MAGELLAN®
Autologous Platelet Separator System Including
Associated Disposables
Explanation of symbols

WITH RESPECT TO ELECTRIC SHOCK
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL2601-01/CAN/CSA C22.2 No. 601.1

Caution, Consult Accompanying Documents

On (Power)

Off (Power)

Start/Select menu option

Stop/Back to previous menu

Increase platelet rich plasma (PRP) volume/Scroll up in menu

Decrease platelet rich plasma (PRP) volume/Scroll down in menu

Platelet poor plasma (PPP) collection

Fuse

Dangerous Voltage

Potential Equalization Conductor

Alternating Current

Date of Manufacture

Sterile

Sterilized Using Ethylene Oxide

Sterilized Using Irradiation
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<td><strong>LATEX</strong></td>
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<tr>
<td><strong>PYROGEN</strong></td>
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</tr>
<tr>
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<td><strong>This Way Up</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Quantity</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Open Here</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Fragile, Handle with Care</strong></td>
<td></td>
</tr>
<tr>
<td><strong>For US Audiences Only</strong></td>
<td></td>
</tr>
<tr>
<td><strong>U.S.P.</strong></td>
<td>United States Pharmacopeia</td>
</tr>
<tr>
<td><strong>T</strong></td>
<td>Do not dispose of this product in the unsorted municipal waste stream.</td>
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**Operator's Manual**

**English**
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INTRODUCTION

The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System consists of a microprocessor-controlled centrifuge and syringe pumps and the necessary single-use processing components. With the Platelet Separator Instrument, platelet rich plasma (PRP) is automatically and quickly separated from anticoagulated blood and dispensed into a separate sterile syringe.

Indications for Use

The Magellan® Autologous Platelet Separator system is designed to be used in the clinical laboratory or intraoperatively at point of care for the safe and rapid preparation of platelet poor plasma and platelet concentrate (platelet rich plasma) from a small sample of blood or a small mixture of blood and bone marrow. The plasma and concentrated platelets produced can be used for diagnostic tests. Additionally, the platelet rich plasma can be mixed with autograft and/or allograft bone prior to application to an orthopedic site. The platelet poor plasma can mixed prior to application to an orthopedic site as deemed necessary by the clinical use requirements.

Disclaimer

The platelet rich plasma prepared by this device has not been evaluated for any clinical indications. Platelet rich plasma prepared from a mixture of whole blood and bone marrow may contain higher levels of plasma free hemoglobin than platelet rich plasma prepared from whole blood.

System Description

The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System consists of

- The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument.
- The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit.

The complete system is shown in Figure 1.

Each procedure requires the use of one Arteriocyte Medical Systems Magellan® Platelet Separator Disposables Kit, which includes components necessary for a single patient platelet separation procedure. The separation chamber and associated tubing can be used with the same patient for up to three complete separation cycles.
INTRODUCTION

Figure 1. The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System.

How Supplied

The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument is supplied fully assembled with one electrical power cord.

An Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit is sold separately and is required for each procedure.

The Separator Kit is supplied in a tray and consists of the following components:

- One (1) separation chamber with tubing and two (2) attached luer connectors
- One (1) 10-mL syringe (Syringe 1)
- One (1) 60-mL syringe (Syringe 2)
- One (1) 5-mL syringe
- One (1) 17-gauge needle and IV tubing
- One (1) 30-mL vial of ACD-A anticoagulant
- One (1) IV Site Prep Kit
- One (1) 18-gauge x 3.8 cm (1.5") needle

Note: If more than one separation cycle will be performed with the same patient, additional 10-mL and 60-mL BD™ syringes are required and can be purchased from Arteriocyte Medical Systems.

1 BD™ is a trademark of Becton, Dickinson and Company.
Principles of Operation

The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument operates by separating anticoagulated whole blood into individual components by centrifugation. Blood is an ideal biologic mixture for such a technique because it is a suspension of elements of significantly different densities and, thus, is easy to separate.

When subjected to a centrifugal force, the components migrate relative to their respective density, with the higher density components moving farther from the axis of rotation than those of lesser density.

With the Platelet Separator Instrument, the user can select a desired amount of platelet rich plasma (PRP), three (3) to ten (10) mL, to be collected.

After the separation chamber is installed, and the two syringes are locked into the pumps on the front of the instrument, the separation process is automatic.

The procedure begins with syringe pump 2 activation to empty approximately 30 to 60-mL of anticoagulated blood from the larger syringe into the centrifuge chamber while the centrifuge spins at filling speed.

When fluid is in the separation chamber, the centrifuge will spin at a higher speed, which causes heavier red blood cells (RBC) to gradually migrate to the outer ends of the chamber. The centrifuge speed will then automatically reduce, and syringe pump 2 will withdraw RBC until the sensor detects the presence of plasma at the outer ends of the chamber.

The centrifuge speed will again increase, prompting separation of platelets from the remaining plasma. Gradually a layer of platelet rich plasma is concentrated at the outer end of the chamber. Once this layer is formed, the instrument speed will reduce and a small amount of the remaining RBC is drawn out of the chamber and back into syringe 2. With the RBC removed, the selected volume of PRP is then withdrawn into syringe 1.

The clinician has the option of collecting platelet poor plasma (PPP) into a separate syringe after the PRP is withdrawn. At the end of the cycle, the instrument will draw remaining PPP into syringe 2.

