MAGELLAN®

MAR0Max Complete Disposable Kit

Explanation of symbols on package labeling

LOT	Lot Number
REF	Catalog Number
	Use by
X	Quantity
	Do Not Reuse
STERILE EO	Fluid Path Sterilized Using Ethylene Oxide
STERILE R	Fluid Path Sterilized Using Irradiation
STERILE	Fluid Path Sterilized Using Steam or Dry Heat
LATEX	Not made with natural rubber latex
PYROGEN	Nonpyrogenic
U.S.P.	United States Pharmacopeia
	This Way Up
	Manufacturer
	Fragile, Handle with Care
	Consult Instructions for Use
	Caution, Consult Accompanying Documents
Rx	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).

INTRODUCTION

Indications for Use

The Arteriocyte Medical Systems, Inc. MAGELLAN® Complete Disposable Kit is intended for use only with the MAGELLAN® Autologous Platelet Separator Instrument. See Magellan® Platelet Separator Indications for Use.

Contraindications

The Use of the Arteriocyte Medical Systems, Inc. MAGELLAN® Disposables Kit 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 affect a patient's coagulation system may inhibit the use of platelet separation system therapy.

Warning: Reprocessing may compromise the structural integrity of the device and/or lead to device failure. Reuse of this single patient use device creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness, or death of the patient.

Precautions

1. Only Arteriocyte Medical Systems sterilized disposable kits are approved for patient use with the MAGELLAN® Platelet Separator Instrument. It is important that aseptic technique be used to minimize the possibility of contamination of the disposable components and/or patient.
2. Store all disposable components in a dry place away from extremes of environmental conditions.
3. Materials used in the Arteriocyte Medical Systems, Inc. MAGELLAN® Disposables 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.

System Description

The Arteriocyte Medical Systems, Inc. MAGELLAN® Complete Disposable Kit consists of sterile fluid pathway single-patient-use components necessary for each platelet separation procedure with the MAGELLAN® Autologous Platelet Separator Instrument.

Cautions

1. Caution: Federal Law (USA) restricts this device to be sold by or on the order of physician.
2. Refer to the System Operator's manual supplied with the instrument before performing a platelet separation procedure using the components of this kit. Treat all blood and fluids using Universal Precautions for bloodborne pathogens.
3. Each platelet separation procedure using the Arteriocyte Medical Systems Inc, MAGELLAN® Platelet Separator Instrument requires one MAGELLAN® Platelet Separator Disposable Kit. The separation chamber and associated tubing can be used with the same patient for up to three complete separation cycles.
4. Use only Arteriocyte Medical Systems disposable accessories.
5. Inspect the kit prior to use. Do not use the kit if any component or the tray is damaged or opened.
6. Throughout procedure, make certain all tubing is free of any kinks, twists, or flat areas. All components of this kit are sterile fluid pathway single-patient-use. Do not resterilize. Do not use the ACD-A anticoagulant unless the solution is clear, and the seal is intact. The ACD-A anticoagulant supplied in this kit is not for preparation of blood products for transfusion or for direct intravenous infusion. Discard the unused portion. Do not reuse.

How Supplied

Contents of the Arteriocyte Medical Systems, Inc. MAGELLAN® Complete Disposable Kit (see Figure 1):

A. One (1) Separation chamber with attached tubing
B. One (1) 50-mL bag ACD-A anticoagulant
C. One (1) 5-mL syringe
D. One (1) 18-gauge x 3.8 cm (1.5") needle
E. Four (4) syringe tip caps
F. One (1) 10-mL syringe (Syringe 1)
G. One (1) 60-mL syringe (Syringe 2)
H. Instruction for Use

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

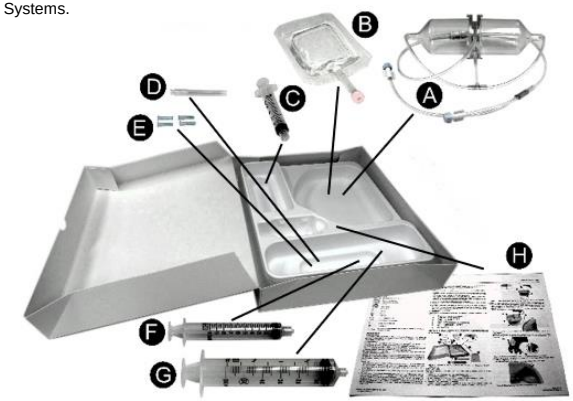

Figure 1. Contents of the Arteriocyte Medical Systems, Inc. MAGELLAN® Complete Disposable Kit.

