

PAL-650 MicroAire® PAL® System

Instructions for Use



MICROAIRE®
For Surgery. For Life.™

TABLE OF CONTENTS

Indications for Use and Contraindications	2
Applicable Part Numbers	2
Symbol Definition	3-4
Warning, Caution, and Note Definitions	5-6
System Setup	6-7
Cleaning and Sterilization	8-13
Technical Description	13-14
Environmental Parameters	14
Service and Repair Information	14-15
Warranty	15

INDICATION FOR USE

The MicroAire PAL System is indicated for the removal of tissue and fluid from the body during general surgical procedures, including suction lipoplasty for the purpose of aesthetic body contouring.

CONTRAINDICATIONS

Patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity are contraindicated for the MicroAire PAL System.

APPLICABLE PART NUMBERS*

REF Number	Description
REF CAP-600E	Washer Disinfectant Cap
REF PAL-730	PAL Manual Wand, Blue
REF-PAL-730-XX	PAL Manual Wand, Alternative Color
REF PAL-1200	PAL Single-Use Aspiration Tubing (12 foot), 5 PK
REF 5020	Electric Instrument Console
REF PAL-650	PAL Electric Handpiece, Blue
REF PAL-650-XX	PAL Electric Handpiece, Alternative Color

TYPE BF APPLIED PARTS

REF Number	Description
REF 5006-PAL	PAL Electric Handpiece Cable
REF PAL-700	PAL Single-Use Luer Lock Adapter
REF PAL-XXX	PAL Single-Use Aspiration Cannula
REF PAL-XXXB	PAL Single-Use Bent Aspiration Cannula
REF PAL-XXXT	PAL Single-Use Turbo Aspiration Cannula
REF PAL-RXXXXXX	PAL Multi-Use Cannulas

*See www.microaire.com for cannula part numbers and specifications.

SYMBOL DEFINITION

Name	Ref# (ISO 7000) ²	Symbol	Description	Use Standard
Consult Instructions For Use (IFU)	1641		Indicates the need for the user to consult the Instructions For Use (IFU).	ISO 15223-1:2012 ¹
Type BF Applied Part	5333		Indicates a medical device complying with the specified requirements of IEC 60601-1 to provide a higher degree of protection against electric shock than that provided by Type B Applied Parts.	IEC 60601-1:2005
REF (Catalog #)	2493		Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1:2012 ¹
Authorized Representative in the European Community	N/A		Indicates the authorized representative in the European Community. This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol.	ISO 15223-1:2012 ¹
Serial #	2498		Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1:2012 ¹
Lot #	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2012 ¹
Do Not Immerse	5995		Indicates a medical device that is not to be immersed in any liquid.	IEC 60335-2-15
Do Not Lubricate	N/A		Indicates a medical device that is not to be lubricated.	N/A
Date of Manufacture	2497		Indicates the date when the medical device was manufactured. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29).	ISO 15223-1:2012 ¹
Manufacturer	3082		Indicates the medical device manufacturer.	ISO 15223-1:2012 ¹
Use-By Date	2607		Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the month shown. The date is expressed as YYYY-MM (e.g. 2015-11) or YYYY-MM-DD (e.g. 2015-11-29).	ISO 15223-1:2012 ¹
Single sterile barrier system with protective packaging inside	3708		Aseptic presentation technique requires opening of the outer packaging by an assistant nurse. Sterile nurses or surgeons must not touch the surface of the outer packaging. The inner layer with the sterile product may be handled by sterile personnel. Product in inner layer can be placed on sterile surfaces.	ISO 15223-1:2012 ¹
Single sterile barrier system	3707		The packaging system for a sterile medical device is composed of one or more sterile barriers and potentially additional layer(s) of protective packaging without microbial barrier. Subclause 6.1.8 of ISO 11607-1:2019 requires that a packaging system consisting of more than one layer that is to be opened at the point of use, shall have an indication of the layer that forms the sterile barrier.	ISO 15223-1:2012 ¹
CE Mark with NB	N/A		Indicates the European Conformity Mark with Notified Body Number. 0086 is the BSI-UK-registered Notified Body.	Council Directive 93/42/EEC
CE Mark with NB	N/A		Indicates the European Conformity Mark with Notified Body Number. 2797 is the BSI-NL-registered Notified Body.	Council Directive 93/42/EEC
Single Use	1051		Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.	ISO 15223-1:2012 ¹

Name	Ref# (ISO 7000) ²	Symbol	Description	Use Standard
Do Not Use if Package is Damaged	2606		Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1:2012 ¹
Non-Sterile	2609		Indicates a medical device that has not been subjected to a sterilization process. Also indicates a medical device that is provided non-sterile but must be sterilized prior to use.	ISO 15223-1:2012 ¹
Sterilized using Ethylene Oxide (EtO)	2501		Indicates a medical device that has been sterilized using ethylene oxide (EtO).	ISO 15223-1:2012 ¹
Sterilized using Irradiation (gamma)	2502		Indicates a medical device that has been sterilized using irradiation (gamma).	ISO 15223-1:2012 ¹
Standby	5266		Indicates stand-by or preparatory state for a part of a piece of equipment.	IEC 60878:2015
On	N/A		Indicates on state for a part or a piece of equipment.	N/A
Temperature Limitation	0632		Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits to temperature shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012 ¹
Atmospheric Pressure Limitation	2621		Indicates the range of atmospheric pressure to which the medical device can be safely exposed. The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012 ¹
Humidity Limitation	2620		Indicates the range of humidity to which the medical device can be safely exposed. The humidity limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2012 ¹
Do Not Expose to Stray Magnetic Fields	N/A		Indicates a medical device that is not to be exposed to stray magnetic fields.	N/A
Prescription	N/A		Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).	FDA Title 21, Chapter 1, Subchapter H, Part 801.15(F)
Dispose of per WEEE Directive 2012/19/EU	N/A		Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU.	Council Directive 2012/19/EU
Dispose of per WEEE Directive 2012/19/EU	N/A		Indicates a medical device that is not to be disposed of as unsorted municipal waste. Medical device is to be disposed of per WEEE Directive 2012/19/EU. This symbol is used in place of the above symbol if the product entered the market after 13 August, 2005.	Council Directive 2012/19/EU (Symbol: European Standard EN 50419)
UL symbol	N/A		MEDICAL-GENERAL MEDICAL EQUIPMENT AS TO ELECTRIC SHOCK, FIRE, AND MECHANICAL HAZARDS ONLY. IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 (2005) + A1 (2012) + CAN/CSA C22.2 No. 60601-1 (2014) Control Number: E494242	UL

