

Intravesical instillations with **laluadapter**[®]



Training manual



Caring Innovation

Intravesical instillations with **laluadapter**[®]

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What is laludapter®?



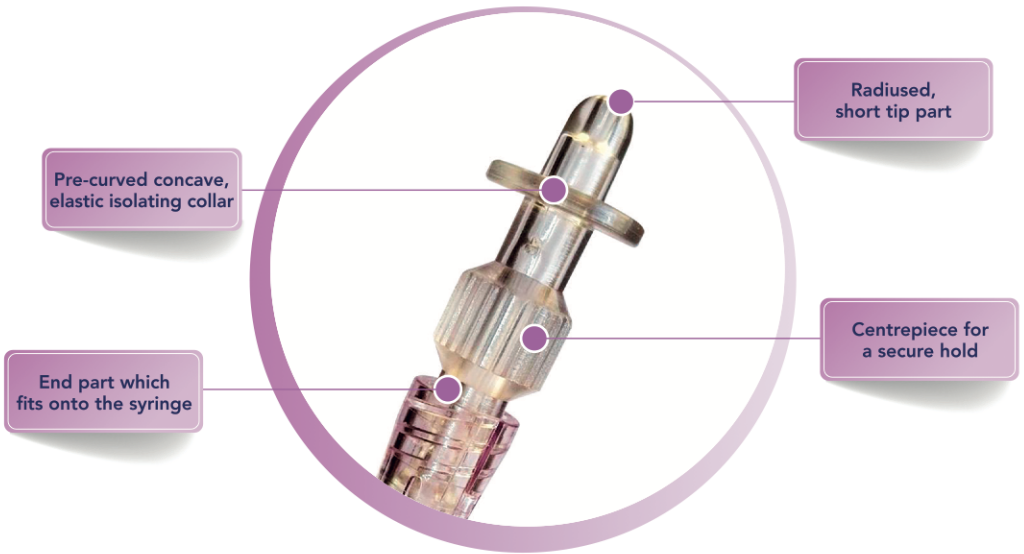
1.

- laludapter® is a **Class I medical device** that allows **the introduction of solutions into the bladder using a minimally invasive procedure** without the need for catheterization.
- laludapter® can **be an alternative to standard male and female catheterization for intravesical instillation.**
- The procedure with laludapter®, compared to standard catheterization, can **be considered as being far less invasive.**
- laludapter® **makes minimal contact with the urethral opening** during the entire intravesical instillation procedure.
- laludapter® **design allows it to be securely sealed into the urethral opening** so that the liquid can flow into the bladder, without leakage or solution loss.
- As the solution passes through the urethra into the urinary bladder, laludapter® also enables **simultaneous treatment of the urethral and bladder mucosa.**
- laludapter® was primarily **designed to facilitate the efficient administration of intravesical solutions**, in particular, to eliminate the pain that can be caused to patients due to their frequent catheterization.
- laludapter® is a **method that enables treatment in all cases of relative urethral stenosis**, when a catheter cannot be introduced, but the patient can still urinate adequately.
- It can also significantly decrease **complaints in patients affected by painful disorders in the bladder area.**

Technical description

2.

laluadapter® consists of four main parts (see Figure):



1. The **end part**, when attached to the syringe, allows the adapter to be used both for Luer-lock and Luer-slip syringes.
2. The wider **ribbed centrepiece** enables the user to hold the adapter securely when fitting it onto the syringe.
3. The concave **isolating collar** made of an elastic material adapts to the surface surrounding the orifice and facilitates instillation without leakage.
4. The **radiused tip part** is the only part of the device that penetrates into the urethral opening. It prevents the adapter from slipping out, even if the force applied deviates from the central axis.

Advantages of catheter-free bladder instillation with laladapter®

The main advantage of the catheter-free bladder instillation method is that the device does not come into contact with most of the urethra during the procedure.

- With laladapter®, **only the solution comes into contact** with the highly sensitive, bloody mucosal surface that is often injured and painful.
- While the solution is being instilled slowly, **try to divert the patient's attention and help him to relax**, this will also facilitate bladder sphincter relaxation.
- These precautions mean that **no excess pressure**, which could be painful even without causing mechanical injury, **will occur inside the urethra**.
- **The treatment is thus practically painless** for almost all patients.
- Another major advantage of this method is that **as the viscous solution streams through the urethra into the bladder, it also adheres to the walls of the urethra**, where it remains undiluted and exerts its effect until the first urination.
- Using laladapter® means that both **the bladder mucosa and urethral mucosa are treated at the same time**.

Important information before using laladapter®

4.

laladapter® is supplied as a sterile device for single use, and it is packaged individually.



It is recommended that sterility is maintained during use.

laladapter® cannot be used to treat the patient if the packaging is damaged, or if the “best before date” on the packaging has expired.

laladapter® is for **administering solutions only**, and not for withdrawing them.

laladapter® cannot be used to drain the bladder.

Re-sterilization of the adapter is not permitted, laladapter® is **for single use only** and is not suitable for re-use.

How to use laladapter[®] with laluril[®] Prefill

5.

Before starting the treatment, the patient is asked to urinate and empty his/her bladder completely before the instillation.



