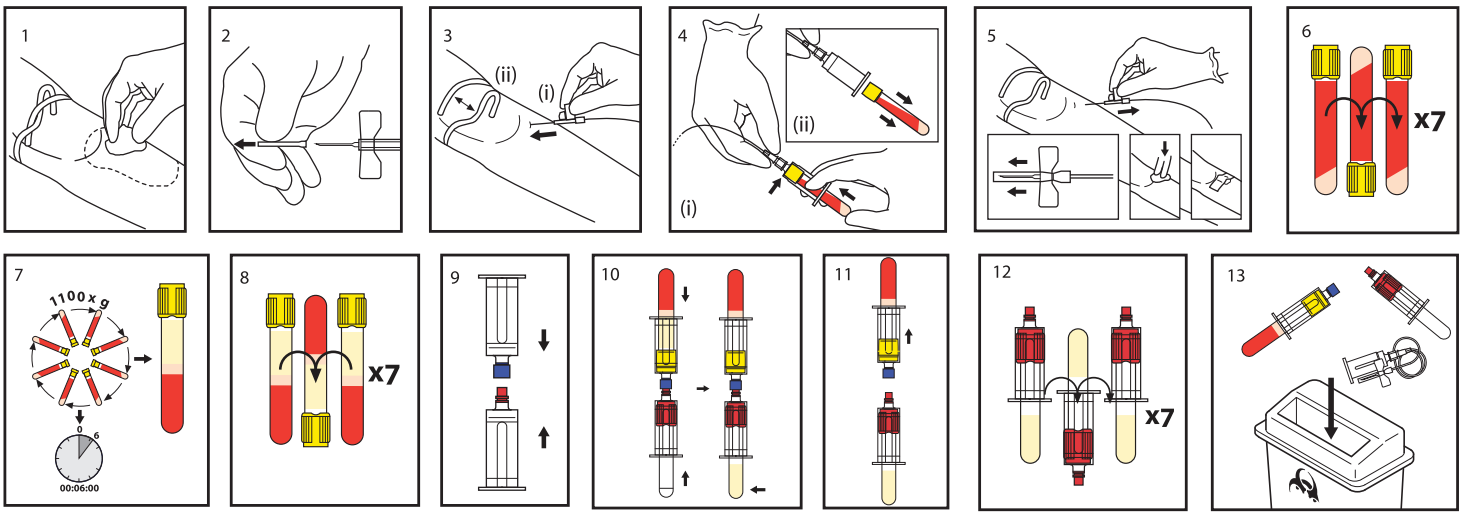
SELPHYL®

PRP & PRFM tube use in an Autologous Fibrin & Platelet System



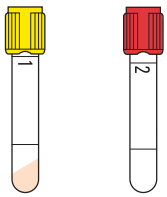
REF 420910

Method of use

1. Apply latex free tourniquet provided and prepare venipuncture site with the alcohol pad provided.
2. Remove needle shield from SLBCS (butterfly).
3. Insert blood collection needle into arm according to accepted blood collection guidelines.
4. As soon as blood is seen in the base of the butterfly needle hub (flash), insert yellow top PRP tube into tube holder of SLBCS.
   - Ensure PRP tube is aligned and firmly seated in the tube holder.
   - Once blood starts to enter yellow top PRP tube, loosen tourniquet.
   - Allow yellow top PRP tube to fill. Flow of blood. will stop when the fill is complete.
   - Pull yellow top PRP tube straight out to remove it from tube holder and gently invert tube seven times to ensure complete mixing of blood with anticoagulant.
5. After completion of blood draw, withdraw blood collection needle from arm and activate needle shield.
   - Apply pressure to puncture site until bleeding stops.
   - Apply bandage.
   - Dispose of blood collection needle according to accepted safety disposal guidelines.
6. Immediately after filling the yellow top PRP tube in Step 4, gently invert the yellow top PRP tube seven times to ensure complete mixing of blood with anticoagulant.
   - Wipe top of yellow top PRP tube with alcohol pad.
7. Place all six red sleeves with yellow caps in Drucker centrifuge model # 642VFD-Plus or HORIZON 6. Place yellow top PRP tube into centrifuge. Use the counterbalance to ensure the centrifuge is properly balanced by placing the counterbalance in opposing red sleeve.
   - Run centrifuge at 1100 x g for six minutes. (Yellow setting for Drucker model # 642 VFD-Plus).
8. Once the centrifuge has stopped, remove yellow top PRP tube and gently invert tube seven times to resuspend platelets into the plasma; this is PRP.
9. Assemble the blood tube transfer device by connecting the red tip Blood Transfer Device to the blue tip Luer Access Device.
10. <u>This step should not begin until physician is ready to treat the patient.</u> Holding the assembled blood tube transfer device vertically with the blue tip luer access device on top, position the yellow top PRP tube in the blue tip luer access device tube holder (on top) and the red top PRFM tube in the red tip Blood Transfer Device tube holder (on bottom).
    - Ensure yellow top PRP tube is mixed prior to transfer.
    - Ensure the yellow top PRP tube and the red top PRFM tube are aligned (yellow on top and red on bottom) and loosely seated in the respective tube holders.
    - When both tubes are in position, initiate PRP transfer by simultaneously pushing the yellow top PRP tube and the red top PRFM tube into the transfer device assembly so that the stoppers are pierced simultaneously, and tubes are firmly seated in the respective tube holders.
    - Allow PRP to transfer completely into red top PRFM tube.
11. When all the PRP has been transferred into the red top PRFM tube, disassemble the transfer device.
12. Immediately after transfer, gently mix the red top PRFM tube with seven inversions to mix the PRP with $CaCl_2$. This is PRFM.
    - Use the PRFM immediately (less than 10 minutes) after transfer.
13. Dispose of all used components according to accepted safety disposal guidelines.