¹ ISO 15223-1:2012 – “Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements”

² ISO 7000 – “Graphical symbols for use on equipment – Registered symbols”

GENERAL WARNINGS

WARNING	Used to indicate that the safety of patients and hospital personnel could be involved.
CAUTION	Used to indicate procedures that must be followed to avoid damaging an instrument.
NOTE	Used to indicate the easiest means of carrying out the techniques.

WARNING: See IM-5025 Instruction Manual for detailed information on the 5020 Electric Instrument Console.

WARNING: Use care to ensure that there is no electromagnetic interference between these devices and other devices in use. See IM-5025 for EMC information.

WARNING: Do not place Handpiece or Cable on the patient. Failure to comply may result in patient injury.

WARNING: This device will not, in and of itself, produce significant weight reduction.

WARNING: The volume of blood loss and endogenous fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

WARNING: Failure to comply with maximum intended re-use may result in injury to patients.

WARNING: Do not use the Cannula to lift or elevate tissue. Avoid excess loading and bending of the Cannula tip. Inspect after each use for defects. Discard if defects are found to avoid potential injury.

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

WARNING: Single-use Cannulas are designed for a single surgery. Do not attempt to clean, re-sterilize, or reuse.

WARNING: Do not immerse Cable or Handpiece.

WARNING: Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the parameters outlined in the sterilization instructions contained in this IFU.

WARNING: Cleaning of the Cannula cannot be guaranteed if the allotted time between end-of-use and processing exceeds 30 minutes. In such cases the Cannula must be discarded.

WARNING: Inadequate rinsing or flushing may leave residual detergent on the Cannula. Read and review the hazards and precautions associated with the cleaning detergent.

WARNING: Do not modify this equipment.

WARNING: PAL equipment can only be serviced by MicroAire or an Authorized MicroAire Repair Facility. DO NOT attempt to service the equipment. Unauthorized service will void the warranty.

CAUTION: This device is designed to contour the body by removing localized deposits of excess fat through small incisions.

CAUTION: Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.

CAUTION: Results of this procedure may or may not be permanent.

CAUTION: Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.

CAUTION: The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.

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

- CAUTION:** DO NOT twist or force the Cable pins into the receptacles. Doing so can bend the pins.
- CAUTION:** All multi-use components of the device must be sterilized prior to use.
- CAUTION:** All multi-use components of the device must be sterilized and all disposable components replaced before using the system on another patient.
- CAUTION:** Use only cleaning solutions of a mild pH. Do not use cleaning solutions with chlorine or chloride as the active ingredient as these are corrosive to stainless steel.
- CAUTION:** DO NOT lubricate or oil the PAL Handpiece. Lubrication may damage the internal motor mechanism. Also take special precautions to avoid the use of cleaners that contain lubricants.
- CAUTION:** Turbo Cannulas are not to be used for fat harvesting.
- CAUTION:** Do not remove the blue plug from the Turbo Cannula.
- CAUTION:** Do not pull the yellow tab on the Cannula hub.
- CAUTION:** Do not bend or twist Cannula during removal.
- NOTE:** Only use MicroAire Aspiration tubing (REF PAL-1200). Using other tubing may result in tubing failure and unfavorable results.
- NOTE:** It is recommended that the devices shall be cleaned within 30 minutes of end-of-use to minimize the potential for organic material to dry on the devices.
- NOTE:** If there is concern that the functionality of a device may be compromised, please contact MicroAire.
- NOTE:** If a problem occurs with your PAL System, return all three System components (PAL-650 Handpiece, 5006-PAL Cable and 5020 Console). The equipment works as an integrated system, returning only one or two of the System components may result in a false diagnosis.
- NOTE:** Original owners (based on serial number registration) may request a loaner System while their System is being repaired. This option is not available to owners of PAL Systems from secondary sources.
- NOTE:** Do not return equipment without an RMA number. This may cause delays in service and problems tracking returns.
- NOTE:** It is recommended that personnel shall become familiar with the equipment before it is setup for use in any procedure. Such personnel may include central processing personnel, members of the surgical team, and the bioengineering department.

