NOTES

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PAL-650 Instrument System Instruction Manual

INDICATIONS FOR USE

The PAL-650 Power Assisted Lipoplasty device is intended to assist the surgeon with the removal of tissue or fluid from the body during general surgical procedures including suction lipoplasty. These procedures are performed to treat a variety of conditions, including, but not limited to:

- Localized Deposits of Subcutaneous Fat
- Gynecomastia
- Lipomas
- Lymphedema

APPLICABLE INSTRUMENT PART NUMBERS

REF Number	Description
PAL-650	PAL Electric Handpiece
1006-PALE	Electric cable
1020	Standard Electric Console
1025	Universal Electric Console

APPLICABLE ACCESSORY PART NUMBERS

REF Number	Description
PAL-900	Aspiration Tubing Set
PAL-9006	Aspiration Tubing Set (sold in a box of six)
6401-000	1025 Electric Console Foot Pedal
PAL-500	PAL Sterilization Tray
PAL-R508LL	5mm 30cm Multi-Use Flared Mercedes Cannula
PAL-R508LS	5mm 22cm Multi-Use Flared Mercedes Cannula
PAL-R507LL	5mm 30cm Multi-Use Helixed Tri-Port III Cannula
PAL-R507LS	5mm 22cm Multi-Use Helixed Tri-Port III Cannula
PAL-R407LL	4mm 30cm Multi-Use Helixed Tri-Port III Cannula
PAL-R407LS	4mm 22cm Multi-Use Helixed Tri-Port III Cannula
PAL-R506LL	5mm 30cm Multi-Use Mirrored Tri-Port II Cannula

THE MICROAIRE PAL INSTRUMENT IS COVERED BY THE FOLLOWING PATENTS

US Patent No. 5911700, 6139518, 6258054

Canadian Patent No. 2,282,516

Brazilian Patent No. PI 9808317-1

Mexican Patent No. 233624

European Patent No. 1 006 895

Austrian Part of EP Patent No. 1 006 895

Belgium Part of European Patent No. 1 006 895

Denmark Part of European Patent No. 1 006 895

Italy Part of European Patent No. 1 006 895

French Part of EP Patent No. 1 006 895

Netherlands Part of European Patent No. 1 006 895

Finland Part of European Patent No. 1 006 895

German Part of European Patent No. 1 006 895

Greece Part of European Patent No. 1 006 895

Luxembourg Part of European Patent No. 1 006 895

Portugal Part of European Patent No. 1 006 895

Spain Part of European Patent No. 1 006 895

Sweden Part of European Patent No. 1 006 895

Swiss Part of EP Patent No. 1 006 895

British Part of European Patent No. 1 006 895

Other International Patents May Apply or Pending

WARRANTY

MicroAire Surgical Instruments LLC warrants its PAL system to be free from defects in material and workmanship in their manufacture for a period of 1 year from the original purchase date by the end customer. The warranty is limited to the repair or replacement of the product without charge.

This warranty is void in the event of abuse, misuse, or use in other than normal surgical environment, or in the event of disassembly, alteration, or repair of the product not authorized by the manufacturer, or in the event that the product has not been used in a reasonable manner and in compliance with the written instructions furnished by the Manufacturer.

All other expressed or implied warranties of fitness and merchantability are excluded here from, and the manufacturer shall have no liability of any kind for incidental or consequential damages.

EXTENDED WARRANTY / SERVICE AGREEMENT

Extended warranties and service agreements are available on MicroAire power equipment. Extended warranties may be purchased while the equipment is covered by the original warranty. If the equipment is out of warranty, it must first be restored, if necessary, to full serviceable condition before being eligible for a service agreement.

REFERENCES

Association for the Advancement of Medical Instrumentation (AAMI)

AAMI Good Hospital Practices: Steam Sterilization and Sterility Assurance. 1995 Edition. pp. 1-60.

AAMI Good Hospital Practices: Flash Sterilization-Steam Sterilization of Patient-Care Items for Immediate Use. 1995 Edition. pp. 61-79.

AAMI Good Hospital Practices: Handling and Biological Decontamination of Reuseable Medical Devices. 1995 Edition. pp. 393-414.

Association of Operating Room Nurses (AORN)

Association of Operating Room Nurses. "Recommended practices for care of instruments, scopes, and powered surgical instruments." In Standards & Recommended Practices. Denver, CO: AORN, 1995. pp. 197-204.

