SHENYUN

INSTRUCTIONS FOR USE

Silicone Urinary Catheters





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CE 1639

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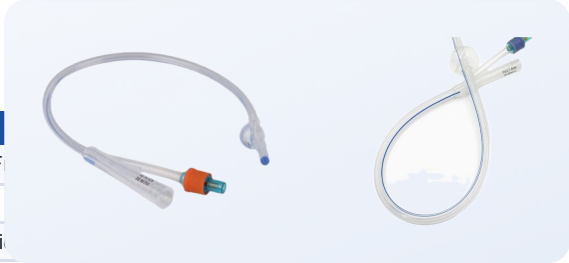
1. PRODUCT INFORMATION

2-way Foley, 3-way Foley and Nelaton catheters, 100% silicone, latex-free. Sterile (ethylene oxide), single use.

Type	Codes	Sizes	Balloon / length
2-way Foley	SY03-08 – SY03-26	8–26 Fr	3–5 mL (8–12 Fr) · 5–10 mL (14–24 F
3-way Foley	SY03-18T – SY03-30T	18–30 Fr	5–10 mL / 30 mL
Nelaton	SY04-06 – SY04-24	6–24 Fr	No balloon · length 250 mm (paediatri



2. STRUCTURAL COMPOSITION

- **2-way Foley**: catheter shaft with drainage lumen and inflation lumen, retention balloon, drainage funnel and inflation valve.
- **3-way Foley**: as 2-way, with an additional irrigation lumen and irrigation port.
- **Nelaton**: straight catheter with drainage eyes and funnel, without balloon.

3. INTENDED PURPOSE

- Foley catheters are intended for transurethral drainage of urine from the bladder; the retention balloon holds the catheter in place for indwelling drainage.
- 3-way Foley catheters are additionally intended for bladder irrigation.
- Nelaton catheters are intended for intermittent transurethral bladder drainage.

4. INTENDED PATIENTS, USERS AND ENVIRONMENT

- Patients requiring bladder drainage, selected by the physician; paediatric sizes and lengths are available.
- Intended user: healthcare professionals trained in urethral catheterisation.
- Intended environment: hospitals and other healthcare facilities.

5. CONTRAINDICATIONS

- Known or suspected urethral injury, for example after pelvic trauma or with blood at the urethral meatus.
- Urethral stricture or obstruction that prevents passage of the catheter.
- Acute urethritis, prostatitis or epididymitis.
- Known allergy to silicone.

6. WARNINGS AND PRECAUTIONS

> ! Inflate the balloon with sterile water only, after urine flow confirms that the balloon is in the bladder. Do not use saline or air, and do not exceed the balloon volume marked on the catheter.

- Use aseptic technique. Do not use if the package is opened or damaged, or after the expiry date.
- Do not test-inflate the balloon before insertion.
- Do not use a syringe with a needle to inflate the balloon, and do not puncture the catheter shaft.
- Use only a water-soluble lubricant.
- Never force the catheter; if resistance is felt, stop and consult a physician.
- Deflate the balloon completely before removal; let the water return into the syringe slowly and do not cut the catheter.
- Single use only. Do not re-sterilize or reuse.
- Duration of indwelling and replacement intervals are determined by the physician according to clinical practice.

7. INSTRUCTIONS FOR USE

Foley catheter

1. Select the catheter size and balloon volume. Check the package and expiry date, and prepare a sterile field.
2. Clean the urethral meatus according to hospital protocol.
3. Lubricate the catheter tip with a water-soluble lubricant and insert it gently into the urethra.
4. Advance until urine flows, then advance a further 2–3 cm to make sure the balloon is in the bladder.
5. Connect a needle-free syringe with sterile water to the inflation valve and inflate the balloon with the volume marked on the catheter.
6. Pull back gently until resistance is felt, then connect the catheter to a closed drainage system and secure it.
7. For 3-way catheters, connect the irrigation line to the irrigation port.
8. To remove, attach a syringe to the valve, allow the balloon to deflate completely, then withdraw the catheter gently.

Nelaton catheter

1. Prepare and lubricate as above and insert the catheter gently until urine flows.
2. Drain the bladder into a suitable container, then withdraw the catheter slowly and dispose of it.

8. STORAGE AND SHELF LIFE

- Store in the original packaging in a cool, dry place away from direct sunlight.
- Batch number and expiry date: see the product label.

9. DISPOSAL

After use, the product may be contaminated. Dispose of it as medical waste according to hospital procedures and local regulations.

10. INCIDENT REPORTING

Any serious incident related to this device should be reported to the manufacturer and to the competent authority of the country (in the EU, the Member State) where the user and/or patient is located.

11. SYMBOLS

CE 1639	CE marking		Do not use if the package is damaged	EC REP	Authorized representative in the European Community / European Union
MD	Medical device		Refer to the instructions	STERILE EO	Sterile by EO
	No secondary use		Limit of stacking layers		Keep dry
LOT	Batch code		Vertically upward		Use-by date
	Date of manufacture		Single sterile barrier system with protective packaging inside		Keep away from sunlight
UDI	Unique device identifier		Manufacturer		Caution

Symbols according to ISO 15223-1:2021.

MANUFACTURER

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