

INSTRUCTIONS FOR USE

MicroAire® PAL®
Manual Wand and Multi Use Cannulas

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INTRODUCTION

This document, MicroAire PAL Manual Wand and Multi Use Cannula Instructions for Use (IFU), is intended to describe the procedures required to safely assemble, clean and maintain the PAL-730 Manual Wand and Multi Use Cannulas. MicroAire does not provide instruction for the suction lipoplasty procedure.

INDICATIONS FOR USE

The MicroAire PAL Manual Wand and Multi Use 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 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: 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 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 parameters outlined in the sterilization instructions contained 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 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.

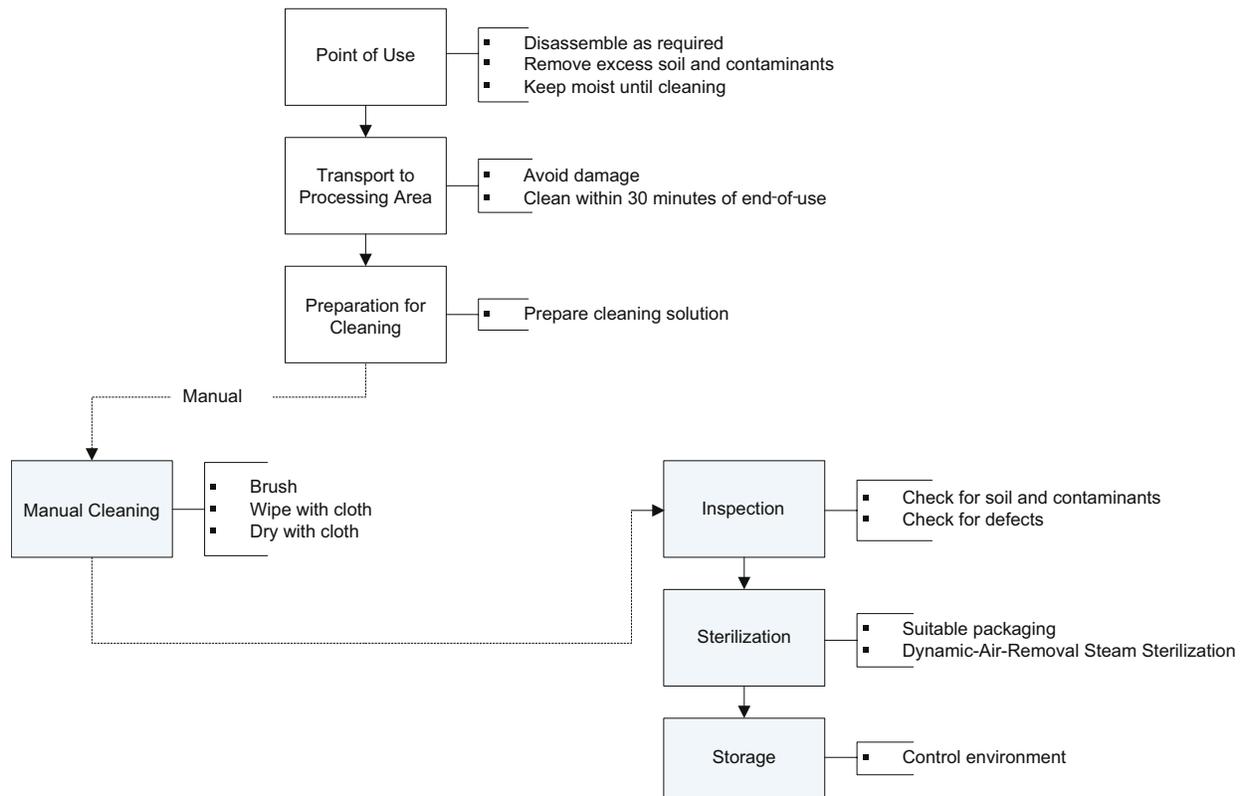
WARNING: Inadequate rinsing or flushing may leave residual detergent on the cannula. Read and review the hazards and precautions associated with the cleaning detergent.

WARNING: All multi-use components of the device must be sterilized prior to use.

- 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:** 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.

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 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 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 dampened 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. Cleaning agents shall be determined by local or country regulations.

4. Cleaning: Manual

- a. Wet a bristled brush, (such as Sklar® 10-1650), with prepared cleaning solution. Brush the Wand for 2-5 minutes paying close attention to instrument crevices, agitating and removing all visible soil and contaminants.
- b. Wipe the Wand using a lint-free cloth wetted with warm water, paying particular attention to crevices until no visible soil remains.

