

## DEVICE DESCRIPTION

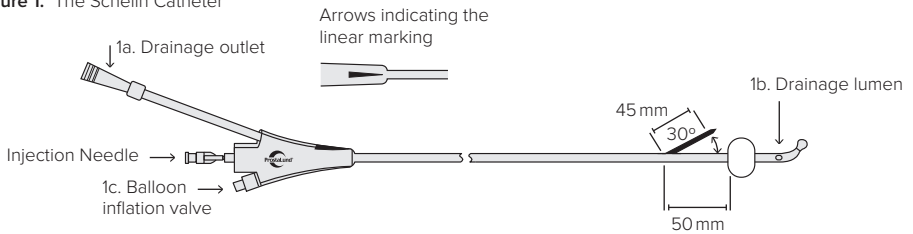
The device is used for delivery of legally marked drugs into prostate tissue during prostate diagnostic and treatment procedures, for example during prostate biopsies and treatment of benign prostatic hyperplasia (BPH/BPE), to manage patient pain or to inject astringents.

The administration of local anaesthesia/analgesia via the Schelin Catheter reduces or eliminates the administration of systemic anaesthesia and/or sedatives.

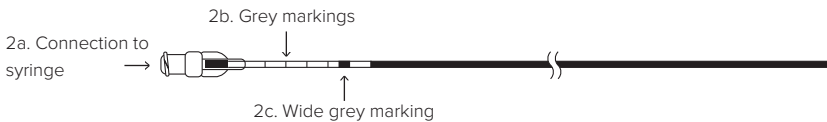
This means that injections can be performed in different directions using the bladder neck as an anatomical landmark. The Schelin Catheter can be rotated to allow injections into different tissue regions with respect to the bladder neck.

The Schelin Catheter is comprised of a transurethral catheter (Fig. 1) and an injection needle (Fig. 2) inserted into the catheter.

**Figure 1.** The Schelin Catheter



**Figure 2.** Injection needle incorporated in the Schelin catheter



### Transurethral catheter

- The diameter of the catheter is 20Fr/ Ch/ 6.7mm.
- The length of catheter is 36cm
- The Schelin Catheter has a balloon at its proximal end, to anchor it in the bladder, and a drainage lumen (Fig. 1b).
- The balloon is inflated using a medical syringe connected with a luer taper to the balloon inflation valve (Fig. 1c).
- For drainage, a urinary bag can be attached to the Drainage Outlet (Fig. 1a).

### Injection needle

- The injection needle is inserted into the transurethral catheter and cannot be removed.

- The needle diameter is 1.2mm and is used as the injection needle when drugs are injected into the prostate tissue.
- The injection needle has two outlet openings in the tip; one on each side, located 3mm from the tip.
- The injection needle can be connected to a syringe via a Luer lock connector (Fig. 2a).
- When the needle is fully inserted it protrudes 45mm through an opening in the catheter at an angle of about 30°.
- The opening is located 50mm from the base of the balloon.
- Along the visible part of the injection needle there are 4 thin grey markings at an interval of 10mm (Fig. 2b).

- 5mm after the last of these 4 markings there is a 5th wider marking (Fig. 2c). When all 5 markings are visible in their entirety the hypodermic needle is fully retracted into the catheter.

**The Schelin Catheter is for single use only, delivered sterile and ready to use.**

## INTENDED PURPOSE

### Intended use

The Schelin Catheter is intended for intra- and periprostatic injection of legally market drugs during transurethral procedures.

### Intended patient population

The intended patient population is adult men, requiring a prostate diagnostic or treatment procedure.

### Intended user profile

Injections shall be carried out by trained medical personnel and in accordance with the instructions from the physician in charge.

## INDICATIONS

Intended medical indications are for disease or condition where intraprostatic and periprostatic injection of drugs are indicated, for example:

- Management of pain during treatment of BPH/BPE by injection of anaesthetics/ analgesics.
- Use in treatment procedure for BPE/BPH where intra- and periprostatic injections of drugs are indicated, e.g. by injection of an astringent.

## CONTRAINDICATIONS

Patients with bladder neck sclerosis or urethral stricture (unable to pass a catheter)

## WARNINGS

There is a risk for complications if the Schelin Catheter is not handled carefully and correctly. The risk for complications can be minimized by using the product as described in these instructions for use.

### Incorrect injection can cause damage

Injections may only be administered by trained medical personnel.

