

System for the Preparation of Autologous Platelet-rich Fibrin Matrix (PRFM)

SELPHYL® PLATELET-RICH FIBRIN MATRIX (PRFM)

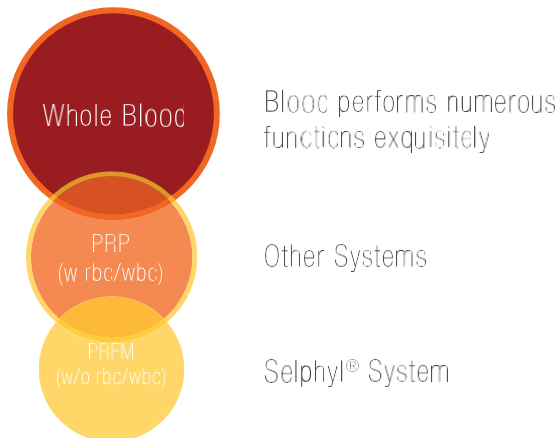
The Selphyl® System is designed for the safe and rapid preparation of Platelet-rich Fibrin Matrix (PRFM) from a small sample of blood at the patient point of care. Many PRP systems require operator skill, have varying results and have extensive contamination with red blood cells and white blood cells. Selphyl® removes virtually all contaminating cells and is independent of operator technique. PRP is converted to PRFM through a controlled process, creating a scaffold that serves to protect and preserve platelets. Think of Selphyl® PRFM as the next generation PRP.

WHAT IS PLATELET-RICH PLASMA (PRP)?

PRP, by definition refers to platelets in plasma, where the platelet concentration is generally considered to be twice the normal concentration in whole blood. Nowhere in the definition of PRP is there a description for including red blood cells (RBC) or white blood cells (WBC) - in fact, these cells should be removed as much as possible from a PRP preparation. Some kits that tout high platelet concentrations often do so at the expense of having contaminating RBCs or WBCs - these cells are known to have inflammatory and catabolic effects - just the opposite of the desired effect. If the PRP in the syringe has any tinge of pink or red, it is mostly likely that you are injecting a preparation that has RBC contamination. The ideal PRP solution will be a golden, straw-like color.

HOW IS SELPHYL® PRFM DIFFERENT?

The Selphyl® System is a completely closed system and can convert PRP to PRFM with the addition of a precise amount of calcium chloride, which initiates the conversion of fibrinogen to fibrin, as part of the clotting cascade. The fibrin matrix serves as a three dimensional scaffold to maintain the platelets at the site of injection. The scaffold also serves to protect the platelets so their release of growth factors can be sustained over a longer period of time.



ULTRAPURE PRFM “LIQUID GOLD”

Selphyl® is based on the principle that human blood and platelets possess all the essential elements needed for tissue. It is designed to produce PRFM devoid of contaminating red and white blood cells. Other systems are designed to collect white blood cells for diagnostic testing. The proprietary gel separator design is one of the key advantages of the Selphyl® System.

THE POWER OF BLOOD

As part of the body’s capacity to heal itself, platelets and other components in human blood migrate to a site of injury. Platelets are known to release a variety of factors that respond to tissue injury, where they initiate and promote healing. By concentrating platelets at the site of injury, physicians have the potential to enhance the body’s natural capacity for healing.^{1,2}

1. Anitua E, Andia I, Ardanza B, Nurden P, Nurden AT. Autologous platelets as a source of proteins for healing and tissue regeneration. *Thromb Haemost.* 2004; 91(1):4-15

2. Foster TE, Puskas BL, Mandelbaum BR, Gerhardt MB, Rodeo SA. Platelet-rich plasma. *Am J Sports Med.* 2009; 37:2259-2272.



THE SELPHYL® PROCESS

1. During a short office visit (30 minutes), a small amount of a patient's own blood is drawn into a vacuum collection tube containing a cell separator gel.
2. The tube is then placed into a centrifuge and spun for six minutes to separate the blood into a supernatant plasma/platelet suspension.
3. The red and white blood cells are located below the cell separator gel.
4. The platelets and plasma are then transferred in a closed system to a second vacuum tube containing a small amount of calcium chloride solution.
5. Fibrin polymerization begins and the PRP remains liquid for approximately 10 minutes before forming PRFM.
6. The patient's own PRFM is ready for use as deemed appropriate by the clinical user requirements.

ADVANTAGES & BENEFITS:

- Superior Technology
- Visual Guide to Quality
- Completely Closed System
- Extensive Safety Profile
- Ultrapure PRFM
- Operator Independent
- Fibrin Matrix Scaffold
- Over 150K Patients Treated
- Viable Platelets
- Sustained Growth Factor Release

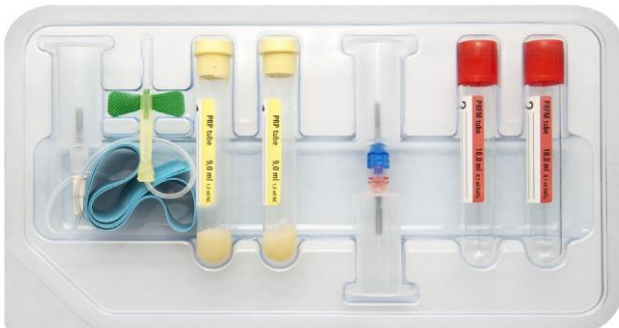
THE SELPHYL® KIT

Affordable and Cost-effective

4cc or 8cc of PRFM available for administration

- STERILE TRAY WITH TYVEK® PEEL-BACK LID**
- SAFETY BLOOD COLLECTION SET — "Butterfly Wing"**
- PROPRIETARY VACUTAINER® PRP TUBE — "Yellow Top"**
 - Proprietary 9cc whole blood collection tube with cell separator gel
- DEVICE FOR THE STERILE TRANSFER OF FLUID**
 - Safe, closed system
 - Needle protection sleeve (Jacketed)
- PRFM PREPARATION TUBE — "Red Top"**
 - 4cc liquid per tube
 - Hemogard™ Cap
 - Calcium Chloride Solution
- ADDITIONAL MATERIALS REQUIRED** (not included in the kit)
 - Alcohol swab, adhesive bandage, syringes and needles

Regulatory status: FDA cleared 510(k) Class II medical device



To order the SELPHYL® System, call
IMPACT AESTHETICS (310)486-2082