

INTENDED USE

ProGen Advantage PRP 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 point-of-care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

PRODUCT DESCRIPTION

A blood collection tube in a peel pouch or blister tray kit used for Platelet Rich Plasma (PRP) preparation from peripheral blood. The product is provided sterilized and non-pyrogenic. The product contains ACD-A anti-coagulant and is to be used only for the preparation of PRP with ProGen PRP.

NOTE:

- For Single Patient Use Only. Once used, the item must be discarded following the protocol for biohazardous waste disposal, as required by the facility where it was used.
- The PRP needs to be centrifuged within 6 (six) minutes of the blood being drawn into tube.
- The PRP needs to be used within 4 (four) hours after being processed.

STORAGE

Store tubes at 4-25° C unless otherwise noted on the package label.

CAUTION

- PRP must be used on the same patient from which blood was drawn.
- Do not use PRP tube if any foreign matter is visible.
- Do not use tubes that are, or appear to be cracked or damaged.
- Do not use PRP tube after its sterilization expiration date.
- Do not re-sterilize or attempt to clean the PRP tubes.
- Once prepared, use PRP within 4 (four) hours after drawing blood.
- Practice Universal Precautions to protect from blood spatter, blood leakage to minimize the potential exposure to blood-borne pathogens.
- Handle all biologic samples and blood collection devices per the procedures established by your facility.
- Appropriate medical attention is required in the event of any exposure to biologic samples.
- Underfilled tubes may result in poor product performance. It is recommended to discard and underfilled tube and re-draw blood into a second tube.
- Use sterile technique.

REQUIRED ITEMS NOT PROVIDED FOR SPECIMEN ACQUISITION AND PROCESSING

Have these items assembled and ready prior to drawing blood:

- Centrifuge capable of generating 1600 G Force.
- Appropriate items to draw the blood specimen.
- Use gloves, eye protection, gowns, other apparel and disposable items to protect personnel from exposure to blood-borne pathogens or other potential harmful materials. Follow the policies and procedures of your facility for venipuncture and blood draw procedures.
- Alcohol swabs for cleansing draw site.
- Sterile gauze.
- Tourniquet.
- Sharps disposal container for needles, syringes and needle/holder device.
- PRP tube, mixing tube and transfer device.
- Sterile 3 inch needles and 10 ml syringes

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

GLOSSARY OF SYMBOLS

REF	Catalog Number	LOT	Batch Code	Use By Date
Single Patient Use		Do Not Use If Damaged		Manufacturer
Temperature Limit		Keep Out of Sunlight		Keep Dry
STERILE R	Sterilized using Irradiation	Instructions for Use		Do Not Resterilize

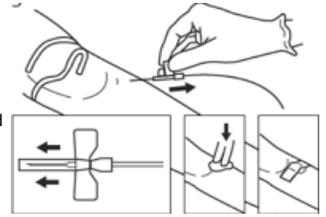
Distributed by: Crown Aesthetics
 5005 LBJ Freeway, Ste 370
 Dallas, TX 75244
 888-372-3982
 Web: www.crownaesthetics.com

BIMINI HEALTH TECH
 420 Stevens Ave, Suite 220
 Solana Beach, CA 92075, USA
 Phone: 858-348-8050
 www.biminihealthtech.com

PROCEDURE STEPS TO OBTAIN PRP

1) DRAW BLOOD

Remove PRP tube from pouch. Wipe top with clean alcohol swab prior to blood draw. Following accepted blood collection guidelines, draw the patient's blood into PRP tube.



2) INVERT TUBE

Invert PRP tubes 7 (seven) times to mix anti-coagulant with patient blood. Wipe tops with clean alcohol swab. Centrifuge tube within 6 (six) minutes of blood draw.

3) SPIN PRP

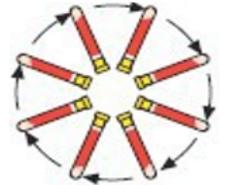
Turn on centrifuge and unlock lid. Place PRP tubes into individual tube holders across from each other to achieve a balanced load in the centrifuge, or use appropriate counter balance. Lock the lid.

IMPORTANT NOTE!

Choose the appropriate tube volume setting prior to centrifugation as instructed below:

ProGen 15 ml tube - Spin for 10 (ten) minutes at **1100 G's**

ProGen 30 ml tube - Spin for 10 (ten) minutes at **1600 G's**



Please refer to your facility's centrifuge manual for proper use and rotor style.

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4) PRP EXTRACTION

15ML TUBE:

Remove tubes from centrifuge. Holding the top of the tube at a slightly upward angle, vigorously shake the tube for approximately 5 seconds. The plasma should have a frothy or foamy appearance and a slightly darker color. Rotate the tube a quarter turn and repeat the moderate shaking procedure for 5 seconds. Rotate and repeat 3 more times. Next, using aseptic technique, connect sterile syringe to a needle and insert the needle through the stopper at the top of the tube. Invert the tube 180 degrees and aspirate the PRP into the syringe. Once the PRP is transferred into the syringe, the product is ready to use.

30ML TUBE:

Remove tubes from centrifuge. Keeping the tubes vertical, attach up to a 3 inch needle to a 10-20 ml syringe and fully insert through the top of the rubber stopper. Aspirate your PRP until you see air bubbles in the syringe. Remove the syringe and needle from the PRP tube and properly discard in a sharps waste container. Holding the top of the tube at a slightly upward angle, vigorously shake the tube for approximately 5 seconds. The plasma should have a frothy or foamy appearance and a slightly darker color. Rotate the tube a quarter turn and repeat the vigorous shaking procedure for an additional 5 seconds. Rotate and repeat 3 more times. Next, using aseptic technique, connect sterile syringe to a needle and insert needle through the stopper; invert the tube and aspirate the PRP into the syringe. Once the PRP is transferred into the syringe, the product is ready to use.

Please refer to Table 1 for appropriate PRP volume.

TABLE 1:

BLOOD DRAW VOLUME	APPROXIMATE PRP VOLUME
15 ml	7 ml
30 ml	7 ml

CAUTION: Do not insert the needle into the separating gel. If needle comes into contact with the separating gel, discard the product.

CENTRIFUGATION

CAUTION: Follow manufacturers instructions on the use of the centrifuge at your facility.

- Centrifuge carriers and inserts should be of the size specific for the tube used.
- Always allow the centrifuge to come to a complete stop before removing tubes.
- Counter balance tubes will be required to balance the weight of the tubes during centrifugation. When using a counter balance tube, place the balance tube with the same weight as the filled PRP tube, opposite of the PRP tube.
- Once the centrifugation spin cycle has stopped, open lid of centrifuge and examine tubes or any breakage or leaking prior to use.

CAUTION: Do not attempt to remove any broken tubes, pieces of glass or other debris with your hands. Use some type of hemostat or forceps to remove items that are damaged. Follow centrifuge manual provided by the manufacturer for disinfection instructions.