

WELLS JOHNSON

Infusion System (WIS)

REF: 20-6000-00

INSTRUCTIONS FOR USE



CAUTION: *Federal law restricts this device to sale by or on the order of a physician.*

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Device Description

The Wells Johnson Infusion System uses a peristaltic pumping mechanism to deliver infiltration solution through the sterile, single-use tubing. The pump operates by sequentially compressing the tubing to move the solution through the tubing and into the infiltration cannula.

The power ON/OFF function is controlled by the power switch located on the rear of the unit. Pump speed is adjusted using the pump speed control knob located on the front panel.

CAUTION: *Carefully read these instructions before using the Wells Johnson Infusion System. Keep these instructions in a safe place for future reference.*

Intended Use

The Infusion System is intended to deliver infiltration solutions used during liposuction procedures.

WARNING: *The Infusion System is intended for subcutaneous administration only. Do not use the Infusion System for intravenous infusion.*

Intended Users

The Infusion System is intended to be used by qualified and trained healthcare professionals, such as licensed surgeons and operating room personnel.

Use Environment

The Infusion System is intended for use in healthcare settings, including operating rooms and other clinical environments where liposuction procedures are performed.

Contraindications

No known contraindications.

Setup and Operation

1. Pump Setup

- 1.1. Place the Infusion System on a stable, level surface outside the sterile operating field.
- 1.2. Insert the stand into the bracket located on the back of the pump. Center the hooks over the pump bracket and ensure that the stand is securely seated.
- 1.3. Connect the pneumatic foot switch tubing to either port located on the side of the pump.
- 1.4. The pump control unit and pump head must remain outside the sterile operating field.

2. Infiltration Tubing

CAUTION: *Use only sterile, single-use Wells Johnson infiltration tubing specified for use with the Infusion System. Refer to the “Part List” for approved tubing.*

WARNING: *Infiltration tubing is sterile and for single use only. Do not reuse the tubing. Reuse may result in cross-contamination.*

3. Loading the Pump Head

- 3.1. Spike the infiltration solution container using the spike provided on the Infiltration Tubing.
- 3.2. Close the tubing clamp.
- 3.3. Rotate the pump head lever counterclockwise to open the pump head.
- 3.4. Insert the enlarged center section of the tubing into the pump head opening and position the tubing over the rollers. Ensure that the flow direction is from left to right, as indicated on the pump head.
- 3.5. Rotate the pump head lever clockwise to close the pump head and secure the tubing.

4. Connecting the Infiltration Cannula and Handle

- 4.1. Connect the distal end of the infiltration tubing to the cannula handle using the luer-lock connection. Ensure that the connection is secure before operating the pump.
- 4.2. Connect the infiltration cannula or spinal needle to the handle using the luer-lock connection.
- 4.3. Verify that the tubing is not kinked, compressed, or otherwise obstructed.

5. Priming

CAUTION: *To prevent delivery of air to the patient, always prime the tubing before administering infiltration solution. Ensure that the tubing and infiltration cannula are filled with infiltration solution and that air has been removed from the fluid path before beginning infiltration.*

- 5.1. With the infiltration tubing, cannula, and handle connected, activate the pump and allow infiltration solution to flow through the tubing and cannula until the fluid path is filled with solution and visible air has been removed.
- 5.2. Stop the pump before beginning infiltration.

6. Operation

- 6.1. After installing the tubing in the pump head and completing the connections, connect the power cord to an appropriate electrical outlet with the voltage specified for the device.
- 6.2. Turn the power switch located on the rear of the unit to ON.
- 6.3. Adjust the speed control knob located on the front panel to the desired pump speed.
- 6.4. Activate the footswitch to operate the pump. Release the footswitch to stop pumping.

CAUTION: *The footswitch must be activated for the pump to operate.*

NOTE: *The numbers around the speed control knob are for reference only and do not indicate a specific flow rate.*

- 6.5. Monitor the tubing, connections, and infiltration site during operation. If leakage, tubing obstruction, abnormal resistance to flow, or other unexpected conditions occur, release the footswitch and turn the power switch OFF before investigating the cause.

7. Fluid Path and Sterile Field

The peristaltic pump head maintains the infiltration solution within the tubing and isolates the fluid path from the pump head and pump control unit. The pump head and pump control unit must remain outside the sterile operating field.

8. After Use

- 8.1. Turn the power switch located on the rear of the unit to OFF.
- 8.2. Close the tubing clamp and disconnect the tubing from the infiltration solution container and infiltration cannula and handle.
- 8.3. Dispose of the sterile, single-use tubing according to applicable facility procedures.
- 8.4. Clean and disinfect the Infusion System according to the cleaning and disinfection instructions provided in this IFU.

Device Specifications

Specification	Value
Weight	11 lb
Dimensions	7.25 in x 12.50 in x 6.25 in
Voltage Range	100 - 240 VAC, 50/60 Hz

Specification	Value
Motor Speed	0 to 800 rpm $\pm$ 100, depending on speed setting
Maximum Flow Rate	1290 mL/min

Cleaning and Disinfection

Clean and disinfect the exterior surfaces of the Infusion System between patients and whenever contamination occurs.

