

WELLS JOHNSON

High Volume Harvesting Canister

5000 mL

REF: 20-5188-00

INSTRUCTIONS FOR USE

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

IFU-01262
30-Sep-2026

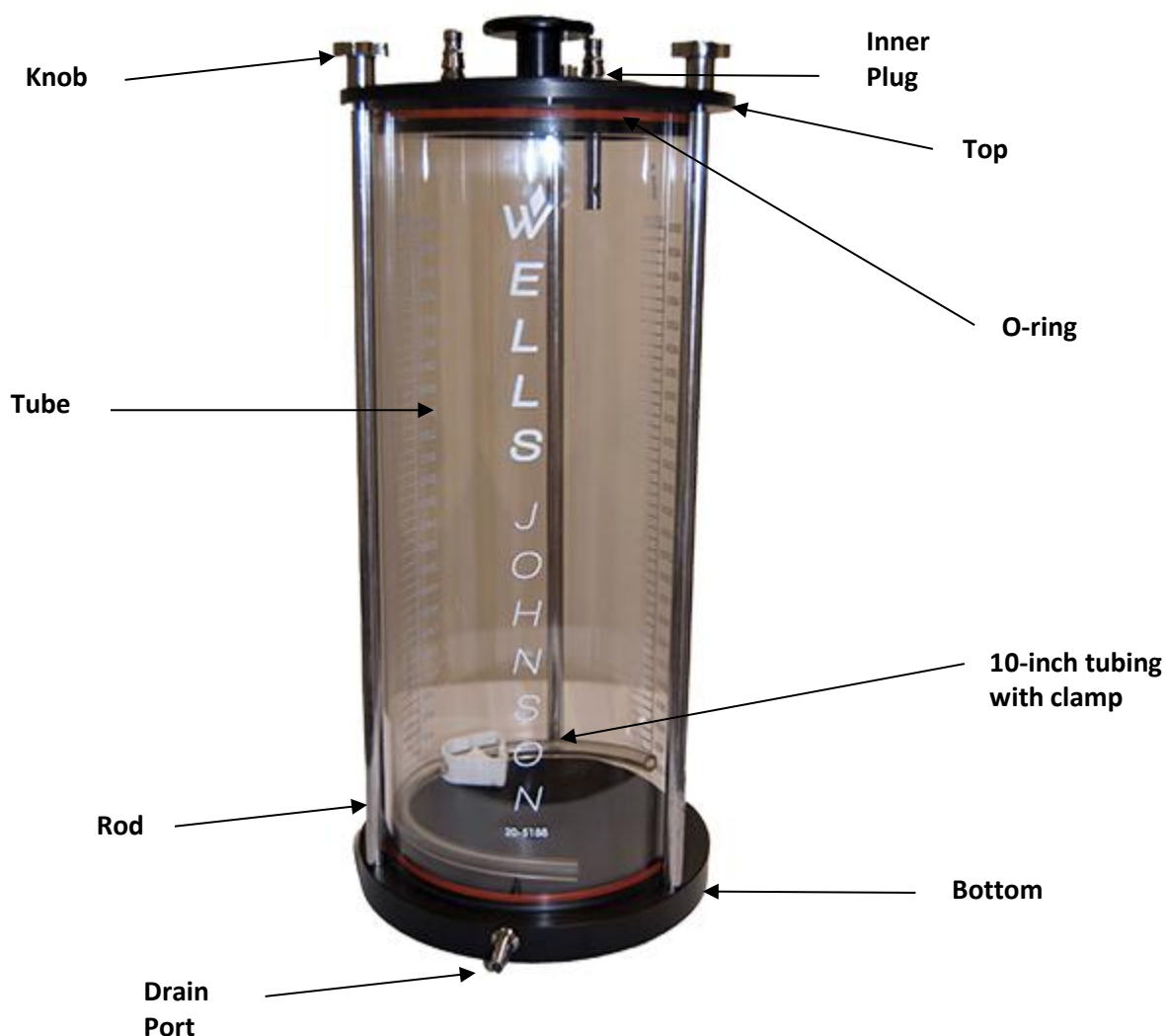
Device Description

The Wells Johnson High Volume Harvesting Canister is a reusable device supplied pre-assembled and in a non-sterile condition. The canister must be cleaned and sterilized before use in accordance with the reprocessing procedures provided in these Instructions for Use.

Rods, Knobs and Barbs are made of Stainless Steel. Tops, bottoms and plugs are made of aluminum. The canister tube is made of polycarbonate. The O-rings and drain tube are made of silicone. Silicone components may become brittle or hard after repeated normal reprocessing. The drain tube ratchet-style clamp is made of durable plastic.

