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WELLS JOHNSON HVC3™

High Volume Canister, 3L

INSTRUCTIONS FOR USE

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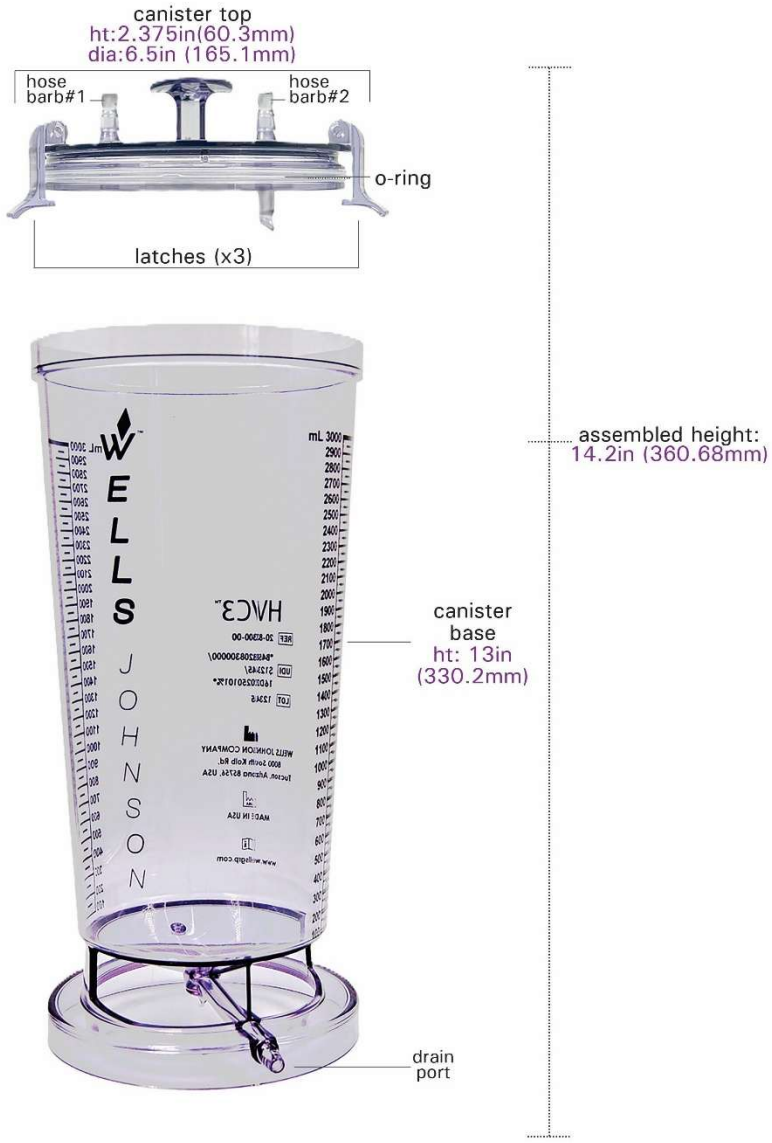
Device Description

HVC3™ canisters are reusable, non-sterile devices shipped pre-assembled. They must be cleaned and sterilized prior to use.
The HVC3™ canister base, top and three latches are constructed from medical-grade Polysulfone (PSU) plastic. The drain tube's ratchet-style clamp is made of durable acetal (POM). All plastics are subject to a normal aging process, which can be accelerated by mechanical, chemical and thermal processes such as autoclaving. Evidence of aging may include discoloration, cracking or warping. The O-ring and drain tube are made of medical-grade silicone. Silicone material may become discolored, brittle or hardened after repeated normal reprocessing.

Device Diagram

The image below illustrates the features and components of the HVC3™ canister.
These components, referenced throughout these instructions, are included with each unit sold.
For details, see 'HVC3™ Canister Components and Part Numbers' section in these instructions.