Association of Operating Room Nurses. "Recommended practices for care sterilization in the practice setting." In Standards & Recommended Practices. Denver, CO: AORN, 1995. pp. 267-278.

U.S. Centers for Disease Control and Prevention (CDC)

Centers for Disease Control. "Recommendations for HIV transmission in health-care settings." In Morbidity and Mortality Weekly Report 36 (August 21, 1987): 1S-12S.

Garner, Julia S., and Martin S. Favero. Guideline for Handwashing and Hospital Environmental Control, 1985. Atlanta: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, 1985.

U.S. Occupational Safety and Health Administration (OSHA)

Occupational Safety and Health Administration. "Occupational exposure to bloodborne pathogens, final rule." Federal Register 56 (December 6, 1991): 64004-64182.

REF Number	Description
PAL-R506LS	5mm 22cm Multi-Use Mirrored Tri-Port II Cannula
PAL-R406LL	4mm 30cm Multi-Use Mirrored Tri-Port II Cannula
PAL-R406LS	4mm 22cm Multi-Use Mirrored Tri-Port II Cannula
PAL-R505LL	5mm 30cm Multi-Use Double Mercedes Cannula
PAL-R505LS	5mm 22cm Multi-Use Double Mercedes Cannula
PAL-R405LL	4mm 30cm Multi-Use Double Mercedes Cannula
PAL-R405LS	4mm 22cm Multi-Use Double Mercedes Cannula
PAL-R504LL	5mm 30cm Multi-Use Mercedes Cannula
PAL-R504LS	5mm 22cm Multi-Use Mercedes Cannula
PAL-R404XL	4mm 40cm Multi-Use Mercedes Cannula
PAL-R404LL	4mm 30cm Multi-Use Mercedes Cannula
PAL-R404LS	4mm 22cm Multi-Use Mercedes Cannula
PAL-R304LL	3mm 30cm Multi-Use Mercedes Cannula
PAL-R304LS	3mm 22cm Multi-Use Mercedes Cannula
PAL-R304LM	3mm 15cm Multi-Use Mercedes Cannula
PAL-R244LM	2.4mm 15cm Multi-Use Mercedes Cannula
PAL-R408LL	4mm 30cm Multi-Use Flared Mercedes Cannula
PAL-R403LL	4mm 30cm Multi-Use Tri-Port III Cannula
PAL-R403LS	4mm 22cm Multi-Use Tri-Port III Cannula
PAL-R303LL	3mm 30cm Multi-Use Tri-Port III Cannula
PAL-R303LS	3mm 22cm Multi-Use Tri-Port III Cannula
PAL-R402LL	4mm 30cm Multi-Use Tri-Port II Cannula
PAL-R402LS	4mm 22cm Multi-Use Tri-Port II Cannula
PAL-R302LL	3mm 30cm Multi-Use Tri-Port II Cannula
PAL-R302LS	3mm 22cm Multi-Use Tri-Port II Cannula
PAL-R300LL	3mm 30cm Multi-Use Single Port Cannula
PAL-R300LS	3mm 22cm Multi-Use Single Port Cannula
PAL-R300SS	3mm 15cm Multi-Use Single Port Cannula
PAL-R240LS	2.4mm 22cm Multi-Use Single Port Cannula - 7.5mm port length
PAL-R240SS	2.4mm 22cm Multi-Use Single Port Cannula - 5mm port length
PAL-R240LM	2.4mm 22cm Multi-Use Single Port Cannula
PAL-R30S3	3mm 15cm Multi-Use 3-Hole Spatula Cannula
PAL-R30S2	3mm 15cm Multi-Use 2-Hole Spatula Cannula
PAL-R24S1	2.4mm 15cm Multi-Use 1-Hole Single Port Cannula
PAL-507LL	5mm 30cm Single Use Helixed Tri-Port III Cannula

