

UroStill® – Assistive Device for Intravesical Self-Instillation for Female Patients by Using UroDapter® Syringe Adapter

User's Manual

Thank you for purchasing UroStill® self-instillation device (henceforth: UroStill®, Self-Instillator), which is to be used exclusively with UroDapter® urological syringe adapter.

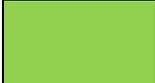
With the help of UroDapter® urological syringe adapter it is possible to deliver medicine and medicinal composition through the urethra into the bladder without using a catheter. It is more comfortable, hygienic and safer to treat the bladder with UroDapter® syringe adapter than with a catheter. Moreover, UroDapter® enables the treatment of the bladder and the urethra at the same time, which is not possible with a catheter.

With UroStill® the local treatment of the bladder can be performed at home, without any help from other people. It is not needed to visit the therapist for every single instillation, which saves the patients money and time.

Before starting to use the Self-Instillator, please, read this manual carefully, since it contains important information.

Keep the User's Manual because you might need the information written in it later, too.

Regarding safety, the Manual uses the following symbols and definitions.

	Danger! Prohibition	It refers to situations which will result in serious injury or even death, and to prohibitions to avoid them.
	Warning!	It refers to situations which could result in serious injury or death.
	Caution!	It refers to situations which could cause moderate or minor injury, and/or property damage.
	Notice	It refers to information which make the use of the product more efficient and/or comfortable.

1. General Safety Precautions

- 1.1 The intended use of UroStill® is: delivering medicine or medicinal composition through the urethra into the bladder, which can be performed by the patient.

	Prohibition	Never use the Self-Instillator for delivering any liquid into any other organ than the urethra and the bladder. This could result in the worsening of the condition and in the damage of UroStill®!
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1.2 UroStill® must be used exclusively for instilling the medicine and/or medicinal composition prescribed by your therapist, in the exact way prescribed by your therapist or stated in this manual.

	Prohibition	Never use UroStill® for instilling any solution not prescribed by your therapist into your urethra. This could result in the worsening of the condition!
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1.3 UroStill® must be used together with UroDapter® medical adapter.

	Warning!	Do not use UroStill® with a catheter or with any other device which is capable of delivering solution into the bladder. This could result in injuries, lower efficacy of the treatment and the worsening of the condition.
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1.4 Do not share UroStill® with other persons. Inappropriate use of the Self-Instillator could result in infections or injuries.

1.5 The elements in sterile packaging and/or labelled as sterile can be used once.

	Warning!	Do not use any of the disposables more than once. Re-sterilization of these elements is prohibited. Using the disposables when they are not sterile could result in infections or injuries.
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1.6 Do not use any of the components of UroStill® for any other purposes. This applies for the non-sterile elements, too.

1.7 Providing none of the conditions in which using UroStill® is not recommended prevails (see Chapter 3), the Self-Instillator causes no side-effects. Should during or after the self-treatment unusual pain or other symptoms originated from the use of UroStill® occur, consult your therapist immediately.

1.8 Regarding the side-effects of the medicine and/or medicinal composition used for self-instillation consult your therapist before starting to use UroStill®. Should any unexpected symptoms occur during or after the self-treatment of the known side-effects be considerably more severe, consult your therapist or pharmacist immediately.

- 1.9 Only those people who are aware of the benefits and possible risks of using the Self-Instillator are allowed to use the product.

	<p>Caution!</p>	<p>If you ask help from another person in the self-treatment, be sure that the person in question is aware of the benefits and possible risks of using the Self-Instillator.</p>
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2. Information, Precaution and Recommendation About the Use of UroStill®

- 2.1 The Self-Instillator is designed primarily for indoor use.

	<p>Warning!</p>	<p>Do not use or store UroStill® at places which do not match basic hygienic conditions. Self-treatment at places exposed to dust (lying or flying), contamination, leaking or evaporating toxic, corrosive, reactive, inflammable, explosive or any other dangerous materials could result in infections or other injuries.</p>
	<p>Caution!</p>	<p>In case of using the Self-Instillator outdoors and/or at a public place, mind the hygienic conditions. Do not commit public indecency either.</p>

- 2.2 Do not use the product in extreme environmental conditions (temperature, pressure, humidity).

Consult the specifications of UroStill® detailed in the corresponding chapter.

- 2.3 Do not use the Self-Instillator on moving vehicles unless your health condition and the length of the trip makes the self-treatment inevitable. In this case, be extremely cautious. Moving vehicles are subject to change their speed without any warning, which could result in the failure of the self-treatment, damage of the product, and personal injuries.

- 2.4 Do not use the Self-Instillator if it cannot be assured that you do not have to change posture against your will.

- 2.5 Keep away all the elements of UroStill® from children under 3 years old. The small parts of the device could be swallowed, which could result in suffocation.

3. Health and Environmental Conditions that Exclude the Use of UroStill®, or Make it Not Recommended

- 3.1 The Self-Instillator is designed for female patients.

Due to the anatomical differences male patients are able to perform the self-treatment with the UroDapter® urological syringe adapter alone. Consult your therapist or the distributor of UroStill® about purchasing UroDapter®.

- 3.2 Using the Self-Instillator is not recommended for people under 16.
- 3.3 Using the Self-Instillator without external help is not recommended for patients whose condition makes precise movement impossible (e.g. Parkinson's disease) or whose sight impairment makes assembling the Self-Instillator or monitoring the self-treatment on the display impossible.
- 3.4 If exposing the urethra cannot be performed safely due to any temporal or permanent condition or anatomical reason for the efficient self-treatment with the UroStill®, using the Self-Instillator is not recommended. Consult your therapist for further details.
- 3.5 Do not have a sexual intercourse within 3 days prior to the self-treatment, since an intercourse can raise the risk of infection as a complication of the treatment.
- 3.6 Do not use UroStill® during the period to avoid the risk of infection as a complication of the treatment. In case of severe symptoms that make self-treatment undelayable, consult your therapist for further instructions.

 <p>Danger!</p>	<p>Using UroStill® for any other purposes than its intended use could result in the lower efficacy of the treatment, the worsening of the condition or major injuries.</p> <p>For any injury or property damage originated from the inappropriate use of UroStill® the manufacturer or the distributor take no responsibility.</p> <p>For further details consult Chapter 1 and 2 of this manual.</p>
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4. Composition of UroStill®

 <p>Warning!</p>	<p>Be sure that the packaging contains all the elements described here.</p> <p>Do not use any element if it appears to be damaged or if its warranty is expired.</p> <p>Do not use any of the sterile elements if the packaging is damaged or broken.</p> <p>Using an element which is damaged and/or lost its sterility could result in the lower efficacy of the treatment, infections or personal injuries.</p>
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	Notice	The images presented in this manual are illustrations. The actual color of the elements might be different.
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Standards

- 4.1 – UroDapter® urological syringe adapter, disposable, sterile packaging, 1 pc.
- 4.2 – Extension tube for connecting the adapter (henceforth: extension), disposable, sterile packaging, 1 pc.
- 4.3 – Three-way tap, with a screw thread on one of its endings (henceforth: tap), disposable, sterile packaging, 1 pc.



Figure-1: The disposable elements of UroStill® in their sterile packaging. From left to right: tap (with safety cap), extension, UroDapter®

- 4.4 – Plastic holder, with a flip lock and a slot on its side (henceforth: holder), whose purpose is holding the syringe and the camera fast, 1pc.
- 4.5 – Constrictor ring, which can be put into the holder in case a 20ml syringe is used for self-instillation, 1pc. (Regarding the original packaging, it is placed in the holder.)

