

Deflux[®]

Brochure for Caregivers



Vesicoureteral Reflux (VUR)
in Children

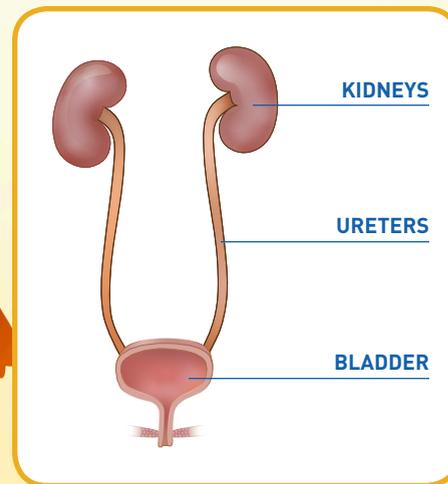
Your child has a condition known as vesicoureteral reflux (VUR). There are treatments that can help. In this brochure, you'll learn about VUR and how it can be treated.

Understanding VUR

About 1% of children in the world have VUR

Urine is made in the kidneys. Normally, it only flows one way: down the ureters and into the bladder. VUR occurs when urine flows back from the bladder through the ureters. This can happen in one or both sides.

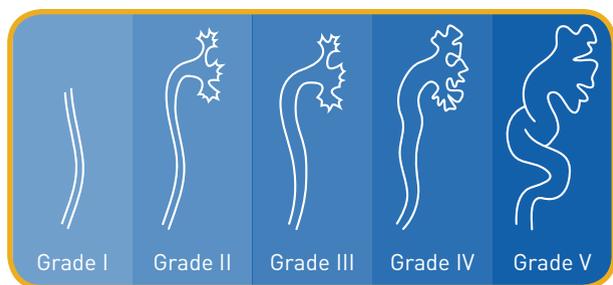
Some children are born with VUR. It results when the connection between the bladder and ureter is not normal. The lower part of the ureter tunnels through the muscle of the bladder. If this tunnel is too short or too much to one side, VUR may occur. Behaviors such as infrequent or incomplete urination and related constipation are also associated with VUR.



Understanding VUR

Is VUR serious?

Using X-rays of the urinary system, your doctor can tell you how serious your child's VUR is with a grading scale. This scale ranges from grade I (mild) to grade V (severe). Most of the time, milder grades of VUR will go away on their own. However, the more severe the VUR, the less likely it will go away on its own.



There can be serious consequences of VUR. Kidney infections can occur when infected urine flows back into the kidneys. These infections can lead to scarring and damage to the kidneys. This damage can cause poor kidney function and high blood pressure later in life.

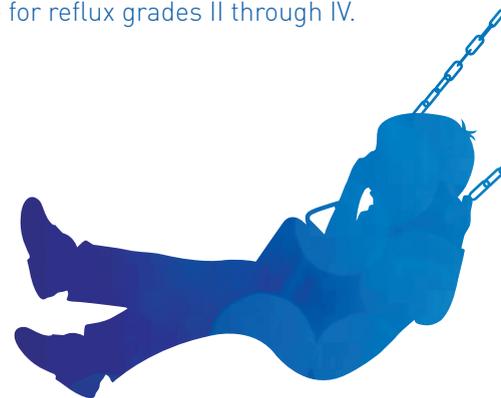
Testing for VUR

A test using X-rays and special dye will show if your child has VUR. This test is called a voiding cystourethrogram, or VCUG. If VUR is present, this test also shows whether it is a mild or severe grade. If you had VUR as a child, there is a chance that your children will have VUR. Also, if one of your children has VUR, his or her brothers and sisters may have it too. For these reasons, it is important to discuss testing options with your child's doctor.

There is help for VUR

It is important to treat VUR to prevent possible infections and kidney damage. There are 3 options for managing or treating VUR:

- **Antibiotics** may be used to prevent infections until VUR goes away by itself. This treatment may take several years, and children must take medicine every day. These children must be retested for VUR on a regular basis. Antibiotics are most suitable for milder grades of VUR. However, long-term treatment with antibiotics may cause the bacteria to become resistant, leading to more infections.
- **Surgery** can fix the ureters to stop VUR. This type of treatment cures most children. However, the operation can be stressful and painful to the child and they will need to stay in the hospital for a few days. Surgery is most suitable for higher reflux grades.
- In **endoscopic treatment**, a substance is injected where the ureter joins the bladder. The treatment usually takes about 15 minutes and allows children to go back to normal activities the next day. Endoscopic treatment is most suitable for reflux grades II through IV.