CAUTIONS

READ THIS OPERATOR’S MANUAL COMPLETELY PRIOR TO USING THE ARTERIOCYTE MEDICAL SYSTEMS MAGELLAN® AUTOLOGOUS PLATELET SEPARATOR SYSTEM.

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

- Actual performance results may vary depending on many in-use variables. It is important to read and understand this Operator's Manual and understand the principles of platelet separation before undertaking clinical operation of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System.

- Medications that adversely affect a patient's coagulation system may inhibit the use of a platelet separation system.

- The AABB Standards for Perioperative Autologous Blood Collection and Administration (1st Edition, 2001) recommends that non-red-cell components be used prior to the patient leaving the operating room. Blood components produced by this device are not intended for patient transfusion. Treat all blood and fluids using Universal Precautions for bloodborne pathogens.

- The disposable components are STERILE and NONPYROGENIC as long as package integrity has not been violated. Do not use if package is damaged or open. Disposable components are single-patient-use. Do not resterilize.

- The ACD-A anticoagulant supplied in the disposables kit is not for intravenous use. Discard the unused portion. Do not reuse. Do not use the ACD-A anticoagulant unless the solution is clear and the seal is intact.

- Do not restrict the flow in any tubing line. If a tubing line is inadvertently clamped or kinked during operation, pressure may build up causing failure, fluid leakage, or incomplete separation. The operator should always check the disposable kit to confirm that all tubing is free of any kinks, twists or flat areas.

- The centrifuge cover seal should be inspected for cuts, tears or other defects prior to each use.

WARNING

- Safety rules related to the use of centrifuges must be followed. Do not attempt to open the centrifuge or remove the chamber before it comes to a complete stop.

PRECAUTIONS

1. The responsibility for the use of this device in all cases belongs solely to the physician ordering its use.

2. The safe operation of all platelet separator equipment requires the presence of a dedicated operator. It is the responsibility of the clinical facility to ensure that the individuals assigned to this task are properly trained in the operation of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System and be alert to potential problems. Never leave the machine unattended during operation.
3. Only Arteriocyte Medical Systems sterilized disposable kits are approved for patient use with the Magellan® Autologous Platelet Separator Instrument. It is important that aseptic technique be used to minimize the possibility of contamination of the disposable components and/or patient.

4. Store all disposable components in a dry place away from extremes of environmental conditions.

5. The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System must not be used in the presence of flammable agents.

6. Do not use the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System at temperatures higher than 30°C (86°F). Operation at temperatures over 30°C (86°F) may cause overheating of the centrifuge, which could cause hemolysis.

7. Materials used in the Arteriocyte Medical Systems Magellan® disposable kit may be sensitive to chemicals (such as solvents and certain detergents). Under certain adverse conditions, exposure to these chemicals (including vapors) may cause the plastics to fail or malfunction. Visually inspect the contents of the disposable kit. Should any evidence of damage to the components be found during inspection or setup, do not use the disposable components. Do not use silicone oils or greases near disposable components.

8. In the unlikely event of a power failure or other failure of the instrument, the clinician must start a new procedure using new disposable components.

9. Inside the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument cabinet are various electrical components and wiring. Physical contact with any of these components, while the unit is plugged in, could result in severe electrical shock. Always turn off and unplug the unit prior to working inside the cabinet or changing any fuses. For continued protection against risk of fire, replace fuses only with the same type and rating. Internal grounding is provided for safety.

10. Although the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument has been tested for EMC compliance and passed, the potential exists that, in some situations, the system and other devices might electromagnetically interfere with each other. The operator should take steps that minimize this possibility.

11. Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed portion of the equipment. Each Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument is checked during the final quality inspection to verify that leakage current is less than 300 µA. The owner or operator should have leakage current checked at least yearly or as required by the operating facility’s biomedical engineering department or other qualified service technician. In addition, particular attention should be given to checking the leakage current and insulation after an event such as a fluid spill or major voltage surge in the power source has occurred, or after any machine repair.
SPECIFICATIONS AND DESCRIPTION

12. It is important that the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument be maintained in good working order and serviced on a regular basis.

13. Do not attempt to override/bypass any safety mechanisms. Any attempt to disable or bypass the centrifuge cover latch/lock mechanism could result in damage to the device or injury to the operator.

Contraindications

The use of the Arteriocyte Medical Systems Magellan® Platelet Separation System is contraindicated for a hemodynamically unstable or hypercoagulable patient.

Use of this product for pediatric patients should be approached carefully. Withdrawing blood from pediatric patients should be at a physician’s specific direction with attention given to avoiding any significant reduction in the patient’s blood volume.

Caution: Medications that adversely effect a patient’s coagulation system may inhibit the use of platelet separation system therapy.

SPECIFICATIONS AND DESCRIPTION

System Specifications

Note: Technical data, features and options referenced in this manual are based on the latest information available at the time of printing. Arteriocyte Medical Systems reserves the right to change specifications without notice.

