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Brillant (All-Silicone)

Directions for use

READ THE ENTIRE DIRECTIONS FOR USE THOROUGHLY BEFORE USE!

Description:
Brillant catheters are available as 2-way Foleys (with proximal funnel, non-return inflation valve and bladder fixation balloon) and 3-way Foleys (additional irrigation channel with proximal funnel).

Balloon inflation volume, catheter external diameter, name and REF are printed on valve sleeve, with additional information on each pouch and shelf carton.

Products are manufactured from 100% silicone.

⚠ Warning: Pre-filled syringe is to inflate catheter balloon only. Not for injection.

For community pack only: empty syringe included for deflation of previous indwelling catheter only.

Indications:
Brillant catheters are indicated for continuous drainage and/or irrigation of the bladder.

A) for transurethral use respectively
B) suprapubic use (exchange only)

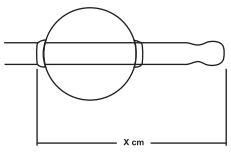
A) FOR TRANSURETHRAL USE

Contraindications:
None known.

Preparation for use:
Have the following ready before starting catheterisation:

1. Sterile Field
2. Catheter
3. Soap, water and a towel
4. Syringe containing sterile water for balloon inflation.
5. Aqueous based analgesic lubricant
6. Sterile gloves
7. Urine collecting container
8. Leg bag, night drainage bag or catheter valve

Firstly, measure the distance between the catheter tip and base of balloon:



(Catheter must be in the bladder to at least this depth, to avoid possible urethral injury during balloon inflation).

Place patient in supine position for men, lithotomy for women.

Wash and dry hands thoroughly (Fig. 1).

Remove catheter from pouch (Fig. 2) and place on sterile field.

Put on sterile gloves (Fig 3) and snap off top of catheter sleeve.

Clean opening of urethra and surrounding area, using established techniques.

Insert analgesic lubricant into urethra and allow time to become effective.

Use one hand to spread open vulva (Fig. 4), or hold penis (Fig 5). With other hand, place catheter tip in opening of urethra and advance into bladder (using normal caution).

If urine runs out of end of catheter funnel whilst advancing, it may be assumed catheter tip and eyes have reached the bladder. Allow urine to flow into collecting container.

Advance catheter further, until balloon is in bladder (see **Preparation for use**).
Note: For safety, add 2cm to distance measured).

Caution:
Balloon must only be inflated when entirely in bladder (Fig. 6). Use Luer slip (Fig. 7) or Luer lock syringe (Fig. 8) to inflate balloon with volume of sterile water printed on catheter funnel and product label. Volume must not be exceeded. Gently and carefully, retract the catheter until resistance is felt. This indicates that balloon is at bladder neck and retention mechanism is working. Connect urine collector to catheter (Fig. 9).

Catheter care:
Section of catheter protruding from patient, as well as entry site, must be kept as clean as possible. Check at least daily, or in accordance with medically accepted hygiene regimes.

Should pain (stinging) occur at meatus, or inflammatory signs (such as fever) be observed, if the catheter no longer drains urine, or is being bypassed, please notify a doctor immediately.

Catheter removal:
Balloon must be completely deflated before catheter removal. A syringe should be used to remove water through the valve. Use only gentle suction for this procedure, to give balloon time to deflate.

Potential complications:
In rare cases, deflating the balloon with a syringe may present problems. In such cases, normal procedures should be followed, or those described in specialist literature may be used. Balloons must never be inflated above the stated volume to try and rupture them, as they normally take a far greater capacity before this occurs and can lead to further complications. If method chosen requires balloon to be ruptured, all fragments must be carefully removed from bladder. All methods must only be performed by a physician or other suitably qualified medical personnel. Catheters not positioned correctly may cause injury if balloon is not correctly inflated in bladder. Irritation of urethral mucosa, blockage of drainage lumen by encrustation and infections are all complications known to be generally associated with indwelling urethral catheters.

⚠ **Warnings:**
Patients should be routinely monitored in accordance with accepted procedures to ensure continued catheter patency and function. Catheters should be removed after a suitable interval as determined by a physician, or other suitably qualified personnel who are both familiar with these devices and potential complications associated with their placement. Do not use petroleum-based lubricants. Only inflate balloons with sterile water. Never clamp catheters: if necessary, use a catheter valve, catheter plug, or clamp drainage bag tubing.

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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 only medical devices 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.

B) FOR SUPRAPUBIC USE (EXCHANGE ONLY)

Indications:
Exchanging (replacement) of suprapubic catheters for drainage of the bladder in patients with stable suprapubic tracks (mature suprapubic stomata)

Contraindications:
Immature, instable suprapubic stoma/track (about 4 weeks post establishing the suprapubic stoma)

⚠ **Warning:**
In case of any risk to lose the track due to instable stoma/track or due to any other circumstances, do not exchange the suprapubic catheter with a new Foley catheter with closed tip. In this we would recommend use of a guide wire aided approach and use a Silicone Foley catheter with open tip.

