Surgical Lavage Units Instruction Manual

REF 2500041 Model no.2500

General Description

This Surgical Lavage Units has an easy disposal BUILT-IN Battery Pack, which avoids bulky cables and motion limitation. It is fully disposable single use, minimizing potential contamination, designed for use in orthopaedic surgical procedures, trauma and general wound care.

Orthopaedic Bone Bed Preparation
Surgical Lavage Units is an important equipment used to prepare bone bed before orthopaedic cementing during arthroplasty. It has been proven to increase cement penetration into the cancellous bone, potentially improving fixation strength leading to longer survival of implants, thus reducing revision rates.

Wound Care
With the adequate steady pressurized, pulsed solution it can achieve a mechanical debridement for wounds, removing dirt, infectious microorganisms, wound exudates, necrotic tissue and debris. Thereby assisting visual examination and optimizing wound healing by stimulating granulation tissue formation.

Standard package includes:
- 1 Hand piece
- 1 Standart 30mm Cone Tip (ST 01K)
- 1 Coaxial canal tip (CT 02K)
- 1 Sterilized, Coaxial Canal Tip
- 1 Coaxial Canal Brush Tip (Sterilized)

Read the operating instruction carefully before use.
Failure to follow may cause damage or injuries.

Indications

- Arthroplasty bone cleansing
- Wound cleaning

Contraindications

- Should not be performed in the presence of active profuse bleeding (precautionary measures for patients on anticoagulation medication)

⚠ Warnings

Failure to follow may cause harm to person.

- The device must be carried out solely by Orthopedic surgeons and health professionals with wound care knowledge.
- Wear protective equipment, such as fluid-proof gown, gloves, mask or face shield, hair cover to avoid infectious splash backs.
- Use a drape or towel to cover all patient lines, ports, and wounds that aren't being treated.
- When applied on nerves, tendons and bones, should take precautions depending on tissue condition and the judgement of professional personnel.
- Follow standard practices to minimize potential contamination.
- Sterile only if package is unopened and undamaged.
- Single use only! DO NOT Re-sterilize!
- DO NOT operate damaged or malfunctioning instrument.

⚠ Caution

Failure to follow may cause damage to product.

- DO NOT use this product in any other manner other than the purpose or the operation method described in this instruction manual.
- DO NOT submerge instrument in liquid.
- DO NOT drop or hit the instrument.
- Store in a cool dry place.
- No modification of this equipment is allowed
- Do not mix with used or other types of batteries
- Some national laws restricts this device to sale by or on the order of a physician.
- The user/patient should report any serious incident relating to the device to the manufacturer and competent authority of its Member State.

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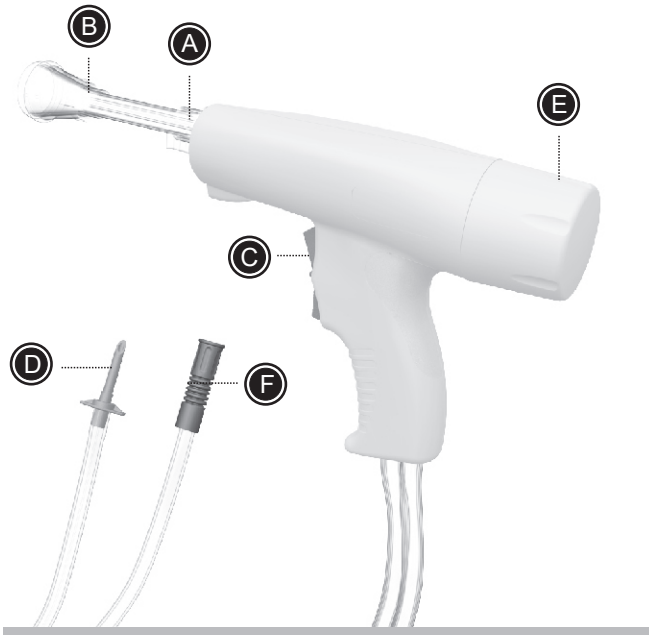
STERILE EO CE 0197

Instructions for Use

1. Peel open the package and remove all the items in a sterile way.
2. Attach the selected tip to the handpiece and push on until the connection is secured (A)(B).
   (When using the Intramedullary Tip ensure the **tip cover** has been removed before use)
3. Attach the irrigation tube to the irrigation solution (D)
4. Attach the suction tube to the suction system (F).
5. Remove the protector from the Trigger Switch (C).
   - High speed: depress the upper half.
   - Low speed: depress the lower half.

