

INFORMATION TO THE PATIENT WITH AN IMPLANTED DEVICE

Dear Madam, Sir

You have been implanted with Releen® InLine 2-way Foley catheter for urological treatment purpose. Please, read carefully the below information for optimal use.

1. What is Releen® InLine catheter?

Releen® InLine 2-way Foley catheter is implantable medical device, to treat urological diseases. It is a Silicone catheter for urinary drainage equipped with a balloon for maintenance in right position.

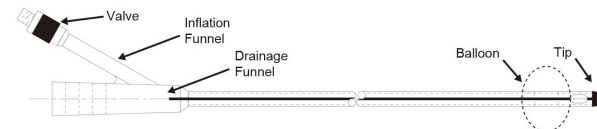


Fig. Releen® InLine catheter

2. What is Releen InLine catheter used for?

Releen® InLine is a catheter intended for continuous urine drainage from your bladder, used in the case of some surgical procedures, monitoring urine output, urinary leakage or if you cannot urinate on your own.

Duration of use: Releen® InLine catheter can be used for up to 12 weeks maximum.

Kind of patients: Releen® InLine catheter can be used in adult male and female patients.

Placements: Releen® InLine catheter is implanted within bladder either by natural urethral route or through a surgical incision in the lower abdomen (suprapubic route).

In both cases, the catheter is held in the bladder by the balloon inflated with sterile water, which prevents it falling out. Urine is drained from the bladder through the tube (drainage channel) connected to a urine collection bag, which can either be strapped to your leg or attached to a stand on the floor.

3. What are the operating instructions for me ?

⇒ It is recommended to maintain a good fluid intake (water) after surgery and, if needed, to follow specific diet as advised by your physician.

⇒ Ensure scrupulous local hygiene

For urethral placement: Wash the genital and anal areas every morning and evening with soap and water, wiping away from the body.

For suprapubic placement: Wash the area around the catheter exit site gently with soap and water, every day. Change your dressing every day if you have one.

Don't pull on the tube. Don't use powders, creams, or sprays near the exit site.

⇒ Ensure your urine bag is emptied before it reaches two-thirds full.

⇒ Be aware that: Releen® InLine catheter is for single use device. After removal, the device shall be discarded.

4. What is the performance of Releen® InLine catheter?

Releen® InLine catheter is meant for insertion into your body.

The size has been chosen by your surgeon to fit your bladder and urethra:

- The balloon is inflated to the maximum volume indicated by the manufacturer to maintain the catheter in place.
- The diameter of the drainage channel allows urinary drainage with a flowrate corresponding to your needs.

Undesirable side effects

Problems reported that could be caused by the use of Releen® InLine catheter are listed below:

Depending on your health condition:

Bladder irritation symptoms, pain, urinary tract infection, incrustation, stone formation or allergy.

Related to the procedure: Urinary tract trauma.

Related to the catheter: Leakage, balloon burst or deflation.

Some undesirable side effects of Releen® InLine catheter are specific to the suprapubic way:

Depending on your health condition: Hematuria, any type of skin irritation.

Related to the procedure: Peritoneal perforation with or without bowel perforation, misplacement/displacement.

Related to the catheter: Migration of the catheter, catheter knotting.

5. What are the residual risks associated with the use of Releen InLine catheter?

Residual risks associated with Releen® InLine catheter described in above paragraph 4 “Undesirable side effects” have been reduced as far as possible.

⇒ This type of medical device is used by trained and experienced professionals.

6. Can I safely pass medical imaging exams or airport security?

In case of any medical, surgical or exploratory procedure, you are advised to inform the attending Physician of your implanted medical device and show your implant card

No risks of electrical interference
from electrosurgical devices with
Releen® InLine catheter.

No risks of X-ray interference
from radiographic imaging
environment with Releen® InLine
catheter which is radiopaque.



7. How to use or manage follow-up of my implanted device safely?

Preventive actions

Releen® InLine catheter is meant to stay within your urinary bladder for a certain while, from a few days to several weeks (maximum 12 weeks), depending on your disease and as prescribed by your physician.

You are advised to:

⇒ Keep the date of your Releen® InLine catheter removal in your Agenda.

⇒ Consult your physician for preventative examination, regular monitoring or maintenance of Releen® InLine catheter as planned after the procedure to evaluate the treatment efficacy and check for any complication.

Monitoring should also be daily implemented to check that the balloon is still inflated, that the catheter is correctly placed. It is good practice to empty leg bags before they reach two-thirds full. It is recommended to drain the balloon every 1-2 weeks and to refill it with sterile water to the maximum volume indicated depending on the size of catheter.

The monitoring schedule greatly depends on the intended implantation duration and your condition.

Symptoms that could indicate that the device is malfunctioning

The warning symptoms include:

- Pain, trauma and discomfort.
- Urethral swelling around the catheter.
- Bleeding into or around the catheter / pink or red urine.
- Catheter draining problem: little or no urine despite adequate fluid intake.
- Leakage of large amounts of urine around the catheter.
- Symptoms of infection: Burning sensation, increased lower abdominal pain, fever, chills dizziness, nausea and vomiting, foul-smelling discharge coming from the urethra or in the genital area / urine with a strong smell or becomes thick or cloudy, redness or swelling in the genital area. Pain in the urethral or genital areas.

8. What is Releen® InLine composed of?

Releen® InLine 2-way Foley catheter is made of Silicone and contains:

- No Latex, no Phthalates, no Alkylphenols.
- No medicinal substances, no substances of animal origin or human origin.