### Intravenous injection of drugs can cause serious adverse events

Carefully read and follow the instruction for use of the injected drug, and follow the dose, contraindications, and potential safety measures.

Aspirate routinely prior to injection to check that the needle has not penetrated any blood vessels. If blood is visible, correct needle position in depth. If blood is still visible after correcting position, retract needle completely and insert to a new adjacent position.

### Injection needle incorrectly positioned

If the balloon is not filled in accordance with the instructions, the injection needle can be incorrectly positioned. It is therefore important to ensure that the catheter balloon is filled during injection and that it is correctly positioned in the bladder.

### The injection needle can damage the urethra

Always retract the needle fully into the catheter before rotating or removing the catheter, to avoid the injection needle damage the urethra.

## PRECAUTIONS

Patients with urinary tract infection or who use a Foley catheter or practice self-catheterization shall initiate treatment with antibiotics according to resistance pattern 3-5 days before treatment with the Schelin Catheter.

### Damaged packaging

If the packaging has been damaged, the Schelin Catheter is no longer sterile. Non-sterile products must not be used.

### Single use only

The Schelin Catheter is for single use only and shall not be reused or re-sterilized. Failing to comply may cause risks to patient such as: transfer of bacteria due to non-sterile product.

## ADVERSE EVENTS

The following adverse events has been rare, but could be associated to the Schelin Catheter or the following procedures:

- Infections
- Mild hematuria

Clinical benefit
Allow intra-and periprostatic injection of legally marketed drugs
Allow the use of local anesthesia for pain management in procedures in the prostate
Reduced treatment time in treatment of LUTS due to BPH/BPE

## REPORTABILITY

Any serious incident that has occurred in relation to the medical device shall be reported to ProstaLund AB and to the authority having jurisdiction in your locale.

## Devices and medicals for use of Schelin

### Catheter (not provided by ProstaLund):

- Medical syringe, with Luer taper - for injection of sterile water to inflate/deflate the balloon of the catheter
- Medical syringe, with Luer lock - for injection of drugs through the needle
- Urinary bag (optional) - for collection of urine while emptying of bladder
- Lubricating gel/ anaesthetic gel - to enable insertion of the catheter into the urethra

## DIRECTIONS FOR USE

**Note: Carefully read and follow the instruction for use of the injected drug, and follow the dose, contraindications, and potential safety measures.**

### Preparation

1. In all situations, aseptic and basic hygiene procedures, and local medical practice and operating procedures should be followed.
2. Make sure that the sterile packaging is not damaged. Then proceed to remove the Schelin Catheter from the sterile packaging and handle it as a sterile product.
3. Visually inspect the Schelin Catheter for any damage. In particular, check that there is no balloon leakage by filling the catheter with 20 ml of air by use of a medical syringe with a luer lock connection. If there are any signs of damage, dispose the Schelin Catheter and continue treatment with a new, sterile catheter. Before moving onto next step, deflate the balloon.
4. Check that the opening for the injection needle should be located on the line along the shaft. Make sure that the line is not rotated.
5. Insert the injection needle fully and visually inspect that the visible part of the injection needle has no cracks or other signs of physical damage.
6. Use sterile water in a medical syringe with a luer lock connection to check that the two outlet openings in the tip of the injection needle function.

7. Retract the needle so that only 2-3 mm of the tip is visible. Note the position relative to the 5 mm wide grey marking on the injection needle.

**Note: This needle position can cause an injection into the urethra. Make sure that the complete 5 mm marking is visible to ensure the injection needle is fully retracted into the catheter before inserting the Schelin Catheter into the patient.**

8. Prior urethral insertion lubricate catheter with anaesthetic gel.

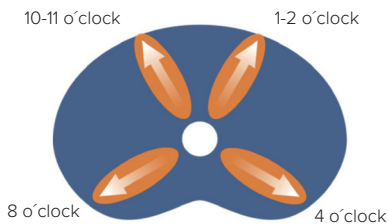
## CATHETERIZATION

1. Insert the catheter into the urethra with the angled catheter tip pointed in the direction of the inflation valve. When the catheter has reached the urinary bladder, using a Luer tip syringe, inflate the balloon with 20 ml of sterile water.

