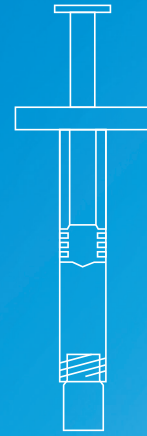


DEXELL® VUR 1 ml syringe contents

Cross-linked Sodium Hyaluronate (Hylan Gel)
DEAE Sephadex Dextranomer
Water for injection ad

15 mg
50 mg
1 ml



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DEXELL® VUR

Injectable Implant for the treatment of vesicoureteral reflux (VUR)



CE 2292

Date of Preparation: March 2018 Code: DX001

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DEXELL[®]VUR What is Vesicoureteral Reflux - VUR

Vesicoureteral reflux (VUR) is the retrograde passage of urine from the bladder into the upper urinary tract. It is the most common urological diagnosis in children, occurring in approximately 1% of newborns and as high as 30 to 45% in children with Urinary Tract Infection(UTI). Additionally, there is a high association between VUR, UTI, hypertension and renal damage. ¹⁻³

Treatment Options

- **Conventional Low Dose Antibiotic Therapy**

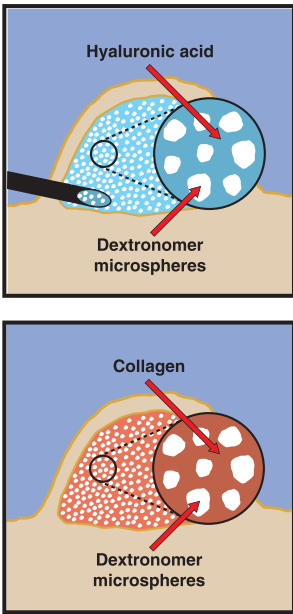
 - Extended treatment time
 - Patient/parent non-compliance
 - Risk of antibiotic resistance
 - Break through UTI
- **Surgical Ureter Reimplantation**

 - Invasive
 - Reimplantation of ureter into bladder
 - High success rate
- **Endoscopic Dextranomer/Hyaluronic Acid Injection**

 - Surgical injection of dextranomer/hyaluronic acid
 - Minimally invasive
 - Immediate correction of VUR
 - High success rate

Endoscopic correction of VUR offers a minimally invasive, day case procedure with a very low risk of complications compared to open surgery ⁴.

DEXELL[®]VUR



DEXELL[®]VUR consists of positively charged DEAE dextranomer microspheres (active ingredient) suspended in a cross linked hyaluronic acid gel solution (transporter). Both the dextranomer micro-particles and hyaluronate gel are biocompatible, non-immunogenic and biodegradable.

After initial injection the dextranomer microspheres and hyaluronate gel provide volume. The dextranomer microspheres stimulate collagen synthesis and fibroblast ingrowth into the degrading hyaluronic matrix, consolidating the implant within the bladder wall through endogenous tissue augmentation.

DEXELL[®]VUR Advantages

- Non rigid microspheres
 - No migration from injection site
 - Non-allergenic
- Non-immunogenic
 - Biodegradable
 - Biocompatible

Subureteral Injection with Small-Size Dextranomer/Hyaluronic Acid Copolymer: Is It Really Efficient? ⁵

Objective Does the size of dextranomer microspheres affect efficacy?

Method 75 children, VUR grade I-IV treated with Deflux[®] / DEXELL[®]VUR

Results Post operative VUR resolution at 30.1 (12–48) months, the success rate of the procedure was 100% in patients whose reflux grades were 1 and 2 before treatment according to the preoperative VCU. Subureteral small-size Dx/HA injection procedure was successful in 91% of patients with 3rd grade VUR before treatment and 82.6% of patients with 4th grade of VUR. Overall success rate of the treated patients was 97%. The success rates were demonstrated in Figure 1. The demographic features of patients were demonstrated in Table 1.

Conclusion The size of dextranomer microspheres (Deflux 80-250 µm, Dexell VUR 80-120 µm) does not affect short term success.

TABLE 1: The demographic features of patients.

	The degree of VUR before treatment				p
	Grade 1 (n:1)	Grade 2 (n:9)	Grade 3 (n:38)	Grade 4 (n:27)	
Age (mean)	11	7,1 (2–14)	7,1 (1–12)	5,5 (1–12)	0,155
Follow-up (months)	20	21,8 (5–48)	10,8 (1–36)	9,8 (1–40)	0,012
Sex					
Male (n:19)	0	3 (4%)	6 (8%)	10 (13,3%)	0,219
Female (n:56)	1 (1,3%)	6 (8%)	32 (42,7%)	17 (22,7%)	
VUR side					
Left	0	3 (4%)	12 (16%)	6 (8%)	0,077
Right	1 (1,3%)	6 (8%)	10 (13,3%)	7 (9,3%)	
Bilateral	0	0	16 (21,3%)	14 (18,7%)	
Treatment indication					
Infection	1 (1,3%)	9 (12%)	22 (29,3%)	15 (20%)	0,075
Scar	0	0	16 (21,3%)	12 (16%)	

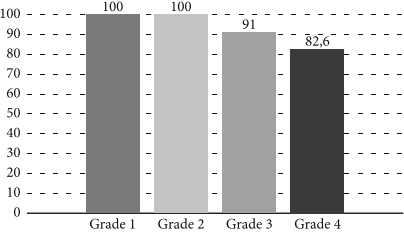
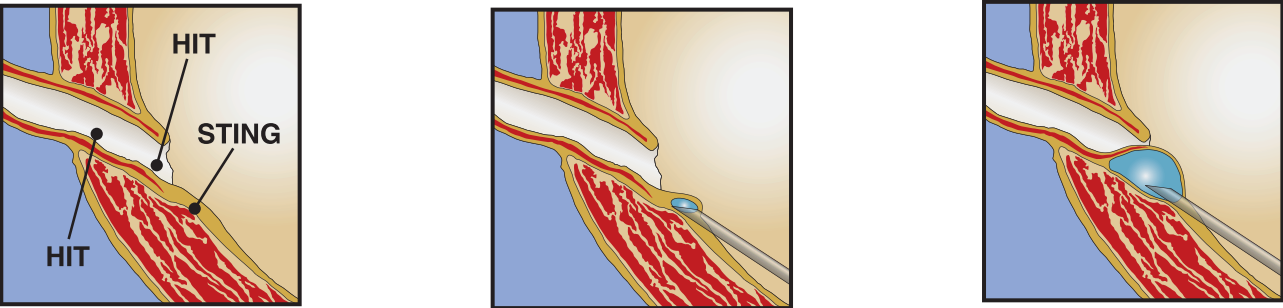


FIGURE 1: The success rates according to VUR grade (%).

DEXELL[®]VUR Application

DEXELL[®]VUR is suitable to be used with a cystoscopic injection needle in all injection methods e.g. STING and HIT.



DEXELL[®]VUR Methods of Application

For treatment of vesicoureteral reflux (VUR), the product is introduced to the locality of injection by way of a dedicated sterile needle through a cystoscope or cystoureteroscope working channel.

The injection should be done by a physician experienced in urology or gynecology who has a thorough knowledge of the anatomy of the ureter and the urinary bladder and is experienced with injections techniques in the relevant area. The treatment facility must be suitable for performance of aseptic procedures.