Instructions for Use

PALAVAGE® Pulse Lavage System

Description and Function
The PALAVAGE® Pulse Lavage System consists of a reusable pneumatic handpiece and a sterile single use Nozzle Kit composed of a pump cartridge, nozzle tips (short and long), irrigation tubing with spike tip and a clamp. This Nozzle kit is available with or without suction connector. Suction pump is not included.

Intended Use
- The device purpose is to enhance the preparation of the intramedullary canal and/or bone surfaces during cementation in orthopedic procedures, including primary and/or revision total joint arthroplasty.

- In Wound Management, it facilitates quick, efficient removal of necrotic tissue, bacteria, and foreign material from the wound. Soft Tissue management use low speed irrigation that provides gentle, optimal pressure.

Technical information

Inlet pressure:	6-7 bar (80-100psi)
Pulsations per minute:	4000
Delivered solution per minute:	800ml
Delivered pressured by Nozzle tip:	65psi

Intended Purpose
The PALAVAGE® Pulse Lavage System is intended to be used in the preparation of the intramedullary canal and/or bone surfaces in orthopaedic procedures, including primary and/or revision total joint arthroplasty. The pulsatile action of the pump helps to remove blood, tissue debris and foreign matter from the operative/wound site. When connected to a suction source the device can be used to aspirate material/fluids from the operative/wound site.

Connection to other Devices and Accessories
No other devices are needed to be connected, but if suction is desired make sure to only use suction pumps that are compliant with ISO 10079-1.

Risk with the use of the device
No residual risks, nor undesirable side-effects, have been noticed by the manufacturer.

Contraindications
The use of pulsatile lavage may be contraindicated in situations where the tissue to be irrigated is too friable implying sensible tissues such as nerves or open active bleeding wounds, where irrigation might not be indicated.

Warnings
1. The PALAVAGE® Pulse Lavage Handpiece and the PALAVAGE® Nozzle Kit can only be used together. Use of either the handpiece or the sterile Nozzle Kit with any other manufacturer´s equipment is not recommended, as performance of the PALAVAGE® device with other manufacturer´s equipment has not been tested.
2. The device is intended to be connected to a nitrogen/air source. Do not connect to CO^2 gas source because the gas will be vented into the room atmosphere.
3. Do not exceed 7 bars (100 psi) maximum source pressure.
4. If leakage of irrigation fluid is detected from the tubing during use, discard and replace the PALAVAGE® Nozzle Kit.
5. Inspect sterile packaging of the PALAVAGE® Nozzle Kit prior to use. If packaging is damaged or compromised, discard the Kit.
6. If any malfunction is noted in the handpiece the user should return the components to the distributor for evaluation. No service of the equipment should be carried out by the user.
7. No modification of this equipment should be carried out by the user.
8. The Nozzle Kits are delivered sterile and are for single use only and must not be reprocessed for re-use.
9. The PALAVAGE® Pulse Lavage System should only be used by medical professionals with adequate training in orthopaedic surgery.
10. Do not use the PALAVAGE® Pulse Lavage System in any other setting than a sterile OR environment where proper sterile technique can be applied.
11. If for some reason the PALAVAGE® Pulse Lavage System does not stop when the Handpiece trigger is released a safety shut down can be carried out simply by removing the airhose from the wall outlet.

12. The PALAVAGE® Handpiece is delivered nonsterile and the instructions for cleaning, sterilization, inspection and maintenance must be followed before use.
13. The PALAVAGE® Handpiece is normally not used in surgical procedures where it can contact low or high risk TSE (Transmissible Spongiform Encephalopathies) infective tissue as defined by World Health Organization. Therefore, decontamination procedures with highly aggressive agents are not necessary and for normal processing, are not recommended because material degradation may occur. The sterilization parameters recommended in this document are not intended and not suitable for inactivation of prions.
14. If suction is desired make sure to only use suction pumps that are compliant with ISO 10079-1.

Guidelines to check proper functionality of the PALAVAGE® Handpiece
A failure mode may be caused by end of life of the product, improper use or improper maintenance. PulseLavage AB does not define the maximum number of uses for the PALAVAGE® handpiece. The useful life of these products depends on many factors including method and duration of each use, and the handling between uses. Careful inspection and functional test of the device before use is the best method determining the end of serviceable life for the product.

Typical failure Modes:
• Worn out O-rings on the pneumatic connector on PALAVAGE® Handpiece (only applicable for REF 66022827).
• Hole in the membrane of the PALAVAGE® Handpiece.
• Dents on the pneumatic connectors of the PALAVAGE® Handpiece.