REF Number	Description
PAL-507LS	5mm 22cm Single Use Helixed Tri-Port III Cannula
PAL-407LL	4mm 30cm Single Use Helixed Tri-Port III Cannula
PAL-407LS	4mm 22cm Single Use Helixed Tri-Port III Cannula
PAL-506LL	5mm 30cm Single Use Mirrored Tri-Port II Cannula
PAL-506LS	5mm 22cm Single Use Mirrored Tri-Port II Cannula
PAL-406LL	4mm 30cm Single Use Mirrored Tri-Port II Cannula
PAL-406LS	4mm 22cm Single Use Mirrored Tri-Port II Cannula
PAL-505LL	5mm 30cm Single Use Double Mercedes Cannula
PAL-505LS	5mm 22cm Single Use Double Mercedes Cannula
PAL-405LL	4mm 30cm Single Use Double Mercedes Cannula
PAL-405LS	4mm 22cm Single Use Double Mercedes Cannula
PAL-504LL	5mm 30cm Single Use Mercedes Cannula
PAL-504LS	5mm 22cm Single Use Mercedes Cannula
PAL-404LL	4mm 30cm Single Use Mercedes Cannula
PAL-404LS	4mm 22cm Single Use Mercedes Cannula
PAL-304LL	3mm 30cm Single Use Mercedes Cannula
PAL-304LS	3mm 22cm Single Use Mercedes Cannula
PAL-304LM	3mm 15cm Single Use Mercedes Cannula
PAL-244LM	2.4mm 15cm Single Use Mercedes Cannula
PAL-403LL	4mm 30cm Single Use Tri-Port III Cannula
PAL-403LS	4mm 22cm Single Use Tri-Port III Cannula
PAL-303LL	3mm 30cm Single Use Tri-Port III Cannula
PAL-303LS	3mm 22cm Single Use Tri-Port III Cannula
PAL-402LL	4mm 30cm Single Use Tri-Port II Cannula
PAL-402LS	4mm 22cm Single Use Tri-Port II Cannula
PAL-302LL	3mm 30cm Single Use Tri-Port II Cannula
PAL-302LS	3mm 22cm Single Use Tri-Port II Cannula
PAL-300LL	3mm 30cm Single Use Single Port Cannula
PAL-300LS	3mm 22cm Single Use Single Port Cannula
PAL-300SS	3mm 15cm Single Use Single Port Cannula
PAL-240LS	2.4mm 22cm Single Use Single Port Cannula - 7.5mm port length
PAL-240SS	2.4mm 22cm Single Use Single Port Cannula - 5mm port length
PAL-240LM	2.4mm 15cm Single Use Single Port Cannula
PAL-30S3	3mm 15cm Single Use 3-Hole Spatula Cannula
PAL-30S2	3mm 15cm Single Use 2-Hole Spatula Cannula

MICROAIRE REPAIR SERVICE

Responsive service comes with every MicroAire product. If a problem should arise with your equipment, contact our Customer Service Department at:

	Telephone:	FAX:	Email:
USA:	800-722-0822	800-438-6309	inquiry@microaire.com
OUTSIDE USA:	434-975-8000	434-975-4134	intlsvc@microaire.com

NOTE: *Mailing address information located on back cover.*

We may be able to help solve the problem quickly without returning the item for service. **DO NOT** disassemble or attempt to service the equipment. It can only be serviced by MicroAire or an Authorized MicroAire Repair Facility. Unauthorized service will void the warranty.

To return an item for service, follow this procedure:

1. Contact Customer Service for a Return Material Authorization (RMA) number.

   NOTE: DO NOT return equipment without an RMA number. This could cause delays in service, and/or problems tracking your return.

2. Clean and sterilize equipment before sending for repair.

3. Along with the items sent for repair, enclose a description of the problem encountered, the type of use, the place of use, a contact name and a telephone number. This information is helpful to our repair technicians.

4. If the instrument is out of warranty, enclose a purchase order number with the instrument. If the instrument is under warranty, include the purchase date.

5. In the United States, ship the merchandise by Express Mail, Federal Express, or UPS Blue Label to prevent shipping delays. From outside the United States, return goods by Federal Express or Air Freight.

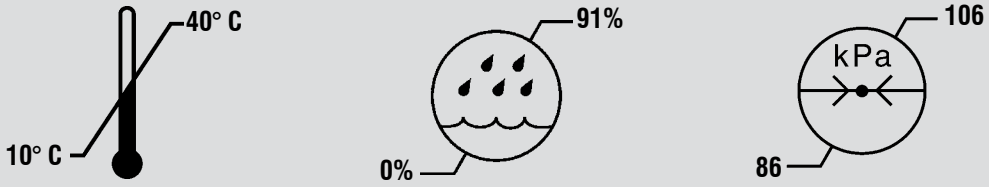
6. Return the merchandise prepaid.

7. If an estimate of repair costs is needed before the repair technicians start work, include the name and telephone number of the person to contact.

8. We will repair and reship the item by 2nd Day Air within the United States and by Federal Express or Air Freight outside the United States unless specified otherwise.

