

WOUND DEBRIMENT AND DRAINAGE SYSTEM USER MANUAL

1. INSTRUCTIONS

Name: Wound Debriment and Drainage System

Intended use: The Pulse Lavage is used for open wounds/trauma and total joints

This sterile device is designed to be used for cleaning the general soft tissues and orthopedic surgical areas by using a sterile liquid (ex. Removing the bone cement residue, cleaning the operational area for soft tissue release or bone debriment).

The kit contains an integrated battery-powered pump, a handpiece for controlling the suction and irrigation, a disposable battery group, hoses and various forms of removable applicators for specific surgical operations. Active pulsatile ensures convenient conditions and energy for irrigation and debridement flow. The main clinical user is the orthopedic department. Can be used for hip and knee replacement surgeries and trauma debriment. If requested, the device can be used in some neurosurgical operations. Can be used for wound treatments of diabetics.

2. Technical Specifics

Handle Dimensions: **Battery Chamber:** **Total weight of the device:** 230 gr

Length: 16,8 cm

Thickness: 2 cm

Injection pressure (IP), flow rate: at low speed, IP ≤ 600 ml/min at high speed, IP ≤ 1200 ml/min

Height: 15,7 cm

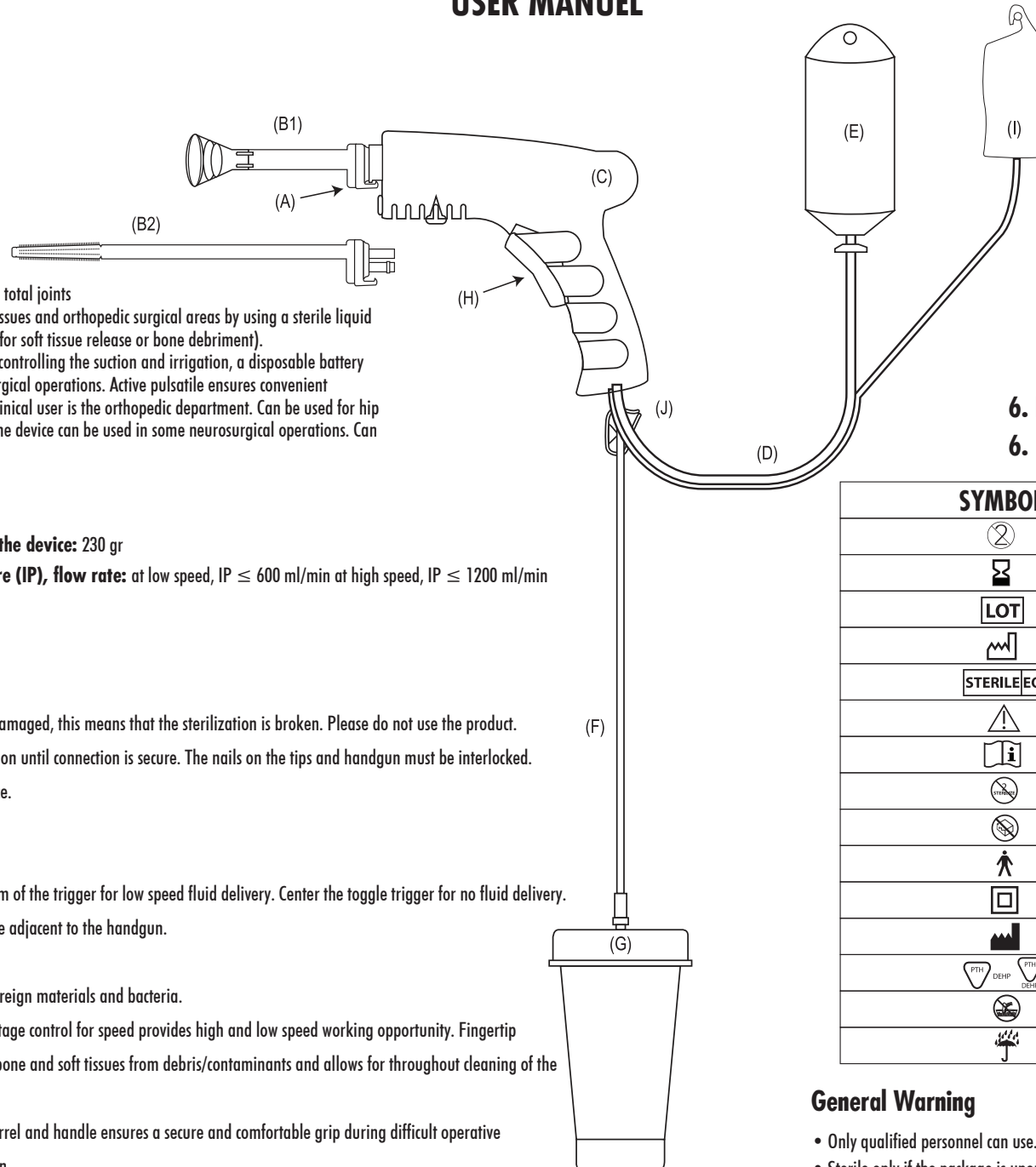
Length: 19,1 cm

Width: 5,4 cm

Width: 7,9 cm

3. Directions for Use

1. Open the package and remove all the items. If the package is damaged, this means that the sterilization is broken. Please do not use the product.
2. Attach the appropriate tip (B1), (B2) to the handgun (C), and push on until connection is secure. The nails on the tips and handgun must be interlocked.
3. To provide ease of use, attach the battery pack (I) to a suitable place.
4. Link the irrigation tube (D) to the irrigation liquid (E).
5. Link the suction line (F) to suction collecting source (G).
6. Depress the top (H) for high speed fluid delivery, depress the bottom of the trigger for low speed fluid delivery. Center the toggle trigger for no fluid delivery.