Preparation for Use:
- Lay the patient in a supine position or as comfortable as possible.
- All equipment used must be sterile and within expiry dates. Wash hands and put sterile gloves on.
- Remove the new catheter from the packaging using aseptic technique.
- Before use check the new catheter for any possible mechanical damage and the balloon for leaks and make sure that the balloon is completely deflated again after functional testing.

Removal of the catheter in situ:
- Remove all existing fixation plasters or devices and remove the dressing at the puncture site.
- Clean and disinfect the area around the catheter using normal established technique.
- Fully deflate the balloon of the catheter to be exchanged by careful active aspiration with the syringe.
- Slowly commence removal in an upward direction to avoid causing unnecessary trauma to the bladder wall and insertion channel. Following 1-2cm removal resistance may be encountered and the catheter seems to be stuck. This is because the catheter balloon is in the bladder wall (detrusor muscle) and the

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detrusor muscle as well as the rectal muscle has been stimulated, gripping the catheter balloon and dragging it towards the catheter tip.
- Place fingers on either side of the catheter and gently press down. Gently rotate the catheter and pull in an upward direction to remove the catheter. Often a little force is required.
- Judge the catheter length which was inserted and make sure that the catheter is removed in one piece including the complete cuff and the catheter tip.
- Clean cystostomy site again.
- Discard the old suprapubic catheter in normal fashion.

Insertion of the new catheter
- Gently slide the new catheter down the cystostomy tract.
- Make sure that the balloon of the catheter is fully inserted through the suprapubic track into the bladder. Thereafter inflate the catheter balloon with 3ml to 5 ml of sterile water asking the patient if discomfort is experienced. If resistance is encountered either gently insert (balloon is still located within the bladder wall) or remove a little further (if catheter tip found its way into the bladder neck or urethra).
- Gently pull back until the catheter is felt against the inside of the bladder and fully inflate the catheter balloon to the recommended nominal inflation volume. It is experience in changing such catheter which helps to know it is safely in situ. Judging the length on removal helps avoid over-insertion, e. g. entering the urethra in cases of weak pelvic floors.
- Apply new sterile dressing to the puncture site using established techniques.
- If necessary, apply new skin fixation plaster to hold the catheter to the skin surface.
- Connect to a new drainage collector.

Potential Complications
Swelling, painful or difficult catheter change as a result of the catheter balloon forming ridges or a cuff that remains proud of the catheter and therefore hampers catheter withdrawal, discomfort, bladder stone formation, over granulation occurring of the stoma, irritation of the bladder, blockage of the catheter due to encrustation, bleeding from the site, haematuria or operative debris and post-insertion infection, recurrent urinary tract infections, balloon failure to inflate or deflate and balloon ruptures are documented complications associated generally with suprapubic catheterization, depending on patient. Following a traumatic catheter removal episode, difficulties have been experienced with the insertion of a new catheter as the suprapubic cystostomy track obliterated as the detrusor fibres contracted.
Rare complication referring to catheter retention is catheter knot in the bladder especially when using small gauge or pediatric catheters. In cases of weak pelvis floors the catheter may pass into the urethra. Leakage of urine around the catheter is very rare and can occur in patients in whom the urethra is closed due to severe strictures or previous surgery. Rarely peritoneal perforation or injury of adjacent organs, development of hour glass bladder in spinal cord injury patients. Possible long term risk of squamous cell carcinoma. Three incidents of death were reported in the literature.
The patient should be routinely monitored in accordance with accepted procedures to ensure continued catheter patency and the catheter should be removed or replaced after a suitable interval as determined by a physician or other suitably qualified personnel who are familiar with these devices and the potential complications associated with their placement.

Cautions
- When changing a suprapubic catheter speed is very important, the new catheter should be inserted within 5 – 10 minutes of the removal of the old one. Never remove a suprapubic catheter unless it is going to be changed immediately!
- Always have a spare catheter available in case of accidental removal.
- Suprapubic catheter should only be placed by physicians or other suitably qualified medical personnel who are trained and experienced in the placement techniques and equipment normally used to place these devices.
- Patients with neuropathic bladder: After having replaced the catheter, health professionals should observe the patient for at least thirty minutes and ensure that the suprapubic catheter drains clear urine and patients do not develop abdominal spasm or discomfort, symptoms and signs of sepsis or autonomic dysreflexia are absent.

Packaging:
Each catheter is supplied in a sterile pouch.
Catheter and its components are guaranteed sterile unless pouch is open or damaged.
Products are for single use only. Do not resterilise or reuse.

Storage Instruction:
Keep away from sunlight and keep dry. Do not use if the product sterilisation barrier or its packaging is compromised.

All information is in accordance with the state of the art when going to press. Subject to technical alterations.

