

DEXELL®

Endoscopic
Treatment
of VUR



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MEDİKAL TIBBİ CİHAZ VE SANAYİ LTD.ŞTİ.

DEXELL® 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 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

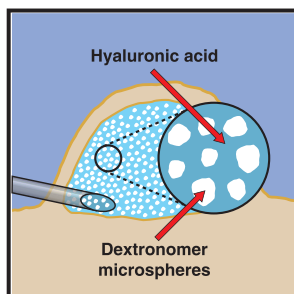
- Surgical injection of dextranomer/hyaluronic acid
- Minimally invasive
- Immediate correction of VUR
- High success rate

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

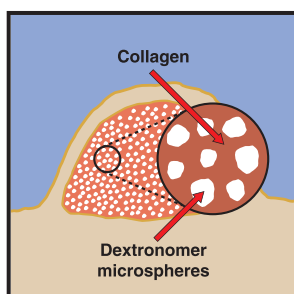
DEXELL® Advantages

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

DEXELL®



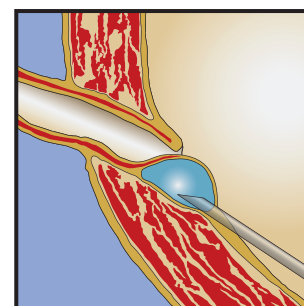
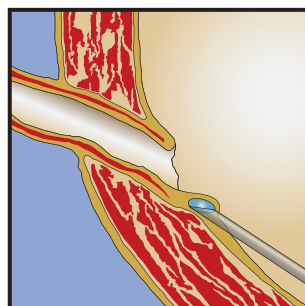
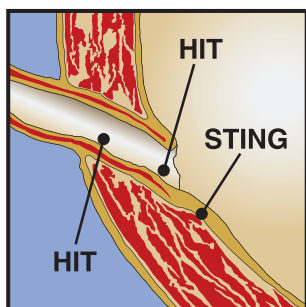
DEXELL® consists of positively charged DEAE dextranomer microspheres (active ingredient) suspended in a cross linked hyaluronic acid gel solution (transporter). Both the dextranomer micro-particles and hyaluronate gel are biocompatible, non-immunogenic and biodegradable.



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® Application

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



Dextranomer/Hyaluronic Acid for Pediatric VUR: Systematic Review ⁵

Objective Systematic review of dextranomer/hyaluronic acid for pediatric VUR.

Method Database search 1990 to 2008.

Results 1157 clinical reports (89 full review, 47 included in pooled analysis).
Of 7303 ureters injected, 77% of patients were successfully treated.

Conclusion 77% success rate after 3 months. Increased grade VUR negatively affected success.

Pre-operative VUR Grade	No. of Ureters	Pooled Success Rate (95% CI)	(95% CI) Higgins-Thompson measure of heterogeneity
All patients	7303	75% (71-78%)	87% (84-90%)
1	164	89% (69-90%)	61% (32-77%)
2	1399	83% (76-90%)	89% (86-92%)
3	2354	71% (64-79%)	93% (91-94%)
4	1109	59% (59-66%)	79% (70-85%)
5	123	62% (54-72%)	6% (0-40%)

Does the Diameter of Dextranomer Microspheres Affect the Success in Endoscopic Treatment of Vesicoureteral Reflux ⁶

Objective Does the size of dextranomer microspheres affect efficacy?

Method 116 children, VUR grade II-IV treated with Deflux® / Dexell®.

Results Post operative VUR resolution at 3 months, Deflux® 79.5% and Dexell® 78%.
de novo scarring at 3 months, Deflux® 3 of 60 and Dexell® 2 of 56 children.

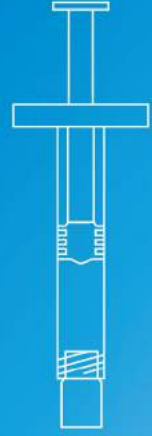
Conclusion The size of dextranomer microspheres does not affect short term success.

	Deflux®	Dexell®	p-value
Dextranomer size (50mg/ml)	80-250µm	80-120µm	
Hyaluronic Acid	17mg/ml	17mg/ml	
Children treated	60	56	NS
Ureters treated	102	90	NS
Age (yrs)	4.6	4.0	NS
VUR resolution - VCUG - 3 months	79.5%	78%	p>0.05
<i>de novo</i> scarring - DMSA scan - 3 months	3/60	2/56	P=0.001

DEXELL®

DEXELL® 1 ml syringe contents

Cross-linked Sodium Hyaluronate (Hylan Gel)	15 mg
DEAE Sephadex Dextranomer	50 mg
Sodium Chloride	6.9 mg
Water for injection ad	1 ml



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