



Biocalis

BIOCALIS UROLOGY

- **HYADEX[®]** (For the Treatment of Stress Urinary Incontinence (SUI) and Vesicoureteral Reflux (VUR))

www.biocalis.com

HYADEX® for SUI and VUR



- **HYADEX** **Injectable Gel** for the treatment of **Stress Urinary Incontinence (SUI)**
- **Injectable Gel** for the treatment of **Vesicoureteral Reflux.**

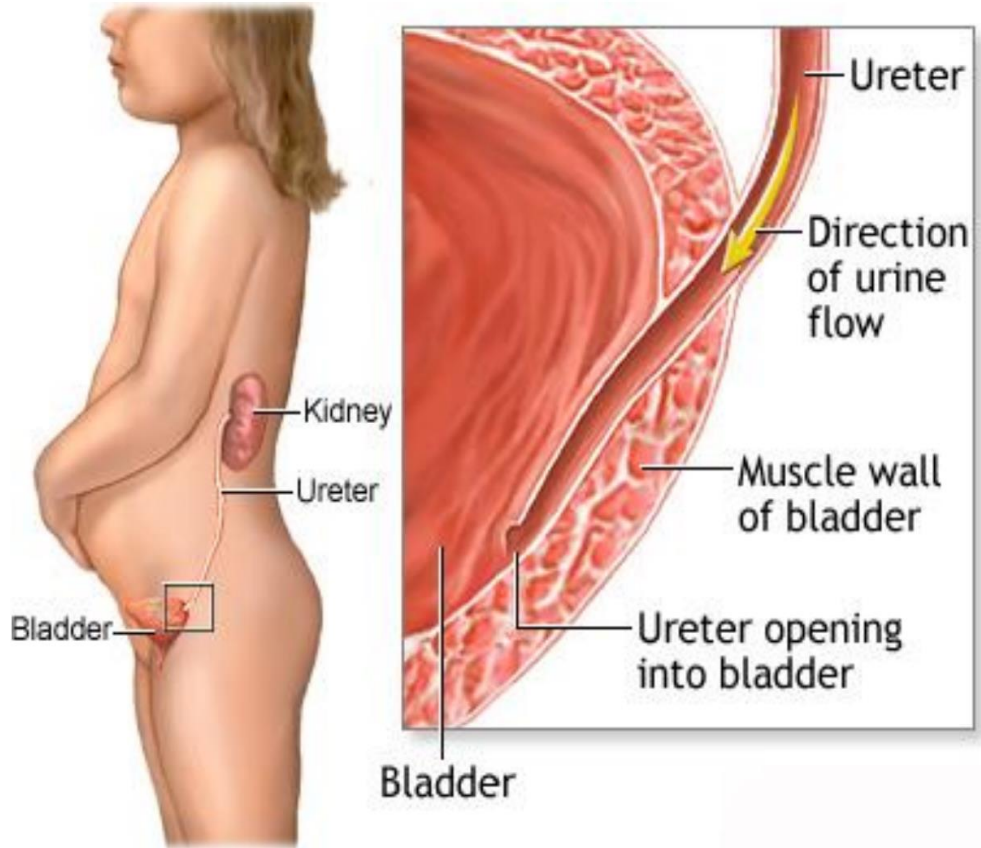
HYADEX®

- Hyadex® is a sterile viscous gel containing Dextranomer microparticles and non-animal based cross-linked hyaluronic acid.
- It is a biocompatible and biodegradable reaction material used in the treatment of;
 - Vesicoureteral Reflux (VUR) and
 - Stress Urinary Incontinence (SUI).
- Crosslinked hyaluronic acid acts as a carrier for basic Dextranomer-microparticles. Dextranomer- microparticles form volume on the connective tissue in the injected region.

VESICoureTERAL REFLUX - OVERVIEW

- When the ureters enter the bladder, they travel a distance through the wall of the bladder in such a way that they create a tunnel, forming a flap-like valve inside the bladder. This valve prevents urine from flowing back into the ureters and kidneys. In some children, the valves may be abnormal or the ureters in the bladder may not travel far enough along the bladder wall, which can cause vesicoureteral reflux. Such reflux is a condition that allows urine to flow back into the ureters and kidneys causing repeated urinary tract infections. Reflux of urine exposes the ureters and kidneys to bacterial infection and high pressure, which is generated by the bladder during urination. Without treatment, UTIs can cause kidney damage and scarring with loss of potential kidney growth and high blood pressure later in life.
- Primary VUR is ten times more common in Caucasian children than Blacks, and seen more commonly in girls than in boys. It is generally diagnosed in children under 5 years. As the child grows, the ureters elongate and become straighter, which may improve valve function with spontaneous resolution of the reflux. Primary vesicoureteral reflux has a tendency to run in families, which indicates that it may be genetic, but the exact reason for the defect is unknown.