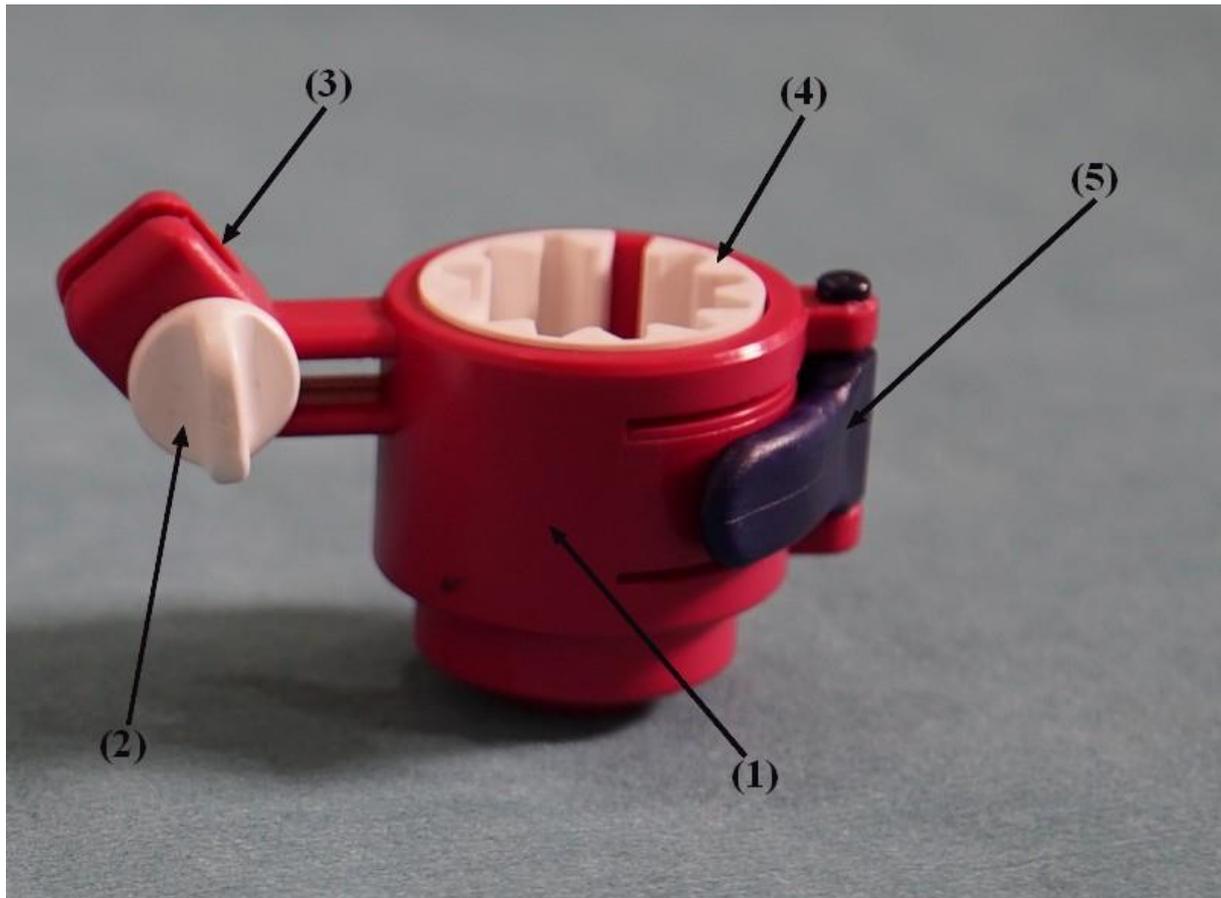


Figure-2: The major features of the holder. (1) body – (2) screw for holding the camera fast – (3) slot for the camera – (4) plastic constrictor ring for 20ml syringes (5) flip lock for holding the syringe fast (closed) (The channel for holding the cable of the camera on the side of the holder is not shown.)

4.6 – User's Manual, 1 pc.

4.7 – Purse for packing the elements described under 4.1–4.6, 1 pc.

Options

The self-treatment of the bladder can be performed without any displaying system (e.g. endoscope camera), too. However, the design UroStill® enables the use of a camera as an option so that the patient can perform the self-treatment more easily and safely, without the need of any extensional help. UroStill® can be used together with our options (which can be purchased from the manufacturer or the distributor) just as well as with other displaying systems (camera, smart-device or mirror).

Our options consist of the following items.

4.8 – Endoscopic camera with LED light sources; on its 1-meter long cable a switch can be found with which brightness can be adjusted gradually (henceforth: camera), 1 pc.

- 4.9 –Huawei MediaPad T3 tablet (henceforth: display), to which the camera can be attached via a micro USB port.
- 4.10 – Main charger (henceforth: charger) for the display, 1 pc.
- 4.11 – Cable for the main charger, 1 pc.
- 4.12 – Foldable display stand (henceforth: stand), 1 pc.



Figure-3: The options of UroStill®. From left to right, from top to bottom: camera, tablet (arrow shows the ON/OFF switch), charger and its cable, stand (unfolded).

	Notice	In case you use UroStill® with other displaying systems, consult the manual of the corresponding products.
	Notice	Both the tablet and the camera, as options, are compatible with the free-to-download application, OTG View. Consult the Appendix about installing and using OTG View.
	Notice	The purse of UroStill® is designed for being able to store the options, as well.



Figure-4: In the purse of UroStill® it is possible to store the options and the syringe, too. The image shows one possible arrangement. In the upper part the camera (black), two syringes (20ml and 50ml) and the holder can be seen. In the lower part the stand (folded, in the middle) and the tablet can be stored. Under them there are separate sockets for the disposables: the tap, the extension and the UroDapter® (not shown).

If you use UroStill® with any other displaying system, make it sure that they match the following specifications.

Camera

- Diameter (camera): 7 mm
- Diameter (cable): 3 mm
- Connector: USB, micro USB or USB-C (see the display part)

Display:

- Operating system: Android, OTG compatible (smartphone or tablet)
- Connection: USB, micro USB or USB-C (matching that of the camera)

	Notice	In case of using a device with Windows or iOS operating system, consult the manual of the camera regarding their compatibility.
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Mirror, mirror systems:

- Grip diameter: 7 mm

The UroStill® self-instillation device matches all the necessary certificates needed for medical devices in the EU. The list of the certificates is to be found at the end of this Manual.

	<p>Warning!</p>	<p>If you intend to use UroStill® with another displaying system, make it sure that its elements have the necessary certifications. Using elements without the necessary certifications affect the safety and effectiveness of the Self-Instillator.</p> <p>For any personal injuries and property damages originated from using UroStill® with products lack the necessary certifications the manufacturer and the distributor take no responsibility.</p>
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Syringes (not included)

UroStill® can be used with both 20ml and 50ml syringes, it is possible to store both of them in its pouch.

The recommended specifications are the following.

- Luer-lock tip
- Silicone plunger system
- single use
- Diameter: 21 mm (for 20ml syringes), 31 mm (for 50ml syringes)

	<p>Warning!</p>	<p>The type of the syringe, the medicine and/or medicinal composition used for self-treatment depends on the therapy prescribed by your therapist. Therefore, the packaging does not include these elements.</p> <p>For details on purchasing them, consult your therapist or your pharmacist.</p> <p>Never ignore the safety and precaution measurements of the syringe, medicine and/or medicinal composition you use! Ignoring them could result in personal injuries and property damages for which the manufacturer and the distributor take no responsibility.</p>
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Figure-5. UroStill® can be used with several types of syringes. From left to right: 20ml syringe (empty), 20ml prefilled syringes (in their sterile packaging), 50ml syringe (empty)

5. Directions and Suggestions Before Performing Self-Instillation

Whenever it is possible, try to perform the self-treatment in calm circumstances. Try to be alone, or with the only person who gives you help in the treatment. If it is possible, have any children in your household supervised by other persons.