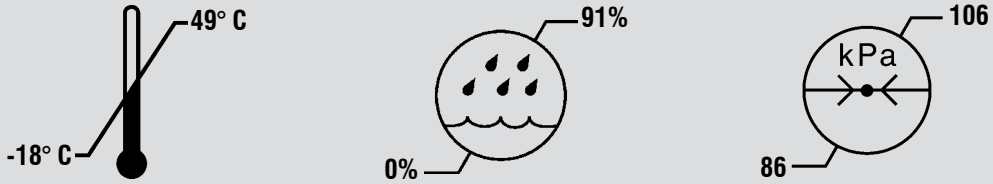
ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS



WARNING: *Monitor instrument temperature if operating handpiece at ambient temperatures above 80° F / 27° C to prevent burning of personnel or patient.*

SHIPPING AND STORAGE CONDITIONS



Shipping: *The materials and components used in the contruction of these devices were selected to ensure that the devices could be shipped by any standard commercial method without special handling conditions.*

IN HOSPITAL SERVICE

All MicroAire equipment should be inspected and tested periodically in accordance with the facility's bioengineering policy. Such service should be documented within the bioengineering department.

WARNING: *Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product's warranty, and the customer will be responsible for any costs related to returning the product to working condition.*

PERIODIC INSPECTION

Because of the stressful nature of surgical use, decontamination, and sterilization, we recommend that all instruments be returned for routine inspection and service at least once a year. There is no charge for this service during the warranty periods.

REF Number	Description
PAL-24S1	2.4mm 15cm Single Use 1-Hole Spatula Cannula
PAL-507LLT	5mm 30cm Single Use Turbo Helixed Tri-Port III Cannula
PAL-505LLT	5mm 30cm Single Use Turbo Double Mercedes Cannula
PAL-405LLT	4mm 30cm Single Use Turbo Double Mercedes Cannula
PAL-404LLT	4mm 30cm Single Use Turbo Mercedes Cannula
PAL-404LST	4mm 30cm Single Use Turbo Mercedes Cannula
PAL-700	Luer Lock Adapter for Manual Cannula
CAP-600E	Washer Disinfector Cap

INTRODUCTION

This manual has been written to help describe the procedures required to keep the MicroAire PAL-650™ system operating properly.

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

1. **NOTE:** *Used to point out the easiest means of carrying out the techniques.*
2. **WARNING:** *Used to indicate that the safety of the patient and hospital personnel could be involved.*
3. **CAUTION:** *Used to point out special procedures or precautions that must be followed to avoid damaging the instrument.*

GENERAL WARNINGS

WARNING: *Use care to ensure that there is no electromagnetic interference between these devices and other devices in use.*

CAUTION: *Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).*

CAUTION: *See REF 1020 Instruction Manual IM-1020/REF 1025 Instruction Manual IM-1025 for detailed information on the 1020 and 1025 electric consoles.*

NOTE: *All personnel should become familiar with the power equipment before it is setup for use in any procedure. Personnel that are trained should include, but not be limited to, central processing personnel, members of the surgical team, and the bioengineering department.*

WARNING: *Only use MicroAire aspiration tubing, REF PAL-900. Using other tubing may result in tubing failure and unfavorable results.*

DUTY CYCLE

The PAL-650 Handpiece is designed to operate for up to 20 minutes of continuous use with intermittent operation over a period of 1-2 hours.

SYMBOL DEFINITIONS

C	**Attention, See Instructions For Use**
CE 0086	European Conformity Mark with MicroAire Notified Body Number
a	**DO NOT** Lubricate
b	**DO NOT** Immerse
h	**DO NOT** Expose to Stray Magnetic Fields
m	Date of Manufacture - YYYY-MM
REF	Product Catalog Number
SN	Product Serial Number
LOT	Product LOT Number
	Temperature Limitations
	Humidity Limitations
	Atmospheric Pressure Limitations
EC REP	Authorized European Representative
SAFE	Instrument is OFF
RUN	Instrument is running

NOTE: *Where there is a concern about TSE/vCJD contamination, the World Health Organization (WHO) 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).*

NOTE: DO NOT *process powered surgical instruments in equipment that uses peracetic acid as a liquid sterilant.*

NOTE: *Ethylene Oxide (EtO) is* **NOT** *recommended for powered surgical instruments because lengthy aeration time is needed to assure that no ethylene oxide is left in the internal mechanisms or on the surface of the instrument.*

11. 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.

12. Additional Information

a. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

b. "Flash" Gravity-Steam.