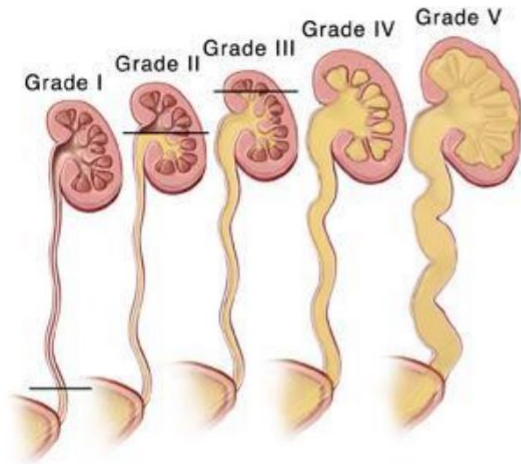
SIGNS and SYMPTOMS - VUR



- VUR in children is usually asymptomatic
- Some children may present with bedwetting (nocturnal enuresis)
- It is usually suspected when a child under 5 years has recurrent urinary tract infections (UTIs) with fever, abdominal pain, frequency and burning sensation while passing urine.
- Untreated reflux in childhood may lead to chronic kidney disease during adolescence with hypertension, urine protein and evidence of deranged kidney function on blood tests

HOW VESICOURETERIC REFLUX CAN BE TREATED ?

Vesicoureteric reflux (VUR) is **divided into five grades**. Grades 1 and 2 indicate mild disease whereas Grades 3,4 and 5 indicate more severe disease.



With VUR, urine flows backward from the bladder into the ureter (refluxes) and can cause the ureter and kidney to swell. Grades I-V are given depending on the severity of the reflux.

The treatment depends on the grade and severity of the VUR. Most children outgrow the VUR with spontaneous resolution by 5 years and treatment may be required only in their preschool years. Children who have VUR should also be assessed for presence of bladder and bowel dysfunction (BBD). Children with BBD symptoms such as constipation, fecal incontinence, sudden urge to pass urine, daytime wetting, or pain in the genital area are at greater risk of kidney damage due to infection.

MILD - VUR

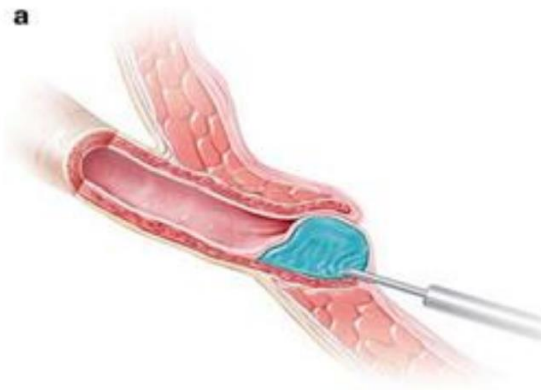
Children with mild degree of VUR may be referred to a child specialist (pediatrician), who may prescribe antibiotics to treat urinary infections. These children should have regular urine tests to rule out urinary infections and ultrasound scans periodically to ensure the kidneys are normal and not getting damaged.

SEVERE - VUR

Children with more severe VUR and presence of BBD may be given antibiotics at a low dose to prevent urinary infections, while simultaneously treating the BBD as well. They should undergo periodic urine examinations and ultrasound scans to monitor for scarring or damage to the kidneys. Children who continue to have recurrent infections despite antibiotics or have reflux even after five years of age may be referred to the pediatric urologist who will assess the need for surgery. Surgery may be recommended to treat severe VUR and prevent kidney damage and scarring.

GEL INJECTION

- The initial procedure that is usually recommended is to inject a gel into the terminal portion of the ureter within the bladder. This reduces gap, preventing urine reflux out of the bladder into the ureters, without obstructing urine flowing into the bladder. This is a quick procedure usually done as a day procedure. It can be done on babies and children of any age. The child will usually be discharged on the same day.



HYADEX®

- HYADEX® is a Injectable Gel for treatment of Vesicoureteral Reflux (VUR) and contained in a single use disposable 1 ml syringe. The 1 ml syringe is equipped with a tip cap, plunger and plunger rod. The syringe is terminally steam sterilized.
- The gel is a sterile, viscous gel containing Dextranomer microspheres range in size between 80-250 microns and non-animal based cross-linked hyaluronic acid. It is a biocompatible reaction material used in the treatment of vesicoureteral reflux (VUR) and Stress Urinary Incontinence (SUI). Cross-linked hyaluronic acid acts as a carrier for basic Dextranomer-microparticles. Dextranomer-microparticles form volume on the connective tissue in the injected region.
- The gel is injected submucosally in the urinary bladder in close proximity to the ureteral orifice. The injection of the gel creates increased tissue bulk thereby providing coaptation of the distal ureter during filling and contraction of the bladder. The dextranomer microspheres are gradually surrounded by host connective tissue.

