

Uro-Tainer®

0.9% NaCl / Solutio R / Suby G

Maintenance solution for urethral and suprapubic catheters

1. What Uro-Tainer® are and what they are used for
Uro-Tainer® are solutions for the maintenance of indwelling urethral and suprapubic catheter. They are sterile, endotoxin-free, ready-to-use medical devices in a PVC-free bag with the following purpose:

- Uro-Tainer® 0.9% NaCl: For routine rinsing of catheters (removal of small blood clots, tissue, debris).
- Uro-Tainer® Solutio R: Dissolution of persistent encrustation, treatment of encrusted catheter to reduce trauma during removal of catheter
- Uro-Tainer® Suby G: Dissolution of encrustation

2. What you need to know before Uro-Tainer® are used
Do not use Uro-Tainer®

In case of hypersensitivity (allergy) to any of the ingredients of the solution (listed in section 6).

In case of cystitis or other uro-genital condition that can produce haematuria (blood in the urine).

Several days after surgery on the bladder or the urinary tract.

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before using Uro-Tainer®.
- Under no circumstances should the solution be injected or infused.
- Instill the solution by gravity feed, avoid force.
- Apply using aseptic technique. A port disinfection before use is recommended.
- Only to be used if the bag and the sealing cap are intact, and the solution is clear.
- This is a single-use system. After opening, it must be used and disposed of promptly. Re-use of such devices creates a potential risk of patient or user. It may lead to contamination and/or limited functionality of the device, which causes to injury, illness or death of the patient.
- Discard properly after use.
- If the solution leaks during the flushing process from the urethra, the catheter is not correctly placed in the bladder. In that case the catheter needs to be replaced by anew one.
- If the solution is not flowing, it may be the catheter is bent or plugged. In that case the catheter needs to be replaced by a new one.
- Precautions should be taken when operating on patients with spinal injuries because of the risk of autonomic dysreflexia.

3. How to use Uro-Tainer®

- Uro-Tainer® are closed and sterile systems to be connected to the urinary catheter and work all according to the operating instructions on the next page.

- The Uro-Tainer® sachet is supplied sterile and should not be removed from its overwrapping until required for use.
- If desired, bring the solution up to body temperature by immersing the wrapped sachet in warm water.
- The bag that contains the rinsing solution collects the liquid after rinsing of the catheter. Catheter rinsing and liquid collecting after rinsing are performed by gravity alone, by maintaining the device above and below the level of the bladder respectively.
- Uro-Tainer® 0.9 % NaCl, acting with a mechanical rinsing effect, can be administered as "in and out" application, while Uro-Tainer® Suby G and Solutio R, based on acidic solutions, need to be administered into the catheter and left there for 5 minutes to fully exploit their chemical action. This process is recommended 1 to 2 times per day.
- In general the daily use is only indicated for post-operative patients during a short period. In contrast to that, long-time catheterized patients have catheters for very long periods. In this case the catheter is only rinsed with Uro-Tainer® 2-3 times per week.
- If you use Uro-Tainer® more often than you should, no adverse events are expected.

4. Possible side effects

Citric acid may cause some patients to experience slight irritation and even temporary pain, a burning sensation, or spasms of the bladder (desire to urinate). If these effects occur, the less concentrated solution Suby G is recommended, carry out the instillation less frequently, or alternate it with an instillation of NaCl 0.9 %, because this solution is not known to cause such effects.

5. How to store Uro-Tainer®

Keep the Uro-Tainer® out of the sight and reach of children. Do not use the Uro-Tainer® after the expiry date which is stated on the outer plastic bag. Do not refrigerate or freeze. Store in the original package. Only use clear solutions in undamaged bottles. After opening, the Uro-Tainer® must be used and disposed of promptly.

6. Contents of the pack and other information

What Uro-Tainer® contains

- Uro-Tainer® 0.9% NaCl
100 ml solution contains: Sodium chloride 0.9 g in Water for Injections
- Uro-Tainer® Solutio R
100 ml solution contains: Citric monohydrate acid 6.0 g, Gluconolactone, Light magnesium carbonate, Disodium edetate dihydrate in Water for Injections

- Uro-Tainer® Suby G
100 ml solution contains: Citric monohydrate acid 3.23 g, Light magnesium oxide, Sodium bicarbonate, Disodium edetate dihydrate in Water for Injections

What Uro-Tainer® looks like and contents of the pack
The solution appears as a clear and colorless liquid.

Uro-Tainer® are made of a soft bag free of poly(vinyl chloride) (PVC) welded with a flexible PVC-free tube and a

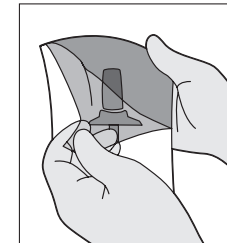
urologic closure. The bag material used is a colorless and transparent pharmaceutical film.

Uro-Tainer® are available in package sizes of 50 ml, and 100 ml.

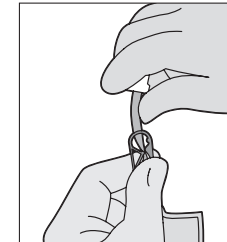
This leaflet was last revised in 09/2016.



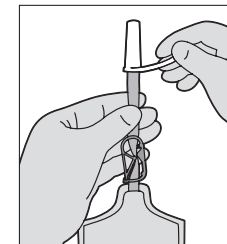
1. Tear open overwrapping and remove Uro-Tainer® sachet.



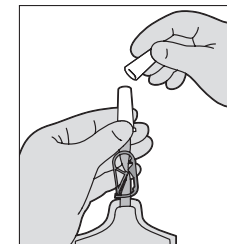
2. Close Uro-Tainer® tube with plastic clamp.



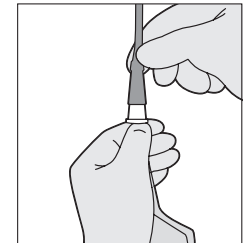
3. Remove tamper proof seal.



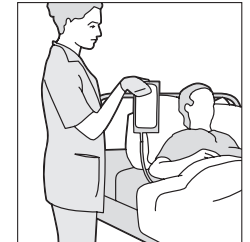
4. Twist and withdraw cap without touching sterile connector.



5. Insert connector into the catheter funnel.



6. Holding the Uro-Tainer® above the level of the bladder, release the clamp to allow the fluid to drain in by gravity.



7. After 5 minutes, lower the Uro-Tainer® below the level of the bladder to drain fluid back into the bag.



8. Clamp tube and remove the connector from the catheter by turning gently. Connect the catheter to a sterile drainage bag. Dispose of Uro-Tainer® sachet and wash hands.