SELPHYL®
PRP & PRFM TUBES

The SELPHYL Platelet-rich Plasma PRP Tube and Platelet-rich Fibrin Matrix (PRFM) Tube Instructions for Use



PN 0363 PN 0364

FACTOR MEDICAL

CE 2797 Rx

Prescription Medical Device

Precautions

- The PRP & PRFM Tubes are provided STERILE by irradiation. Discard and do not use if the sterile packaging is damaged or compromised.
- Follow Universal Safety Precautions for blood collection and sharps disposal.
- During blood draw, failure to align and firmly seat tubes in tube holder can result in loss of vacuum and loss of blood draw.
- During PRP transfer, failure to align and firmly seat tubes simultaneously in assembled blood transfer device tube holders can result in loss of vacuum and failure of PRP to transfer to the red top PRFM tube.
- Do not initiate transfer of PRP into red top PRFM tube until the physician is ready to complete the procedure.
- It is not recommended that PRFM be mixed or used with agents known to cause significant platelet activation and degranulation, as these can affect the output of the device.

Special Populations:
• Use of the SEPHYL® Device is not recommended with patients who are experiencing conditions that impact the quality of the autologous PRP. These include low platelet count, sepsis, localized infection in treatment area, anemia, malignancy with hematologic or bony involvement, patients on anticoagulation therapy, or patients with platelet and clotting disorders.
• Patients on non-steroidal anti-inflammatory agents (NSAIDS) or long-term, low dose aspirin therapy may exhibit prolonged clotting times.

United States / FDA Indications:
The SELPHYL® product is indicated for the safe and rapid preparation of autologous platelet-rich plasma from a small sample of the peripheral blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a boney defect for improving handling characteristics.

European Union Indications:
The SELPHYL® product is indicated for the safe and rapid preparation of autologous platelet rich-plasma from a small sample of the peripheral blood at the patient's point of care. Placement of the PRP or PRFM output of the device provides a concentration of autologous platelets to support localized healing. If you or your patient experience a serious incident as defined by MDR Article 2(65) related to use of this device, report the incident to the manufacturer and to your country's competent authority.

Contraindication:
Direct connection to a patient's vascular system of circulating blood volume.

READ INSTRUCTIONS FOR USE BEFORE USING THE MEDICAL DEVICE.

WARNING:

DO NOT REUSE. This device is for single use only. Single use is defined as use with one patient only during one therapy session. Reuse may result in infection or transmission of disease possibly resulting in serious injury or death.

CAUTION: Federal (USA) law restricts this device to sale by or on the order or a physician.

Description:
The SELPHYL® Platelet-rich Plasma (PRP) tube and Platelet-rich Fibrin Matrix (PRFM) tube are for collecting autologous blood for preparation of Platelet-rich Plasma and Platelet-rich Fibrin Matrix.

Intended Use:
SELPHYL® PRP and PRFM tubes are intended for the collection and processing of a patient's blood to obtain fibrin and platelet concentrates for use as deemed appropriate by the physician's clinical use requirements.

Performance Characteristics:
The following device performance measures ensure that the PRP and PRFM produced surpass clinically useful thresholds:
• Blood draw volume: 8.1 ml (nominal range of 7.1-8.4
• PRP Volume: >50% of blood draw volume
• PLT: >50% of the drawn blood platelet concentration
• PRFM formation: Clotting Times: >10 min

PRP & PRFM Tubes Included in Kits:
1 – Sterile pouched Yellow Top PRP Tube
(Vacuum tube contains0.9 ml buffered tri-sodium citrate solution as blood anticoagulant)
1 – Sterile pouched Red Top PRFM Tube
(Vacuum tube contains0.1 ml calcium chloride solution for clotting anticoagulated plasma)

PRP & PRFM Tubes must be used with compatible accessories, which include:

4 – Patient labels
1 – Alcohol pad
1 – Stretch latex free tourniquet
Sterile packaged:
1 – Blood Collection Set with Pre-attached Holder (SLBCS); commonly known as "butterfly"
1 – Blood Transfer Device (red tip female luer adapter)
1 – Access Device (blue tip male luer)

Kits 420910 and 440910 are identical except 440910 contains an additional yellow top PRP and red top PRFM tube.

510(k) Clearance BK170096. SELPHYL® is a brand name for FIBRINET®.

Tubes can be safely used up to 3 years beyond the manufacturing date indicated on the tube pouch label.

FACTOR MEDICAL, INC., 300 Baker Avenue, Suite 300, Concord, MA 01742. U.S.A.

Store and use at ambient conditions. Do not exceed.

EC REP MedEnvoy Global B.V., Prinses Margrietplantsoen 33, Suite 123, 2595AM The Hague, The Netherlands

Glossary of Symbols

EC REP	Authorized representative in the European community		STERILE R	Sterilized using irradiation	
CE	CE mark	LOT	Batch code	Rx	Prescription only
	Do not reuse		Do not use if packaging is damaged		Date of manufacture
REF	Catalog number		Expiry date		Manufacturer
UDI	Unique device identifier	MD	Medical device		Consult instructions for use