All plastics are subject to aging, which can be accelerated by mechanical, chemical and thermal processes, including autoclaving. Evidence of aging may include discoloration, formation of cracks and/or warping.

Device Diagram



Intended Use

The High Volume Harvesting Canister is intended for use during liposuction procedures with an external vacuum source to collect and temporarily contain adipose tissue.

CAUTION: *Carefully read these instructions before using the canister. Keep these instructions in a safe place for future reference.*

WARNING: *Improper use or handling of the canister may result in serious injury, infection, or other adverse patient outcomes.*

Intended Users

The High Volume Harvesting Canister is intended to be used in healthcare settings by qualified and trained healthcare professionals, such as licensed surgeons and operating room personnel.

Use Environment

The High Volume Harvesting Canister is intended for use in healthcare settings, including operating rooms and other clinical environments where liposuction procedures are performed.

Contraindications

No known contraindications.

Prior to Use

CAUTION: *The High Volume Harvesting Canister is supplied non-sterile. Cleaning and sterilization must be performed before initial and each subsequent use.*

The canister is shipped assembled and must be fully disassembled for inspection, cleaning, and sterilization before use or sterile storage. Following sterilization, assembly must be performed in a sterile field immediately before use.

Before each use, visually inspect all canister components for damage, wear, cracking, brittleness, warping, or other signs of deterioration. If any component appears defective or damaged, do not use it. Discard the component in accordance with your facility's procedures. Part numbers and product descriptions are provided in these Instructions for Use for reordering.

Before each use, fully assemble the canister and verify its vacuum integrity. Evacuate the canister to the maximum specified vacuum level at least three times. The canister must maintain vacuum without leakage during each cycle. If the canister fails to maintain vacuum during any cycle, do not use the device.

Reprocessing Instructions

CAUTION: *Wear appropriate personal protective equipment (PPE) when cleaning and handling used instruments.*

1. Soak

CAUTION: *Begin cleaning within 30 minutes after use. Do not allow blood, adipose tissue, or other*

contaminants to dry on the canister or its components. Do not place contaminated components in a dry container.

- 1.1. Within 30 minutes after use, completely disassemble canister and remove excess debris with disposable cloth or non-shedding wipe and rinse with lukewarm water not exceeding 40 °C or cover components with cloth moistened with distilled water temporarily.
- 1.2. In a basin or sink large enough to accommodate all of the components, prepare enzymatic solution for soaking in accordance with enzymatic solution manufacturer instructions. The recommended enzymatic cleaning solution is McKesson Multi-Enzymatic Cleanser.
- 1.3. Place the components into the enzymatic cleaning solution, flush all ports and passages with a 60 mL syringe and soak for a minimum of 10 minutes. Additional soaking time may be necessary to loosen difficult to remove matter.

2. Manual Clean

- 2.1. Remove canister components from enzymatic solution and rinse thoroughly with lukewarm tap water, not exceeding 40 °C to remove gross debris.
- 2.2. Place the components back in the enzymatic solution to continue cleaning.
- 2.3. Using a suitable flexible cleaning brush (e.g., Wells Johnson Part No. 20-5230-00) clean the inside surfaces of all cannulated ports and passages, including patient and vacuum barbs, drain hose barb on base, the drain tube, the threaded portion of the three rods, and the three holes in both the top and base where the rods are inserted.
- 2.4. Thoroughly flush the cannulated ports and passages with the enzymatic solution using a 60 mL syringe. Repeat this step at least two times.
- 2.5. With a non-shedding wipe or disposable towel with the enzymatic solution, clean the inner and outer surfaces of the canister tube and the remaining components, including the O-ring channels until all debris has been removed.
- 2.6. If necessary, use forceps to remove difficult debris in smaller areas. After the debris is removed, wrap the tip of the forceps with a non-shedding wipe and wipe the area where debris was removed.
- 2.7. Remove the components from the enzymatic solution. Drain enzymatic solution and thoroughly rinse all components with tap water, not exceeding 40 °C.

3. Ultrasonic Cleaning

- 3.1. In an ultrasonic cleaner (bath) large enough to fully immerse all components, prepare enzymatic solution for ultrasonic cleaning (bath) according to enzymatic solution instructions. The recommended enzymatic solution is McKesson Multi-Enzymatic Cleanser.
- 3.2. Place all components into ultrasonic bath, completely submerged, for 10 minutes according to the ultrasonic cleaner manufacturer instructions.
- 3.3. Remove all components from ultrasonic bath and thoroughly rinse with distilled water, not

exceeding 40 °C, for 3 minutes.

