Instructions for Use

Precautions

Caution: The use of 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 this device is contraindicated for a hemodynamically unstable or hypercoagulable patient. Use of this device is contraindicated for a patient with known allergy or sensitivity to the components of this kit. Use of this device is contraindicated for a patient with known allergy or sensitivity to the components of this kit.

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 the device may lead to injury, illness or death of the patient.

Precautions

1. Use the components of this kit only with the Arteriocyte Medical Systems, Inc. MAGELLAN® Complete Disposable Kit. Do not use silicone oils or greases near disposable components.

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® 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. Use the components of this kit. Should any evidence of damage to the components be found during inspection or setup, do not use the kit.

4. Holding the platelet separation chamber with the vent facing upward, thread the attached tubing through the center of the chamber caddy (see Figure 2A and B).

5. Install the platelet separation chamber into the centrifuge caddy, making certain to use a platelet separation chamber attachment to prevent its movement into the centrifuge (see Figure 3A).

6. Place T-connector in slot (see Figure 3A), and tubing under retainer on top surface of caddy (see Figure 3C). Press tubing down into groove on outer edge of chamber caddy (see Figure 3D).

7. Use ACD-A anticoagulant unless the solution is clear and the seal is intact. Use ACD-A anticoagulant in this kit is not for preparation of blood products for transfusion or for direct intravenous infusion. Discard the unused portion. Do not reuse.

8. Press tubing down into groove on top of chamber caddy (see Figure 3D) and tubing under retainer on top surface of caddy (see Figure 4B).
Instructions for Use

Arterioocyte Medical Systems, Inc.
45 South St. Hopkinton, MA 01748 USA - Internet: www.arteriocyte.com

THE FOLLOWING LIMITED WARRANTY APPLIES TO CUSTOMERS OUTSIDE THE UNITED STATES.

A. This LIMITED WARRANTY provides assurance for the customer who receives an Arterioocyte 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 in 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 returned in conformity with the Product, of which this LIMITED WARRANTY is an integral part.

C. This LIMITED WARRANTY is limited to its express terms.
1) The Product may not have been used by any other person.
2) The Product must be returned to AMS within sixty (60) days after use and shall be in the property of AMS.
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 person.
5) 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.
6) 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 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 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.

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.

Manufacturer:
Arterioocyte Medical Systems, Inc.
45 South St. Hopkinton, MA 01748 USA - Internet: www.arteriocyte.com

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MAGELLAN®
Ratio Dispenser Kit

Instructions For Use
Explanation of symbols on package labeling

Caution, Consult Accompanying Documents
Lot Number
Catalog Number
Sterilized Using Ethylene Oxide
Latex Free
Nonpyrogenic
Do Not Reuse
Use By
Open Here
Fragile, Handle with Care
This Way Up
Quantity
For US Audiences Only
INTRODUCTION

The ArterioCyte Medical Systems, Inc. Magellan® Ratio Dispenser Kit consists of single use components to be used in conjunction with a ArterioCyte Medical Systems, Inc. Magellan® Dispenser Tip.

Intended use

The components of this ArterioCyte Medical Systems, Inc. Magellan® Ratio Dispenser Kit, when used with a tip, are intended to assist the user in simultaneously delivering two non-homogenous liquids to the same treatment area(s).

The Magellan® Ratio Dispenser Kit is intended for the application of fluids, as deemed necessary by the surgeon’s determination of the clinical use requirements, to facilitate the preparation of soft tissue prior to repair.

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.

How Supplied

All components are shipped sterile.

The Magellan® Ratio Dispenser Kit consists of the following components:

One (1) procedure tray
Three (3) 60-mL sample cups with lids
Two (2) 12-mL syringes
Two (2) 1-mL syringes
Two (2) dispenser handles
Two (2) dual syringe plunger clips

Accessories

One (1) Magellan® Dispenser Tip is required for the use of this dispenser kit. Dispenser Tips are available from ArterioCyte Medical Systems.

Cautions

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

Kit components are for single use only. Do not resterilize.

INSTRUCTIONS

1. Using aseptic technique, remove the components of the dispenser kit from the sterile package and a dispenser tip from its sterile package.
2. Fill the larger 12-mL syringe with liquid.
3. Fill the smaller 1-mL syringe with a second liquid to approximately the same level.
4. Snap the dispenser handle to the 12mL syringe (see Figure 1, number 1).
5. Attach each syringe to the dispenser tip (see Figure 1, numbers 2 and 3).
6. Snap the plunger clip to both syringe plungers (see Figure 1, number 4).
   Figure 2 shows the assembled dispenser.
7. Depress the syringe plunger clip to dispense the desired volume of the two liquids.
INTRODUCTION

Intended use

How Supplied

Accessories

Cautions

INSTRUCTIONS
ARTERIOCYTE MEDICAL SYSTEMS INC. DISPOSABLES KIT LIMITED WARRANTY¹ (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® Ratio Dispenser 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 and 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

¹ This Limited Warranty is provided by Arteriocyte Medical Systems, Inc., 45 South Street, 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.