The Deflux Advantage

Deflux is a safe and effective treatment for VUR. A gel is placed into the body where the ureters meet the bladder. In a study involving children with moderate VUR, 80% of parents preferred an endoscopic treatment over antibiotics or surgery.¹

The Deflux procedure

Deflux gel is placed 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.

Your doctor will use a small camera called a cystoscope (a type of endoscope used to view the bladder) to properly place the gel. During the procedure, your child may be under general anesthesia.

Following the 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 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.

Deflux – effective treatment for VUR

Deflux works well to stop VUR in children. Many children have success after one injection, while some may need more injection procedures. 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 II-IV.²

Deflux is indicated for children that have reflux grades II-IV.

Deflux – safe treatment for VUR

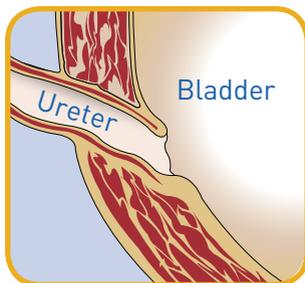
Deflux is made from two tissue-friendly polysaccharides (types of sugar molecules)— dextranomer and hyaluronic acid. The hyaluronic acid (HA) is naturally broken down (biodegraded) over a short time and replaced by the body's own material, while the dextranomer remains in place longer. Treatment with Deflux has some potential risks. There is a small risk of infection and bleeding from the procedure. Although a rare event, the gel might block the ureter and not allow the urine to flow down from the kidneys. You should ask your doctor about these side effects.

Deflux has been used safely for VUR for over two decades and the HA in Deflux has been used in more than 40 million procedures worldwide³, often as a dermal filler for wrinkle correction.

Answers to questions about VUR

What is vesicoureteral reflux (VUR)?

Urine is made in the kidneys. Normally, it only flows one way: down the ureters and into the bladder. VUR occurs when urine flows back from the bladder through the ureters. This can happen in one or both sides.



Close-up view of where the ureter enters the bladder.

What causes VUR?

Some children are born with VUR. It results when the connection between the bladder and the ureter is not normal. The lower part of the ureter tunnels through the muscle of the bladder. If this tunnel is too short or too much to one side, VUR may occur. Behaviors such as infrequent or incomplete urination and related constipation are also associated with VUR.

How is VUR evaluated?