Note: *Drain Tube Assembly is not pictured. See the* ***'HVC3™ Canister Components and Part Numbers'*** *section for an image.*



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Intended Use

The HVC3™ canister is intended for use with an external vacuum source to safely collect and temporarily contain body fluids. This device is designed for use by licensed healthcare professionals in clinical or hospital settings.

Carefully read these instructions before using the Wells Johnson Company HVC3™. Keep them in a safe place for future reference.

Use devices for their intended use only.

Intended Users

HVC3™ canisters should be used and operated by licensed healthcare professionals who are trained and familiar with their assembly, disassembly, and proper use.

℞ Only *Federal (USA) law restricts this device to sale by or on the order of a physician.*

Performance Characteristics

- Recommended Maximum Vacuum Level: 0–22 inHg (0-74.5 kPa)
  Validated up to 27 inHg (0-91.4 kPa), which corresponds to maximum vacuum of the vacuum source at manufacturer's altitude.
- Fits aspiration tubing with inner diameters from 0.354 inch to 0.492 inch (9 mm - 12.5 mm)

Lifetime

The HVC3™ canister has been validated for a minimum of 100 autoclave cycles using the reprocessing parameters specified in these instructions.

Prior to use

A visual inspection of all canister components must be performed prior to assembly for each use. If any component appears defective, worn, cracked, brittle, warped or otherwise damaged, do not use it. Discard the component in accordance with your facility's procedures. To test functionality, fully assemble the HVC3™ canister and evacuate it to maximum vacuum levels at least three times before actual use. The canister should maintain vacuum without leakage during each cycle. If any component fails to hold vacuum do not use the device.
Part numbers and product descriptions for re-ordering are provided in these instructions. Canisters are shipped assembled and must be fully disassembled for inspection, cleaning, and sterilization before use or sterile storage. Assembly must be performed in a sterile field prior to use. *Refer to the Disassembly and Assembly Instructions section for detailed guidance.*

NON STERILE *The HVC3™ canisters are packaged non-sterile. Cleaning and sterilization must occur prior to use.*

It is the responsibility of the user to inspect the canister components prior to use. If the device does not function properly, or there are damaged components, do not use and discard the affected item(s).

Do not use phenol based cleaning and disinfecting agents.

Do not reuse HVC3™ Canister if it has been used on a patient with or suspected of having Creutzfeldt-Jakob Disease (CJD), or possible variants of CJD (vCJD).

Reprocessing Instructions

1. Soak

1.1. Within 30 minutes after use, completely disassemble HVC3™ canister and remove excess debris on all components with disposable cloth or non-shedding wipe and rinse with lukewarm water not

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exceeding 40 °C or cover components with cloth moistened with Distilled or Deionized Water temporarily.

1.2. In a basin or sink large enough to accommodate all of the components, prepare neutral pH (7) enzymatic cleaner for soaking in accordance with enzymatic cleaner manufacturer instructions. The recommended enzymatic solution is STERIS® Prolystica® 2XConcentrate Enzymatic Cleaner or similar and should be suitable for manual and automated ultrasonic systems.

1.3. Place the components into the enzymatic solution, flush all ports/passages with a 60cc syringe filled with solution and then let soak for a minimum of 10 minutes. Additional flushes and soak time may be necessary for hard to remove matter.

⚠ *Cleaning and rinsing must take place immediately after each use to minimize drying of soil and debris.*

⚠ *Always wear appropriate protective gear when performing cleaning procedures.*

2. Manual Clean

2.1. Remove canister components from enzymatic solution soak and rinse thoroughly with lukewarm tap water, not exceeding 40 °C to identify and remove any 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 #: 20-5230-00) clean the inside surfaces of all cannulated ports/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/passages with the enzymatic solution using a 60 ml Syringe. Repeat this step at least 2 times or until visible debris is removed.

2.5. With a non-shedding wipe or disposable towel and the enzymatic solution, clean all inner and outer surfaces of the canister components, including the O-Ring channel on the top and the spaces under the base 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 and inspect all items for remaining debris. Repeat steps 2.2-2.6 until debris is removed.

