Instructions for use

Surgical Drain tube
Wound closed suction system

[Product name] Surgical Drain tube, Wound closed suction system

INTENDED USE

Surgical drains are used in a wide variety of different types of surgery. Generally speaking, the intention is to decompress or drain either fluid or air from the area of surgery

• To prevent the accumulation of fluid (blood, pus and infected fluids).
• To prevent accumulation of air (dead space).
• To characterise fluid (for example, early identification of anastomotic leakage[3]).

Specific examples of drains and operations where they are commonly used include:

• Plastic surgery including myocutaneous flap surgery.
• Breast surgery (to prevent collection of blood and lymph).
• Orthopaedic procedures (associated with greater blood loss).
• Chest drainage[4, 5].
• Chest surgery (with, for example, the associated risks of raised intrathoracic pressure and tamponade).
• Infected cysts (to drain pus).
• Pancreatic surgery (to drain secretions).
• Biliary surgery.
• Thyroid surgery (concern over haematoma and haemorrhage around the airway).
• Neurosurgery (where there is a risk of raised intracranial pressure).
• Urinary catheters.
• Nasogastric tubes.

COMPOSITION

Closed Wound Drainage System is a sterile, disposable, portable system used for closed wound drainage. It consists of two component parts: Reservoirs and Drain tubes.

Drains can be:

Open or closed

- Open drains (including corrugated rubber or plastic sheets) drain fluid on to a gauze pad or into a stoma bag. They are likely to increase the risk of infection.
- Closed drains are formed by tubes draining into a bag or bottle. Examples include chest, abdominal and orthopaedic drains. Generally, the risk of infection is reduced.

Active or passive

- Active drains are maintained under suction (which may be low or high pressure).
- Passive drains have no suction and work according to the differential pressure between body cavities and the exterior.

Plastic or rubber

- Silastic drains are relatively inert and induce minimal tissue reaction.
- Red rubber drains can induce an intense tissue reaction, sometimes allowing a tract to form (this may be considered useful - for example, with biliary T-tubes).

General guidance for surgical drains

- If active, the drain can be attached to a suction source (and set at a prescribed pressure).
- Ensure the drain is secured (dislodgement is likely to occur when transferring patients after anaesthesia). Dislodgement can increase the risk of infection and irritation to the surrounding skin.
- Accurately measure and record drainage output.
- Monitor changes in character or volume of fluid. Identify any complications resulting in leaking fluid (particularly, for example, bile or pancreatic secretions) or blood.
- Use measurements of fluid loss to assist intravenous replacement of fluids.

RESERVOIR

Reservoir is available in either a 150 ml, 300 ml, or 450 ml size. All are packaged sterile in a pre-compressed state and are capable of dual drainage. A standard anti-reflux valve has also been incorporated to help prevent the reverse flow of wound exudates during emptying and reactivation. Markers are provided at increments along the side of the reservoir to facilitate the approximate measurement of fluid. A drain port with attached plug is provided as a method of emptying exudate collected by the unit.

Caution: This Product Contains Natural Rubber latex Which May Cause Allergic Reactions.

BULB SUCTION RESERVOIR

Bulb Suction Reservoir is available in 100 cc size. It is packaged sterile and has a standard anti-reflux valve.

Markers are provided at increments along the side of the reservoir to facilitate the approximate measurement of fluid.

A drain port with an attached plug is provided as a method of emptying exudate collected by the unit.

SUCTION DRAINS TUBES

Drains are made from silicone or PVC and are available in a wide variety of sizes and configurations. All are individually packaged, sterile, and include an adapter used to attach the drain to the reservoir. All are made from materials shown to be nonpyrogenic.

• Drains (Flat, Full, or 3/4-Fluted) The product consists of a flat drain tube with holes along the sides, a round extension tube, and an adapter. The flat drain is channeled along either 75% or 100% of its length. Flat drains are available with or without a trocar.

• Drains (Round Hubless)

The product consists of a drain with holes along the sides, a round extension tube, and an adapter. It is available with or without a troca

INDICATIONS

Closed Wound Drainage Systems have been used as an adjunct in surgery to evacuate potentially detrimental collections of certain fluids (e.g., pus, extravascular blood, bile) from wounds in body cavities and to reduce the risk of infection..

CONTRAINDICATIONS

Blood collected using the J-VAC™ Drain Adapter or in the J-VAC™ Suction Reservoir and J-VAC™ Bulb Suction Reservoir should not be reinfuse

INSTRUCTION FOR USE:

1. Drain Placement

• The surgeon should irrigate the wound with sterile fluid, then suction the irrigating fluid and gross debris from the operative site.

