PRECISE™

Precise Cell Concentration System (120mL)

Explanation of symbols on package labeling

LOT	Batch code (Lot number)
REF	Catalog number
	Use-by date
X	Quantity
	Single sterile barrier system with protective packaging outside
STERILE EO	Fluid Path Sterilized Using Ethylene Oxide
STERILE R	Fluid Path Sterilized Using Irradiation
STERILE	Fluid Path Sterilized Using Steam or Dry Heat
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
LATEX	Not made with natural rubber latex
	Non-pyrogenic
U.S.P.	United States Pharmacopeia
	Keep dry / Temperature Limit
	Manufacturer
	Consult instructions for use or consult electronic instructions for use
	Caution
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)
MD	Medical device
UDI	Unique device identifier

INTRODUCTION

The Arteriocyte Medical Systems, Inc. Precise Cell Concentration System is intended for use with a general centrifuge to produce platelet rich plasma (PRP) from peripheral blood.

Indications for Use

The Precise Cell Concentration System is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect to improve handling characteristics.

Contraindications

The Use of the Arteriocyte Medical Systems, Inc. Precise Cell Concentration System is contraindicated for a hemodynamically unstable or hypercoagulable patient.

Warning

1. 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.
2. Some blood contacting components of the device have been sterilized with ethylene oxide, which can cause serious allergic reactions in some sensitized individuals.

Precautions

1. Federal Law (USA) restricts this device to sale by or on the order of a physician.
2. Store all disposable components in a dry place away from extremes of environmental conditions.
3. Materials used in the Arteriocyte Medical Systems, Inc. Precise Cell Concentration System 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.
4. Visually inspect the contents of the disposable kit. Should any evidence of damage to the components or trays be found during inspection or setup, do not use the disposable components.
5. Do not use silicone oils or grease near disposable components.
6. Follow manufacturer instructions when using centrifuge.
7. Do not use sterile components of this system if the package is opened or damaged.
8. Do not use after expiration date.
9. The physician is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
10. The patient is to be made aware of the general risks associated with drawing whole blood.
11. The safety and effectiveness of this device for in vivo indications for use, such as bone healing and hemostasis have not been established.
12. The PRP prepared by this device has not been evaluated for any clinical indications.
13. The PRP prepared by this device is NOT indicated for delivery to the patient's circulatory system.
14. The device is single use only. Do not reuse. Do not attempt to clean or re-sterilize this product. After use, this product may be a potential biohazard.
15. The use of this device 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.

Sterility

The Precise Cell Concentration Disposable Kit is sterilized by Irradiation. Do not use any component from an opened or damaged package. Do not re-sterilize. Single Use Only. Do not use past the expiration date.

How Supplied

Contents of the Arteriocyte Medical Systems, Inc. Precise Cell Concentration System:

A. Two (2) Precise Canisters.
B. Two (2) 5-mL syringes.
C. One (1) 18 Gauge x 3.8 cm (1.5") needle.
D. One (1) IV Site Prep Kit.
E. One (1) tubing clamp (For phlebotomy needle set).
F. Eight (8) syringe tip caps.
G. One (1) 50 mL Bag Anticoagulant Citrate Dextrose Solution, Solution A (ACD-A) anticoagulant.
H. One (1) phlebotomy needle set with luer-lock connector.
I. Two (2) 60-mL syringes.
J. Two (2) 10-mL syringes.
K. Two (2) 30-mL syringes.
L. Instructions For Use.

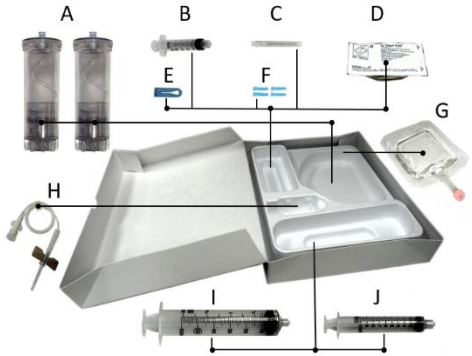

Figure 1. Contents of the Precise Cell Concentration System including Precise Cannisters (A).
Note: Additional components may be placed outside the carton shown in figure 1.

INSTRUCTIONS FOR USE

Note: Use standard aseptic technique throughout the following procedure.

1. Remove the cover from the Precise Cell Concentration System. 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.
2. Remove the inner tray containing the Precise cannisters from the disposable kit tray.
3. Peel open the lid on the inner tray containing the Precise.
4. Keep the Precise cannisters ready for blood separation.

Blood Draw

Note: Follow each step (5-29) below for each Precise device.

5. Prepare the patient for venipuncture according to standard clinical practice using the IV Site Prep Kit, if necessary.
6. Using aseptic technique, draw the appropriate volume of anticoagulant from the ACD-A anticoagulant bag into a 60 mL syringe using the 18-gauge needle. Refer to Table 1 for the appropriate volumes of ACD-A and blood.
7. Table 1. Volume of ACD-A and corresponding volumes of blood to achieve anticoagulated blood containing ~ 7 parts blood: 1-part ACD-A.

Table 1

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. Discard unused portion.

Note: Alternative methods can be used to collect patient blood. As appropriate, disregard references to the phlebotomy needle set.