If more than 50 ml of urine remain in the bladder, it will dilute the solution being administered, thus reducing its efficacy significantly.

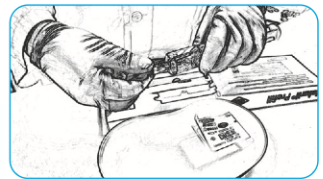
Therefore, it is important to check the volume of residual urine by suprapubic ultrasound examination.

If a significant residuum is detected by ultrasound examination, the bladder should be emptied completely using a catheter, and only after this should the solution be administered.



The first step before using laladapter[®] is to unwrap the prefilled syringe and remove the sealing cap.

Then, fix the laladapter[®] onto the syringe. A half twisting motion will enable you to fasten it safely onto the Luer-lock syringe and achieve a stable attachment.



Hold the sterile adapter by the ribbed centrepiece only (make sure that you do not touch the isolating collar or the radiused tip).

Now place the laladapter[®] with the syringe attached, back into the opened, but inwardly still sterile packaging.



The complications and pitfalls of intravesical instillation are discussed separately in male and female patients in the following pages, as their anatomical differences mean that the manoeuvre to administer the solution differs between the sexes.

A. Bladder instillation in the female patient

The **female patient** lies supine and spreads her legs, pulling her knees as far apart as possible and supporting her legs on her heels.

The doctor stands to the patient's right (if he/she is right-handed) and using index and middle fingers he/she will open up the small labia, making sure that the urethral opening is visible.

It is very important to wash the area around the urethral opening and the entire area of the small labia thoroughly using a solution suitable for disinfecting the skin and mucosa (i.e. Betadine) by wiping these areas carefully twice with a well-soaked gauze sheet.

Now pick up the syringe. We recommend pressing out a few drops of the viscous solution onto the isolation collar - while releasing air from the syringe - so that the tip of the adapter becomes slippery and helps to protect the mucosa of the urethral opening from injury.

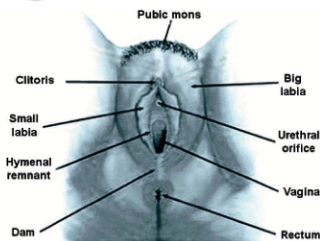
Slowly instil all of the solution contained in the syringe through the laladapter® into the bladder.

Keep laluril® Prefill in the bladder for as long as possible (minimum time recommended: 30 minutes).

When the product has been instilled into the bladder, carefully remove the laladapter® with the syringe and dispose of it.



Location of female urethra and "critical cases" to be treated:



- The female urethral opening is located between the small labia, above the vagina, or in rare cases, it may be behind the vaginal inlet.
- In some cases, the urethral opening can interfere with the easy application of the adapter:
 - ▶ if the urethral opening is located too deep
 - ▶ if it is cicatricose, or cannot be made visible
 - ▶ if, mainly in older patients, the strictured vaginal opening is covered with scars.

B. Bladder instillation in the male patient

The **male patient** lies supine with his legs stretched out straight and flat on the bed.

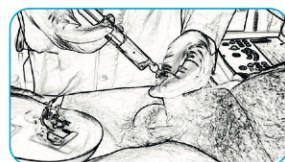


The doctor stands on the patient's right (if he/she is right-handed) and grasps the penis just below the glans, holding it upright.

If the patient is uncircumcised, retract the foreskin. Replace the foreskin at the end of the procedure.

It is very important to wash the area around the urethral opening thoroughly. The doctor cleanses the glans using cotton wool balls soaked with a solution that is suitable for disinfecting the skin.

Use each cotton wool ball once only in a single circular motion.



With the right hand, gently straighten and stretch the penis. Lift it to an angle of 60-90 degrees.

Now pick up the syringe. We recommend pressing out a few drops of the viscous solution onto the isolation collar - while releasing air from the syringe - so that the tip of the adapter becomes slippery and helps to protect the mucosa of the urethral opening from injury.

Slowly instil all of the solution contained in the syringe through the laluardapter® into the bladder.

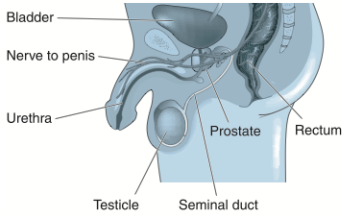


Immediately after introducing the solution into the bladder compress the urethra with two fingers to stop the solution from leaking. Meanwhile, fill the same syringe with 20 ml of air, then slowly fill up the urethra with this volume of air. We stop pushing air into the urethra as soon as we hear and feel the air bubbling into the bladder. When a stronger resistance during the filling is perceived or the patient feels expressed pain, the procedure should be stopped immediately.

Keep laluril® Prefill in the bladder for as long as possible (minimum time recommended: 30 minutes).

When the product has been instilled into the bladder, carefully remove the laluardapter® with the syringe and dispose of it.

i Location of the male urethra and “critical cases” to be treated:



- The male urethral opening is generally located at the end of the penis, on top of the glans. It can be easily be made visible by pulling back the foreskin.
- In the event of a developmental anomaly, when the urethra opening is either on the lower side of the penis or on its upper surface (hypo- or epispadiasis), this makes the intended use of the adapter more difficult or even impossible. In this case, the traditional replenishment therapy using a catheter is still applicable.



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