

*Instructions
For Use*

 urolon™

aqlane™
MEDICAL



Manufacturer:
AQLANE Medical BV
Yalelaan 1
3584 CL Utrecht
The Netherlands
+31 30 760 2610
www.aqlanemedical.com



Attention:
see instructions
for use



Electronic instructions
for use:
www.urolon.com/ifu



Syringe contains a sterile fluid path
that is sterile by aseptic processing
Syringe exterior is non sterile



Do not
re-use



Storage
temperature limits

REF

Ref

LOT

Batch No.



Use by

DESCRIPTION

Urolon™ is a non-pyrogenic, totally bioresorbable, non-permanent implant, whose principle component is synthetic polycaprolactone (PCL) microspheres suspended in a gel carrier of phosphate buffered saline (PBS), glycerin and carboxymethylcellulose (CMC). PCL is a well-known totally bioresorbable soft medical polymer. PCL is used in numerous CE-marked and Food and Drug Administration (FDA) approved commercial bioresorbable product applications for several decades world-wide and has demonstrated an excellent safety profile.

MODE OF ACTION

Urolon™ is injected sub-mucosally between the bladder neck and mid-urethra. The injection of Urolon™ creates increased tissue bulk and soft tissue augmentation of the urethra. The gel carrier suspends the PCL particles and allows delivery through injection needles and is dissipated *in vivo*, while the PCL particles remain at the injection sites and provide the tissue bulking to increase urethral resistance to urine leakage.

INDICATIONS FOR USE

Urolon™ is indicated for soft tissue augmentation in the treatment of stress urinary incontinence (SUI) in adult females.

CONTRAINDICATIONS

- In patients with significant history of urinary tract infections without resolution.
- In patients with current or acute conditions of cystitis or urethritis.
- In patients with fragile urethral mucosal lining.
- In patients with uncontrolled detrusor overactivity.
- In patients with high grade pelvic organ prolapse.
- In patients with confounding bladder pathology.
- In patients with morbid obesity.
- In patients with vulvar vestibulitis.
- In patients that had any previous permanent bulking agent treatment.

WARNINGS

- Only the syringe content is sterile. The exterior of the syringe is non sterile. Prevent cross-contamination.
- Overcorrection using Urolon™ may lead to obstruction or urinary retention.
- Avoid injecting Urolon™ in blood vessels. Urolon™ injection into blood vessels may cause vascular occlusion.
- Avoid using Urolon™ in patients with non-viable tissue, e.g., history of significant pelvic irradiation, multiple pelvic surgeries, etc. Scar tissue and significantly compromised tissue will not coapt appropriately.
- Urolon™ should not be used in patients with urethral or bladder neck strictures until the strictures have been corrected. Use of Urolon™ in patients with strictures may cause injury and/or urethral obstruction.
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- The safety and effectiveness of Urolon™ treatment during pregnancy has not been established.
- As with any implant material possible adverse reactions that may occur include, but are not limited to: hypersensitivity, allergic reactions, inflammation, erythema, embolic phenomena, vascular occlusion, worsening of incontinence, urinary urgency, hypertonic bladder, urinary retention, urethral disorder, back pain, bladder spasm, dysuria, injection site reaction, mucosal erosion, nodule or granuloma formation, peripheral edema, urinary tract obstruction, hematuria, inflamed introitus, anterior bladder neck swelling, urinary tract infection, urge incontinence and burning on urination.
- Adverse events, other than mentioned above, could occur as with any medical intervention.
- If corrective surgery is required to remove the device this may lead to urethral obstruction.
- Women with peripheral vascular disease and prior pelvic surgery may be at increased risk for tissue erosion following injection of Urolon™.

PRECAUTIONS

- As with similar urologic procedures, the treatment and instrumentation associated with the injection of Urolon™ carry a risk of infection and/or bleeding. The usual precautions associated with urologic procedures, specifically cystoscopy, should be followed.
- It is recommended to administer prophylactic broad-spectrum antibiotics.
- Safety and effectiveness of Urolon™ in patients with any form of previous SUI surgery has not been established.
- Safety and effectiveness of periurethral injection of Urolon™ has not been established.
- Safety and effectiveness of Urolon™ in men has not been established.
- Safety and effectiveness of Urolon™ in patients with a previous bulking agent treatment has not been established.
- Safety and effectiveness of Urolon™ in patients with a history of (pelvic) radiation treatment or currently undergoing (pelvic) radiation treatment has not been established.
- The effect of Urolon™ on subsequent pregnancy and delivery, and the impact of subsequent pregnancy on the effect of Urolon™, is unknown. Therefore, the risks and benefits of the device in women of childbearing potential should be carefully assessed.
- Do not re-sterilize.
- Do not use if the foil pouch is compromised or the syringe has been damaged.