6 English Instructions for Use
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 Arteriocte 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® Ratio Dispenser Kit (“Product”), that should the Product fail to function to specification, AMS will issues 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 user instructions in the “User Manual” delivered to the customer together 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 Ohio, USA.
Manufacturer:
Artericyte Medical Systems, Inc.
45 South St.
Hopkinton, MA 01748
USA
Internet: www.artericyte.com
Toll-free USA: 1-866-660-AMSI(2674)
Fax: 1-508-497-8951

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AMS95125LBL Rev. 2
MAGELLAN®

Aspiration Kit

Instructions For Use
Explanation of symbols on package labeling

⚠️ Caution, Consult Accompanying Documents

LOT Lot Number

REF Catalog Number

STERILE EIO Sterilized Using Ethylene Oxide

Latex Free

Nonpyrogenic

Do Not Reuse

Use by

Fragile, Handle with Care

This Way Up

Quantity

Phthalate

Open Here

For US Audiences Only
INTRODUCTION
The Arteriocyte Medical Systems, Inc. MAGELLAN® Aspiration Kit is a sterile convenience kit for aspirating bone marrow.

Intended Use:
The Arteriocyte Medical Systems, Inc. MAGELLAN® Aspiration Kit is intended for use only with the MAGELLAN® Autologous Platelet Separator Instrument.

Note: Refer to the MAGELLAN® Autologous Platelet Separator Operator’s Manual for Usage Instructions, Disclaimers, Warnings, Precautions, and Contraindications.

Cautions
• Federal Law (USA) restricts this device to sale by or on the order of a physician.
• Kit components for single patient use only. Do not resterilize
• Refer to the System Operator’s Manual supplied with the instrument, as well as Instruction for Use for components from other manufacturers inside this convenience kit before performing the procedure. Treat all blood, tissue and fluids using Universal Precautions for bloodborne pathogens.
• Use only Arteriocyte Medical Systems disposable accessories.
• Inspect the kit prior to use. Do not use the kit if any component of the tray is damaged or opened.

Precautions
1. Only Arteriocyte Medical Systems, Inc. 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.
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® Disposable Kit may be sensitive to chemicals (such as solvents and certain detergents).
4. 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.

How Supplied:
The MAGELLAN® Aspiration Kit consists of the following components:

- Two (2) 30 mL Syringes
- One (1) 60 mL Syringe
- One (1) 200 Micron Blood Component Filter
- One (1) Bone Marrow Aspiration Needle
- One (1) 3-Way Stopcock
- One (1) 18-G Needle
- Four (4) Syringe Tip Caps
200 Micron Blood Component Filter and Syringe Adapter
Instructions for use

Prime heparin flushed filter and syringes. Residual priming volume
of saline is 6 mL. Maximum volume of product is 300 mL.

Directions:
Use aseptic technique. Single patient use.
1. Close the pinch clamp on the distal end of filter tubing.
2. While holding adaptor upright, squeeze the filter chamber
   and attach the syringe containing the blood component to the
   proximal end.
3. Release hold on chamber allowing blood components to enter
   filter chamber. Release pinch clamp and allow blood compo-
   nents to flow into distal tubing just to luer connector to de-air
   tubing and close pinch clamp.
4. Attach the collection syringe to distal tubing luer connector of
   the filter and open pinch clamp.
5. Gently pull back on the plunger of the collection syringe until
   resistance is met, or until the desired volume is reached. If re-
   sistance is met before desired volume is reached, disconnect
   proximal syringe and pull remaining blood components into
   collection syringe. Repeat if more than one syringe of blood
   component is drawn.
6. Disconnect the filtered blood component syringe from filter tub-
   ing and attach a sterile syringe cap.

Follow AABB guidelines.

Manufacturer:
Arteriocyte Medical Systems, Inc.
45 South Street
Hopkinton, MA 01748
USA
Internet: www.arteriocyte.com
Toll-free: 1-866-660-AMSI (2674)
Fax: 508-497-8951
Instructions for use of this Bone Marrow Aspiration Needle

A. INTENDED USE
The Bone Marrow Aspiration Needle is intended for use in aspirating bone marrow specimen.

B. CONTRAINDICATIONS
For use only for bone marrow aspiration as determined by a licensed physician. The device is intended to be used by a physician familiar with the possible side effects, typical findings, limitations, indications and contraindications of bone marrow aspiration. The procedure should be performed on patients that are suitable for such procedure only.

Caution: For single patient use only. Do not attempt to clean or resterilize this product. The design of this device may not perform as intended by the manufacturer if it is reused. The manufacturer cannot guarantee the performance, safety and reliability of a reprocessed device.

After use, this product may be a potential biohazard. Handle in a manner which will prevent accidental puncture. Dispose in accordance with applicable laws and regulations. Carefully place the used needle in a sharps biohazard container after the procedure is completed.

Note: These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.

C. DIRECTIONS FOR USE
1. Inspect the package for proper integrity. If undamaged, open the package using aseptic technique.
2. Remove the needle from the pouch and inspect the cutting edge of both cannula and stylet for any damage or other imperfections that would prevent the proper operation of the needle.
3. Following proper placing technique, locate the needle adjacent to the biopsy site.
4. Using gentle (but firm) pressure, advance the needle by rotating in an alternating clockwise-counterclockwise motion. Entrance into the marrow cavity is generally detected by decreased resistance.
5. Rotate the stylet cap counterclockwise, and pull the stylet out of the cannula.
6. Attach a luer syringe to the cannula hub.
   **Note:** Avoid using glass syringes because they may result in an inadequate seal and may break and fragment.
7. Apply negative pressure by quickly withdrawing the syringe plunger. Disengage the syringe and remove the aspirated sample.
   **Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured by:
Ranfac Corp.
30 Doherty Ave.
Avon, MA 02322 USA
ARTERIOCYTE MEDICAL SYSTEMS, INC. DISPOSABLES KIT
LIMITED WARRANTY1 (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® Aspiration 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 and 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.

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