

## USER'S MANUAL

# High Volume Precision (HVP™) Auto-Graft System



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**\*READ THIS MANUAL THOROUGHLY BEFORE USE AND  
PERIODICALLY THEREAFTER\***

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## GENERAL DESCRIPTION

The High-Volume Precision (HVP™) Auto-Graft System is a completely integrated system. This means that from the harvesting cannula to the re-injection cannula, the contents are completely contained. The HVP™ unit is custom designed to re-inject with precise speed and pressure controls.

The HVP™ System consists of eight components; starting with tissue harvesting and moving through the various intermediate steps:

1. HVP™ Harvesting Cannulas (4)
2. Aspiration Tubing
3. HVC3™ Canister
4. VTS™ Canister Plate
5. VTS™ Vibratory Tissue Separator
6. HVP™ Auto-Graft Infuser
7. HVP™ Re-Injection Tubing
8. HVP™ Re-Injection Cannulas (3)

## SAFETY INFORMATION

- Read all instructions carefully before operating equipment.
- Always disconnect the power supply to the HVP™ before cleaning.
- Motors are thermally protected and will automatically restart when protector resets.
- Current leakage tests are performed and are certified within the AAMI maximum 300µA limit for medical devices.
- Safety checks should be scheduled according to purchaser's policies.
- Additional warnings and power requirements, which are part of the labeling, are located on the back of the HVP™.

**IMPORTANT:** It is strongly recommended that the pressure sensor be used at all times of operation. The pump head can generate high positive pressures and use of the pressure sensor allows the operator to set, monitor and limit the pressure within an acceptable range.

**\*Caution:** Federal Law restricts this device to sale by or on the order of a physician.

## SPECIFICATIONS

### HVP™ Auto-Graft Infuser:

Item number	20-6200-00
Input Power Requirements	115 - 240 VAC, 50/60 Hz
Weight	10 lb
Dimensions	15.25" x 11" x 5.25"
Maximum Pressure (without Pressure Sensor)	40 psig (relative to atmospheric pressure (276 kPa, 2080 mmHg)
Maximum flow rate	800 mL/min (with specified tubing)
Display Unit - Speed	rpm (revolutions per minute)
Display Unit - Pressure	psi (measured as psig pounds per square inch gauge)
Display Unit - Pulse	ppm (pulses per minute)
Over Pressure Protection	External Pressure Sensor and Auto-Reverse
Pump Type	Peristaltic
Number of Rollers	4
System Power	360 W

### VTS™ Vibratory Tissue Separator:









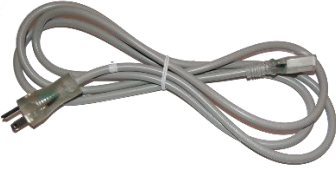

Item Number	20-1825-00, 20-1826-00
Input Power Requirements	120 VAC 60 Hz, 220 VAC 60Hz
Weight	19 lb
Dimensions	10.5" x 7.5" x 4.5"

### Accessory:

Dome Bag	18" Deep, Clear
Item number	24-6038-00

# CHECKLIST

Unpack the HVP™ system from its shipping container(s) and check that the following accessories are included in the package and received in good condition:

<b>HVP™ Auto-Graft Infuser (1)</b> 	<b>VTST™ Vibratory Tissue Separator (1)</b> 
<b>Aspiration Tubing, Sterile (10pcs)</b> 	<b>HVP™ Re-Injection Tubing, Sterile (10pcs)</b> 
<b>HVP™ Harvesting Cannulas (4)</b> 	<b>HVP™ Re-Injection Cannulas (3)</b> 
<b>HVC3™ Canister (1)</b> 	<b>Pneumatic Foot Switches (2)</b> 
<b>HVP™ Power Cord (1)</b> 	<b>VTST™ Canister Plate (1)</b> 

Call customer service immediately to report any damaged or missing items: +1 520-298-6069

# COMPONENT DESCRIPTIONS

## HVP™ Harvesting Cannulas

HVP™ Harvesting Cannulas are specifically designed to harvest live tissue for re-injection.