Depending on your experience and anatomy self-treatment takes 15...30 minutes long.

- 5.1 Void before starting the treatment, empty your bladder totally.
- 5.2 Make it sure that you are able to perform the self-instillation in a comfortable posture.

	Notice	For most people the most comfortable position for the self-treatment is lying on her back with legs slightly pulled up. Self-instillation can be performed in other positions, too, providing it is neither tiring, nor uncomfortable, and it enables the proper exposition of the urethra.
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- 5.3 During the treatment – especially while the solution is being instilled – try to be fully relaxed. This makes the sphincter relaxed as well, which lowers the pressure building up in the urethra.
- 5.4 Take out all the elements you need for the self-treatment and place them within reach.
- 5.5 Maintain the sterility of the disposables to the largest possible extent.

	Notice	The easiest way of keeping the single-use items sterile to unpack them only when the step they are being used in comes. Afterwards, these elements can be placed on the
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		inner surface of their unfolded wrapping, or, if it is possible, inside the opened wrapping.
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The following illustrations show the parts of the disposables which are in contact with the urethra, its surroundings, and/or the solution being instilled during the self-treatment. Regarding maintaining sterility these are the areas must be focused on. All the other parts can be touched with clean hands or placed on clean surfaces without any health risk.

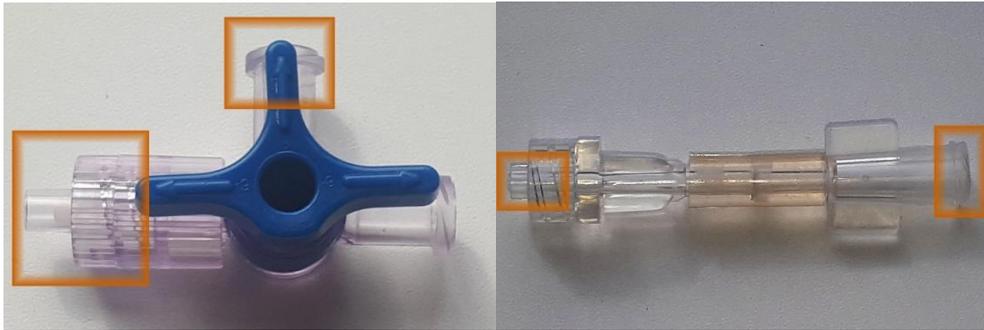


Figure-6. In case of the tap and the extension sterility must be maintained at the areas where the solution which is being instilled flows through (framed). Both of the elements can be placed on any level surface without the parts described contact with the surface itself. (Safety caps are not shown in the picture.)

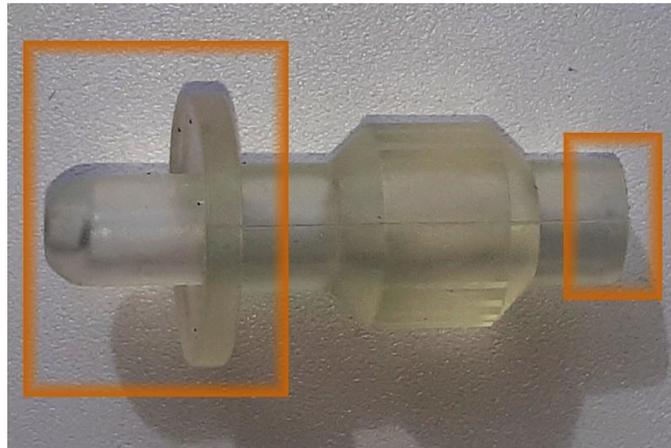


Figure-7. Regarding UroDapter® the tip and the isolating collar (left), and the part where the solution flows in (right) must remain sterile. Remove the adapter from its packaging only before it is being used. Putting back UroDapter® into its packaging while following the steps of assembling UroStill® is the best way to maintain its sterility. The safest way to use UroDapter® is to grab its thick, ribbed part (in the middle).

6. Assembling UroStill®

This chapter explains how to assemble the Self-Instillator. We recommend you follow the sequence written here. In case you find it more comfortable, certain steps can be swapped. Even if you do so, maintain sterility to the highest possible extent.

If you are not using any display for the self-instillation, skip steps 6.1–6.3.

6.1 Set up the stand and place the display on it.

The stand should be set up on a solid, level surface so that it can hold the display in a fixed position.

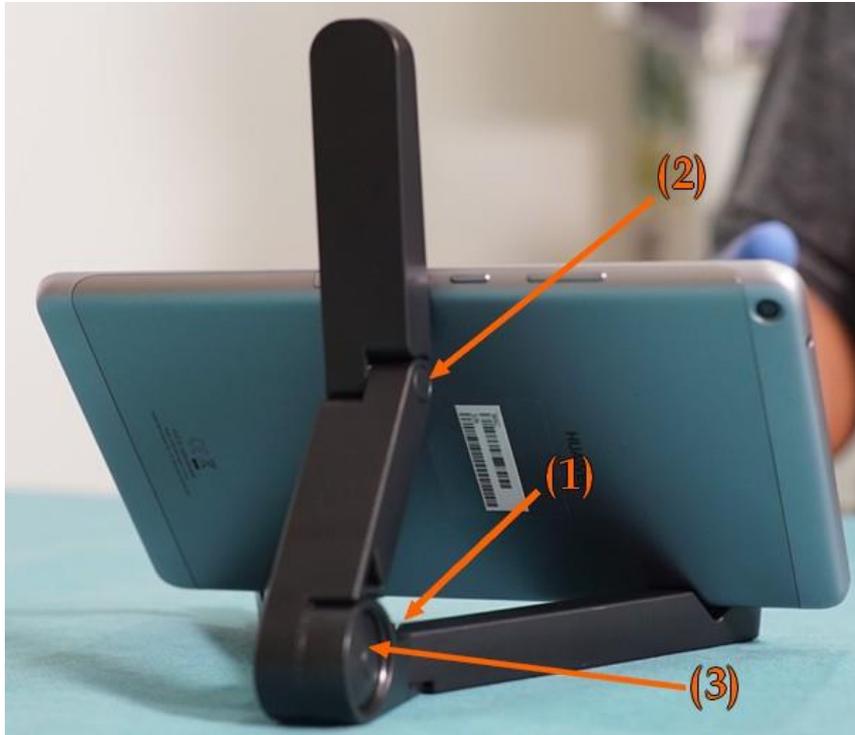


Figure-8: The display on the stand (options). The width of the stand base can be adjusted at point (1). The angle of the stand for the display can be adjusted at points (2) and (3).

Check it whether the battery of the display is not low or flat.

6.2 Mount the camera in its slot. It should face in the opposite way as the syringe will do. Fasten the camera with the screw.

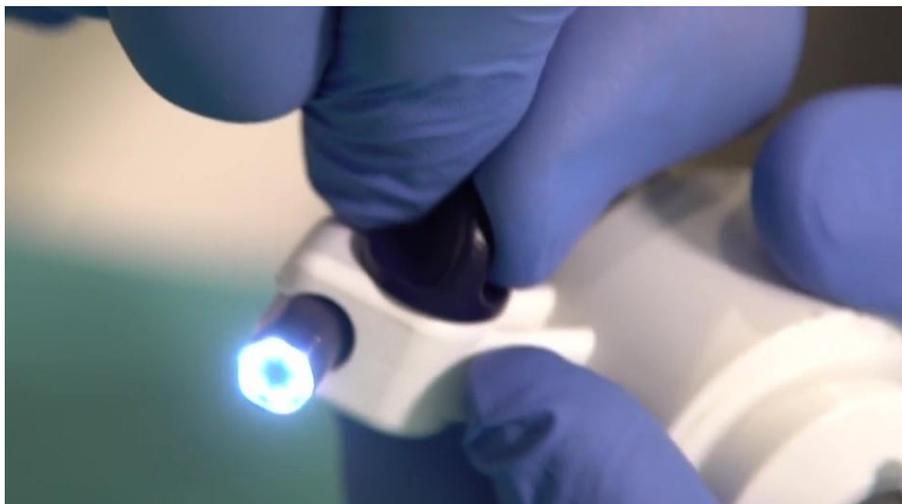


Figure-9: Fastening the camera

6.3 Push the cable of the camera in the channel designed for this purpose. Do not block the way of the syringe with the cable.

