

# INSTRUCTIONS FOR USE

MicroAire® PAL®  
Manual Wand and Cannulas (Single and Multi-use)

## Contents

Indications for Use .....	2
Warnings and Cautions .....	2-3
PAL 730 Manual Wand Cleaning and Sterilization Instructions .....	4-6
Multi-use Cannula Cleaning and Sterilization Instructions .....	7-10
System Set Up .....	11
Service and Repair Information .....	12
Warranty .....	13
Disposal .....	13
Part Numbers .....	13
Symbol Definitions .....	14-15

## INTRODUCTION

This document, MicroAire PAL Manual Wand and Cannula Instructions for Use (IFU), describes how to safely assemble, clean and maintain the PAL-730 Manual Wand, and both Single and Multi-use Cannulas. MicroAire does not provide instruction for the suction lipoplasty procedure.

## INDICATIONS FOR USE

The MicroAire PAL Manual Wand and Cannulas are indicated for the removal of tissue or fluid from the body during general surgical procedures, including suction lipoplasty, for the purpose of aesthetic body contouring.

## TERMS

**WARNING** Used to indicate that the safety of patients and hospital personnel may 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:** This device will not, in and of itself, produce significant weight reduction.

**WARNING:** This device should be used with extreme caution in patients with chronic medical conditions such as diabetes, heart, lung or circulatory system disease, or obesity.

**WARNING:** The volume of blood loss and endogenous body 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:** 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.

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

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

**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.

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

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

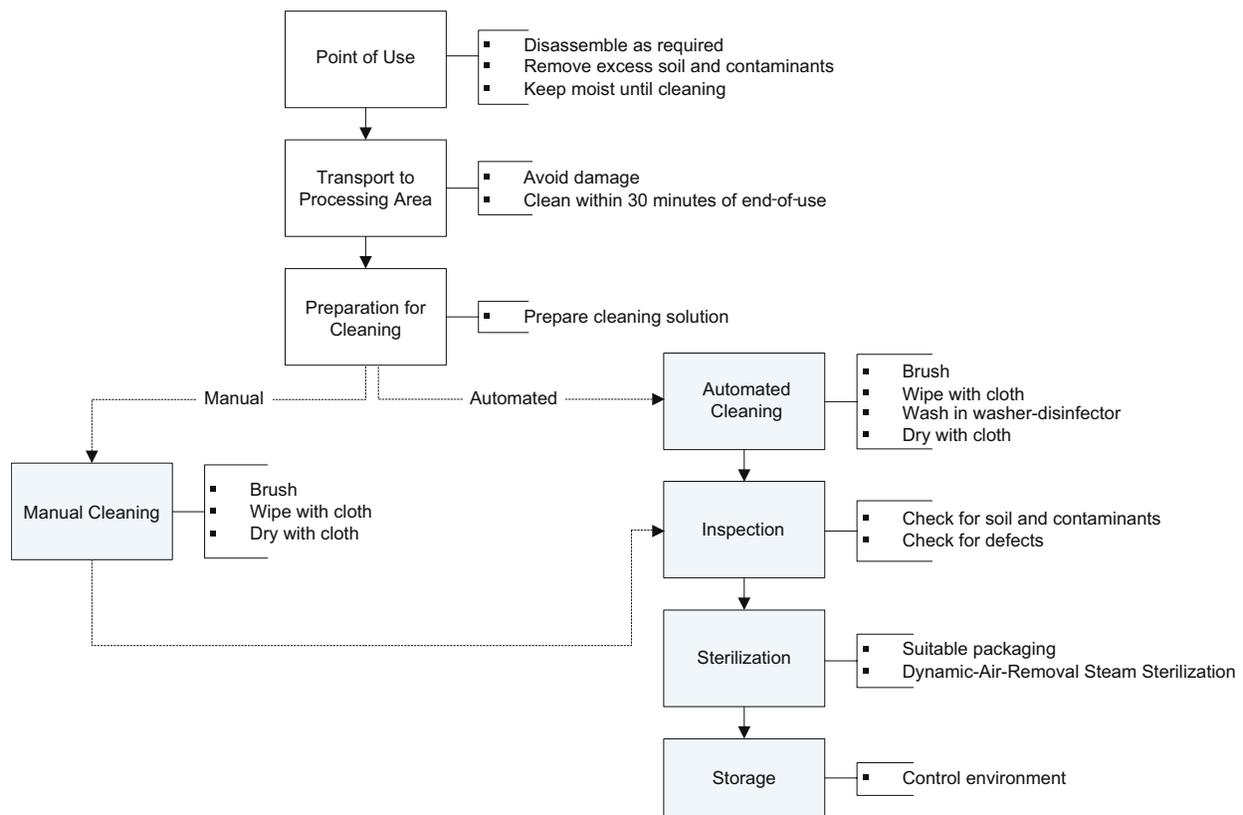
**WARNING:** Single, outer sterile barrier only. Inner package is for product protection only and does not constitute a second sterile barrier.

