

INTENDED USE:

For the collection of autologous blood and preparation of Platelet-Rich Fibrin (PRF) for use in regenerative medical procedures.

PRODUCT DESCRIPTION:

Sterile, vacuum-sealed, additive-free glass tube (15 mL) for single use only. No anticoagulants or clot activators are present.

STORAGE:

Store at room temperature (15-30°C). Keep dry and away from direct sunlight. Do not freeze or expose to extreme temperatures.

PRECAUTIONS:

- Single-use only. Reuse may cause infection, cross-contamination, or patient harm.
- Failure to use this product in accordance with the Instructions for Use may result in device failure or compromised safety.
- Do not autoclave or re-sterilize.
- Verify pack integrity before each use. Do not use if damaged or expired.
- For professional use only by trained medical personnel.
- The blood collection tube needs to be centrifuged within 5 (five) minutes after being drawn.
- The PRF needs to be used within 2 (two) hours after being processed.
- Handle all blood collection activities using standard precautions.
- Treat all body fluids using Universal Precautions for blood-borne pathogens.
- Use caution when drawing blood from patients with hemophilia, epilepsy, or other medical conditions requiring special care.
- Use proper safety precautions to guard against needle stick injury.
- 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.
- Proper centrifuge balance must be maintained to avoid equipment damage or tube breakage.

DISPOSAL:

- Dispose of all used tubes and contaminated materials in compliance with local biohazard waste regulations.

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

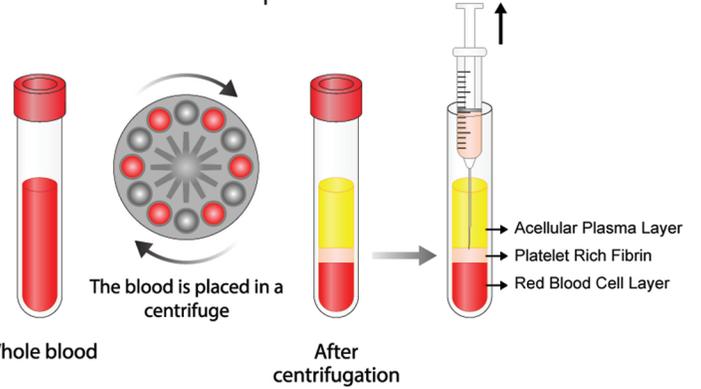
EXPLANATION OF SYMBOLS ON PACKAGING LABELING:

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

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

CAUTION: Use aseptic technique as applicable.

For Platelet-Rich Fibrin Preparation



PRF/ PRFM PROCEDURE:

1.) BLOOD COLLECTION

Prepare all required equipment and position it within easy reach. Remove the PRF tube from its packaging and verify package integrity. Perform hand hygiene, don gloves, and disinfect the venipuncture site. Collect the patient's blood into the PRF tube following standard blood draw protocols. Once the final tube is filled, withdraw the needle by grasping the wings and apply sterile gauze to the puncture site until bleeding stops. Dispose of the needle in an approved sharps container. Centrifuge the tube within five (5) minutes of collection to ensure optimal PRF quality.

2.) CENTRIFUGATION

Turn on centrifuge and unlock lid. Insert the tube(s) into individual tube holders on opposite sides of the centrifuge. Centrifugation should be completed at room temperature (15°– 30°C). Close the lid and select the appropriate centrifuge settings. Centrifugation for 8 minutes with a RPM speed of 2,600 is recommended.

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.

3.) PRF SEPARATION AND COLLECTION

Using aseptic technique, attach a 5 mL Luer-Lok™ syringe to a long collection needle. Carefully insert the needle through the rubber stopper of the tube and aspirate the PRF layer into the syringe. After collection, remove and safely discard the needle. Administer the PRF into the target site following your standard clinical protocol and prior training. Note: The PRF should resemble a dermal filler in texture, though consistency may vary slightly. Choose the cannula or needle gauge that best matches your technique.

4.) PRF CLOT / PRFM PREPARATION

Using aseptic technique, open the tube and carefully extract the PRF clot with sterile forceps or a collection instrument, avoiding disturbance of the red cell layer. Gently separate any residual red blood cells from the PRF clot using sterile gauze or a spatula.

To prepare a Platelet-Rich Fibrin Matrix (PRFM) membrane, place the PRF clot on sterile gauze or in a PRF compression device. Apply light, even pressure until the desired membrane thickness is achieved.

The PRF clot or PRFM membrane may then be applied directly to the treatment site in accordance with clinical protocols and practitioner training.

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, and A puncture-resistant sharps container