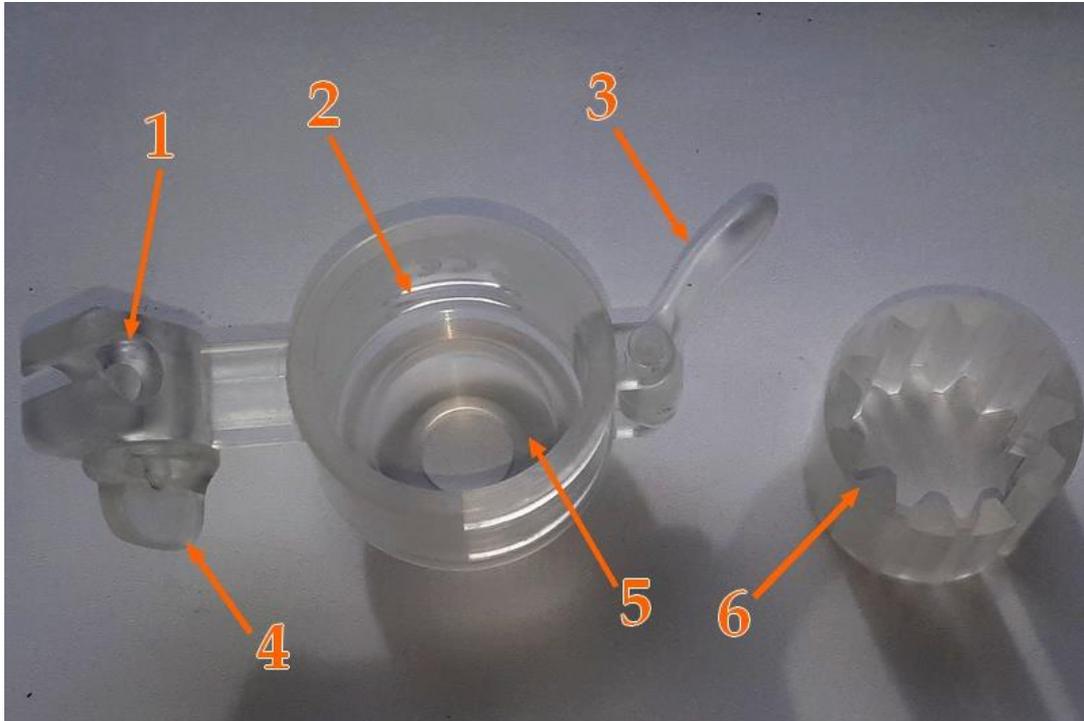


Figure-10: The features of the holder.

- 1 – Slot for the camera**
- 2 – Channel for holding the camera cable**
- 3 – Flip lock for holding the syringe fast (open)**
- 4 – Screw for holding the camera fast**
- 5 – Hole for the syringe**
- 6 Constrictor ring (for 20ml syringes it should be placed into (5))**



Figure-11: Mounting the camera. The body of the camera is placed in the small slot to the right. The screw (below the camera, white) is used for fixing the position of the camera. The cable can be pushed into the channel (left), which makes the way free for the syringe (in the background)

6.4 Remove the tap from the sterile packaging.

The three ways of the tap should point in the direction of the openings.

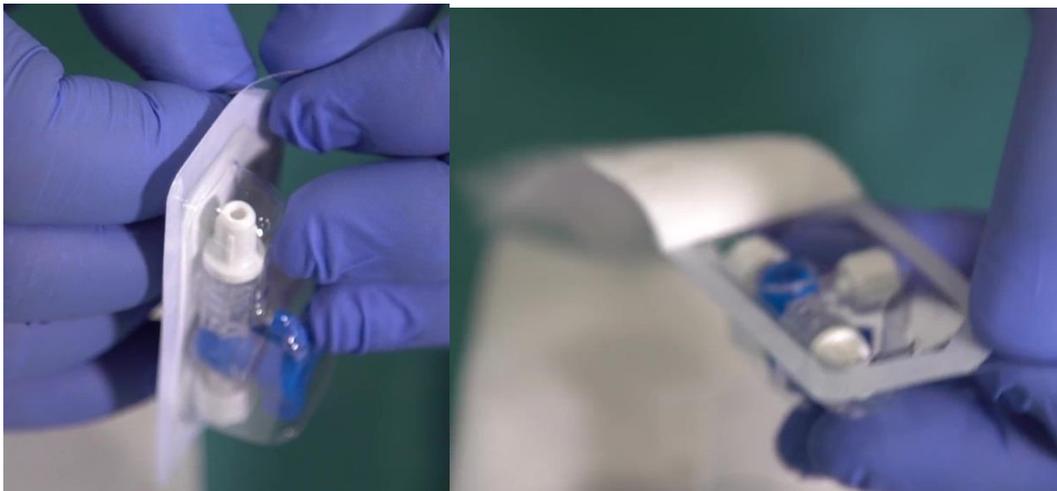


Figure-12: The easiest way to remove the sterile packaging is to grab the upper and the lower layers of the packaging with two fingers each and pull the layers apart. In the picture the tap is shown in its packaging.

If the safety cap does not happen to be attached to the opening opposite the screw-thread ending opening, put it on. If the cap is there, check whether it is closed firmly.

6.5 Remove the extension from its packaging and screw it on the screw-thread opening of the tap.

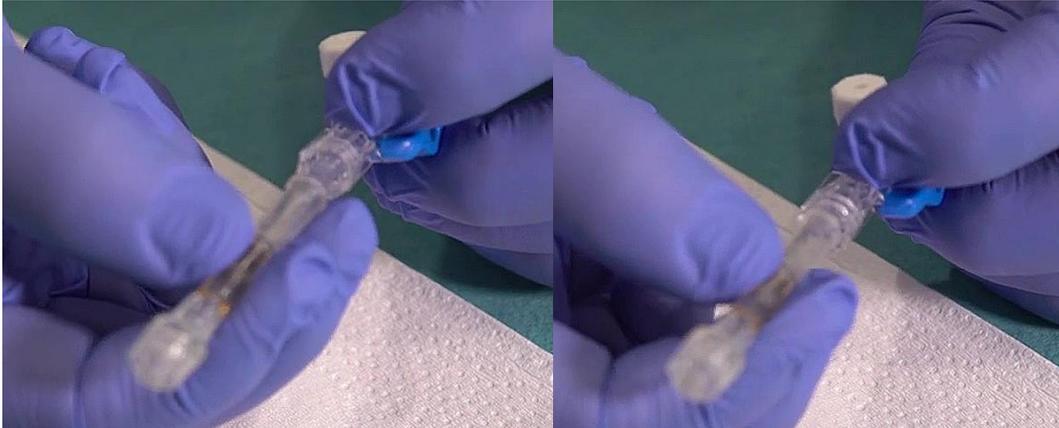


Figure-13: The sterile elements are to be screwed to each other. In the picture the extension and the tap are shown