- **Electrical**
  - Classification: Class I, Ordinary, Continuous Operation
- **Power:**
  - Voltage: 100 – 240 V~
  - Frequency: 50 – 60 Hz
  - Phase: Single
  - Current: 1.3 amps
  - Fuses: 5 x 20 mm / 6.3 amps
  - Power cord: 2 wires plus ground (earth) connector 3-prong hospital grade
- **Speed and Flow Rate Specifications:**
  - Centrifuge: 0 – 4,000 rpm (± 5%)
  - Syringe Pump: 0 – 60 mL/min (± 5%)
  - Separation Chamber Maximum Fluid Volume: 60 mL
  - Separation Chamber Maximum Fluid Density: 1.1 kg/dm³
- **Dimensions:**
  - Width: 47 cm (18 inches)
  - Height: 32 cm (13 inches)
SPECIFICATIONS AND DESCRIPTION

- Depth: 44 cm (17 inches)
- Weight: 11 kg (24 lb.)

- Temperature Limit:
  - Operational: 10°C – 30°C (50°F – 86°F)
  - Storage: -40°C – 66°C (-40°F – 150°F)

- Humidity Range:
  - Operational: 10 – 95% noncondensing
  - Storage: 10 – 95% noncondensing

- RS-232 Port: This port is to be used only by authorized service personnel.

Phases of Operation

<table>
<thead>
<tr>
<th>Phase</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>FILLING</td>
<td>Both ends of the centrifuge chamber fill simultaneously during the FILLING phase.</td>
</tr>
<tr>
<td>PROCESSING</td>
<td>The centrifuge will automatically spin at various speeds as it processes blood within the separation chamber and removes red blood cells into syringe 2.</td>
</tr>
<tr>
<td>COLLECTING</td>
<td>The instrument will automatically withdraw platelet rich plasma (PRP) into syringe 1 during the COLLECTING phase.</td>
</tr>
<tr>
<td>EMPTYING</td>
<td>At the end of the procedure the instrument will automatically progress to the EMPTYING phase in which it will draw remaining PPP into syringe 2.</td>
</tr>
<tr>
<td>PAUSE</td>
<td>The user has the option of pausing the cycle in order to draw platelet poor plasma (PPP) from the separation chamber into an alternate syringe.</td>
</tr>
</tbody>
</table>
SPECIFICATIONS AND DESCRIPTION

Front of the Instrument

![Figure 2. Front view of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument.](image)

- a. user interface keys
- b. message screen

**Cycle Progression Lights**

On the top of the centrifuge are four cycle progression lights. These will gradually illuminate through the phases of a cycle. One light will be illuminated during the **FILLING** phase; two during **PROCESSING**, three during **COLLECTION**, and four during the **EMPTYING** phase. At the end of a completed cycle all four cycle progression lights will be illuminated.

**Sensor Lights**

There are four sensor lights on the front of the instrument (see Figure 3). The syringe lights are under the syringe cover but can be seen when the cover is closed. When the instrument is powered up, these four sensor lights will always be either red or green. All must be green for the instrument to function. If any one is red the instrument will not function.

Where there is a red light, user intervention is required.

- The syringe sensor indicator lights will be red if the syringe tubing or the syringe is incorrectly placed in the syringe pump receptacle.
- The syringe and centrifuge cover indicator lights will be red if that cover is not completely closed.
a. syringe 1 sensor  
b. syringe cover sensor  
c. syringe 2 sensor  
d. centrifuge cover sensor

**Message Screen**

The instrument message screen includes two lines that indicate instrument status, required user actions, cycle time remaining, and platelet rich plasma (PRP) volumes.

The top line includes text indicating instrument status and user prompts such as [ENTER VOLUME] (see Figure 4).

![Figure 4. Message screen during a single cycle.](image)

Before and during a separation cycle, the lower line includes a timer indicating approximate time remaining in the current cycle and the requested volume of PRP to be collected in the cycle.

Upon completion of a cycle, the cumulative amount of PRP collected for that patient will replace the timer and be displayed on the left side of the lower line (see Figure 5).
SPECIFICATIONS AND DESCRIPTION

<table>
<thead>
<tr>
<th>CYCLE COMPLETE</th>
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<tr>
<td>TOTAL: 10 ML</td>
</tr>
<tr>
<td>5 ML</td>
</tr>
</tbody>
</table>

Figure 5. Message screen following cumulative cycles for the same patient.

**Menu Mode**

**Note:** Menu Mode options only apply to software version 3.0 and higher.

Before a cycle is initiated, special operating programs may be selected by putting the instrument into “Menu Mode.” The programs that can be selected are:

- **PURGE:** Use to immediately purge blood out of the centrifuge into the 60-mL syringe. Once the centrifuge is purged, the unit returns to the previously selected mode (either STANDARD or MIN. RBC).

- **MIN. RBC:** Increases line clear volume in order to minimize red blood cells in subsequent cycles. This mode is signified by the text “– RBC” on line 2 of the display.

  **Note:** When using this program, all cellular content will be slightly less than the standard program and cycle time will be shortened to approximately 10 minutes.

- **ST ANDARD:** The normal, general purpose operating mode.

In order to select one of the programs using the Menu Mode, do the following:

- Before a cycle has been initiated, continually press the minus (-) key until “OPTIONS” is displayed on line 2.

- Press the [START] key.

- Use the plus (+) and minus (-) keys to scroll through the options described above.

- When the desired option is visible, press the [START] key.