SYSTEM SETUP AND OPERATION

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

- NOTE:** It is recommended that personnel shall become familiar with the equipment before it is setup for use in any procedure. Such personnel may include central processing personnel, members of the surgical team, and the bioengineering department.
1. Inspect the Handpiece, Console, Cable and Cannulas for damage, corrosion or excessive wear.
 2. Inspect sterile disposable items to make sure packaging is not damaged.
 3. Attach the electrical connection cable from the back of the Console (REF 5020) to a wall outlet.
 4. To attach the Cable (REF 5006-PAL) from the Console to the PAL Handpiece (REF PAL-650), locate the end of the Cable with the tethered end caps. To remove the caps pull back on the collar with one hand (*Figure A*) while removing the cap with the other hand (*Figure B*). With the white dot on the Cable facing upward, insert the Cable into either of the two Cable receptacles on the front of the Console. Attach the other end of the Cable to the PAL Handpiece by aligning the red dot on the Cable with the red dot on the Handpiece.

CAUTION: DO NOT twist or force the Cable pins into the receptacles. Doing so can bend the pins.



Figure A - Pull back on collar with one hand



Figure B - Remove the cap with other hand

5. To attach a Cannula (REF PAL-XXX, REF PAL-XXXB, REF PAL-RXXXXXX, or REF PAL-XXXT) to the PAL Handpiece, place the thumb-throttle of the PAL Handpiece in the STAND-BY position (PAL-650 only). Slide the small end of MicroAire Aspiration tubing (REF PAL-1200) onto the end of the Cannula (*Figure C*). Attach the square opening of the Cannula hub onto the corresponding square shaft of the PAL Handpiece, with the Tubing on the bottom of the Handpiece (*Figure D*). Secure the Tubing along the underside of the PAL Handpiece by pushing the Tubing into the groove on the bottom of the PAL Handpiece (*Figure E*).

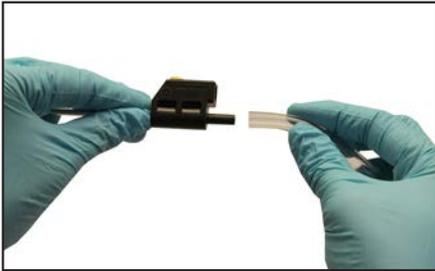


Figure C - Attach PAL tubing to cannula



Figure D - Attach hub to PAL Handpiece



Figure E - Push Tubing into PAL Handpiece

6. Connect the large end of the Tubing to a collection canister.

NOTE: Only use MicroAire Aspiration tubing (REF PAL-1200); Using other tubing may result in tubing failure and unfavorable results.

WARNING: Do not use the Cannula to lift or elevate tissue. Avoid excess loading and bending of the Cannula tip. Inspect after each use for defects. Discard if defects are found to avoid potential injury.

7. To operate the powered reciprocation of the PAL Handpiece, gently slide the thumb-throttle from STAND-BY to ON. Use the thumb-throttle to adjust the speed of reciprocation during the procedure; use the Console to set the maximum speed. The PAL Handpiece is designed to operate at full speed for most procedures.

8. To remove the Cannula from the PAL Handpiece, stop the reciprocation by sliding the thumb-throttle to the STAND-BY position. Pull the Tubing out of the groove on the underside of the PAL Handpiece. Press the colored tab on the Cannula hub to release the Cannula from the shaft, and slide the Cannula off of the PAL Handpiece.

DUTY CYCLE

PAL-650: The PAL Electric Handpiece operating duty cycle is 2 hours ON, 2 hours OFF.

CLEANING AND STERILIZATION

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

CAUTION: All multi-use components of the device must be sterilized and all disposable components replaced before using the system on another patient.

