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Caring for Life since 1829

CLEANEST PULSE Lavage

Disposable Pulse Lavage for Hip and Knee Arthroplasty

USER MANUAL

Model No.: W-203

STERILE EO

CE 0123

The Fannin Cleanest Pulse Lavage

Disposable Electronically Pulsed Lavage Suction Apparatus

Model No.: W-203

Indications (Intended Use)

- This device is used together with normal sterile saline or other applicable solutions, vacuum extractor. Vacuum extractor is not a must.
- This device can be used for open wound cleaning, soft tissue cleaning, and surgical operation location cleaning.
- This device is suitable to be used in operation room, emergency room and treatment room.

Features

- This device is easy to use and portable with significant cleansing effect.
- This device is powered by 10 pieces of d.c. 1.5V mercury-free AA alkaline batteries.
- This device is portable and can be installed and handled easily.
- This device is suitable for any kind of open wound cleansing.
- This device cleans the wound completely with proper pressure.
- This device avoids cross contamination due to its disposability.
- This device removes waste solution with suction, if the waste pipe is connected with a vacuum extractor.

Working Principle

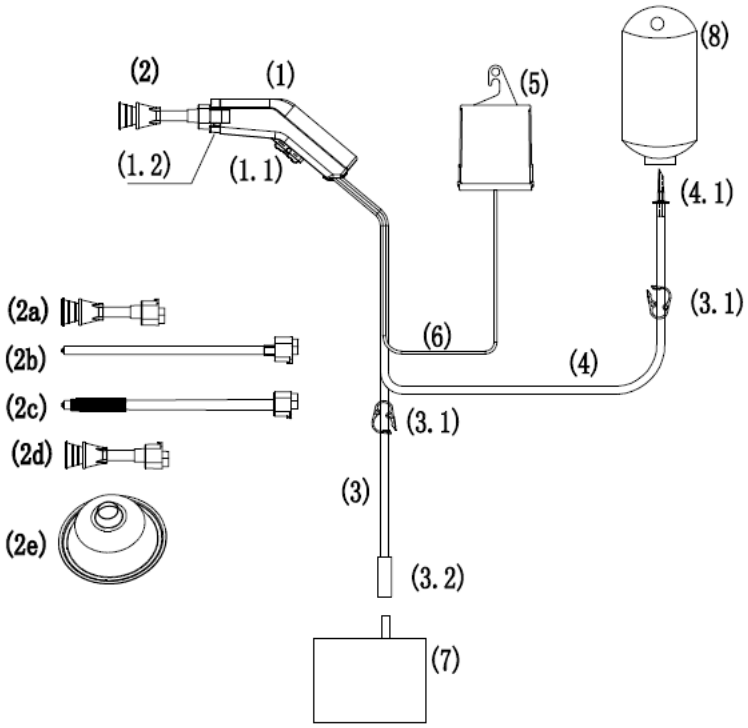
- This device is a portable and internal battery powered.
- This device consists of DC motor, compression pump, handpiece, enclosure, batteries and nozzles.
- When squeezing the trigger, power is on. When power is turned on, the DC motor drives the compression pump in reciprocating motion, engender cavity volume changes, thus it can pump the solution in and out. The power is DC battery. There are a low power position (DC 9V), a high power position (DC 15V) and a stop tap position. Different nozzles can be fitted on during operation.

Components

- This device consists of **Handpiece (1)** 【Including DC motor, Compression pump, Trigger (1.1), Nozzle lock (1.2), Enclosure.】, **Nozzle (2)** 【Such as Fan Spray Nozzle (Short Nozzle) (2a), Femoral Nozzle (Long Nozzle) (2b), Femoral Brush Nozzle (Long Nozzle) (2c), Shower Spray Nozzle (Short Nozzle) (2d), Large Splash Shield (2e) or other nozzles. See the package and labels for details.】, **Waste pipe (3)** 【Including Clamp (3.1), Connecting pipe (3.2).】, **Irrigation pipe (4)** 【Including Clamp (3.1), Luer fitting (4.1).】,**Battery bag (5)**, **Power wire (6)**.
- The **Vacuum extractor (7)** and **Irrigation bag (8)** are not included in this device, but prepared by medical institution.