**User Interface Keys**

<table>
<thead>
<tr>
<th>Normal Mode</th>
<th>Start</th>
<th>Platelet poor plasma (PPP) collection</th>
<th>Stop</th>
<th>Increase of platelet rich plasma (PRP) volume</th>
<th>Decrease of platelet rich plasma (PRP) volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menu Mode*</td>
<td>Select</td>
<td>Back</td>
<td>Scroll up</td>
<td>Scroll down</td>
<td></td>
</tr>
</tbody>
</table>

*Menu Mode options only apply to software version 3.0 and higher.
Covers

Both the centrifuge and the syringe pump receptacles have covers which must be closed and latched prior to the beginning of a cycle of operation. When one is incorrectly closed or not properly latched, the corresponding sensor light will be red. The centrifuge cover stays locked in the closed position whenever the centrifuge is spinning.

Back of the Instrument

![Back view of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument.]

*Figure 6. Back and side view of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument.*

- a. volume adjustment
- b. on/off switch
- c. power cord port
- d. RS-232-Serial Port (for authorized service only)

Volume Adjustment

The user can adjust the volume of the audible alarms by turning the volume adjustment screw.

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AMS Confidential

AMS95068LBL    Rev. 2
INSTRUCTIONS FOR USE

Set Up

Equipment Required

- Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument
- Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit

Components of the system are shown in Figure 7.

Figure 7. The Arteriocyte Medical Systems Magellan® Platelet Separator Instrument and associated disposable components.

- centrifuge caddy
- instrument power cord port, on/off switch
- tubing support arm
- syringe pump receptacles
- plunger drivers
- 30-mL vial of ACD-A anticoagulant
- three syringes (60 mL, 10 mL, 5 mL)
- IV Site prep kit
- separation chamber with attached tubing
- 18-gauge x 3.8 cm (1.5") needle
- 17-gauge needle and IV tubing
- Instructions For Use
INSTRUCTIONS FOR USE

Instrument Set Up

1. Open the platelet separator instrument package and make sure the contents include one (1) machine, one (1) electrical power cord, and one (1) operator's manual.

2. Set the machine on a stable surface and thoroughly inspect all components for damage.
   **Caution:** If any instrument component is missing or damaged, do not use it. Contact your Arteriocyte Medical Systems service representative.

3. Plug the electrical power cord into the side of the instrument and into a standard electrical outlet (100–240 volt AC).

4. Turn on the instrument using the on/off switch on the side panel.

5. When the platelet separator instrument is powered on it will perform a system check during which the software version message will appear on the screen.

6. When the system test is complete, the message [LOAD SYSTEM - ENTER VOLUME] will appear on the message screen.

7. Open the syringe cover and the centrifuge cover and prepare an Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit as described below.

Separator Disposables Kit Set Up

**Note:** For platelet separation with the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument, an Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit is required.

**Caution:** All components of the disposables kits are single-patient-use. The separation chamber and associated tubing can be used with the same patient for up to three complete separation cycles. Do not resterilize.

1. Remove the cover from the separator disposables kit tray.

2. Be certain that all components are present and undamaged.
   **Caution:** Do not use the kit if any component or the tray is damaged or open.

   Contents of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit:
   - One (1) separation chamber with attached tubing and luer connectors
   - One (1) 10-mL syringe (Syringe 1)
   - One (1) 60-mL syringe (Syringe 2)
   - One (1) 5-mL syringe
   - One (1) 17-gauge needle and IV tubing
   - One (1) 30-mL vial of ACD-A anticoagulant
   - One (1) IV Site Prep Kit
   - One (1) 18-gauge x 3.8 cm (1.5") needle
INSTRUCTIONS FOR USE

Note: If more than one separation cycle will be performed with the same patient, additional 10-mL and 60-mL BD™ syringes are required and can be purchased from Arteriocyte Medical Systems.

3. Remove the separation chamber package from the tray.
4. Peel open the lid on the chamber package.
5. Holding the platelet separation chamber with the vent facing upward, thread the attached tubing through the center of the chamber caddy (see Figure 8a and b).

Figure 8. Thread the separation chamber tubing through the center of the chamber caddy.

6. Install the platelet separation chamber into the centrifuge caddy making certain that both ends of the chamber are properly located in the caddy notches (see Figure 9a). Place T-connector in slot (see Figure 9b), and tubing under retainer on top surface of caddy (see Figure 9c). Press tubing down into groove on outer edge of chamber caddy (see Figure 9d).

Caution: Failure to install the separation chamber properly may result in error codes.

Figure 9. Install the separation chamber into the caddy and place tubing into slot and under retainer.
7. Rotate the tubing collar so that its shape aligns with the opening in the support arm. Slide the tubing collar into the support arm (see Figure 10a) and close the latch (see Figure 10b).

**Caution:** Make certain all tubing is free of any kinks, twists, or flat areas.

![Figure 10. Attach chamber tubing collar to instrument tubing support arm.](image)

8. Press tubing down into groove on support arm and place tubing through notch in centrifuge ridge (see Figure 11).

![Figure 11. Place tubing through notch in centrifuge ridge.](image)
INSTRUCTIONS FOR USE

9. Prepare the syringe pumps on the front of the instrument by rotating the plunger drivers to the open position (see Figure 12a), while sliding them to the lowest points (see Figure 12b).

![Figure 12. Within the syringe receptacles, slide the open plunger drivers to the lowest points.](image)

10. Prepare the patient for venipuncture according to standard clinical practice using the IV Site Prep Kit, if necessary.