7. To limit suction, The Pulse Lavage has a clamp (J) on the suction line adjacent to the handgun.
8. Irrigation liquid should be located above from the handgun.
9. The Pulse Lavage is designed for cleaning operation region from foreign materials and bacteria.
10. Pulse Lavage is lightweight, portable and disposable system. Two-stage control for speed provides high and low speed working opportunity. Fingertip control is available for liquid jet. The device effectively clears both bone and soft tissues from debris/contaminants and allows for throughout cleaning of the surgical operation area.
11. Tip fixing mechanism provides easy change of the tips. Textured barrel and handle ensures a secure and comfortable grip during difficult operative procedures. The device fits well to hands due to its ergonomic design.
12. Independent tubes for fluid and suction provides concentric fluid delivery and suction.



4. Storage

- Store in a cool and dry place at room temperature.
- Do not pack the kit, which may cause deterioration of sterilization.
- If the device is stored for more than 1 year, it is recommended to check the battery.

5. Shelf Life and Disposal

- Expiration date is on the label.
- Do not use the device after the expiration date.

6. IMPORTANT INFORMATION FOR USERS

6. 1 SYMBOLS

SYMBOLS AND EXPLANATIONS OF LABELS	
	Single use only
	Expire date
	Lot number
	Production date
	Sterilized with ethyleneoxide
	Caution
	User manual
	Can not be resterilized
	Do not use if the package is damaged
	Type B applied part
	Class II hardware
	Manufacturer
	Contains phthalate
	Do not immerse in liquid
	Keep dry

General Warning

- Only qualified personnel can use.
- Sterile only if the package is unopened and undamaged.
- Explosion hazard.
- Do not use in presence of flammable anesthetics or gases.
- Do not immerse the handle to liquid since it might reduce the effectiveness of the pump or change the pH of the liquid.

Warning

- It may harm the patient or user if the device is not fully implemented.
- Do not use until providing necessary conditions.
- Caution! Please check the supplementary documents.