**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:** This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
- CAUTION:** Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
- CAUTION:** Results of this procedure may or may not be permanent.
- CAUTION:** The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
- CAUTION:** All multi-use components of the device must be sterilized and all disposable components replaced before using the device system on another patient.
- CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- CAUTION:** Use only cleaning solutions of a mild pH. Do not use cleaning solutions with chlorine or chloride as the active ingredient is corrosive to stainless steel.
- CAUTION:** Turbo Cannulas are not to be used for fat harvesting.
- CAUTION:** Do not remove blue plug on Turbo Cannula.
- CAUTION:** Do not pull the yellow tab.
- CAUTION:** Do not bend or twist Cannula during removal.

## PAL 730 MANUAL WAND CLEANING AND STERILIZATION INSTRUCTIONS

The steps required to properly clean and sterilize the PAL Manual Wand are summarized in the chart below. Complete cleaning and sterilization instructions are detailed in the following pages.



**WARNING:** Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the sterilization requirements 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 is corrosive to stainless steel.

### LIMITATIONS ON REPROCESSING

Repeated processing has minimal effect on the PAL Manual Wand. End of life is determined by wear and damage due to use.

#### 1. At Point of Use

- Remove the tubing and Cannula from the Wand.
- 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.

**NOTE:** It is recommended that the PAL-730 Manual Wand shall be cleaned within 30 minutes of end of-use to minimize the potential for organic material to dry on the instrument.

## 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 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. Wet a bristled brush, (such as Sklar® 10-1650), with prepared cleaning solution. Brush the Wand for a minimum of 2 minutes paying close attention to instrument crevices, agitating and removing all visible soil and contaminants.
2. Wipe the Wand using a lint-free cloth wetted with warm water, paying particular attention to crevices until no visible soil remains.

### b. Automated

1. Wet a bristled brush, (such as Sklar® 10-1650), with prepared cleaning solution. Brush the Wand for a minimum of 2 minutes paying close attention to instrument crevices, agitating and removing all visible soil and contaminants.
2. Wipe the Wand using a lint-free cloth wetted with warm water, paying particular attention to crevices until no visible soil remains.
3. 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	< = 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 (200°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

Wipe off any water with a lint-free dry cloth.

## 6. Maintenance and Inspection

- a. Using 10x-15x magnification, inspect the Wand to ensure that all visible soil and contaminants have been removed. Repeat the cleaning process if soil and contaminants are 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.

## 7. Packaging

Once cleaned and inspected, wrap the dry Wand 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.