11. Using aseptic technique, draw the appropriate volume of anticoagulant from the ACD-A anticoagulant vial into syringe 2 (60-mL syringe) using the 18-gauge needle. Refer to Table 1 for the appropriate volumes of ACD-A and blood.

<table>
<thead>
<tr>
<th>Total Volume of Anticoagulated Blood (mL)</th>
<th>Volume of ACD-A (mL)</th>
<th>Volume of Blood Drawn (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>4.0</td>
<td>26.0</td>
</tr>
<tr>
<td>40</td>
<td>5.0</td>
<td>35.0</td>
</tr>
<tr>
<td>50</td>
<td>6.0</td>
<td>44.0</td>
</tr>
<tr>
<td>60</td>
<td>8.0</td>
<td>52.0</td>
</tr>
</tbody>
</table>

**Caution:** Do not use the ACD-A anticoagulant unless the solution is clear and the seal is intact. Do not reuse the ACD-A supplied in this kit except for multiple separation cycles with the same patient. Discard unused portion.
INSTRUCTIONS FOR USE

Note: Alternative methods can be used to collect patient blood. As appropriate, disregard references to the 17-gauge needle and IV tubing.

12. Using the 17-gauge needle and IV tubing, slowly draw 2 to 3 milliliters of patient blood into the 5-mL syringe.

13. Disconnect the 5-mL syringe from the IV tubing and discard the syringe.

14. Attach syringe 2 to the IV tubing and slowly draw the appropriate volume of patient blood. Gently mix with ACD-A for thorough distribution. Refer to Table 1 for the appropriate volumes of ACD-A and blood.

Note: Do not exceed 60 mL total volume.

Note: If multiple separation cycles will be performed with the same patient, repeat steps 11 and 14 to prepare and fill syringes.

15. Disconnect syringe 2 from the IV tubing. Set aside the syringe and discard the needle and IV tubing utilizing appropriate local procedures.

16. Remove the luer connector cap from the shorter length of chamber tubing and attach syringe 1 (10-mL syringe, see Figure 13a).

17. Evacuate all air from syringe 1 into the chamber tubing line.

18. Place syringe 1 into the appropriate syringe pump receptacle.

19. Rotate and slide the plunger driver to engage the syringe 1 plunger (see Figure 13b).

20. Ensure whole blood is thoroughly mixed using gentle agitation prior to placing in the syringe pump receptacle.

21. Remove the luer connector cap from the longer length of chamber tubing and attach syringe 2 (see Figure 13c).

22. Evacuate all air from syringe 2 into the chamber tubing line.

Note: Failure to remove air from syringes may compromise the quality of the product.

23. Place syringe 2 into the appropriate syringe pump receptacle.

24. Rotate and slide the plunger driver to engage the syringe 2 plunger (see Figure 13d).

Caution: Make certain all tubing is free of any kinks, twists, or flat areas.
INSTRUCTIONS FOR USE

Figure 13. Attach tubing, load syringes, and engage syringe plunger drivers.

25. Gently stretch the tubing attached to syringe 2 and slide it completely into pinch valve opening (see Figure 14).

Figure 14. Stretch syringe 2 tubing and slide into pinch valve.
26. Close the centrifuge cover and the syringe cover on the instrument (see Figure 15a). Confirm that all indicator lights are green (see Figure 15b).

Figure 15. Close centrifuge and syringe covers and confirm green indicator lights.

User Options

PPP Collection

If the user intends to collect platelet poor plasma (PPP), the user should select the PPP collection option at any time prior to the completion of the collecting phase. Pressing the [PPP] key will cause the key to be lit, indicating selection of the PPP collection option. Pressing the [PPP] key while it is lit will turn the PPP collection option off.

Selecting the PPP collection option will allow the user to attach an alternate syringe after the collecting phase is complete, and to draw platelet poor plasma (PPP) into it.

Multiple Cycles

If the user intends to perform multiple separation cycles with the same patient blood, the separation chamber and associated tubing can be used for up to three complete separation cycles. Additional 10-mL and 60-mL BD™ syringes are required.
INSTRUCTIONS FOR USE

Manual Pause
If the user needs to pause the instrument, this can be done by opening the syringe cover. This manual pause option can only be initiated when the centrifuge is spinning at the lower speed used during operation of the syringe pumps.

During this pause the syringe pumps and the timer will become inactive and the centrifuge will continue to spin at the lower speed.

The cycle will resume when the user closes the syringe cover and presses the [START] key.

Notes:
- If the user opens the syringe cover when the instrument is spinning at a high speed, the cycle will continue and the instrument will not pause until the centrifuge slows to the lower speed.
- If the user fails to restart the cycle within ten minutes of initiating the pause, the centrifuge will stop. To resume, press the [START] key.
  Note: Resume operation only applies to software version 3.0 and higher.

Instrument Operation

Program Selection
Note: Program selection options only apply to software version 3.0 and higher.

Before a cycle is initiated, special operating programs may be selected by putting the instrument into “Menu Mode.” The programs that can be selected are:
- PURGE: Use to immediately purge blood out of the centrifuge into the 60-mL syringe. Once the centrifuge is purged, the unit returns to the previously selected mode (either STANDARD or MIN. RBC).
- MIN. RBC: Increases line clear volume in order to minimize red blood cells in subsequent cycles. This mode is signified by the text “– RBC” on line 2 of the display.
  Note: When using this program, all cellular content will be slightly less than the standard program and cycle time will be shortened to approximately 10 minutes.
- STANDARD: The normal, general purpose operating mode.

