

Device(s):	1000 & 2000 Series Electric and Pneumatic Motors and Couplers; 5000 Series Electric Motors and Couplers, SmartDriver Electric, Battery and Pneumatic Instrument and Couplers; 7000 Series Electric, Battery and Pneumatic Instruments and Couplers, Power Assisted Lipoplasty Electric and Pneumatic Instrument; Pulse Lavage Instrument, Hoses, Cables, Carpal Tunnel Release System (CTRS)
Warnings:	<ul style="list-style-type: none"> • Universal precautions for handling contaminated materials should be observed at all times. • DO NOT lubricate or oil the handpieces. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubrication. • DO NOT immerse the handpiece in any fluid. • DO NOT utilize cleaning solutions that are not mild pH unless they are approved for use with Anodized Aluminum and Surgical Instruments. • DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.
Limitations on reprocessing	Repeated processing, according to the instructions below, has minimal effect on MicroAire reusable surgical instruments. End of life is normally determined by wear and damage due to use.

INSTRUCTIONS

Point of Use:	Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a cloth dampened with purified water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning (MAXIMUM 30 minutes).																																													
Preparation for decontamination	<ol style="list-style-type: none"> 1) Remove all inserted surgical cutting accessories (blades, burs, rasps, drill bits, etc.) from the handpiece. Disposable surgical accessories should be discarded after use, handling them as any contaminated sharp accessory is handled. Reuse of surgical cutting accessories is not recommended. 2) Disassemble instruments and accessories 3) For Automated Cleaning install the Washer Cap for the instruments listed <table border="1" style="margin-left: 20px;"> <tr> <td>MicroAire Style Hose Connector – CAP-100</td> <td>Hall Style Hose Connector – CAP-200</td> </tr> <tr> <td>3M Mini Style Hose Connector – CAP-300</td> <td>3M Maxi Style Hose Connector – CAP-300MAX</td> </tr> <tr> <td>Stryker Style Hose Connector – CAP-400</td> <td>Synthes Style Hose Connector – CAP-600</td> </tr> <tr> <td>PAL-600E -- CAP-600E</td> <td></td> </tr> </table> 4) For Manual Cleaning install the Washer Cap (as defined above) or the appropriate pneumatic hose or electric cable for the instrument. If pneumatic hose is used in lieu of a washer cap, the hose must be drained of all residual fluids prior to sterilization. This can be accomplished by holding the hose end over end to allow all liquid to drain. 	MicroAire Style Hose Connector – CAP-100	Hall Style Hose Connector – CAP-200	3M Mini Style Hose Connector – CAP-300	3M Maxi Style Hose Connector – CAP-300MAX	Stryker Style Hose Connector – CAP-400	Synthes Style Hose Connector – CAP-600	PAL-600E -- CAP-600E																																						
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Preparation of Cleaning Agent	Prepare mild pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Determination of cleaning agents shall be by local or country regulations.																																													
Cleaning: Automated	<ol style="list-style-type: none"> 1) Load the medical devices into the Washer Disinfector. <ol style="list-style-type: none"> a) Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed). DO NOT overload the trays. b) Arrange medical devices so that cannulations are not horizontal and battery openings are oriented downwards (to assist drainage). 2) The minimum recommended Washer/Disinfector cycle is below: <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>#</th> <th>Title</th> <th>Detergent</th> <th>Minutes</th> <th>Temp</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Pre-Wash</td> <td>Mild pH Enzymatic *</td> <td>4</td> <td>< = 50 °C (122 °F)</td> </tr> <tr> <td>2</td> <td>Rinse</td> <td>None</td> <td>1**</td> <td>< = 50 °C (122 °F)</td> </tr> <tr> <td>3</td> <td>Wash</td> <td>Mild pH</td> <td>4</td> <td>> = 60 °C (140 °F)</td> </tr> <tr> <td>4</td> <td colspan="4">Drain for 1 minute minimum</td> </tr> <tr> <td>5</td> <td>Rinse</td> <td>None</td> <td>2**</td> <td>> = 60 °C (140 °F)</td> </tr> <tr> <td>6</td> <td colspan="4">Drain for 1 minute minimum</td> </tr> <tr> <td>7</td> <td>Thermal Disinfect</td> <td>None</td> <td>10</td> <td>> = 93 °C (200 °F)</td> </tr> <tr> <td>8</td> <td colspan="4">Drain for 1 minute minimum</td> </tr> </tbody> </table> <p style="margin-left: 20px;">* Detergent can be omitted at the pre-wash stage if the equipment does not have this ability. ** If not using mild pH detergent, extend rinse time if possible to reduce possible degradation.</p> <p style="margin-left: 20px;"><i>Note: Washer/Disinfectors should comply with the requirements of ISO 15883. They should be properly installed and be regularly tested in accordance with ISO 15883.</i></p> 	#	Title	Detergent	Minutes	Temp	1	Pre-Wash	Mild pH Enzymatic *	4	< = 50 °C (122 °F)	2	Rinse	None	1**	< = 50 °C (122 °F)	3	Wash	Mild pH	4	> = 60 °C (140 °F)	4	Drain for 1 minute minimum				5	Rinse	None	2**	> = 60 °C (140 °F)	6	Drain for 1 minute minimum				7	Thermal Disinfect	None	10	> = 93 °C (200 °F)	8	Drain for 1 minute minimum			
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Cleaning: Manual	<ol style="list-style-type: none"> 1. Clean the handpiece and couplers thoroughly with warm (>60°C/140°F) water, mild pH enzymatic detergent, and soft brush. Scrub the handpiece with the brush, paying close attention to instrument crevices. 2. If using pneumatic devices, please clean the pneumatic air hose thoroughly with warm (>60°C/140°F) water
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- with a mild pH enzymatic detergent.
3. Rinse handpieces, couplers and pneumatic air hoses thoroughly under running (<50°C/122°F) water for a minimum of 2 minutes.
 4. Clean the handpiece and couplers thoroughly with warm (>60°C/140°F) water, mild pH enzymatic detergent, and soft brush. Scrub the handpiece with the brush, paying close attention to instrument crevices.
 5. Flush the lumens of instruments and the nose of drills and wire drivers with a Water-Pik or similar device. Flushing removes blood, debris and saline deposits.
 6. Rinse handpieces, couplers and pneumatic air hoses thoroughly under running (<50°C/122°F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.
 7. After rinsing all pneumatic air hoses it is required that the air hose be drained of all residual cleaning fluids. This can be accomplished by holding the hose end over end to allow all liquid to drain.

