UROLASTIC INSTRUCTIONS FOR USE

CE 0482

PRODUCT DESCRIPTION
Urolastic is a proprietary LSR elastomer composition. The product is presented in a pre-filled, sterile, 5 ml dual syringe with 2 x 2.5 ml Urolastic. It is supplied with a static mixer, which permits adequate pre-mixing to prevent component dissociation during injection, and an attached sterile 1.20 x 50 mm (18G x 2") needle.

Urolastic is a minimally invasive flexible peri-urethral implant for the treatment of SUI. It is easy to inject and polymerises in situ into a uniform elastomer within seconds of application. The product will remain flexible and adapt to the form of the environment during injection, reducing the chances of migration. It is not biodegradable, resulting in a long-term effect. As the product is clearly visible via ultrasonic imaging, it allows for retrospective investigation or removal in the event of an emergency. Reflux of the material after injection as a consequence of the interstitial pressure is unlikely after polymerisation.

MODE OF ACTION
Urolastic is a two-component product supplied in a dual syringe, mixed in a static mixer and subsequently dispensed through a 18 Gauge needle. Urolastic is injected peri-urethral in the mid urethral submucosal tissue.

The injection of Urolastic creates increased tissue bulk and subsequent coaptation of the tissue around the mid-urethra. Over time, collagen is deposited around the silastic material.

INDICATION
Urolastic is intended to be used as peri-urethral implants for the treatment of female stress urinary incontinence (SUI).

CONTRAINDICATIONS
Urolastic is contraindicated in the following conditions:
- acute urogenital tract inflammation
- gross utero-vaginal prolapse
- detrusor overactivity
- neurogenic bladder
- overflow incontinence
- pregnancy, within one year post-partum
- urinary tract infection
- active herpes genitalis
- autoimmune diseases or patients receiving systemic corticosteroid treatment

WARNINGS / PRECAUTIONS
Urolastic is only to be administered by trained qualified physicians with experience in urological procedures. Improper patient selection, improper surgical implantation of the implant and/or overcorrection may result in unsatisfactory performance.
Pre-operative microbiological cultures of urine must be performed to ensure the absence of urinary tract infection. Evaluate the condition of the tissue (e.g. hardness, oedema, haematoma, atrophy) at the site of injection prior to treatment. Do not inject if the tissue is damaged. Patients receiving treatment interfering with blood coagulation have an increased risk of haematoma or urethral bleeding. Do not inject intravascularly. In the event of accidental contamination of the needle after assembly, discard the device.
Do not use needles other than those supplied with the package. The cystoscope used should fit an Olympus A2213, Tian Song A1103.1, Shenda N4021 or equivalent sheath. The applicator support can be used as an alternative to the use of a cystoscope depending on the preference of the user and availability of an appropriate sheath. A safe procedure can only be performed using the instruments and materials that are supplied by Urogyn BV.
During the procedure an indication of a too deep injection of material may be observed. The injection sequence should be stopped and the depth of the injection checked to correspond with the intended depth of injection if the following arises (if there are any doubts the procedure should be aborted):
- patient perceives excessive pain
- excessive amount of blood loss, including blood in urine when coughing, or formation of hematoma
- material reflux on cystoscope sheath or applicator support
- physician cannot feel any material after injections
- no excess material to remove from injection site

This product is single use only. In theory, multi-use can increase the risk of cross-infection. In practice multi-use is not possible, because all product contacted components become unusable due to the curing of the silicone material during application. Any co-packed instruments are supplied as single use disposable and not considered to increase the risk of cross-infection through their extra-corporal use.
Providing the package is undamaged, sterility is guaranteed. Do not use the package if it is damaged. Do not re-sterilise.
Note that (potentially) contaminated materials may be returned only following Urogyn's instructions, e.g. in a sealed container/bag. Apply hospital procedures to safely dispose of contaminated material and components, e.g. used needle.

ADVERSE EVENTS
The following adverse events might be seen with peri-urethral implant injections:

- urinary tract infection
- urinary urgency
- dysuria
- acute retention (< 7 days)
- non-acute urinary retention (> 7 days)
- nausea, vomiting, diarrhea
- genitourinary problems
- dyspareunia, vaginal pain
- hematuria
- urinary frequency
- outlet obstruction (slow, prolonged stream)
- excreted peri-urethral implants

Bladder inflammation may result from the handling during the procedure. For this reason a prophylactic antibiotic is recommended. Any known allergy to this drug should be investigated.

Some bleeding may occur at the injection site and some difficulty may be experienced with voiding during the first days after the procedure as a consequence of the changed anatomical position of the urethra.

Any side-effects or adverse events considered to be related to the product should be reported to the manufacturer or local retailer.