6.6 Remove UroDapter® from its packaging and screw it on the extension.

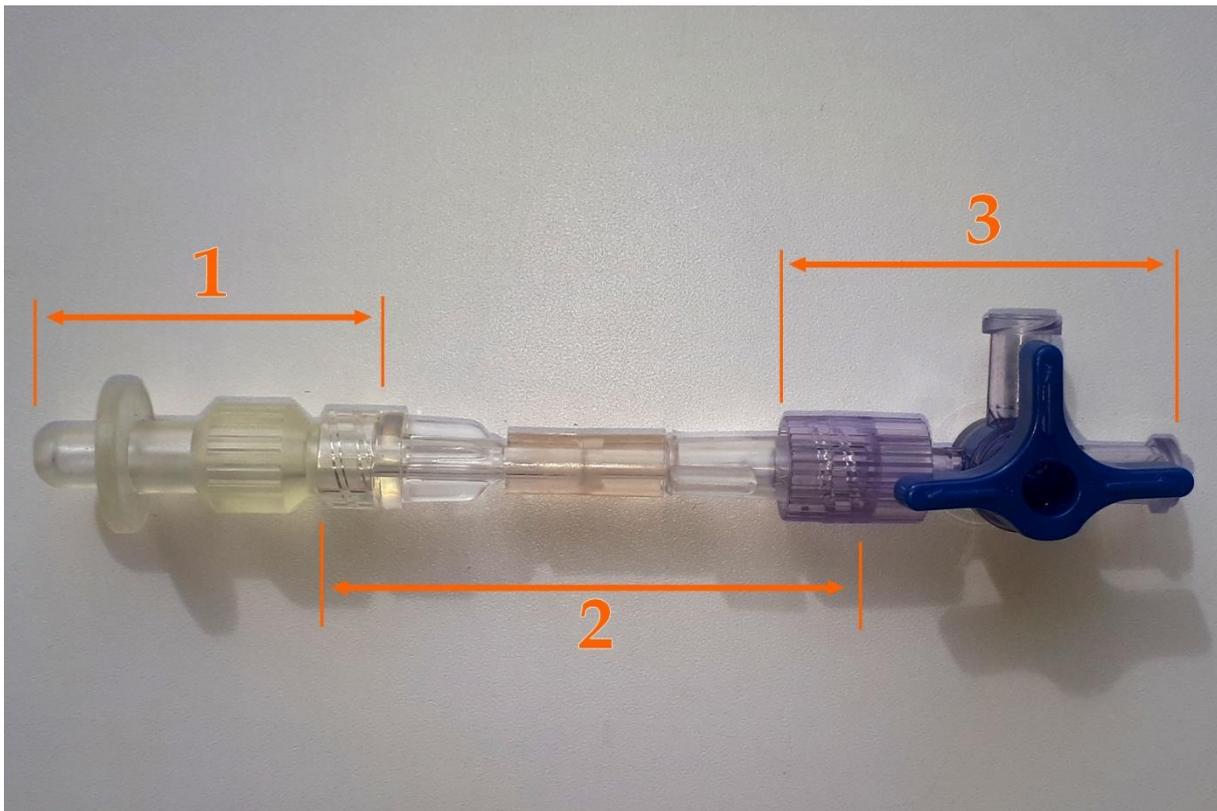


Figure-14: The correct order of the sterile elements.

- 1 – UroDapter®**
- 2 – Extension**
- 3 – Tap (safety cap is not shown)**

6.7 Remove the syringe from its sterile packaging and perform the steps necessary for its use.

It depends on the type of the syringe which is used for self-instillation.

- Pre-filled syringes are in ready-to-use state: apart from unpacking you need do nothing.
- Empty syringes should be filled up. Consult the instructions received from your therapist and/or pharmacist.
- In case of a 20ml syringe the constrictor ring should be placed in the holder.
- In case of a 50ml syringe the constrictor ring should be removed from the holder.
- In case of a pre-filled syringe which is packed as two separate parts, for assembling them follow the manual provided by your manufacturer and/or distributor.

6.8 Put the syringe into the holder and fix its position with the flip lock.



Figure-15: The syringe can be hold fast with the flip lock

Ensure that the syringe is hold firmly.

6.9 Remove the safety cap from the tap's opening which is perpendicular to the other two openings. In case there is a safety cap on the opening of the syringe, remove that one, too.

6.10 Screw the disposables assembled in 6.4–6.6 on the syringe (a half circle is to be performed). Use the tap's opening which is perpendicular to the other two openings.

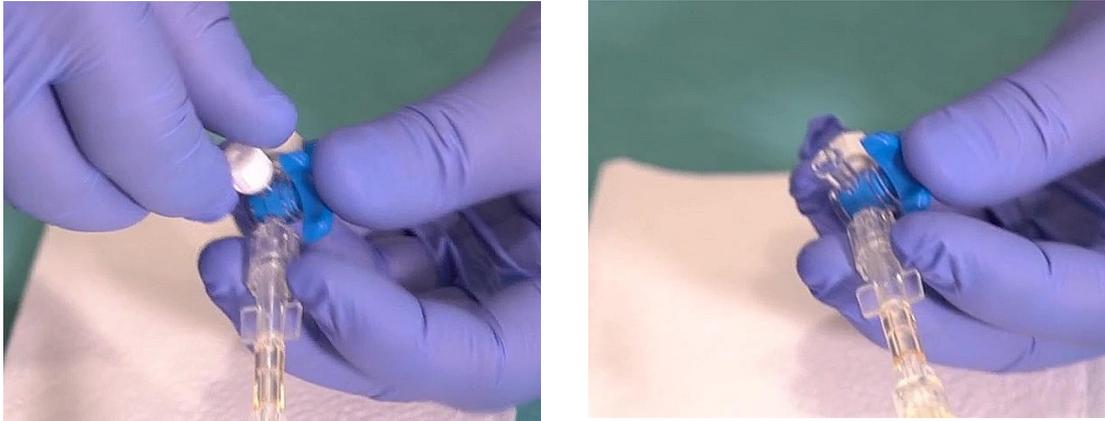


Figure-16: Removing the safety cap of the tap



Figure-17: Screwing the disposables on the syringe

If you perform the self-treatment without following it on the display, skip steps 6.11–6.15.

- 6.11 Find a place for the assembled UroDapter® where you can reach it easily. The isolating collar of UroDapter® should not contact any surface. If needed, cover it with the inside of its original packaging (which is still sterile).
- 6.12 Turn on the display (if it is off), wait until it boots, and connect the camera to it.

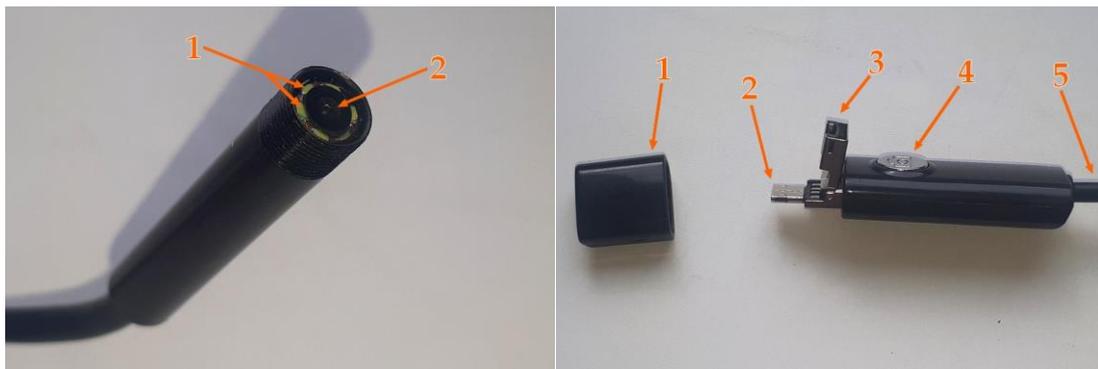


Figure-18: The features of the camera (option).

