

UroDapter® – User’s Manual

Introduction.

Thank you for purchasing UroDapter®, which enables the catheter-free instillation of the bladder.

Compared to the traditional way of bladder instillation – which involves a catheter – using UroDapter® has a number of advantages. The process is minimally invasive and entirely painless. A catheter, even if it is used in the most cautious way, can cause microlesions and be the source of infections. These issues are not experienced if UroDapter® is used. Moreover, UroDapter® enables the treatment of the bladder and the urethra at the same time, which is difficult to impossible with a catheter. After the instillation the mucosa of the surface of the urethra becomes covered with a thin layer of the instilled solution which has a regenerative effect until the next voiding.

Intended use.

Performing the bladder instillation with the solution prescribed by the therapist without a catheter, in a safe, painless and non-invasive way.

Solutions generally used include substances for regenerating the inner mucosal surface of the bladder (the GAG-layer), local anesthetics (e.g. lidocaine), antibiotics, certain hormones or chemotherapeutic agents. *Indications* whose treatment UroDapter® can be successfully applied in are Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS), Urinary Tract Infections (UTIs), certain forms of Hemorrhagic Cystitis (Chemotherapy Induced Cystitis, Radiation Cystitis), Severe Overactive Bladder Syndrome (OAB), Chemotherapy of Bladder Cancer (female patients).

UroDapter® can be used by male or female patients. *Sterile. Single use.*



Danger!

Only a professional person can prescribe the use of UroDapter® for self-instillation.

Before starting a self-therapy with UroDapter® always consult with your therapist about

- the way how the self-treatment should be performed
- the solution you have to instill into your bladder
- the frequency and the total number of occasions of self-treatment.

Improper use of UroDapter® could result in injuries or worsening the condition of the patient!

For the inappropriate use of UroDapter® neither the manufacturer, nor the distributor take any responsibility.

For any complications or adverse effects caused by the solution instilled with UroDapter® neither the manufacturer, nor the distributor take any responsibility.

Precautions.

UroDapter® is designed for administering solutions into the bladder, through the orifice of the urethra. Never use UroDapter® for delivering any liquid into any other organ.

UroDapter® is for instilling solution into the bladder. Do not use it for draining the urine or any other liquid.

Do not use UroDapter® if the product or its packaging appears to be damaged.

Do not reuse or sterilize UroDapter®.

Keep UroDapter® away from children younger than 3 years, since it is a suffocation hazard for them.

The patient must not have a sexual intercourse within 3 days prior to the treatment.

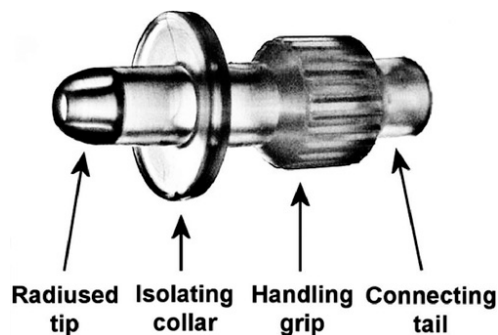
In case of performing an instillation without any help from medical professionals,

- mind the hygienic conditions
- ensure that you will not have to change posture during the self-treatment against your will
- do not commit public indecency
- inform your therapist immediately if any complication during or after the self-treatment has occurred.

In case of performing an instillation with the help of a non-professional person, make it sure that they have read this User's Manual before starting the treatment, and have understood fully the instructions of your therapist.

Keep UroDapter® in a dry, clean place. It does not require cooling or any other special storing conditions.

After using UroDapter® can be handled as communal waste. Regarding the solution being instilled with the UroDapter® consult the waste management manual of the material in question.



Parts of UroDapter®.

1. Radiused tip – this enters the urethra (appr. 6–8mm deep).
2. Isolating collar – this prevents leakage during the instillation.
3. Handling grip – by this part UroDapter® can be hold firmly.
4. Connecting tail – this part is to be connected to any Luer Lock or Luer Slip syringe.

Before Starting the Treatment

- Before starting the treatment disinfect not only the urethral orifice but also the 3 cm area of the orifice and on the inner surface of the labia. For this process any mucosal antiseptic solution can be used.
- Unpack UroDapter® and attach its connective tail to the syringe. UroDapter® can be attached to both Luer Slip and Luer Lock syringes easily.
- Disinfect freshly unpacked UroDapter®, from the tip to the sealing collar, too. This prevents the drift of the bacteria into the bladder and it inactivates the bacteria located in the first couple of millimeters of the urethra, too.

Using UroDapter®: Performing the Instillation

- Ensure that the patient is relaxed enough for the treatment, which makes the instillation process easier and quicker.
- Always make it sure that UroDapter® is inserted into the urethra, and not into the vagina in case of female patients.
- For exposing the orifice of female patients, the fingers should lie as close to the orifice as they can be. The exposition has to happen by pulling the labia apart laterally, too (and not only upwards).
- The optimal instillation can be performed if the axis of the urethra and the syringe are parallel. In this case, the resistance can be experienced by using the syringe decreases characteristically. In general, for younger female patients UroDapter® should be situated slightly upwards (given that the patient is lying on her back), for older patients, it should be situated slightly downwards.

- Only the tip of UroDapter® should penetrate the urethra, which means approximately 6–8 mm. The isolating collar should cover the orifice properly and be pushed against the nearby structures gently.
- Start performing the instillation. Given that the isolating collar is covering the orifice properly, the instilled solution raises the intra-urethral pressure, which opens the sphincter, thus the solution enters the bladder. That said, the instillation itself can be performed in one minute. The exact time, obviously, depends on the patient.
- If the sphincter becomes constricted due to pain or fear and muscle tone increases making the instillation hard to impossible. In this case the patient must be told to relax, a couple of deep sighs may help them, too. It is important to wait until the constrictions end: the speed of the instillation should be decreased, or, if needed, paused.
- In case of leakage, a part of the solution does not reach the urethra, it flows away instead. By treating female patients, the leaking solution might enter the vagina, and it re-appears only after the instillation has ended and the patient has stood up. During the instillation proper lighting and the constant observation of the sealing collar are essential so that leakage can be noticed immediately and it can be avoided by certain minor corrections.
- The two most frequent situations in which leakage happens are applying too low or too high pressure with UroDapter®. Adjust the pressure accordingly; the ideal amount can be experienced as the suddenly lowering resistance of the plunger of the syringe.
- In the majority of cases, the leaking solution causes neither infections nor complications by entering the vagina or contacting the nearby structures. In case of doubt, consult the User’s Manual or general description of the solution being instilled.
- When the treatment has ended, the patient must try to hold her urine back for at least 3 hours, so that the solution can affect the bladder and the urethra for an ample amount of time. Besides this, any action can be performed by the patient.

Specifications

Material: medical grade elastic polymers

Dimensions: 15×33mm







Manufactured by: Dispomedicor Zrt. Hungary

Distributed by: Urosystem Kft. Hungary

Date: June. 30. 2020

Amended: November 3. 2020

Version: v1.3

	Can be used for 5 years after production date, see packaging		Store between: 4–30 °C (39–86 °F)		Danger!
	For lot number see packaging		Single use only		Do not use if packaging is damaged

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For further information visit our webpage: www.urosystem.com, where a detailed [UroDapter® user guide for therapists](#) can be found.