1.) "Flash" sterilization: Surgical centers that wish to steam sterilize patient care items for immediate use shall at a minimum follow the requirements as outlined in ANSI/AAMI ST37:1996. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Please follow the steps for decontamination of the instrument prior to any sterilization process including "flash" sterilization. The processed items must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use. There is **NO** storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed. When performed correctly,flash sterilization is safe and effective for sterilization of medical devices (AAMI ST37:1996).

2.) Re-usable surgical instruments with moving parts require a dry cycle to keep the product functioning appropriately. "Flash" Gravity-Steam sterilization with **NO** dry time is **NOT** recommended as a normal process of sterilization.

3.) Instrument/Accessory ONLY Exposure.
Time = **11 minute FULL CYCLE**
Exposure Temperature = **270-275 °F (132-135 °C)**
Minimum Dry Time = **8 minutes**
Materials - **UNWRAPPED ONLY**

NOTE: "Flash" sterilization poses special challenges to maintaining sterility once the device has been removed from the sterilizer.

c. Because of the stressful nature of surgical use, decontamination, and sterilization, MicroAire recommends that the Handpiece, Electric Cable, and Electric Console be returned to the factory for routine inspection and service at least once a year. There is no charge for service during the warranty period.

1. At 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 cannulae prior to cleaning (MAXIMUM 30 minutes).

2. Preparation for Decontamination
Disassemble the cannulae from the instrument and disposable tubing. Locate the appropriate sized soft bristled cylindrical brush:

- For 2.4mm cannulae utilize REF 9600-124
- For 3.0mm cannulae utilize REF 9600-130
- For 4.0mm cannulae utilize REF 9600-140
- For 5.0mm cannulae utilize REF 9600-150

3. Preparation of Cleaning Agent
Prepare neutral pH enzyme cleaning agents at the maximum use-dilution and temperature recommended by the manufacturer. Determination of cleaning agents shall be by local or country regulations.

4. Cleaning: Auto
NOT Recommended

5a. Cleaning: Manual with Ultrasonic
a. Pre-soak the cannulae for 20 minutes in enzymatic cleaner.
b. Clean the inside diameter of the cannulation shaft (lumen) using the appropriate sized soft bristled cylindrical brush, while submerged in the enzymatic cleaner. The inside diameter of the cannulae is to be brushed until no visible soil comes out of the tip of the cannulae or out of the back of the cannulae where the brush is inserted.
c. Scrub the hub and exterior cannulae shaft (lumen) with a soft bristled brush while submerged in the enzymatic cleaner until all visible soil has been removed from the exterior surfaces.
d. Place the cannulae in an ultrasonic bath (40 kHz) for an additional 20 minutes in enzymatic cleaner.
e. Rinse all items thoroughly under running (<50 °C / 122 °F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.

5b. Cleaning: Manual without Ultrasonic
a. Pre-soak the cannulae for 60 minutes in enzymatic cleaner.
b. Clean the inside diameter of the cannulation shaft (lumen) using the appropriate sized soft bristled cylindrical brush, while submerged in the enzymatic cleaner. The inside diameter of the cannulae is to be brushed until no visible soil comes out of the tip of the cannulae or out of the back of the cannulae where the brush is inserted.
c. Scrub the hub and exterior cannulae shaft (lumen) with a soft bristled brush while submerged in the enzymatic cleaner until all visible soil has been removed from the exterior surfaces.
d. Rinse all items thoroughly under running (<50 °C / 122 °F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.

6. Disinfection
Disinfection is only acceptable as an adjunct to full terminal sterilization for Multi-Use surgical instruments. See sterilization section below.

7. Drying
Wipe off any water from the cannulae with a soft lint-free towel. An air gun can also be used.

8. Maintenance, Inspection and Function Testing
a. Carefully inspect each device to ensure that all visible blood and soil has been removed.
b. Visually inspect for damage and/or wear.
c. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
d. 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.

9. Packaging
a.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).
b. 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).