**Note: Do not fill the balloon with more than 20 ml of sterile water.**

2. Carefully stretch the catheter so the balloon rests against the bladder neck.
3. Empty the bladder through the drainage outlet. It is possible to connect a urinary bag via the catheter drainage outlet connection.
4. Rotate the catheter into the desired angle to be used when injecting the drug. This is done by carefully pushing the catheter forward, rotating it and then gently stretching it. It may be necessary to push the catheter back and forth a couple of times to guarantee that the catheter shaft is not twisted inside the patient's urethra. When the desired rotational angle has been obtained carefully stretch the catheter so the balloon rests against the bladder neck.
5. With the aid of TRUS, and with the patient lying on his left side, it is relatively easy to control the position of the injection needle by push the injection needle in and out with a short, sharp movement (2 to 3 mm). The injection needle can then be clearly seen in the ultrasound image, transversally and sagittal.
6. Identify the tip of the injection needle and verify that it is correctly positioned.
7. When the Schelin Catheter is in place the injection needle can be inserted into the prostate gland.

8. Aspirate routinely prior to injection to check that the needle has not penetrated any blood vessels.
9. Use a medical syringe with a luer lock connection to inject pharmaceuticals according to the doctor's instructions.
10. Intraprostatic injections can be given in different directions, for example before a CoreTherm treatment where anaesthesia is injected into four quadrants in position at 1-2, 4, 8 and 10-11. Fully inserted in the deep position (45 mm) the needle tip meets the prostate base area, regardless of prostate size. The patient only feels a sting when the needle is inserted directly into its deep position.
11. Withdraw the injection needle until the 5 mm wide grey mark (see Fig 3) is fully visible. This indicates that the injection needle is fully retracted into the catheter, and it is possible to change the direction of the injection needle for a new injection.
12. For further injections in another rotational angle of the catheter repeat steps 3 to 10 above. For CoreTherm treatment it is typically injected in 4 different rotational angles.

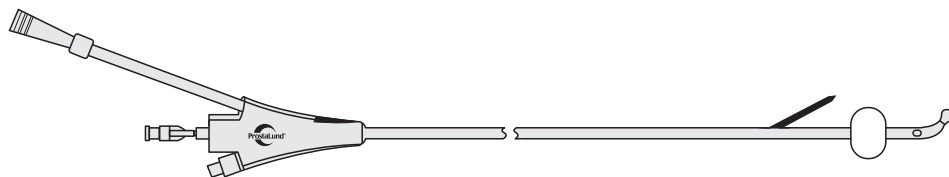


**Figure 3.** Recommendation of injection position in the prostate

**Figure 4.** 5mm marking on injection needle



**Figure 5.** Fully inserted needle for inspection



## CATHETER REMOVAL

1. To remove the catheter when treatment is completed, the injection needle must be retracted all the way into the catheter until the complete 5 mm marking, see Fig 4 is visible to the user and the injection needle is fully retracted into the catheter.
2. Deflate the balloon by reinserting the Luer syringe into the valve and aspirate the fluid. Ensure that all fluid has been aspirated before removing the catheter.
 

**Note: If the fluid cannot be aspirated, flush drainage outlet with a saline solution or sterile water. If this does not work, deflate balloon by cutting off the valve.**
3. Retract the catheter. When the catheter is retracted, fully insert the needle to be visible for visual inspection, see Fig. 5, and control that the needle is intact.

## SAFE DISPOSAL

















Dispose of the catheter after use in accordance with established hospital routines.

## STORAGE AND HANDLING

The Schelin Catheter is a disposable sterile product intended for single use only. It is sterilized using ethylene oxide and is to be used before the expiry date stated on the product label.

The Schelin Catheter shall be stored in a clean and dry environment at a temperature between 10 – 30°C. Relative humidity (non-condensing) shall be between 10 – 80% R.H.

## SYMBOLS

	Manufacturer		Do not use if product sterile barrier system or its packaging is comprised
	Read instructions for use		Range of humidity
	Date of expiry		Range of temperature
	Sterilized by Ethylene oxide		Medical Device - Indicates the item is a medical device
	Balloon capacity		Singel sterile barrier system with protective packaging outside
	Size of the shaft		Manufacturing date
	Article number		The device is not tested to be safe in MR environment
	Batch number		
	Do not re-use. Single use device		

---

### ORDERING INFORMATION

Device	Article number
Schelin Catheter	SK812100



### CONTACT INFORMATION

**ProstaLund AB**  
Scheelevägen 19  
SE-223 63 Lund  
Tel: +46 (0)46 12 09 08  
E-post: info@prostalund.com  
www.prostalund.se

Medical Device