2.8. Remove items, 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 HVC3™ components, prepare enzymatic solution for Ultrasonic Cleaning (bath) according to enzymatic solution instructions. The recommended enzymatic solution is STERIS® Prolystica® 2X Concentrate Enzymatic Cleaner, or similar, and is suitable for manual and automated ultrasonic systems.

3.2. Place all components into ultrasonic bath, completely submerged and not touching one another, for 10mins according to the Ultrasonic Cleaner (bath) manufacturer instructions.

3.3. Remove all components from ultrasonic bath and very thoroughly rinse with Distilled or Deionized Water, not exceeding 40 °C, for 3 minutes.

3.4. Repeat steps 3.2 and 3.3 until there is no sign of debris, soil or enzymatic solution in the rinse stream.

⚠ *Prior to autoclaving, all chemical disinfectant residues must be completely removed by thorough rinsing.*

4. Drying

4.1. Ensure all the components are completely and properly clean.

4.2. Thoroughly and completely wipe any moisture from components using a clean, absorbent, and non-shedding towel, and let air-dry. Medical grade filtered compressed air may also be used.

4.3. Repeat step 4.2 as necessary until completely dry and free of moisture.

5. Packaging

5.1. When completely dry, inspect each component for damage or signs of fatigue. If signs of damage or

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fatigue are identified, do not use and discard.

⚠ *If signs of damage or fatigue are identified, do not use and discard.*

5.2. The inspected and unassembled HVC3™ components should be terminally wrapped in accordance with ANSI/AAMI ST79.
5.3. Packaging should ensure sufficient protection of the device components and sterilization packaging from mechanical damage.
5.4. The HVC3™ canister components are recommended to be individually packaged for terminal sterilization.

6. Sterilization

Only the sterilization method below should be used; other sterilization methods are not permitted.

6.1. HVC3™ Canister Sterilization Procedure

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

⚠ *Do not use flash sterilization on any HVC3™ components.*

Storage and Transport Conditions

Canisters must be stored until subsequent use in suitable sterilization packaging according to the standards. The storage area must be dust-free, low microbiological contamination, dark and free of temperature fluctuations. Identify and store sterile products in accordance with ISO 11607. Storage and Transport limits:
-40 °C to 70 °C
15% to 90% Relative Humidity
620 hPa to 1060 hPa Atmospheric Pressure

Disassembly Instructions

Follow the steps below to disassemble the HVC3™canister in preparation for cleaning, and sterilization. HVC3™canisters are delivered to customers pre-assembled.

1. Disengage all three latches from the base by rotating the latches upward as shown in the image below.

2. When all three latches have been disengaged from the base, continue rotating the latches upward and over until they release from canister top.

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3. Using the knob on the canister top, pull up until the base and top have been separated.

4. Remove O-Ring on the canister top by placing your thumb and index finger on the O-Ring about 2-3 inches apart. Firmly squeeze your thumb and index finger together until a portion of the O-Ring is elevated.

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.

5. Using the elevated portion of the O-Ring, remove from canister top.

6. Pull the drain tube off the drain port located near the bottom of the canister base.
Note: Skip this step for the first disassembly of a new unpackaged canister.

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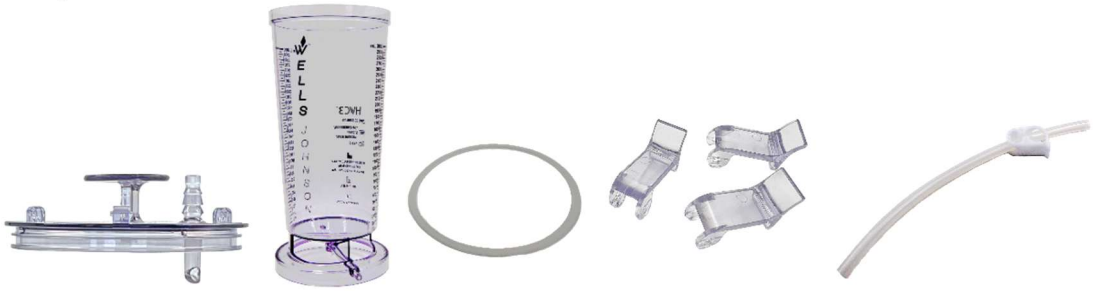
7. Open the white clamp, if not already open, and slide off the drain tube.