In order to select one of the programs using the Menu Mode, do the following:
- Before a cycle has been initiated, continually press the minus (-) key until “OPTIONS” is displayed on line 2.
- Press the [START] key.
- Use the plus (+) and minus (-) keys to scroll through the options described above.
- When the desired option is visible, press the [START] key.
Changing the Default Program

Note: Program selection options only apply to software version 3.0 and higher.
The following steps should be followed to change the program that is set by default when the unit is powered on:

- With the unit powered off, press and hold the [PPP] and plus (+) keys.
- While continuing to press the keys, power on the unit.
- Use the plus (+) and minus (-) keys to scroll through the programs.
- When the desired default program is visible, press the [START] key.

The program selected will now be the default program for subsequent processing.

PRP Volume Selection

The user must select the volume of platelet rich plasma (PRP) to be collected in syringe 1 by pressing the volume indicator keys on the front of the instrument. The volume selected will be displayed on the message screen.

The default volume of PRP is set at 0-mL. The user must indicate a volume between three (3) and ten (10) mL before the instrument will begin a cycle.

Cycle Initiation

When the separation chamber and both syringes are properly installed, PRP volume has been selected, and both covers are closed, the user should press the [START] key.

Note: The instrument timer will indicate the approximate amount of time left in the cycle. The timer will begin when the user presses [START].

The Arteriocyte Medical Systems Magellan® Autologous Platelet Separator instrument will go through the following phases:

Filling

The Platelet Separator instrument will pump blood mixed with anticoagulant from syringe 2 into the separation chamber. The message [FILLING] will appear on the message screen.

Processing

When the chamber is full, the instrument will proceed with the red blood cell (RBC) separation and platelet separation. The message [PROCESSING] will appear on the message screen.

Collecting

During the collection phase, the instrument will pump the desired amount of PRP into syringe 1 and the message [COLLECTING] will appear on the message screen.
INSTRUCTIONS FOR USE

(Optional) PPP Collection

Note: At the end of the collecting phase, the user has the option to collect platelet poor plasma (PPP) into an alternate syringe.

1. If the user has pressed the [PPP] key earlier in this cycle, the instrument will automatically pause and prompt the user to change the syringe. During this phase the [START] key will be blinking.

2. Open the syringe cover.

3. Disconnect syringe 2 from the chamber tubing.

4. Attach an empty 60-mL BD™ syringe to the chamber tubing, place the syringe into the receptacle, and engage the plunger driver around the syringe base.

5. Close the syringe cover.

6. Press the [START] key to complete the cycle.

Notes:

- The cycle timer will pause during the PPP collection phase and restart again when the user presses [START].

- If the user fails to restart the cycle within ten minutes of initiating the pause, the centrifuge will stop. To resume, press the [START] key.

Emptying

During the emptying phase, platelet poor plasma (PPP) will be automatically emptied into syringe 2, and the message [EMPTYING] will appear on the message screen.

When the emptying phase is complete, the centrifuge and syringe pump will stop. The message [CYCLE COMPLETE] will appear on the message screen.

Cycle Completion

At the completion of a cycle, the instrument will display the message [+ = CONTINUE / - = CLEAR TOTAL / CYCLE COMPLETE].

No Additional Cycles

If no additional cycles will be run with the same patient, the user should press the [CLEAR TOTAL] key to clear the PRP totals.

Multiple Cycles with the Same Patient Blood

If additional cycles will be run with blood from the same patient, the user can press the [ADD CYCLE] key indicating that cumulative PRP volumes from multiple cycles of the same patient blood should be calculated and displayed.

This cumulative total will appear in the lower left side of the message screen at the end of the individual cycle.
To begin another cycle:

- Attach and load new syringes. Refer to steps 9 through 26 of the instructions for use, as appropriate.
- Close syringe cover.
- Press the [START] key.

When the final cycle is complete, luer connector caps should be replaced on chamber tubing. The tubing, separation chamber, and other blood contact materials should be appropriately disposed of according to appropriate biohazard waste procedures.

TROUBLESHOOTING

System Errors

During a system error an audible alert will sound and the following information will be displayed on the screen:

1. A reference number for the technical service representative.
2. The failure location.
3. Appropriate user response.

If the user is not able to resolve the issue from the information displayed on the screen, they should contact their service representative and provide the reference number.

User Intervention Conditions

When user intervention is required, an audible alert will sound and the following information will be displayed on the screen:

1. The suggested user action.
2. A direction to restart [PRESS START].

The user should follow the instructions provided in the message. Details regarding user intervention messages are provided in Table 2.