PATIENT INFORMATION
The patient should be informed about the intended use, expected results, contraindications, precautions, warnings and potential adverse events.
The patient should be advised that Urolastic may not give a permanent therapeutic result and that additional treatment sessions may be required to achieve and maintain the treatment’s effect.

METHOD OF ADMINISTRATION:
Urolastic is a two-component product supplied in a dual syringe, mixed in a static mixer and subsequently dispensed through an 18G needle. Urolastic is injected peri-urethral in the submucosal tissue around the mid urethra using the appropriate Urolastic applicator head and dispenser gun.
The injection of Urolastic creates increased tissue bulk and subsequent coaptation of the tissue around the mid-urethra. Over time, collagen is deposited around the elastomeric material.

The Urogyn applicator head has been designed with four openings for guiding the needle and facilitating injections at different positions. Peri-urethral injection is chosen to prevent damage to the urethral mucosa or back flow of the material. Using the droplet technique, Urolastic is injected at the 2, 5, 7 and 10 o’clock positions. Depending upon the effect measured after 6 weeks, the treatment can be repeated by injecting Urolastic next to the initial deposits at the 3 and 9 o’clock positions. To prevent overcorrection, total amounts of up to 1.4 ml of Urolastic at both the 5 and 7 o'clock positions and up to 0.8 ml at both the 2 and 10 o'clock positions may be injected. This procedure can be performed either blind (using the applicator support) or under cystoscopic vision.

A not or sub optimal injection result can be due to a not or sub optimal injection technique or anatomic variations. The optimal position of a bolus of bulking agent is directly under the mucosa. Intra-mucosally injected material will lead to mucosa rupture and loss of the implant. Implants that are injected too deep will disappear via tissue clefts or will not lead to any visible effect at the location of the urethral lumen.

PRE-OPERATIVE PROCEDURES
Prior to treatment the patient should undergo a physical examination and be thoroughly evaluated to ensure proper patient selection. Test the patient’s urine in order to exclude urinary tract infection (UTI). Do not proceed if

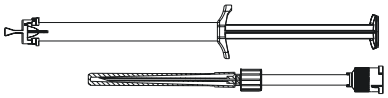
infection is present.
A radiographic examination of the thorax (X-Thorax) is to be performed prior to the peri-urethral implant injections. Make sure the product is conditioned at room temperature before use.
One dose of an oral prophylactic antibiotic (such as Ciprofloxacin®, 500 mg) and one dose of an oral NSAID (such as Naproxen sodium®, 500 mg) should be given just at the start of the procedure. If the patient is allergic for one of these drugs, other drugs may be chosen.
Prepare for routine cystoscopy; if the procedure is done under local anesthetic the patient is asked to cough, to demonstrate stress urinary incontinence.
Place the patient in lithotomy position. Disinfect according to local routine procedure. 5–10 minutes prior to the procedure, place anaesthetic gel inside the urethra, and/or inject 5–10 ml lidocaine hydrochloride with adrenalin 0.5–1 % or similar preferrably 1 cm bilaterally to the mucosa along the urethra (3 o'clock and 9 o'clock).

