5740 Pulse Lavage Instrument

Instructions for Use

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Instructions For Use – REF 5740 Pulse Lavage Instrument

APPLICABLE INSTRUMENT PART NUMBERS

REF Number	Description
5740-100	Pulse Lavage Pneumatic Handpiece, with MicroAire® Hose Connector
5740-200	Pulse Lavage Pneumatic Handpiece, with Hall® Style Hose Connector

ACCESSORIES

REF	Description
4740-013	Small Splash Shield [1.6" (4 cm)]
4700-015	Large Splash Shield [6" (15 cm)]
4700-016	Medium Splash Shield [4" (10 cm)]
5740-004	Single Orifice Nozzle
5740-004S	Single Orifice Nozzle with Suction
5740-005	Shower-head Nozzle
5740-005S	Shower-head Nozzle with Suction
5740-006	Femoral Spray Nozzle
5740-006S	Femoral Spray Nozzle with Suction
5740-008	Angled Shower-head Nozzle
5740-009	Extended Femoral Spray Nozzle
5740-009S	Extended Femoral Spray Nozzle with Suction
5740-010S	Femoral Brush with Suction
5740-020	Tubing Set
5740-020S	Tubing Set with Suction
5740-060	General Tubing Set
5740-061	Hip Tubing Set
5740-061S	Hip Tubing Set with Suction
5740-062	Knee Tubing Set
5740-062S	Knee Tubing Set with Suction

INTRODUCTION

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

NOTE: Used to point out the easiest means of carrying out techniques.

CAUTION: Used to point out special procedures or precautions that must be followed to avoid damaging the system/instrument.

WARNING: Used to indicate that the safety of the patient and hospital personnel could be involved.

GENERAL WARNINGS

NOTE: Clinical personnel should become familiar with the Pulse Lavage System before it is set up for use in any procedure.

NOTE: Use the MicroAire 9500-000 or similar pressure regulator. The main tank pressure gauge should indicate a minimum of 500 psi (35kg/cm^2). Set the output pressure gauge to indicate 100 psi (7kg/cm^2). If you have a wall or ceiling mounted air system and the air hose is longer than 3 meters, the air pressure must be increased by 6 psi (0.4kg/cm^2) for each additional meter of hose length.

CAUTION: It is essential to dry and filter compressed air, as the air lines frequently contain oil vapor, moisture, and bacteria.

CAUTION: If instrument will not hold the 4740/5740 pulse lavage disposable attachments securely, discontinue use and return to factory for service.

CAUTION: Examine product for cracks, loose or missing parts, air leaks and other defects before using.

WARNING: Prior to use, system components should be inspected and operated to detect any damage or malfunction. Do not use if damaged.

WARNING: Check air hose and tubing connector for proper fit prior to use.

WARNING: If the instrument is damaged, do not use and return to factory for service.

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

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

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** use an ultrasonic cleaner. Ultrasonic cleaning can damage the bearings in the handpiece, potentially resulting in overheating or failure of the handpiece.

CAUTION: Dried blood, saline, and other deposits inside the handpiece are a major cause of equipment malfunction. Proper cleaning and inspection prior to sterilization will avoid delays during the surgical procedure.

SYMBOL DEFINITIONS

Name	Ref# (ISO 7000)[2]	Symbol	Description	Use Standard
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[1]
REF (Catalog #)	2493		• Indicates the manufacturer's catalog number so that the medical device can be identified. • Per EN980:2008, the REF symbol may be used without surrounding box.	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. • Per EN980:2008, the SN symbol may be used without surrounding box.	ISO 15223-1:2012[1]
Lot / Batch Code	2492		Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2012[1]
Do Not Immerse in any Liquid	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). • 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.	ISO 15223-1:2012[1]
Manufacturer	3082		• 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. • When using MicroAire as the manufacturer, use the MicroAire LLC symbol.	ISO 15223-1:2012[1]
CE mark (with Notified Body #)	N/A		Indicates the European Conformity Mark with Notified Body Number. 0086 is the BSI-UK-registered Notified Body. 2797 is the BSI-NL-registered Notified Body.	Council Directive 93/42/EEC
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)
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]