10. Sterilization
Steam sterilize using one of the following cycles:

a. Prevacuum Steam Sterilization for a single device or in a sterilization tray: **4 minute Full Cycle at 132-135 °C (270-275 °F), 8 minute minimum heated dry time**

b. Gravity Displacement Steam Sterilization for a single device or in a sterilization tray: **35 minute Full Cycle @ 132 - 135 °C (270-275 °F), 8 minute minimum heated dry time**

SYSTEM SETUP

1. Starting with the console, plug the wall outlet power cord into the back of the unit. The plug only inserts one way.

2. Plug the handpiece cable into one of the handpiece receptacles located on the left front of the console.

   NOTE: *Be sure to match the red dot on the cable with the red dot on the console receptacle before inserting.*

   NOTE: *If using a foot pedal, make sure the handpiece cable is plugged into the receptacle immediately to the right of the foot pedal receptacle.*

3. Firmly hold the handpiece and insert the handpiece cable into the back end of the handpiece.

   Note: *Be sure to match the red dot on the cable with the red dot on the handpiece before inserting.*

4. If using a foot pedal, connect the foot pedal cable to appropriate outlet on the front of the console. Again, make sure the red dot on the cable is aligned with the red dot on the receptacle before inserting.

   WARNING: *When using the foot pedal, be careful not to activate the throttle while unplugging the foot pedal.*

5. Before plugging the wall outlet power cord into the wall outlet, check to see that the power switch on the bottom right hand side is in the "OFF" position. Plug the cable, from the back of the console, into a grounded outlet and turn the power switch to "ON" to activate the unit. The console will operate on 100-130 or 200-230 VAC grounded outlets. Once the unit is activated all the LED displays will light up.

   NOTE: *The "OFF" position is designated by "O" and the "ON" position by "I".*

6. To attach cannula to instrument make sure the throttle is in the "SAFE" position. Slide small end of tubing over the sterile cannula connector *(Figure A)*. Slide cannula on to instrument; tubing should be on bottom *(Figure B)*. Push tubing into groove on bottom of instrument *(Figure C)*. Then connect large end of tubing to suction device.

7. To operate the handpiece without the foot pedal, gently slide the safety throttle from the "SAFE" to the "RUN".

8. To set the maximum speed at other than 100%, slide the throttle to the "RUN" position or depress the foot pedal and hold until the instrument begins to run. Use the control knob on the console to set the desired maximum speed.

9. To remove cannula from instrument make sure the throttle is in the "SAFE" position. Detach tubing from cannula then press down tab on cannula and pull cannula away from instrument.

   WARNING: *Always make sure the throttle is in the "SAFE' position when the handpiece is not in use or when inserting or removing cannulae.*

Figure A

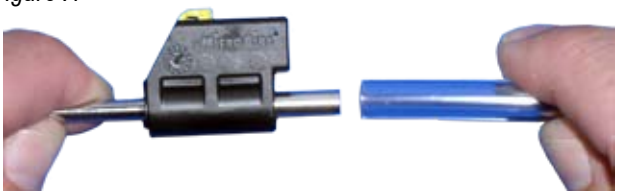


Figure B

Figure C

PRE USE CHECKLIST

Make sure unit functions properly prior to use. If not, contact the factory for service repair.

HANDPIECE

The PAL-650 handpiece can be operated by sliding a throttle or by pressing on a foot pedal. When the throttle is in the “SAFE” position the handpiece will not operate, unless used with 6401-000, foot pedal *(Figure D & E)*.

WARNING: *Always slide the throttle to the “SAFE” position when attaching the cannula and tubing or when the instrument is not in use.*

NOTE: *The handpiece throttle lever will not operate the instrument if the foot pedal is plugged into the console.*

To operate the handpiece by the throttle, start in the “SAFE” position and gradually slide throttle until desired speed is achieved.

Figure D “SAFE”

Figure E “RUN”

CANNULA AND TUBING

The PAL-650™ accepts only MicroAire cannula with the special connector.

WARNING: *Only use MicroAire aspiration tubing, REF PAL-900. Using other tubing may result in tubing failure and unfavorable results.*

MULTI-USE CANNULAE CLEANING & STERILIZATION INSTRUCTIONS

CAUTION: DO NOT sterilize single-use cannula. The connector will warp or crack.

WARNING: Universal precautions for handling contaminated materials should be observed at all times.

CAUTION: *DO NOT utilize cleaning solutions that are not mild pH*, unless they are approved for use with anodized aluminum and surgical instruments.

CAUTION: DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.

CAUTION: DO NOT utilize cleaning agents that are phenol based.

CAUTION: *MicroAire powered surgical instruments (including multi-use cannulae) are normally sterilized by steam, using either a gravity displacement or prevacuum autoclave sterilizer.*

WARNING: *Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers. Prevacuum sterilization is the preferred method of sterilization for powered surgical instruments because it allows for rapid sterilization of the internal components.*

CAUTION: *Automatic cleaning is NOT recommended.*

Limitations on Reprocessing

Repeated processing, according to the instructions below, has minimal effect on the MicroAire multi-use surgical instruments. End of life is normally determined by wear and damage due to use.

