

INSTRUCTIONS FOR USE



INTENDED USE

The Face Med PRP is intended to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood collected at the patient's 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

The Face Med PRP consists of a blood collection tube in a single blister package or double tray. The product is provided sterilized and non-pyrogenic. The product contains Anticoagulant Citrate Dextrose A Solution (ACD-A) to prevent coagulation during processing and is to be used only for the preparation of PRP with Face Med PRP.

STORAGE

Store tubes at 4-25°C. Do not freeze.

PRECAUTIONS

- Failure to use this product in accordance with the Instructions for Use may result in device failure or compromised safety.
- Inspect product prior to use. Do not use sterile components if package is open or damaged.
- Do not use tubes after sterilization expiration date.
- For single patient use only.
- PRP must be used on the same patient from which blood was drawn.
- The blood collection tube needs to be centrifuged within 5 (five) minutes after being drawn.
- The PRP needs to be used within 4 (four) hours after being processed.
- Do not reuse, reprocess, re-sterilize or attempt to clean the PRP tubes, as it may create a risk of contamination of the product, which could result in patient injury or illness.
- Do not use tubes if foreign matter is present
- Use aseptic technique as applicable
- Treat all body fluids using Universal Precautions for blood-borne pathogens.
- Use proper safety precautions to guard against needle stick injury.
- Discard all product components using acceptable disposal method for blood contaminated products as required at the facility where it was used.
- Under-filled tubes may result in poor performance. It is recommended to discard any under-filled tube and re-draw blood into a second tube.
- PRP prepared with this product is not intended for transfusion.

CONTRAINDICATIONS

- Any active infection.
- Blood supply limitations and previous infections, which may retard healing.
- Use in hemodynamically unstable or hypercoagulable patients.

POSSIBLE ADVERSE EVENTS

- Allergic and other reactions to device materials.
- Damage to blood vessels, hemorrhage/bleeding, pain, erythema, bruising, swelling, hematoma, nerve damage, delayed wound healing and/or infection associated with blood draw.

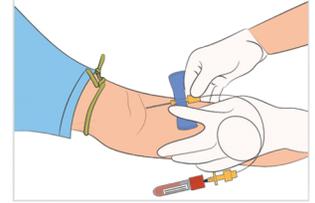
REQUIRED ITEMS FOR BLOOD DRAW NOT PROVIDED

- Collect all the equipment needed for the procedure and place it within safe and easy reach
- Appropriate blood collection equipment: Use gloves, eye protection, gowns, and any other disposable items to protect from blood-borne pathogens. Your safety and the safety of others is very important, follow all instructions or procedures your health-care facility has to reduce accidental exposure to blood and body fluids.
- Alcohol swab or iodine to cleanse the area
- Sterile gauze
- Tourniquet
- A puncture-resistant sharps container

FOUR-STEP PRP PROCESS:

1.) COLLECT WHOLE BLOOD

Assemble all the equipment needed for the procedure and place it within safe and easy reach. Remove PRP tube from pouch or double tray. Perform hand hygiene and put on gloves. Disinfect the entry site. Draw the patient's blood into the PRP tube by following accepted blood collection guidelines. As soon as the last vacuum tube is filled and mixed, remove the needle from vein by grasping the wings and withdrawing. Apply pressure to puncture site with dry, sterile gauze until bleeding stops. Dispose of the needle using an appropriate disposal device.



2.) INVERT TUBE

Do not shake the tube. Invert the filled tube gently 4 to 5 times to mix the anticoagulant additive with the patient's blood. Centrifuge tube within 5 (five) minutes of blood draw.

3.) CENTRIFUGATION

Turn on centrifuge and unlock lid. Insert the tube(s) into individual tube holders on opposite sides of the centrifuge.

WARNING: Tubes in the centrifuge must be carefully balanced. If using an odd number of tubes the utilization of the balancing tubes will be necessary.

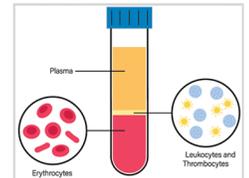
Centrifugation should be completed at room temperature (18°–25°C). Close the lid and select the appropriate centrifuge settings. Centrifugation for 8 minutes with a RPM speed of 3500 is recommended. **NOTE:** Please consult your Centrifuge's manufacturer's operating manual.



4.) PLATELET PREPARATION

After centrifugation, blood components will be separated, the platelet poor plasma will be resting above the platelet rich plasma. Re-suspend the top layer of platelet plasma supernatant by gently inverting the unopened PRP tube 2 to 3 times.

Using aseptic technique, connect the 5-ml Luer-Lok™ syringe to the long needle. Insert the needle through the stopper top of the tube and advance to just above the gel separator layer. Collect the supernatant fraction using the 5-ml Luer-Lok™ syringe. Remove the collection needle from the 5-ml Luer-Lok™ syringe and discard. The product is ready for use at this point.



EXPLANATION OF SYMBOLS ON PACKAGING LABELING:

LOT	Batch Number	REF	Catalog Number	Do Not Re-Sterilize	
Do Not Re-Use		Do Not Use If Damaged		Rx Only	Prescription Only
Expiration Date		Temperature Limit		STERILE R	Sterilized using Irradiation
Non-Pyrogenic		Keep Dry		Keep Out of Sunlight	

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

CAUTION: Use aseptic technique as applicable.