They feature the following:

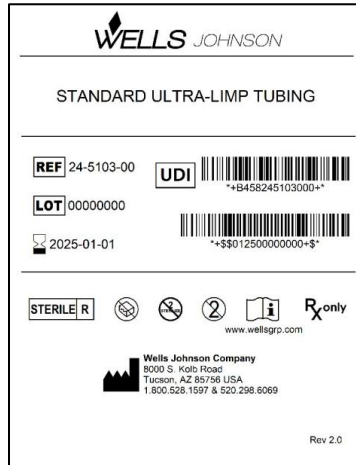
- A continuous lumen to avoid wrenching forces caused by sudden inner-lumen diameter changes.
- Holes/ports sized for direct compatibility with the re-injection cannula hole sizes.
- A compliant hose barb to accept the aspiration tubing so that the live tissue may be harvested prior to re-implantation in patient.
- These cannulas may be autoclaved according to sterilization instructions.

See Cannulas & Accessories IFU.



# Aspiration Tubing

This tubing will enable you to attach the HVP™ Harvesting Cannula to the Collection Canister. It is 9 feet in length and compatible with the HVP™ Harvesting Cannulas, HVC3™ Canister, and High Volume Collection Canisters. The tubing is flexible for ease of use, disposable and comes in pre-sterilized individual packs.



## HVC3™ Canister 3L

For best results, use the HVP™ Auto-Graft Injector with a Wells Johnson HVC3™ Canister.

Each Collection Canister features the following:

- Tissue for re-injection can be harvested into this HVC3™ canister. It will allow contained tissue processing with the unwanted fluids drained from the bottom.
- Comes in 3L capacity.
- Extremely durable for long-lasting use
- Reusable and fully autoclavable (>100 cycles)  
See HVC3™ IFU.
- Designed for optimum tissue flow with compatible lumen sizes for input and output
- It is recommended to have the HVP™ Re-Injection Tubing correctly installed on said canister BEFORE harvesting.



## High Volume Collection Canister

For best results, use the HVP™ Auto-Graft Injector with a Wells Johnson collection canister.

Each collection canister features the following:

- Tissue for re-injection can be harvested into this canister. It will allow contained tissue processing with the unwanted fluids drained from the bottom.
- Comes in 5-liter capacity
- Reusable and fully autoclavable  
See High Volume Collection Canister IFU.
- Designed for optimum tissue flow with compatible lumen sizes for input and output
- It is recommended to have the HVP™ Re-Injection Tubing correctly installed on said canister BEFORE harvesting.





## VTS™ Canister Plate

The VTS™ Canister Plate is made from a durable metal that is autoclavable. Once sterilized, the HVP™ Canister Plate may be placed on the VTS™ Vibratory Tissue Separator as an additional sterile barrier between the HVC3™ and the tissue separator. Additionally, the VTS™ Canister Plate allows for a more reliable placement of the HVC3™ Canister.



## VTS™ Vibratory Tissue Separator

Wells Johnson recommends using the VTS™ to reduce the time it takes for different layers of fluids to separate. The VTS™ separates the harvested tissue components using low level vibratory action. This eliminates centrifugal forces and accelerates separation.