Note: Message wording may vary slightly on older software versions.
## TROUBLESHOOTING

### Table 2. Conditions requiring user intervention.

<table>
<thead>
<tr>
<th>Message</th>
<th>Explanation</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>[CLOSE COVERS] [PRESS START]</td>
<td>This message will appear if either of the covers is not completely closed or latched.</td>
<td>Make certain that the centrifuge cover and the syringe cover are both completely closed and latched. Confirm that all sensor lights are green. Press the [START] key.</td>
</tr>
<tr>
<td>[LOAD SYRINGES] [PRESS START]</td>
<td>This message will appear if either of the syringes is not accurately attached to the chamber tubing or is incorrectly placed in the syringe pump receptacles. A red sensor light will indicate the failure area.</td>
<td>Check syringes 1 and 2 and tubing connections. Confirm that all sensor lights are green. Press the [START] key.</td>
</tr>
<tr>
<td>[ENTER VOLUME] [PRESS START]</td>
<td>This message will appear if the PRP volume remains at the default volume (0 mL). A volume must be entered.</td>
<td>Enter a PRP volume. Press the [START] key.</td>
</tr>
<tr>
<td>[LOAD SYSTEM] [ENTER VOLUME] [PRESS START]</td>
<td>This message will appear if either of the covers is not completely closed or latched. A red sensor light will appear at the failure area.</td>
<td>Check syringe 1 and syringe 2. Check centrifuge cover and syringe cover. Enter PRP volume. Press the [START] key.</td>
</tr>
<tr>
<td>[CHECK OPTICS] [PRESS START]</td>
<td>This message will appear if the separator sensor did not calibrate.</td>
<td>Check for obstructions, dirt, or damage to the optical components. Press the [START] key.</td>
</tr>
<tr>
<td>[CHECK CENTRIFUGE] [RECLOSE COVER] [PRESS START]</td>
<td>This message will appear if the centrifuge door latch will not lock properly.</td>
<td>Open and close the cover, making sure it latches properly. Press the [START] key.</td>
</tr>
<tr>
<td>[CHECK TUBING] [PRESS START]</td>
<td>This message will appear if the pinch valve is not operating correctly. It is sometimes caused by the tubing not being properly seated in the pinch valve.</td>
<td>Re-seat the tubing in the pinch valve. Press the [START] key.</td>
</tr>
</tbody>
</table>
TABLE 2. Conditions requiring user intervention. (Continued)

<table>
<thead>
<tr>
<th>Error Conditions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>[ERROR 4]</strong> [CHECK SYRINGE VOLUME] [PRESS START]</td>
<td>This message will appear if the unit cannot detect a clear light path after attempting to empty the chamber. It is often caused by too much blood being left in the chamber from a previous cycle or overfill of the 60-mL syringe. Visually inspect the chamber to check for blood. If blood is seen, attach an empty 60-mL syringe and purge the chamber. Replace the 60-mL syringe filled with blood and try running the cycle again. If the problem persists, call service.</td>
</tr>
<tr>
<td><strong>[ERROR 5]</strong> [CHECK PINCH VALVE]</td>
<td>This message will appear if the pinch valve is not operating correctly. It is sometimes caused by the tubing not being properly seated in the pinch valve. Re-seat the tubing in the pinch valve. Press the [START] key. If the problem persists, call service.</td>
</tr>
<tr>
<td><strong>[ERROR 6]</strong> [CHECK DISPOSABLE INSTALLATION]</td>
<td>This message will appear if the unit’s optics are not able to detect a light path running through the disposable. It may sometimes be caused by the disposable not being properly seated in the centrifuge. Open the centrifuge cover and re-seat the disposable, making sure it snaps into place on both ends of the centrifuge caddy. Close the cover and press the [START] key. If the problem persists, call service.</td>
</tr>
</tbody>
</table>
TROUBLESHOOTING

Table 2. Conditions requiring user intervention. (Continued)

| [ERROR 7] | [NO RBC INTERFACE] | This message will appear if the unit is not able to detect the RBC interface. It may occur if clotted blood is in the chamber or if the 60-mL syringe plunger is not properly seated in the plunger driver. |
| [ERROR 10] | [CHECK CENTRIFUGE COVER] | This message will appear if the centrifuge door does not remain latched during cycle. |

Visually inspect chamber for possible clotted blood. If blood has clotted, a new sample will need to be taken. Check 60-mL syringe plunger to be sure it is properly seated in plunger driver. If it was not seated properly, purge the chamber and restart the cycle. If neither of the above conditions apply, call service.

Open and close the cover, making sure it latches properly. Purge the chamber if necessary. Press the [START] key to try running another cycle. If the problem persists, call service.

Stopped Timer

The approximate amount of time remaining in a single cycle will appear on the left in the lower line of the message screen. The timer will stop for one of the following reasons:

- The instrument is in the pause mode.
- A condition is present which requires user intervention.
- A system error exists.

Except for system error conditions, when the user addresses any interventions and presses [START], the timer will continue and will show the time remaining in that cycle.

Blank Screen Message

1. Check the power connections at the source and at the instrument.
2. Check that the ON/OFF switch is turned ON.
3. Contact a service representative.
CLEANING AND SERVICE

CAUTION: BEFORE USING ANY CLEANING OR DECONTAMINATION METHODS EXCEPT THOSE RECOMMENDED BY THE MANUFACTURER, USERS SHOULD CHECK WITH THE MANUFACTURER THAT THE PROPOSED METHOD WILL NOT DAMAGE THE EQUIPMENT.

Cleaning

Anytime the external portions of the Platelet Separator Instrument become dirty (eg, blood spills), they should be cleaned with a 10% bleach solution or other appropriate disinfectant solution (according to approved hospital protocols). After cleaning, the unit should be wiped with a cloth using water to remove any cleaning solution residue. Then the unit should be wiped with a dry cloth.

If it is suspected that fluid has penetrated into the machine, the machine should be unplugged and immediately examined by a trained service or biomedical technician.

