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J-VAC™

Closed Wound Drainage System

ar جهاز التصريف للجروح المغلقة
cs Drenážní systém pro uzavřené rány
da Drænagesystem til lukkede sår
de Drainagesystem für geschlossene Wunden
el Σύστημα κλειστής παροχέτευσης τραύματος
es Sistema de drenaje para heridas cerradas
fi Haavaimujärjestelmä
fr Système de drainage pour plaies fermées
hu Zárt sebdrenázs rendszer
it Sistema di drenaggio chiuso delle ferite
ko 폐쇄성 창상 배액 장치
nl Drainagesysteem voor gesloten wonden
no Drenasjesystem til lukkede sår
pl System zamkniętego drenażu ran
pt Sistema de drenagem para feridas fechadas
ro Sistem de drenaj al plăgilor închise
ru Система для закрытого дренирования ран
sk Uzavretý systém na drenáž rán
sv Slutet system för sårdränage
tr Kapalı yara drenaj sistemi
zh-cn 闭合伤口引流系统
zh-tw 封閉式傷口引流系統

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CE 0086

J-VAC™

ENGLISH

Closed Wound Drainage System

J-VAC™ CLOSED WOUND DRAINAGE SYSTEM

The J-VAC™ Closed Wound Drainage System is a sterile, disposable, portable system used for closed wound drainage. It consists of two component parts: J-VAC™ Reservoirs and Suction Drains.

J-VAC™ RESERVOIR

The J-VAC™ 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.

J-VAC™ BULB SUCTION RESERVOIR

The J-VAC™ 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

Drains are made from silicone 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.

BLAKE™ Silicone Drains (Flat, Full, or 3/4-Fluted)
The product consists of a radiopaque flat silicone drain with four channels along the sides, a round silicone 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.

BLAKE™ Silicone Drains (Round Hubless)
The product consists of a silicone drain with four channels along the sides, a blue radiopaque stripe along the length of the drain, a round silicone extension tube, and an adapter. It is available with or without a trocar.

BLAKE™ Drain Kits
The BLAKE™ Drain Kits include one J-VAC™ Bulb Suction Reservoir packaged with one BLAKE™ Silicone Drain and an adapter.

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 reinfused.

WARNINGS

1. J-VAC™ Reservoirs of size 150 ml, 300 ml, and 450 ml contain a metal spring and should not be exposed to strong magnetic fields such as those used in magnetic resonance imaging (MRIs). An effective closed suction drain system requires maintenance of the system to preserve patency.
2. The drain must not be allowed to occlude nor the reservoir to completely fill, and reservoir suction must be maintained.
3. In the event of occlusion of the drain, all wound drainage via the drain ceases. Careful attention to the drain will minimize the possibility of this problem. If occlusion does occur, the drain can be aspirated by connecting suction to the reservoir outlet or by temporarily disconnecting the drain from the reservoir and applying suction directly to the drain.
4. If an airtight seal between the drain and the skin where the drain emerges is not achieved, the air leak must be rectified or the system must be converted to open drainage.
5. An airtight seal between all system components (drain, adapter, and reservoir) is necessary for proper system function.
6. Leaving the soft silicone elastomer drain implanted for any period of time so as to cause tissue ingrowth around the drain can interfere with easy removal and affect the performance of the drain. The surgeon should monitor the patient's rate of wound healing.
7. J-VAC™ Bulb Suction Reservoir or J-VAC™ Reservoir Systems should be used in cardiothoracic surgery only after the lung is fully expanded and all air leaks have sealed.
8. Drain channels must lie within the wound or cavity to be drained, otherwise inadequate drainage may result.
9. Use with appropriate care and attention to prevent tissue and blood vessel damage since the trocar needle is sharp. It has been reported that when trocar needles were used in the cephalic region, serious complications such as epidural bleeding and subdural bleeding due to vascular damage occurred.
10. Special attention is necessary when handling the drain with instruments. The drain may be cut or torn by coming in contact with sharp objects or when subjected to compression or excessive overpressure by a milking roller, etc.
11. These products are designed for single use only. Discard promptly after single patient use. Do not resterilize/reuse. Reuse of this device (or portions of this device) may create a risk of product degradation, which may result in device failure and/or cross-contamination, which may lead to infection or transmission of blood-borne pathogens to patients and users.

PRECAUTIONS

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 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.
11. Do not suture through or cut into the drain as this may result in drain breakage and/or fragment retention within the wound.

DIRECTIONS 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 J-VAC™ Bulb Suction Reservoir

It is important that the patency of the J-VAC™ 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, BLAKE™ Drains may be connected to a J-VAC™ Bulb Suction Reservoir only after the lung is fully expanded and all the air leaks have sealed.

4. Activating the J-VAC™ 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.
- When used in cardiothoracic surgery, BLAKE™ Drains may be connected to a J-VAC™ Reservoir only after the lung is fully expanded and all the air leaks have sealed.

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 J-VAC™ Reservoir, approximate fluid levels may be determined against the calibrations indicated on the side walls.
- Empty exudate into an appropriate container.

6. Reactivating the System

- With the exit plug still removed, place the J-VAC™ Reservoir between fingers. Press firmly in the center until the reservoir clicks.
- Bend the bottom flap backward slightly to secure.
- Replace the exit plug.
- Start suction by gently bending up the bottom flap until the reservoir clicks.

7. Attaching BLAKE™ (19 FR, 24 FR Hubless) Drains to a Chest Drainage System Using BLAKE™ Cardio Connectors

- BLAKE™ Cardio Connectors are compatible with 19 FR and 24 FR Round Hubless BLAKE™ Drains and are available in 1:1, 2:1, and 3:1 configurations.
- Using a twisting motion, connect BLAKE™ (19 FR, 24 FR Hubless) Drains to the smaller barbed fitting.
- Connect the vacuum source tube to the larger barbed fitting.

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, BLAKE™ 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.

STORAGE

No special storage conditions required. Do not use after expiry date.

HOW SUPPLIED

All drains, reservoirs, and kits are packaged sterile, ten (10) units per box. Cardio connectors are packaged sterile, twenty (20) units per box.

One standard drain adapter is included with each drain and drain kit. Additional standard drain adapters are available in boxes of 100 units.

SYMBOLS USED ON LABELING

LATEX	Contains or presence of natural rubber latex	!	Caution
STERILE R	Sterilized using irradiation	2	Do not reuse
	Use-by date	2 STERILIZE	Do not resterilize
LOT	Batch code	REF	Catalogue number
	Manufacturer	PHT DEHP DINP DIDP	Contains or presence of phthalates
	Do not use if package is damaged	MR	MR unsafe
	Bulb Suction Reservoir	EC REP	Authorised representative in the European community
	Drain Adapter		Suction Reservoir
	Silicone Round Drain		Cardio Connector 1:1
	Silicone Flat Drain		Cardio Connector 2:1
CE 0086	CE mark and Identification Number of Notified Body. The product meets the essential requirements of the Medical Device Directive 93/42/EEC.		Cardio Connector 3:1