8. The canister is disassembled and ready for processing.

Assembly Instructions

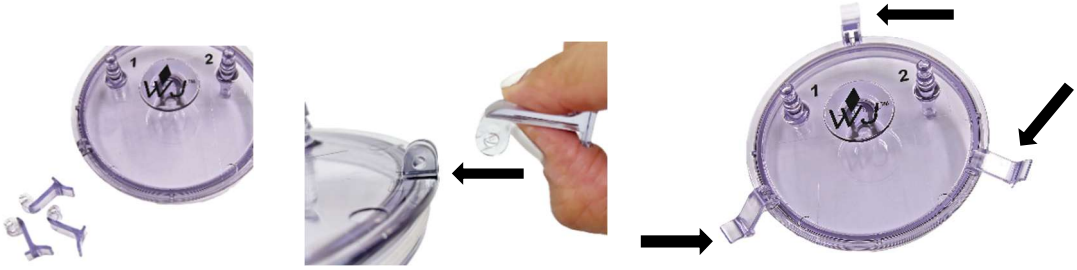
Assembly of the canister must be performed in a sterile field prior to patient use.

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 snuggly in the groove. To verify the correct installation, gently run your index finger along all sides of the O-ring. It should remain securely seated in the grove.

3. Locate the three latches and canister top. Attach each latch to the latch connections on the canister top as shown below.
Applying firm pressure may be necessary to securely attach the latches. The latches are properly engaged when they resemble the figure below and do not disengage when gently tugged.



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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. Attach sterile aspiration tubing (not included) to hose barb port #2 by firmly pressing tubing over barb.
   Note: Connect the opposite end to the suction cannula.

b. Attach a second piece of sterile aspiration tubing (not included) to hose barb port #1 by firmly pressing tubing over barb.
   Note: Connect the opposite end to the vacuum source.

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

#1

#2

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

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⚠ *Do not pull or tug on aspiration tubing, or drain tube when contents are present in HVC3™ as this may cause the HVC3™ to tip over.*

⚠ *Do not lift HVC3™ by knob on lid when contents are present in HVC3™. Hold base with 2 hands to lift.*

HVC3 Canister Components and Part Numbers

REF	Description	Image
20-8300-01	Base, Canister	
20-8300-02	Top, Canister	
20-8300-03	Latch, Canister	
20-8300-04	O-ring, Canister, Silicone	
20-5179-21	10” Tubing Assembly, Silicone	

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Optional Accessories

REF	Description	Image
20-8300-05	HVC3™ plate	
24-5103-00	Standard aspiration tubing	
24-5104-00	MB Ultra limp tubing	

Symbols Used

Symbol	Description
	Symbol for: Manufacturer
REF	Symbol for: Catalog or Part Number
LOT	Symbol for: Batch Code
	Symbol for: Consult the Instructions for Use
	Symbol for: Non-Sterile
	Symbol for: Caution
℞ Only	Caution: Federal law restricts this device to sale by or on the order of a physician
	Symbol for: Date of Manufacture
UDI	Symbol for: Unique Device Identifier

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User Responsibility

It is the responsibility of the re-processor to ensure that reprocessing is performed using appropriate equipment, materials, and trained personnel to achieve effective and safe results. The re-processor must ensure compliance with validated procedures and maintain routine oversight to confirm that all personnel are properly trained and adhere to reprocessing requirements.