STRESS URINARY INCONTINENCE OVERVIEW



- Urinary incontinence is one of the most common problems faced by women. Research shows that 20-46% of women of childbearing age and 40-69% of menopausal women struggle with urinary incontinence. This complaint, which occurs in the form of urine leakage from the bladder in cases such as coughing and straining, which may cause sudden increase in intra-abdominal pressure, can also be seen as inability to reach the toilet after urination.
- Women who suffer from urinary incontinence generally try to solve this problem by themselves, such as using pads and not leaving the house. However, urinary incontinence problem, which can cause psychological problems besides physical disorders, can be easily treated. The bladder which urine is collected after draining from the kidneys and the urethra which carries urine out of the body are located in the pelvis.
- These organs are kept fixed by the muscles supporting the pelvic cavity from the lower part. Relaxation and weakening of these muscles can cause urinary retention and incontinence. The most important reasons for muscle relaxation and weakness are previous pregnancies and normal births, long-term constipation, overweight, diseases that cause chronic cough, menopause and old age. As a result of the relaxation of the pelvic muscles, bladder sagging (cystocele), rectum sagging (rectocele) and incontinence (urinary incontinence) can be seen

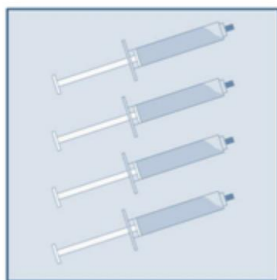
What are the Treatment Options of SUI

- Women have both non-surgical and surgical options to treat SUI. HYADEX is the Injectable Gel for nonsurgical treatment option for Stress Urinary Incontinence (SUI). Hyadex is contained in a single use disposable 1 ml syringe.
- The 1 ml syringe is equipped with a tip cap, plunger and plunger rod. The syringe is terminally steam sterilized. The gel is a sterile, viscous gel containing Dextranomer- microspheres range in size between 80-250 microns and non-animal based cross-linked hyaluronic acid. It is a biocompatible reaction material used in the treatment of Stress Urinary Incontinence (SUI).
- Crosslinked hyaluronic acid acts as a carrier for basic Dextranomer-microparticles. Dextranomer-microparticles form volume on the connective tissue in the injected region.

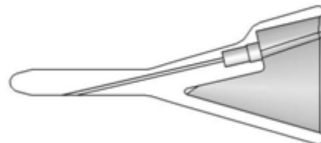
APPLICATION and TOOLS

Stress urinary incontinence Kit

- 4 syringes - 1 ml each
- 5 sterile needles 20G
- 1 Applicator
- 1 Catheter

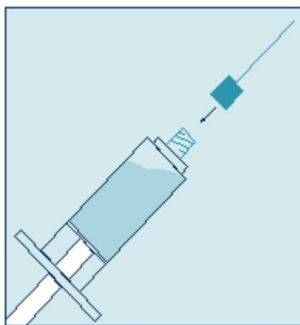


Applicator



- Specially designed for minimal-invasive intervention and safe implantation.
- Controlled symmetrical implantation at 3, 6, 9 and 12 o'clock

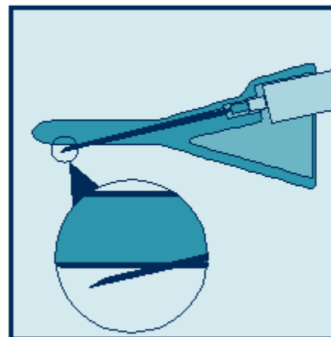
Syringes



- (20G) a needle is mounted to the luer lock lock mechanism at the end of the syringe

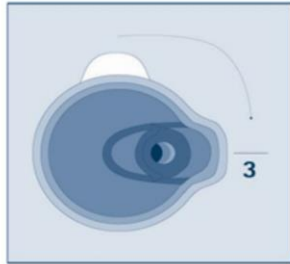
SUI INJECTION

- Insert the needle in the syringe into the applicator.
- Important! Bevel section (cut section) above!



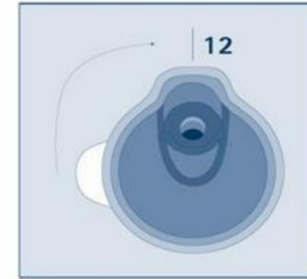
IMPLANTATION

Implantation



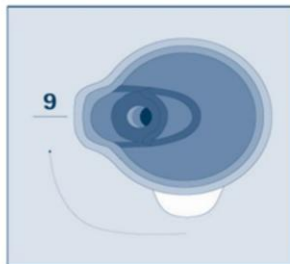
- Inject 1 syringe / 1 ml at the 3 o'clock position

Implantation



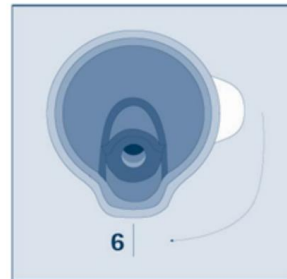
- Rotate the applicator to the 12 o'clock position (90°)
- Inject 1 syringe / 1 ml

Implantation



- Rotate the applicator at 9 o'clock (180°).
- Inject 1 syringe / 1 ml

Implantation



- Turn the applicator to the 6 o'clock position (180°)
- Inject 1 syringe / 1 ml



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“Health is
our greatest wealth”

‘To serve as the most trusted, convenient multichannel provider of innovative health solutions, products and services by enabling access to high quality medical devices.’