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Co. Westmeath, Ireland

Explanation of important symbols and markings on the product label.

SIZE	Product size
Ch.	1 Ch. = 1/3mm
LATEX	This product does not contain natural rubber latex
	Do not use if package is damaged

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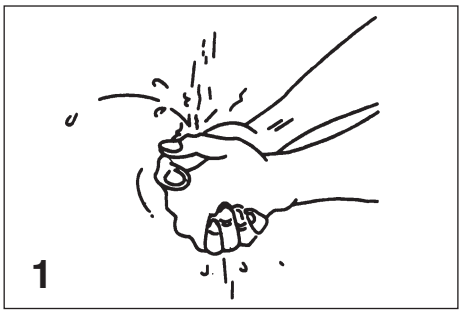

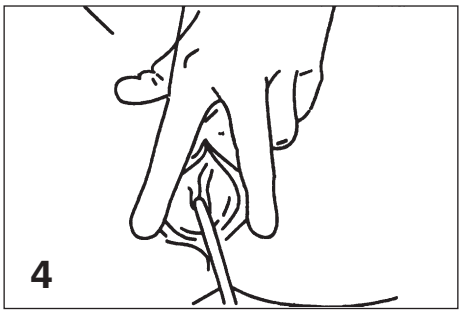

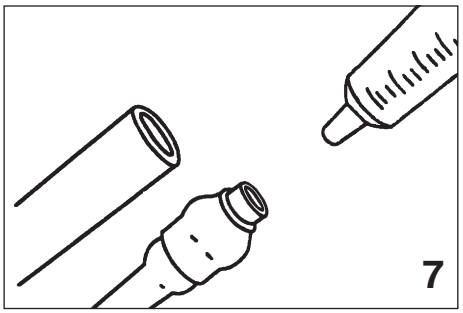

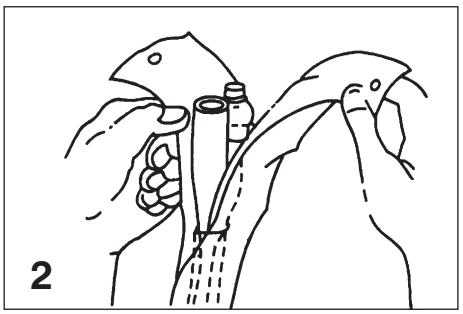

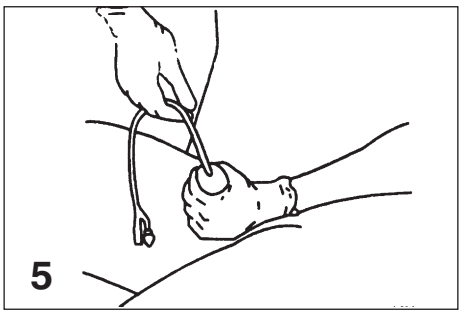

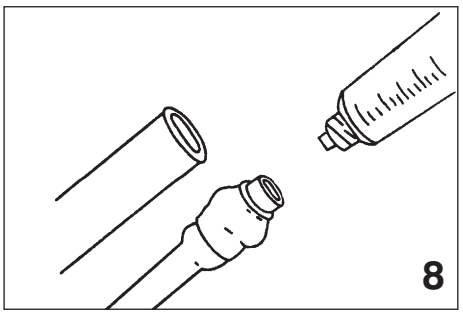

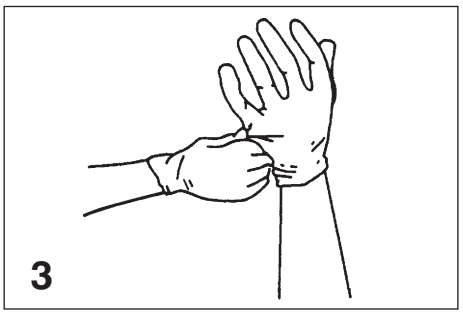

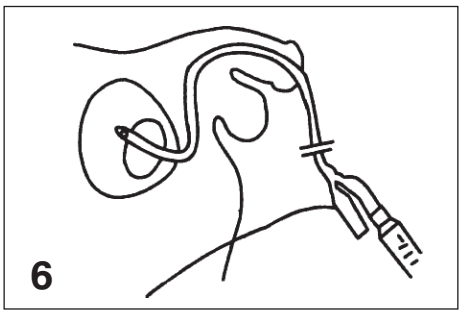

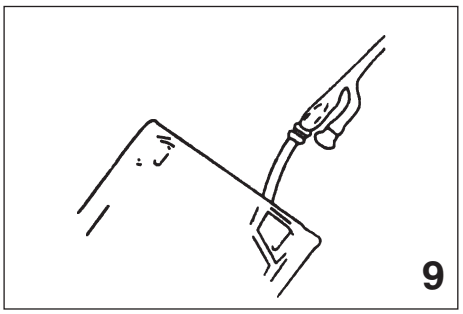

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