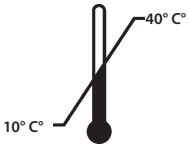
Name	Ref# (ISO 7000)[2]	Symbol	Description	Use Standard
Sterilized using Ethylene Oxide (EtO)	2501	STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide (EtO). Use of the Sterile symbol requires a use-by date (see Use-By Date symbol).	ISO 15223-1:2012[1]
Sterilized using Irradiation (gamma)	2502	STERILE R	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[1]
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[1]
Does not contain DEHP	N/A		Contains less then0.1% Phthalates—DEHP	BS EN 15986:2011 EN 15986:2011(E) Annex B
Double sterile barrier system	3704		To indicate that there are two sterile barrier systems.	ISO/TC 145/SC 3/ ICS : 01.080.20
Single sterile barrier system	3707		To indicate that there is a single sterile barrier system.	ISO/TC 145/SC 3/ ICS : 01.080.20
Single sterile barrier system with protective packaging inside	3708		To indicate that there is a single sterile barrier system with protective packaging inside.	ISO/TC 145/SC 3/ ICS : 01.080.20

[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"

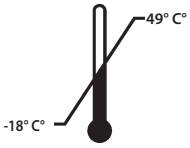
[2] ISO 7000 – "Graphical symbols for use on equipment – Registered symbols"

ENVIRONMENTAL PARAMETERS

OPERATING CONDITIONS



SHIPPING & STORAGE CONDITIONS



NOTE: The materials and components used in the construction of this device were selected to ensure that the device could be shipped by any standard method without special handling conditions.

INDENTED USE

The MicroAire REF 5740 Pulse Lavage Instrument is intended to provide pulsatile irrigation and debridement during orthopedic or general surgery in combination with MicroAire 5740 or 4740 accessories.

DUTY CYCLE

The MicroAire REF 5740 Pulse Lavage instrument is designed for a 1 minute typical continuous run time, and an 8 minute maximum continuous run time.

Product Number		5740 Pulse Lavage Pneumatic
Power Output	kW-KiloWatts 0.05	0.05
Vibration Exposure	$a_{hv}(m/s^2)$	1.68
	Uncertainty K (m/s^2)	1.5
Noise Emission Value	L_{PA} (db(A))	74
	$L_{C,peak}$ (db(C))	–
	L_{WA} (dbA))	–
Mass	Weight (kg)	0.47

INSTRUMENT COMPONENTS

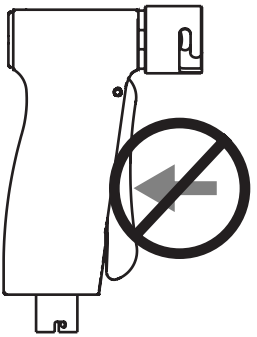
Features & Descriptions

1. Bayonet
Attach the 5740 or 4740 pulse lavage tubing pump cartridge to the instrument using the twist lock fitting. Check to ensure that the tubing is locked into place securely.

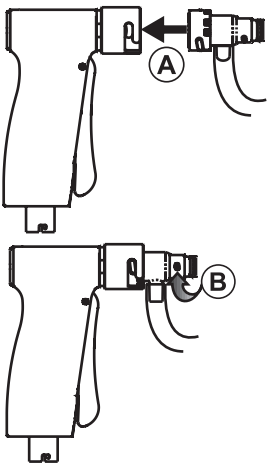
2. Instrument Trigger
The REF 5740 pulse lavage instrument features a variable speed trigger. Depress the trigger to start the pulsatile action.

3. Air Hose Connector
The pulse lavage instrument is available with a choice of air hose connectors. Be certain the connector type on the instrument matches the air hose type.