9. Packaging

a. 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).

b. 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).

10. Sterilization

Steam sterilize using one of the following cycles:

a. Prevacuum Steam Sterilization for a single instrument or in a sterilization tray:

1.) 3 minute Full Cycle at 134-137 °C (273-279 °F), 8 minute minimum heated dry time **OR**

2.) 4 minute Full Cycle at 132-135 °C (270-275 °F), 8 minute minimum heated dry time

b. Gravity Displacement Steam Sterilization for a single instrument: *30 minute Full Cycle at 132 - 135 °C (270-275 °F), 8 minute minimum heated dry time*

c. Gravity Displacement Steam Sterilization for in a sterilization tray:3*5 minute Full Cycle at 132 - 135 °C (270-275 °F), 8 minute minimum heated dry time*

NOTE: *Where there is a concern about TSE/vCJD contamination, the World Health Organization (WHO) 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).*

NOTE: DO NOT *use instruments when they are still warm. They need to cool down to room temperature. Cool by exposure to room temperature.* **DO NOT** *soak instruments in liquid to cool them down or wrap cold towels around them.*

NOTE: DO NOT *process powered surgical instruments in equipment that uses peracetic acid as a liquid sterilant.*

NOTE: *Ethylene Oxide (EtO) is* **NOT** *recommended for powered surgical instruments because lengthy aeration time is needed to assure that no ethylene oxide is left in the internal mechanisms or on the surface of the instrument.*

11. 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.

12. Additional Information

a. Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.

b. "Flash" Gravity-Steam

1.) "Flash" sterilization: Surgical centers that wish to steam sterilize patient care items for immediate use shall at a minimum follow the requirements as outlined in ANSI/AAMI ST37:1996. Reduction of bioburden and removal of gross soil are essential steps in preparing an item for sterilization by any method. Please follow the steps for decontamination of the instrument prior to any sterilization process including "flash" sterilization. The processed items must be transferred immediately, using aseptic technique, from the sterilizer to the actual point of use. There is **NO** storage or shelf life of flash-sterilized items because of the probability of contamination after the sterilizer door is opened and the items are removed. When performed correctly, flash sterilization is safe and effective for sterilization of medical devices (AAMI ST37:1996).

2.) Re-usable surgical instruments with moving parts require a dry cycle to keep the product functioning appropriately. "Flash" Gravity-Steam sterilization with **NO** dry time is **NOT** recommended as a normal process of sterilization.

3.) Instrument/Accessory ONLY Exposure Time = **11 minute FULL CYCLE**
Exposure Temperature = **270-275 °F (132-135 °C)**
Minimum Dry Time = **8 minutes**
Materials - **UNWRAPPED ONLY**

NOTE: "Flash" sterilization poses special challenges to maintaining sterility once the device has been removed from the sterilizer.

c. Because of the stressful nature of surgical use, decontamination, and sterilization, MicroAire recommends that the Handpiece, Electric Cable, and Electric Console be returned to the factory for routine inspection and service at least once a year. There is no charge for service during the warranty period.

TROUBLESHOOTING

1. **Difficulty inserting the cable.**
   Align connectors and receptacles carefully. Make sure the red dot on the cable is aligned with the matching red dot on the console or handpiece receptacle. The connection is a tight fit to keep particles from getting inside the handpiece.

   NOTE: *The connectors should retract back into the plug while pulling back on the notched portion of the plug sleeve. If the connectors do not retract, send the cable to the factory for repair.*

2. **The handpiece will not start.**
   a. Check that the console is "ON" (the main power control is in the "I" position) and that the front lights are lit.
   b. If using the handpiece throttle make sure the foot pedal is not plugged in.
   c. If using the foot pedal make sure the foot pedal is plugged in properly.
   d. Make sure there is a maximum speed light lit.
   e. Replace the handpiece cable.
   f. If using a foot pedal, disconnect the foot pedal and see if the handpiece runs properly. If the handpiece runs properly send the foot pedal to the factory for repair.
   g. If the handpiece still does not run properly send it to the factory for repair.

3. **The handpiece runs slowly or lacks power.**
   a. Check that the throttle is in the full **RUN** position.
   b. Check that the cable is correctly plugged in.
   c. Replace the handpiece cable.
   d. If not set at 100% speed, reset the maximum speed to 100% and see if the handpiece runs properly.
   e. If the handpiece continues to not run properly, contact the factory for repair.

