Instructions For Use – Silicone 3-way hematuria catheters

Art.Nr.	Product line / Description
MD5541 -MD5544	Silstar®Fortune Dufour hematuria catheter CH 18, 20, 22, 24 -3-way
MD5551 -MD5554	Silstar®Fortune Couvelaire hematuria catheter CH 18, 20, 22, 24 - 3-way
MD5561 -MD5566	Silstar®Fortune Nelaton hematuria catheter CH 14, 16, 18, 20, 22, 24 -3-way

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 hematuria catheter consist of a 3-way transparent shaft with two proximal funnels, a blocking valve, and distally the blocking balloon, for a safe retention in the urinary bladder. The specific data of 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). Depending on the product line, catheters may be delivered with Dufour or Couvelaire tip, and may be tailored with a spigot.
The catheters can easily be confirmed for correct intubation using X-ray due to their X-ray opaque line.
A soft, rounded shaft reduces the risk of trauma during catheter intubation and removal.Several alternate openings next to the tip as well as the central opening serve for easy fluid drainage.

Intended Use / Indications.

The hematuria catheter is intended for use as a urinary catheter to pass fluids to and from the urinary bladder, particularly after surgery to the lower urinary tract e.g. prostatectomy coinciding frequently with hematuria.
The recommended maximum retention period for silicone catheters is 30 days. The use is intended only for urological purposes. Single use only.For professional use only.

Contraindications.

The product may not be used in case of (1) suspicion of injuries or strictures of the urethra, (2) significant symptoms of urinary obstruction, or (3) history of abdomino-perineal resection for rectal cancer, rectal stenosis, or other major rectal pathology.

Adverse events and possible complications:

Transurethral drainage systems are, based on the underlying pathology, frequently associated with strictures of the urethra. Similary, irritations of the bladder sphincter are possible.
During intubation of the catheter, mucosal injuries may cause transient hematuria.
In case of dislocation of the catheter injuries to the urethra can occur. With longer-lasting retention times, catheter-associated urinary tract infection may occur.
As consequence of overfilling the balloon may rupture which can cause secondary injuries to surrounding vessels. Similary, 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 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.
The product must not be re-sterilized.

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.

Procedure.

Intubation into the urethra shall be performed according to a well-established aseptic technique. Ensure that the catheter is correctly placed into the urinary bladder. Dislocated catheters can cause severe injuries, as can the balloon if inflated in the urethra or within tissue.

For intubation, you may use a lubricant (containing or not containing a local anesthetic). Lubricate the catheter, or instill the lubricant into the urethra. We recommend lubricant on aqueous base or gel, prefilled in Luer syringes. With silicone Foleys do not use lubricants on petroleum base nor silicone spray.

For blocking of the catheter fill the balloon using sterile water or 10% glycerin solution, and applying the fluid with an appropriate needleless, e.g. Luer syringe through the catheter blocking valve.
Fill the balloon slowly and with the volume indicated on the valve and the sterile packaging, only, to avoid overfilling and rupturing.
When using a guide wire with the intubation, first inflate the balloon after the catheter is correctly placed. Hold the catheter straight when carefully pulling out the guide wire to maximally reduce resistance.

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 mostly regained. Then carefully and slowly pull the catheter back. Should major resistance occur, repeat the deflating process.

Hematuria is usually present after Prostatectomy. Frank bleeding is considered as serious emergency and a potential complication, which would last for several days after this surgery.
Notice color and color changes of the urine and the presence of any clots, as clots could obstruct the catheter and cause spasm, pain and further bleeding. The catheter should remain patent at all times.
Regularly check the bladder for fullness and tenderness. Patients with a catheter for purpose of hemostasis may have a sensation of full bladder even though the bladder is well-drained.
Irrigation is generally kept to a minimum and should follow the doctor’s order about when to irrigate, what kind and how much solution to use.
After catheter removal, closely record for several days times and amount of each voiding. If drainage is unsatisfactory, consider re-intubation with a new catheter.

Warnings and precautions.

Due to diffusion, the blocking fluid volume left 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 it is recommened to 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 the 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 be difficult. In such case cut the catheter with scissors at the bifurcation (do not cut the shaft) behind the blocking valve. Consult an urologist.

Bladder irritations, dislocations of the catheter from incrustations, hematuria, and postoperative infections at the site of surgery or the bladder are complications occurring in some patients. Accordingly, Foley 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.
If possible and indicated, ensure sufficient fluid intake to prevent urinary tract infections and obstructions.

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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