Preventive Maintenance
• The PALAVAGE® equipment should be returned to Distributor every two years for maintenance. No service should be carried out by the user.
• Never handle the PALAVAGE® Handpiece using any sharp instruments.
• Never bundle any sharp instruments close to the PALAVAGE® Handpiece during surgery and handling.
• Never force the pneumatic connections on the PALAVAGE® Handpiece using other instruments.

Set-up
To set up the system for lavage you will need the following equipment:
1. PALAVAGE® Pulse Lavage Handpiece (REF 66022825 or 66022827).
2. PALAVAGE® Pulse Lavage Sterile Nozzle Kit (REF 66022830 Hip/Knee Set without suction, REF 66022828 Hip/Knee Set with suction).
3. Air hose
4. Compressed nitrogen or air source with an appropriate pressure regulator.
5. Irrigation bags

To set up the system for suction you will require the following optional items:
1. Suction source.
2. Suction tubing.

Use of System

Step 1:	Sterilized Handpiece is placed in sterile field. Connect Handpiece to air hose.
Step 2:	Open Nozzle Kit and deliver contents onto the sterile field.
Step 3:	Connect pump cartridge to Handpiece.
Step 4:	Connect irrigation tubing to irrigation bag and clip it using the clamp.
Step 5:	Connect the Handpiece with the air hose to compressed air or nitrogen source. Set the source pressure to 6-7 bars (80-100 psi) for maximum flow and pulsing force.
Optional:	Connect suction tubing to suction source (not included). Connect tubing to pump cartridge.
Step 6:	To irrigate: Activate trigger on Handpiece. To change nozzle tips: Unscrew tips and screw new tips into place. To shut off suction: Shut off suction pump.

After use
Reduce pressure regulator to 0 bar (0 psi) at nitrogen/air source. Detach pump cartridge from Handpiece. Activate trigger of Handpiece to relieve line pressure. Detach air hose from air source.
Sterile Nozzle Kit unit is not reusable: dispose in accordance with accepted medical practice.
Air hose and Handpiece are reusable and may be cleaned and sterilized in the following manner:

Processing Instructions

More detailed instructions are given on the following pages

Point of Use

Remove the excess soils with a disposable cloth or paper wipe promptly after any use. Do not allow saline, blood, body fluids, tissue, or other organic debris to dry on instruments prior to cleaning.

Transport to Processing Area

- Avoid mechanical damage
- Max. 2 hours before cleaning

Preparation for cleaning

- Disconnect air hose from Handpiece
- Attach wash plug to Handpiece

Manual

Manual Cleaning and Disinfection

- Clean with brushes using mild detergent and warm water
- Rinse with running water
- Dry with wipes

Automatic

Automated cleaning and disinfection in washer-disinfector

- Load into washer-disinfector
- Operate washer-disinfector cycle
- Inspect, dry

Inspection

- Disconnect wash plug from Handpiece
- Visual inspection
- Functional check
- Lubricate O-rings

Packaging

- Store devices in trays
- Double packaging

Sterilization

- Steam autoclave

Storage

- Control environment
- Control shelf life

Cleaning Instructions for the PALAVAGE® handpiece

Point of Use
Remove the excess soils with a disposable cloth or paper wipe promptly after any use. Do not allow saline, blood, body fluids, tissue, or other organic debris to dry on instruments prior to cleaning

Transport to Processing Area
Before cleaning: Minimize the time before cleaning which should not exceed 2 hours. A damp cloth may be used to cover the instrument to avoid drying of soil.

Preparation for Cleaning
Connect the PALAVAGE® washplug (FL1601 or FL1602) to the handpiece to avoid any water from entering the equipment.

Cleaning
Two methods of cleaning PALAVAGE® equipment are provided in these instructions, a manual method and a method using an automated washer disinfector.
Whichever method is used, staff should always use suitable protective clothing and equipment. Take note of the instructions provided by the cleaning agent manufacturer for correct handling and use of the product.
Use only cleaning or disinfecting medical devices specifically formulated for aluminium products.

Manual Cleaning
1) Clean the Handpiece with a soft brush, warm water and a mild detergent.
2) Rinse all parts with water until all traces of disinfectant solution are removed. Pay particular attention to blind holes and hinges like the one under the trigger.
3) The last rinse should be with distilled water.
4) Dry the equipment using lint free single use wipes.
5) Visually inspect and repeat complete manual cleaning and disinfection if necessary.

If the handpiece has mistakenly been immersed in disinfectant solution:
- Put the handpiece in water for 10 minutes.
- Rinse under a faucet.
- Connect the air hose and dry the handpiece by running it dry for 45 seconds.

If water has gotten into the motor
- Connect the air hose to an air source and run the unit dry for 45 seconds.