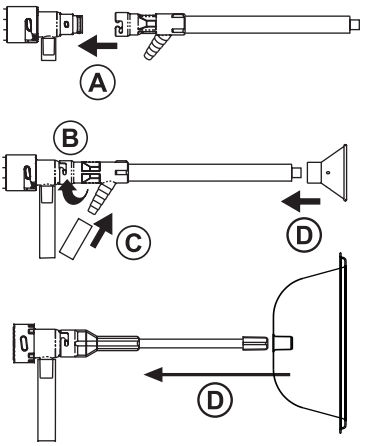
Product Number	Air-Hose Type Needed	MicroAire® 10 ft (3m) Hose REF #
REF 5740-100	MicroAire® Style Air Hose	9000-000
REF 5740-200	Hall® Style Air Hose	9013-000



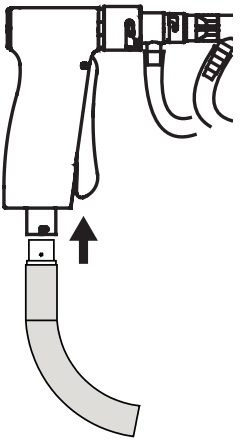
1. Make sure that that the trigger is not depressed.



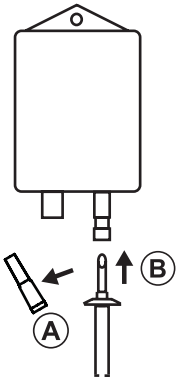
2. (A) Insert desired 5740 tubing pump into instrument and (B) twist until it locks in place.



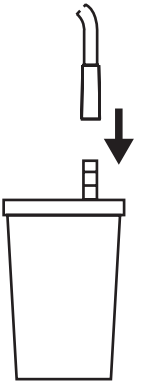
3. (A) Push attachment onto end of pump.
(B) Twist until it locks in place.
(C) Attach suction hose (if applicable)
(D) Attach splash shield (if applicable)



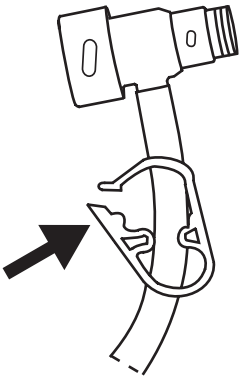
4. Connect the appropriate air hose to the instrument.



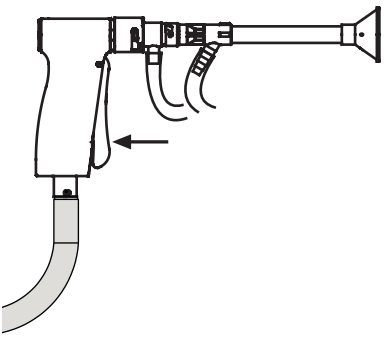
5. To connect irrigation:
   (A) Remove bag spike cap
   (B) Insert bag spike into port on irrigation bag.



6. If using a tubing set with integrated suction, connect the blue-striped suction hose to the suction canister.



7. To limit irrigation flow, or to prevent dripping, tighten the tubing clamp that is attached to the irrigation tubing.



8. Depress trigger on instrument to begin irrigation.

CLEANING AND STERILIZATION INSTRUCTIONS

Per ISO17664:2003 and AAMIST81:2004
Devices: REF 5740

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.
- **DO NOT** immerse the handpiece.
- **DO NOT** use cleaning solutions that are not mild pH unless they are approved for use with Anodized Aluminum and Surgical Instruments.
- **DO NOT** use cleaning agents with chlorine or chloride because it is corrosive to stainless steel.
- **DO NOT** use an ultrasonic cleaner. Ultrasonic cleaning can damage the bearings in the handpiece, potentially resulting in overheating or failure.
- Dried blood, saline, and other deposits inside the handpiece are a cause of equipment malfunction. Proper cleaning and inspection prior to sterilization will avoid delays.

Limitations On Reprocessing:

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

Point Of Use:

Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover with a cloth dampened with purified water. Body fluids and tissue should not be allowed to dry on instruments prior to cleaning (MAXIMUM 30 minutes).

Preparation For Decontamination

1. Disposable surgical accessories should be discarded after use.
2. Disconnect the handpiece from air source.

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.