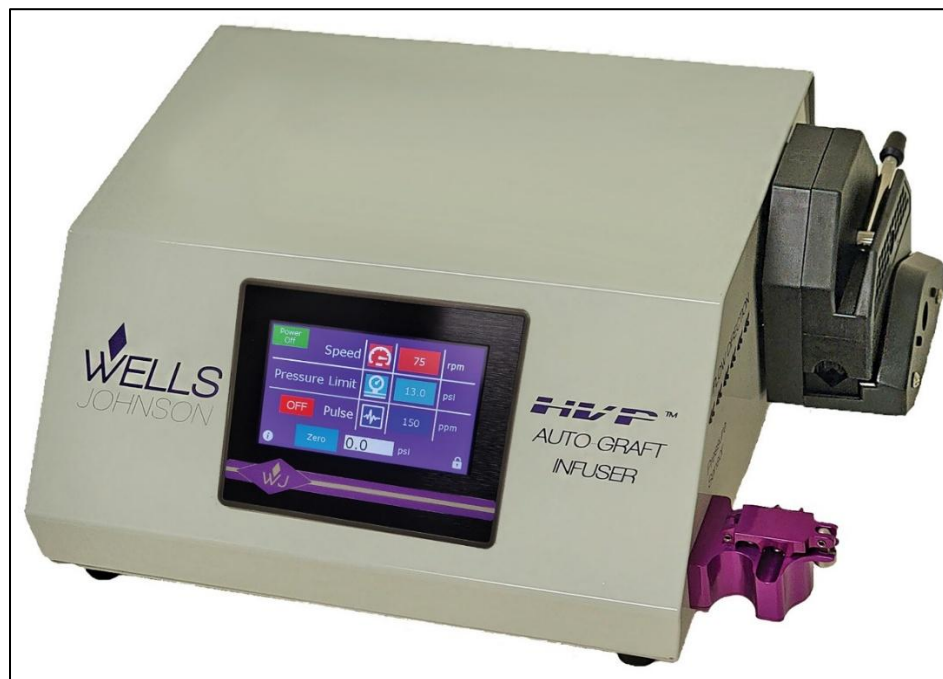
The VTS™ Canister Plate is sterilized and placed on top of the VTS™ Vibratory Tissue Separator. The HVC3™ Canister is then set on top of the VTS™ Canister Plate and the tissue can be continuously separated during active tissue harvesting.



## HVP™ Auto-Graft Infuser

This unit is specifically designed to aid in live tissue re-injection. Controls are custom set by the surgeon and can be changed at will. Re-Injection pressure levels can be set to not exceed harvesting pressure levels. The HVP™ features the following:

- Precision controls for:
  - Pump speed which affects flow rate
  - Maximum flow pressure
  - Pulse rate
  - Pulse volumes
- An innovative pressure sensor that mounts externally to the tubing
- Universal power input



## HVP™ Touch Screen Interface Controls

User friendly interface allows changes in settings and parameters by simply touching the appropriate area on the screen. All values will be retained when the unit is powered off.

1. Speed: Allows the user to change the speed of the motor.
2. Pressure Limit: Allows the user to adjust values for the maximum pressure allowed in the tubing-to-patient portion of the system.
3. Pulse: Defaulted to OFF. Once turned ON, it will cause the motor to start/stop in increments, creating a pulse effect. The settings for speed and pulses per minute can be modified to find the correct size and frequency required of pulse.

When the unit is plugged into power and the switch in the back is ON, the touch screen will be illuminated. Adjust values by directly touching the number to input the value desired, or by pressing the arrow buttons for smaller adjustments.

The HVP™ should remain outside the sterile field. The pump head assures the contents remain within the tubing, never allowing direct contact with either the pump head or pump control unit.



## Pump Head Loading

Tissue may be pumped through the HVP™ Re-Injection Tubing after the following technique to load the pump head has been completed:

1. Rotate the pump head lever counterclockwise to open the head.
  2. Insert the Re-Injection Tubing into the pump head opening over the rollers. The flow direction will be from right to left (when facing the pump side of the machine) or from back to front (when facing the front of the machine). A graphic on the unit shows the correct direction.
  3. Rotate the pump head lever clockwise to carefully close the pump head and clamp the tubing.
- \*\*Make sure the tubing is not punctured by the black teeth when the pump head is closed.**



## Pressure Sensor Operation and Loading

The pressure sensor measures the force of the pressure from the fluid inside the tubing. The tubing is installed into the clamp and zeroed with the push of a button. The pressure limit can be set using the touch screen with an adjustable range of 0.5-13 psig. The pressure limit represents the maximum pressure allowed in the tubing system before the auto-reverse function is activated. The auto-reverse function will relieve the pressure to a near zero value by reversing the rotational direction of the pump.

When loading the tubing into the sensor, place it gently into the slot and lock the clamp into place. Avoid extreme pulling or pushing on the tubing during and after installation to maintain the accuracy of the system.



