

	IFU OrthoPulse	Document TF01.22.01PLIFUOP
	Date Jan 2024	Rev D

Instructions for Use Pulse Lavage System

Description and Function

The OrthoPulse Lavage System consists of a reusable pneumatic handpiece/air hose and a sterile single use Nozzle kit composed of a pump cartridge, irrigation tips (short, long or both), irrigation tubing with spike tip and a clamp. This Nozzle kit is available with or without suction tubes (short, long or both). Suction pump is not included.

Intended Users

Devices are used in Orthopedic Surgeries or in Wound Management by professional personnel. Not used by lay persons. Not used by patient. Operation Theatre sterile barrier used only.

Patient Populations

- Patients where Hip or Knee replacement has been recommended by an orthopedic doctor.
- Patients in situations where irrigation may be indicated. The pulsatile action of the pump helps to remove blood, tissue debris (in the form of devitalized tissue) 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.

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.

Clinical Benefits

- Reducing the risk of revision for aseptic loosening by improving the cement penetration depth
- Faster wound healing by removing surface debris and reducing bacterial load.
- User satisfaction because of improved cleaning efficiency

Technical information

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

Intended Purpose

The OrthoPulseLavage System is intended to be used in the preparation of the intramedullary canal and/or bone surfaces in orthopedic procedures, including primary and/or revision total joint arthroplasty. The Soft Tissue Kit is a device that may also be used to provide lavage in situations where irrigation may be indicated. 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. 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 OrthoPulseLavage Handpiece and the OrthoPulse Lavage 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

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recommended, as performance of the OrthoPulse device with other manufacturer's equipment has not been tested.

2. Device is intended to be connected to a nitrogen/air source. Do not connect to CO2 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 disposable portion of the system.
5. Inspect air hose prior to connection to air supply. If the air hose is damaged, do not attempt to repair with an adhesive such as tape. Discard the air hose and use another OrthoPulse air hose for the procedure.
6. Inspect sterile packaging prior to use. If packaging is damaged or compromised, discard disposable portion of the system. Disposable parts are sold STERILE and should not be re-use. Re-use of single use components can lead to patient contamination.
7. If any malfunction is noted in the handpiece or air hose, the user should return the components to the producer for evaluation. No service of the equipment is to be carried out by the user.
8. No modification of this equipment is to be carried out by the user.
9. The nozzle kits are delivered sterile and are for single use only and must not be reprocessed for re-use.
10. The OrthoPulse system should only be used by medical professionals with adequate training in orthopaedic surgery.
11. Do not use the OrthoPulse system in any other setting than a sterile OR environment where proper sterile technique can be applied.
12. If for some reason the OrthoPulse system does not stop when the trigger is released a safety shut down can be carried out simply by removing the airhose from the wall outlet.
13. The OrthoPulse system handpiece and airhose are delivered non sterile and the instructions for cleaning, sterilization, inspection and maintenance must be followed before use.
14. The OrthoPulse system handpiece and airhose are normally not used in surgical procedures where they contact low or high risk TSE 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
15. 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 OrthoPulse system handpiece and airhose

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 OrthoPulse handpiece and airhose. 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 OrthoPulse handpiece (only applicable for OML9000)
- Leakage in the OrthoPulse airhose
- Hole in the membrane on the OrthoPulse handpiece
- Dents on the pneumatic connectors on the OrthoPulse handpiece or airhose.

Preventive Maintenance

- The OrthoPulse equipment should be returned to PulseLavage AB every two years for maintenance. No service is to be carried by the user.
- Never handle the OrthoPulse airhose or handpiece using any sharp instruments.
- Never bundle any sharp instruments close to the OrthoPulse airhose or handpiece during surgery and handling.
- Never force the pneumatic connections on the OrthoPulse handpiece or airhose using other instruments.

Set-up

To set up the system for lavage you will need the following:

1. OrthoPulseLavage Handpiece (REF OML9000 or OML9010).
2. OrthoPulseLavage Air hose (REF FL1014, FL1015 or FL1016).
3. OrthoPulseLavage Sterile Nozzle Kit (REF OMP9000 Hip without suction, OMP9100 Hip with suction, OMP9200 Soft Tissue Set)
4. Compressed nitrogen or air source with appropriate regulator.

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5. Irrigation bags

To set up the system for suction you will require the following optional items that are not included:

1. Suction source (compliant with ISO10079-1)
2. Suction tubing.

Use of System

- Step 1: Sterilized handpiece and air hose are placed in sterile field. Connect air hose to handpiece.
- 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 pinch clamp.
- Step 5: Connect 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 tips: Unscrew tube(s) and screw new tube(s) into place.
To shut off suction: Shut off suction pump.