Automated cleaning and disinfection using washer-disinfector
1) Load the equipment into the washer-disinfector.
2) Avoid contact between devices.
3) Operate the washer-disinfector cycle.
4) On completion visually inspect each device for remaining soil.
5) If soil remains repeat the cleaning process.

Drying
If necessary, additional manual drying can be achieved using a lint-free cloth. Dry hollow spaces of instruments with sterile compressed air.

Inspection
1) Disconnect the wash plug from the Handpiece.
2) Visually inspect the Handpiece for any lose parts and that the membrane is intact.
3) Connect the equipment to a high-pressure air source and check that the membrane of the Handpiece is moving upon depressing the trigger.
4) Lubricate the two O-rings on the trigger (only applicable for 66022827) making sure not to spray any lubrication into the air inlet of the handpiece. Doing so will damage the motor.

Packaging
The cleaned, disinfected and checked equipment should be placed into the sterilization tray and double wrapped according to AAMI/CRS technique.

The packaging for terminally sterilized equipment should be suitable for steam sterilization and resist temperatures up to at least 141°C.
The packaging should also provide sufficient protection for the instruments to mechanical damage and fulfil the requirements of ISO 11607.

Sterilization
The Handpiece is sold non-sterile. Please note that according to EN ISO 17665 the final responsibility for validation of sterilization techniques and equipment lies directly with the hospital. To ensure optimal processing all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations.

For initial sterilization or re-sterilization the following parameters are an alternative:

Method	Moist heat sterilization according to EN ISO 17665
Cycle	Saturated steam with fractional force air removal
Exposure Time	3 minutes
	Exposure time can be extended to 18 minutes to comply
	with the recommendation from World Health Organization
	(WHO). The PALAVAGE® Handpiece is designed to
	sustain such sterilization cycles.
Temperature	134°C
Drying Time	Recommended: 30 minutes (minimum, in chamber)

Limitations and restrictions on processing
Repeated processing cycles that include, mechanical washing and sterilization have minimal effect on device´s life span and function. The life span is mainly affected by wear or damage during surgical use as well as proper care and handling techniques.

Storage
After sterilization make sure to store the equipment in the sterilization packaging in a dry and dust-free place in room temperature (5 to 40^0C, RH <90%). The shelf life is depending on the sterile barrier employed, handling and storage conditions. A maximum shelf life for sterilized medical devices before use should be defined by each health care facility.

Transportation
To prevent damage to the medical device during transit, it is recommended the use of racks, trays or rigid containers that protects the device.

Disposal
Single use components should be disposed according to hospital protocol for contaminated waste.

Environmentally friendly materials
All materials and components used are “Medical Grade” and do not contain any PVC or Latex. No toxic by-products from incineration.

References
1. EN ISO 11607 (ANSI AAMI ISO 11607): Packaging for technically sterilized medical devices
2. EN ISO 17665 (ANSI AAMI ISO 17665): Sterilization of health care products, moist heat
3. ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurances in health care facilities
4. EN ISO 17664 (ANSI AAMI ST81): Sterilization of medical devices
5. Steam Sterilization Report No. 12003
6. World Health Organization (WHO) recommendations regarding exposure time: WHO/CDS/CSR/APH/2000.3, Annex III, section 2, 6.

List Devices and Accessories
Only use the device with the corresponding accessory form the list below, any other device or accessory has not been tested for functionality nor safety.

UDI	Catalog Name	Ref
17350093650607	Hip/Knee Set With Suction Unit	66022828
17350093650614	Hip/Knee Set (without Suction)	66022830
17350093650621	Power Pulse Lavage Handpiece AO/Synthes Connector	66022825
17350093650638	Power Pulse Lavage Handpiece Zimmer/Hall Connector	66022827

Symbols seen in the label:

	Patient Information website		Do not use if package is damaged
UDI	Unique Device Identification		Consult electronic instructions for use eIFU Indicator
MD	Medical Device	LOT	Batch Code
	Do not resterilize	SN	Serial Number
	Do not reuse	REF	Catalog Number
	Manufacturer		Use by Date
STERILE EO	Single sterile barrier system with protective packaging inside. Sterilized using ethylene oxide		Distributor
NON STERILE	Non-sterile		Temperature limit
	Humidity Limitation		Keep Dry
	Caution		

Reporting of Incident to Manufacturer (see below) & Competent Authority
In case any patient/user faces a serious incident, please IFU report the incident to the manufacturer, and the Competent Authority of the country where the user/patient resides.

CE
2862

Manufacturer:
PulseLavage AB
Rubanksgatan 8
SE-74171 Knivsta
SWEDEN

Distributed by:
Heraeus Medical GmbH
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