Instructions For Use – Silicone Foley Catheters

Art.Nr.	Product line / Description
MD5500 -MD5502	Silstar® Nelaton CH 6, 8, 10 - 2-way
MD5144 -MD5150	Silstar® Nelaton CH 12, 14, 16, 18, 20, 22, 24 - 2-way
MD5151 -MD5156	Silstar® Tiemann CH 12, 14, 16, 18, 20, 22 - 2-way
MD5561 -MD5566	Silstar® Nelaton CH 14, 16, 18, 20, 22, 24 - 3-way
MD5093 -MD5099	Bluestar® Nelaton CH 12, 14, 16, 18, 20, 22, 24 - 2-way
MD5707 -MD5713	Siflex®Nélaton CH 12, 14, 16, 18, 20, 22, 24 - 2-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 Foley balloon catheter consist of a 2-way or 3-way shaft with a proximal tube, 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, Foley catheters may be delivered tailored with a spigot.

All Foley catheters can easily be confirmed for correct intubation using X-ray: Silstar®-catheters are transparent and contain a X-ray opaque line, Bluestar®-catheters are of an X-ray opaque blue color, Siflex®-catheters are of an X-ray opaque green color.

A soft, rounded shaft reduces the risk of trauma during catheter intubation and removal.All Foley catheters have to alternate openings next to the tip for fluid drainage. An additional third, central opening at the tip of the 3-way Foley catheter allows the use of a guide wire (stylet) in case of complicated intubation.

Intended Use / Indications.

The 2-Way (3-Way) Foley Balloon Catheter is intended for use as a urinary catheter to pass fluids to and from the urinary bladder.

The recommended maximum retention period for silicone Foley 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) injuries or strictures of the urethra, (2) recent surgery involving urethra or urinary bladder, (3) history of TURP (transurethral resection of the the prostate) with a large tissue defect, (4) significant symptoms of urinary obstruction, or (5) history of abdominoperineal 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 Foley 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 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.

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 from Foley 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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