- 3.4. Repeat steps 3.2 and 3.3 until there is no visible debris or soil and no residual enzymatic cleaning solution is present in the rinse water.

CAUTION: *Prior to autoclaving, completely remove all cleaning solution residues by thorough rinsing.*

4. Drying

- 4.1. Ensure all the components are completely clean.
- 4.2. Thoroughly dry all components using a clean, absorbent, non-shedding towel. Allow the components to air-dry completely. Medical-grade filtered compressed air may also be used.
- 4.3. Repeat step 4.2 as necessary until all components are completely dry and free of visible moisture.

5. Sterilization Packaging

- 5.1. When completely dry, inspect each component for damage or signs of fatigue. If signs of damage or fatigue are identified, do not use; dispose of the component.

CAUTION: *Do not use or sterilize any component that shows signs of damage or deterioration. Replace or discard the component in accordance with your facility's procedures.*

- 5.2. After inspection, package the clean, dry, and unassembled canister components in sterilization packaging in accordance with ISO 11607.
- 5.3. The sterilization packaging should provide sufficient protection for the device components from mechanical damage.
- 5.4. The polycarbonate canister tube must be packaged separately because it requires a different sterilization cycle than other canister components.

CAUTION: *Do not sterilize the polycarbonate canister tube using the sterilization cycle specified for the other canister components. Use only the sterilization cycle specified for the polycarbonate canister tube. Failure to follow the specified sterilization cycle may damage or deform the tube.*

6. Sterilization

CAUTION: *Use only the sterilization methods specified in this section. Do not use any other sterilization methods.*

6.1. Polycarbonate Tube Sterilization Procedure

- | | |
|-----------------------|----------------------|
| 6.1.1. Cycle: | Gravity Displacement |
| 6.1.2. Temperature: | 121 °C (250 °F) |
| 6.1.3. Exposure Time: | 30 minutes |
| 6.1.4. Dry Time: | 30 minutes |

CAUTION: *The polycarbonate tube must be sterilized in accordance with the Polycarbonate*

Tube Sterilization Procedure provided above. Failure to follow the specified sterilization procedure may damage or deform the tube.

6.2. Canister Components Sterilization Procedure

- | | |
|-----------------------|----------------------|
| 6.2.1. Cycle: | Gravity Displacement |
| 6.2.2. Temperature: | 132 °C (270 °F) |
| 6.2.3. Exposure Time: | 15 minutes |
| 6.2.4. Dry Time: | 30 minutes |

CAUTION: *Do not use flash sterilization on any canister components.*

Storage

Store the sterilized canister components in suitable sterilization packaging until subsequent use. Maintain the integrity of the sterilization packaging during storage, handling, and transport.

Store packaged canister components in a clean, dry, dust-free area protected from contamination, direct sunlight, excessive heat, and moisture. Avoid conditions that may adversely affect the integrity of the sterilization packaging or the device.

Disassembly Instructions

1. Unscrew the three metal knobs from the top of the canister.



2. Remove the three metal rods through the bottom of the canister.



3. Remove black top from canister. For first-time use, remove silicone tubing from inside the canister.



4. Remove inner plug by gently pulling knob.



5. Remove the two orange O-rings from the inner plug. To remove an O-ring, position your thumb and index finger at approximately the 10 o'clock and 2 o'clock positions on the O-ring. Squeeze your thumb and index finger toward each other until a portion of the O-ring lifts out its groove. Hold the exposed portion of the O-ring to remove it.



6. Remove orange O-ring from canister top using same method as in Step 5.



7. Remove polycarbonate tube from canister bottom.



8. Remove orange O-ring from black canister bottom using same method as in Step 5 to complete disassembly.



Assembly Instructions

CAUTION: *Assemble the canister on a sterile field prior to patient use.*

1. Locate canister top, canister bottom, plug and four orange O-rings: two larger O-rings and two smaller O-rings.



2. Place one large O-ring along the groove of the canister top. Ensure the O-ring fits snugly in the groove. Gently run your index finger along the O-ring to verify that it is properly seated. The O-ring should not move within the groove.