## 8. Sterilization

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

## PAL Manual Wand Sterilization Instructions

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

## 9. Storage

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

## Multi-use CANNULA CLEANING AND STERILIZATION INSTRUCTIONS

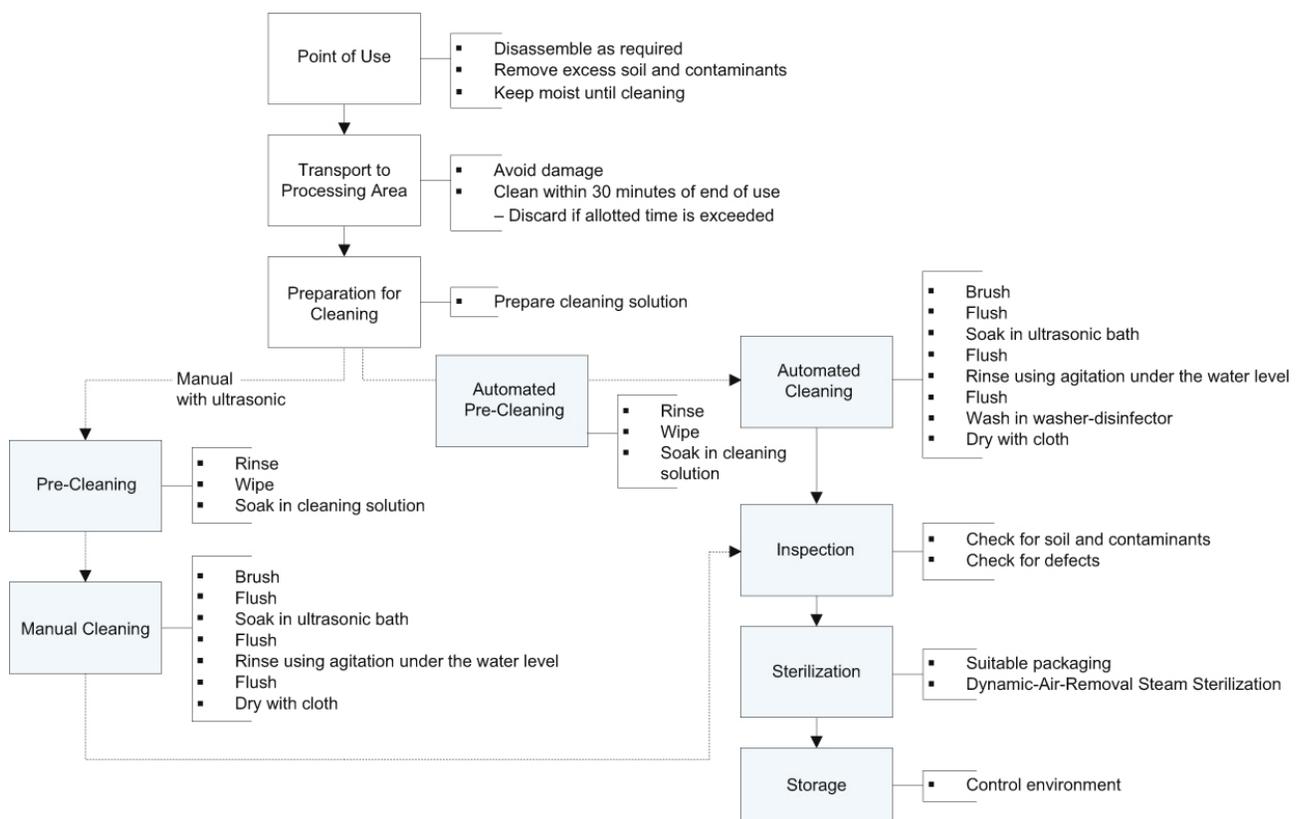
**WARNING:** Sterilizers vary in design and performance parameters. Verify that the cycle parameters of the sterilizer meet the sterilization requirements in this IFU.

**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 is 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 19 times (for a total of 20 uses). 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.

### 1. At Point of Use

- a. Remove the tubing and Cannula from the Wand.
- b. Remove excess soil and contaminants with a disposable, lint-free wipe and cover with a cloth wetted with water.
- c. 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 ultrasonic bath 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	$\geq 90^{\circ}\text{C}$ (200°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.

