

Instruction for Use

Intended Use: Disposable Surgical Lavage System is designed to irrigate, wash, and evacuate debris from general soft-tissue and orthopedic surgical sites (for soft-tissue wound or bone debridement, site cleaning, bone cement residue removal) with a pulse jet of sterile fluid (saline). It consists of a handpiece with a battery-power supply and irrigation/ suction controls, tubing and detachable tips for surgical applications. This is a single use device. This device offers a powerful cleaning action for bone or a gentle lavage for soft tissue. Suction and irrigation is to thoroughly remove debris and contaminants.

Applicable Scope: Wound debridement of orthopedic surgery, marrow cavity cleansing, soft tissue debridement, surgical parts cleansing in orthopedics and trauma cases.

Product type: Attachment 1

Structure for systems with external battery pack (Figure1)

- 1---Locking ring
- 2a--- Short tip
- 2b--- Long tip
- 2c--- Femoral brush tip
- 3--- Pistol-Grip Handle
- 4--- Irrigation Line
- 5--- Suction Line
- 6--- Battery pack (8 AA 1.5V alkaline batteries)
- 7--- Switch
- 8--- Flow control clamp
- 9--- Vacuum suction pump (supplied by hospital)
- 10--- Normal Saline Solution (supplied by hospital)
- 11--- Splash shield

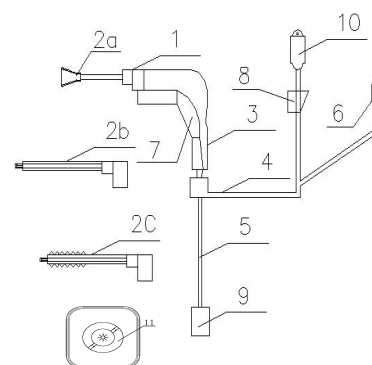


Figure 1

Electric Circuit Diagram for systems with external battery pack (Figure 2)

- 1---Battery pack(8 AA 1.5V alkaline batteries)
- 2---Switch
- 3---Motor
- 4---Eccentric gear
- 5--- Normal Saline Solution (supplied by hospital)
- 6--- Vacuum suction pump (supplied by hospital)
- 7---Irrigation Line
- 8---One way valve

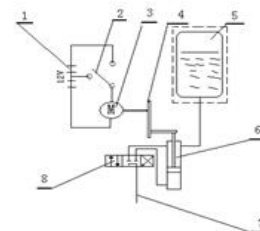


Figure 2

Structure for systems with internal battery pack (Figure3)

- 1---Locking ring
- 2a--- Short tip
- 2b--- Long tip
- 2c--- Femoral brush tip
- 3--- Pistol-Grip Handle
- 4--- Irrigation Line
- 5--- Suction Line
- 6--- Battery pack (7 AA 1.5V alkaline batteries)
- 7--- Switch
- 8--- Flow control clamp
- 9--- Vacuum suction pump (supplied by hospital)
- 10--- Normal Saline Solution (supplied by hospital)
- 11--- Splash shield

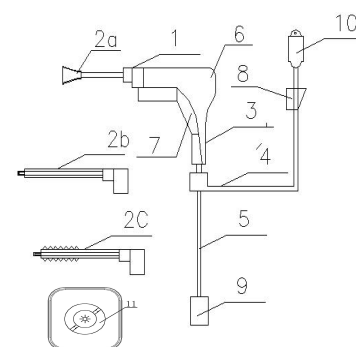


Figure 3

Electric Circuit Diagram for all-in-one systems (Figure 4)

- 1---Battery pack (7 AA 1.5V alkaline batteries)
- 2---Switch
- 3---Motor
- 4---Eccentric gear
- 5--- Normal Saline Solution (supplied by hospital)
- 6--- Vacuum suction pump (supplied by hospital)
- 7---Irrigation Line
- 8---One way valve

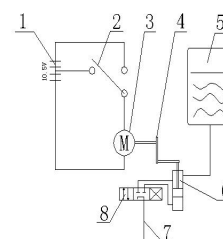


Figure 4

How to use

- 1 Open the package and take out the items. Refer to Figure1.
- 2 Pressing up locking ring prepare for connecting tips.
- 3 Attach debridement tip (2a or 2b or 2c) to Pistol-Grip Handle (3). Push locking ring until connection is locked.
- 4 Short tip (2a) is for large area wound debridement. (2b) is for depth wound debridement. (2c) is for depth wound scouring.
- 5 Connect suction line (5) to Vacuum suction pump (9) (supplied by hospital).
- 6 Guide Irrigation line (4) to (10) Normal Saline Solution (supplied by hospital).
- 7 Switch (7) on “O” means power off, switch on “ / ” means slow phase, switch on “ / ” means fast rate.
- 8 Irrigate the surgical site as needed. To limit irrigation flow, or to prevent dripping, tighten the flow-control clamp (8) that is attached to the irrigation tubing.

