



## The UroDapter® – User Manual

### Introduction

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

Compared to the traditional way of bladder instillation – which involves a catheter – using the 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 the UroDapter® is used. Moreover, the 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 a 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 anaesthetics (e.g. lidocaine), antibiotics, certain hormones or chemotherapeutic agents. Indications whose treatment the 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).

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



#### **Danger!**

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

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

- 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 the UroDapter® could result in injuries or worsening the condition of the patient! For the inappropriate use of the UroDapter® neither the manufacturer, nor the distributor take any responsibility.*

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

### Precautions



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

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

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

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

The patient must not have sexual intercourse within 3 days prior to the treatment. In case of performing an instillation without any help from medical professionals,

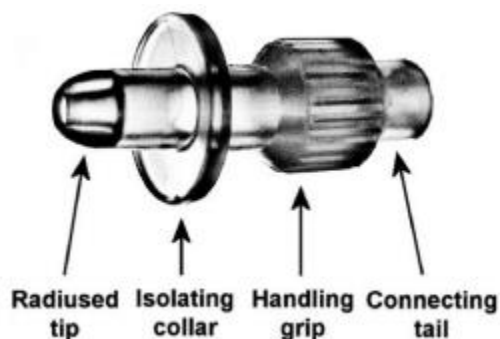
- ensure hygienic conditions
- ensure that during the self-treatment, you are comfortable and that you do not have to change posture inadvertently
- do not commit public indecency
- inform your therapist immediately if any complications during or after self-treatment occur

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

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

After usage, the 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 the 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, the UroDapter® can be held firmly.
4. Connecting tail – this part is to be connected to any Luer Lock or Luer Slip syringe.

#### **Before Starting Treatment**

- Before starting the treatment, disinfect not only the urethral orifice but also the area within a 3 cm radius of the orifice and on the inner surface of the labia. For this process any mucosal antiseptic solution can be used.



- Unpack the UroDapter® and attach its connective tail to the syringe. The UroDapter® can be attached to both Luer Slip and Luer Lock syringes easily.
- Disinfect the freshly unpacked the UroDapter®, from the tip to the sealing collar, too. This prevents the drift of bacteria into the bladder, and it inactivates the bacteria located in the first couple of millimeters of the urethra as well.

### **Using the UroDapter®: Performing an Instillation**

- Ensure that the patient is relaxed enough for the treatment, which makes the instillation process easier and quicker.
- Always make sure that the UroDapter® is inserted into the urethra, and not into the vagina in case of female patients.
- For exposing the urethral orifice of female patients, the fingers should lie as close to the orifice as possible. The exposition has to happen by pulling the labia apart laterally, too (and not only upwards).
- The instillation can be performed optimally if the axis of the urethra and the syringe are parallel. In this optimal position, the resistance can be experienced by using the syringe decreases characteristically. In general, for younger female patients the UroDapter® should be situated slightly upwards (given that the patient is lying on her back), while for older patients, it should be situated slightly downwards.
- Only the tip of the 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. Thus, 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, performing the instillation becomes difficult 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 portion of the solution does not reach the urethra, so it flows away instead. When treating female patients, the leaked solution might enter the vagina, and 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 can be avoided by certain minor corrections.
- The two most frequent situations in which leakage happens are applying too little or too much pressure with the UroDapter®. Adjust the pressure accordingly – the ideal amount



can be experienced when the resistance of the plunger of the syringe suddenly decreases.

- In the majority of cases, any leaked solution causes neither infections nor complications by entering the vagina or contacting the nearby structures. In case of doubt, consult the User 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 polymer

Dimensions: 15 mm x 33 mm

Manufactured by: Dispomedicor Kft. Hungary

Distributed by: Urosystem Zrt. Hungary







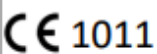
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User Guide



	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
	1011		<a href="http://www.urosystem.com">www.urosystem.com</a>		FDA registered product

User Manual Date: 30 June 2020; Amended: 28 September 2021; Version: v1.32 For further information please visit our website: [www.urosystem.com/en/urodapter](http://www.urosystem.com/en/urodapter) where you can find detailed instructions for therapists for using the UroDapter® in our Tips & Tricks guide.