INSTRUCTIONS

Caution: All components of this kit are sterile fluid pathway single-patient-use. Do not resterilize.

1. Remove the cover from the separator disposable 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.
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 2, A and B).

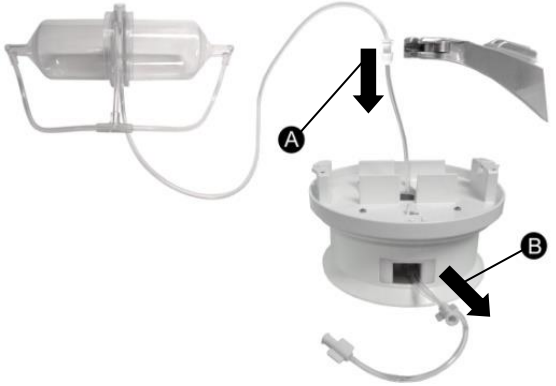

Figure 2. Thread the separation chamber tubing through the center of the chamber caddy.

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 3, A). Place T-connector in slot (see Figure 3, B), and tubing under retainer on top surface of caddy (see Figure 3, C). Press tubing down into groove on outer edge of chamber caddy (see Figure 3, D).
   Caution: Failure to install the separation chamber properly may result in error codes.

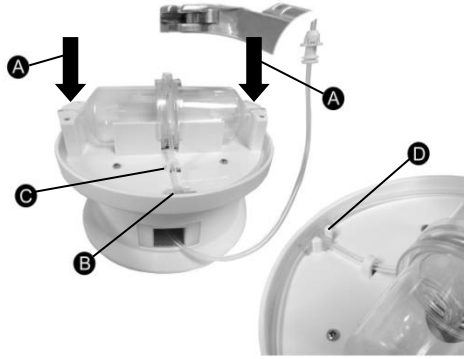

Figure 3. Install the separation chamber into the caddy and place tubing into slot and under retainer.

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 4, A) and close the latch (see Figure 4, B).

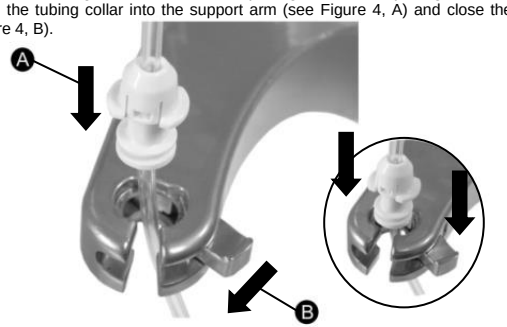

Figure 4. Attach chamber tubing collar to the instrument tubing support arm.

8. Press tubing down into groove on support arm and place tubing through notch in centrifuge ridge (see Figure 5).

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

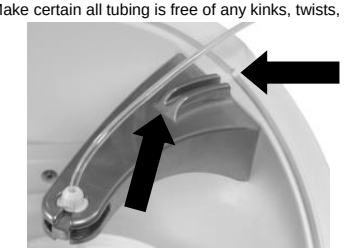

Figure 5. Place tubing through notch in centrifuge ridge.

9. Prepare the syringe pumps on the front of the instrument by rotating the plunger drivers to the open position (see Figure 6, A), while sliding them to the lowest points (see Figure 6, B).

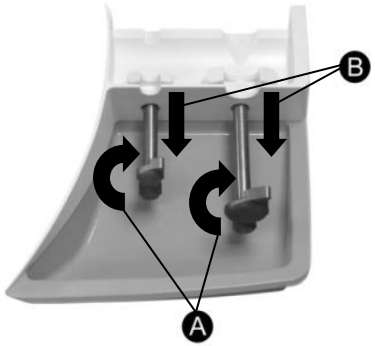

Figure 6. Within the syringe receptacles, slide the open plunger drivers to the lowest points.

10. Prepare the patient for venipuncture according to standard clinical practice
11. Using aseptic technique, draw the appropriate volume of anticoagulant from the ACD-A anticoagulant bag 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 1. Volume of ACD-A and corresponding volumes of blood to achieve anticoagulated blood containing ~ 7 parts blood: 1 part ACD-A.

Total Volume of Anticoagulated Blood (mL)	Volume of ACD-A (mL)	Volume of Blood Drawn (mL)
30	4.0	26.0
40	5.0	35.0
50	6.0	44.0
60	8.0	52.0

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.

