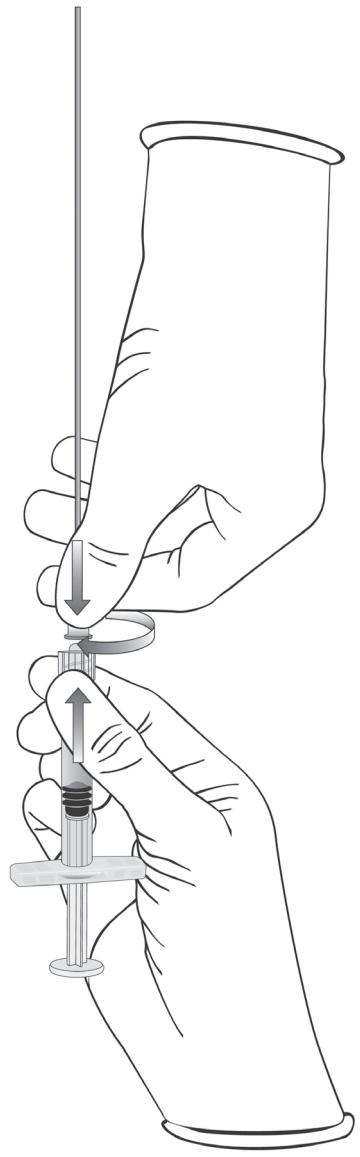

Fig. 1

Deflux®

June 2017
90-20969-05

Deflux® Instructions for Use

Composition

Each mL contains:

Dextranomer	50 mg
Hyaluronic acid, stabilized	15 mg
Phys. sodium chloride solution	q.s.

Description

Deflux is a STERILE, viscous gel of dextranomer microspheres and stabilized hyaluronic acid of non-animal origin constituting a biocompatible and biodegradable implant. Deflux is intended for submucosal injections in the urinary bladder and distal ureter. The stabilized hyaluronic acid acts mainly as a carrier, leaving the dextranomer microspheres at the implant site where they are gradually surrounded by host connective tissue. Deflux is supplied in a glass syringe with a luer-lock fitting containing 1 mL. Each syringe is terminally moist heat sterilized in a pouch and packed in a paper carton. The product is for single use only. The syringe label is furnished with indicative volume markings at 0.1 mL intervals. Patient record labels are included in the package to facilitate traceability of the product.

Indications

- Vesicoureteral reflux in children.

Contraindications

- Primary refluxing megaureters with distal stenosis.
- Uncontrolled voiding dysfunction.

Warning

- Deflux is only intended for submucosal injections in the urinary bladder and distal ureter.
- Do not resterilize Deflux as this will damage the product.
- Do not inject intravascularly.
- Do not mix with other products.
- Do not inject if the patient is known to be allergic to hyaluronic acid-based products or dextran.

Precautions

- The procedure and instrumentation associated with the injection of Deflux carry an inherent risk of urinary tract infection or bleeding, as do similar urological procedures. The usual precautions associated with urological procedures performed under sterile conditions, specifically cystoscopy, should be followed.
- Do not inject more than 6 mL of Deflux in children at the same treatment session.
- Inject slowly to avoid undue stress on the luer-lock connection which could cause leakage of the gel.
- Care should be taken with the handling of the glass syringe and needle to avoid laceration or other injury.
- In the event of accidental contamination of the device it should be discarded.
- The safety and effectiveness of Deflux in pregnant or lactating women has not been established.
- Do not use the product if the package is damaged.

Interactions

Treatment with Deflux in combination with drugs and other medical devices has not been studied.

Adverse Events

Postoperative dilatation of the upper urinary tract that resolves spontaneously within a few days has been observed in clinical investigations in less than 1% of treated patients. However rare cases of postoperative dilatation of the upper urinary tract with or without hydronephrosis leading to a temporary placement of a ureteric stent have been reported. In very rare cases of ureteral obstruction, ureteric reimplantation has been required.
Incidental findings of injection site calcifications which have been mistaken for distal ureteral calculi on imaging studies have been reported. Treating physicians should make the patients aware of this possible diagnostic confounder in imaging studies. Future physicians should be informed that the patient had a treatment with Deflux.

Adverse events thought to be related to the product should be reported to the manufacturer or local retailer.

Recommended needles

Contact the local retailer for details regarding suitable needles for use with Deflux. Be aware of a possible malfunction of the device with breakage of the syringe and leakage of injectable gel in the luer lock connection in case an improper needle is used. Due to pressure-flow relationships it is not recommended that long needles with a lumen diameter of less than 0.7 mm be used. In the treatment of vesicoureteral reflux the Deflux metal needle (3.7F x 23G x 350 mm) is recommended for safe and accurate administration of Deflux.

Treatment Procedure

Prior to treatment the patient should undergo a physical examination and be thoroughly evaluated to ensure proper patient selection. The patient should be advised that Deflux may not give a permanent therapeutic result and that additional treatment sessions may be required to achieve and maintain the effect of the treatment.

Deflux is to be administered only by qualified physicians or surgeons experienced in the use of a cystoscope and trained in the technique for subureteric injections (with Deflux or other materials).

Before injecting Deflux the following is recommended:

1. Flush physiological sodium chloride solution through the needle.
2. Fasten the needle tightly to the syringe.
3. Remove the air from the needle by injecting the gel into the needle up to a point where a droplet is visible at the tip.

The luer lock adapter is snapped onto the syringe and held in place with friction only. It can rotate freely or be pulled off should enough force be applied. Because of this it is recommended that the thumb and forefinger are held firmly around both the glass syringe barrel and the luer lock adapter when assembling the needle and syringe. To facilitate proper threading/fastening of needle hub and luer lock adapter, both **push and rotate** them firmly together (see Fig. 1).

To avoid any interruption in patient treatment or the need to repeat a procedure because of leakage, or accidental contamination or damage of a syringe or needle, it is recommended that extra syringes and needles be kept in inventory.

Deflux is preferably to be injected through a long metal needle, see Recommended needles, via a cystoscope with a minimum 4 French straight working channel. The material should be injected submucosally in the urinary bladder in proximity to the ureteral orifice or in the distal ureter at the 6 o'clock position. A volume of 0.5-1 mL is usually sufficient to create a prominent subureteric bulge and a crescent-like orifice. Normally 1 puncture gives a satisfactory result but in some cases 2-3 punctures may be required. Do not inject more than 3 mL at each ureteral orifice at the same treatment session. After injection the needle should be kept in place for 15-30 seconds and withdrawn slowly to prevent extrusion of the gel.

Do not re-shield used needles. The syringe, the needle and any unused material must be discarded immediately after the treatment session and must not be reused due to risk for contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable requirements for handling of sharp devices and potential biohazards.

Shelf life and storage

The expiry date is indicated on package. Store below 25 °C. Protect from direct sunlight. Do not Freeze.

Legal Manufacturer

Oceana Therapeutics Ltd
3013 Lake Drive
Citywest Business Campus
Dublin 24, Ireland

Sponsor

Link Medical Products Pty Ltd,
5 Apollo Street
Warriewood NSW 2102

Link Pharmaceuticals Ltd
Auckland
New Zealand

Symbols on packaging

CE 0344	CE-marked according to MDD 93/42/EEC; 0344 is the notified body number