(Left)

1 – LED lights (6 pcs)

2 – Lens

(Right)

1 – Safety cap (removed)

2 – Micro USB port (this is used for the option display)

3 – USB port (can be turned up, as the picture shows)

4 – Shoot button for taking photos (not needed for self-treatment)

5 – Cable



Figure-19: The USB port of the display (option) is situated on the lower edge of the device. Mind the correct position of the connection

If you use the option camera and display, the application for showing the image of the camera starts automatically. (See Appendix 3 for the manual of the application.)

If the application does not start automatically – or if you use other electronic displaying systems – launch the application and consult its manual for further details.

Check whether the display shows the image of the endoscope camera, and not the image of the built-in camera of the display.

	Notice	<p>If you have checked earlier that the camera, the display and the application you use are compatible, the following actions (in that order) resolve the situation if you cannot see the image recorded by the camera on the display.</p> <ul style="list-style-type: none"> - Check whether the illumination is sufficient - Check whether the camera is connected correctly - Restart the application - If there is still no change, restart the display
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6.13 Check the quality of the image on the display.

	Notice	<p>In the majority of the cases blurred image is a result of the inappropriate illumination. Whenever it is possible adjust not only the LED lights but also the external illumination, too, so that the area of the self-treatment should be neither too bright, nor too dark.</p>
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If needed, the power of the LED lights can be adjusted with the knob on the side of the connection of the camera.



Figure-20: The power of LED lights can be adjusted with the knob (framed)

6.14 Rotate the syringe gently in the holder until the image of UroDapter® appears on the screen.

The most convenient position for the syringe is when the UroDapter® is shown in the bottom middle part of the picture.



Figure-21 The camera and UroDapter® should be in a parallel position. In this case, UroDapter® appears in the middle of the screen on the display. (To the left: external view, to the right: the image on the display)

6.15 If UroDapter® does appear on the display but its position is wrong (e.g. upside down), loosen the screw of the camera and rotate the camera until UroDapter® becomes shown in the bottom of the picture. Fix the camera once more with the screw.

	Notice	The application OTG View (recommendation) enables the conversion of the image recorded by the camera, e.g. rotating and mirroring. Using these features may make self-instillation easier.
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7. Performing the Self-Treatment with UroStill®

7.1 Find a comfortable posture for the self-treatment.

7.2 Open up your labia with one hand so as to expose the orifice of the urethra.

7.3 Disinfect the affected area with your other hand. For this procedure any mucosal antiseptic product can be used.

	Warning!	<p>Not only the orifice, but its 3cm area and the inner surface of the labia have to be disinfected.</p> <p>In case of inadequate disinfection, the tip of UroDapter® might drift some bacteria into the urethra. The instilled solution might drive them into the bladder, which might lead to infections.</p>
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7.4 Disinfect the upper part of the UroDapter®, including the tip and the isolating collar. Not only does this prevent bacteria drifting into the urethra, but also it kills the bacteria present on the outmost part (a couple of millimeters) of the urethra.

7.5 Keep the labia open and hand the assembled UroStill®. Approach the orifice with the UroDapter®.

7.6 These events can be followed on the display. Watch the screen for navigating UroDapter®.

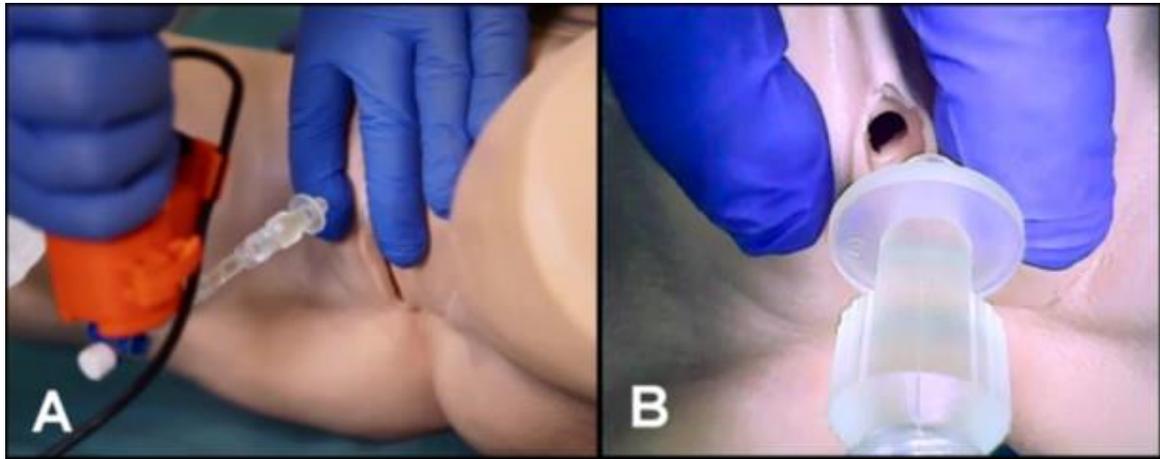


Figure-22: Approaching the orifice. External view (A) and the image recorded by the camera appearing on the display (B).

If you are performing self-instillation for the first time, be sure that you can navigate the Self-Instillator safely and effectively.

7.7 Insert the tip of UroDapter® into your orifice. Apply some pressure so that the isolating collar can be pushed against the nearby tissues, which prevents the leakage of the instilled solution. (The tip of UroDapter® penetrates the urethra only in a length of approximately 6mm.)

7.8 Start instilling the solution by pressing the plunger of the syringe.



Figure-23: Most syringes can be operated easily with one hand: the plunger can be pushed with the thumb

	<p>Caution!</p>	<p>Always check whether the solution is being instilled into the urethra, not into the vagina!</p> <p>Instilling medicines or medicinal compositions used for the bladder treatment into the vagina is not dangerous, but makes the self-treatment ineffective, since the solution does not reach its target, the bladder.</p> <p>„Mis-instillation” sometimes can be seen only after the self-treatment; when the solution flows out of the vagina.</p>
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The plunger of certain 50ml syringes are multi-rimmed. By holding the body of the syringe in one hand the instillation can be done easily by pressing the plunger down by the rims slowly, one by one.



Figure-24: Even if 50ml syringes are bigger, it is easy to perform the instillation with them, since with the thumb the rims of the plunger can be pushed down in more steps, one by one

7.9 If you experience any leakage, pause the instillation and check whether the position of UroDapter® is correct.

	<p>Notice</p>	<p>Too high and too low pressure can cause leakage, too. When the plunger of the syringe is moving easily, with little-to-no resistance, the applied pressure is ideal.</p>
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7.10 If you use one single solution for the self-treatment or if you have instilled the last solution, try to hold back your urine for at least 3 hours, so that the medicine or medicinal composition can affect your bladder (and your urethra) for an ample amount of time.

7.11 If you use more than one solution (packed in separate syringes), follow the next steps:

- After finishing the first instillation remove the disposables (the tap, the extension and UroDapter®) from the syringe and place it on a level surface. The ends of the

UroDapter® and the tap should not contact any non-sterile surfaces. Use the original packaging of the disposables if needed

- Open the flip lock of the holder and remove the syringe
- Place the next (pre-filled) syringe into the holder and fix its position with the flip-lock
- Screw the disposables to the syringe by using the free end of the tap. Rotate the syringe until the image of UroDapter® appears on the display.
- Repeat steps 7.1–7.10 for self-instillation.

	Caution!	The affected areas have to be disinfected again!
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7.12 When you have finished self-instillation, disassemble UroStill® as it is explained in the next chapter.

	Warning!	If you are helped by someone during the self-treatment, make it sure this person is aware of the information detailed in Chapters 6 and 7.
	Notice	For further tips and details on self-instillation see Appendix 4.

