

# ARTERIOCYTE

Helping Patients Heal Faster™

## MAGELLAN®






















Aspiration Kit

Instructions For Use

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## Explanation of symbols on package labeling

	Lot Number
	Catalog Number
	Use by
	Quantity
	Do Not Reuse
	Sterilized Using Ethylene Oxide
	Not made with natural rubber latex
	Nonpyrogenic
	Manufacturer
	Consult Instruction for Use/Consult Electronic Instructions for Use
	Caution, Consult Accompanying Documents
	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).
	Contains or presence of phthalates bis(2-ethylhexyl) phthalates (DEHP)
	Medical Device
	Unique device identifier
	Do not use if package is damaged and consult instruction for use
	Do Not Resterilize
	Keep dry
	(MR) Unsafe
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside

## **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 components 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 resistance 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 tubing and attach a sterile syringe cap.

Follow AABB guidelines.

### **Manufacturer:**

Arteriocyte Medical Systems, Inc.  
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Hopkinton, MA 01748, USA  
[www.istobiologics.com](http://www.istobiologics.com)  
[customerservice@istobiologics.com](mailto:customerservice@istobiologics.com)  
Phone: +1 888-705-4786

## 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 WARRANTY<sup>1</sup> (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 Arterioocyte Medical Systems, Inc. Magellan<sup>®</sup> 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", Arterioocyte Medical Systems, Inc. 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 Arterioocyte Medical Systems, Inc. and within 60 days after use and shall be the property of Arterioocyte Medical Systems, Inc.
- (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, INC. 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, INC. 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 Arterioocyte Medical Systems, Inc. to any representation, condition or warranty except this Limited Warranty.

1 This Limited Warranty is provided by Arterioocyte Medical Systems, Inc., It applies only in the United States. Areas outside the United States should contact their local Arterioocyte Medical Systems representative for exact terms of the Limited Warranty.



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