## 7. 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.

## 8. Sterilization

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

### Multi-use Cannula Sterilization Instructions

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

## 9. Storage

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

## SYSTEM SET UP

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

**CAUTION:** Do not remove blue plug on Turbo Cannula.

**CAUTION:** Turbo Cannulas are not to be used for fat harvesting.

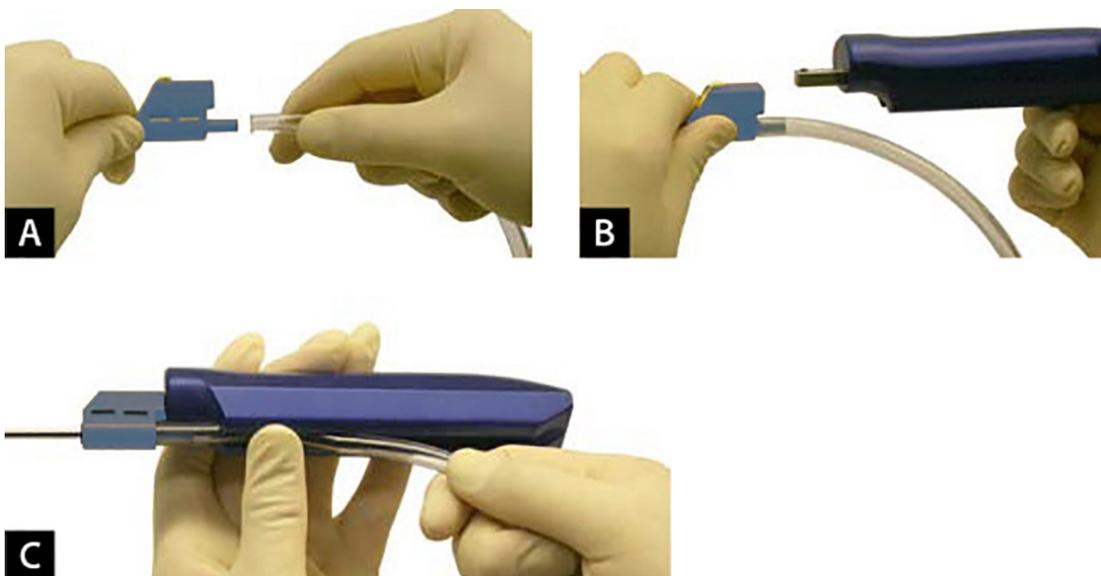
**NOTE:** It is recommended that personnel shall become familiar with the equipment before it is set up for use in any procedure. Such personnel may include central processing personnel, members of the surgical team, and the bioengineering department.

Ensure PAL Manual Wand and Cannula assemble and function properly prior to use. If assembly or functionality is compromised, contact MicroAire Customer Service at (800) 722-0822.

1. Inspect the Wand for defects, such as corrosion or excessive wear. If these are identified contact MicroAire for repair.
2. Inspect sterile, disposable items to ensure packaging is not damaged.
3. Prior to each use of a Multi-use Cannula, 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.
4. To attach a Cannula to the Wand slide tubing onto the end of the Cannula (Figure A).
5. Attach the square opening of the Cannula hub onto the corresponding square shaft of the Wand, with the tubing on the bottom of the Wand (Figure B).
6. Press the tubing into the underside groove of the Wand (Figure C).
7. Connect the free end of the tubing to a collection canister.
8. To remove the Cannula from the Wand, pull the tubing out of the underside groove. Depress and hold the yellow tab on the hub to release the locking pin. Slide the Cannula off the Wand.

**CAUTION:** Do not pull the yellow tab.

**CAUTION:** Do not bend or twist the Cannula during removal.



## PREVENTATIVE MAINTENANCE

The MicroAire PAL Manual Wand and Cannulas do not require maintenance other than the required cleaning, sterilization, and visual examination between each use.

## REPAIR SERVICE

The MicroAire Cannulas are not serviceable, nor do they have any serviceable parts. If a problem should arise with your MicroAire PAL 730 Manual Wand, contact MicroAire Customer Service at:

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

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

- NOTE:** MicroAire may be able to solve the problem without physically receiving the equipment.
- NOTE:** Do not attempt to service the equipment. Unauthorized service will void the warranty.
- NOTE:** The MicroAire PAL Manual Wand can only be serviced by MicroAire or an Authorized MicroAire Repair Facility.

### 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.

2. Clean and sterilize the equipment before sending for repair.
3. Along with the items sent for repair, please enclose a detailed description of the problem along with contact information.
4. If the instrument is out of warranty, enclose a purchase order number.
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**

For complete warranty information visit [www.microaire.com/warranty-information](http://www.microaire.com/warranty-information).

## **DISPOSAL**

To reduce the risk of contamination by biological waste, it is recommended that all devices shall first be cleaned and sterilized prior to disposal. Disposal shall comply with all local and federal laws and regulations.

## **APPLICABLE PART NUMBERS\***

<b>REF Number</b>	<b>Description</b>
PAL-XXX	PAL Single Use Aspiration Cannula
PAL-XXXT	PAL Single Use Turbo Aspiration Cannula
PAL-XXXB	PAL Single Use Bent Aspiration Cannula
PAL-RXXX	PAL Multi-use Aspiration Cannula
PAL-RXXXB	PAL Multi-use Bent Aspiration Cannula
PAL-730	PAL Manual Wand

\*See [store.microaire.com](http://store.microaire.com) for Cannula part numbers and specifications.