**NOTE: Not using the pressure sensor will result in uncontrolled pressure levels that could exceed 40 psig.**

## Pneumatic Foot Switch

The foot switch tubing is inserted into receptacle 1 or 2, located on the left side of the unit when facing the front. The second port allows two-foot switches to be connected at the same time.



## Circuit Breaker

To protect the equipment and reduce shock hazard, a re-settable circuit breaker is installed on the back of the unit. This is integrated into the ON/OFF switch and is labeled as "RESET". If there is a voltage surge or an over-current situation, the circuit breaker will trip and switch the unit OFF. To reset the HVP™, turn the unit back ON with the switch in the back. **If the unit fails to start**, the unit may require a cool-down period, or technical repairs may be required.

**NOTE: DO NOT LET TECHNICIANS BY-PASS THE CIRCUIT BREAKER**





# HVP™ Re-Injection Tubing Set

Proprietary HVP™ Re-Injection Tubing is 12 ft in length and specifically engineered for use with the HVP™ Auto-Graft Infuser. The HVP™ Re-Injection Tubing is required for the correct operation and functionality of the HVP™ system features. This tubing is precision-extruded and optically inspected to ensure top performance with the pump head. Other commercial tubing may not meet, or perform, to specifications. Inspect the tubing package prior to opening for any damage and discard entire packaging and contents if the packaging appears compromised.





## HVP™ Re-Injection Cannulas

HVP™ Re-Injection Cannulas are specifically designed for large volume re-injection of live tissues using HVP™ Re-Injection Tubing. They feature the following:

- A continuous lumen to avoid wrenching forces caused by sudden inner-lumen diameter changes.
- Holes sized to be compatible with the harvesting cannula inner lumen and hole/port sizes.
- A custom hose barb designed to maintain both maximum hold and flow rates with the HVP™ Re-Injection Tubing
- May be autoclaved according to sterilization instructions.

See Cannulas & Accessories IFU.

**CAUTION: To prevent air infusion, always prime tubing prior to administering any contents to the patient.**



# SET-UP AND OPERATION

## Collection System Setup and Operation

1. Place the sterile VTS™ Canister Plate on the Vibratory Tissue Separator.  
*\*optional: if purchased, the sterile dome bag can be placed over the VTS™ Canister Plate and VTS™ Vibratory Tissue Separator to provide additional sterility as shown below*
2. Follow the instructions and procedures for HVC3™ canister setup provided with the canister.
3. Place the sterile HVC3™ canister onto the VTS™ Canister Plate.
4. Attach the 3" (only section without clamp) HVP™ Re-Injection Tubing to the hose barb on the bottom of the HVC3™ Canister.
5. Close clamps on HVP™ Re-Injection Tubing prior to harvesting.
6. Harvest tissue into the HVC3™ Canister.
7. After the tissue has been harvested and separated, turn off the VTS™ Vibratory Tissue Separator. Place a bed pan under the short tube section to drain materials. Open the clamp to drain unwanted fluid out of the HVC3™ canister and into the bed pan.
8. Once all unwanted fluid is drained, close the clamp on the drain tube and open the other clamp.

THE HVC3™ CANISTER SYSTEM IS NOW READY FOR OPERATION WITH THE HVP™.



## **HVP™ Auto-Graft Infuser Setup and Operation**

1. Carefully remove the HVP™ from the shipping container. Be sure to save the box and packing material for convenient maintenance returns.
2. Read all instructions carefully before operating the unit.
3. Place the HVP™ in the desired location for the procedure.
4. Open the accessory box and locate the power cord and the foot switch.
5. Plug the power cord into the back of the HVP™ and then into an appropriate wall outlet.
6. Power ON the machine by pushing the power switch located on the back of the unit.
7. While the HVP™ boots up, please make sure the settings for speed and pressure limit are at the desired values.
8. Complete the steps for setting up the Collection System on the previous page.
9. Attach the desired HVP™ Re-Injection Cannula to the distal (patient) end of the tubing.
10. Open the pump head and pressure sensor.
11. Place the tubing into both, then close the pump head first. Gently line up and close the clamp to the pressure sensor.
12. Push the 'ZERO' button on the touch screen to reset the sensor.
13. Plug the pneumatic foot switch into the appropriately labeled ports.
14. Prime the tubing to remove all air.
15. If sensor is reading something other than zero, press the 'ZERO' button again before the procedure.
16. Press and maintain pressure on the footswitch to begin operation.

