INSTRUCTIONS FOR USE

CLOSED WOUND SUCTION SET

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/CWS/01 Rev. No.:00, Dt. 12.08.2023

PRODUCT DESCRIPTION:

Wound drainage is described by type, colour, amount, and odour. Drainage can be (1) serous (clear and thin; may be present in a healthy, healing wound), (2) serosanguineous (containing blood; may also be present in a healthy, healing wound), (3) sanguineous (primarily blood), or (4) purulent (thick, white, and pus-like; may be indicative of infection and should be cultured). Colour is generally clear to pale yellow (normal), red (fresh blood), brown (dried or old blood), white (see above), or blue-green (usually indicative of Pseudomonas infection and should be cultured). The amount of drainage is generally documented as absent, scant, minimal, moderate, large, or copious. (Note: there is no consistent objective measurement that correlates to these descriptions.) A large amount of drainage can indicate infection, whereas a reduction in the amount of drainage can indicate an infection that is resolving or inadequate arterial circulation.

Closed wound drainage, once standard, has become rather controversial. The routine use of suction drainage theoretically can reduce the incidence of wound hematomas, therefore decreasing the incidence of postoperative wound drainage and possibly infection. However, multiple studies have shown that postoperative wound drainage offers no distinct advantages.

Closed Wound Suction Set (with Acc.-Redon Catheter (PVC) (SMD 1003):

PVC Closed Wound Suction Set consists of Bellow Container, Allen Needle, Redon drain tube, and Connecting tube. It is intended for drainage from closed wound under negative pressure. Redon tube has smooth and atraumatic multiple eyes for easy drainage and prevents post operative trauma. Trocar needle assist in placement of catheter inside wound. Leak proof cap and single step pinch clamp for easy and one hand operation. Main connecting tube has been equipped with colour coded Y connector to connect compatible redon tube. It is intended for short term use.

Closed Wound Suction Set (with Acc.-Redon Catheter (Silicone) (SMD 1003 SL):

Closed Wound Suction Set consists of Bellow Container, Allen Needle, Silicone Redon drain tube, and Connecting tube. It is intended for drainage from closed wound under negative pressure. Redon tube has smooth and atraumatic multiple eyes for easy drainage and prevents post operative trauma. Trocar needle assist in placement of catheter inside wound. Leak proof cap and single step pinch clamp for easy and one hand operation. Main connecting tube has been equipped with colour coded Y connector to connect compatible redon tube. It is intended for short term use.

Acc.- Redon Drainage Catheter (PVC) (SMD 1010):

It is spare PVC redon tube supplied with Closed Wound Suction Set and sold separately. Redon tube has smooth and atraumatic multiple eyes for easy drainage and prevents post operative trauma. It is intended for short term use.

Acc.- Redon Drainage Catheter (Silicone) (SMD 1010 SL):

It is spare Silicone redon tube supplied with Closed Wound Suction Set and sold separately. Redon tube has smooth and atraumatic multiple eyes for easy drainage and prevents post operative trauma. It is intended for short term use.

INTENDED PURPOSE:

Used for short-term close wound drainage under negative Pressure with the option to use one catheter or two catheters simultaneously.

INDICATIONS:

After surgery or infection

- To eliminate and prevent the accumulation of fluid (blood, pus and infected fluids) at surgical site.
- To eliminate dead space.

CONTRAINDICATIONS:

Vacuum therapy is contraindicated in patients with malignant wound, untreated osteomyelitis, fistulae to organs or body cavities, presence of necrotic tissue and those with exposed arteries/nerves/anastomotic site/organs.

LIMITATION

Closed Wound suction Set used in short-term uses.

INTENDED USER

Doctors or Trained healthcare professional.

INTENDED PATIENT POPULATION

Infants, Paediatric and Adult

DIRECTIONS FOR USE:

- Wash up and scrub hands and preferably use pre-sterile protective gloves.
- Peel opens the pack and removes the device aseptically.
- Close wound drainage device under negative pressure
- Provided with the option to use one or two catheters post-operatively
- The connecting tube is kink resistant and is provided with additional strength to withstand the suction
- Multiperforated catheters provided with radio-opaque line and satin smooth perforation/eyes for trauma free performance
- Available in different sizes with matching size curved needle to meet moderate to heavy drainage needs.
- Graduated bellow allows the user to measure the drainage volume
- Flexible bottle chamber is easy to be depressed by one person single-handedly for activating the suction of bellow unit
- Sterile, individually packed in a box

WARNING:

Researchers have found biofilm has caused a range of serious health problems including Salmonella, Shigella, E. Coli, Campylobacter and Yersinia. Drains are breeding grounds for bacteria that cause illness

PRECAUTIONS AND CAUTIONS:

