

Reorder Number

REF

0067500



The SIMPULSE™ SOLO System

Includes:



• SIMPULSE™ SOLO Suction/Irrigator



• SIMPULSE™ Tip(s)



• Cojoined Suction and Irrigation Tubing

Instructions for Use



Do Not Re-use

R_x only

STERILE

EO



Contains phthalates

DEHP

BAIRD

DAVOL INC.

Precautions:

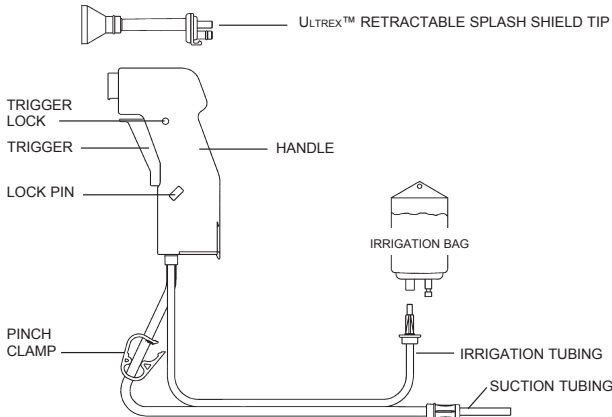
- Single use. Do not reuse.
- If package is damaged or open, do not use product.
- Read all instructions prior to use.
- Do not submerge handle in liquid as this may compromise efficiency of the pump or alter the pH of the liquid.
- Install medical equipment according to the EMC information provided.
- Mobile RF communications equipment can effect medical equipment.

Warning:

- Do not resterilize.
- This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
- Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user.
- Do not use in an oxygen-enriched atmosphere due to explosion hazard.
- Do not incinerate the batteries as this can cause a risk to the environment.
- Do not recharge batteries, put in backwards, or mix with used or other battery types as these actions may cause explosion or leakage leading to personal injury or can cause a risk to the environment.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.
- Do not use in the presence of flammable substances due to explosion hazard.
- Follow Occupational Safety and Health Administration (OSHA) standards or Universal Precautions for bloodborne pathogens (29 CFR-1910.1030). These may be found by searching the OSHA website at www.osha.gov.
- In order to limit contact with infectious agents from mist and splashing, personnel using the SIMPULSE™ SOLO Suction/Irrigator with tips for cleansing of wounds must wear personal protective equipment.
- When using the SIMPULSE™ SOLO Suction/Irrigator Tips for the cleansing of wounds, to prevent possible exposure of other patients to aerosol, the patient should be treated in a private area, enclosed with walls and doors, separate from other patients.
- Use continuous suction at 60-100 mmHg to keep operative or wound site clean.
- When using the SIMPULSE™ SOLO Suction/Irrigator with tips containing splash shields for the cleansing of wounds, keep splash shield in contact with wound/periwound at all times to prevent aerosolization.
- NOTE: Please reference the Davol edited version of "Loehne HB. Pulsatile Lavage with Suction. In: Sussman C, Bates-Jensen BM, eds, Wound Care – A Collaborative Practice Manual for Physical Therapists and Nurses, ed 2. Gaithersburg MD: Aspen Publishers, Inc.; 2001: 643 – 660" for detailed information on Infection Control and Personal Protective Equipment. For a copy of this article, please contact Davol at 1-800-562-0027.
- Do not occlude suction tip side holes or splash shield side holes as tissue damage may occur.
- If SOLO is used stacked with or adjacent to other equipment, SOLO should be observed to verify normal operation.
- SOLO is approved as a Class A device per IEC 60601-1-2 for use in hospital or health care setting. Testing for use in other environments (i.e. home use) has not been performed and may affect the operation of other devices in the same environment.

Safety Information and Symbols Definition:

	CAUTION		Do Not Re-use	STERILE EO	Sterilized using Ethylene Oxide
	Danger: Explosion Hazard. Do not use in the presence of flammable anesthetics.			IPX4	Protected against ingress of splashing water.
	CAUTION: Pulsed Lavage Indicated For: Total Joints, Trauma/Open Wounds				Do not resterilize
	Consult Instructions for Use				Type B applied part



Storage:

Temperature: 15°C to 30°C (approx. 59°F to 86°F)

Relative Humidity: 30% to 65% (Non-Condensing)

**Indications**

The SIMPULSE™ SOLO Suction/Irrigator is designed to provide controlled powered irrigation during open orthopaedic and general surgical procedures and for the cleansing of burns or wounds. Appropriate fluids for use include fluids with specific gravity of approximately 1 (e.g. saline). The pulsatile action of the pump helps to remove blood, tissue debris and foreign matter from the operative or wound site. When connected to a suction source, the device can be used to aspirate fluids from the operative or wound site.

