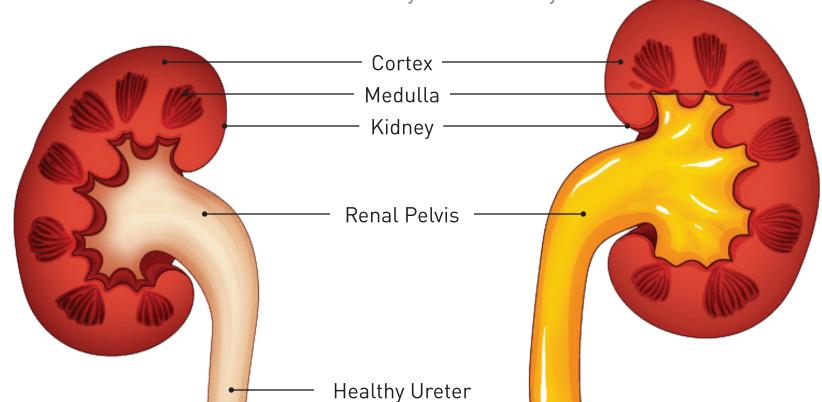


# Understanding Vesicoureteral Reflux (VUR)

#### What is VUR?

VUR occurs when the ureter opening located at the joining of the ureter and the bladder does not close properly. This causes urine to flow back up (reflux) from the bladder to the ureters and eventually to the kidneys.



Refluxing Ureter

Bladder

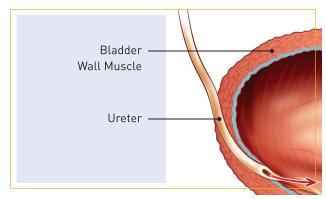
Wall Muscle

## How does a healthy kidney, ureter and bladder function?

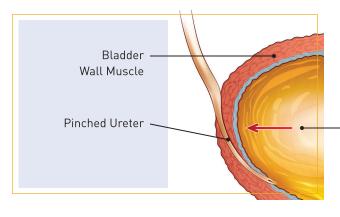
- Urine normally flows in one direction: down from the kidneys, through the ureters, to the bladder
- The urine is stored in the bladder until urination occurs

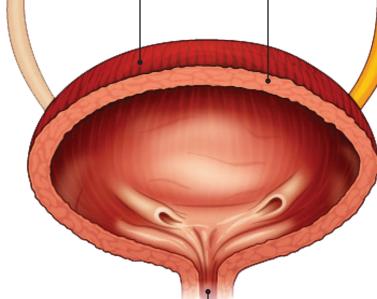
Urine is released from the bladder and flows out of the body through the urethra

#### Healthy Bladder (empty)



#### Healthy Bladder (with urine)





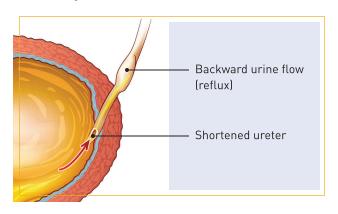
Urethra

Bladder

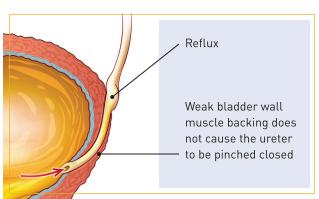
### What conditions are associated with VUR?

- Urinary tract infection (UTI) is associated with VUR
- Some children with VUR and febrile UTI have an increased risk of developing renal (kidney) scars
- Renal scars suggest that areas of renal damage exist, which may have been present from birth, or may have occurred due to other causes such as a kidney infection, called pyelonephritis

#### Anatomy of VUR (with urine)



#### Anatomy of VUR (with urine)



#### What is Deflux®?

Deflux is a gel made from two naturally occurring sugars, hyaluronic acid and dextranomer, and is indicated for the treatment of children with VUR grades 2-4. A pediatric urologist injects Deflux in or around the ureter opening (where the ureter joins the bladder). Deflux has been used safely and effectively for over 20 years, showing up to 93% success rates after one treatment.

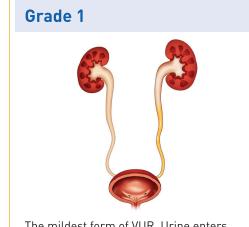
#### Will VUR resolve on its own?

The percent chance of reflux resolution after specified number of years (95% confidence interval)<sup>2\*</sup>

