RüSCH

PTFE Coated Latex

Directions for use

Description:
PTFE coated latex 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 funnel, with additional information on each pouch and shelf carton.

Products have a coating containing PTFE to reduce friction on insertion and removal, as well as during the indwelling period.

⚠ 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:
PTFE coated latex catheters are indicated for continuous drainage and/or irrigation of the bladder.

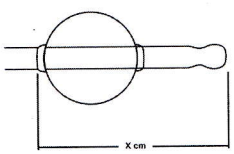
Contraindications:
These products contain latex. Latex and devices containing latex should not be used on patients with allergic reactions to materials contained in these devices.

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.

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 on products containing latex.
Only inflate balloons with sterile water.
Never clamp catheters: if necessary, use a catheter valve, catheter plug, or clamp drainage bag tubing.

Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.

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.

Explanation of important symbols and markings on the product label.

SIZE	Product size
Ch.	1 Ch. = 1/3mm
O.D.	Outer diameter
Qty	Quantity, Number of items
LATEX	This product contains natural rubber latex
	Do not use if package is damaged
STERILE	Sterile Fluid Path: Content of prefilled syringe sterilized using steam

Sterilization method: see product label

STERILE EO STERILE R

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Teleflex®

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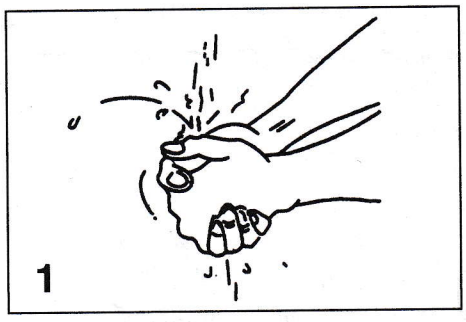
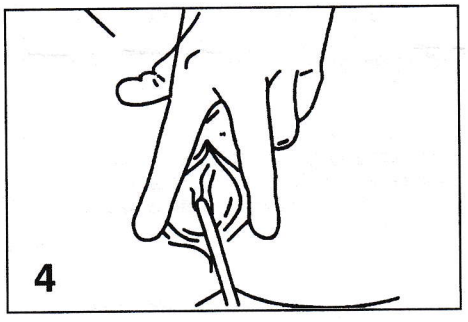
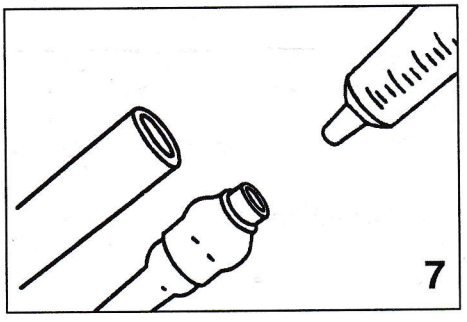
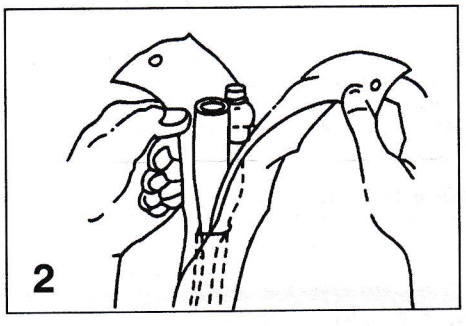
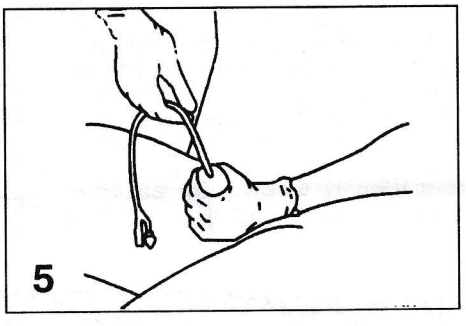
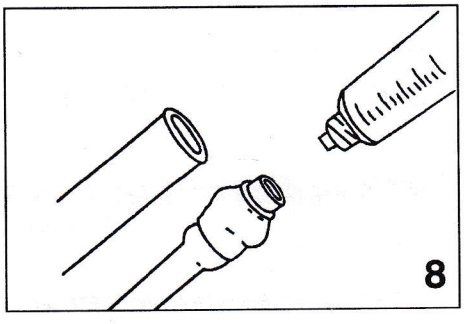


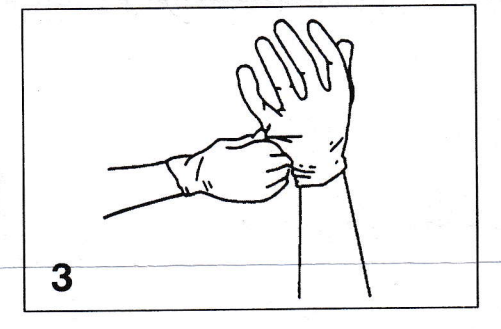


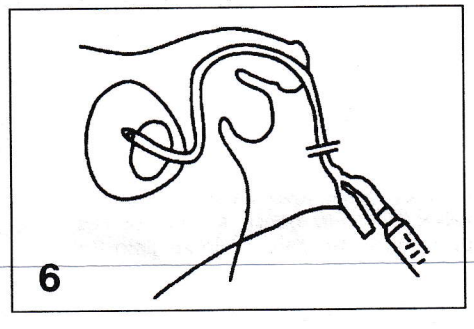


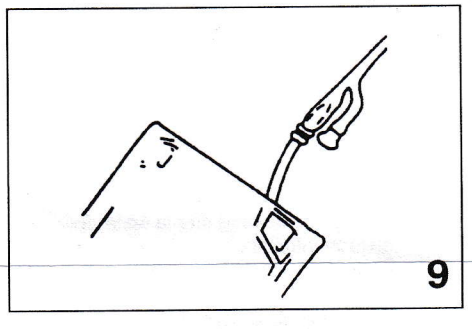












Teleflex®

RüSCH

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)

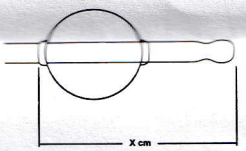
A) FOR TRANSURETHRAL USE

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.

Single use: Do not reuse, reprocess or re-sterilize. Reuse of device creates a potential risk of serious injury and/or infection which may lead to death. Reprocessing of medical devices intended for single use only may result in degraded performance or a loss of functionality.

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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