SHENYUN

INSTRUCTIONS FOR USE

Negative Pressure Drainage Set



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1. PRODUCT INFORMATION

Series	Catheter design	Catheter sizes
SY-SX-I – IV	Spiral (cross)	8–24 Fr
SY-YX-I – IV	Round	7/10–24 Fr
SY-LX-I – IV	Flat	8–24 Fr
SY-TX-I – IV	T-type	12, 18 Fr
SY-BX-I – IV	Flat (sizes 1–6)	1–6

Type	Connector	Guide needle	Reservoir (mL)	Collection bag (mL)
I	XS / S / L	—	100 / 200	—
II	—	A / B	—	—
III	XS / S / L	A / B	100 / 200	—
IV	XS / S / L	A / B	100 / 200	500 / 1000

Sterile (ethylene oxide), single use. Shelf life 3 years.



2. STRUCTURAL COMPOSITION

Sterile drainage catheter, optional connectors, guide needle, negative-pressure reservoir (bulb) and, for Type IV, a collection bag. Materials: medical-grade silicone or PVC.

3. INTENDED PURPOSE

To drain body fluids (e.g. blood, serous fluid) from superficial wounds or surgical incisions in a closed, sterile system.

4. INTENDED USERS AND ENVIRONMENT

- Intended user: trained healthcare providers.
- Intended environment: hospitals and surgical facilities.

5. CONTRAINDICATIONS

Known allergy to silicone or PVC materials.

6. WARNINGS AND PRECAUTIONS

- Single use only; do not re-sterilize.
- Maintain strict asepsis.
- Verify the sterilization indicator (blue means sterile). Do not use if the package is damaged or shows a non-sterile indicator.
- Discontinue immediately if signs of allergic reaction or infection appear.
- For use by trained healthcare providers only; improper operation may put patient safety at risk.
- Use only manufacturer-provided or validated connectors that match the catheter inner diameter; perform a leak test before use.
- If lubrication is needed, use only a sterile water-soluble lubricant (e.g. medical glycerin); do not use petroleum-based products.

7. INSTRUCTIONS FOR USE

Pre-use inspection

1. Verify packaging integrity and the sterilization indicator.
2. Confirm that the product is within its 3-year shelf life.

Catheter placement

1. Perform hand hygiene and don sterile gloves.
2. Attach the guide needle assembly to the catheter.
3. Under aseptic conditions, puncture the target site and advance the catheter to the desired depth.
4. Withdraw the guide needle, leaving the catheter in place.

System assembly

1. Select the matching connector and secure it to the catheter hub.
2. Attach the reservoir to the connector and squeeze it fully to create vacuum.
3. Open the valve to start drainage.

Transition to collection bag (Type III and IV)

1. When the reservoir is full or continuous drainage is required, empty or collapse the reservoir.
2. Connect the collection bag inlet to the connector valve outlet.
3. Hang the bag below the insertion site to maintain gravity drainage.

Removal

1. Clamp the catheter near the insertion site.
2. Disconnect all tubing and remove the adhesive anchor.
3. Withdraw the catheter gently and apply a sterile dressing.
4. Dispose of all components as medical waste.

8. ROUTINE CARE AND MONITORING

- Flush the catheter every 8–12 hours with 10–20 mL sterile saline (clamp vacuum, flush, then re-establish vacuum).
- Change the dressing daily; inspect the site for leakage, redness or infection.
- Record drainage volume, colour and characteristics each shift; monitor vital signs and pain at the insertion site.
- Maximum recommended duration: 29 days (clinical judgement prevails). Assess every 8 hours.
- If drainage stops, blood appears, or signs of infection or distress occur, notify the physician and consider adjustment or removal.

9. STORAGE, TRANSPORT AND SHELF LIFE

- Batch number and production date: see the product label.
- Shelf life: 3 years from the production date.
- Storage: cool, ventilated and dry area.
- Transport: protect against dampness, compression and rain; avoid collisions, friction or scratches with hard objects.

10. DISPOSAL

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

11. 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.

12. SYMBOLS

	Do not use if the package is damaged		Medical device		Refer to the instructions
	Sterile by EO		No secondary use		Limit of stacking layers
	Keep dry		Batch code		Vertically upward
	Use-by date		Date of manufacture		Single sterile barrier system with protective packaging inside
	Keep away from sunlight		Unique device identifier		Manufacturer
	Caution				

Symbols according to ISO 15223-1:2021.

MANUFACTURER

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