

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

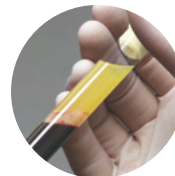
SELPHYL® PLATELET-RICH FIBRIN MATRIX (PRFM)

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)?

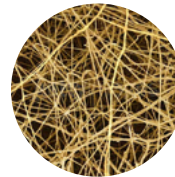
- PRP is a solution of plasma and platelets where the platelet concentration is higher than whole blood.
- Optimal platelet concentration is 2-3X greater than whole blood.
- Definition of PRP does NOT include red blood cells (RBC) or white blood cells (WBC).
- RBC and WBC should be removed as much as possible from PRP preparation.
- PRP kits that tout high platelet concentrations often have contaminating RBCs or WBCs which have inflammatory and catabolic effects causing opposite effect of desired outcome.
- Pink or red PRP has RBC contamination.
- The ideal PRP solution will be a golden, straw-like color.

PLATELET-RICH FIBRIN MATRIX (PRFM)



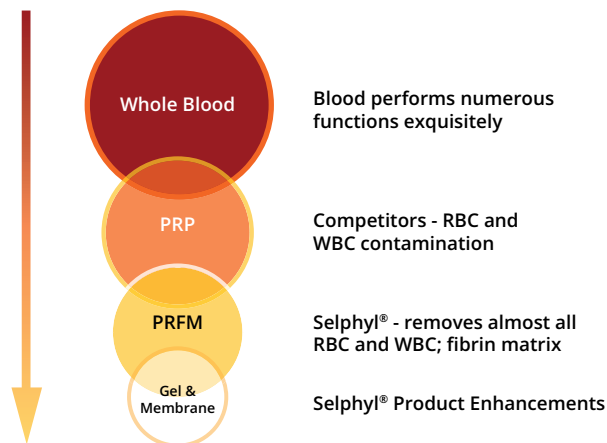
Features

- "Golden" Visual Guide to Quality
- Purest PRP/PRFM
- Closed-System
- Secondary Proprietary Step
- Converts PRP to PRFM



Fibrin Matrix Scaffold is KEY!

- Calcium chloride allows for controlled fibrin polymerization
- Scaffold is a biologic connector
- Platelets are localized and viable
- Sustained growth factor release

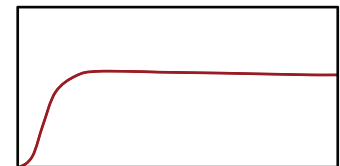


PRP VS. PRFM



PRP

- Platelets in plasma
- Activation is immediate
- Alpha granules release growth factors quickly (bolus)
- Short-term tissue signaling
- Minutes - hours



PRFM

- Platelets in fibrin matrix
- CaCl₂ binds to Na Citrate 1:1
- Clotting cascade resumes (Fibrinogen - Fibrin)
- Platelets remain viable with controlled GF release
- Hours - days

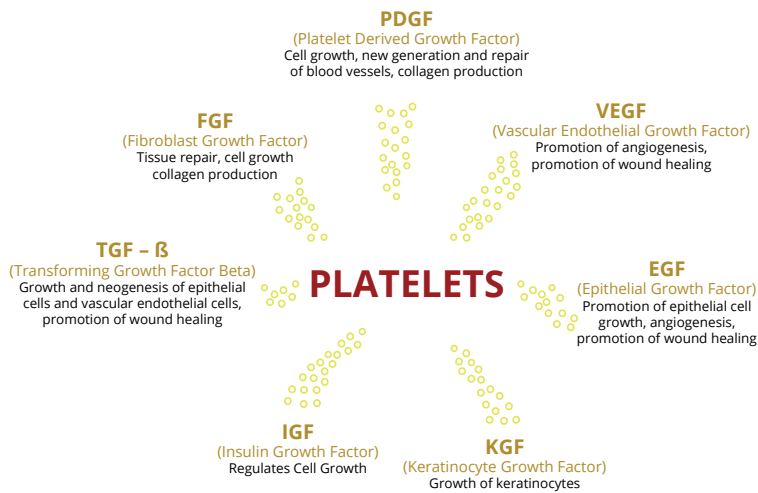
THE POWER OF BLOOD

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}

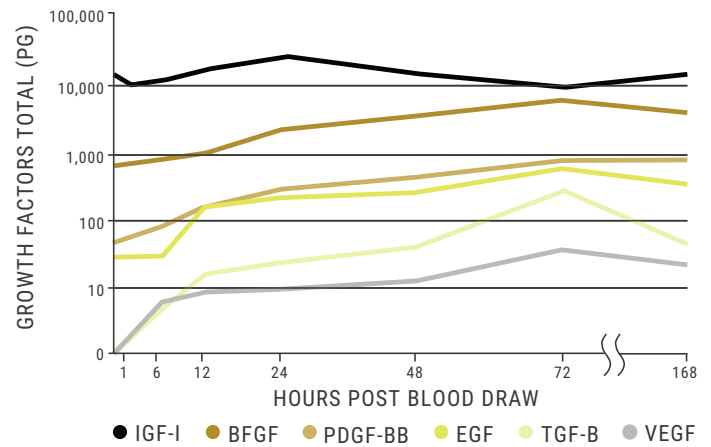
1. Anitua E, Andia I, Ardanza B, Nurden P, Nurden AT. Autologous platelets as a source of proteins for healing and tissue regeneration. *Thromb Haemost.* 2004; 91(1):4-15

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

PLATELETS RELEASE GROWTH FACTORS



SUSTAINED GROWTH FACTOR RELEASE



THE SELPHYL® PROCESS

Blood Draw

Centrifugation

Transfer

Application

OPTIMAL PLATELET CONCENTRATION

In Vitro, Animal and Human Studies Physiologic Range is Better Than Pharmacologic Range [Wound Healing, Bone, Spinal Cord Injury]

“Those methods with lower concentrations of platelets – 1 to 3 times baseline – showed more robust healing rates than those with higher concentrations 3 to 8 times baseline.”

Rappl LM et al., Int Wound J 2011; 8:187-195

“the use of highly concentrated platelet preparations appeared to have an inhibitory influence...reasons could be unwanted inhibitory and cytotoxic effects of growth factors at such high concentrations.”

Weibrich G et al., Bone 2004; 34:665-671

“PRP might exert positive effects...in a dose-dependent manner up to a certain level, but adverse effects occur when it is highly concentrated.”

Yamaguchi R et al., J Surg Res 2012; 173(2): 258-266

“Optimal results were observed at a platelet concentration of 2.5 X... increased concentrations resulted in a reduction in proliferation and a suboptimal effect on osteoblast function.”

Graziani F et al., Clin Oral Impl Res 2006; 17: 212-219

THE SELPHYL® KIT

Affordable and Cost-effective

4cc or 8cc of PRFM available for administration

A. SAFETY BLOOD COLLECTION SET — “Butterfly Wing”

B. PROPRIETARY VACUTAINER® PRP TUBE — “Yellow Top”

- Proprietary 9cc whole blood collection tube with cell separator gel

C. DEVICE FOR THE STERILE TRANSFER OF FLUID

- Safe, closed system
- Needle protection sleeve (jacketed)

D. PRFM PREPARATION TUBE — “Red Top”

- 4cc liquid per tube
- Hemogard™ Cap
- Calcium Chloride Solution

E. ADDITIONAL MATERIALS REQUIRED (not included in the kit)

- Adhesive bandage, syringes and needles

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

To order the SELPHYL® System, call
Toll Free: 1.877.SELPHYL (1.877.735.7495)

(SEL-DB-USA-0517)