  The negative pressure of Vacuum extractor (7) within the range of 5kPa to 40kPa shall be adjustable. The Irrigation bag (8) should be used with normal sterile saline or other applicable solutions (not suitable for viscous solutions).
- Accessories: **Nozzles (2).**
- Detachable parts: **Nozzle (2).**
- Applied parts: **Nozzle (2).**
- Associated devices: **Vacuum extractor (7)** and **Irrigation bag (8).**

Device Structure Diagram

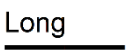
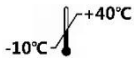


Operating Instructions

- Inspect the package. Do not use the device if the package is damaged.
- Consult the user manual and the attached documents.
- Open the package, and install **Nozzle (2)** to **Handpiece (1)**. Press down the **Nozzle lock (1.2)** to lock the **Nozzle (2)**.
- Connect the **Waste pipe (3)** to the **Vacuum extractor (7)** (if prepared). Vacuum extractor is not a must.
- Connect the **Luer fitting (4.1)** to the **Irrigation bag (8)**.
- Hang up or place the **Battery bag (5)**. The **Battery bag (5)** should be hanged up on the same horizontal with the **Irrigation bag (8)** and avoid the liquid from the **Irrigation bag (8)** spillage on the battery bag.
- Use the **Nozzle (2)** to aim the treatment area. Squeeze the **Trigger (1.1)** to activate the device and start irrigation. The **Trigger (1.1)** have a low power position (DC 9V) with symbol short "—", a high power position (DC 15V) with symbol long "——", and a stop tap position with symbol "O".
- Slide **Clamp (3.1)** can control the liquid flow in the **Irrigation pipe (4)** and **Waste pipe (3)**. Please lock the **Clamp (3.1)**, when you stop operating the device.
- It can suck the waste solution concurrently while spraying or after, if **Vacuum extractor (7)** is prepared.
- To press **Nozzle lock (1.2)** upward first, when withdraw the **Nozzle (2)**.
- Optional: The **Large Splash Shield (2e)** is to be used in conjunction with the short nozzle.
  To install: Pinch the soft head of the short nozzle, insert into the opening of the splash shield and slightly pull in opposite directions to fixate the shield on the nozzle head.
  To uninstall: Pinch the soft head of the short nozzle and remove the splash shield.

Symbol Descriptions

The following symbols will appear on user manual, labels and packages. Some of the symbols represent standards and compliances associated with the device and its use.

	Sterilized using ethylene oxide		Do not re-use
	Consult instructions for use		Do not resterilize
	Do not use if package is damaged and consult instructions for use		Caution
	CE marking of conformity		Medical device
	Authorized Representative in the European Community/ European Union		UK Responsible Person
	Catalogue number		Model number
	Batch code (Lot number)		Serial number
	Date of manufacture		Use-by date
	Manufacturer		Importer
	Unique device identifier		Distributor
	This symbol on the trigger side means stop tap position		Type B applied part
	This symbol on the trigger side means low power position (DC 9V)		Direct current
	This symbol on the trigger side means high power position (DC 15V)		Temperature limit
	This way up		Fragile, handle with care
	Keep dry		Keep away from sunlight
	Double sterile barrier system		Single sterile barrier system with protective packaging inside
	DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.		

Specification

- Power source (Ratings): 15V DC, 10×1.5V AA (LR6) alkaline batteries. Power rating: 37.5W.
- Handpiece dimensions: About 185mm * 55mm * 40mm (Long* Wide* High).
- Net weight: About 0.9kg.
- Flow rate (high power position): not less than 0.9L per minute.
- Maximum irrigation length (high power position): not less than 2.5 meters.
- Noise (Decibel): less than 75dB(A).
- Solution form: Fog-like and thread-like.
- This device is sterilized using ethylene oxide before delivery.
- Valid period (Shelf life): 2.5 years.

IEC Classification

- Internal electrical power source equipment.
- Type B applied part.
- IPX0.
- Not category AP/APG equipment.

Contraindications

Not found.

Adverse Effect

Not found.

