

General Description

This Surgical Lavage Units has an easy disposal Alkaline Battery Pack.

It is fully disposable single use, minimizing potential contamination, designed for use in orthopedic surgical procedures, trauma and general wound care.

Orthopedic Bone Bed Preparation

Surgical Lavage Units is an important equipment used to prepare bone bed before orthopedic 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 Alkaline battery pack (non rechargeable)
- 1 Small cone tip (ST01Z) - Optional
- 1 Coaxial canal tip (CT02Z) - Optional



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

Indications

- Arthroplasty bone cleansing
- Wound cleaning

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
- 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.
- The user/patient should report any serious incident relating to the device to the manufacturer and competent authority of its Member State.

Instructions for Use

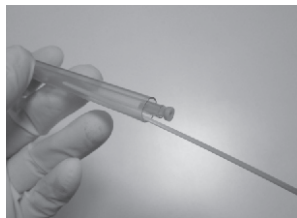
1. Peel open the package and remove all the items in a sterile way.
2. Push up the Locking Ring (A).
3. Attach the selected tip (B) to the handpiece.
(When using the Intramedullary Tip ensure the **tip cover** has been removed before use)
4. Lock the selected tip in place by pushing back the Locking Ring.
(Retract the Locking Ring for tip removal (A))
5. Hang the battery pack on a convenient place (G)
6. Attach the irrigation tube to the irrigation solution (D)
7. Attach the suction tube to the suction system (C).
8. Remove the protector from the Trigger Switch (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.

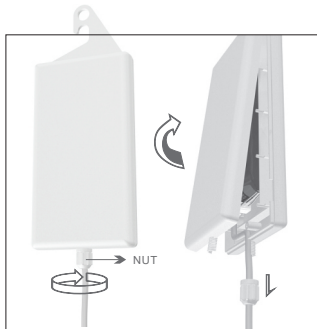
In Case of Tip Obstruction: (Optional)

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



Battery Removal

1. Unscrew the NUT (F), open the front cover of battery box (G).
2. Disconnect the connector from Battery Pack.



Shelf Life

3 years

Disposal


- Make sure to remove the battery pack in case of 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: 860hPa~1060hPa
- Altitude limit: 2,000 meter

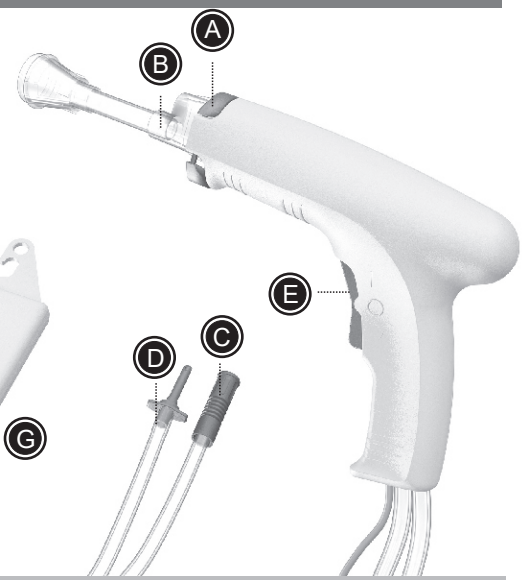
Transportation and Storage

- Temperature: 5°C ~ 40°C
- Relative Humidity: 15%~75%RH
- Atmospheric Pressure: 860hPa~1060hPa

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



MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster,
Germany.



ALKALINE














DO NOT dispose battery in fire
DO NOT recharge

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
- Batteries: 12V / AA Alkaline Batteries x 8 cells.
- High speed power rate: 12V / 28.5W
- 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
-  Sterilized using ethylene oxide
-  Complies with EU directives
-  Manufacturer
-  Authorized representative in the European Community
- IP2X Solid particle protection:> 12.5mm
-  Not made with latex
-  Premature unpacking warning
-  Type B applied part
-  Direct current
-  Use by date
-  Recycle alkaline battery
-  Date of manufacture
-  European Union WEEE Directive Logo
-  Consult instructions for use

 Medical Device

 Catalog number

 Batch code



Dongguan Kaiser Technology Co.,Ltd.
No.6, 2nd Road, Sanjiang Industrial Block,
Hengli Town, Dongguan City, 523462
Guangdong P.R.China