

# Silicone Wound Drainage

## Silicone Closed Wound Drain System

**STERILE.** Do not reuse or re-sterilize. Do not use product if packaging is damaged/compromised, losing sterility. Reuse may cause a risk of infection and/or compromise functional reliability.

### Instructions for Use

#### Initial Testing of Bulb:

- Remove bulb from packaging and test for efficacy as follows:
  - Fully compress bulb (D).
  - For **100cc** bulbs:
    - Close disposal port (C) with screw cap (A).
    - Occlude patient port (B) and release bulb (D).
  - For **400cc** bulbs:
    - Close disposal port (C) with plug (A2).
    - Close inlet port (E) with plug (A1).
    - Occlude patient port (B) and release bulb (D).
  - If vacuum is effective, bulb should remain compressed. If bulb expands, it should be discarded.
  - Release occlusion from patient port (B). Bulb (D) should recover within 5 seconds.

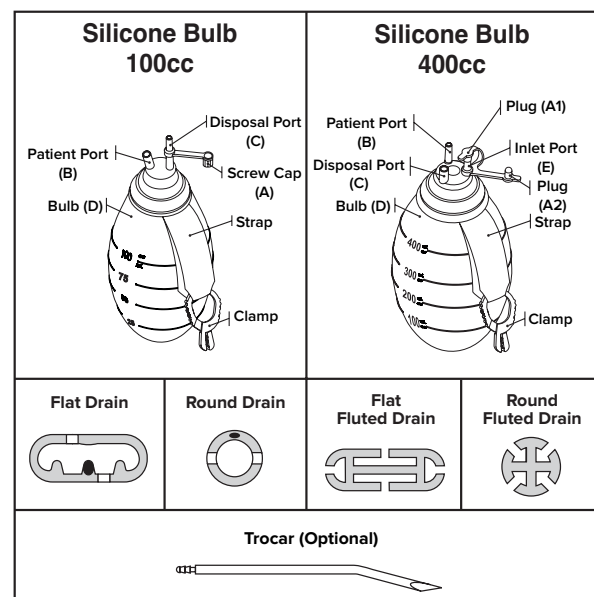
- Open disposal port (C) by releasing screw cap (A).
- Slowly compress bulb (D).
- Empty all exudate into collection basin. Do not release bulb.
- Close disposal port (C) with screw cap (A) and twist 2-3 times or until it feels snug. Do not over twist the cap.
- For **400cc** bulbs:
  - Open disposal port (C) by releasing plug (A1).
  - Slowly compress bulb (D).
  - Empty all exudate into collection basin. Do not release bulb.
  - Both the inlet port (E) and disposal port (C) need to be closed with plug (A1) and plug (A2) respectively.
- Renewed closed wound drainage will begin.

#### Initial Activation of System:

- Place drain in wound site, ensuring that all channels or holes are located within the wound site. (Correct placement will ensure an airtight seal at the wound exit, maintaining vacuum after closed wound drainage begins. Air leakage will cause the system to be converted to open drainage and must be rectified accordingly.)
- For **100cc** bulbs:
  - Remove screw cap (A) from disposal port (C) to open system.
  - Attach drain or drain adapter to patient port (B).
  - Firmly compress bulb (D) to evacuate air.
    - Do not use excessive force when compressing bulb.
  - Close disposal port (C) with screw cap (A) and twist 2-3 times or until it feels snug. Do not over twist the cap.
  - Release bulb (D). Closed wound drain system has commenced.
- For **400cc** bulbs:
  - Remove the plug (A1) from inlet port (E) and plug (A2) from disposal port (C) to open system.
  - If applicable, attach second drain or drain adapter to inlet port (E).
  - Firmly compress bulb (D) to evacuate air.
    - Do not use excessive force when compressing bulb.
  - Close disposal port (C) with plug (A2).
    - If a second drain or drain adapter was not attached to inlet port (E), close inlet port with plug (A1).
  - Release bulb (D). Closed wound drain system has commenced.
- Bulb should be located at or below drain's exit for adequate suction to be maintained.
- Drainage should be monitored such that bulb is not filled to excess.

#### Caution:
















- One drain may be indwelling for up to 30 days and may be replaced by another drain if long-term therapy is required.
- Excessive force applied to evacuator bulbs may cause air leakage and loss of suction strength. Avoid excess compression force for maximum effectiveness.
- Do not suture through these drains or handle with any instruments. During placement and removal of drains, be careful not to nick, cut, scratch, tear, or otherwise damage the drains, as this may lead to breakage. Drains should be placed and removed carefully, by applying slow, steady pressure.
- Excessive force may cause the drains to break. During drain implementation, tissue in-growth may occur around the drain and into the holes. This could cause the drain to break up on removal. The patient's rate of healing should be monitored carefully by the surgeon. If tissue in-growth occurs, drain's removal may need to be accompanied by surgical intervention.



#### Emptying Bulb Contents:

- Raise bulb above collection basin and tip.
- For **100cc** bulbs:

# Symbols Glossary

Symbol	Meaning	Description of Symbol	ISO 15223-1
	Consult Instructions for Use	Indicates the need for the user to consult the Instructions for Use	5.4.3
	Prescription device	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	N/A
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	5.2.3
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	5.4.4
	Not made with phthalates plasticizers	Indicates that a medical device or the packaging of a medical device was not made with phthalate plasticizers	N/A
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	5.2.8
	Do not reuse	Indicates a medical device that is intended for one single use only	5.4.2
	Package recycling	Indicates that the inner carton and saleable case can be recycled	N/A
	Keep dry	Indicates a medical device that needs to be protected from moisture	5.3.4
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized	5.2.6
	Not made with BPA	Indicates that a medical device and the packaging of a medical device was not made with BPA	N/A
	Keep away from sunlight	Indicates a medical device that needs to be protected from light sources	5.3.2
	Manufacturer	Indicates the medical device manufacturer	5.1.1
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	5.3.7
	Product was not made with natural rubber latex	Indicates that a medical device was not made of natural rubber	N/A