ART PRP 2-Step



Product Technique Leukocyte Poor Preparation

*Be sure that all blood is collected with the provided ACDA (10% ACDA by volume of blood).



Remove the ART PRP
TWO STEP from its
sterile packaging and
keep the plastic
container to discard
blood filled syringes. Be
sure to practice sterile
techniques when
working with the
device and syringes.



Fill the counterbalance with water to match the weight of the ART PRP 2-Step and place in opposing buckets.



Unscrew cap from PORT 1.



Centrifuge for 10 minutes at 1900rpm. When spin cycle is complete, transfer the ART PRP 2-Step to a flat working surface.



Be sure to place the cap face up to ensure sterility.



Turn the thumbwheel to lower the collection window to the bottom of the acqueous plasma. The O ring should be hovering over but not touching the surface of the buffy coat.



Connect the syringe containing blood to PORT 1.



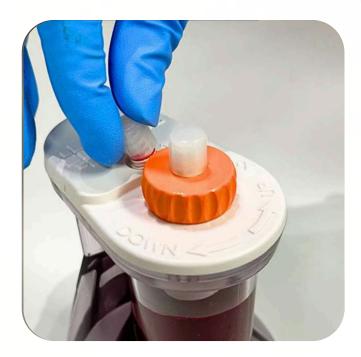
Attach a 35cc syringe to PORT 2 to collect the acqueous plasma from the main chamber. Be sure to unlock your syringe by pulling back on the plunger and pushing it back into place. Slowly collect the liquid untill air bubbles are seen in the syringe.



Transfer the blood to the main chamber through PORT 1.



Transfer the acqueous plasma to the back chamber. Attach the syringe to PORT 3 and slowly inject the fluid.



Return the cap back to PORT 1.



Centrifuge for 10 minutes at 3200rpm. When spin cycle is complete, transfer the ART PRP 2-Step to a flat working surface.

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Attach a fresh 35cc syringe to PORT 3. Be sure to unlock the syringe by pulling back on the plunger and pushing it back into place.



VERY slowly start removing the acqueous plasma. A platelet pellet should be visible in the back chamber.



Use the markings of the back chamber to confirm the final volume of your injectate.



Attach a fresh 10cc syringe to PORT 3. Be sure to unlock the syringe by pulling back on the plunger and pushing it back into place.



Pump the remaining liquid in and out of the device. Completely dissolve the cell pellet. Proceed slowly as not to create a foamy product.



Remove the syringe from the device.

ART PRP 2-Step

Product Technique Continued



INDICATIONS FOR USE

The Celling Biosciences Autologous Platelet Concentrator/Separator (APC/APS)™ System is indicated for the rapid preparation of autologous platelet rich plasma / platelet poor plasma from a small sample of blood at the patient's point of care. The autologous platelet rich plasma / platelet poor plasma is mixed with autograft and/or allograft prior to a bony defect to improving handling characteristics.

CONTRAINDICATIONS

Use of the ART PRP 2-Step System may be contraindicated when there is clinical or laboratory evidence of septicemia and for patients who have taken aspirin, or other medications that alter platelet function within 3 days prior to surgery, or patients with disorders associated with platelet dysfunction.

WARNINGS AND PRECAUTIONS

- Plasma and platelets prepared with this system are not intended for transfusion.
- Do not use as a dialyzer or for dialysis with a dialysate.
- Do not directly connect to a patient's vascular system or circulating blood.
- Use prepared platelet rich plasma / platelet poor plasma within 4 hours after blood collection.
- The safety and effectiveness of this device for bone healing, hemostasis, or other clinical use have not been established.
- CAUTION: Use only a Celling Biosciences approved centrifuge. Outcomes using untested centrifuges are unknown.
- CAUTION: Do not use if the ART PRP 2-Step protective package is unsealed or torn.
- CAUTION: Aseptic technique should be used when making all connections and fluid transfers.
- CAUTION: ART PRP 2-Step Kit is Single Use Only. Do not reuse.
- NOTE: The items contained in the ART PRP 2-Step Kit are provided sterile. The ART PRP 2-Step Device is sterilized by gamma radiation. All other kit components are sterilized by the respective supplier using irradiation or ethyleneoxide gas (EtO). Do not re-sterilize. Do not use after expiration date.
- NOTE: The ART PRP System should only be used by qualified personnel who are trained on its operation.