Warning and Precautions

- This device should be operated only by qualified professionals.
- This device should not be used after the expiry date shown on the package.
- This device is for single patient use only. Do not reuse the device.
- Prior to each use, inspect the package. Do not use the device if package is damaged.
- This device is not evaluated as category AP or APG equipment.
  This device is not suitable for use in the presence of flammable anesthetic mixtures with air or oxygen or nitrous oxide.
- No modification of this equipment is allowed.
- Except the Nozzle, there is no replaceable part and accessory within the unit.
- This device sterilized using ethylene oxide before delivery. Sterilization validity is 2.5 years.
- Follow current local/national regulations to properly dispose the device after use.

Disposal of the Batteries

- This device contains alkaline batteries. The battery will be utilizable and safe, if the device is used before date of expiry.
- Follow local/national current regulations to properly recycle or dispose of the batteries after use.
- Do NOT cut the power wire at any time before removing the batteries to prevent short-circuit, which may cause overheating of the battery pack and result in a potential fire risk. In case of short circuit, do not pour liquid over it nor cover it, simply leave it and dispose after it is cooled down. There is a very slim chance of short circuit but proper means of disposal is highly recommended.
- To safely remove the batteries, please press down on flap and remove the lid, then remove batteries from the housing.

Maintenance, Cleaning and Sterilization

- This device is maintenance free and does not require routine maintenance.
- This device does not contain user repairable parts.
- Caution! Do not open this device, do not repair this device.
- This device is for single patient use only. There is no cleaning or sterilization requirement for user. Do not resterilize.

Electromagnetic Compatibility Descriptions

- Conform to the requirements of IEC 60601-1-2:2014 and EN 60601-1-2:2015.
- Instructions for use of electromagnetic compatibility
  1) The ME (MEDICAL ELECTRICAL) EQUIPMENT or ME SYSTEM is suitable to be used in operation room, emergency room and treatment room.
  2) **Warning**: Don't near active HF (HIGH FREQUENCY) surgical equipment and the RF (RADIO FREQUENCY) shielded room of an ME system for magnetic resonance imaging, where the intensity of EM (ELECTROMAGNETIC) disturbances is high.
  3) **Warning**: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
  4) This device doesn't contain user repairable cables, transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION.

5) **Warning**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Disposable Electronically Pulsed Lavage Suction Apparatus (W-203), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
6) **NOTE**: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

- Technical description of electromagnetic compatibility
  1) All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE. Disposable use product. Do not change any parts of the product.
  2) In the table below the guidance and manufacturer's declaration -electromagnetic emissions and Immunity are shown:

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions (CISPR 11)	Group 1
RF emissions (CISPR 11)	Class A
Harmonic emissions (IEC 61000-3-2)	N/A
Voltage fluctuations/ flicker emissions (IEC 61000-3-3)	N/A

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity test	IEC 60601-1-2 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ff18 kV Air: ff12 kV, ff14 kV, ff16 kV, ff18 kV, ff115 kV	Contact: ff18 kV Air: ff12 kV, ff14 kV, ff18 kV, ff115 kV
Electrical fast transient / burst IEC 61000-4-4	Power supply lines: ff12 kV input/ output lines: ff11 kV 100 kHz repetition frequency	N/A
Surge IEC 61000-4-5	line(s) to line(s): ff10.5kV, ff11 kV. line(s) to ground: ff10.5kV, ff11 kV, ff12 kV.	N/A
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% U_T 1 cycle And 70% U_T 25/30 cycles Single phase: at 0 0% U_T 250 cycle	N/A
Power frequency magnetic field IEC 61000-4-8	50Hz: 30 A/m 60Hz: 30 A/m	50Hz: 30 A/m 60Hz: 30 A/m
Conduced RF IEC 61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2700 MHz 80 % AM at 1 kHz	3 V/m 80 MHz to 2700 MHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
	Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
Radiated RF IEC 61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
	450	430– 470	GMRS 460, FRS 460	FM ffl 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

Environmental Requirements

- Storage conditions:

  This device should be stored in non-corrosive gases, cool, dry, and ventilated place.

  Temperature: between -10℃ and +40℃; Humidity: ≤95％RH; Air pressure: between 50kPa and 106kPa.

- Operating conditions:

  Temperature: between 5℃ and 30℃; Humidity: ≤80％RH; Air pressure: between 86kPa and 106kPa.

Fannin
Caring for Life since 1829

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