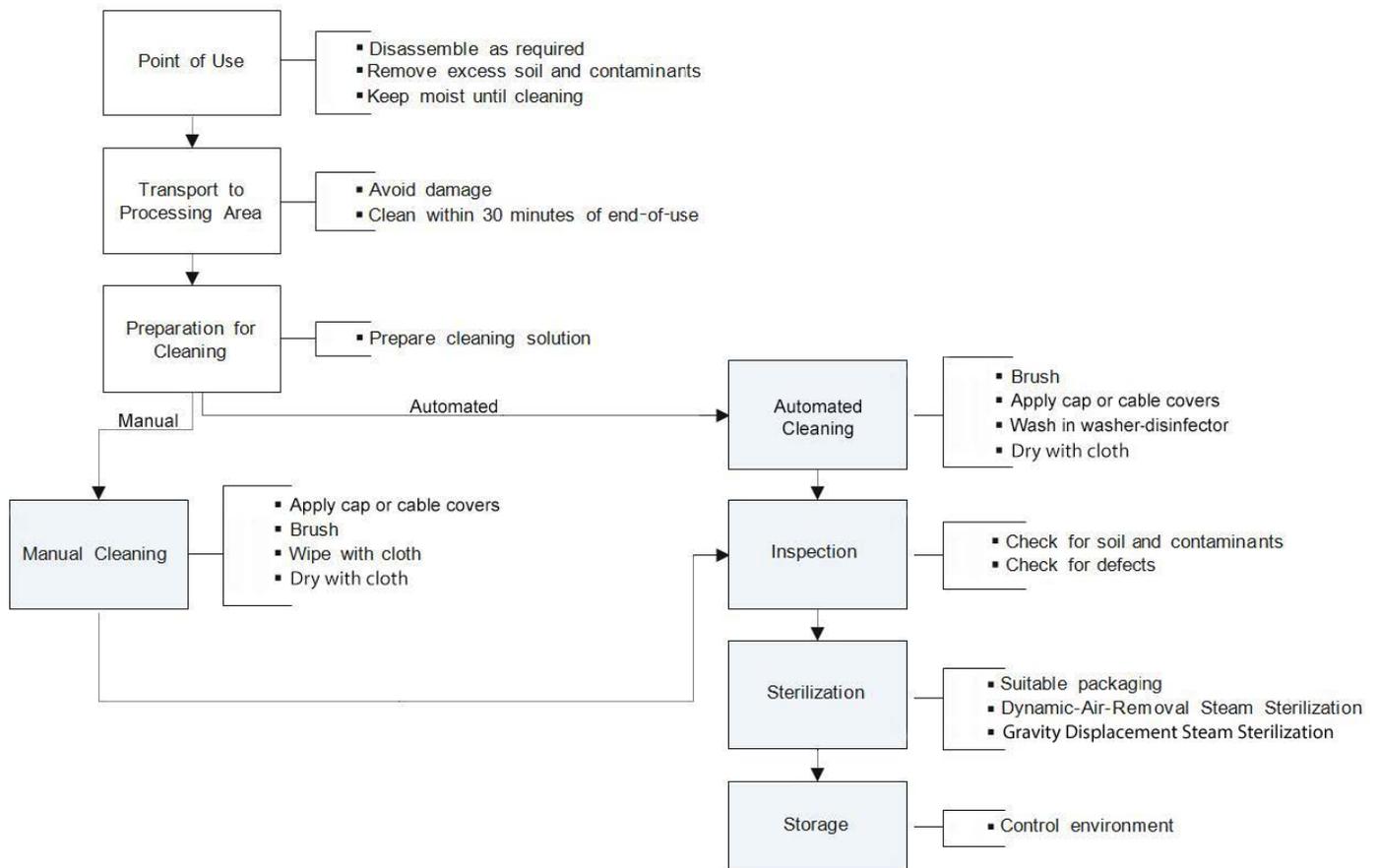
PAL SYSTEM CLEANING AND STERILIZATION INSTRUCTIONS

The steps required to properly clean and sterilize the PAL-650 Handpiece and PAL Cable are summarized in the chart below. Complete cleaning and sterilization instructions are detailed in the following pages.

WARNING: Do not immerse Cable or Handpiece.

WARNING: Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the parameters outlined in the sterilization instructions contained in this IFU.

CAUTION: Use only cleaning solutions of a mild pH. Do not use cleaning solutions with chlorine or chloride as the active ingredient as these are corrosive to stainless steel.



LIMITATIONS ON PAL-650 HANDPIECE AND PAL CABLE REPROCESSING

Repeated processing, according to the instructions below has minimal effect on the PAL Handpiece and Cable. End of life is determined by wear and damage from use.

PAL HANDPIECES AND CABLE CLEANING

1. At Point of Use

- Remove Tubing, Cable and Cannula from the Handpiece.
- Remove excess soil and contaminants with a disposable, lint-free wipe. Loosely coil Cable (if applicable), and cover instruments with a cloth wetted with water.
- Keep instruments moist until processing. The instruments must be processed within 30 minutes of end-of-use.

2. Transport to Processing Area

Transport the instruments to where cleaning will be performed within the allotted time. Take special care to prevent damage to the instrument.

NOTE: It is recommended that the devices shall be cleaned within 30 minutes of end-of-use to minimize the potential for organic material to dry on the devices.

3. Preparation of Cleaning Solution

Prepare an enzymatic solution, (such as Steris® Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner), per manufacturer’s instructions, using warm water (≥ 49°C). Cleaning agents shall be determined by local or country regulations.

4. Cleaning

a. Manual

1. Inspect the proximal end of the Handpiece and the distal end of the Cable (if applicable) for the presence of any soil and contaminants.
2. Wet a bristled brush (such as Sklar® 10-1650), with warm tap water (≥ 49°C). Brush the proximal end of the Handpiece connector and the distal end of the Cable for a minimum of 1 minute to agitate and remove any soil or contaminants.
3. Wipe the Handpiece and Cable using a lint-free wipe wetted with warm water (≥49°C) for a minimum of 30 seconds, until no visible soil or contaminants remain. Pay particular attention to Handpiece and Cable connections (if applicable). Replace soiled wipes as necessary.
4. If cleaning the PAL-650 Handpiece, install the Washer Disinfecter Cap (REF CAP-600E) over the Cable connection.
5. If cleaning the Cable, cover both connections of the Cable with the attached cable caps.
6. Wet a brush with the prepared cleaning solution. Brush the Handpiece and Cable for a minimum of 2 minutes, until no visible soil or contaminants remain. Pay particular attention to crevices. Where applicable, toggle the Handpiece ON/STAND-BY switch multiple times to clean the crevices on both sides of the switch.
7. Wipe the Handpiece and Cable using a lint-free wipe wetted with warm water (≥49°C) for a minimum of 30 seconds, until no visible soil or contaminants remain. Pay particular attention to Handpiece and Cable connections (if applicable). Replace soiled wipes as necessary.

b. Automated

1. Inspect the proximal end of the Handpiece and the distal end of the Cable (if applicable) for the presence of any soil and contaminants.
2. Wet a bristled brush (such as Sklar® 10-1650) with warm tap water (30°-40°C). Brush the proximal end of the Handpiece connector and the distal end of the Cable for a minimum of 1 minute to agitate and remove any soil or contaminants.
3. Wet a bristled brush (such as Sklar® 10-1650) with the prepared cleaning solution. Brush the Handpiece and Cable for a minimum of 1 minute, until no visible soil or contaminants remain. Pay particular attention to crevices. Where applicable, toggle the Handpiece ON/STAND-BY switch multiple times to clean the crevices on both sides of the switch.
4. If cleaning the PAL-650 Handpiece, install the Washer Disinfecter Cap (REF CAP-600E) over the Cable connection.
5. If cleaning the Cable, cover both connections of the Cable with the attached cable caps.
6. Load the device(s) into a washer-disinfecter. Recommended Washer/Disinfecter Cycle is listed in the following chart:

