

REF 2500 K1

General Description

This Pulse Lavage is an environmentally friendly device, that operates with an AC adaptor or a Rechargeable Battery Pack. Integrated LED light source provides deep cavity visual assistance. 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

Pulse lavage 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 Small cone tip (ST 01K) - Optional
- 1 Coaxial canal tip (CT 02K) - Optional
- **AC adaptor (2500AD) or Rechargeable Battery (2500BT) NOT included.**



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 over exposed nerves.
- Should not be performed in the presence of active, profuse bleeding (precautionary measures for patients on anticoagulation medication)
- Improper technique may harm wound bed.
- Patients with sensory impairment are unable to provide accurate feedback needed to guide the clinician if improper technique is used.

⚠ 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
- Dispose of all single use components, as appropriate, immediately after use.
- Ensure that the device is disposed of safely and in accordance with all current national and international waste disposal directives.
- Some national law restricts this device to sale by or on the order of a physician.

⚠ Warnings

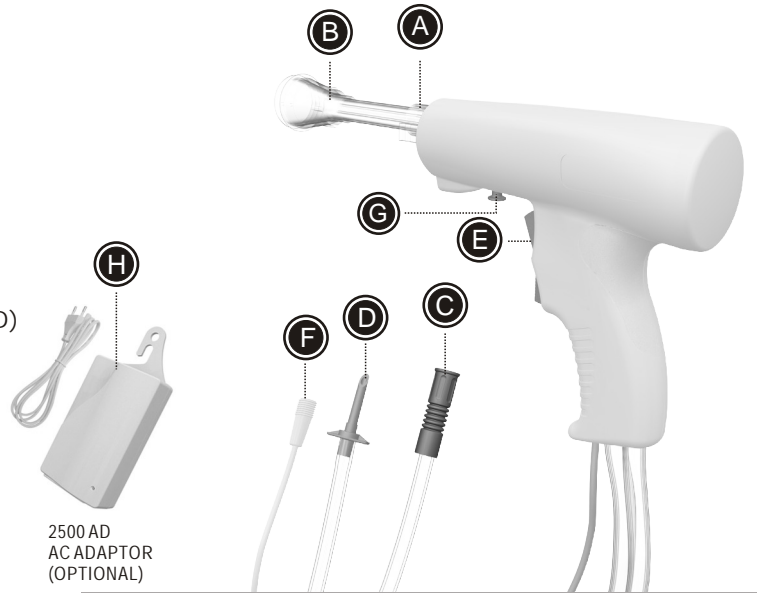
Failure to follow may cause possible injuries to persons.

- 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.
- AC adaptor or Rechargeable Battery - Reusable device. NON sterilized!



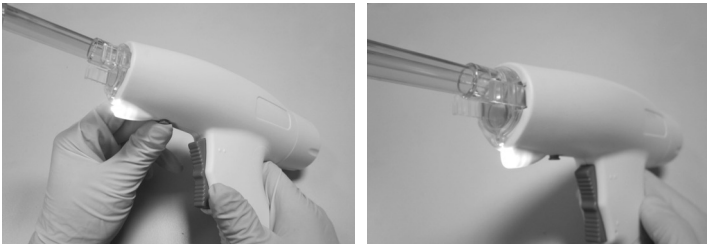
Instructions for Use

1. Peel open the package and remove all of the items in a sterile way.
 2. Hand over handpiece's cord and tubes to Circulating Personnel, for them to connect the cord to the AC adaptor or Rechargeable Battery output socket and ensure it's securely attached (F) (H). Hang the AC Adaptor to an I.V. stand or convenient place.
 3. Attach the irrigation tube to the irrigation solution (D)
 4. Attach the suction tube to the suction system (C).
 5. Attach the required tip to the handpiece and push on until the connection is secured (A) (B). (When using the Intramedullary Tip ensure the white cap is removed before use)
 6. Remove the protector from the Toggle Trigger (E).
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 has clamps to prevent leakage of fluids.
7. Once finished, unplug the power source (F) and dispose of the single use parts.



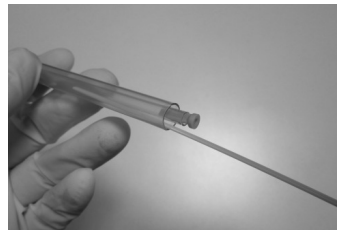
Turn ON/OFF L.E.D

Press the power button (G) to turn ON the light and press again to turn it OFF if needed.



In Case of Tip Obstruction: (Optional)

Insert the cleaning rod (HA 250) from the end of the tip and push until releasing the obstruction.



Shelf Life

3 years

Disposal

- Dispose of all single use components, as appropriate, immediately after use.
- Detach all power source before disposal.
- 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: 8 60hPa~1060hPa
- Altitude limit: 2,000 meter

Transportation and Storage

- Temperature: 5°C ~ 40°C
- Relative Humidity: 15%~85%RH
- Atmospheric Pressure: 8 60hPa~1060hPa

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: 1000~1300ml/min (coaxial tip)
 - Low speed flow rate 700ml/min
 - Tube Length 3 meters
 - DC \equiv 9V input
 - High speed power rate: DC \equiv 9V / 25W
 - Low speed power rate: DC \equiv 6.0V / 14.5W
- (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
- Sterilized using ethylene oxide / Do not re-sterilise
- Catalog number
- Batch Code
- Serial number
- Complies with EU directives
- Manufacturer
- Authorized Representative in the European Community
- Type B applied part
- Direct Current
- Use by Date
- Protected against solid foreign object of 12.5mm \varnothing and greater
- Not made with Latex
- Premature unpacking warning