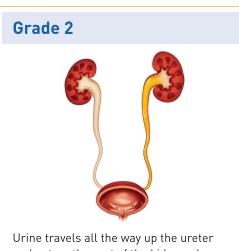
RISK CATEGORY age in months; number of patients on which estimates are based	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
<b>Grade 1</b> <sup>+</sup> N=15	<b>39.3</b> (24.6-51.1)	<b>63.1</b> (43.2-76.1)	<b>77.6</b> (57.2-88.3)	<b>86.4</b> (67.7-94.3)	<b>91.8</b> (75.7-97.2)
<b>Grade 2</b> <sup>+</sup> N=250	<b>28</b> (24.1-31.7)	<b>48.1</b> (42.3-53.4)	<b>62.7</b> (56.2-68.1)	<b>73.1</b> (66.8-78.2)	<b>80.6</b> (74.8-85.1)
<b>Grade 3,</b> unilateral, age 0-24 N=27	<b>21.4</b> (10.8-30.8)	<b>38.2</b> (20.4-52.1)	<b>51.5</b> (29-66.8)	<b>61.9</b> (36.6-77.1)	<b>70</b> (43.5-84.1)
<b>Grade 3,</b> unilateral, age 25-60 N=27	<b>13.4</b> (4.6-21.4)	<b>25</b> (8.9-38.3)	<b>35.1</b> (13.1-51.5)	<b>43.8</b> (17.1-61.9)	<b>51.3</b> (20.9-70.1)
<b>Grade 3,</b> unilateral, age 61-120 N=15	<b>10.8</b> (3.5-17.5)	<b>20.5</b> (6.9-32)	<b>29.1</b> (10.2-43.9)	<b>36.7</b> (13.4-53.8)	<b>43.6</b> (16.5-61.9)
<b>Grade 3,</b> bilateral, age 0-24 N=62	<b>12.7</b> (7-18.1)	<b>23.8</b> (13.5-32.9)	<b>33.5</b> (19.5-45)	<b>41.9</b> (25.1-55)	<b>49.3</b> (30.3-63.1)
<b>Grade 3,</b> bilateral, age 25-60 N=53	<b>7</b> (3.1-10.8)	<b>13.5</b> (6.1-20.4)	<b>19.6</b> (9-28.9)	<b>25.2</b> (11.8-36.6)	<b>30.5</b> (14.6-43.4)
<b>Grade 3,</b> bilateral, age 61-120 N=14	<b>2.6</b> (0.7-4.5)	<b>5.2</b> (1.4-8.8)	<b>7.7</b> (2.1-13)	<b>10.1</b> (2.8-16.9)	<b>12.5</b> (3.5-20.7)
<b>Grade 4,</b> unilateral <sup>‡</sup> N=28	<b>16.1</b> (8.5-23.1)	<b>29.7</b> (16.4-40.8)	<b>41</b> (23.5-54.5)	<b>50.5</b> (30-65)	<b>58.5</b> (36-73.1)
<b>Grade 4,</b> bilateral <sup>‡</sup> N=96	<b>4.5</b> (1-7.9)	<b>6.4</b> (2-15.1)	<b>7.8</b> (3-21.8)	<b>8.9</b> (4-28)	<b>9.9</b> (4.9-33.7)

The yearly rate of reflux resolution remains constant for each group
 No difference shown by age or laterality (unilateral/bilateral); therefore, these categories were combined
 Estimates only apply to the time of diagnosis and are not age specific.

For more information on VUR, visit Deflux.com.



The mildest form of VUR. Urine enters the ureter but does not travel all the way up to the kidney. The ureters look normal in size.



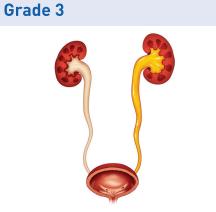
Pressure from a full

bladder causes the

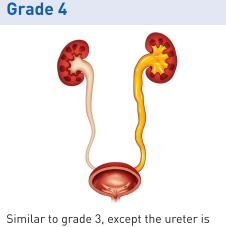
ureter opening to be pinched closed like

a straw

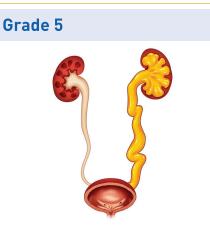
Urine travels all the way up the ureter and enters the part of the kidney where urine is collected before it drains to the ureter (renal pelvis). The ureters and renal pelvis appear normal in size.



Similar to grade 2, except the ureters and/or the renal pelvis appear abnormal in size or shape.



Similar to grade 3, except the ureter grossly enlarged.



The most severe form of VUR. Similar to grade 4, except the ureter is also twisted and curved. The renal pelvis is also enlarged and its normal structural details are no longer detectable

#### **Grades of VUR**



Palette Life Sciences
Medical Information Department
T: 844.350.9656
F: 510.595.8183
E: palettemc@dlss.com
Deflux is a registered trademark.

© 2020 Palette Life Sciences, Inc.

All Rights Reserved.

References

Kalisvaart JF, Scherz HC, Cuda S, Kaye JD, Kirsch AJ. Intermediate to long-term follow-up indicates low risk of recurrence after Double HIT endoscopic treatment for primary vesicoureteral reflux. *J Pediatr Urol*. 2012;9(4)359-365.

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.

#### Important information about Defle

Deflux® is indicated for the treatment of children with VUR Grades II-IV. Children with certain medical conditions should not be treated with Deflux®: non-functioning kidney[s], Hutch diverticulum, ureterocele, active voiding dysfunction, or ongoing urinary tract infection. Discuss these conditions with your healthcare provider. There is a small risk of infection and bleeding from the procedure. Other adverse effects can happen. Some are rare blockages such as in the ureters, which can damage the kidneys if not treated. Discuss these adverse effects with your healthcare provider.