

INSTRUCTIONS FOR USE
ROMED FOLEY BALLOON CATHETERS, STERILE FOR SINGLE USE
REF: CATH-, 3CATH-

PLEASE READ ALL INSTRUCTIONS CAREFULLY BEFORE USE

Product Description

All Catheters basically comprise a 2 lumen or 3 lumen shaft with proximal funnel, inflation valve and distal retaining balloon. Balloon fill volumes in ml and shaft size in French gauge (Fr.), Charriere (Ch) or millimetres (mm) are indicated on the funnel of each individual catheter and the distal tip type can be indicated on the individual pack label and / or outer carton. Sizes range from 6 to 30 Fr./Ch. lengths will vary between 25 and 41cm. Some paediatric balloon catheters include a stylet in order to facilitate insertion if needed.

Indications

These catheters are indicated for routine drainage of the bladder or for routine post-operative drainage and irrigation of the bladder.

Contraindications

Romed Foley Balloon Catheters contain natural rubber latex.

Caution

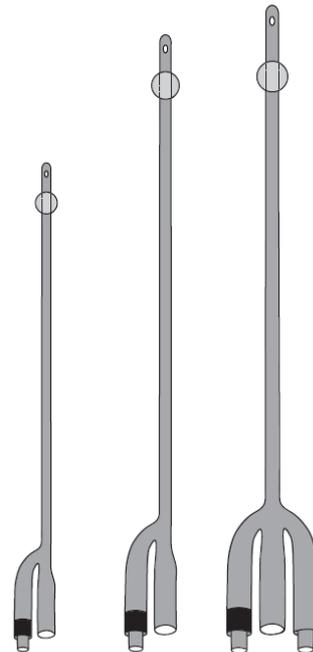
This product contains natural rubber which may cause allergic reactions and risk of reuse may result in infection to the Patient and Clinician.

Preparation for Use

Remove the catheter from its pouch using aseptic technique, visually inspect the catheter for any mechanical damage. Check the balloon for leak before use. Make sure that the balloon is emptied completely before inserting the catheter. Only sterile water of enclosed pre-filled syringe should be used to inflate the balloon.

Note

The catheter tip should be examined prior to insertion of a pediatric balloon catheter, to ensure that the stylet is properly positioned in the tip of the catheter and does not protrude. This is verified by making sure that the tip of the stylet is not visible through the eye of the catheter but has been observed to pass this position. If one wishes to use the stylet for insertion, do not remove it from the catheter and try to re-insert it. Reinserting the stylet is very difficult and may perforate and protrude through the catheter resulting in urethral injury upon insertion.



Instructions for Use

Lubricate the catheter using a water based lubricant or gel with or without local anaesthetic as required, petroleum based lubricant should not be used as they will damage the products and may cause the balloon to burst. Using sterile technique as indicated in published literature, insert the catheter fully into the urethra ensuring that the balloon is beyond the bladder neck.

Note

Withdraw the stylet after correct paediatric balloon catheter placement has been determined. Be careful to avoid dislodging the catheter while removing the stylet. The stylet should be removed before inflating the balloon. Make certain that the catheter does not move from the bladder after removal of the stylet. A Luer syringe or for some catheters a Luer lock syringe may be used to inflate the balloon.

Inflate the balloon with sterile water or use the enclosed pre-filled syringe. The capacity of the balloon is indicated on the funnel of the catheter or on the label of the packaging. Do not overinflate. Ensure function by checking for urine flow from the drainage funnel.

To deflate the balloon prior removal, insert a Luer syringe or a Luer Lock syringe as appropriate. Aspirate the syringe gently to remove the inflation fluid. Do not use excessive aspiration on the syringe during deflation as this may cause a vacuum collapse of the inflation lumen which may impair normal drainage.

Having fully emptied the balloon, inflate it again with 2 ml air to prevent distal balloon folds.

This device falls under class IIa, hence the usage is maximum 14 days and not considered for continuous use with second new device.

The inflated balloon hold the catheter in the bladder. If the balloon loses liquid, e.g. by diffusion of the filling liquid through the balloon membrane, the catheter can, with time, slide out of the bladder accidentally. In order to prevent this danger, the inflation liquid should be withdraw from these catheters at least once a week and the balloon filing volume.

Potential Complications

The stylet may be difficult to remove if the paediatric balloon catheter is bent or kinked in the urethra. If difficulty is encountered aspirating the balloon with a syringe, a rare and infrequently reported event, the leg of the catheter with the valve should be cut with a sharp scissors at the bifurcation or the balloon ruptured according to established procedures reported in medical literature. Should it be necessary to rupture the balloon, care must be taken to remove all fragments from the patient. Incorrectly positioned catheters can cause urethral damage if the balloon is inflated within the urethra. Irritation of the urethral mucosa, blockage of the catheter due to encrustation and catheter induced infections are documented complications with some catheter materials and patients.

The patient should be routinely monitored in accordance with accepted procedures and the catheter remove after a suitable interval as determined by a Clinician or other suitably qualified personnel.

Caution

Romed Foley Balloon Catheters intended only for urological use!

Protrusion of the catheter stylet through the eye of a paediatric balloon catheter during insertion may puncture or damage the urethra. Do not use lubricants or preparations with a petroleum base on products which contain or a water based lubricant or gel. Always inflate the balloon with sterile water or use the enclosed pre-filled syringe. Never clamp the catheter, a catheter, valve or plug may be used, if required. Never use a syringe to puncture the catheter shaft for urine sampling. There is a danger of needle –stick injury and the catheter may be compromised.

Re-Use of Device

Re-processing of medical devices intended for single use only may result in degraded performance or a loss of functionality. Re-use of single use may result in exposure to viral, bacterial, fungal, or prionic pathogens. Validated cleaning and sterilization methods and instructions for reprocessing to original specifications are not available for these medical devices. This product is not designed to be cleaned, disinfected or sterilized.

Presentation

Each product is supplied in an individual sterile pouch and is guaranteed sterile unless the unit packaging has been opened or damaged. All these products are indicated for single use only. Do not resterilize or reuse.

Storage Recommendations

These products should be stored at in their original box in a dry place, preferable away from direct and indirect sources of light and heat.

