

WELLS JOHNSON

HVC3™

High Volume Canister

3000 mL

REF: 20-8300-00

INSTRUCTIONS FOR USE

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

Device Description

The Wells Johnson HVC3™ High Volume 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.

The HVC3 Canister base, top, and three latches are constructed from medical-grade polysulfone (PSU) plastic. The drain tube ratchet-style clamp is manufactured from acetal (POM). The O-ring and drain tube are made of medical-grade silicone.

Repeated mechanical, chemical, and thermal reprocessing, including autoclaving, may cause gradual material degradation over the service life of the canister. Signs of material degradation may include discoloration, cracking, warping, brittleness, or hardening. Inspect the canister and components before each use. Do not use the canister if any component shows signs of damage, degradation, or loss of function.

Device Diagram

The image below illustrates the features and components of the HVC3 Canister. These components, referenced throughout these instructions, are included with each HVC3 Canister.



For component part numbers, refer to the “**HVC3 Canister Components and Part Numbers**” section of these instructions.

NOTE: *Drain Tube Assembly is not shown in the diagram. See the “HVC3 Canister Components and Part Numbers” section for an image.*

Operating Specifications

- Validated Vacuum Level: up to 26.5 inHg (89.8 kPa), corresponding to the maximum vacuum level of the vacuum source at Wells Johnson's manufacturing site 2,388 feet (728 meters) above sea level.
- Compatible Aspiration Tubing: Inner diameters from 0.354 inch to 0.492 inch (9 mm to 12.5 mm).

NOTE: *The maximum achievable vacuum level may vary depending on site elevation. At lower elevations, including sea level, the maximum achievable vacuum level may be higher than the value measured at Wells Johnson's manufacturing site. At elevations higher than Wells Johnson's manufacturing site 2,388 feet (728 meters) above sea level, the maximum achievable vacuum level may be lower.*

Intended Use

The Wells Johnson HVC3 High Volume 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 HVC3 Canister. Keep these instructions in a safe place for future reference.*

WARNING: *Improper use or handling of the HVC3 Canister may result in serious injury, infection, or other adverse patient outcomes.*

Intended Users

The HVC3 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 HVC3 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 HVC3 Canister is supplied non-sterile. Cleaning and sterilization must be performed before initial and each subsequent use.*

The HVC3 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 HVC3 Canister components for damage, wear, cracking, brittleness, warping, or other signs of deterioration. If any component appears defective or damaged, do not use the component. Discard the component in accordance with your facility's procedures.

Before each use, fully assemble the HVC3 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.

Refer to the **Disassembly and Assembly Instructions** section for detailed guidance.

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 HVC3 Canister or its components. Do not place contaminated components in a dry container.*

- 1.1. Within 30 minutes after use, completely disassemble the HVC3 Canister. Remove excess debris from all components using disposable cloth or non-shedding wipe. Rinse the components with lukewarm water not exceeding 40 °C. If immediate rinsing is not possible, temporarily cover the components with a cloth moistened with distilled or deionized water to prevent debris from drying.
- 1.2. In a basin or sink large enough to accommodate all components, prepare a neutral pH (pH 7) enzymatic cleaner in accordance with the enzymatic cleaner manufacturer instructions. The recommended enzymatic cleaner is STERIS Prolystica 2XConcentrate Enzymatic Presoak and Cleaner or an equivalent product that is suitable for manual cleaning and ultrasonic cleaning.
- 1.3. Place the components into the enzymatic cleaning solution. Using a 60 mL syringe filled with the cleaning solution, flush all ports and passages. Soak the components for a minimum of 10 minutes. Additional flushing and soaking time may be necessary to remove visible or difficult-to-remove debris.

CAUTION: *Do not use phenol-based cleaning or disinfecting agents, as they may damage the HVC3 Canister or its components.*

2. Manual Clean

- 2.1. Remove the canister components from the enzymatic solution soak and rinse thoroughly with lukewarm tap water, not exceeding 40 °C to remove gross debris.
- 2.2. Return the components to the enzymatic cleaning solution and keep them immersed during manual cleaning.
- 2.3. Using a suitable flexible cleaning brush (e.g., Wells Johnson Part Number: 20-5230-00), clean the inside surfaces of all cannulated ports and passages; including both barbs (1 and 2) on canister top, drain port barb on base, and the silicone drain tubing.