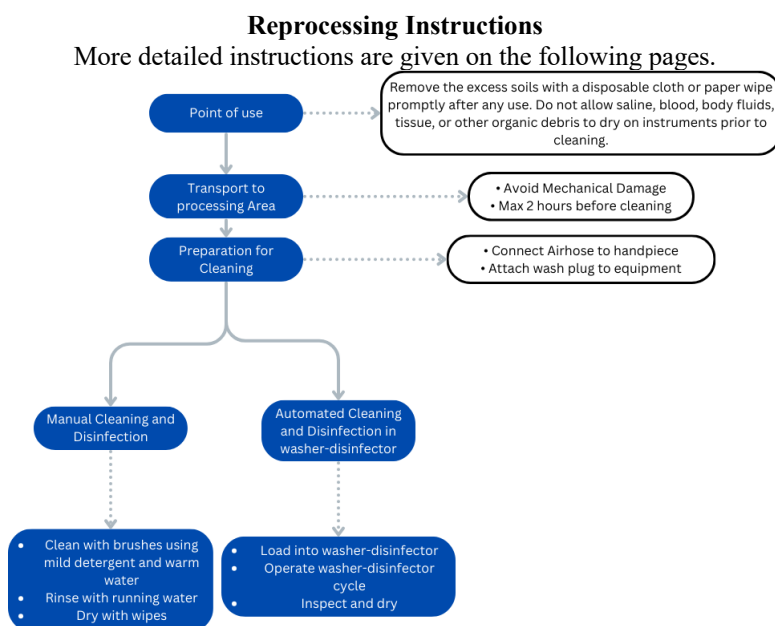
After use

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 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:



Cleaning Instructions for the OrthoPulse handpiece and airhose

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: Make sure not to mix the airhose with sharp instruments as these may damage the tubing.

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

Preparation for Cleaning

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Connect the OrthoPulse airhose to the handpiece and attach wash plug to equipment to avoid any water from entering into the equipment.

Cleaning

Two methods of cleaning OrthoPulse equipment are provided in these instructions, a manual method and a method using an automated washer disinfectant.

Whichever method is used, staff should use suitable protective clothing and equipment at all times. In particular 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 and airhose 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. Special care should be given not to place the airhoses close to sharp instruments (movement during washing could cause damage, and washing action could be obstructed).
- 3) Operate the washer disinfectant 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 Equipment
- 2) Visually inspect the tubing of the airhose for any holes and the connectors for dents.
- 3) Visually inspect the handpiece for any loose parts and that the membrane is intact.
- 4) Connect the equipment to a high pressure air source and check that the membrane of the handpiece is moving upon depressing the trigger.
- 5) Disconnect the Airhose from the Handpiece.
- 6) Lubricate the two o-rings on the trigger (only applicable for OML9000) 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 hand piece and air hose are 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

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optimal processing all cycles and methods should be validated for different sterilization chambers, wrapping methods and/or various load configurations. 2 years under normal Operating Room conditions or 730 cleaning and sterilization cycles.

For initial sterilization or resterilization the following parameters is an alternative:

Method	Moist heat sterilization according to EN ISO 17665
Cycle	Saturated steam with fractional force air removal
Exposure Time	3 minutes
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. After the service life of the instrument is over, it should be submitted for professional disposal or recycling. It shall also be necessary to observe all applicable national laws, regulations or disposable guidelines.

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°C, 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.

Service life of this product: Service provided by manufacturer recommended after 2 years or 730 cleaning and sterilization cycles.

Disposal

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

Environmental friendly Material

All material and components used are "Medical Grade". 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 17664:2017 Processing of health care products
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
07350093650341	Orthopulse Hip Set Suction	OMP9100
07350093650334	Orthopulse Hip Set Standard	OMP9000
07350093650396	Orthopulse Soft Tissue Set	OMP9200

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07350093650310	OrthoPulse Handpiece AO Connector	OML9010
07350093650327	OrthoPulse Handpiece Zimmer	OML9000

Symbols seen in the label:

Labelling Symbols

	Patient information website		Do not use if package is damaged
	Unique Device Identification		Consult instructions for use
	Medical Device		Batch Code
	Do not resterilize		Keep away from sunlight
	Do not reuse		Catalog Number
	Manufacturer		Use by date
	Single sterile barrier system with protective packaging inside sterilized using ethylene oxide.		Temperature Limit
	Humidity Limitation		Keep dry
	Caution		Manufacture Date

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.

Manufacturer:

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