Instructions for Use – Silicone Suprapubic Catheters

Art.Nr.	Riverstar® Product
MD5100, MD5178	Riverstar® supra BK (CH 12, 14), 2-way Puncture set with split cannula
MD5673 -MD5679	Riverstar® supra (CH 12, 14, 16, 18, 20, 22, 24), 2-way
MD5179 -MD5183	Riverstar® supra XC (CH 12, 14, 16, 18, 20, 22), 2-way Catheter exchange set with PTFE-coated guide wire

Thank you very much for choosing a product from AUROSAN. For a secure and successful treatment of your patient, please carefully read the following instructions. The use of these products is permitted only to medical and sufficiently trained staff.

Product Features.
The suprapubic catheters consist of 100% silicone, with a 2-way shaft and proximal tube, a blocking valve, and distally the blocking balloon, for a safe retention in the urinary bladder. The specific data on filling volumes (ml), length (mm) and size (CH/F) can be found on the catheter or the blocking valve, as well as on the label of the peel pouch (the sterile packaging).
Puncture sets for the first placement of a suprapubic catheter also contain a split cannula with 12 cm stitch length. Exchange sets also contain a PFTE-coated guide wire. All catheters are marked with a graduation at 138mm und 185 mm from the tip, for an orientating control of the catheter position, and having 2 sided and a central opening for fluid drainage, the latter also for the operation of the guide wire when exchanging the catheter.

Intended Use / Indications.
The 2-Way suprapubic balloon catheter is intended for suprapubic fluid drainage to and from the urinary bladder.
The recommended maximum retention period is 30 days. The use is intended only for urological purposes. Single use only. For professional use only.

Contraindications.
A suprapubic drainage is contraindicated in case of (1) hemorrhagic diathesis, varicoseor venous congestion, recent or current blood-thinning medication, open or covered injuries in the intended area of puncture, empty or insufficiently filled bladder, tumors of bladder, lower belly or perineum, presence of ascites or pregnancy.

Adverse events and possible complications.
Transient hematuria during intubation.
In case of dislocation of the catheter, injuries to the urethra can occur. With longer-lasting retention times, catheter-associated urinary tract infections or skin infections may occur. As consequence of overfilling, the balloon may rupture which can cause secondary injuries to surrounding vessels. Similarly, there are reports on the development of bladder stones.
In very rare cases, distortions of the catheter can cause urinary congestion.

Preparation for use.
The product is delivered -alone or as set- in a sterilized packaging, for single use only. Its use has to follow aseptic techniques. The product may not be used, if the packaging is damaged or has been opened before, or in case of any indication that the product may no longer be sterile, e.g. if the “use before date” has passed.
Visually inspect the catheter before intubation for intactness. Do not use the product if damaged.
To ensure the balloon will inflate without leaking you may test its proper function prior to intubation by filling and then pulling back again the blocking fluid into the syringe. Only use sterile water or 10% glycerin solution. To avoid injuries during intubation make sure that the balloon is fully deflated and the entire blocking fluid is retained back into the syringe.
Before use, the site of puncture needs to be marked and following an established procedure, to be cleaned and disinfected.
Have a urinary collection system ready available.

Procedure.
1. Puncture and first placement with the Puncture Set.
The bladder should be filled. Sonographic control of filling and bladder position is strongly recommended. Locally anesthetize the site for the puncture before making a small skin incision about 1 cm above the symphysis **in the body middle line**. After removing the cap from the split cannula place the catheter into the split cannula so that the catheter tip is placed within the tip of the cannula. You may use an aqueous lubricant (do not use silicon spray) to ease the passage of the catheter through the cannula.
Through the skin incision, rectangular to the belly skin drive the cannula into the bladder until urine drainage starts. Tightly hold the cannula while moving forward the catheter.
When the balloon of the catheter is securely placed within the bladder,slowly pull the cannula out of the puncturing channel. CAVE: Do not pull back the catheter through the cannula, as its sharp edges may damage or cut off the catheter.
You can remove the cannula by tearing apart the handles until it breaks at its midline. For this the cannula needs to be fully outside the body. Discharge the cannula (sharp disposal) right away to avoid risk of injury for personnel or patient.
For blocking the catheter fill the balloon using sterile water or 10% glycerin solution, and apply the fluid with an appropriate needleless, e.g. Luer syringe through the catheter valve. Fill the balloon slowly and with the volume indicated on the valve and the sterile packaging, only, to avoid overfilling and rupturing.
After blocking gently pull the catheter back until the balloon attaches to the bladder wall. Use an established procedure to fix the catheter to the skin and to dress the wound.