Washer-Disinfecter Parameters

STEP	TITLE	DETERGENT	MINS.	TEMPERATURE
1.	Pre-Wash	Mild pH Enzymatic** (such as Prolystica Enzymatic Cleaner)	4	< = 50 °C (122 °F)
2.	Rinse	None	1***	< = 50 °C (122 °F)
3.	Wash	Mild pH (such as Prolystica Enzymatic Cleaner)	4	> = 60 °C (140 °F)
4.	Rinse	None	2***	> = 60 °C (140 °F)
5.	Thermal Rinse	None	5	> = 90 °C (194°F)
6.	Dry	None	15	> = 82.2°C (180 °F)

** 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.

5. Drying

- a. Dry the Handpiece and Cable with a clean, lint free wipe.
- b. Coil the Cable and remove caps.
- c. Remove cap from Handpiece.

6. Maintenance and Inspection

- a. Using 10x-15x magnification, visually inspect the Handpiece and Cable for the presence of any remaining soil. Repeating the cleaning process if any soil is found.
- b. Visually inspect for defects and wear.

NOTE: If there is concern that the functionality of the device may be compromised, please contact MicroAire.

PAL HANDPIECE AND CABLE STERILIZATION

1. Packaging

- a. Once cleaned and inspected, the Handpiece and Cable can be wrapped individually in a standard FDA cleared medical grade steam sterilization wrap (such as Cardinal Health® Convertors® Bio-Shield® Sterilization Wraps - supplier part #4040). The wrap should be large enough to contain the Handpiece or the Cable without stressing the packaging.

2. Sterilization

Dynamic-Air-Removal Steam Sterilization: full cycle with 4-minute exposure time at 132°C (270°F), 20 minute minimum heated dry time for individually wrapped devices.

Cycle Type	Dynamic-Air-Removal
Pulses	4
Set Point Temperature	132° C / 270° F
Exposure Time	4 minutes
Dry Time	20 minutes

Gravity-Displacement Steam Sterilization: Full cycle with 35-minute exposure time at a minimum temperature of 132°C (270°F), 20 minute minimum heated dry time for individually wrapped devices.

Cycle Type	Gravity-Displacement
Set Point Temperature	132° C / 270° F
Exposure Time	35 minutes*
Dry Time	20 minutes

*Note: This cycle is not a typical cycle as recognized by AAMI ST79.

3. Storage

Sterile, packaged multi-use instruments should be stored in a dry, dust-free location with appropriate environmental controls.

MULTI-USE CANNULA CLEANING AND STERILIZATION INSTRUCTIONS

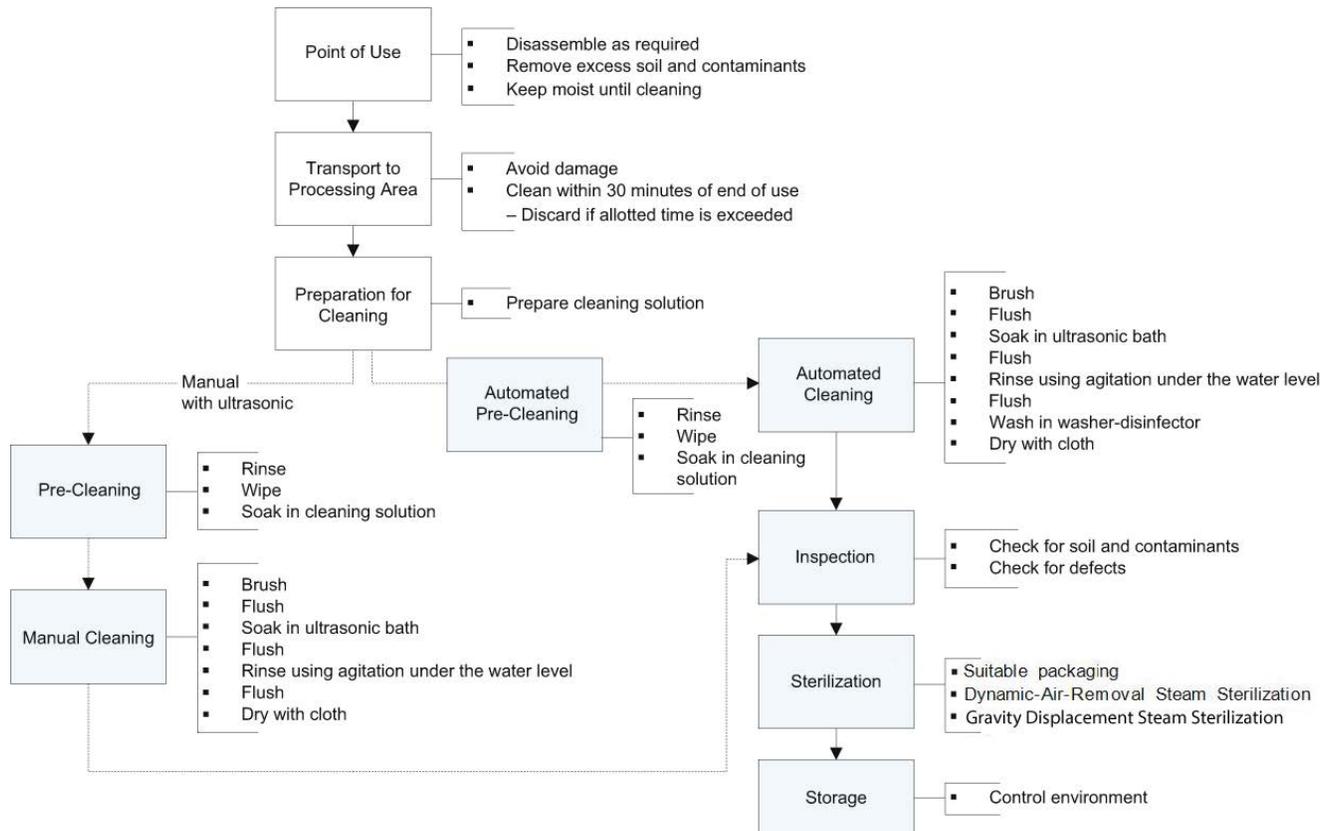
WARNING: Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the sterilization requirements in this IFU.