- Prior to using read entire instructions for use. Failure to do so may result in severe patient injury .
- ***STERIMED DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES FROM IMPROPER USE.***
- Do not clean or Re-use the device,
- For single Patient use only.
- Discard after Single use.
- The product should be used immediately after opening the packing.
- Do not use with a stylet or guide wire
- Do not use the device after expiry Date mentioned on the Label.
- If the patient is sensitive or allergic to PVC, do not use the device

ADVERSE EFFECTS:

- Vascular Damage
- Spread of Neoplastic cells
- Blockage
- Dehiscence
- Electrolyte Imbalance
- Drain failure

CLINICAL BENEFITS:

- Improved rates of healing
- Reduce wound infection rate
- Improve patient comfort
- Decreased hospital stays
- Decrease the complication rate
- Improved the blood circulation
- Reduced wound healing time

RESIDUAL RISKS:

Infection, Edema & Hematoma formation.

INSTRUCTIONS FOR USE
CLOSED WOUND SUCTION SET
***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/CWS/01 Rev. No.:00, Dt. 12.08.2023

SUPPLY:

Closed Wound Suction Set (with Acc.-Redon Catheter (PVC) - SMD 1003

Closed Wound Suction Set (with Acc.-Redon Catheter (Silicone) - SMD 1003 SL

Acc.- Redon Drainage Catheter (PVC) - SMD 1010

Acc.- Redon Drainage Catheter (Silicone) - SMD 1010 SL

MATERIAL USED:

- Closed Wound Suction Set (with Acc.-Redon Catheter (PVC) (SMD 1003) / Acc.-Redon Drainage Catheter (PVC) (SMD 1010)

Component	Material	Specification/Grade
Below Bottle	LDPE (Low Density Poly Ethylene)	Medical Grade
Connecting Tube	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connectors	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Needle	Stainless Steel	Medical Grade
Redon Catheter	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Hanger	PP (Poly Propylene)	Medical Grade
C Clamp	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade

- Closed Wound Suction Set (with Acc.-Redon Catheter (Silicone) (SMD 1003 SL) / Acc.- Redon Drainage Catheter (Silicone) (SMD 1010 SL)

Component	Material	Specification/Grade
Below Bottle	LDPE (Low Density Poly Ethylene)	Medical Grade
Connecting Tube	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Connectors	PVC (Poly Vinyl Chloride) Compound	Medical Grade
Needle	Stainless Steel	Medical Grade
Redon Catheter	100 % silicone	Medical Grade
Hanger	PP (Poly Propylene)	Medical Grade
C Clamp	ABS (Acrylonitrile Butadiene Styrene)	Medical Grade

STERILITY:

This device is sterilized by ethylene oxide gas. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused Device.

STORAGE:

These products should be stored in their original box in a cool and dry place between 5 to 45° C, preferably away from direct and indirect sources of light and heat. Do not use after expiry.

DEVICE DISPOSAL:

Used Closed Wound Suction set may be contaminated with infectious and/or other hazardous materials. Discard used catheters in the container meant for infectious waste. Unused expired catheters should be disposed of as per local regulations.

NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SYMBOLS:

REF	**Catalogue No.**		**See instructions for Use**
	Cautions		**Keep Dry**
	Do not use it if the packaging is damaged.		**Sterile Barrier System**
	Single-Use		**Do not Re-sterilize**
LOT	**Batch / Lot No.**	STERILE EO	**Ethylene Oxide Sterilized**
	Date of Mfg.	LATEX	**Latex Free**
	Date of Exp.	MD	**Medical Device**
	Avoid Direct Sunlight	45°C 5°C	**Keep in a dry place between 5°C to 45°C**
PHT DEHP	**Phthalate Free**		**Pyrogen Free**
UDI	**Unique Device Identifier**		

EC REP CE 0123
OBELIS S.A. Bd, General Wahis, 53,
1030, Brussels, Belgium
Email:mail@obelis.net

INSTRUCTIONS FOR USE

CLOSED WOUND SUCTION SET

***Please Read All Instructions Carefully Before Use (Sterile, for single use only)**

SMDPL/IFU/CWS/01 Rev. No.:00, Dt. 12.08.2023

Sterimed Group, 501 Ring Road Mall,
21, Manglam Place, Rohini Sec-3 Delhi-85

Manufactured by:

Sterimed Medical Devices Pvt. Ltd.

Plot No. 211A, Sector-16, HSIIDC, Bahadurgarh,
Jhajjar, Haryana - 124507 (INDIA)
Customer Care No.: +91-11-42466196/396
Email : info@sterimedgroup.com
Website : www.sterimedgroup.com
EN ISO 13485:2016 Certified Company
Mfg. Lic. No.: MFG/MD/2018/000086