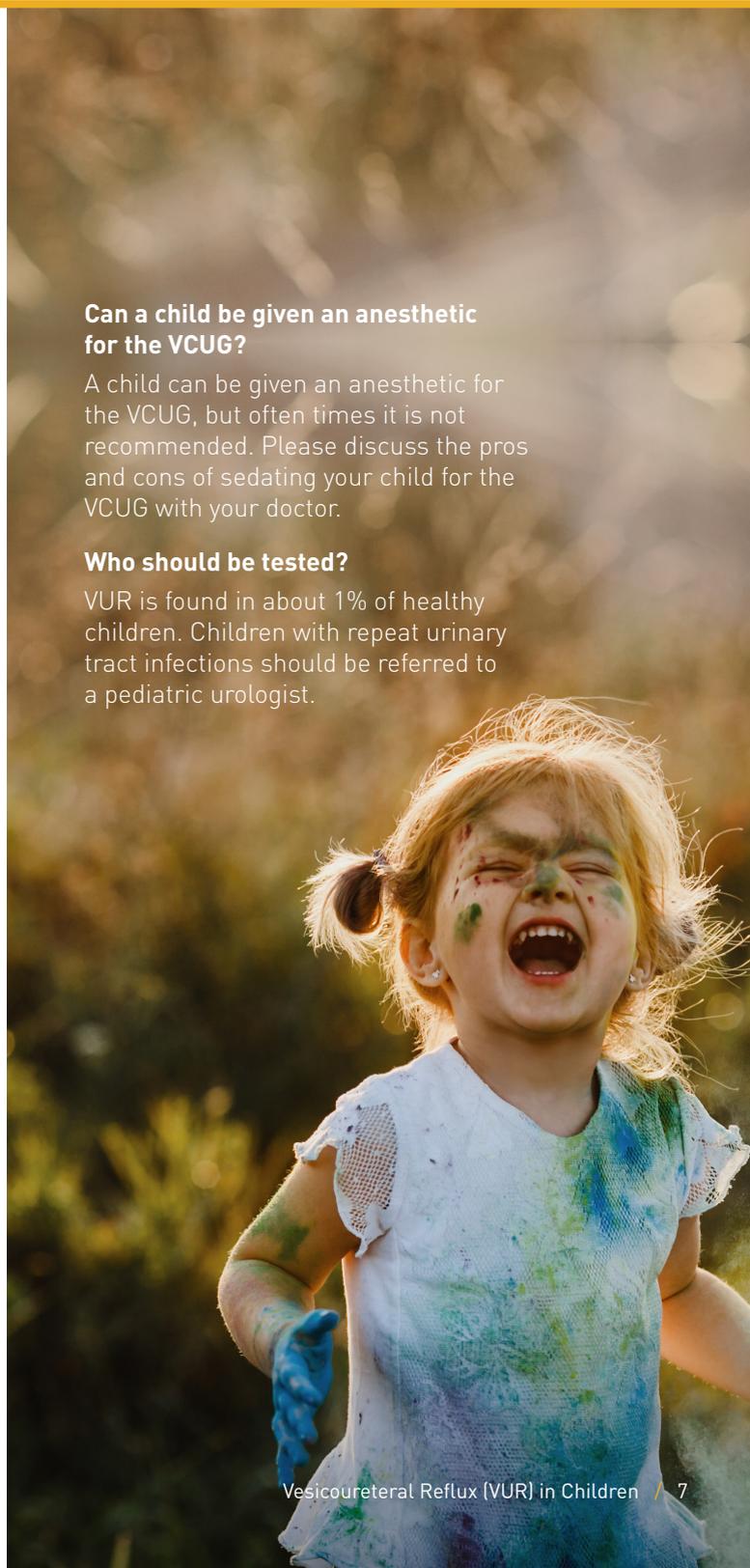
VUR is diagnosed using an X-ray of the bladder. This X-ray is called a voiding cystourethrogram (VCUG). In the VCUG test, a thin, soft tube (catheter) is placed in the bladder through the urethra (the tube we urinate through). Dye is then placed into the bladder through the tube. X-ray pictures are taken 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. The most common grading system includes 5 grades, with grade I being the least severe and grade V being the most severe. If both sides reflux, each side may have a different grade.

Can a child be given an anesthetic 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.

Who should be tested?

VUR is found in about 1% of healthy children. Children with repeat urinary tract infections should be referred to a pediatric urologist.



Answers to questions about VUR

Is VUR inherited?

VUR tends to run in families, VUR is present in 30% of siblings with VUR. If a parent has VUR, about half of his or her children will also have it.

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

Is VUR serious?

Treatment is important to protect the kidneys. Kidney infections may cause damage or scarring in the kidneys. This can result in poor kidney function and high blood pressure.

How do I know if my child has an infection?

Signs of urinary tract infections 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 do I decide what treatment is the best for my child?

You should discuss this in great detail with your doctor. Antibiotics, surgery, and endoscopic treatment of VUR are all good choices. Your family's personal views are most 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.

Deflux is a 15 minute procedure with a clinical success rate of up to 93% after one injection.² 80% of parents said they prefer endoscopic treatment over surgery or antibiotic treatment.¹

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.



Important information about Deflux

Indication

Deflux is a gel that is injected where the ureter connects to the bladder in children with VUR grades II-IV. It is placed to stop urine backflow to the kidneys.

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

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.

Warnings

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.

Precautions

Contact your doctor or your hospital if your child does not want to urinate, feels pain in the abdomen, or gets a fever returning home. Your child could have a blockage in the ureters. These blockages can damage the kidneys.

Adverse effects

There is a small risk of infection and bleeding from the procedure. Other side effects can happen. Some are rare such as blockage in the ureters. You should ask your doctor about these side effects.

Clinical test results

A recent study shows Deflux was proven effective in up to 93% of children, with no febrile UTIs after one injection.³

Deflux is indicated for children have reflux grades II-IV.

For more information or to find a physician trained in endoscopic treatment with Deflux near you, please visit deflux.com.



To learn more about VUR and its treatment, please visit [deflux.com](https://www.deflux.com)

References

- 1 Capozza N, Lais A, Matarazzo E, et al. Treatment of vesico-ureteric reflux: a new algorithm based on parental preference. *BJU International*. 2003; 92:285-288.
- 2 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*. 2021;8(4):359-365.
- 3 Data on file.



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