

DRAFT FOR REVIEW ONLY

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 ProGenPRP.

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 an underfilled tube and re-draw blood into a second tube.

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.

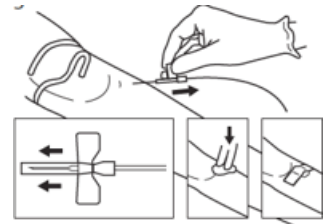
GLOSSARY OF SYMBOLS

REF	Catalog Number	LOT	Batch Code		Expiration Date
	Do Not Reuse		Do Not Use If Damaged		Manufacturer
	Temperature Limit		Keep Out of Sunlight		Keep Dry
STERILE R		Sterilized using Irradiation			

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 tube 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:



HORIZONTAL OR FIXED ANGLE ROTOR -

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.

4) PRP EXTRACTION - INVERT TUBE

Remove tubes from centrifuge tube holders. Gently invert the tube several times to mix the contents. Next, using aseptic technique, connect sterile syringe to a long needle and insert long needle through the stopper; aspirate the PRP into the syringe. Once the PRP is transferred into the syringe, the product is ready for use.

Please refer to Table 1 for appropriate PRP volume:

PRP TUBE SIZE	PRP VOLUME
15 ml	7 ml
30 ml	15 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.
- Contra balance tubes will be required to balance the weight of the tubes during centrifugation. When using a contra 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 for 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.

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



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