WARNING: Single-use Cannulas are designed for a single surgery. Do not attempt to clean, re-sterilize, or reuse.

CAUTION: All multi-use components of the device must be sterilized and all disposable components replaced before using the device on another patient.

CAUTION: Use only cleaning solutions of a mild pH. Do not use cleaning solutions with chlorine or chloride as the active ingredient as these are corrosive to stainless steel.

The steps required to properly clean and sterilize the MicroAire Multi-Use Cannulas are summarized in the chart below. Complete cleaning and sterilization instructions are detailed in the following pages.



LIMITATIONS ON REPROCESSING

MicroAire recommends that the Multi-Use Cannula be reprocessed no more than 20 times. Do not apply excessive force to the metal Cannula. Prior to each use, the user should inspect the plastic hub and the metal Cannula using 10x - 15x magnification for signs of cracking. Pay particular attention to the metal Cannula fenestrations. Discard the Cannula if there are signs of cracking or corrosion, or if the metal Cannula is bent or distorted.

WARNING: Do not use the Cannula to elevate tissue. Avoid excess loading and bending of the Cannula tip. Inspect after each use for defects. To avoid potential injury, discard if defects are found.

MULTI-USE CANNULA CLEANING

1. At Point of Use

- Remove the Tubing and Cannula from the Handpiece.
- Remove excess soil and contaminants with a disposable, lint-free wipe and cover with a cloth wetted with water.
- Keep instruments moist until processing. The device must be processed within 30 minutes of end-of-use.

WARNING: Cleaning of the Multi-use Cannula cannot be guaranteed if the allotted time between end-of-use and processing exceeds 30 minutes. In such cases the device must be discarded.

2. Transport to Processing Area

Transport the instruments to where cleaning will be performed within the allotted time. Take special care to prevent damage to the instrument.

3. Preparation of Cleaning Solution

Prepare an enzymatic solution, (such as Steris® Prolystica® 2X Concentrate Enzymatic Presoak and Cleaner), per manufacturer's instructions using warm water. Cleaning agents shall be determined by local or country regulations.

4. Cleaning

a. Manual

1. Rinse Cannula under warm ($\geq 49^{\circ}\text{C}$) running water (for a minimum of 2 minutes) to remove visible soil. Use a lint-free cloth wetted with water to aid in the removal of excess soil and contaminants.
2. Fully submerge the Cannula in the prepared cleaning solution. Use a syringe to flush the cleaning solution through the lumen, and then allow to soak for a minimum of 2 minutes.
3. After soaking the Cannula, while immersed in the cleaning solution, brush the outer surface for a minimum of 2 minutes using a bristled brush, (such as Sklar® 10-1650), to remove visible soil and contaminants from the distal fenestrations and the exterior of the Cannula.
4. After external cleaning, while still immersed in the cleaning solution, brush the interior (lumen) of the Cannula for a minimum of 2 minutes using an appropriately sized lumen brush, (such as Sklar® 10-1350 for 2.4mm Cannula), to remove soil and contaminants from the interior. Use a syringe to flush the interior (lumen) with the cleaning solution. Repeat this step until no visible soil or contaminants are observed exiting either end of the Cannula.
5. Prepare an ultrasonic bath with the cleaning solution. Immerse the Cannula in the ultrasonic bath and use a syringe to flush with the cleaning solution. Sonicate for a minimum of 10 minutes.
6. Remove the Cannula from the ultrasonic bath and thoroughly rinse under running tap water for a minimum of 1 minute.
7. Prepare an ultrasonic bath of filtered water. Immerse the Cannula in the ultrasonic bath and sonicate for a minimum of 10 minutes.
8. Remove the Cannula from the ultrasonic bath and use a syringe to flush the lumen of the Cannula with 60mL of filtered water a minimum of 3 times. Thoroughly rinse under warm running water for a minimum of 1 minute. Repeat this step at least 2 more times using filtered water for the final rinse.

WARNING: Inadequate rinsing or flushing may leave residual detergent on the Cannula. Read and review the hazards and precautions associated with the cleaning detergent.