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 should 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

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

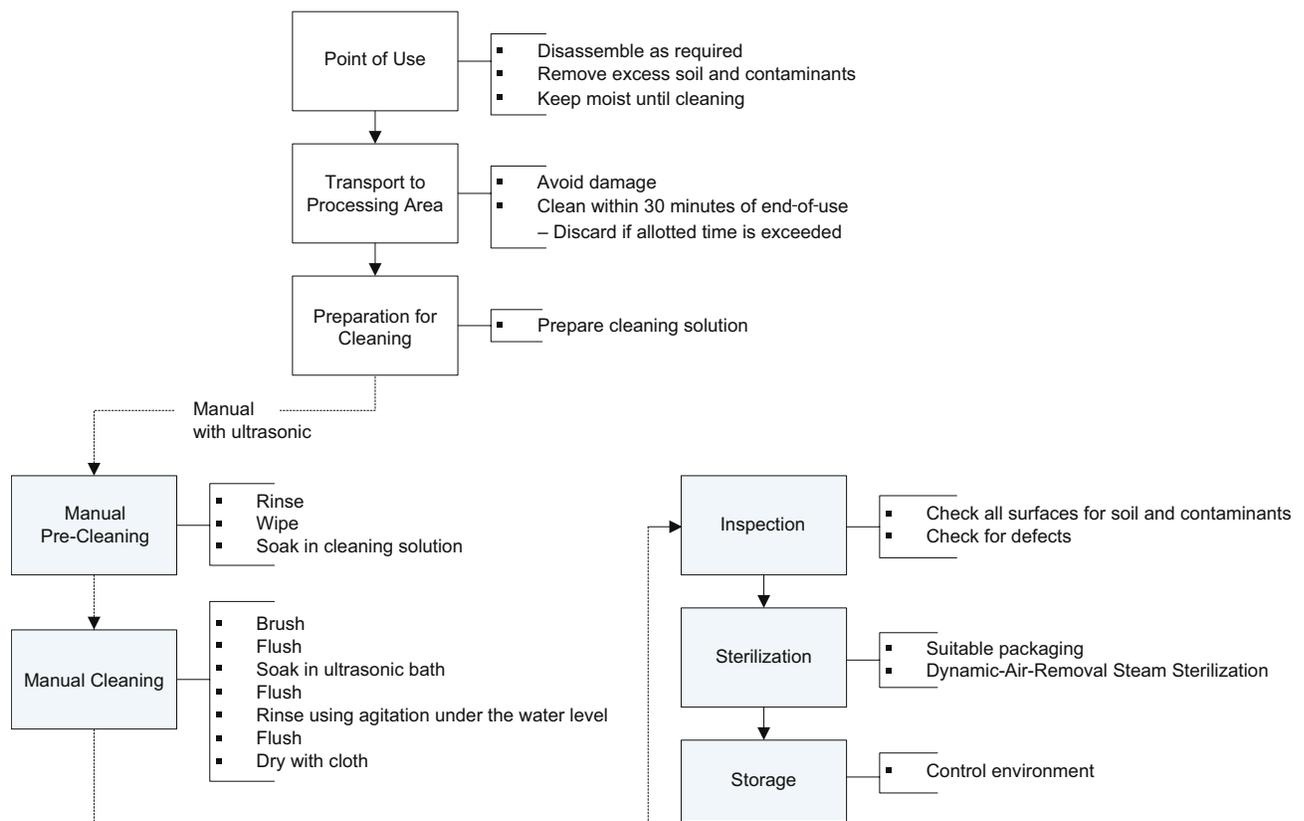
MULTI USE CANNULA CLEANING AND STERILIZATION INSTRUCTIONS

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

WARNING: All multi-use components of the device must be sterilized prior to use.

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 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 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.

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 dampened with water.
- c. Keep instruments moist until processing. The device must be processed within 30 minutes of end-of-use.

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 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: Manual

- a. Rinse Cannula under warm ($\geq 49^{\circ}\text{C}$) running water (for 2-5 minutes) to remove visible soil. Use a lint-free cloth wetted with water to aid in the removal of excess soil and contaminants.
- b. 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 2-5 minutes.
- c. After soaking the Cannula, while immersed in the cleaning solution, brush the outer surface for 2-5 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.
- d. After external cleaning, while still immersed in the cleaning solution, brush the interior (lumen) of the Cannula for 2-5 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.
- e. 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 10-20 minutes.
- f. Remove the Cannula from the ultrasonic bath and thoroughly rinse under running tap water for a minimum of 1 minute.
- g. Prepare an ultrasonic bath of critical water. Immerse the Cannula in the ultrasonic bath and sonicate for a minimum of 10 minutes.
- h. Remove the Cannula from the ultrasonic bath and use a syringe to flush the lumen of the Cannula with 60mL of critical water a minimum of 3 times. Thoroughly rinse under warm running water for a minimum of 1-2 minutes. Repeat this step at least of 2 more times using critical 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.

- i. 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.

