

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.
 - Repeat above bulleted steps with second yellow top PRP tube.
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 each yellow top PRP tube in Step 4, gently invert the yellow top PRP tubes seven times to ensure complete mixing of blood with anticoagulant.
 - Wipe top of yellow top PRP tubes 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 tubes 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 # 642VFD-Plus).
8. Once the centrifuge has stopped, remove yellow top PRP tubes and gently invert tubes 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. This step should not begin until physician is ready to treat the patient. 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 CaCl₂. This is PRFM.
 - Use the PRFM immediately (less than 10 minutes) after transfer.
 - Use all PRFM on patient before continuing with second yellow top PRP tube.
 - Repeat steps 10-12 with second yellow top PRP tube and second red top PRFM tube provided, ensuring the second yellow top PRP tube is mixed prior to transfer.
13. Dispose of all used components according to accepted safety disposal guidelines.

Precautions

- 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.
- Do not transfer the contents of the second yellow top PRP tube until the PRP from the first tube has been transferred to the red top PRFM tube and completely utilized.

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

United States / FDA Indications:

SELPHYL® is designed to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of 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:

Clinical benefits of using PRP and PRFM to facilitate the healing of bone and soft tissue for the medical condition of osteoarthritis has been reported in literature and have not been cleared or approved by the FDA.

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 of a physician.

REF 440910

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.

PRP & PRFM Tubes Included in Kits:

- 2 – Sterile pouched Yellow Top PRP Tubes
(Vacuum tube contains 0.9 ml buffered tri-sodium citrate solution as blood anticoagulant)
- 2 – Sterile pouched Red Top PRFM Tubes
(Vacuum tube contains 0.1 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.

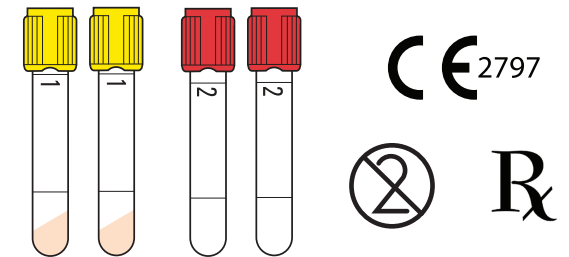
Do Not Reuse.
Risk of infection and non-performance
Ne pas réutiliser.
Le risque d'infection et de la non-exécution
No reutilizar.
Riesgo de infección y la falta de ejecución
Non riutilizzare.
Rischio di infezione e di mancata esecuzione
Não reutilizar.
Risco de infecção e não-cumprimento



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| Glossary of Symbols | | STERILE R | | Sterilized using irradiation | |
|---------------------|----------------|-----------|------------------------------------|------------------------------|---------------------|
| | CE mark | | Batch code | | Prescription only |
| | Do not reuse | | Do not use if packaging is damaged | | Date of manufacture |
| | Catalog number | | Expiry date | | Manufacturer |

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



PN 0363

PN 0364



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Selphyl® is a Registered Trademark of Factor Medical, Inc.

This product and/or use thereof is covered by US Patent No. 6,368,298; 6,979,307; 7,745,106 and 8,491,564.

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Store and use at ambient conditions. Do not exceed.