9. Upon completion of the manual cleaning visually inspect, using 10x - 15x magnification, Cannula shaft, hub and all recessed features to ensure that all visible soil and contaminants have been removed. If soil or contaminants remain, repeat the entire manual cleaning process.

b. Automated

1. Rinse Cannula under warm ($\geq 49^{\circ}\text{C}$) running water (for a minimum of 2 minutes) to remove visible soil. Use a lint-free cloth wetted with water to aid in the removal of excess soil and contaminants.
2. Fully submerge the Cannula in the prepared cleaning solution. Use a syringe to flush the cleaning solution through the lumen, and then allow to soak for a minimum of 2 minutes.
3. After soaking the Cannula, while immersed in the cleaning solution, brush the outer surface for a minimum of 2 minutes using a bristled brush, (such as Sklar® 10-1650), to remove visible soil and contaminants from the distal fenestrations and the exterior of the Cannula.
4. Remove the Cannula from the cleaning solution and thoroughly rinse under running tap water for a minimum of 1 minute.
5. Prepare an ultrasonic bath of filtered water. Immerse the Cannula in the ultrasonic bath and sonicate for a minimum of 5 minutes.
6. Remove the Cannula from the ultrasonic bath and use a syringe to flush the lumen of the Cannula with 60mL of filtered water a minimum of 3 times.
7. Load the device into a washer-disinfector. Recommended Washer/Disinfector Cycle is listed in the following chart:

Washer-Disinfector Parameters

STEP	TITLE	DETERGENT	MINS.	TEMPERATURE
1.	Pre-Wash	Mild pH Enzymatic** (such as Prolystica Enzymatic Cleaner)	4	$\leq 50^{\circ}\text{C}$ (122 °F)
2.	Rinse	None	1***	$\leq 50^{\circ}\text{C}$ (122 °F)
3.	Wash	Mild pH (such as Prolystica Enzymatic Cleaner)	4	$\geq 60^{\circ}\text{C}$ (140 °F)
4.	Rinse	None	12***	$\geq 60^{\circ}\text{C}$ (140 °F)
5.	Thermal Rinse	None	5	$\geq 90^{\circ}\text{C}$ (194°F)
6.	Dry	None	15	$\geq 82.2^{\circ}\text{C}$ (180 °F)

** 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.

5. Drying

Thoroughly dry the exterior of the Cannula with a clean, lint-free cloth and dry the lumen with filtered compressed air.

6. Maintenance and Inspection

- a. Using 10x-15x magnification inspect the Cannula to ensure that all visible soil and contaminants have been removed. Repeat the cleaning process if soil or contaminants are found.
- b. Visually inspect for defects or wear.

NOTE: If there is concern that the functionality of the device may be compromised, please contact MicroAire.

MULTI-USE CANNULA STERILIZATION

1. Packaging

Once cleaned and inspected, wrap the dry Cannula individually in a standard FDA cleared medical grade steam sterilization wrap (such as Cardinal Health® Convertors® Bio-Shield® Sterilization Wraps - supplier part #4040). The wrap must be large enough to contain the instrument without stressing the packaging.

2. Sterilization

Dynamic-Air-Removal Steam Sterilization: full cycle with 4-minute exposure time at 132°C (270°F), 20 minute minimum heated dry time.

Cycle Type	Dynamic-Air-Removal
Pulses	4
Set Point Temperature	132° C / 270° F
Exposure Time	4 minutes
Dry Time	20 minutes

Gravity-Displacement Steam Sterilization: Full cycle with 35-minute exposure time at a minimum temperature of 132°C (270°F), 20 minute minimum heated dry time.

Cycle Type	Gravity-Displacement
Set Point Temperature	132° C / 270° F
Exposure Time	35 minutes*
Dry Time	20 minutes

*Note: This cycle is not a typical cycle as recognized by AAMI ST79.

3. Storage

Sterilized multi-use instruments should be stored in a dry, dust-free location with appropriate environmental controls.

TECHNICAL DESCRIPTION

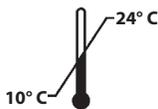
The PAL-650 is a powered surgical instrument that vibrates a cannula used in aesthetic body contouring procedures. It is powered by a MicroAire 5020 Electric Instrument Control Console which provides IEC60601-1 Type BF isolated control signals to the PAL-650 via the 5006-PAL Instrument Cable. The user can command the PAL-650 to ON or STAND-BY via a slider switch located on the instrument. The PAL-650 and the 5006-PAL cable are multi-use. The Cannula come in variety of styles as both single-use and multi-use items. The PAL-1200 single-use Aspiration tubing connects the Cannula to a collection canister and vacuum source.

ESSENTIAL PERFORMANCE

The PAL-650 System has no Essential Performance as defined by ANSI/AAMI/IEC 60601-1 when used with the 5020 Instrument Control Console.

ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS



The MicroAire PAL System and accessories do not have any nonstandard shipping or storage requirements.

Guidance and Manufacturer's Declaration – Power Output, Vibration Exposure, Noise Emission Value and Mass Weight Information for the Power-Assisted Liposuction (Electric) Handpiece - REF PAL-650						
Power Output kW – Kilowatts	Vibration Exposure		Noise Emission Value			Mass Weight (kg)
	ahv(m/s ²)	Uncertainty K (m/s ²)	LPA (dB(A))	LC,peak (dB(C))	LWA (dB(A))	
0.065	3.77	1.5	<70	-	-	0.5

DISPOSAL

In accordance with the 2002/96/EC Directive on Waste Electrical and Electronic Equipment (the WEEE Directive) and the current national provisions, the organization of the transfer of these wastes for devices sold by MANUFACTURER shall be undertaken by DISTRIBUTOR. For this reason, DISTRIBUTOR shall organize a system for the collection, storage and arrange transfer of any and all WEEE components to a Manufacturer's approved WEEE collection facility in Europe. DISTRIBUTOR shall provide on request to MANUFACTURER, the proof of compliance with the European and national provisions regarding the WEEE Directive. Please refer to www.microaire.com/weee for WEEE Compliance Instructions.

SERVICE AND REPAIR INFORMATION

IN HOSPITAL SERVICE

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

Repairs or alterations to MicroAire products made by anyone other than MicroAire or an Authorized MicroAire Repair Facility will void that product's warranty.