2. Removal of the catheter.
Remove the wound dressing and the skin fixation. Clean and disinfect the wound.
Before removal of the catheter, the balloon needs to be deflated. Use an empty Luer syringe adapting to the valve and slowly retract the blocking fluid into the syringe. Avoid force to not cause a vacuum collapse of the filling way. Continue retracting fluid until the filling volume is regained. Then carefully and slowly pull the catheter back. Should major resistance occur, repeat the deflating process.
If only the catheter is to be removed, gently pull the de-blocked catheter out of the puncture channel. Dress the wound following an established procedure.

3. Exchange of the catheter with the XC-Set.
If the catheter is to be exchanged, start by preparing a new catheter and a new urine collection system.The bladder should be sufficiently filled. Different from the above described removal process, and before deblocking the old catheter insert a guide wire to the appropriate position into the catheter. Holding to the guide wire, deblock the catheter and carefully pull it back keeping the guide wire in place.Now insert the new catheter via the guide wire (using the central opening at the tip of the catheter) into the bladder and block its balloon as described above.Then carefully pull out the guide wire and connect the blocked catheter to the new urine collection system. Attach the catheter to the skin and dress the wound as before.

Warnings and precautions.
Due to diffusion, the blocking fluid volume in the balloon may reduce. To prevent a possible subsequent catheter dislocation, it is recommended to exchange the blocking fluid after 2 weeks, and refill using the nominal intended blocking fluid volume. To minimize diffusion use sterile 5% sodium chloride or 10% glycerin solution.
Make sure the catheter is connected in time to a (sterile) urine collection system. The catheter may not be pinched off. The use of sharp instruments with the catheter may cause damages to the product and present a safety risk to the patient. If necessary lock the catheter with a sterile spigot.
Urinary samples may be taken from the urine collection system. To avoid injuries, leakages and the risk of infections, the catheter must not be punctured with a needle.
In rare cases, the retaining of blocking fluid to deflate the balloon may present difficult. In such case, cut the catheter with scissors at the bifurcation (do not cut the shaft) behind the blocking valve. Consult an urologist if you experience further difficulties.

Bladder irritations, dislocations of the catheter from incrustations, hematuria, and post-procedure infections at the site of puncture or the bladder are complications occurring in some patients. Accordingly, catheter intubated patients should be closely monitored, and the retention time of the products should be adjusted in accordance with the indication of the supervising medical doctor.
As appropriate and indicated, ensure sufficient fluid intake to prevent urinary tract infections and obstructions from catheters.

Storage, Sterility and Disposal.
The product should only be stored in the original packaging, and in a cool, dry environment, avoiding direct sun light.
Use the product only until the “use before” date shown on the packaging label, and if the packaging has not been damaged and not be opened before.
This product is for single use, only.
It must not be re-sterilized. Re-used catheters may cause infections and inflammation.
After use, this device should be disposed in accordance with your country’s regulations for similar types of industrial waste.

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CE-0483

REF	Order-No.	CE	CE-certification
LOT	Lot-No.		Manufacturer
	Use before	STERILE EO	Sterilized with Ethylenoxid
	Follow instructions for use		Single use only
	Store dry		Manufacturing date