8. If desired volume of whole blood will require additional syringes (i.e.. 120 mL), hook the tubing clamp onto the tubing of the phlebotomy needle set. Do not clamp at this time.
9. Attach the phlebotomy needle set with tubing clamp to the ACD-A primed 60 mL syringe.
10. Prime the phlebotomy needle set by slowly pushing the plunger of 60 mL syringe until ACD-A reaches the top of the tubing closest to the needle.
11. Perform venipuncture.
12. Slowly draw the appropriate volume of patient blood. Gently mix with ACD-A throughout the blood draw for thorough distribution. Refer to Table 1 for the appropriate volumes of ACD-A and blood.
13. If more than 60 mL blood is to be drawn, close the clamp prior to prepared syringe exchange and continue to draw with a new syringe after re-opening the clamp. Once the appropriate amount of the patient's blood is drawn, remove the phlebotomy needle set from the patient.
    Note: Do not exceed 60 mL total volume for any single syringe.
14. Disconnect 60 mL syringe from the IV tubing. Set aside the syringe and discard the needle and IV tubing utilizing appropriate local procedures.

Loading the Precise Cannister

15. Prepare the device by adding 2 mL of ACD-A as shown in figure 2.
16. Attach the luer of the 60 mL syringe with blood with the luer on the device as shown in figure 3, inject blood into the device.

Figure 2.

Figure 3.

17. Ensure each Precise device has the same volume of anticoagulated blood to ensure proper balance in the centrifuge.
18. Place the cannister and the counterbalance into the centrifuge (Eppendorf Executive Series II, Model 5702 equipped with an A-4-3B rotor or equivalent) directly opposite each other as shown in figure 4.

Figure 4.

19. Close Centrifuge door.

Spin

20. Set RPM to 4400 (Eppendorf Executive Series II, Model 5702 equipped with an A-4-3B rotor or equivalent to achieve RCF = 3000) and the time to 12 minutes as shown in figure 5. Press the start button.

Figure 5.

21. Once the centrifuge processing is complete, open centrifuge and remove the cannister and counterbalance.

Extraction

22. After centrifugation, the platelets will be retained in the upper part of the buoy.
    Caution: Do not shake or flip the cannister.
23. Attach a 5 mL syringe and place the cannister in the vertical position with the alignment rod facing the operator. In this orientation, pull off 2 mL to clear the line tubing of residual whole blood as shown in figure 6.

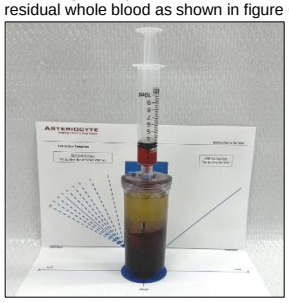

Figure 6.

24. Attach the 60 mL syringe to the device and using the provided template tilt the Precise cannister to approximately 45 degrees to the left (anti-clockwise with alignment marker facing operator) to obtain the platelet poor plasma (PPP). Draw off PPP slowly (approximately 5 mL/sec) until the first bubble of air is seen in the tubing as shown in figure 7.

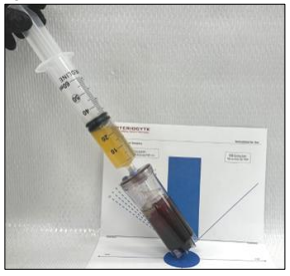

Figure 7.

25. Bring the device to the upright position and remove the 60 mL syringe containing PPP.
26. Attach a 10 mL syringe to the Precise cannister and using the provided template tilt the device to approximately 45 degrees to the right (clockwise with alignment marker facing operator) to obtain the platelet rich plasma (PRP) as shown in figure 8.

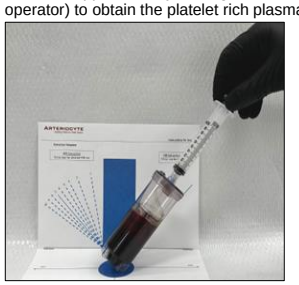

Figure 8.

27. Utilize the 10 mL syringe to harvest the 7 mL PRP. To resuspend the pelleted platelets, begin by drawing back 6 mL of PRP (essentially 1 mL less than the desired volume). Reverse direction of the plunger and expelling the PRP back into the disposable (retaining 1 mL in the 10 mL syringe) to flush the disposable. Repeat process three more times being mindful of the volume to avoid creating bubbles in the syringe.
28. Draw remaining suspension into the 10 mL syringe until bubbles appear in the syringe as shown in figure 9. The PRP should be mixed immediately with autograft and/or allograft bone to improve handling characteristics.

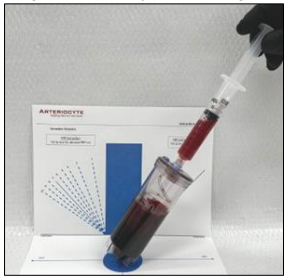

Figure 9.

29. Dispose of blood contaminated materials appropriately.

Storage Conditions

Store at 60˚F – 104˚F (15.5˚C – 40˚C)

WARRANTY

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. Precise Cell Concentration System**, 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") **Precise Cell Concentration System** "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.

Manufactured By:

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

Extraction Template

PPP Extraction
Tilt to line for desired PRP mL

PRP Extraction
Tilt to line for PRP