PROLASTIC INSTRUCTIONS FOR USE

CE 0482

PRODUCT DESCRIPTION
Prolastic 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 Prolastic. It is supplied with two static mixers, which permits adequate pre-mixing and two sterile 1.20 x 75 mm (18G x 3") needles.

Prolastic is a minimally invasive flexible bulking agent used for the treatment of male urinary incontinence. 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
Prolastic is a two-component product supplied in a dual syringe, mixed in a static mixer and subsequently dispensed through a 18 Gauge needle. Prolastic is injected around the urethra near the urethral sphincter.

The injection of Prolastic creates increased tissue bulk and subsequent coaptation of the urethral lumen, to achieve a better anatomy, closure of the urethra and preventing leakage of urine. Over time, connective tissue is deposited around the elastomeric material.

INDICATION
Prolastic is intended to be used as a bulking agent for the treatment of persistent male urinary incontinence still present at least 6 months after radical prostatectomy or TURP (transurethral resection of the prostate) procedure.

CONTRAINDICATIONS
Prolastic is contraindicated in the following conditions:
- acute urogenital tract inflammation
- detrusor overactivity
- neurogenic bladder
- overflow incontinence
- urinary tract infection
- active herpes genitalis
- autoimmune diseases or patients receiving systemic corticosteroid treatment

WARNINGS / PRECAUTIONS
Prolastic 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. A safe procedure can only be performed using the instruments and materials that are supplied by Urogyn BV.
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 bulking agent injections:

- urinary tract infection
- urinary urgency
- dysuria
- acute retention (< 7 days)
- non-acute urinary retention (> 7 days)
- nausea, vomiting, diarrhea
- genitourinary problems
- hematuria
- urinary frequency
- outlet obstruction (slow, prolonged stream)
- excreted bulking material

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 anatomy around 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 Prolastic 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:
Prolastic is a two-component product supplied in a dual syringe, mixed in a static mixer and subsequently dispensed through an 18G needle. Prolastic is injected from the perineum into the submucosa of the urethra and should be placed just caudally of the vesicourethral anastomosis after radical prostate surgery or at the (remainder of) the distal (external) urethral sphincter in adenectomy or TURP, using the Prolastic applicator head and dispenser gun, and the Prolastic applicator support (provided separately).
The injection of Prolastic creates increased tissue bulk and subsequent coaptation of the urethral lumen. Over time, connective tissue is deposited around the elastomeric material.

Using the droplet technique, 1.6 ml of Prolastic is injected at the 3 and 9 o'clock positions (approximate target values, subject to the investigator's observations during treatment). Depending on the effect measured after 6 weeks, the treatment can be repeated by injecting up to 1ml below the initial deposits at the 5 and 7 o'clock positions under cystoscopic vision in order to prevent overcorrection.

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 bulk 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.
Place the patient in lithotomy position.
Disinfect area around the penis and the perineum and make sure that covers used leave enough space for approach of the perineum.

Five to ten minutes prior to the procedure, place anaesthetic gel inside the urethra, and inject 5-10 ml lidocaine hydrochloride solution 1% or similar preferably 1 cm bilaterally to the mucosa but make sure the injections are placed not to deep as the surface is the most sensitive area. Intravenous sedation (midazolam/propofol) may be used as an alternative to minimize patient movement during the application. Make sure the skin is also well anesthetized.
Now wait approximately 5 minutes before starting the procedure.

PERI-OPERATIVE PROCEDURES
Prolastic is injected at the site of the external urethral sphincter through a 18G needle under cystoscopic vision. Considering the initial procedure the implant is situated at the 3 and 9 o'clock position. The urethra may be flushed during the procedure, e.g. to provide sufficient vision.

