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APEX



INSTRUCTION MANUAL

iTool ®

APEXPULSE™

INDICATIONS FOR USE

The disposable pulse lavage is a single-use disposable pulse lavage system that provides controlled pulsatile irrigation and suction. Disposable pulse lavage is used in general osteotomies, for wound debridement, and for cleansing of surgical sites.

A variety of single-use disposable tips and splash shields are offered for disposable pulse lavage.

APPLICABLE PART NUMBERS

KITS

REF Number	DESCRIPTION	UOM
201-02-00	Component Kit (includes disposable instrument, tubing, battery pack)	6/box
201-03-00	Knee Kit (includes Component Kit and shower spray tip with splash shield)	6/box
201-04-00	Hip Kit (includes Component Kit, femoral spray tip and shower spray tip with splash shield)	6/box
201-05-00	Fan Spray Kit (includes Component Kit and fan spray tip with splash shield)	6/box

TIPS

REF Number	DESCRIPTION	UOM
201-00-44	Fan spray tip with splash shield	6/box
201-00-46	Femoral spray tip	6/box
201-00-52	Femoral brush tip	6/box
201-00-37	Shower spray tip with splash shield	6/box
201-00-51	Fan spray tip	6/box
201-00-50	Shower Spray tip	6/box

SPLASH SHIELDS

REF Number	DESCRIPTION	UOM
201-00-80	Splash shield, 6 inch (15.2 cm)	6/box

SYMBOL DEFINITIONS

	Consult Instructions for Use		High Pulsatile Operation
	Sterilized Using Irradiation		Do Not Immerse
	European Conformity Mark		Type BF Applied Part
	Date of Manufacture, YYYY-MM-DD.		Do Not Re-use
	Catalogue Number		Short Time Operation, Maximum 8 Minutes
	Use By Date, YYYY-MM-DD.		Do not use if package is damaged and consult instructions for use
	Batch Code		Dispose of per WEEE Directive 2012/19/EU
	Temperature Limit		Manufacturer
	Humidity Limitation		Medical device
	Atmospheric Pressure Limitation		Single sterile barrier system
	Stop Operation		Authorized representative in the European Community/European Union
	Normal Operation		Authorized representative in the Switzerland

INTRODUCTION

Throughout the manual, the following terms are used to help identify tips and precautions that will help avoid accidental injury to patients or personnel, or prevent damage to the system.

WARNING: Used to indicate that the safety of the patient and hospital personnel could be involved.

CAUTION: Used to point out special procedures or precautions that must be followed to avoid damaging the system / instrument.

NOTE: Used to point out or suggest the easiest means of carrying out techniques.

⚠ GENERAL WARNINGS

WARNING Visually inspect for damage to the package and product prior to use. Do not use product if package integrity has been compromised.

NOTE 1 If concerns are noted that may compromise the function of the device, do not use the product and please contact your representative.

NOTE 2 No absolute Contraindications exist.

CAUTION

- Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- Read Instructions For Use prior to the operation of Pulse Lavage.
- The Pulse Lavage needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the manual.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

INSTRUCTIONS FOR USE

1. Remove Pulse Lavage from packaging tray by peeling the Tyvek blister (Figure A).

Figure A



2. Connect Pulse Lavage irrigation tubing to an irrigation bag by inserting the bag spike into the bag's connection valve. Put irrigation bag no more than 0.8 meters or 2.6 feet above the handpiece (Figure B).

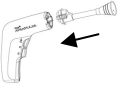
Figure B



3. Connect Pulse Lavage suction tubing to a suction canister by placing the blue suction connector onto the barbed canister fitting (Figure B).

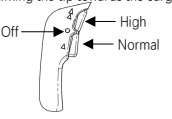
4. Insert the desired tip into Pulse Lavage. Until the click sound is heard, the desired tip is in place (Figure C).

Figure C



5. Prime Pulse Lavage by pushing the trigger to either the normal (►) or high pulsatile position (►►) for a few seconds while aiming the tip towards the surgical site (Figure D).

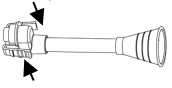
Figure D



6. Irrigate the surgical site as needed. To limit irrigation flow, or to prevent dripping, tighten the tubing clamp that is attached to the irrigation tubing.

7. Release or depress the pinch clamp on the suction tubing to control suction.

8. To change tip, turn off Pulse Lavage, press the plastic shrapnel on both sides of the tip (Figure E). Pull out existing tip and replace with desired tip.