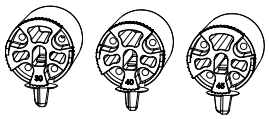
PERI-OPERATIVE PROCEDURES
Urolastic is applied peri-uretherally through an 18G needle under cystoscopic vision of the bladder neck. Considering the initial procedure the implant is situated at the 2, 5, 7 and 10 o'clock positions. The urethra may be flushed during the procedure, e.g. to provide sufficient vision. The applicator support may be used as an alternative to the cystoscope (blind procedure).
A Foley (or similar) catheter of 16-18 F is brought into the bladder and the bladder is emptied. Then 200 ml of physiological salt solution is introduced. After estimating the length of the urethra by taking the Foley catheter at the urethral entrance and removing it from the bladder, unpack the applicator heads and select the correct size for mid-urethral injection (heads are marked 30, 40 and 45). Write down the length of the urethra after measuring and check the right size applicator head has been selected and mounted, and remove the remaining sizes from the area. When the cystoscope or applicator support is pushed into the lumen of the correct applicator head until stopped by the transparent cap, the injection of Urolastic will be at the mid-urethral position and the optical lens will provide a clear image of the urethra and the effect of bulk deposits during injection. Subsequently lock the cystoscope or applicator support to the applicator head and remove the cap.
1. Peel open the blister and remove the Urolastic syringe from the package. Keep the cap on the tip of the syringe while placing the syringe with the printed side up into the dispenser gun. Using aseptic technique, remove the static mixer/needle combination from the package.
2. Remove the protective tip cap from the Urogyn syringe. Without removing the needle's protective sleeve, attach the mixer/needle by firmly tightening the hub of the mixer onto the Urolastic syringe's lock tip. Attach the mixer with attached 18G needle firmly into the lock socket. Check that the needle is tightly connected to the mixer and remove the needle's protective sleeve.
3. Prior to inserting the needle into the applicator head, carefully express the Urolastic material until visible at the tip of the needle. Sqeeuze out a little bit of material and wipe it off with a sterile cloth. Start injecting within 2 minutes, before the increasing viscosity renders it too difficult. Selecting the toggle switch on the dispenser gun to accommodate either a dosage of 0.1 or 0.2 ml per stroke will provide some flexibility as required.
4. As soon as the area is anesthetised, advance the cystoscope or applicator support into the urethra. Place the front end of the applicator head against the urethral meatus and rotate to allow injection at both 10 and 2 o'clock positions. Make sure that the cystoscope or applicator support is in line with the direction of the urethra and prevent pushing.
5. The needle is then passed into the corresponding needle guide of the applicator head. The needle is inserted peri-urethral, on a small angle prefixed by the applicator head. Do not angle the cystoscope or applicator support. Angling can lead to either a too deep or too superficial injection. Correct needle placement within the mucosa is checked by injecting a small amount of the implants. If the needle is properly placed, tissue bulking will immediately appear in the urethral mucosa at mid-urethral position.
6. Slowly inject 0.5-0.8 ml of Urolastic at the 10 o'clock position. After injection is complete, wait approximately 30 seconds before withdrawing the needle from the tissue. Repeat this procedure at the 2 o'clock position.
7. Now inject 0.8-1.4 ml at the 5 o'clock position to obtain the required occlusion of the urethra. Repeat this procedure for the 7 o'clock position.
8. Ask the patient to cough to verify sufficient effect has been obtained. Then remove any product remains at the puncture holes, manually or with a pair of tweezers.
9. Depending on the patient's history of a previous surgical incontinence procedure (i.e. bladder neck suspension, sling procedures, etc.) and morphology of the bladder neck and urethra, the Urolastic implantation sites and volumes may be adjusted to achieve optimal urethral coaption or closure.
10. Withdraw the needle prior to removal of the scope or applicator support from the urethra. Specific care must be taken not to introduce the cystoscope or applicator support again into the bladder for this will compress the injected bolus. If necessary (for additional verification) only the optics part of the scope should be used.
11. The patient must be asked to stay in the hospital until she is able to void normally. No indwelling catheter is to be left behind at any stage.
12. Upon the patient's initiative the physician will verify whether or not to decide for a repeated treatment in case of persistent leakage.

POST-OPERATIVE PROCEDURES
An ultrasonic examination of the implants is to be performed directly following the bulk injections. In case of voiding difficulties, nursing staff responsible for postoperative care should be clearly instructed not to use any catheter with a larger diameter than a 12 Gauge. Intermittent catheterization is carried out until a patient resumes spontaneous voiding. A patient is only discharged when complete, residue free voiding is possible.
Patients should refrain from doing any heavy lifting, exercise or sexual intercourse for 6 weeks to allow for encapsulation of the implant with connective tissue.

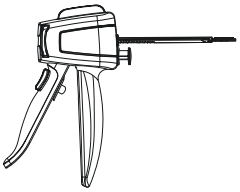
RE-IMPLANTATION PROCEDURES
If a second implantation of additional material is required, reimplantation by injecting next to the initial deposits should not be carried out within six (6) weeks.
Following these instructions for use, the same procedure may be executed with the amounts of bulk material indicated, depending on the physician's observations.

HOW SUPPLIED
Urolastic consists of one pre-filled 5 ml dual PP syringe with a lock fitting containing 2 x 2.5 ml (1:1) Urolastic elastomer composition. The syringe label is indicated with markings and the interval between each marking is 0.2 ml. The syringe's contents are sterile. One static mixer with attached needle 1.20 x 50 mm (18G x 2") is co-packed with the syringe in a blister.
The product comes with the Urolastic applicator heads included, used during the Urolastic procedure for inserting the Urolastic injection-needle at specified places into human tissue and guiding the applicator support or a cystoscope into the urethra. Both the applicator heads set, applicator support and dispenser gun are provided sterile, for single use only.


Product syringe & static mixer


Applicator heads

Applicator support


Dispenser gun

The complete product configuration holding the above components comes ETO sterilized.

STORAGE CONDITIONS
Shelf life as indicated on package. Store at a temperature of up to 25ºC.
Do not use the product if the package is damaged. Symbol used on package:

These instructions for use are also available as a PDF file on www.urogynbv.com or by contacting Urogyn, see details below. Paper versions can be provided upon request within five working days at no additional cost.

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DISCLAIMER OF WARRANTIES
Urogyn excludes all warranties and responsibilities for the improper use of the product and/or the failure to follow the instructions in this insert.

This product is to be handled and/or implanted only by accordingly trained and qualified professionals.

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