

EZ4K

USER GUIDE



EZPRF
PLATELET-RICH FIBRIN

INSTRUCTIONS FOR USE

1 BLOOD COLLECTION

A standard aseptic drawing technique is required:

- a) Disinfect the skin covering the area of the blood vessel selected for blood sampling.
- b) Open each sterile bundle component (including the butterfly and the blister containing tubes).
- c) Tighten tourniquet onto the patient's arm in order to block venous return circulation.
- d) Perform venous puncture with butterfly needle.
- e) When blood becomes visible in the connecting plastic tubing, plug the EZPRF vacuum tube in the collector by piercing the tube stopper with the internal needle of the collector.
- f) **Important:** Fill tubes all the way to the top, or as far as the vacuum can pull.

I.E. EZPRF TYPICALLY HAS A 10 TO 15% YIELD,
4 TUBES OF 13ML WOULD BE REQUIRED FOR 6CC
TO 10CC OF PRF.
- g) When done, close the blood collection needle with the Safety-Lok™ system before discarding in the appropriate biohazardous container.

2 CENTRIFUGATION

Tubes must be spun immediately after the blood draw:

- a) Place tubes in the centrifuge, making sure they are properly balanced.

(SEE GRAPHIC)

- b)** Select the desired setting.
- c)** Hit the spin button and wait for the cycle to be over.
- d)** Depending on setting selected, the centrifugation should result in 1.5cc to 3.5cc of PRF per tube.
- e)** Attach the 22G x 2" needle to the syringe of your choice and withdraw the supernatant liquid.
- f)** If PRF yield seems insufficient, hit the spin button again for an additional minute. Manually stop the rotor by pressing the "Start/Stop" button.

IT IS RECOMMENDED TO USE THE SUPERNATANT LIQUID WITHIN **10 MINUTES** OF WITHDRAWAL TO PREVENT IT FROM COAGULATING.

3 TRANSFER TO SYRINGE

Tubes should not be shaken during this process:

- a)** Carefully remove the tubes from the centrifuge and place them in a tube holder (if available).
- b)** Plug the 22G collection needle to one of the provided syringes (3ml or 5ml) and insert it through the cap.
- c)** Start drawing the concentrate at a 45 degree angle. The **EZPRF** is the top layer, an opaque rose gold gel.

TIP: LEAN THE SHARP END OF THE NEEDLE AGAINST THE WALLS OF THE TUBE TO LOCATE IT DURING THE PROCESS.

2 tubes



3 tubes



4 tubes



CAUTION

Disposable sterile kit. Tubes, syringes and needles come in a single use, disposable sterile package.

Do not use if sterile packaging is open or damaged.

Discard immediately after use.

THIS KIT CONTAINS:

- **4x** sterile **EZPRF** 13ml tubes
- **1 x** Blood collection set
- **1 x** Disposable tourniquet
- **2 x** Luer-lock 3ml syringes
- **1 x** Luer-lock 5ml syringe
- **1 x** Female luer-lock connector
- **2 x** DermaSculpt® Microcannulas (1 x 25G 1½" and 1 x 23G 1½")
- **2 x** Transfer needles (22G 2")
- **2 x** Sharp needles (1 x 30G ½" and 1 x 27G 1½")

MATERIALS

The materials used for syringes, needles, tubing, connectors and platelet separators consist of medical grade polymer, glass, and stainless steel, suitable for use as medical devices.

INDICATIONS OF USE

EZ4K kits are designed to draw blood from the patients safely and easily, which is then centrifuged with the goal of producing autologous Platelet-Rich Fibrin (PRF).

PRE-CARE INSTRUCTIONS

Patients must be well hydrated. They should start their hydration process 72 hours before treatment.

RELATIVE CONTRAINDICATIONS

- Patients affected by hemophilia and epilepsy should be treated with caution during blood collection.
- Patients who smoke may have a lesser response to this treatment.
- Centrifugation time can be extended for an extra minute or 2 if the patient demonstrates signs of excessive coagulation (acquired or genetic).

POSSIBLE SIDE EFFECTS

Infection due to inappropriate or unsterile medical handling.

Temporary or permanent nerve damage leading to pain or numbing (especially with sharp needle).

Damage to blood vessels / hematoma.

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PRECAUTIONS OF USE

PRF blood concentrate must be used within 15 min of blood draw or 10 min after spin to avoid clotting.

An appropriate centrifuge should be used, allowing for the specific centrifugation protocol developed and validated for producing PRF.

A different angle or speed of centrifugation, as well as inappropriate fitting of the tubes, could result in breakage of the tubes and subsequent risk of injury or blood contamination.

The use of the **EZPRF** Centrifuge is mandatory to ensure best results.

Usual safety precautions for the use, storage, and disposal of needles apply. For the safety of any person handling, the needle must be recapped before being discarded in the appropriate biohazardous waste disposal container.

The practitioner is to be familiar with the procedure and devices of the bundle prior to using it.

WARNING

The patient should be made aware of any risk associated with the treatment. This kit should only be used by or under the supervision of a physician. Do not use if sterile packaging is open or damaged.

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