Principle of Operation

The SIMPULSE™ SOLO motor-driven bellows pump is powered by four alkaline batteries, size AA, 1.5 volts each. The batteries, motor, and bellows pump are all located inside the pistol grip handle.

Setup (Additional Equipment Required)

To set up the system you will need irrigation bag(s), ex: normal saline or fluids with specific gravity of approximately 1. If more than one bag of saline or fluid is to be used simultaneously, you will need the SIMPULSE™ Dual Spike Adapter (**REF 0037690**).

Follow the given sequential steps for setup and use of the device to optimize its performance and minimize risk.

Step 1: Open the Package

The circulating nurse opens the package and delivers the contents onto the sterile field.

Step 2: Connect the Irrigation Fluid

A tip set must be connected to the hand piece to ensure appropriate flow and impulse from the pump.

1. The scrub nurse:

- a) if using one irrigation bag, passes the SIMPULSE™ SOLO spike to the circulating nurse.
- b) if using two irrigation bags, connects the SIMPULSE™ Dual Spike Adapter (**REF 0037690**) to the SIMPULSE™ SOLO spike and passes the dual spike tubing to the circulating nurse.
- c) removes the lock pin to release the trigger.
- d) inserts the SIMPULSE™ SOLO tip.

Note: Remove tip protector before using tip. To retract splash shield: Grasp from top, push and rotate downward past retaining ring. To reposition splash shield: Grasp from bottom, pull and rotate upward past retaining ring.

2. If using one irrigation bag, the circulating nurse spikes the irrigation bag with the SIMPULSE™ SOLO spike. (McGAW® and ABBOTT® bottles will need their vented spike adapters).

Note: Activating SOLO while not connected to an irrigation source will cause room air to be drawn through the irrigation tubing.

3. If using two irrigation bags, you will need the SIMPULSE™ Dual Spike Adapter (**REF 0037690**). The circulating nurse spikes the irrigation bags with the adapter spikes. (McGAW® and ABBOTT® bottles will need their vented spike adapters).

4. The scrub nurse primes the unit by squeezing the trigger until irrigant exits the tip.

5. The circulating nurse may squeeze the irrigation bag to facilitate priming.

6. The circulating nurse securely attaches the suction tubing, if used, to suction source or closes suction clamp to prevent irrigation fluid spillage.

Step 3: Use

1. To irrigate, squeeze the handpiece trigger. A whirring sound will be heard. Irrigation flow and force are directly related to trigger depression, e.g. minimal depression of the trigger will yield minimal flow and force while increasing trigger depression will increase flow and force.

2. The trigger lock button may be used to lock the trigger at maximum flow and force for uninterrupted irrigation. To utilize the trigger lock, completely depress the trigger and push the trigger lock button into the handle until it engages. The trigger lock button is released by squeezing the trigger.

3. To change tip, release trigger to turn off irrigation flow. Grasp tip and pull straight out from handle. Insert desired tip.

4. The white pinch clamp on the suction tubing can be used to turn suction on and off as desired.

After Use:

1. Ensure Suction tubing is empty and then disconnect Suction connection from Suction Source.

2. Ensure irrigation tubing is empty and then disconnect spike from irrigation bag.

Note: Failure to remove fluids from all tubing may lead to spillage.

Battery Disposal:

The batteries, which power the product, may be disposed of separately by releasing the latch on the bottom of the handpiece, pulling out the battery holder and removing the batteries from the holder.

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MEDICAL EQUIPMENT

WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1 (2003), ANSI/AAMI ES60601-1 (2005),

AND CAN/CSA-C22.2 NO. 60601-1 (2008)

Product contains no user serviceable parts

EMC TABLES

Guidance and manufacturer's declaration – electromagnetic emissions

The SOLO is intended for use in the electromagnetic environment specified below. The customer or the user of the SOLO should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SOLO uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Not Applicable	The SOLO is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. SOLO is a battery powered device.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	


Guidance and manufacturer's declaration – electromagnetic immunity

The SOLO is intended for use in the electromagnetic environment specified below. The customer or the user of the SOLO should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The SOLO is intended for use in the electromagnetic environment specified below. The customer or the user of the SOLO should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3V/m	$d = 1.2 \sqrt{P/80 \text{ MHz}}$ to 800MHz $d = 2.3 \sqrt{P/800 \text{ MHz}}$ to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- ^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which SOLO is used exceeds the applicable RF compliance level above, the SOLO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SOLO.
- ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the SOLO

The SOLO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SOLO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOLO as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W (Watt)	Separation distance according to frequency of transmitter m (metres)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.116667	0.116667	0.233333
0.1	0.368932	0.368932	0.737865
1	1.166667	1.166667	2.333333
10	3.689324	3.689324	7.378648
100	11.66667	11.66667	23.33333

The transmitter rated maximum output power in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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Assembled in Mexico



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