PREVENTATIVE MAINTENANCE

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

Because of the stressful nature of surgical use, decontamination, and sterilization, MicroAire recommends that the PAL System (PAL-650 Handpiece, 5006-PAL Cable and 5020 Console) be returned to the factory for routine inspection and service at least once a year.

TIPS FOR OPTIMAL PERFORMANCE

NOTE: The most common cause for repair of the PAL Handpiece is improper use of the Washer Disinfectant Cap (REF CAP-600E) and provided cable caps.

- CAP the Cable and PAL Handpiece during cleaning** to prevent liquid from entering the device. For manual cleaning, use either the Washer Disinfectant Cap or keep the Cable plugged into the PAL Handpiece. For automated cleaning, only use the Washer Disinfectant Cap to cap the PAL Handpiece connector.
- UNCAP the Cable and the PAL Handpiece during sterilization** to allow steam to penetrate the device.
- DRY the devices completely using the dry cycle** after sterilization to remove all moisture from within the device. Failure to do so may cause corrosion on the pins and within the motor.

TROUBLESHOOTING

1. **Difficulty attaching the Cable**

Align connectors and receptacles carefully. Ensure the white dot is facing upward when connecting the Cable to the Console. Ensure the red dot on the Cable is aligned with the matching red dot on the PAL Handpiece. Never force the cable into a receptacle because this can bend the pins.

2. **The Handpiece will not start**

- a. Check that the Console is plugged in, turned on, and the touchscreen is indicating a connection to the PAL Handpiece.
- b. Check the pins in the Cable and the PAL Handpiece to see if they are bent or corroded.
- c. If the PAL Handpiece does not start, the problem could be in the Handpiece, the Cable or the Console. Return all three system components to MicroAire for a proper diagnosis.
- d. Note the error number of any error messages that appear on the REF 5020.

REPAIR SERVICE

Responsive service comes with every MicroAire product. If a problem should arise with your equipment, repair requests can be made online at www.microaire.com/repairs or by contacting Customer Service at:

MicroAire Surgical Instruments, LLC, 3590 Grand Forks Boulevard, Charlottesville, VA 22911 USA

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

WARNING: Do not modify this equipment.

WARNING: PAL equipment can only be serviced by MicroAire or an Authorized MicroAire Repair Facility. DO NOT attempt to service the equipment. Unauthorized service will void the warranty.

NOTE: If a problem occurs with your PAL System, return all three System components (PAL-650 Handpiece, 5006-PAL Cable and 5020 Console). The equipment works as an integrated system, returning only one or two of the System components may result in a false diagnosis.

NOTE: Original owners (based on serial number registration) may request a loaner System while their System is being repaired. This option is not available to owners of PAL Systems from secondary sources.

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 may cause delays in service and problems tracking returns.

2. Clean and sterilize equipment before sending for repair.
3. Along with the items sent for repair, please enclose a description of the problem and contact information.
4. If the instrument is out of warranty, enclose a purchase order number with the instrument.
5. Ship the merchandise by Express Mail, Federal Express or UPS to ensure tracking and to prevent mail delays.
6. Indicate if an estimate of repair costs is needed prior to commencing work on the repair.

WARRANTY

MicroAire Surgical Instruments LLC warrants its instruments to be free from defects in material and workmanship in their manufacture for a period of one 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.

The following additional languages are available online at www.microaire.com/resources:

Danske (Danish)

Danske oversættelser af denne brugsanvisning er tilgængelig online på www.microaire.com/resources.

Nederlands (Dutch)

Nederlandse vertalingen van deze handleiding zijn online beschikbaar op www.microaire.com/resources.

Suomalainen (Finnish)

Suomen käännökset tämän käyttöohjeen löytyvät osoitteesta www.microaire.com/resources.

Française (French)

Des traductions françaises de ce manuel d'instructions sont disponibles en ligne à www.microaire.com/resources.

Deutsch (German)

Deutsch Übersetzungen dieser Bedienungsanleitung sind online verfügbar unter www.microaire.com/resources.

Italiano (Italian)

Traduzioni italiane di questo manuale sono disponibili online all'indirizzo www.microaire.com/resources.

Português (Portuguese)

Tradução para português deste manual de instruções estão disponíveis online em www.microaire.com/resources.

Português (Brasil)

Tradução para português deste manual de instruções estão disponíveis online em www.microaire.com/resources.

Español (Spanish)

Traducciones al español de este manual de instrucciones están disponibles en línea en www.microaire.com/resources.

Svenska (Swedish)

Svenska översättningar av denna bruksanvisning finns tillgängliga online på www.microaire.com/resources.

Türk (Turkish)

Bu kullanım kılavuzu Türkçe tercümeleleri sitesinde online olarak mevcuttur www.microaire.com/resources.

中文(Chinese)

本明的中文本可在网上 www.microaire.com/resources.

Русский (Russian)

Русские переводы этого руководства можно ознакомиться на сайте www.microaire.com/resources.

日本語 (Japanese)

このマニュアルのデンマークの翻訳がオンラインで入手可能です www.microaire.com/resources.

MICROAIRE®

MicroAire Surgical Instruments LLC

3590 Grand Forks Blvd
Charlottesville, VA 22911 USA

Telephone (800) 722-0822
(434) 975-8000

Fax (800) 648-4309
(434) 975-4131

www.microaire.com



MediMark Europe

11, rue Emile Zola - BP 2332
F-38033 Grenoble Cedex 2
France



R_xonly