## SYMBOL DEFINITIONS

Name	Ref# (ISO 7000) <sup>2</sup>	Symbol	Description	Use Standard
Refer to Instruction Manual / Booklet	ISO-7010 M002		<ul style="list-style-type: none"> <li>Indicates a MANDATORY action for the user to consult the Instructions For Use (IFU).</li> <li>Symbol must be blue, as shown.</li> </ul>	IEC 60601-1:2005 <sup>1</sup>
Caution	0434A / 0434B		Indicates the need for the user to consult the Instructions For Use (IFU) for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the device itself.	ISO 15223-1:2012 <sup>1</sup>
Consult Instructions For Use (IFU)	1641		Indicates the need for the user to consult the Instructions For Use (IFU). Not required in conjunction with the Caution symbol, if applicable.	ISO 15223-1:2012 <sup>1</sup>
Do Not Reuse	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 <sup>1</sup>
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. This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".	ISO 15223-1:2012 <sup>1</sup>
Non-Sterile	2609		<ul style="list-style-type: none"> <li>Indicates a medical device that has not been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.</li> <li>Also indicates a medical device that is provided non-sterile but must be sterilized prior to use.</li> </ul>	ISO 15223-1:2012 <sup>1</sup>
Sterilized using Irradiation (gamma)	2502		Indicates a medical device that has been sterilized using irradiation (gamma). Use of the Sterile symbol requires a use-by date (see Use-By Date symbol).	ISO 15223-1:2012 <sup>1</sup>
REF (Catalog #)	2493		<ul style="list-style-type: none"> <li>Indicates the manufacturer's catalog number so that the medical device can be identified.</li> <li>Per EN980:2008, the REF symbol may be used without surrounding box.</li> </ul>	ISO 15223-1:2012 <sup>1</sup>
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 <sup>1</sup>
Serial #	2498		<ul style="list-style-type: none"> <li>Indicates the manufacturer's serial number so that a specific medical device can be identified.</li> <li>Per EN980:2008, the SN symbol may be used without surrounding box.</li> </ul>	ISO 15223-1:2012 <sup>1</sup>
Lot / Batch Code	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2012 <sup>1</sup>
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

Name	Ref# (ISO 7000) <sup>2</sup>	Symbol	Description	Use Standard
Date of Manufacture	2497		<ul style="list-style-type: none"> <li>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).</li> <li>If the symbol is filled (see Manufacturer symbol), both the date of manufacture and the name/address of the manufacturer may be combined in one symbol.</li> </ul>	ISO 15223-1:2012 <sup>1</sup>
Manufacturer	3082		<ul style="list-style-type: none"> <li>Indicates the medical device manufacturer. This symbol shall be accompanied by the name and address of the manufacturer. The date of manufacture may be combined with this symbol.</li> <li>When using MicroAire as the manufacturer, use the MicroAire LLC symbol.</li> </ul>	ISO 15223-1:2012 <sup>1</sup>
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 <sup>1</sup>
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 <sup>1</sup>
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)

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

<sup>2</sup> ISO 7000 – “Graphical symbols for use on equipment – Registered symbols”

The following additional languages are available online at [www.microaire.com/resources](http://www.microaire.com/resources):

#### **Danske (Danish)**

Danske oversættelser af denne brugsanvisning er tilgængelig online på [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Nederlands (Dutch)**

Nederlandse vertalingen van deze handleiding zijn online beschikbaar op [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Suomalainen (Finnish)**

Suomen käännökset tämän käyttöohjeen löytyvät osoitteesta [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Française (French)**

Des traductions françaises de ce manuel d'instructions sont disponibles en ligne à [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Deutsch (German)**

Deutsch Übersetzungen dieser Bedienungsanleitung sind online verfügbar unter [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Italiano (Italian)**

Traduzioni italiane di questo manuale sono disponibili online all'indirizzo [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Português (Portuguese)**

Tradução para português deste manual de instruções estão disponíveis online em [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Español (Spanish)**

Traducciones al español de este manual de instrucciones están disponibles en línea en [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Svenska (Swedish)**

Svenska översättningar av denna bruksanvisning finns tillgängliga online på [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Türk (Turkish)**

Bu kullanım kılavuzu Türkçe tercümelere sitesinde online olarak mevcuttur [www.microaire.com/resources](http://www.microaire.com/resources).

#### **中文(Chinese)**

本明的中文本可在网上 [www.microaire.com/resources](http://www.microaire.com/resources).

#### **Русский (Russian)**

Русские переводы этого руководства можно ознакомиться на сайте [www.microaire.com/resources](http://www.microaire.com/resources).

**MICROAIRE®**

*For Surgery. For Life.™*

#### **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](http://www.microaire.com)



**MediMark Europe**

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



**R<sub>x</sub>only**