

Drainage System

DESCRIPTION

The Drainage Systems are made of medical grade Silicone. There are 3 models: Silicone flat & round drainage tube, Silicone flat drainage tube, Silicone Round Perforated Drainage Tube. The product can be used on patient who need body fluid drainage.

FEATURES

- Made from medical grade silicone.
- Soft and smooth tube minimizes trauma.
- Clear connecting tube provides inspection and drainage visibility.
- X-ray opaque line throughout the length.

INTENDED USE / INDICATIONS

The Drainage Systems are intended to use for body fluid drainage for various surgeries.

CLINICAL BENEFITS

The body fluid generated during the drainage procedure is managed to prevent postoperative infection, promote wound healing, and reduce postoperative complications.

PATIENT TARGET GROUP

Infant, Child, Adult.

INTENDED USER

Must be operated by trained professionals.

INDICATIONS

The Drainage Systems are applicable to draining body fluid during the surgical procedure.

CONTRAINDICATIONS

There are no known contraindications.

ADVERSE REACTIONS

- When used in clinic, the Drainage Systems may cause allergic reaction.
- Bleeding into or around the drains
- Drains draining little or no body fluid despite enough fluid intake
- Leakage of large amounts of body fluids around the drains
- Incision infection

DIRECTIONS FOR USE

- Prepare suitable size trocar as per operation need.
- Open the package and take out Drainage Systems after checking the package is unopened or undamaged.
- Make a hypodermal tunnel for passage of drainage tube with a suitable trocar under the doctor's direction.
- Inset the drainage tube into appropriate position, and then fix the drainage tube with tapes.
- Connect the drainage tube to the drainage jar (if any) with the adapter
- Fully squeeze the drainage jar (if any) a negative pressure to perform drainage.

- Connect the drainage tube to the drainage bag (if any) with the drainage tube connector. Drains by means of pressure differential and gravity between body cavities and exterior.

WARNINGS / PRECAUTIONS
PRECAUTIONS

- This device can only be used by trained professionals.
- The drainage tube should be squeezed regularly to keep the drainage flow smooth and prevent the drainage tube from being kinked, twisted and compressed.

WARNINGS

- Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.
- Do not use if it's damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.
- The inflammation patients shall cautiously use.
- Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Dispose of product and packaging in accordance with hospital administrative and/or local government policy.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.

STORAGE CONDITIONS

- Store in dry place, keep away from sunlight.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

APPENDIX A The Key Performance Characteristics of Drainage System

- **Silicone Round Perforated drainage tube**

Flow rate

According to the requirements of the standard ISO20697-2018, the flow rate of the silicone drainage tube should meet the following requirements:

Specifications (Fr)	9	12	14	16	18-36
Flow, ≥mL/min	30	50	70	70	100

- **Silicone flat & round drainage tube**

Flow rate

According to the requirements of the standard ISO20697-2018, the flow rate of Silicone flat &















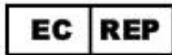






round drainage tube should $\geq 50\text{mL}/\text{min}$

- **Silicone flat drainage tube**

Flow rate

According to the requirements of the standard ISO20697-2018, the flow rate of Silicone flat drainage tube should $\geq 100\text{mL}/\text{min}$

MEANING OF SYMBOLS ON PACKAGE

	Date of manufacture		Use-by-date		Batch code
	Do not re-use		Consult instructions for use		Do not use if package is damaged
	Sterilized using ethylene oxide		Do not resterilize		Single sterile barrier system with protective packaging inside (if applicable)
	Medical Device		Manufacturer		Single sterile barrier system (if applicable)
	CE Marked Product		Keep dry		Authorized representative in the European Community
	Importer		This way up		Keep away from sunlight
	Unique device identifier		Catalogue number		Fragile, handle with care



WELL LEAD MEDICAL CO., LTD.

C-4 Jinhu Industrial Estate, Hualong, 511434 Panyu, Guangzhou, PEOPLE'S REPUBLIC OF CHINA

E-mail: info@welllead.com.cn www.welllead.com.cn

Tel: +86 20 84758878



Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, GERMANY

Version and date: WLIFU-01-200F1-01C /Jan 18, 2025