- Headache
- Vomiting

Infants with infection may not show these signs. Instead, they may have diarrhea, poor feeding, fever, and increased irritability. If there is any question, call your doctor and have your child's urine checked. Children can quickly become very sick.

How is VUR evaluated?

VUR is diagnosed using an X-ray of the bladder. This X-ray is called a voiding cystourethrogram (VCUG). In the VCUG test, a thin, soft tube (catheter) is placed in the bladder through the urethra (the tube we urinate through). Dye is then placed into the bladder through the tube. X-ray pictures are taken to see if the dye flows back into the ureters. The severity of VUR is determined by the amount of urine flowing back through the ureters to the kidneys. The most common grading system includes 5 grades, with grade 1 being the least severe and grade 5 being the most severe. If both ureters reflux, each side may have a different grade.

Can a child be given anesthesia for the VCUG?

A child can be given an anesthetic for the VCUG, but often times it is not recommended. Please discuss the pros and cons of sedating your child for the VCUG with your doctor.

Is VUR hereditary?

VUR tends to run in families. VUR is present in about 35% of siblings with VUR, and in up to 50% of children whose parent had VUR.[13,14]

The risk of kidney damage is greatest during the first 6 years of life.[3] The goal is to find VUR early and prevent infection that could result in kidney damage.[15]

How do I decide what treatment is the best for my child?

You should discuss your treatment options in great detail with your doctor. Antibiotics, endoscopic treatment and surgery are all options available to you. **Your family's personal views are important.**

Some families find it hard to do the routine X-ray test and daily medication required with antibiotic treatment. Surgery may be favored if VUR is severe or if there are related medical conditions.

What should we expect following the Deflux procedure?

There is usually no pain after the procedure. Your child may feel some stinging during the first few times he or she urinates. Be sure to call your doctor if your child cannot urinate, feels pain in his or her tummy, or back, has a fever after returning home.

After the procedure, your doctor will determine what type of follow-up is needed and if additional treatment is required.

What is Deflux made of and is it safe?

Deflux is made from two tissue-friendly polysaccharides (types of sugar molecules) — hyaluronic acid (HA) and dextranomer. The HA in Deflux is Non-Animal Stabilized Hyaluronic Acid (NASHA®) and is naturally broken down (biodegraded) over a short time and replaced by the body's own material, while the dextranomer remains in place longer.

NASHA has a 20 year history of safety, efficacy and biocompatibility, across a wide variety of medical applications.[10]

Your concerns and beliefs matter.

Therefore, it is important to discuss them with your doctor. Make sure you understand the risks, benefits, and follow-up of each treatment option.

Preparing for Your Doctor Visit

Before you visit your child's doctor, write down all the symptoms your child has had, how long your child has had them, and any other recent health issues. Document all medications, vitamins, and supplements your child is taking.

Questions for your doctor may include the following:

- What could be causing my child's symptoms?
- What can I do to reduce my child's risk of future urinary tract infections?
- Will my child get better on his or her own?
- Do you recommend that my child see a pediatric urologist?
- What are the treatment options?
- How will each treatment option affect my child?

You will want to have more specific questions for a pediatric urologist. During your visit, be sure to ask:

- What kinds of tests will you need to run?
- Is my child at risk of complications from this condition?
- Are my other children at increased risk of this condition?
- What are the treatment options?
- How will each treatment option affect my child?

There may be other questions you have. Make sure you ask them so you're comfortable with the treatment option you decide on with your doctor or pediatric urologist.

Important Information About Deflux[16]

Indication

Deflux is indicated for children with VUR grades 2-4. It is a gel that is injected where the ureter connects to the bladder in children with VUR.

Who should not be treated with Deflux?

Children with certain types of medical conditions should not be treated with Deflux:

- Non-functional kidney(s)
- Hutch diverticulum
- Ureterocele
- Acute voiding dysfunction
- Ongoing urinary tract infections
- Patients with megaureters

Your doctor will determine if these conditions are present. Ask your doctor if you have any questions about these conditions, or about how these conditions affect the use of Deflux. Inform your doctor if your child has an ongoing urinary tract infection. Children with urinary tract infections should not be treated with Deflux until the infection is gone.

To Learn More About VUR and Its Treatment,
and for more educational videos and resources, please visit deflux.com

Hear About One Mother's Journey Through VUR Treatment

Watch
Katie's Story
on Deflux.com

"We chose Deflux because it was **simple** and it offered **very good results**."

- Sam, Mother of a patient with VUR

watch Katie's story now

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Teleflex™

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Deflux is indicated for treatment of children with vesicoureteral reflux (VUR) grades II-IV. Individual results may vary. Side effects (>2%) include urinary tract infection typically occurring in patients with persistent reflux and ureteral dilatation with most cases resolving on their own. Calcifications, and blockage of ureter may be delayed and appear years later. Deflux can be seen on radiographic imaging and can be mistaken for ureteral stones. Patients/Caregivers should advise future physicians of prior treatment with Deflux. Consult your doctor to see if Deflux is suitable for your child.

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