Cleaning: Automated

1. Load the medical devices into the Washer Disinfector.
   a) Avoid contact between devices (movement during washing could cause damage and washing action could be obstructed). DO NOT overload the trays.
   b) Arrange medical devices so that cannulations are not horizontal and battery openings are oriented downwards (to assist drainage).
2. The minimum recommended Washer/Disinfector cycle is below:

#	Title	Detergent	Minutes	Temp
1	Pre-Wash	Mild pH Enzymatic *	4	< = 50 °C (122 °F)
2	Rinse	None	1**	< = 50 °C (122 °F)
3	Wash	Mild pH	4	> = 60 °C (140 °F)
4	Drain for 1 minute minimum			
5	Rinse	None	2**	> = 60 °C (140 °F)
6	Drain for 1 minute minimum			
7	Thermal Disinfect	None	10	> = 93 °C (200 °F)
8	Drain for 1 minute minimum			

* Detergent can be omitted at the pre-wash stage if the equipment does not have this ability.

** If not using neutral pH detergent, extend rinse time if possible to reduce possible degradation.

NOTE: Washer/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.

Cleaning: Manual

1. Clean the device immediately with warm (> 60 °C / 140 °F) water, neutral pH enzymatic detergent, and a soft brush. Scrub the handpiece with the brush, paying close attention to instrument crevices. Make sure the handpiece is held upright as often as possible during cleaning and rinsing to keep moisture away from air hose connection..
3. Rinse thoroughly under running (< 50 °C / 122 °F) water for a minimum of 2 minutes.
4. Clean the handpiece thoroughly with warm (> 60 °C / 140 °F) water, neutral pH detergent, and a soft brush. Scrub the handpiece with the brush, paying close attention to the instrument crevices.
5. Flush the lumens of instruments Water-Pik or similar device. Flushing removes blood, debris, and saline deposits.
6. 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.

Disinfection:

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

Drying:

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

Maintenance, Inspection and Function Testing:

1. Carefully inspect each device to ensure that all visible blood and soil has been removed.
2. Visually inspect for damage and/or wear.
3. Check the action of moving parts to ensure smooth operation throughout the intended range of motion.
4. Where instruments form part of a larger assembly, check that the devices assemble with mating components

Accidental Immersion:
If the handpiece is accidentally immersed in saline, disinfectant, cleaning fluid or other corrosive substance, take the following steps:

a. Fully submerge the handpiece in distilled water for 1 minute to dilute the corrosive fluid. DO NOT allow water to dry in the handpiece.
b. Immediately after soaking, steam sterilize in a prevacuum sterilizer at 270°F (132°C) for 4 minutes followed by a minimum drying time of 8 minutes. Sterilizing will dry out the handpiece, and will prevent rust and contamination in the motor.

Packaging:

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

Instrument Sterilization Instructions:

1. Steam Sterilization

	Instrument	Minimum Time & Temp	Min Heated Dry time
Dynamic Air Removal (pre-vacuum)	Single Instrument or Tray	4 minute Full Cycle @ 132 - 135 °C (270 - 275 °F)	8 minutes
Gravity Displacement Steam	Single Instrument or Tray	30 minute Full Cycle @ 132 - 135 °C (270 –275 °F)	8 minutes

NOTE: Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a Dynamic Air Removal (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:
- Sterile instrument packages should be examined closely prior to opening to ensure that there has been no loss of package integrity.
- Do not use instruments that are still warm. Cool to room temperature.
- Do not soak instruments or wrap in cold towels to accelerate cooling.

2. Ethylene Oxide is not recommended or validated.
3. Peracetic Acid is not recommended or validated.

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.

WARRANTY AND REPAIR

WARRANTY

MicroAire warrants the REF 5740 Pulse Lavage Instrument to be free from defects in material and workmanship 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 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 manufacturer shall have no liability of any kind for incidental or consequential damages.

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 service during the warranty period.

REPAIR SERVICE

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.

Clean and disinfect equipment before sending for repair.

℞only

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