- 2.4. Thoroughly flush the cannulated ports and passages with the enzymatic cleaning solution using a 60 mL syringe. Repeat the flushing at least two times or until all visible debris has been removed.
- 2.5. Using a non-shedding wipe or disposable towel moistened with enzymatic cleaning solution, thoroughly clean all internal and external surfaces of the canister components, including the O-Ring channel on the top and the spaces under the canister base until all visible debris has been removed.
- 2.6. If necessary, use forceps to remove difficult debris from 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 and inspect all items for remaining visible debris. If debris remains, repeat Steps 2.2-2.6 until all visible debris has been removed.
- 2.8. Remove the components from the enzymatic cleaning solution and drain the solution. 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 HVC3 Canister components, prepare enzymatic cleaning solution in accordance with the enzymatic cleaner manufacturer's instructions. The recommended enzymatic cleaner is STERIS Prolystica 2X Concentrate Enzymatic Presoak and Cleaner, or an equivalent product suitable for ultrasonic cleaning.
- 3.2. Place all components in the ultrasonic bath, ensuring that they are completely submerged and do not contact one another. Sonicate for a minimum of 10 mins according to the ultrasonic cleaner manufacturer's instructions.
- 3.3. Remove all components from ultrasonic bath and thoroughly rinse with distilled or deionized water, not exceeding 40 °C for a minimum of 3 minutes.
- 3.4. Repeat steps 3.2 and 3.3 until the rinse water is free of visible debris and residual enzymatic cleaning solution.

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

4. Drying

- 4.1. Ensure all 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 signs of damage, wear, cracking, brittleness, warping, or other deterioration.

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, ensure all HVC3 Canister components are unassembled and wrap them in accordance with ANSI/AAMI ST79 using sterilization packaging appropriate for steam sterilization.

5.3. Ensure the packaging provides sufficient protection for the canister components from mechanical damage.

5.4. The HVC3 Canister components are recommended to be individually packaged for terminal sterilization.

6. Sterilization

Only the sterilization method and cycle parameters specified below have been validated for use with the HVC3 Canister. Do not use alternative sterilization methods or cycle parameters, as they may compromise device integrity, performance, or sterility.

HVC3 Canister Sterilization Procedure:

- Method: Moist Heat Sterilization according to ANSI/AAMI ST79
- Cycle: Pre-Vacuum Steam
- Temperature: 132 °C (270°F)
- Exposure Time: 4 minutes
- Dry Time: 30 minutes

CAUTION: *Do not use immediate-use steam sterilization ("flash sterilization"). The validated sterilization cycle and sterilization packaging specified in this IFU must be followed.*

NOTE: *The HVC3 Canister has been validated for a minimum of 100 autoclave cycles when reprocessed using the cleaning, packaging, and sterilization parameters specified in these Instructions for Use.*

Storage and Transport Conditions

After sterilization, store the HVC3 Canister in its sterilization packaging until subsequent use. Sterilization packaging must be selected and used in accordance with ANSI/AAMI ST79 and applicable requirements of ISO 11607.

Store the sterilized HVC3 Canister components in a clean, dry, dust-free area protected from direct sunlight, contamination, and excessive temperature fluctuations. Handle and store packaged components in a manner that prevents damage to the sterilization packaging and maintains package integrity.

Disassembly Instructions

Follow the steps below to disassemble the HVC3 Canister in preparation for cleaning, and sterilization.

The HVC3 Canister is supplied pre-assembled and must be disassembled before cleaning and sterilization.

1. Disconnect the aspiration tubing from ports 1 and port 2 by pulling the tubing straight off the hose barbs.



CAUTION: *To prevent damage or breakage of the hose barbs, pull the tubing straight off the hose barbs in the direction of the barbs. Do not bend, twist, or apply sideways force to the hose barbs during tubing removal.*

2. Disengage all three latches from the base by rotating each latch upward, as shown in the image below.



3. Once all three latches have been disengaged from the base, continue rotating each latch upward and over until it releases from canister top.



4. Using the knob on the canister top, pull the top up until it separates from the base.



5. Remove the O-Ring from the canister top by placing your thumb and index finger on the O-Ring approximately 2-3 inches apart. Firmly squeeze your thumb and index finger together to raise a Portion of the O-ring above the groove.



If the O-Ring is hard to remove, use forceps or pickups to gently lift from channel as shown below.



NOTE: *The O-Ring may be difficult to remove from channel for the first few uses.*

6. Using the elevated portion of the O-Ring, pull the O-ring out of the channel.



7. Pull the drain tube off the drain port located near the bottom of the canister base.

NOTE: *Skip this step during the initial disassembly of a new, unpackaged canister.*