12. Slowly draw the appropriate volume of patient blood. Gently mix with ACD-A throughout the blood draw for thorough distribution. Refer to Table1 for the appropriate volumes of ACD-A and blood.
    Note: Do not exceed 60 mL total volume.
    Note: If multiple separation cycles are to be performed with the same patient, repeat steps 10, 11 and 12 to prepare and fill syringes.
13. Remove the luer connector cap from the end of the shorter length of chamber tubing and attach syringe 1 (10 mL syringe, see Figure 7, A).
14. Evacuate all air from syringe 1 into the chamber tubing line.
15. Place syringe 1 into the appropriate syringe pump receptacle.
16. Rotate and slide the plunger driver to engage the syringe 1 plunger (see Figure 7, B).
17. Ensure whole blood is thoroughly mixed using gentle agitation prior to placing in the syringe pump receptacle.
18. Remove the luer connector cap from the longer length of chamber tubing and attach syringe 2 (see Figure 7, C).
19. 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.
20. Place syringe 2 into the appropriate syringe pump receptacle.
21. Rotate and slide the plunger driver to engage the syringe 2 plunger (see Figure 7, D).

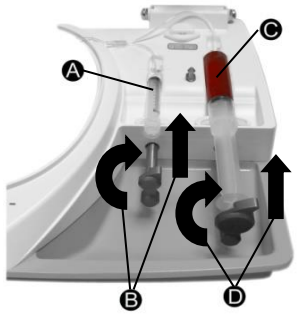

Figure 7. Attach tubing, load syringes, and engage syringe plunger drivers.
Caution: Make certain all tubing is free of any kinks, twists, or flat areas.

22. Gently stretch the tubing attached to syringe 2 and slide it completely into pinch valve opening (see Figure 8).

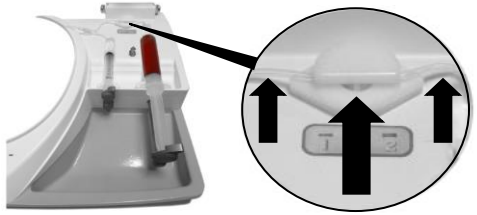

Figure 8. Stretch syringe 2 tubing and slide into pinch valve.

ARTERIOCYTE MEDICAL SYSTEMS INC. DISPOSABLES KIT LIMITED WARRANTY[1] (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, Inc. MAGELLAN® Complete Disposable 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 Inc. 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 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.

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

DISPOSABLES LIMITED WARRANTY – ARTERIOCYTE MEDICAL SYSTEMS, INC. (OUTSIDE U.S.)
THE FOLLOWING LIMITED WARRANTY APPLIES TO CUSTOMERS OUTSIDE THE UNITED STATES.

A. This LIMITED WARRANTY provides assurance for the customer who receives an Arteriocyte Medical Systems® ("AMS") **MAGELLAN® Complete Disposable Kit** "Product", that should the Product fail to function to specification, AMS will issue a credit equal to the original Product purchase price (but not to exceed the value of the replacement Product) against the purchase of any AMS replacement Product used for that customer. THE WARNINGS CONTAINED IN THE PRODUCT LABELLING ARE CONSIDERED AN INTEGRAL PART OF THIS LIMITED WARRANTY. CONTACT YOUR LOCAL AMS REPRESENTATIVE TO OBTAIN INFORMATION ON HOW TO PROCESS A CLAIM UNDER THIS WARRANTY.
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 Product must be returned to AMS within sixty (60) days after use and shall be the property of AMS.
   3) The Product must not have been altered or subjected to misuse, abuse or accident.
   4) The Product must not have been used more than one time for any customer.
   5) The Product must be used in conformity with the Product, of which this LIMITED WARRANTY is an integral part.
C. This LIMITED WARRANTY is limited to its express terms. In particular:
   1) In no event shall any replacement credit be granted where there is evidence of improper handling, improper use or material alteration of the replaced Product.
   2) AMS is not responsible for any incidental or consequential damages based on any use, defect or failure of the Product, whether the claim is based on warranty, contract, tort, patent infringement or otherwise.
D. This LIMITED WARRANTY does not cover those parts that, by their very nature, are likely to deteriorate or which AMS considers should be periodically replaced consistently with normal routine or preventative maintenance requirements.
E. 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 to term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion 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.
F. No representative, agent, dealer, retailer, or intermediary of AMS shall have authorization to amend the contents of this LIMITED WARRANTY.
G. The validity, interpretation, and performance of the agreement for which this LIMITED WARRANTY is issued, as well as any disputes relating or connected thereto is controlled by and construed under the laws of the State of Delaware, USA.

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Toll-free USA: 1-866-660-AMSI (2674) Fax: 1-508 -497-8951

[1] This Limited Warranty is provided by Arteriocyte Medical Systems, Inc., 45 South St., Hopkinton, MA 01748 USA. 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.