Figure E 

WARNINGS

- Equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
- Universal precautions for handling contaminated materials should be observed at all times.
- DO NOT resterilize the instrument. Pulse Lavage is a single-use disposable device.
- DO NOT cut the battery case from the instrument or remove batteries from the battery case. Doing so may produce heat and/or electric shock, which may lead to personal injury and/or fire. The case contains mercury-free alkaline batteries which do not require specific disposal methods in most areas. We do not recommend that the batteries be removed from their pack. Batteries can cause serious burns to both the skin and eyes.
- when liquid leakage occurs, it is not allowed to use, contact local authorized representative for help.
- The equipment shall not be modified without authorization.
- It is not allowed to use the holding method of the pulse lavage with the pipeline facing upwards.
- The essential performance of Pulse Lavage is irrigation. If the Essential Performance is lost or degraded due to EM disturbances, Pulse Lavage will be unable to achieve the intended use.
- In addition to Pulse Lavage manufacturers as internal components of the spare parts (eg.cable) for sale, using the other specified attachment and cable may result in Pulse Lavage emission increases, lower immunity.
- Power cable maximum length: 3 m.
- To prevent damage to the battery box, it is recommended that the hanging height of the battery box is no higher than 1.5 meters.

NOTE

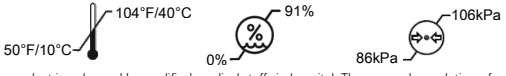
- Prior to use, make sure to hear the click sound when loading the tip. Failure to do so may cause the tip to fall off during use.
- Suction pressure may be reduced by clogs or debris in the suction path. For best performance, keep suction path clear of obstructions.
- Weakened performance after prolonged use may be the result of battery drainage.
- Pulse Lavage is intended to be used only by trained medical professionals who are familiar with its use and application.
- Tips may have limited contact with the surgical sites during operation.
- Positioning irrigation bag below the handpiece may weaken the performance or make the instrument malfunction.

• 0.9% saline is recommended as the irrigation fluid, other types of irrigation fluids or mixtures may cause irrigation efficacy and even product failure.
• Applied part of the device: Shower spray tip with splash shield (201-00-37), fan spray tip with splash shield (201-00-44), Femoral spray tip (201-00-46), Shower Spray tip (201-00-50), fan spray tip(201-00-51) AND Femoral brush tip(201-00-52).

ENVIRONMENTAL PARAMETERS

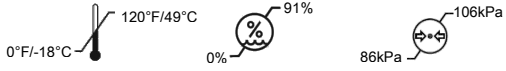
CAUTION Sterile, packaged devices should be stored in a designated, limited access area that is well ventilated and provides protection from dust, moisture, insects, vermin, and temperature/humidity extremes.

OPERATING CONDITIONS



The product is only used by qualified medical staffs in hospital. The age and population of patients is not limited.
The tip and shield may contact the damage surface of the human body during the rinsing process.

SHIPPING AND STORAGE CONDITIONS



The materials and components used in the construction of this device were selected to ensure that the device could be shipped by any standard commercial method without special handling conditions. ORDINARY (IPXO) PROTECTION. INTERNALLY POWERED DEVICE.

LIMITED WARRANTY Surgical instruments warrants to the original purchaser/consumer that this product will be free from manufacturing defects in material and workmanship for a period of thirty days from the original purchase date. The warranty is limited and only guarantees the replacement of the product without charge to the original purchaser/consumer. This warranty is not transferrable. In the event of abuse, misuse, use for anything other than a normal surgical procedure or in the event that the product has not been used in a reasonable manner as described in the Indications for Use and in compliance with the written instructions furnished by the manufacturer, this limited warranty shall be null and void.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE PULSE LAVAGE.

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

Rated maximum output power of transmitter. **WATTS**	Separation distance according to the frequency of transmitter. **METERS**		
	150 kHz to 80 MHz d=1.2 √ P	**80 MHz to 800 MHz** d=1.2 √ P	**800 MHz to 2.5 GHz** d=2.3 √ P
0.01	0.12	0.12	0.23
0.1	0.38	0. 38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Pulse Lavage, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter 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.

GUIDANCE AND MANUFACTURER'S DECLARATION

VIBRATION AND NOISE EMISSION

Vibration Exposure	a_{hv} (m/s^2)	1.22
	Uncertainty K (m/s^2)	-
Noise Emission Value	$L_{PA(dt(A))}$	75

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

EMISSIONS TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions CISPR 11	Group 1	The Pulse Lavage is 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 CISPR11	Class A	The Pulse Lavages are suitable for used for use in all establishments, but if used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, whatever additional measures are necessary.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

WARNING: This Pulse Lavage should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

WARNING: The use of accessories, transducers, and cable other than those specified by the manufacturer, may result in increased emissions or decreased immunity of the Pulse Lavage.

ELECTROMAGNETIC IMMUNITY

The Pulse Lavage is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Lavage 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 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%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40 % U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95 % dip in U_T) for 5 sec	Not applicable.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulse Lavage requires continued operation during power mains interruptions, it is recommended that the Pulse Lavage be powered from an uninterruptible power supply or battery. The device is battery powered.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity concerning Conducted RF & Radiated RF

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

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM Bands	Not applicable Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Lavage, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation distance $d=[3,5/V_1] \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	10 V/m 80 MHz to 2.7GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	$d=1.2 \sqrt{P}$ - 80 MHz to 800 MHz $d=2.3 \sqrt{P}$ - 800 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 meters (m). Field strength 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 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 the Pulse Lavage is used exceeds the applicable RF compliance level above, the Pulse Lavage should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Lavage.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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