8. Open the white clamp, if not already open, and slide off the drain tube.

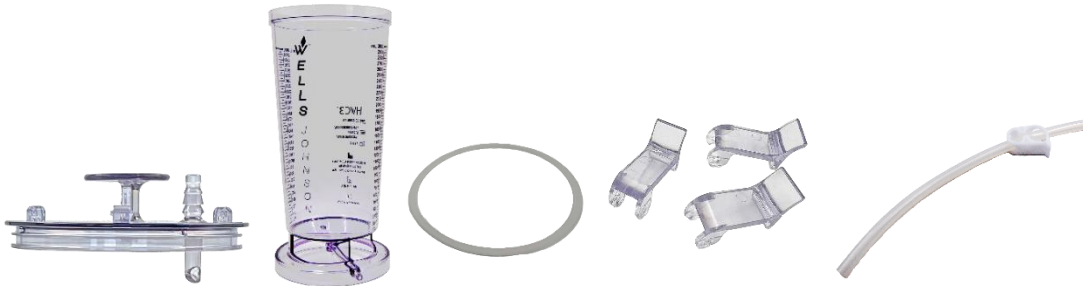


9. The canister is now disassembled and ready for cleaning and sterilization.

Assembly Instructions

Assembly of the canister must be performed in a sterile field prior to patient use. Follow the steps below to reassemble the HVC3 Canister after cleaning and sterilization.

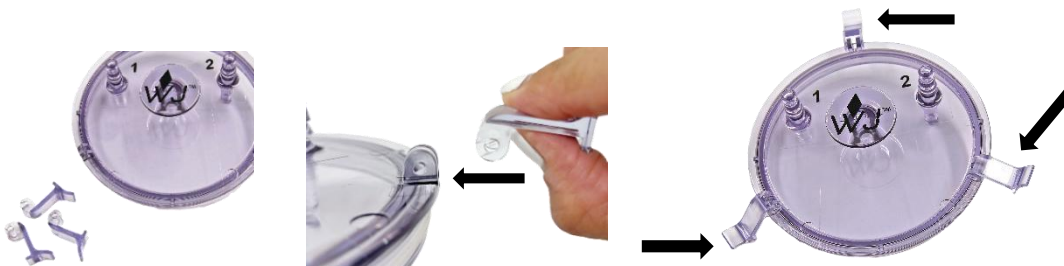
1. Locate the following components: canister top, canister base, O-Ring, three latches, and drain tube with clamp.



2. Place the O-ring in the groove of the canister top with the “fingers” pointed outward, as shown in image below. The O-ring should fit snugly in the groove. To verify the correct installation, gently run your index finger around the entire O-ring. The O-ring should remain securely seated in the groove.



3. Locate the three latches and the canister top. Attach each latch to the latch connections on the canister top, as shown below. Firm pressure may be required to securely attach the latches. The latches are properly engaged when they are positioned as shown in the figure below and remain engaged when gently tugged.



4. Place the canister top on the canister base and press down until there is little to no space between canister base and canister top. Then, engage each latch by rotating downward until it snaps onto the canister base.



5. Install the clamp on the silicone tube. Close clamp and firmly press the tubing on the hose barb located on the canister base ensuring a tight seal.



6. Aspiration Tubing Connection Instructions:

a. **Vacuum Source Connection — Port #1**

Attach sterile aspiration tubing (not included) to hose barb port #1 by firmly pressing the tubing straight onto the hose barb, in line with the direction of the hose barb. Connect the opposite end of the tubing to the vacuum source.

b. **Patient Connection – Port #2**

Attach sterile aspiration tubing (not included) to hose barb port #2 by firmly pressing the tubing straight onto the hose barb, in line with the direction of the hose barb. Connect the opposite end of the tubing to the aspiration cannula.

Ensure all tubing connections are secure and maintain sterility throughout the setup

CAUTION: *To prevent damage or breakage of the hose barb, press the tubing straight onto the hose barb in the direction of the barb. Do not bend, twist, or apply sideways force to the hose barb during connection.*



7. The HVC3 Canister is fully assembled when all components are securely connected and the assembled canister matches the configuration shown below.



CAUTION: Do not pull or tug on the aspiration tubing or drain tube while the HVC3 Canister contains aspirated material. Pulling or tugging on the tubing may cause the HVC3 Canister to tip over.

CAUTION: Do not lift the HVC3 Canister by the knob on the canister top when the canister contains aspirated material. To lift the HVC3 Canister, support the canister base with both hands.

HVC3 Canister Components and Part Numbers

REF	Description
20-8300-01	Base, Canister
20-8300-02	Top, Canister
20-8300-03	Latch, Canister (set of 3)
20-8300-04	O-ring, Canister, Silicone
20-5179-21	10 in Tubing Assembly, Silicone

Optional Accessories

REF	Description
20-8300-05	HVC3™ Plate
24-5103-00	Standard Ultra-Limp Aspiration Tubing
24-5104-00	MB Ultra-Limp Aspiration Tubing

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
	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1:2021, 5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021, 5.1.5

Symbol	Title	Description	Standard
	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
	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

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

Warranty

- The HCV3 is warranted for one (1) year, or 100 reprocesses, whichever comes first.
- Unauthorized handling, modification or use of the HVC3 may void the warranty.
- Improper reprocessing or storage may void the warranty.
- All returns require prior authorization from Wells Johnson Customer Service.



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

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Patents granted and/or pending, see www.wellsgrp.com