INDICATIONS FOR USE

The MicroAire® Pulse Lavage is a single-use disposable pulse lavage system that provides controlled pulsatile irrigation and suction. MicroAire® 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 MicroAire® Pulse Lavage.

APPLICABLE PART NUMBERS

KITS

<table>
<thead>
<tr>
<th>REF Number</th>
<th>DESCRIPTION</th>
<th>UOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>201-02-00</td>
<td>MicroAire® Pulse Lavage Component Kit (includes disposable instrument, tubing, battery pack)</td>
<td>6/box</td>
</tr>
<tr>
<td>201-03-00</td>
<td>Knee Kit (includes MicroAire® Pulse Lavage Component Kit and shower spray tip with splash shield)</td>
<td>6/box</td>
</tr>
<tr>
<td>201-04-00</td>
<td>Hip Kit (includes MicroAire® Pulse Lavage Component Kit, femoral spray tip and shower spray tip with splash shield)</td>
<td>6/box</td>
</tr>
<tr>
<td>201-05-00</td>
<td>Fan Spray Kit (includes MicroAire® Pulse Lavage Component Kit and fan spray tip with splash shield)</td>
<td>6/box</td>
</tr>
</tbody>
</table>

TIPS

<table>
<thead>
<tr>
<th>REF Number</th>
<th>DESCRIPTION</th>
<th>UOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>201-00-37</td>
<td>Shower spray tip with splash shield</td>
<td>6/box</td>
</tr>
<tr>
<td>201-00-44</td>
<td>Fan spray tip with splash shield</td>
<td>6/box</td>
</tr>
<tr>
<td>201-00-46</td>
<td>Femoral spray tip</td>
<td>6/box</td>
</tr>
<tr>
<td>201-00-50</td>
<td>Shower Spray tip</td>
<td>6/box</td>
</tr>
<tr>
<td>201-00-51</td>
<td>Fan spray tip</td>
<td>6/box</td>
</tr>
<tr>
<td>201-00-52</td>
<td>Femoral brush tip</td>
<td>6/box</td>
</tr>
</tbody>
</table>

SPLASH SHIELDS

<table>
<thead>
<tr>
<th>REF Number</th>
<th>DESCRIPTION</th>
<th>UOM</th>
</tr>
</thead>
<tbody>
<tr>
<td>201-00-80</td>
<td>Splash shield, 6 inch (15.2 cm)</td>
<td>6/box</td>
</tr>
</tbody>
</table>
SYMBOL DEFINITIONS

Consult Instruction for Use

**STERILE** Method of Sterilization

European Conformity Mark

Date of Manufacture, YYYY-MM.

Product Catalog Number

Use By Date, YYYY-MM

Product Lot Number

Temperature Limitations

Humidity Limitations

Authorized European Representative

Tip Locked

Tip Unlocked

Normal Operation

High Pulsatile Operation

Do Not Immerse

Type BF Applied Part

Single Patient Use Only - Do not resterilize

Short time operation, maximum 8 minutes

Contents sterile only if package and seal are undamaged and product has not exceeded its Use By Date

cTUVus Certification
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).

INSTRUCTIONS FOR USE

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

![Figure A](image)

2. Connect MicroAire® 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](image)

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

![Figure C](image)

4. Pull up the tip lock to the unlocked position to prepare it for tip insertion (Figure C).

5. Insert the desired tip into MicroAire® Pulse Lavage (Figure D).

![Figure D](image)
6. Push down the tip lock to the locked position to secure the desired tip in place (Figure E).

7. Prime MicroAire® Pulse Lavage by depressing the trigger to either the normal (►) or high pulsatile position (►►) for a few seconds while aiming the tip towards the surgical site (Figure F).

8. 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.

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

10. To change tip, turn off MicroAire® Pulse Lavage, pull up and release tip lock. Pull out existing tip and replace with desired tip.

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. MicroAire® 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.

NOTE
- Prior to use, make sure that the tip lock is fully engaged and the tip is locked to the instrument. 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.
- MicroAire® 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.

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
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  MicroAire® 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 90 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, provided that the faulty handpiece is returned. This warranty is non-transferrable.

In the event of abuse, misuse, or use for anything other than the manner described in 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 MicroAire® PULSE LAVAGE.

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

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter. WATTS</th>
<th>Separation distance according to the frequency of transmitter. METERS</th>
</tr>
</thead>
<tbody>
<tr>
<td>150 kHz to 80 MHz</td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>d=1.2 √P</td>
<td>d=1.2 √P</td>
</tr>
<tr>
<td>0.01 0.12</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1 0.38</td>
<td>0.38</td>
</tr>
<tr>
<td>1 1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>10 3.8</td>
<td>3.8</td>
</tr>
<tr>
<td>100 12</td>
<td>12</td>
</tr>
</tbody>
</table>

IEC 60601-1-2 Table 206

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 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

<table>
<thead>
<tr>
<th>Vibration Exposure</th>
<th>$a_{hv}$ (m/s²)</th>
<th>1.22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncertainty K (m/s²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Noise Emission Value</td>
<td>$L_{PA}$ (db(A))</td>
<td>75</td>
</tr>
</tbody>
</table>

ELECTROMAGNETIC EMISSIONS

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

<table>
<thead>
<tr>
<th>EMISSIONS TEST</th>
<th>COMPLIANCE</th>
<th>ELECTROMAGNETIC ENVIRONMENT - GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td>The MicroAire® Pulse Lavage 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.</td>
</tr>
<tr>
<td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>RF emissions CISPR 14-1</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

IEC 61000-3-2 Table 201

**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.

ELECTROMAGNETIC IMMUNITY

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

<table>
<thead>
<tr>
<th>IMMUNITY TEST</th>
<th>IEC 60601 TEST LEVEL</th>
<th>COMPLIANCE LEVEL</th>
<th>ELECTROMAGNETIC ENVIRONMENT – GUIDANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact</td>
<td>±6 kV contact</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td></td>
<td>±8 kV air</td>
<td>±8 kV air</td>
<td></td>
</tr>
<tr>
<td>Electrical fast transient/ burst IEC 61000-4-4</td>
<td>±2 kV for power supply lines</td>
<td>Not applicable. The device is battery powered.</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±1 kV for input/output lines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV differential mode</td>
<td>Not applicable. The device is battery powered.</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td></td>
<td>±2 kV for common mode</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
--- | --- | --- | ---
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11 | <5% U (95% dip in U) for 0, 5 cycle 40% U (60% dip in U) for 5 cycles 70% U (30% dip in U) for 25 cycles <5% U (>95% dip in U) for 5 seconds | Not applicable. | Mains power quality should be that of a typical commercial or hospital environment. If the user of the MicroAire® Pulse Lavage requires continued operation during power mains interruptions, it is recommended that the MicroAire® 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 | 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.

Conducted RF IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | 3 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the MicroAire® Pulse Lavage, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended Separation distance:  
\[ d = 1.2 \sqrt{P} \]  
\[ d = 2.3 \sqrt{P} - 800 \text{ MHz to } 2.5 \text{ GHz} \]  
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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with following symbol: 

Radiated RF IEC 61000-4-3 | 3 V/m 80 MHz to 2.5 GHz | 3 V/m | 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 MicroAire® Pulse Lavage is used exceeds the applicable RF compliance level above, the MicroAire® 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 MicroAire® Pulse Lavage. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

\[ IEC 60601-1-2 \text{ Table 204} \]

**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.

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.