- Do not use if the syringe end cap or syringe plunger are not in place or removed.
- Dysuria, hematuria, and frequency of micturition are to be expected post-treatment. If any of these conditions persist past 48 hours, the patient should be instructed to contact the treating physician immediately.
- Post-treatment retention may occur which may necessitate intermittent catheterization. If the patient remains unable to void freely, continued intermittent catheterization may be necessary.

PHYSICIAN TRAINING

To use Urolon™, physicians must have training in diagnostic and therapeutic cystoscopy. This device should only be used by practitioners trained in the field of urinary incontinence and bulking agents.

PATIENT COUNSELING

AQLANE Medical™ relies on the physician to advise the patient of all potential risks and benefits associated with a Urolon™ implant procedure. Patients should be fully apprised of the indications, contraindications, warnings, precautions, expected clinical outcomes, adverse events, and methods of implantation. Patients should be advised that bulking agent therapy with Urolon™ is positioned as a single treatment procedure, however, more than one injection procedure may be required to achieve dryness or a desired level of improvement in incontinence. Patients should be counseled to report adverse events to the treating physician. Physicians are advised to report adverse events to AQLANE Medical™.

DIRECTIONS FOR USE

The following is recommended for a transurethral injection of Urolon™:

- 35 cm cystoscopic injection needle with a 23 gauge needle tip.
 - A compatible cystoscope.
1. Using standard procedure, prepare the patient for cystoscopy.
 2. It is recommended to administer prophylactic broad-spectrum antibiotics before treatment.
 3. Prepare the syringes of Urolon™, injection needle(s), and cystoscopic equipment before injection. Be aware that the exterior of the syringe is non-sterile; prevent cross-contamination. A new injection needle may be used for each syringe or the same injection needle may be connected to each new syringe. Prepare cystoscopic equipment according to the manufacturer's instructions for use.
 4. The urethra and bladder neck should be examined prior to injection.
 5. Remove the Luer syringe cap prior to attaching the injection needle. The syringe of Urolon™ can then be twisted onto the Luer lock fitting of the injection needle. The injection needle must be tightened securely to the syringe. Prime the injection needle by slowly pushing the syringe plunger until Urolon™ extrudes from the injection needle.
 6. The injection needle is then advanced through the working channel of the cystoscope. A desired location for the injection into the urethra needs to be identified. This is usually 1 to 1.5 cm distal to the bladder neck. Push the injection needle into the sub-mucosal lining of the urethra at the desired site. Slowly push the plunger shaft of the Urolon™ syringe to start the injection.
 7. When Urolon™ starts to flow into the injection site tissue bulking in the form of a bleb should be visible. If it is not observable, pull back on the injection needle and locate the needle more superficially and begin injecting again. This site should be injected until the bleb meets the midline of the urethra or maximum tissue compliance. Additional sites should be injected until the urethral opening shows optimal coaptation.
 8. Multiple syringes may be required to achieve optimal coaptation. The injection needle already in place may be used with each new syringe of Urolon™ or a new injection needle may be used. If a new injection needle is used, the needle must be secured to the syringe. Prime the needle with Urolon™ prior to insertion into the cystoscope. If a new syringe is used (with the same needle) ensure the syringe is primed before connecting it to the needle.
 9. After the injections have been completed, it is important not to pass the cystoscope through the coaptation site as this may deform the tissue blebs that have been formed.
 10. Prior to discharge patients must be able to void freely. In case of urinary retention, intermittent catheterization (12 Fr or smaller) may be required until normal voiding resumes.
 11. Used syringes and used injection needles represent biohazardous waste and should be disposed of in accordance with facility medical practices and applicable regulations.

HOW SUPPLIED

Urolon™ is a non-pyrogenic bulking agent, supplied in single use, 1 ml syringes. The syringe is packaged in a foil pouch. The Urolon™ product box contains 3 pouches.

Upon receipt of shipment, check the packaging to ensure that the packaging is intact and there has been no damage from shipment. The contents of the syringe are intended for single patient use only and cannot be re-sterilized.

SHELF LIFE AND STORAGE

Urolon™ should be stored at a controlled room temperature (15°C - 25°C: 59F - 77F). The expiration date, when stored in these temperatures, is two years from date of manufacture. Do not use if the expiration date has been exceeded. Do not use if package is opened or damaged.

WARRANTY

AQLANE Medical™ warrants that reasonable care has been exercised in the design and manufacture of this product.

THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ITS PARTICULAR PURPOSE.

Handling and storage of this product, as well as factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond AQLANE Medical™'s control directly affect the product and the results obtained from its use. AQLANE Medical™'s obligation under this warranty is limited to the replacement of this product and AQLANE Medical™ shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly, arising from the use of this product. AQLANE Medical™ neither assumes, nor authorizes any person to assume for AQLANE Medical™, any other or additional liability or responsibility in connection with this product.

OBSONET

For more information please visit

www.urolon.com