1. Unpack the sterilized Prolastic applicator support components. Attach the applicator support block to the sheath (17 to 21 F) approximately 2-4 cm from the stopcocks and tighten. Place the applicator support rod into the applicator support bow and tighten according to the instructions in the Prolastic manual.
2. Unpack and place the applicator head on the applicator support rod. Slide the other end of the applicator support bow into the applicator support block and tighten. The complete assembly of the applicator support is now attached to the sheath.
3. Using aseptic technique, remove the needles from the package. Insert the needles through the applicator head holes (3 and 9 o'clock positions) and position the applicator head so that the needle tips are positioned approximately 3-5 mm past the tip of the sheath. Disassemble the applicator support from the sheath and lay aside.
4. Insert endoscope (17 to 21 F) sheath into the urethra. Inspect the urethra and bladder for any abnormalities or unexpected anatomical matters (if abnormalities are observed that may prevent of significantly influence the procedure, abort the procedure). If no abnormalities are observed, the endoscope can be positioned in the prostatic urethra, or just caudally of the anastomosis of the urethra and bladder in case of a radical prostatectomy.
5. Localize the bladder neck and sphincter (patient may cough to allow visualization). Keep the scope in position just before the sphincter. Empty the bladder through the scope flushing channels if needed, to allow visualization of the scope tip during the procedure (with intravenous anaesthesia this should be performed before the anaesthesia).
6. Attach the applicator support to the applicator support block on the sheath.
7. Place the applicator head against the perineum and insert the needles into the tissue as far as possible through the applicator on the 9 and 3 o' clock positions. X-ray visualization may be used to verify that the needle tips are positioned beyond the sheath tip.
8. Peel open the blister and remove the Prolastic 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.
9. Remove the protective tip cap from the syringe. Attach the mixer by firmly tightening the hub of the mixer onto the Prolastic syringe's lock tip.
10. Carefully express the Prolastic material (±0.25ml) until visible at the tip of the mixer. Squeeze out a little bit of material and wipe it off with a sterile cloth. Remove the inner part of one of the needles at the 3 o'clock position and tightly connect the mixer to the needle, while keeping the endoscope and needles in a fixed position in the tissue. 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.
11. 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 the target position.
12. Slowly inject aproximately 1.6 ml of Prolastic at the 3 o'clock position (while keeping the endoscope and needles in a fixed position). During the injection of material the bulking of the tissue should be visible endoscopically. Bulking can be sufficient before reaching the 1.6 ml of injected material. In this case inject less material to prevent retention. After injection is complete, wait approximately 30 seconds before withdrawing the needle from the tissue. The other needle remains in position.
13. Detach the used needle from the syringe with static mixer. Disconnect the static mixer and fix a new one. Repeat the above injection procedure at the 9 o'clock position, using a new mixer.
14. 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 Prolastic implantation sites and volumes may be adjusted to achieve optimal urethral coaption or closure.
15. Withdraw the needle. Specific care must be taken not to introduce the scope again into the bladder for this will compress the injected bolus. If necessary only the optics part of the scope should be used.

16. The bladder is emptied with a 12G Nelaton catheter. No indwelling catheter is to be left behind at any stage. The patient must be asked to stay in the hospital until he is able to void normally.
17. Make a final x-ray to inspect t he positioning of the material.
18. Retract the endoscope from the urethra.

POST-OPERATIVE PROCEDURES

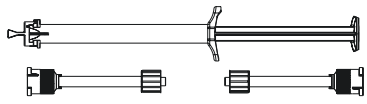
An ultrasonic examination of the implants is to be performed directly following the bulk injections. In case of voiding difficulties, nursing staff responsible for postoperative care should be clearly instructed not to use any catheter with a larger diameter than a 12 Gauge. Intermittent catheterization 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 below 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.

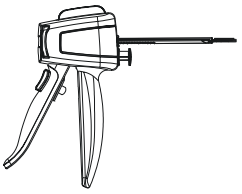
HOW SUPPLIED

Prolastic consists of one pre-filled 5 ml dual PP syringe with a lock fitting containing 2 x 2.5 ml (1:1) Prolastic 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. Two static mixers are co-packed with the syringe in a blister. Two sterile 1.20 x 75 mm (18G x 3") needles are separately packaged and included in the kit.
The product comes with the Prolastic dispenser gun and applicator head, provided sterile in blister pack, for single use only.


Product syringe & static mixers


Needle


Applicator head


Dispenser gun

The complete product configuration holding the above components comes ETO sterilized.
The reusable Prolastic applicator support is provided separately unsterilized.

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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