3. Repeat Step 2 using the second large orange O-ring and the canister bottom.



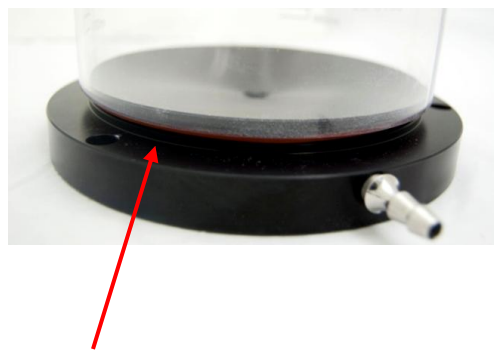
4. Place one smaller orange O-ring into each of the two grooves on the plug. Ensure that all O-rings are properly seated in their respective grooves to ensure a proper seal.



5. Align the Wells Johnson vertical logo on the polycarbonate tube with the silver hose barb on the canister bottom. Firmly press the tube onto the canister bottom until it is securely attached. Ensure that the tube is fully seated against the canister bottom with no gaps between the tube and the canister bottom.



Correctly attached:
Tube fully seated against canister bottom with no gap.



Incorrectly attached: Gap present

6. Tilt the canister slightly onto its side. Insert the three metal rods through the canister bottom.



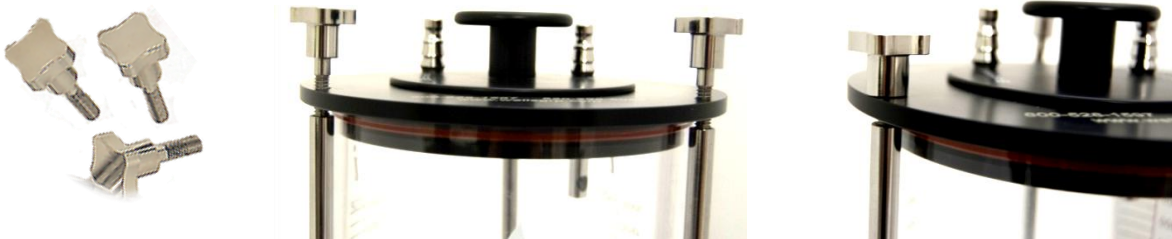
7. Attach the black canister plug to the canister top by pressing the plug firmly into the opening until it is fully seated.



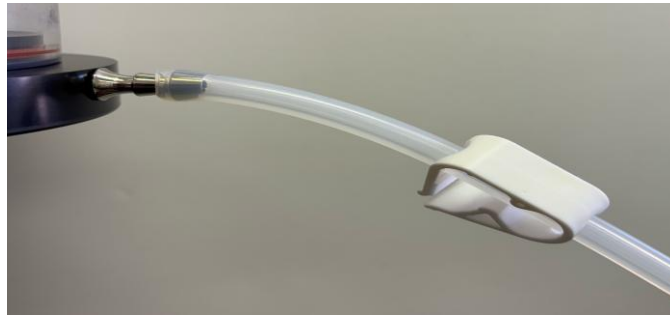
8. Align the three holes in the canister top with the three metal rods. Firmly press the canister top onto the polycarbonate tube until it is securely attached. Ensure that the polycarbonate tube is fully seated against the canister top with no gaps. See Step 5 for reference.



9. Locate the three metal knobs. Insert each screw through a hole in the canister top and into the corresponding metal rod. Rotate the knobs clockwise to secure the canister top.



10. Place the ratchet clamp onto the 10-inch tubing without closing the clamp. Firmly press the tubing onto the hose barb on the canister bottom. Slide the clamp over the hose barb and pinch the clamp closed to occlude the tubing. Ensure the tubing is securely attached, and the clamp is fully closed before use.



Canister Components and Part Numbers

Part Number	Description
20-5178-05	Rod
20-5178-00	Knob
20-5177-65	Tube
16-5196-00	Canister top
16-5197-00	Canister bottom
20-5191-50	Plug large
20-5180-59	O-ring kit (4 O-rings)
20-5179-21	10-inch tubing and clamp

Symbols Used

Symbol	Title	Description	Standard
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2021, 5.1.3
	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, 5.1.5
	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
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021, 5.2.7
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021, 5.7.7

Symbol	Title	Description	Standard
R_x Only	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
UDI	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021, 5.7.10
QTY	Quantity	Indicates the quantity of product contained in the labeled container.	None

User Responsibility

It is the responsibility of the user to ensure that reprocessing is performed using appropriate equipment, materials, and trained personnel to achieve effective and safe results. The user is responsible for following the validated reprocessing procedures provided in this IFU and ensuring that personnel performing reprocessing are properly trained and follow the specified reprocessing requirements.

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 +1 800-528-1597

Email: customerservice@wellsgrp.com



8000 S. Kolb Road
Tucson, AZ 85756 USA
Phone: +1 520-298-6069
eFax: +1 520-885-1189
www.wellsgrp.com