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 should 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

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

SYSTEM SET UP

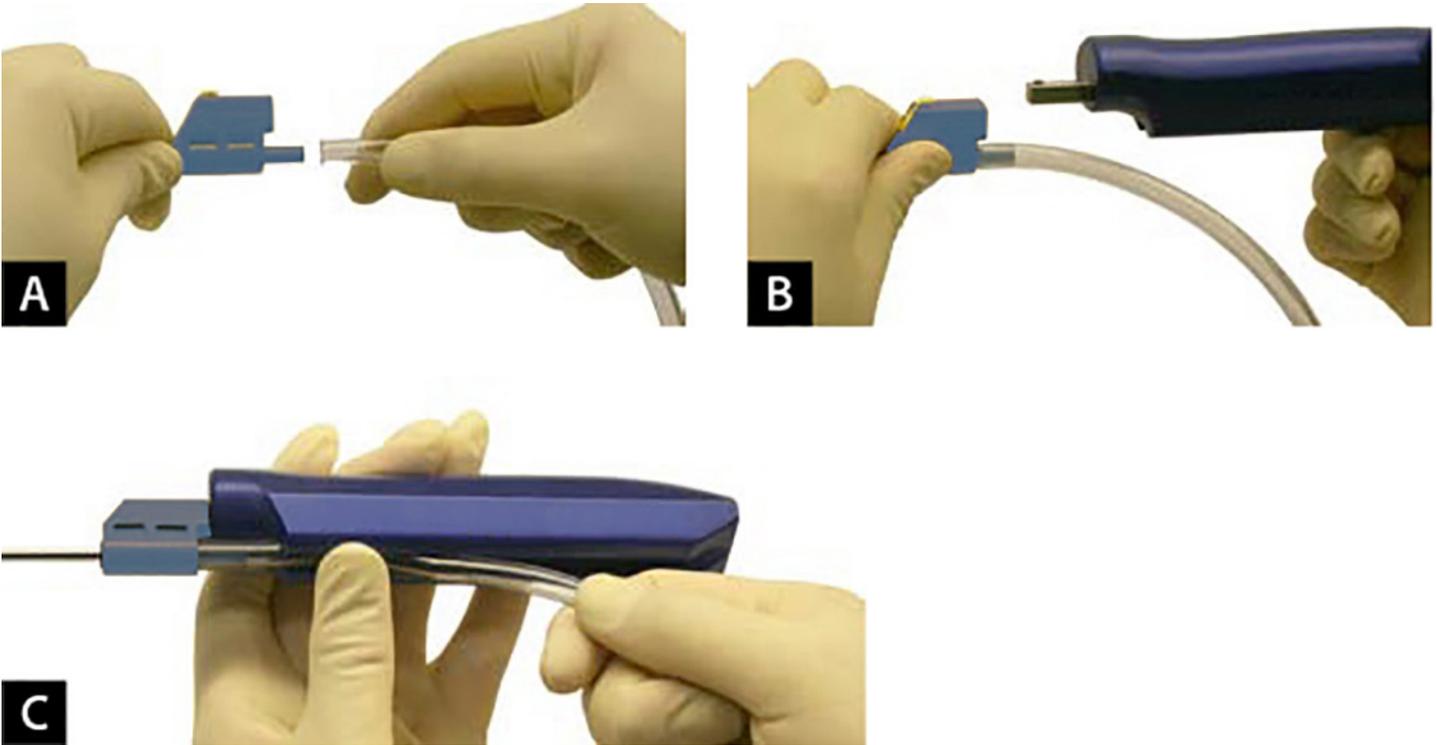
WARNING: All multi-use components of the device must be sterilized prior to use.

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 Multi Use 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. Prior to each use, 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.

3. To attach a Cannula (REF PAL-RXXX, REF PAL-RXXXB) to the Wand (REF PAL-730) slide aspiration tubing onto the end of the Cannula (Figure A).
4. Attach the square opening of the Cannula hub onto the corresponding square shaft of the Wand, with the aspiration tubing on the bottom of the Wand (Figure B).
5. Press the tubing into the underside groove of the Wand (Figure C).
6. Connect the free end of the aspiration tubing to a collection canister.
7. 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. DO NOT pull the yellow tab.



PREVENTATIVE MAINTENANCE

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

REPAIR SERVICE

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

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

USA:	Telephone:	FAX:	Email:
OUTSIDE USA:	800-722-0822	800-438-6309	inquiry@microaire.com
	+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 equipment 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 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.

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.

Appendix 1

APPLICABLE PART NUMBERS*

REF Number	Description
REF PAL-RXXX	PAL Multi-Use Aspiration Cannula
REF PAL-RXXXB	PAL Multi-Use Bent Aspiration Cannula
REF PAL-730	PAL Manual Wand

*See store.microaire.com for Cannula part numbers and specifications.

SYMBOL DEFINITIONS



Refer to Instruction Manual/Booklet



Attention: See Instructions for Use



European Conformity Mark

REF

Product Catalog Number



Manufacturer



Date of Manufacture YYYY-MM-DD



Waste Electrical and Electronic Equipment (WEEE) European Community Symbol. Regarding Electrical Equipment European Union end of life of product, indicating separate collection for electrical and electronic equipment. ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its usual life.

SN

Product Serial Number



Lot Number Example (1010175891)



Authorized European Representative



Non Sterile



Prescription

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

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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.

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

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Türk (Turkish)

Bu kullanım kılavuzu Türkçe tercümelere 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.

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

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For Surgery. For Life.™

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