

ART PRP® Processing Kit



Celling Biosciences®
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- Sterile Instruments - Single Use Only



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

Rx Only

INDICATIONS FOR USE:

The Celling Biosciences Autologous Platelet Separator (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 application to a bony defect for improved handling characteristics.

Carefully read all instructions prior to using this product.

DESCRIPTION:

The Celling Biosciences ART PRP System (formerly the APS System) allows for point of care preparation of platelet rich plasma (PRP) /platelet poor plasma (PPP) through centrifugation of a fraction of autologous blood. The ART PRP Kit contains the ART PRP Device and a group of components necessary for the preparation of platelet rich plasma / platelet poor plasma; all Kit

components are single use and provided sterile. The Centrifuge is provided as a non-sterile component to be used with the Kit.

CONTRAINDICATIONS:

Use of the ART PRP 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: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
- CAUTION: Use only a Celling Biosciences approved centrifuge. Outcomes using untested centrifuges are unknown.
- CAUTION: Do not use if the ART PRP Kit protective package is unsealed or torn.
- CAUTION: Aseptic technique should be used when making all connections and fluid transfers.
- CAUTION: ART PRP Kit is Single Use Only. Do not reuse.
- NOTE: The items contained in the ART PRP Kit are provided sterile. The ART PRP Device is sterilized by gamma radiation. All other kit components are sterilized by the respective supplier using irradiation or ethylene oxide 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.

MATERIALS:

The ART PRP Device and Kit components are composed of medical grade polymers, elastomers

and stainless steels suitable for use in medical devices. Kit components are packaged, labeled and sterilized as indicated by their individual labeling. All components in the kit are latex free.

INSTRUCTIONS FOR USE:

1. Ensure centrifuge is placed level on a sturdy surface and within reach of power outlet. Turn on and verify centrifuge has two buckets, and two inserts if using an RC-4 centrifuge to contain the processing unit and counterbalance.
2. Set up a scale and tare. This will be used to verify the weight of the processing unit and counterbalance.
3. Break the kit seal and inspect the integrity of the sterile components. If undamaged, transfer components to the surgical field.
4. Remove the luer lock cap from Port A, and attach the clot filter.
5. Sterilely transfer the anti-coagulated blood to the device by attaching the syringe to the clot filter. Up to 60cc can be added through Port A. Recap Port A.
6. Weigh the processing unit and prepare the counterbalance by filling with water to match the weights.
7. Ensure the flow valve is in the vertical position and place the units into the centrifuge buckets.
8. If using a RC-4 centrifuge, close the lid and set to 3000 rpm for 15 min. Otherwise, close the lid and set to 3200 rpm for 15 min.
9. Open the lid and transfer the device to a sturdy working surface. Be careful to not disturb the fractionation of the platelet-rich plasma.
10. Turn the thumb wheel to position the collection window slightly above the PRP

layer, attach a syringe to Port B, and adjust the flow valve to the "Draw" position.

11. Draw the platelet-poor plasma (PPP) into the syringe. Adjust the flow valve to the "Reserve" position and transfer PPP to the back chamber.
12. Attach a 10cc syringe to Port B, reposition the collection window to the needed position and draw the PRP. Recap Port B.

WARRANTY DISCLAIMER AND LIMITATIONS:

Although the ART PRP Kit has been carefully manufactured, tested, and packaged, it is not possible to ensure that every ART PRP Device will be free from leakage during use. THEREFORE, THIS ART PRP SYSTEM IS SOLD "AS IS" AND THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE ART PRP SYSTEM IS WITH PURCHASER. No express warranties are made concerning this ART PRP Kit. If, in the opinion of Celling Biosciences, this ART PRP Kit does not perform properly, Celling's sole obligation shall be to replace the kit or refund the purchase price, and this shall be the Purchaser's exclusive remedy. Under no circumstances shall Celling be liable for any indirect or consequential damages (including without limitation loss of profits, claims of customers of the Purchaser, or personal injury) whether such claim is based on contract, negligence, tort, or warranty.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Celling for current information.

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For product information or questions pertaining to sales and service, please contact your local sales representative or SpineSmith customer service.

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