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 vulcanizes 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 small size particle migration. It is not biodegradable, and so will maintain its bulking effect over a longer period of time. 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 vulcanization.

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 area.

The injection of Urolastic creates increased tissue bulk and subsequent coaptation of the tissue around the mid-urethra, thus increasing the urethral maximal pressure. Over time, the implants are encapsulated in connective tissue, making the tissue firmer and providing partial stabilization of the mid-urethra.

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 qualified physicians trained in the Urolastic procedure (Urolastic-certified). 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 and replace the needle.
A safe procedure can only be performed using the instruments and materials that are supplied by Urogyn B.V. Do not use needles other than those supplied with the package. If application under vision is preferred, the applicator support may be replaced with a cysto/urethroscope; the applicators fit to Olympus A2213, Tian Song A1103.1, Shenda N4021 or equivalent sheaths.
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 applicator support
- physician cannot feel any material after injections
- no excess material to remove from injection site

If excessive pressure is needed to squeeze out the material, do not continue. The needle tip may be blocked by connective tissue or material from earlier procedures (slings). Reflux of Urolastic material along the needle may be observed. Retract the needle and slightly change the position before injecting again.

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
- urinary retention
- 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.

Erosion may occur in particular when the implant is placed too superficial.

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 mid-urethral area, 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. To prevent overcorrection, total amounts of up to 0.8 ml of Urolastic may be injected at each of the 2, 5, 7 and 10 o'clock positions. This procedure can be performed blind, using the applicator support. 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.

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 peri-urethral in the mid-urethral area. Intra or submucosally

injected material will lead to mucosa rupture and loss of the implant. Implants that are injected too far from the urethral wall 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.

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) may 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 ml lidocaine hydrochloride with adrenalin 0.5–1 % or similar preferably 1 cm bilaterally to the mucosa along the urethra (3 o'clock and 9 o'clock).

PERI-OPERATIVE PROCEDURES

1. 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. Measure the length of the urethra by clamping the Foley catheter at the urethral entrance and removing it from the bladder. Perform the cough test. Take the protective sleeve from the needle assembly, put the tip into the meatus and determine the direction of the urethra. Remember this angle.
2. Unpack the applicator heads and select the correct size for mid-urethral injection (heads are marked 30, 40 and 45) based on the length of the urethra measured; remove the remaining sizes from the area.
3. Prepare the protective sleeve to correspond to the length of the applicator head by cutting off the top end, thus creating an application port for the 5 and 7 o'clock positions. In case the applicator head cannot be correctly positioned (e.g. small, narrow vagina or short 1-2 cm urethra) the prepared needle sleeve may also be applied at the 2 and 10 o'clock positions.
4. Take 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.
5. Remove the protective tip cap from the Urogyn syringe. 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.
6. Unpack the applicator support and slide into the lumen of the correct applicator head until stopped by the transparent cap. Subsequently lock the applicator support to the applicator head and remove the cap.
7. Ensure again, that the selected applicator head and prepared sleeve will guide the fully inserted needle tip up to the mid-urethral area.
8. As soon as the area is anesthetized, advance the 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 applicator support is angled in the direction of the urethra and prevent pushing.
9. Prior to inserting the needle into the applicator head, carefully express the Urolastic material until visible at the tip of the needle. Squeeze 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.
10. The needle is then passed into the corresponding needle guide of the applicator head and inserted peri-urethral, while maintaining the applicator support in the direction of the urethra. Do not change the angle of the applicator support because this can lead to either a too deep or too superficial injection. Correct needle placement is checked by injecting a small amount of the implants. If the needle is properly placed, tissue bulking will immediately appear in the mid-urethral area.
11. Slowly inject 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.
12. Withdraw the needle prior to removal of the applicator support from the urethra. Specific care must be taken not to introduce the applicator support (or cysto/urethroscope) 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.
13. Now carefully place the prepared needle sleeve over the needle and inject 0.8 ml at the 5 o'clock position to obtain the required occlusion of the urethra. Repeat this procedure for the 7 o'clock position.
14. 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.

15. 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 coaptation or closure.

POST-OPERATIVE PROCEDURES

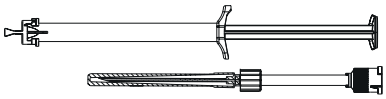
After the procedure the patient is asked to void. In case of voiding difficulties, nursing staff responsible for postoperative care should be clearly instructed not to use any catheter with a larger diameter than a 12 Gauge. Intermittent catheterization is carried out until a patient resumes spontaneous voiding.
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

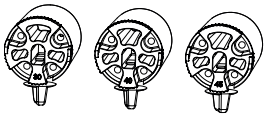
Upon the patient's initiative the physician will verify whether or not to decide for a repeated treatment in case of persistent leakage. If a second implantation of additional material is required, reimplantation by injecting next to the initial deposits should not be carried out within six (6) weeks. 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 into the urethra. Both the applicator heads set, applicator support and dispenser gun are provided sterile, for single use only.

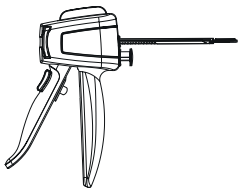


Product syringe & static mixer



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.

Manufactured by:
Urogyn B.V.
Middenkampweg 17
6545 CH Nijmegen
The Netherlands
Tel.: +31 247114130

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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