1. Turn the Infusion System OFF and disconnect the power cord from the electrical outlet before cleaning.
2. Remove and dispose of single-use tubing according to facility protocols.
3. Wipe the exterior surfaces of the Infusion System with a soft, lint-free cloth moistened with an appropriate hospital-grade disinfectant. Follow the disinfectant manufacturer's instructions for application and contact time.
4. Allow the surfaces to dry completely before reconnecting the device to the power supply or using the device on another patient.

CAUTION: *Do not immerse the Infusion System in water or other liquids. Do not allow liquid to enter the device, electrical connectors, switches, or other openings.*

CAUTION: *Do not spray cleaning or disinfecting solutions directly onto the Infusion System.*

Disposal

After use, disconnect the infiltration tubing from the Infusion System and dispose of the tubing in accordance with the healthcare facility's policies and applicable local, state, and federal regulations for disposal of medical waste.

Maintenance

No scheduled maintenance is required.

WARNING: *Do not modify or alter the Infusion System. Servicing or modifications must be performed only by authorized personnel.*

Part List

Description	Part Number
Power Cord 120 VAC	18-2820-00
Power Cord 240 VAC	20-5101-11
Power Cord 240 VAC Type G	20-5101-14
Pneumatic Footswitch	20-6010-02
Bag Stand	18-4200-01
Multi-Hole 6 Infiltration Cannula	20-1218-00
3-Hole Spatula Infiltration Cannula	20-1223-00
Spiral Infiltration Cannula	20-1243-00

Description	Part Number
Multi-Hole 12 Infiltration Cannula	20-1252-00
Open-Ended Infiltration Cannula	20-1257-00
Infiltration Handle	16-5181-00
Spinal Needle, sterile, single-use, 18G x 6 in	24-6002-00
Spinal Needle, sterile, single-use, 25G x 3 in	24-6003-00
Spinal Needle, sterile, single-use, 20G x 3.5 in	24-6004-00
CB Infiltration Tubing, sterile, single-use, case of 10	24-6008-00
“Y” Small Bore Infiltration Tubing, sterile, single-use, case of 10	24-6009-00
Large Bore Infiltration Tubing, sterile, single-use, case of 10	24-6028-00

Troubleshooting

Problem	Possible Cause	Recommended Action
System will not power on	Power cord is not fully connected.	Ensure the supplied power cord is fully inserted into the power receptacle on the back of the unit and into an appropriate wall outlet.
	Power switch is not in the ON (RESET) position.	Place the power switch in the ON (RESET) position.
	Circuit breaker has tripped.	Reset the circuit breaker by pressing the power switch to the ON (RESET) position.
	Unit still does not power on.	Contact Wells Johnson Customer Service.
Footswitch does not operate	Footswitch connector is not fully seated.	Ensure the footswitch connector is fully inserted into a footswitch receptacle on the side of the unit.
	Footswitch receptacle may not be functioning.	Disconnect the footswitch and connect it to the other footswitch receptacle.
	Footswitch remains nonfunctional.	Contact Wells Johnson Customer Service.
Little or no infiltration flow	Pump speed is set too low.	Turn the speed control knob clockwise to increase pump speed until the desired flow is achieved.
	Tubing is incorrectly positioned in the pump head.	Verify that the infiltration tubing is correctly positioned in the pump head and follows the flow direction indicated on the front of the unit.
	Tubing is kinked, pinched, or clamped.	Stop the pump and inspect the infiltration tubing. Remove any kink, pinch, or clamp before resuming operation.
	Tubing is not properly connected.	Stop the pump and verify that the tubing is securely connected to the fluid source and infiltration cannula or handle.
	Incorrect tubing is being used.	Verify that the infiltration tubing is an approved Wells Johnson Company tubing.
	Flow remains inadequate.	Stop the pump and inspect the tubing, connections, and pump head for an obstruction or other abnormal condition. If the problem persists, contact Wells Johnson Customer Service.

Symbols Used

Symbol	Title	Description	Standard
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021, 5.1.1
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1:2021, 5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1:2021, 5.1.7
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021, 5.4.3
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021, 5.7.7
	Prescription Only	Federal law restricts this device to sale by or on the order of a physician	FDA-recognized prescription-device designation under 21 CFR 801.109
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021, 5.7.10
	Quantity	Indicates the quantity of product contained in the labeled container.	None

Warranty

- The Infusion System is warranted for five (5) years for parts and labor from the date of shipment.
- Unauthorized handling, modification, or servicing of the Infusion System may void the warranty.
- All returns require prior authorization from Wells Johnson Customer Service.

Customer Service and Technical Support

Report any product malfunction, adverse event, or complaint to Wells Johnson Customer Service or Technical Support:

Phone: +1 520-298-6069 or 800-528-1597

Email: customerservice@wellsgrp.com



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