**\*WARNING: Failure to properly attach or bypass the sensor unit will result in pressure levels that could exceed 40 psig. The operator will no longer control or manage pressure levels. The pressure limit and live pressure feed displayed on the touchscreen will no longer be accurate.**

**\*The HVP™ System is designed to be used with HVP™ Harvesting and Re-Injection Cannulas. Failure to use HVP™ Harvesting and Re-Injection Cannulas will prevent/impair proper functioning of the system.**

**\*Caution: To prevent air infusion, always prime tubing prior to administering any fluid to patient.**

**\*Caution:** Continual verifications shall be made to ensure the tubing is not kinked, blocked or occluded in any way during operation. Failure to do so may cause fluid leakage from tubing and tubing failure.

**\*Warning:** HVP tubing sterile, single-use and not intended to be reused under any circumstances to prevent cross-contamination.

**\*Warning:** Explosion Hazard. Do not use in the presence of flammable anesthetics.

**\*Caution:** Do not use the HVP™ with power cords or power adapters not provided by Wells Johnson.

## TROUBLESHOOTING

### PROGRAMMING REPAIR PROCEDURE

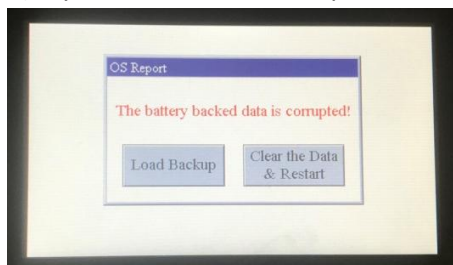
**FIRST CHECK:** Locate your serial # plate on back of the machine.

If the first 4 digits of the serial number are MORE THAN 0566, then follow **PROCEDURE 1 (below)**

If the 4 digits are 0566 or less, then proceed to **PROCEDURE 2 (see next page)**

#### PROCEDURE 1

1) If you are at this screen, press the button “Clear the Data & Restart”

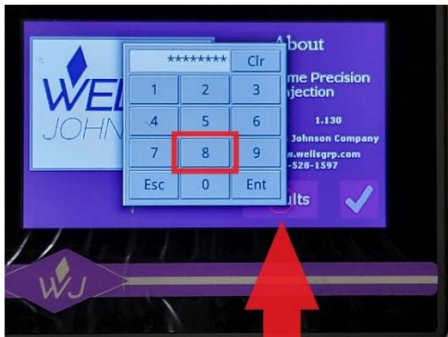


2) From the Main Screen, press the ‘i’ icon in the bottom left corner.

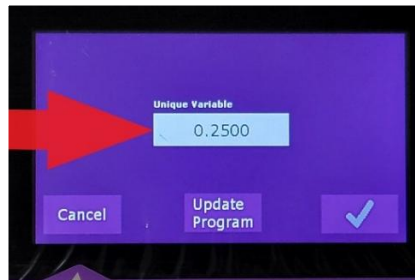
(don't have to wait for 'Please Wait' to clear)



3) Press the 'Defaults' button and a keypad will pop up. Type the password '88888888' (eight eights) and press 'Ent'.



4) Touch the box under 'Unique Variable', a keypad will open. Then check the blue tag on the back of the HVP™. There is a 4-digit decimal. Type that number into this keypad and press 'Ent', then press the check mark. **IMPORTANT: Make sure you type the period before the number**



5) Press the Power Off button, wait for the blue letter message then switch OFF the HVP™ from the back.



6) Try running the HVP™ with the footswitch. It will be working correctly now. Change the speed and pressure settings you want.

## **PROCEDURE 2**

IMPORTANT: Only units with program version 122, 126 or 130 can be fixed remotely.