Technical Parameters

1. Connection joint can withstand 15N under axial static tension. Under normal temperature, withstand 0.05 Mpa pressure without leakage.
2. Two flow rates. Slow rate: 600±300mL/min; Fast rate: 900±300mL/min.
3. When at fast rate, flow pulsation frequency is not less than 4 times/s, at slow rate, flow pulsation frequency is not less than 3 times/s.
4. Irrigation Line diameter: 2.8mm, Suction line diameter: 7.5mm (Long tip length: 27.3cm).
5. Irrigation Line diameter: 2.8mm, Suction line diameter: 10 mm (Short tip length: 12.4cm).
6. Irrigation Line diameter: 2.8mm, Suction line diameter: 7.5mm (Femoral brush tip: 27.3cm).
7. Equipment type: Type B applied Part.
8. Power Supply: Systems with extra battery boxes are powered by 8 AA 1.5V alkaline batteries, All-in-one systems are powered by internal 7 AA 1.5V alkaline batteries.
9. Enclosure protection IPX0 ordinary equipment.
10. EMC comply with EN 60601-1-2.
11. Environmental conditions

Environmental Conditions	Operation	Storage and Transportation
Temperature	10 -- 40 °C	-20 --40 °C
Relative Humidity	30--75%	10--75%
Atmospheric Pressure	700—1050hPa	500—1050hPa

IMPORTANT INFORMATION















WARNINGS:

- Disposable Surgical Lavage System is only operated by professional medical personnel.
- Disposable Surgical Lavage System is for SINGLE USE. Reuse may cause patients infection.
- Do not use when the sterile package is broken prior using, may cause patients infection.
- Disposable Surgical Lavage System is ETO sterilized. Pay attention to the indicator color on the inner package.
- Follow infection control protocols for lavage treatments. Failure to comply may result in the transmission of dangerous bacteria into the air and onto surfaces from wounds.
- Normal Saline Solution (supplied by hospital) should be positioned 20 cm higher than Disposable Surgical Lavage System.
- Switch off flow control clamp while pause to use.
- Stop use and change new one while malfunction happen during operation.
- Disposable Surgical Lavage System is only used for one wound debridement, change tips or complete system when there are more than two wounds to treat.
- DO NOT cut the power pack from the unit for disposal. Cutting through the power cable could result in shock, excessive heat and/or sparks, which may cause personal injury and/or fire.

- The power pack contains mercury-free alkaline batteries. Manufacturing company does not recommend the removal of batteries from the power pack. Batteries contain electrolytes that can cause serious chemical burns to skin and eyes.
- DO NOT submerge handle in liquid as this may compromise the efficiency of the pump or alter the pH of the liquid.
- This device contains alkaline batteries. Follow WEEE regulations to dispose / proper recycle.
- Prior to use, check operate system components and inspect on damage. DO NOT use if damage is apparent.
- Do NOT use this equipment in the presence of a mixture consisting of a flammable anesthetic and air or oxygen or nitrous oxide.
- Keep far away the electromagnetic interference factors to avoid potential interference.
- During transportation, keep from rain, humidity. Pile up less than 5 layers.
- Storage humidity is 30-75%, with good ventilation. Keep the room clean and dry. Packages are away from wall and floor higher than 15 cm.
- The manufacture of medical devices contained in the materials "DEHP", they are classified as carcinogenic, mutagenic or reproductive toxicity, not recommended for newborn babies, children, pregnant and nursing women.

Symbols Definitions

	For single use only
	Method of sterilization: EO
	Consult instructions for use
	The medical device contains "DEHP"
	Safety and precautionary information
	This symbol indicates that the waste of electrical and the electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Type B Applied Part
	Manufacturing company
	European Representative
	Batch code
	Date of Manufacture
	Use By

Contraindication

1. Severe hemorrhagic shock patients
2. Severe diabetic patients
3. Hypoalbuminemia patients



Ningbo Five Continents Medical Instrument Co., Ltd.

No.63-9, Modao Bridge Road, Yuyao, Zhejiang Province 315400, China.



Caretechion GmbH

Add: Niederrheinstr. 71, 40474 Dusseldorf, Germany.

Tel: +49 211 3003 6618; Fax: +49 211 3003 6619

Attachment 1:

Type	Figure	Product Structure
WZ-WDS-01	Figure 1	1. Locking ring; 2a. Short tip; 2b. Long tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WDS-02		1. Locking ring; 2a. Short tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WDS-03		1. Locking ring; 2b. Long tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WDS-04		1. Locking ring; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WDS-05		1. Locking ring; 2a. Short tip; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WDS-06		1. Locking ring; 2b. Long tip; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WDS-07		1. Locking ring; 2a. Short tip; 2b. Long tip; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-01/MPPL01/ FNM2010400	Figure 3	1. Locking ring; 2a. Short tip; 2b. Long tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-02/MPPL06		1. Locking ring; 2a. Short tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-03/MPPL04		1. Locking ring; 2b. Long tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-04/MPPL05		1. Locking ring; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-05/MPPL02		1. Locking ring; 2a. Short tip; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-06/MPPL07		1. Locking ring; 2b. Long tip; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-WPL-07/MPPL03		1. Locking ring; 2a. Short tip; 2b. Long tip; 2c. Femoral brush tip; 3. Pistol-Grip Handle; 4. Irrigation Line; 5. Suction Line; 6. Battery pack; 7. Switch; 8. Flow control clamp; 11. Splash shield.
WZ-PT-01	2a	2a. Short tip.
WZ-PT-02	2b	2b. Long tip.
WZ-PT-03/ MPPLFB	2c	2c. Femoral brush tip.
WZ-SH-01	11	11. Splash shield.