

INSTRUCTIONS FOR USE

INTENDED USE

Amplifine HD PRP Tube 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 blister tray used for preparation of Platelet Rich Plasma (PRP) from peripheral blood. The product is provided sterile and non-pyrogenic. The product contains Anticoagulant Citric acid, Sodium citrate and Dextrose Solution, (ACD-A) and is to be used only for the preparation of PRP with Suneva Amplifine HD PRP Tube.

NOTE:

- For Single Patient Use Only. Once used, the blood collection tube must be discarded following the protocol for biohazardous waste disposal, as required by the facility of use.
- The blood collection tube must be processed via centrifuge within 6 (six) minutes following blood draw.
- The PRP must be used within 4 (four) hours after drawing blood.

STORAGE

Store tubes at 4-40°C (39-104°F). Do not freeze.

CAUTION

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

CONTRAINDICATIONS

- a) Amplifine HD PRP Tube is not for direct intravenous infusion.
- b) Amplifine HD PRP Tube is not for cases where there is active systemic infection or system heparinization.

REQUIRED ITEMS NOT PROVIDED FOR BLOOD SAMPLE ACQUISITION AND PROCESSING

Have these items assembled and ready prior to drawing blood:

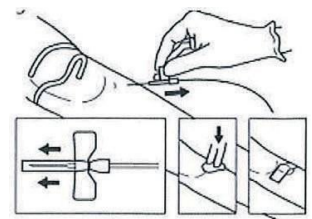
- a) Centrifuge capable of generating 1500 G Force.
- b) Appropriate items to draw the blood specimen.

- c) Use appropriate personal protective equipment (PPE) - gloves, eye protection, gowns or other apparel, to protect personnel from exposure to blood-borne pathogens or other potential harmful materials. Follow the policies and procedures of facility of use for venipuncture and blood draw procedures.
- d) Alcohol swabs for cleansing draw site.
- e) Sterile gauze.
- f) Tourniquet.
- g) Sharps disposal container for needles, syringes and needle/holder device.
- h) Sterile syringe and needle for PRP transfer and application.

PRP PROCEDURE

1) DRAW BLOOD

Remove PRP blood collection tube from blister tray. Wipe top of PRP tube with a clean alcohol swab prior to blood draw. Following accepted blood collection guidelines, draw the patient's blood into PRP tube from a peripheral location.



2) INVERT TUBE

- Invert PRP tube(s) 7 (seven) times to mix ACD-A anti-coagulant with the patients' blood.
- Wipe the top of the tube with a clean alcohol swab.
- PRP tube to be processed within six (6) minutes after blood draw.

3) SPIN PRP - CENTRIFUGE SETTINGS: SIX (6) MINUTES; 1,100 G-FORCE

Power on centrifuge and unlock lid. Place PRP tube(s) into individual tube holders in order to achieve a balanced load within the centrifuge. Place tubes across from each other or use counterbalance, as appropriate. Lock the lid.

IMPORTANT NOTE!

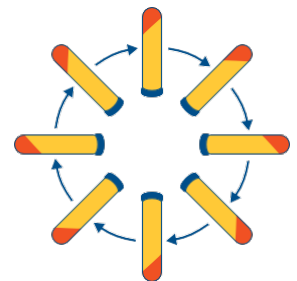
Please refer to the centrifuge Instructions for Use for proper use, rotor style and to set-up the equivalence between G-Force and RPM's.

USE WITH HORIZONTAL OR SWINGOUT ROTOR.

Calculate the RPMs to achieve 1,100 G-Force according to the Centrifuge operation manual.

- Formula to Calculate RPM

$$\text{RPM} = 9,919 / (\sqrt{\text{rotational radius "centimeters"}})$$
 [9,919 divided by the square root of the rotational radius in centimeters]

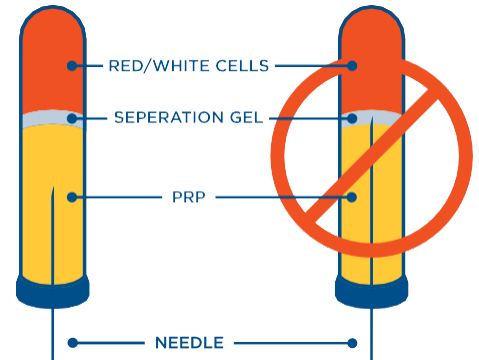


GLOSSARY OF SYMBOLS

REF	Catalog Number	LOT	Batch Code	Rx	Prescription Only		Do not resterilize
	Do Not Reuse		Do Not Use if Damaged		Temperature Limit		Consult instructions for use
	Expiration Date		Manufacturer		Keep Dry		Non-pyrogenic
	Keep Out of Sunlight	STERILE R		Sterilized using irradiation			Not made with natural latex

4) PRP EXTRACTION – INVERT TUBE

- Remove PRP tube(s) from centrifuge tube holders. Gently invert PRP tube(s) 7 (seven) times to re-suspend platelets.
CAUTION: Do not insert the needle into the separating gel. If needle comes in contact with the separating gel, discard the product.
- Alcohol swab the top of the PRP tube.
- Invert PRP tube
- Insert sterile syringe to a long needle (e.g. 18Ga x 1.5 inch)
- 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.



CENTRIFUGATION

CAUTION: Follow manufacturer’s Instructions for Use for the centrifuge at the facility of use.

- 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.
- Counterbalance tubes will be required to balance the weight of the tubes during centrifugation. When using a counterbalance 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 or other debris with your hands. Use some type of hemostat or forceps to remove items that are damaged. Follow centrifuge Instruction for Use provided by the manufacturer for disinfection instructions.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician or licensed health care professional.

Table 1: Components Volume.

COMPONENT	VOLUME
BLOOD DRAW	30 mL
PRP	15 mL
ACD-A	3 mL
SEPARATOR GEL	8 - 10 gr

Table 1. Components volume.

- **Component blood draw. Volume 30 mL.**
- **Component PRP. Volume 15 mL.**
- **Component ACD-A. Volume 3 mL.**
- **Component Separator Gel. Volume 8 – 10 gr**

Manufactured by:

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