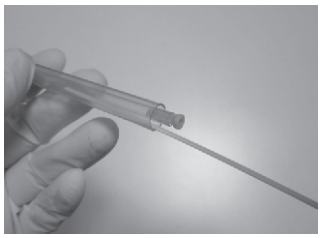
   Stop the flow: return to the original position.

NOTE:
- Both irrigation and suction tubes have clamps to prevent leakage of fluids.



In Case of Tip Obstruction: (Optional)

Insert the cleaning rod (HA 250) from the distal end of the tip and push until the obstruction has been released.



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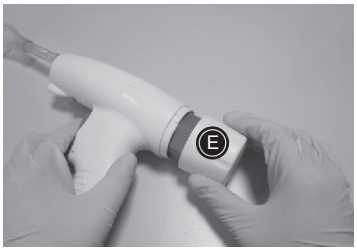
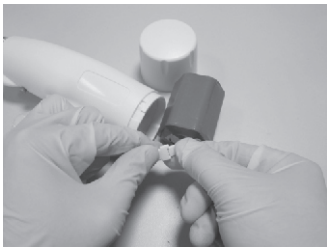
DO NOT dispose battery in fire
DO NOT recharge

Battery Removal

1. Rotate to remove battery cap (E) and pull out the Battery Pack.
2. Pull and disconnect the small cable connection.





Shelf Life

3 years

Disposal

- Make sure to remove the battery pack.
- Ensure that the device is disposed of safely and in accordance with all current national and international waste disposal directives.
- Please contact the local authorities responsible for waste disposal if questions arise.

Operation

- Temperature: 10°C ~ 40°C
- Relative Humidity: 30%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa
- Altitude limit: 2,000 meter

Transportation and Storage

- Temperature: 5°C ~ 40°C
- Relative Humidity: 15%~75%RH
- Atmospheric Pressure: 80kPa ~106kPa

Please dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment).

Specifications

- Adjustable spray speed: High or Low
- Pressure: <15 PSI
- Pulse rate: 1500~1700 cycle/min
- High speed flow rate:1100~1400ml/min (30mm cone tip)
- High speed flow rate: 1000~1300mil/min (coaxial tip)
- Low speed flow rate 700ml/min
- Tube Length 3 meters
- Batteries: ⎓ 10.5V / AA Alkaline Batteries x7 cells.
- High speed power rate: ⎓ 10.5V / 25W
- Low speed power rate: ⎓ 6.0V / 14.5W
- Type B applied part: small cone tip (optional), coaxial canal tip (optional).

(Data may vary according to type of power source, type of tip, distance and length of operation)

Labeling Symbols

- Refer to instruction manual/booklet
- General warning sign / Caution
- Do not use if package is damaged
- Do not re-use
- Keep dry
- Temperature limit
- STERILE EO — Sterilized using ethylene oxide
- CE 0197 — Complies with EU directives
- Manufacturer
- EC REP — Authorized representative in the European Community
- IP2X — Solid particle protection:> 12.5mm
- LATEX — Not made with latex
- Premature unpacking warning
- Type B applied part
- ⎓ — Direct current
- Use by date
- ALKALINE — Recycle alkaline battery
- Date of manufacture
- European Union WEEE Directive Logo
- Consult instructions for use
- MD — Medical Device
- REF — Catalog number
- LOT — Batch code

Electromagnetic Environment

- Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
- Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
- Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Lavage, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d=1.2\times P^{1/2}$ *80 MHz to 800 MHZ*
$d=2.3\times P^{1/2}$ *800 MHz to 2.7 GHz*

where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).
Interference may occur in the vicinity of equipment marked with the following symbol:

Recommended separation distance between portable and mobile RF communications equipment
The Pulse Lavage are intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the Pulse Lavage can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Lavage are recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

This instructions for use contains technical descriptions.

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