• Tubes should lie flat and in line with the anticipated skin exit. To facilitate later removal by manual traction, the tubing should not be curled, pinched, or sutured internally.

• Positioning of the drain in the body cavity, as well as the number of drains indicated, should be determined by the operating surgeon.

• Drain tubing should be placed within the wound by approximating the areas of critical fluid collection.

• Care must be taken to ensure that all drain channels lie completely within the wound or cavity to be drained.

• Taping or a triple loop suture (around and not through the tubing) will aid in preventing accidental drain displacement.

• Deep drainage is best accomplished by using one or more drains for each level of tissue. Each level should be evacuated by a separate source of vacuum.

• Care must be exercised to avoid damage to the drain. The tubing should be repeatedly checked during closure for free motion to avoid breakage and/or fragment retention within the wound.

2. Additional Steps for Placement of Drains in Open Surgical Procedures

• The drain tubing should be brought out through the stab wound made with a trocar or scalpel 2 cm to 5 cm from the wound edge for connection to the reservoir. Use of bendable trocar (available on certain sizes only)

• Holding the trocar with both hands, bend the trocar in a downward motion until desired angle is achieved.

• Once the angle of the trocar has been adjusted, avoid repeated bending as this could result in structural failure.

3. Activating the Bulb Suction Reservoir

It is important that the Bulb Suction Reservoir be verified immediately prior to connecting it to the drain:

• With the drainage plug removed, squeeze the reservoir until it has collapsed.

• Holding the reservoir in a collapsed position, insert the drainage plug to seal the

drainage opening.
• Release the squeezing pressure to allow the reservoir to inflate. In the event the reservoir does not completely inflate, the following corrective procedure should be employed:
– Repeat above steps for verifying patency of the bulb suction reservoir. This repeated action should open the anti-reflux valve and permit it to function normally.
– If the reservoir does not completely reinflate when tested according to the procedure described above, the reservoir should not be used.

Connection to the Drain

• After drain placement, push the silicone drain tubing over the adapter. To ensure a secure connection, use a twisting motion to seat the drain over all adapter barbs. Remove the plug from the drainage port and insert the adapter to the suction port. A tight fit is necessary to ensure the system's integrity.
• With the drainage plug removed, squeeze the reservoir until it has collapsed.
• Holding the reservoir in a collapsed position, insert the drainage plug to seal the drainage opening.
• Release the squeezing pressure to allow the reservoir to inflate for fluid collection.
• When used in cardiothoracic surgery, drains may be connected to a Bulb Suction Reservoir only after the lung is fully expanded and all the air leaks have sealed.

4. Activating the Suction Reservoir

• After drain placement, push the silicone drain tubing over the adapter. To ensure a secure connection, use a twisting motion to seat the drain over all adapter barbs. Remove the plug from the port and insert the adapter. A tight fit is necessary to ensure the system's integrity.
• After drain tubing is connected to the port, start suction by gently bending up the bottom flap. The unit will release and suction will begin.

5. Measuring Exudate and Emptying Reservoir

• To measure exudate, relieve negative pressure by opening the exit plug. This completely expands the reservoir.
Once equilibrium pressure has been established within the Reservoir, approximate fluid levels may be determined against the calibrations indicated on the side walls.
• Empty exudate into an appropriate container

6. Removal

Generally, drains should be removed once the drainage has stopped or becomes less than about 25 ml/day. Drains can be 'shortened' by withdrawing them gradually (typically by 2 cm per day) and so, in theory, allowing the site to heal gradually. Usually drains that protect postoperative sites from leakage form a tract and are kept in place longer (usually for about a week).

- Warn the patient that there may be some discomfort when the drain is pulled out.
- Consider the need for pain relief prior to removal.
- Place a dry dressing over the site where the drain was removed.
- Some drainage from the site commonly occurs until the wound heals.

When to remove:

- Drains left in place for prolonged periods may be difficult to remove.