Caution: If blood or fluids are spilled, use appropriate universal precautions and engineering controls (such as eye protection, mask and gloves) to protect yourself from the blood and/or the cleaning fluids.

Periodic Maintenance and Safety Inspection

Maintenance and safety inspections of the platelet separator instrument must be performed at least once every 12 months, or following 750 separation cycles, whichever comes first. This work must be done by persons, who, based on their training, knowledge, and practical experience, are capable of adequately performing such inspections and who do not require additional instructions with regard to the technical and safety inspection.

Warning: If a technical and safety inspection reveals a defect which could cause harm, the device should not be used until it has been properly repaired. The operator must immediately notify the appropriate individuals and Arteriocyte Medical Systems Service Department of these defects.

Service

Arteriocyte Medical Systems maintains a professional staff to provide technical consultation to product users. For more information, contact your local Arteriocyte Medical Systems representative, or contact Arteriocyte Medical Systems at the address or telephone number listed on the back cover.

The platelet separator instrument has been carefully engineered, manufactured and quality tested to provide long, trouble-free service. Should service or repair be required, contact an Arteriocyte Medical Systems representative at the address or telephone number listed on the back cover of this manual.
CLEANING AND SERVICE

Note: Ship the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument back to Arteriocyte Medical Systems in its original shipping container. If the original shipping container is not available, contact your Arteriocyte Medical Systems representative. A serial number identifying each individual device is printed on the back of the device. This serial number should be referenced in any correspondence regarding this device.

Contact Arteriocyte Medical Systems for additional disposable components and accessories. Arteriocyte Medical Systems locations are listed at the back of this manual.

At the end of its useful life, dispose all components of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator System in accordance with local environmental requirements.

End of Life Disposition

Do not dispose of this product in the unsorted municipal waste stream. Follow local regulations for proper disposal.
INSTRUMENT LIMITED WARRANTY (U.S.)

INSTRUMENT LIMITED WARRANTY¹ (U.S.)

THE FOLLOWING LIMITED WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

A. This LIMITED WARRANTY provides the following assurance to the purchaser of the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Instrument, hereafter referred to as the "Instrument":

(1) Should the Instrument fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Instrument to the purchaser, Arteriocyte Medical Systems will at its option: (a) repair or replace any defective part or parts of the Instrument; (b) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A (2), against the purchase of the replacement Instrument; or (c) provide a functionally comparable replacement Instrument at no charge.

(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Instrument.

B. To qualify for the repair, replacement or credit set forth in Section A, the following conditions must be met:

(1) The Instrument must be returned to Arteriocyte Medical Systems within sixty (60) days after discovery of the defect (Arteriocyte Medical Systems may, at its option, repair the Instrument on site).

(2) The Instrument must not have been repaired or altered outside of Arteriocyte Medical Systems' factory in any way which, in the judgment of Arteriocyte Medical Systems, affects its stability and reliability. The Instrument must not have been subjected to misuse, abuse or accident.

C. This LIMITED WARRANTY is limited to its express terms. In particular:

(1) Except as expressly provided by this LIMITED WARRANTY, ARTERIOCYTE MEDICAL SYSTEMS IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE INSTRUMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

(2) This LIMITED WARRANTY is made only to the purchaser of the Instrument. AS TO ALL OTHERS, ARTERIOCYTE MEDICAL SYSTEMS MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING

¹ This Limited Warranty is provided by Arteriocyte Medical Systems, Inc., 45 South Street, Hopkinton, MA, 01748. It applies only in the United States. Areas outside the United States should contact their local Arteriocyte Medical Systems representative for exact terms of the Limited Warranty.
INSTRUMENT LIMITED WARRANTY (U.S.)

FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this LIMITED WARRANTY is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid. This LIMITED WARRANTY gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Arteriocyte Medical Systems to any representation, condition or warranty except this LIMITED WARRANTY.
DISPOSABLES KIT LIMITED WARRANTY (U.S.)

THE FOLLOWING LIMITED WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

A. This Limited Warranty provides the following assurance to the customer who receives the Arteriocyte Medical Systems Magellan® Autologous Platelet Separator Disposables Kit, hereafter referred to as the “Product”:

1) Should the Product fail to function within normal tolerances due to a defect in materials or workmanship prior to its “Use Before Date”, Arteriocyte Medical Systems will at its option: (a) issue a credit equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement Product or (b) provide a functionally comparable replacement Product at no charge.

2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Product.

B. To qualify for the Limited Warranty, these conditions must be met:

1) The Product must be used prior to its “Use By” date.

2) The unused portion of the Product must be returned to Arteriocyte Medical Systems within 60 days after use and shall be the property of Arteriocyte Medical Systems.

3) The Product must not have been altered or subjected to misuse, abuse or accident.

4) The Product may not have been used by any other customer.

C. This Limited Warranty is limited to its express terms. In particular:

1) Except as expressly provided by this Limited Warranty, ARTERIOCYTE MEDICAL SYSTEMS IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

2) This Limited Warranty is made only to the customer in whom the Product was used. AS TO ALL OTHERS, ARTERIOCYTE MEDICAL SYSTEMS MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE CUSTOMER SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS

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DISPOSABLES KIT LIMITED WARRANTY (U.S.)

LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the customer specific legal rights. The customer may also have other rights which vary from state to state.

(4) No person has any authority to bind Arteriocyte Medical Systems to any representation, condition or warranty except this Limited Warranty.
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