Disinfection: Disinfection is only acceptable as an adjunct to full terminal sterilization for reusable surgical instruments. See sterilization section below.

Drying: Wipe off any water from the handpiece with a soft lint-free towel. An air gun can also be used to dry the handpiece.

- Maintenance, Inspection and Function Testing:**
1. Remove the Washer Cap, Pneumatic Hose or Electric Cable from the handpiece.
 2. Carefully inspect each device to ensure that all visible blood and soil has been removed.
 3. Visually inspect for damage and/or wear.
 4. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
 5. Where instruments form part of a larger assembly, check that the devices assemble with mating components

Note: If concerns are noted that may compromise the function of the device, please contact your MicroAire representative.

- Packaging:**
1. Single Instruments -- A standard medical grade steam sterilization wrap may be used. Ensure that the wrap is large enough to contain the instrument without stressing the packaging. (ANSI/AAMI ST46-1993)
 2. Sets of Instruments – sets of instruments may be loaded into dedicated instrument trays or general purpose sterilization trays for sterilization. If applicable, use standard medical grade steam sterilization wrap following the AAMI double wrap method (ANSI/AAMI ST46-1993)

Sterilization: Steam sterilize using one of the following cycles per ISO 17665:

Sterilization Cycle	Instrument	Minimum Time & Temp	Min Heated Dry time
Pre-Vacuum Steam	Single Instrument OR In Sterilization Tray	3 minute Full Cycle @ 134 - 137 °C (273 - 279 °F)	8 minutes
		4 minute Full Cycle @ 132 - 135 °C (270 - 275 °F)	8 minutes
Gravity Displacement	Single Instrument	30 minute Full Cycle @ 132 - 135 °C (270 - 275 °F)	8 minutes
	Sterilization Tray	45 minute Full Cycle @ 132 - 135 °C (270 - 275 °F)	8 minutes

Note: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes at 134 °C (273 °F). (WHO/CDS/CSR/2000.3, “Who Infection Control Guidelines for TSE,” March 1999).

Storage: Sterile, packaged instruments 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.

- Additional Information:**
- Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
 - Do not use instruments when they are still warm. They need to cool down to room temperature
 - Do not soak instruments to cool them down or wrap cold towels around them.

Manufacturer Contact: MicroAire Surgical Instruments, LLC
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 Charlottesville, VA 22911
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Inside the USA dial 1-800-722-0822
 Outside the USA, dial the local international access code followed by +1-434-975-8000