

WELLS JOHNSON HARVESTING CANISTERS

INSTRUCTIONS FOR USE



Intended Use

Harvesting Canisters are intended to be used with an external vacuum source for collection of body fluids and processing by licensed healthcare professionals. Canister size variations include Small Volume (SV): 250ml and 500ml, and High Volume (HV): 1000ml, 2000ml, 3000ml and 5000ml.



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Carefully read these instructions before using Wells Johnson Company Harvesting Canisters. Keep them in a safe place for future reference.

Use devices for their intended use only.

Device Diagram

The image below provides a diagram of the product in a (3L) 3000ml version with components and parts that are referenced throughout these instructions and included with each sale.





Device Description

Harvesting Canisters are reuseable devices that are shipped assembled and "non-sterile". Cleaning and sterilization must occur prior to 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 plastic. The O-rings and drain tube are made of silicone. Silicone 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 a normal aging process, which can be accelerated by mechanical, chemical and thermal processes such as autoclaving. Evidence of aging may present as discoloration, formation of cracks and/or warping.

Intended Users

Harvesting Canisters should be used and operated by licensed healthcare professionals familiar with their assembly, disassembly and use.



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

Prior to use

A visual Inspection of each canister component should be performed prior to assembly for each use. If a component is defective, worn, cracked, brittle, or warped, do not use and discard according to facility procedure. Part numbers are contained in these instructions with product descriptions for re-ordering. While Canisters are shipped assembled and should be completely disassembled for inspection, cleaning, sterilization and storage, they are required to be assembled in the sterile field.



The Harvesting 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 function properly, or there are damaged components, do not use and discard.

Reprocessing Instructions

1. Soak

- 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 solution, flush all ports/passages with a 60cc syringe and let soak for a minimum of 10 minutes. Additional 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 patient and vacuum barbs, drain hose barb on base, the drain tube, the threaded portion of the (3) rods, and the (3) holes on both the top and base where the rods are inserted.
- 2.4. Thoroughly flush the cannulated ports/passages with the enzymatic solution using a 60ml Syringe. Repeat this step at least 2 times.



- 2.5. With a non-shedding wipe or disposable towel and 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 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 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 10mins 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 sign of debris, soil or enzymatic solution in the rinse stream.

Failure to completely rinse enzymatic solution from canister tube may result in damage during sterilization.

4. Drying

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- 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 nonshedding towel, and let air-dry. Medical grade filtered compressed air may also be used.
- 4.3. Repeat step 4.2 as necessary until completely free of moisture.

5. 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 and dispose.

If signs of damage or fatigue are identified, do not use and dispose.

- 5.2. The inspected and unassembled canister components should be terminally wrapped/pouched in accordance with ISO 11607.
- 5.3. Packaging should ensure sufficient protection of the device components or sterilization packaging from mechanical damage.
- 5.4. The polycarbonate canister tube is to be wrapped individually as it requires a different sterilization cycle than other Canister components.

6. Sterilization

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

- 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

The polycarbonate tube must be sterilized in accordance with the Polycarbonate Tube Procedure above. Failure to do so will damage the tube.

- 6.2. Canister Components Sterilization Procedure (*do not use for polycarbonate tube)
 - 6.2.1. Cyle: Gravity Displacement
 - 6.2.2. Temperature: 132°C (270°F)
 - 6.2.3. Exposure Time: 15 minutes
 - 6.2.4. Dry Time: 30 minutes

Do not use flash sterilization on any canister components.



Storage

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.

Disassembly Instructions

1. Unscrew the 3 silver knobs from the top of the canister.



2. Remove the 3 silver rods through the bottom of the canister.



3. Remove black top from canister and remove silicon tubing from inside the canister (if 1st time using).





4. Remove inner plug by gently pulling knob.



5. Remove the 2 orange O-rings from the inner plug. To do this, position your thumb and index finger at about 10 o'clock and 2 o'clock on the O-ring. Squeeze your thumb and index finger toward each other until part of the O-ring pops out of place. Use that portion of the O-ring to remove it.



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





7. Remove polycarbonate tube from black bottom.



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





Assembly Instructions

Assembly of canister must be done on sterile field prior to patient use.

1. First, locate canister top, bottom, plug and 4 orange O-rings. These 4 should consist of 2 larger and 2 smaller O-rings.



2. Place 1 large O-ring along the groove of the canister top. O-ring should fit snuggly in groove, to check run index finger gently up and down on O-ring. If O-ring does not move it is properly placed.





3. Repeat using 2nd large orange O-ring and canister bottom





4. Canister top plug requires smaller O-rings to be placed along the 2 grooves found on the plug. Always check that all O-rings have been properly placed along grooves to ensure canister will be sealed correctly.



5. Take polycarbonate tube and line up Wells Johnson vertical logo with silver hose barb on canister bottom. Firmly apply pressure onto the tube to securely attach onto the canister bottom. It is important to check that polycarbonate tube is completely attached to canister bottom with no spaces between tube and canister bottom.





6. Tilt the canister slightly onto its side and attach the 3 metal rods through the canister bottom.



7. Attach black canister plug to top of canister by pressing into black top until bottomed out.







8. While having the canister on the sterile field, line up the 3 holes on the canister top with the 3 metal rods. Firmly apply pressure to attach canister top to polycarbonate tube. It is important to check the polycarbonate tube is completely attached to canister top with no spaces between tube and canister top. See Step 5 for reference.



9. Locate the metal rod screws (3) and attach screws to metal rods through the 3 holes found on top of the canister. Rotate screws clockwise to attach.



10. Place rachet clamp on 10" tubing and squeeze tightly to lock in place. Securely press the tubing onto the hose barb on the canister bottom and slide the clamp over the tubing. Pinch the clamp tightly to occlude drain tube prior to use and to conclude assembly.





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Canister Components and Part Numbers

	5L Canister	3L Canister	2L Canister	1L Canister	500ml Canister	250ml Canister
Rods	20-5178-05	20-5178-03	20-5178-02	20-5178-01	20-5178-01	20-5178-04
Knobs	20-5178-00	20-5178-00	20-5178-00	20-5178-00	20-5178-00	20-5178-00
Tube	20-5177-65	20-5177-03	20-5177-02	20-5177-01	20-5177-50	20-5177-25
Black top	16-5196-00	16-5177-00	16-5177-00	16-5177-00	16-5194-00	16-5194-00
Black bottom	16-5197-00	16-5176-00	16-5176-00	16-5176-00	16-5195-00	16-5195-00
Black plug Lg.	20-5191-50	20-5191-50	20-5191-50	20-5191-50	-	-
Black plug Sm.	-	20-5191-00	20-5191-00	20-5191-00	20-5191-00	20-5191-00
O-ring kit	20-5180-59	20-5180-55	20-5180-55	20-5180-55	-	-
Lg. plug						
O-ring kit	-	20-5180-00	20-5180-00	20-5180-00	20-5193-00	20-5193-00
Sm. plug						
*10" tubing/clamp	20-5179-21	20-5179-21	20-5179-21	20-5179-21	20-5179-01	20-5179-01









Black Bottom

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Black Top with small plug Black Top for large plug



Canister Rods and Knobs



10" Tubing w/clamp



O-Ring Kit



8000 South Kolb Rd. Tucson, AZ 85756

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Symbols Used

Symbol	Description			
	Symbol for: Manufacturer			
REF	Symbol for: Catalog or Part Number			
LOT	Symbol for: Batch Code			
ī	Symbol for: Consult the Instructions for Use			
NON	Symbol for: Non-Sterile			
\triangle	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			