8. Cleaning and Maintaining UroStill®

8.1 The sterile elements – the syringe, UroDapter®, extension, tap and their safety caps – are to be discarded with their packaging.

	Caution!	<p>The sterile elements are not considered hazardous waste.</p> <p>The precise procedure of waste management depends on the medicines and/or medicinal compositions used for self-treatment. Consult the manuals of these products and/or your therapist, pharmacist for further details.</p>
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8.2 If you have urinary tract infection or any other infection spread by body fluids, disinfect all the disposables before discarding them to prevent the spread of the disease.

8.3 The holder, the constrictor ring and the camera can be cleaned by gauze or cotton cloth soaked with any antiseptic liquid.

8.4 The display and its cable do not require special cleaning measurements. They can be cleaned by any product can be used for electronic devices.

	Caution!	Before cleaning any electronic device, remove its charger from the electrical outlet to avoid the danger of electric shock.
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8.5 The stand can be washed with soap and tepid water, or it can be wiped clean with a slightly wet piece of gauze or cotton cloth.

8.6 The non-disposables – including the options: the camera, the display, the stand, the charger and its cable – do not require special maintenance. Before using them always check they are intact. Do not use any of these elements if it appears to be damaged.

	Warning!	Damaged electronic devices and cables can cause electric shock!
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9 Storing of UroStill®

9.1 After using, the non-disposable elements are to put back in the pouch in clean and dry condition.

9.2 Keep the electronic elements – the camera, the display and their cables – away from moisture.

9.3 Do not expose the non-disposable elements to extreme temperature, heat radiation, direct sunlight, reactive or any other dangerous chemical substances. These may damage the Self-Instillator.

9.4 Do not break the packaging of the sterile elements until you plan to use them for self-treatment. Breaking the packaging result in losing sterility.

	Notice	It is able to store more than one set of disposables in the pouch for self-treatment.
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9.5 Never put back used disposables into the pouch! If it is not possible to discard them after the self-treatment, put them into any sort of holder you do not need any more until you can discard them.

9.6 Consult your therapist and/or your pharmacist for further details on the storing conditions of the medicine and/or medicinal composition used for the self-treatment.

Should you have further questions, contact your therapist or the distributor of UroStill®.

Distributed by: Happy Business Services Zrt. (18 Szent István krt, 1137 Budapest, Hungary)

Date: Sept. 01. 2019

Amended: Dec. 10. 2019

Version: v1.2

Certificates

UroStill® manufacturer: Happy Business Services Zrt. (18 Szent István krt, 1137 Budapest, Hungary)

Holder manufacturer: Happy Business Services Zrt. (18 Szent István krt, 1137 Budapest, Hungary)



UroDapter®: See the packaging for details

Extension: See the packaging for details

Three-way tap: See the packaging for details

Appendix 1 – Options' Guide: The Camera and the Tablet

The following section provides information on the camera and the tablet we recommend as options. UroStill®, however, can be used with any other displaying systems, too.

This summary does not replace the original documents of any product.

1.1 The display should be used with a fully charged battery whenever it is possible to avoid any issues regarding imaging and/or recording.

1.2 In case of using a non-waterproof camera and/or display, keep these devices off any moisture to avoid damage. Waterproof products have special signs and certificates that refer to this specification.

1.3 Keep the display off the solution being instilled, otherwise it might damage the device.

1.4 The cables of the camera and the charger must not be broken or damaged. Using a damaged cable might result in malfunctions of the Self-Instillator or electric shock.

1.5 Damaged electronic devices can be repaired only by professionals. Do not try to repair them at home.

1.6 During the self-treatment neither the camera nor the cable contact the skin or the mucosa. They do not penetrate any body part either.

	<p>Caution!</p>	<p>Do not put the camera or its cable into any body part. Providing the device is intact, it will not cause electric shock. However, these elements are not sterile so any contact between them and the mucosa or open wounds might cause infections.</p>
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1.7 During operation the LED lights of the camera generate mild heat. Therefore, prolonged use may make the camera warm, but this amount of heat will not result in the risk burn or fire.

1.8 If the camera becomes exceptionally warm during the self-treatment (touching it with hand is unpleasant), that refers to the malfunction of the device. By following the User's Manual neither the camera nor its lead lights get so close to any body surface that they can cause burn. However, if the object touches the mucosa – which, depending on your condition may be wounded or inflamed –, it can cause minor burn. In conclusion, do not use the camera if it becomes hot during its operation.

1.9 Similarly to any other electronic device, the camera and the display emit radiation. The gauge of this radiation means no risk of health. It might, on the other hand interfere with other electronic devices, which might result in malfunctions. If malfunctions occur, do not use the camera and the display near the affected electronic devices.

Appendix 2 – A Guide for the Camera

Read this guide carefully if you use the camera recommended as an option for self-treatment.

2.1 The camera is compatible with devices using Android operating system or computers with Windows operating system.

	Notice	<p>The option display is compatible with the camera. In case you use the camera together with a different smart-device check the specifications for compatibility issues under point 2.7.</p> <p>This camera does not support iOS devices.</p>
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	Warning!	<p>Due to hygienic reasons never use the camera for any other purposes than self-instillation. This could result in infections and the worsening of your condition.</p> <p>This warning applies to any other electronic or non-electronic displaying systems as well.</p>
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2.2 For the features of the camera see Figure-18 in the User's Manual.

2.3 The camera can be connected to the display via micro USB port. The correct way to connect the camera to the option display is shown in Figure-19 of the User's Manual.

	Notice	<p>By default, the camera can be connected to the USB port. If your display has this port, you need do nothing further.</p> <p>For exposing the micro USB plug, flip the USB part of the camera as it is shown in Figure-18. The option display has micro USB port.</p> <p>If you use the camera with a display which has a different port (e.g. USB-C), you have to use an adapter which transfers data and power, too. Certain cameras come with USB-C port, or with a USB-C adapter.</p>
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2.4 After connecting the camera, its application starts automatically (which is default in case of our recommendation, OTG View), or the application has to be launched in the way it is described in its manual.

Before starting the self-treatment always check that the display shows the image recorded by the camera.

2.5 Camera control functions are available in the menu of the application.

For downloading, installing and launching OTG View, see Appendix 3. If you use a different application, consult its manual for details.

2.6 For connecting the camera and using it during the self-treatment see Chapter 6 in the User's Manual.

After the self-treatment has been performed, dismount the camera from the holder and disconnect it from the display.

2.7 Specifications

- Camera type 1,6" VGA CMOS
- Frame rate: 30 FPS
- Diameter (external): 7mm
- USB cable length: 1m
- USB cable diameter: 3mm
- Focal length: 3–10cm
- Angle of view: 60°
- Light source: LED, 6 pcs
- Connection: USB2.0/microUSB
- Waterproof standard: IP67
- Video format: .avi
- Picture format: VGA/QVGA
- Image standard: PAL/NTSC
- Operating system: Android (smart devices); Windows 2000/7/8/10/Vista (PC)

Appendix 3 – OTG View User's Guide

OTG View is a free-to-download application for using external cameras.

	Notice	Depending on the settings of your smart device the appearing messages might be different to those explained here.
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3.1 If OTG View is not present on the smart device you use for self-instillation, by following these steps you can download it for any devices using Android operating system.

- Launch Google Play by touching the corresponding icon. Alternatively, you can use the browser of your smart device.

- Enter in the appearing field the following: '*otg view*', and start searching. (This can be performed either by touching an icon or by selecting the corresponding text.)
- In the list which appears select '*otg view*', which is usually the first element of the list. Download it by touching the '*download*' icon.
- After the download is complete the icon of OTG View appears on the main screen of the smart device, or in one of its menus.