4. **Handpiece Overheat**
   Turn the instrument off and let it cool down. When the instument has cooled, put the instrument in SAFE and turn the console to "OFF". Then turn the console "ON".

   NOTE: *The console must be turned "OFF" and "ON" again so the software can recheck the heat.*

   NOTE: *When the instrument is removed from the autoclave it must go through a cooling process before it can be used. This process can take up to 60 minutes.*

5. **Foot pedal will not operate.**
   a. Make sure the cable is fully seated in the console.
   b. Make sure the handpiece cable is plugged into the left receptacle when using the 1025 console.
   c. Make sure the maximum speed display indicates a maximum speed.
   d. If foot pedal still does not operate, send foot pedal, consoles, and cables to the factory for repair.

6. **Panel lights do not illuminate.**
   a. All panel lights should be illuminated when the console is first turned on. If the ights do not illuminate turn the console "OFF" and "ON" to reset.
   b. Make sure power cord is fully seated in the wall outlet.
   c. If panel lights still do not illuminate, send the console and cables to the factory for repair.

HANDPIECE CLEANING AND STERILIZATION INSTRUCTIONS

WARNING: *Universal precautions for handling contaminated materials should be observed at all times.*

CAUTION: *DO NOT lubricate or oil the handpiece. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubrication.*

CAUTION: *DO NOT immerse the handpiece in any fluid.*

CAUTION: *DO NOT utilize cleaning solutions that are not mild pH*, unless they are approved for use with anodized aluminum and surgical instruments.

CAUTION: *DO NOT utilize cleaning agents with chlorine or chloride as the active ingredient is corrosive to stainless steel.*

CAUTION: *DO NOT utilize cleaning agents that are phenol based.*

CAUTION: *MicroAire powered surgical instruments (including handpieces and handpiece cables) are normally sterilized by steam, using either a gravity displacement or prevacuum autoclave sterilizer.* **DO NOT** *sterilize the console or its power cord*.

WARNING: *Sterilizers vary in design and performance parameters. Verify cycle parameters against the written instructions of the sterilizer and container manufacturers. Prevacuum sterilization is the preferred method of sterilization for powered surgical instruments because it allows for rapid sterilization of the internal components.*

Limitations on Reprocessing

Repeated processing, according to the instructions below, has minimal effect on the MicroAire multi-use surgical instruments. End of life is normally determined by wear and damage due to use.

HANDPIECE AND CABLE CLEANING AND STERILIZATION INSTRUCTIONS:
NOTE: DO NOT IMMERSE INSTRUMENT OR CABLES.

1. At 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).

2. Preparation for Decontamination

a. Remove all inserted surgical accessories (cannula, tubing, etc.) from the handpiece. Single use surgical accessories should be discarded after use, handling them as any contaminated accessory is handled. Reuse of single use surgical accessories is not recommended.
b. Disassemble instruments and accessories.
c. For Automated Cleaning install the Washer Cap REF CAP-600E.
d. For Manual Cleaning install the Washer Cap REF CAP-600E or the electric cable REF 1006-PALE.

3. Preparation of Cleaning Agent

Prepare neutral 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.

4. Cleaning: Automated

a. Load the medical devices into the Washer Disinfector. Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed). DO NOT overload the trays.
b. The minimum recommended Washer/Disinfector cycle is listed in the chart below:

5. Cleaning: Manual

a. Clean the handpiece thoroughly with warm (> 60 °C / 140 °F) water, pH neutral enzymatic detergent, and a soft brush. Scrub the handpiece with a brush, paying close attention to instrument crevices.
b. Rinse thoroughly under running (< 50 °C / 122 °F) water for a minimum of 2 minutes. If possible, use distilled water for the final rinse.

6. Disinfection

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

7. 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.

8. Maintenance, Inspection and Function Testing

a. Remove the Washer Cap or Electric Cable from the handpiece.
b. Carefully inspect each device to ensure that all visible blood and soil has been removed.
c. Visually inspect for damage and/or wear.
d. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
e. 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.

#	Title	Detergent	Minutes	Temp
1	Pre-Wash	Neutral pH Enzymatic*	4	< = 50 °C (122 °F)
2	Rinse	None	1**	< = 50 °C (122 °F)
3	Wash	Neutral 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			

* 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.

NOTE: *Washers/Disinfectors should comply with the requirements of ISO 15883 (in preparation). They should be properly installed and be regularly tested in accordance with ISO 15883.*