Injection Training Guide for Urolon™

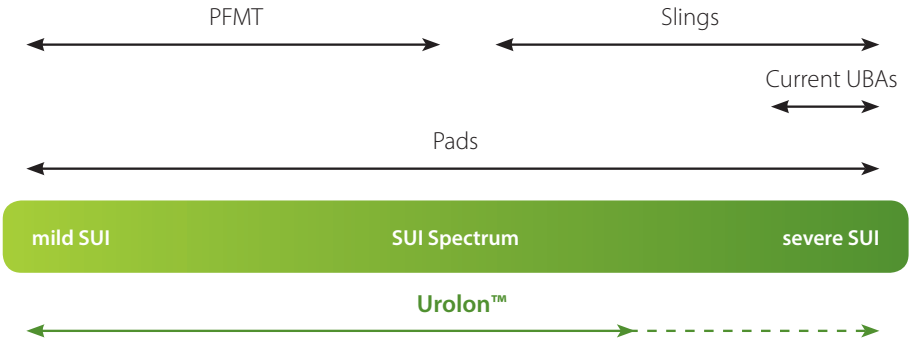
Bioresorbable Urethral Implant

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.

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 provides 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. More specifically, Urolon™ is ideally indicated as a first-line, minimally invasive procedure for female mild-to-moderate SUI and as such bridges the gap between low-risk conservative treatment and more invasive higher-risk surgical approaches.



PRE-TREATMENT RECOMMENDATIONS

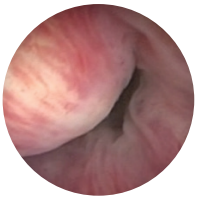
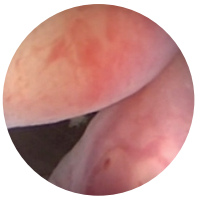
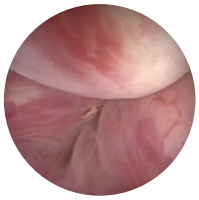
It is recommended to administer a prophylactic antibiotic (e.g. 1g Cefuroxime) before the procedure to prevent potential urinary tract infections. For comfort of the patient it is also recommended to provide sedation or anesthesia. For example, intravenous propofol (e.g. Diprivan®, Recofol®) may be used for sedation, or local infiltration with e.g. lidocaine can be used (with or without oral diazepam). General anesthesia or spinal block is not recommended as this will prolong the recovery period of the patient and delay the time to spontaneous voiding (required for discharge of the patient).

UROLON™ GENERAL DIRECTIONS FOR USE

(please also refer to the Urolon™ IFU for detailed directions for use)

Urolon™ is administered via cystoscope guided submucosal injection. Therefore, a cystoscope and suitable cystoscopic injection needle (23G or larger) is required:

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.
4. The urethra and bladder neck should be examined prior to injection to ensure there are no (anatomic) abnormalities.
5. Remove the Luer syringe cap and connect the Urolon™ syringe to the injection needle. The injection needle must be tightened securely to the syringe.
6. Prime the injection needle by slowly pushing the syringe plunger until Urolon™ extrudes from the injection needle.
7. Advance the injection needle through the working channel of the cystoscope.
8. Insert the cystoscope into the urethra and move proximally to the bladder neck.
9. Retract the cystoscope approximately 1.0 - 1.5 cm distal to the bladder neck.
10. Typically, 3 injections are done, at the 2, 6, and 10 o'clock position.

11. Place the injection needle approximately 5mm into the sub-mucosal lining of the urethra and slowly push the plunger rod of the syringe to start the injection.
12. When Urolon™ starts to flow into the injection site, tissue bulking in the form of a bleb should be visible. If this is not observable, relocate the needle slightly more superficial and begin injecting again.
13. Continue to slowly inject until the bleb meets the midline of the urethra or maximum tissue compliance.
14. Leave the needle in place for 10 – 15 seconds after the injection before moving to the next injection site to prevent back-flow from the puncture site.
15. Repeat steps 10 to 13 for each injection site, obtaining optimal coaptation.
16. Multiple syringes may be required to achieve optimal coaptation. The injection needle already in place may be used with each new syringe of Urolon™. Prime the syringe before connecting it to the needle to avoid introduction of air.

POST-TREATMENT RECOMMENDATIONS

- Patients must void freely before discharge
- In case of urinary retention, intermittent catheterization (12 Fr or smaller) may be required
- EAU post treatment recommendations (*http://patients.uroweb.org/ui/surgery-for-women-with-sui/bulking-agents/*)

For 3-4 weeks post treatment you may recommend:

1. Drink 1-2 liters every day
2. Do not lift anything heavier than 5Kg
3. Do not do any heavy exercise
4. Take showers instead of baths
5. Avoid thermal baths and saunas
6. Prevent constipation by adapting your diet
7. Avoid sexual activity with vaginal penetration for 1 month

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.

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