	<p>Caution!</p>	<p>Before starting to download the application check whether your smart device is connected to the Internet. In case of WIFI connection, downloading has no cost. In case of mobile internet connection, it may be charged by your telephone company. Check your contract for details.</p> <p>If you use the Internet abroad, there can be considerable extra costs occurring. Before starting to download the application consult your contract with your telephone company or their other sources of information (e.g. system messages, customer service) for details.</p>
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2.8 OTG View can be launched by touching its corresponding icon.

	<p>Notice</p>	<p>After connecting the camera, a pop-up message might appear whether you want to use this application for the camera, as default. Select '<i>yes</i>'.</p>
	<p>Notice</p>	<p>OTG View might request access to other applications of your smart device, e.g. your picture folder (gallery). If it occurs, you can select '<i>allow</i>' – during the self-treatment there is no Internet traffic emerging, therefore allowing OTG View to access to other applications mean no risk.</p>



Figure-25: The main screen of OTGView. If the camera has been connected, the image it is recording appears on the screen instead of the picture shown above

On the main screen the following icons can be found. If it is not stated otherwise, you can close any menu by touching its icon again.

- (1) Setup. You can adjust aspect ratio and the timing of recording here. You can also check the software specifications. Using this menu is not needed for the self-treatment.

	Notice	In case of certain displays, the appearing image might be distorted, with black stripes on the sides. By pressing the first icon of this menu (to the left) two other icons appear. Press the left one, then press the arrow in the top left corner twice. With these actions you can set the aspect ratio back to normal.
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- (2) Flipping and rotating. The icons appearing stand for the following functions: vertical mirroring, horizontal mirroring, rotating 180°, rotating 90° counter-clockwise, rotating 90°clockwise.

Use any of these icons if you face difficulties at navigating with UroStill®

- (3) Searching for connected cameras.

If you use the option display, the image recorded by the camera appears on the display as soon as OTG View is started. In this case, you do not have to use this icon.

If you use a different display, you might touch this icon once so that the image can appear.

	Notice	If you use a different electronic displaying system to the options, it is possible that OTG View cannot detect the camera. In this case, try to download a different application. Google Play offers several free applications for using endoscope cameras. Check the specifications of
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		<p>your smart device and the application to learn which application can be used.</p> <p>If you use an adapter for connecting the camera and the image does not appear on the display, it is possible that the adapter does not transfer data and/or power. Use an adapter which is able to transfer both data and power.</p>
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- (4) Contact. This icon is for contacting the developers of the application via the Internet. Using this icon is not needed for the self-treatment.
- (5) Gallery. By touching the icon, you can check the path of the pictures and footages recorded by the application. Since you need take no photos or footages during the self-treatment using this icon is not necessary.
- (6) Record mode. If the icon shows a still camera, you can record pictures. If it shows a video camera, you can record footages. By pressing icon (7) you can switch between the two modes. Using this icon is not needed for the self-treatment. However, you can document your self-treatment with pictures or footages by using this icon if the need arises.
- (7) Select mode. By touching the icon, you can select whether OTG View can record still pictures or footages. Using this icon is not needed for the self-treatment.
- (8) Image settings. In the menu which appears you can adjust certain parameters of the image recorded by the camera, such as brightness, saturation, contrast. Normally, using this menu is not needed for the self-treatment. However, if neither changing the external illumination nor adjusting the power of the LED lights help improve the quality of the image, you can use this menu for the same purpose. In very rare cases, the image appearing on the display is odd (e.g. everything is red). Use this menu for restoring the quality.
- (9) Image resolution. You can specify the resolution of the image by touching this icon. Using this menu is not needed for the self-treatment.
- (10) Full screen mode. (Not shown in the figure, it appears to the left from icon (9).) By touching it OTG View leaves full screen mode, by touching it again the application returns to full screen mode. Using this icon is not needed for the self-treatment.
- (11) Display icons. (Not shown in the figure, it appears to the left from icon (10).) By pressing this icon, you can make all other icons disappear, by pressing it again you can bring the icons back. Using this icon is not needed for the self-treatment.

2.9 You can close OTG View in the same way you close any other application on your smart device. After closing OTG View you can disconnect the camera from your smart device.

Appendix 4 – Tips and Tricks for Better Self-Treatment

This guide does not replace the instructions and prescriptions of your therapist.

If the guide and the instructions, orders and/or suggestions of your therapist contradict each other, always take the latter into account!

4.1 Identifying and Exposing the Orifice of the Urethra

Regarding the size and the exact location of the labia the anatomy of the female external reproductive organs are of high diversity.

It is important to know that the fingers used for exposition should lie as close to the orifice as they can be. The exposition has to happen by pulling the labia apart laterally (and not only upwards).

In many cases the wrinkles located at the edge of the orifice (the pseudolabia) are entirely clenched, which makes the identification of the opening hard. It is worth wiping the area with some antiseptic solution. The piece of gauze used for this process – if it is being moved slowly and downwards – can part the pseudolabia for a short time. The location of the orifice can be identified easily afterwards.

After UroDapter® has been put into the orifice, move the orifice a bit downwards, closer to the rectum, with your fingers used for exposing the orifice. Perform a gentle “spooning” move with the adapter downwards to move the orifice under your symphysis – the isolating collar of UroDapter® helps.

4.2 Finding the Best Angle for the Syringe

The optimal instillation (when the least resistance can be experienced) can be performed if the axis of the urethra and the syringe are parallel.

After the orifice has been driven under the symphysis with the „spooning” described before, the best angle for the instillation is the horizontal one – in most of the cases.

Your anatomy must be focused on, too.

In case of younger patients, the tissues situated nearby are tight. When UroDapter® is situated slightly upwards (its tip is slightly above its other end), the instillation can be performed with the most efficiency.

Older patients' tissues are significantly looser (they are particularly „sloppy” after a considerable weight loss). In this case, the urethra is orientated downwards, therefore the angle of the instillation should follow it: the adapter should be situated slightly from up to down (approximately 20–40 degrees).

When the optimal angle has been found the instillation becomes suddenly easier. Since the sealing collar is flexible, the treatment can be done safely even if the syringe is not perpendicular to the orifice.

4.3 Leakage Prevention

One of the most common issues is leakage. If it happens, a part of the solution does not reach the urethra, it flows away instead. In some cases, it can be observed instantly. However, the leaking solution might enter the vagina – which is in a downwards position during the instillation –, and it re-appears only after the instillation has ended and you have stood up. Solutions used for bladder instillation do not cause pain nor complications in the vagina, but the liquid coming out of that organ might be frightening even if its amount is not more than a few drops.

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 ceased by certain minor corrections.

Leakage can occur when the adapter is not pressed properly against the orifice. If there is not enough pressure, the collar cannot cover the nearby tissues properly and the opening remains „unplugged”. By applying more pressure, the flexible collar can adapt itself to the surface of the nearby tissues and the orifice will be sealed properly.

Too much pressure can cause leakage, too. In this case the urethra – which is already squeezed longitudinally – may bulge. This is called kinking. The intra-urethral pressure increases and exceeds the sealing pressure of the collar. If this happens the applied pressure has to be decreased gradually. When the resistance of the plunger of the syringe suddenly disappears, the urethra is in the right condition for the instillation.

4.4 The Speed of 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 multiple factors.

If the sphincter becomes constricted due to pain or fear and muscle tone increases, the pressure in the urethra increases, which can lead to more pain and the spasmodic contraction of the sphincter. If this happens, try to relax. A couple of deep sighs may help, too. Feel free to slow the instillation down or pause it until the constrictions end.

4.5 Special Cases

In case of an orifice of unusual shape, size or position, consult your therapist for further details.