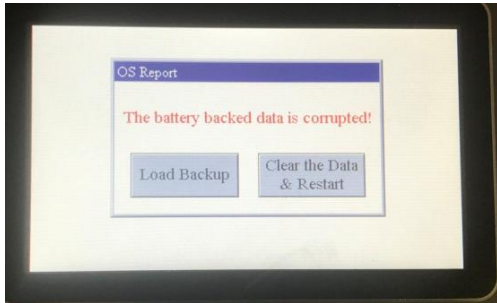
There are two possible starting points when the HVP™ is ON:

Situation A) At the message '**The battery backed data is corrupted!**' (below)

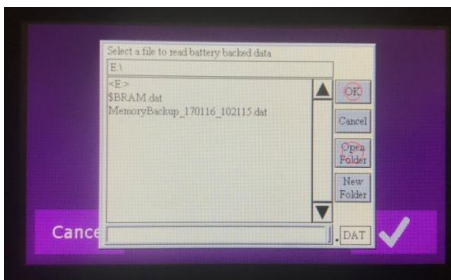
Situation B) Or on the main screen with speed, pressure, and pulse (see pg. 23)

### **\*If Situation A**

1. Make sure the HVP™ is ON and the message below is showing.

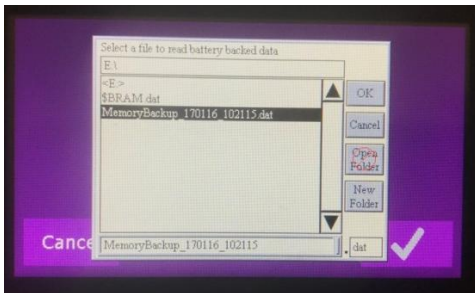


2. '**The battery backed data is corrupted!**'
3. You will see two buttons - 'Load Backup' and 'Clear the Data & Restart'
4. Press the 'Load Backup' button, the screen below will show



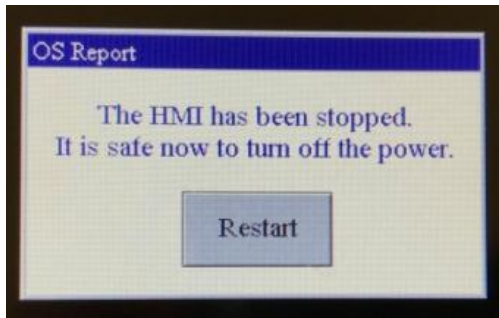
How many files start with Memory Backup:

- a. If only 1, move to Step 6
  - b. If there is more than 1, you must select the bottom most file
5. Touch the file name **MemoryBackup\_xxxxxx\_xxxxxx.dat**



6. File will be selected with a black bar
7. Press 'OK'
8. Unit will load file and restart itself. Then boot itself to main screen.
9. Push the GREEN 'Power Off' button in the top left, wait for unit to power down safely.
  - a. NOTE: if you don't touch exactly in the green area you might hit the speed screen
  - b. just hit the check mark and try again

10. Wait for blue letter message saying safe to turn off.



11. DO NOT hit the 'Restart' button, or 'yes' button. If so screen will go black. Just go to next step.
12. Switch OFF power to the HVP™ using the switch in the back.
13. Wait 5 seconds and switch power back ON.
14. Unit should now work correctly.
15. Set the SPEED and PRESSURE to desired settings
16. Wait for the 'Please Wait' box to disappear and make sure HVP™ is zeroed correctly.
17. Test that motor runs with the footswitch.

**\*If Situation B**

If on the main screen and not the Error screen in Situation A, do the following:

1. Start with the HVP™ powered off.
2. Power on the HVP™ with the switch in the back.
3. Allow the unit to boot up to the main screen
4. Touch the 'i' icon in the bottom left corner





5. Touch the 'Defaults' button, a keypad appears



Type 8 eight times, 88888888, press enter (bottom right)



6. Press the 'Load Backup' button



7. Continue from step 5 in Situation A (previous page)



## PRESSURE LIMIT

- If the system seems to be hitting the pressure limit and reversing too often:
  - Reduce the pump speed. Pumping too fast can build up excessive pressure.
  - Make sure the tubing is properly installed into the pump head and sensor. Be sure to follow the correct procedures for zeroing the sensor.
  - Make sure there is no pressure in the tubing when zeroing.
  - Increase the pressure limit. Pumping the living tissue at 75 RPM can require a normal working pressure up to 5 or 6 psig to pump the tissue from the cannula.
  - Reduce interstitial pressure. Pull the cannula back toward the insertion site, change plane or angle and begin pumping again. Repeat as necessary.
  - Turn off the unit and remove the tubing from the pump head and sensor. Turn the unit back on and re-install the tubing following the correct procedures.