- Early removal may decrease the risk of some complications, especially infection

COMPLICATIONS

1. Complications which may result from the use of this suction drainage system include the risks associated with methods utilized in the surgical procedure, as well as the patient's degree of intolerance to any foreign object placed in the body.
2. The advantages of wound drainage, particularly closed system drainage, are lost if an airtight seal between the drain and the skin where the drain emerges is not achieved, the drain is allowed to become occluded, or the reservoir is filled to capacity and not emptied.
3. In the event an airtight seal is not achieved, the reservoir will rapidly fill with air from the leak; subsequent drainage to the reservoir will occur only if allowed by gravity and by wound exudate forcing the flow. Entry into the reservoir is allowed only by displacement of air in the reservoir by wound exudate flow. In this displacement process, air reflux from the reservoir to the wound can occur and increase the likelihood of back-contamination across the anti-reflux valve. In the event of drain occlusion by fibrin, clots, or other particulate matter, all wound drainage via the drain ceases.
4. If the reservoir is not emptied when it is full, equilibrium between the drain and reservoir at wound pressure will ultimately occur and drainage from the wound site will cease. When the reservoir and drain are at the same pressure and the reservoir is full of fluid, the likelihood of back-contamination across the anti-reflux valve is increased.
5. When used to drain the pleural cavity in the presence of an air leak, drains must be attached to an appropriate pleural cavity drainage system to prevent tension pneumothorax.
6. The silicone elastomer suction drain tubing is soft and pliable. It should not be handled or come into contact with pointed, toothed, sharp-cornered, or even blunt instruments, as punctures, surface cuts, nicks, crushing or other overstressing can lead to tearing or warping of the tubing and to subsequent structural failure of the drain and/or fragment retention within the wound.
7. Do not suture through or cut into the drain as this may result in drain breakage and/or fragment retention within the wound

[Precautions and warnings]

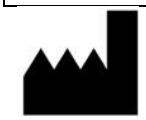
1. The operative site should be dry and free of debris prior to closure.
2. Proper placement of the wound drain(s) in tissue layers and at the exit site should be observed to prevent tube kinking.
3. An adequate number of wound drains should be used to ensure that all areas will be drained.
4. Fluid retention may result from inefficient evacuation. This could occur as a result of the drain channels being outside of the tissue layers
5. An airtight junction between the tubing and tissue at the drain entrance site must be ensured for proper functioning of the system.

6. A tight fit must occur between the adapter and drain tubing, and between the adapter and the reservoir to ensure proper system function. Although the adapter included with the drain is designed to allow the drain to fit most reservoirs, the user must ensure there is a tight fit between the adapter and drain tubing, and between the adapter and reservoir for proper system integrity.
7. If occlusion of a drain occurs, it may be necessary to irrigate or aspirate the drain.
8. Frequent inspection of the quantity and quality of fluid drainage in the reservoir should be made and reported to the surgeon as ordered. Failure to empty the reservoir when full will reduce drainage efficiency.
9. Suction should be discontinued prior to drain removal.
10. The suction drain tubing is soft and pliable. It should not be handled or come into contact with pointed, toothed, sharp-cornered, or even blunt instruments, as punctures, surface cuts, nicks, crushing, or other overstressing can lead to tearing or warping of the tubing and to subsequent structural failure of the drain and/or fragment retention within the wound.
11. Do not suture through or cut into the drain as this may result in drain breakage and/or fragment retention within the wound.

[Maintenance] None
[Medical device accessories] All drains and reservoirs are packaged sterile, ten (10) units per box.
One standard drain adapter is included with each drain.
Additional standard drain tubes are available in boxes of 100 units.
[Storage and transportation] Appropriate methods should be used to stack the goods when loading the truck. Products should be handled with care when handling, loading, unloading, stacking, and effective protective measures should be taken in strict accordance with the requirements of the external packaging icon and signs. It should be stored in a normal room with a relative humidity of no more than 80%, no corrosive gas and good ventilation.
[Expiration date] Check the package.
[Shelf life] 5 years.
[Explanation of medical device label symbols]

	Manufactuer		Authorized representative in the European Community
	Date of manufacture		Use-by date

	Batch code		Consult instructions for use
	Do not use if package is damaged		Fragile,handle with care
	Keep away from sunlight		Keep dry
	Do not re-use		Consult instructions for use
	Caution		Non-Sterile
CE 0123	CE marking of conformity, and Notified Body Code	 DEHP	Contains or presence of Phthalate
	latex free		



Headquater Shanghai: No. 1328 Hengnan road Minhang district Shanghai P.R. China Post code: 201114
Factory Nantong: North Jiangxin Road Jianghai Linkage Development Zone Tongzhou Bay, Jiangsu, P.R. China Post code: 226400
PHONE: 00 - 86 - 21 - 6429 6676 / 78
FAX: 00 - 86 - 21 - 6429 6676 / 78 ext 814
EMAIL: sheng@hitecmed.com (Sales director)

EC REP

Shanghai International Holding Crop.GmbH(Europe)
Eiffestraβe 80 20537 hamburg germany
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