## MAINTENANCE

- All HVP™ units are thoroughly checked by the Quality Assurance Department before being released for shipping. Inspect the unit upon receipt to ensure the equipment was not damaged during shipping.
- No scheduled maintenance is recommended or required.  
Follow the procedures established by your engineering/biomed department.
- **Prior to long durations of inactivity, it is recommended to leave the HVP™ plugged into power and powered ON with the switch on the back, for 48 hours. This will fully charge the battery backup and prevent programming failure.**
- Warnings are part of the labeling and are indicated on the HVP™. The serial number is stamped on a small metal tag located on the back of the unit. Record the serial number.

In-services on new equipment can be provided by telephone with either your sales representative, or our technical support staff. If additional information is needed, call Customer Service or Technical Support at +1 520-298-6069.

## **PARTS LIST**

<b>ITEM DESCRIPTION</b>	<b>PART NO.</b>
<b>Complete HVP™ Cannula (set of 7)</b>	<b>20-1347-00</b>
<b>Consists of:</b>	
HVP™ Harvesting Cannula (3 mm x 27 cm)	20-1350-00
HVP™ Harvesting Cannula (4 mm x 27 cm)	20-1350-00
HVP™ Harvesting Cannula (4 mm x 27 cm)	20-1239-00
HVP™ Harvesting Cannula (5 mm x 27 cm)	20-1350-00
HVP™ Re-Injection Cannula (4 mm x 27 cm)	20-1352-00
HVP™ Re-Injection Cannula (4 mm x 27 cm)	20-1239-00
HVP™ Re-Injection Cannula (5 mm x 27 cm)	20-1352-00
<b>Standard Aspiration Tubing</b>	<b>24-5103-00</b>
<b>HVP™ Re-Injection Tubing</b>	<b>24-6037-00</b>
<b>3000 mL HVC3™ Canister</b>	<b>20-8300-00</b>
<b>5000 mL High Volume Collection Canister</b>	<b>20-5188-00</b>
<b>VTSTM Canister Plate (for 1 L, 2 L &amp; 3 L canisters)</b>	<b>18-2821-00</b>
<b>VTSTM Canister Plate (for 5 L canisters only)</b>	<b>18-2821-01</b>
<b>VTSTM Vibratory Tissue Separator (110 VAC)</b>	<b>20-1825-00</b>
<b>VTSTM Vibratory Tissue Separator (220 VAC)</b>	<b>20-1826-00</b>
<b>HVP™ Unit (115 - 240 VAC, 50/60Hz)</b>	<b>20-6200-00</b>
<b>Power Cord (115 - 240 VAC, 10A max)</b>	<b>18-2820-00</b>
<b>Pneumatic Foot Switch, single</b>	<b>20-6010-01</b>

[illegible]

## **WARRANTY**

- The Wells Johnson Company will void warranty on any products indicating negligence or noncompliance with operating and maintenance instructions.
- Products are warranted against defect in material and workmanship for a period of one (1) year from date of purchase. If repair or adjustment is necessary, and are not the result of abuse or misuse, please return, freight prepaid, and correction will be performed without charge.
- All returns require prior authorization from the Wells Johnson Customer Service Department.
- **Retain the custom-made packing box with foam for returns.**
- For questions about the warranty, call the Customer Service Department: +1 520-298-6069

**\*Patents granted and/or pending. See [www.wellsgrp.com](http://www.wellsgrp.com)**

**For technical assistance call  
Customer Service or Technical Support:  
+1 520-298-6069**

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## USER'S MANUAL



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