Leukocyte - Platelet Rich Fibrin
L-PRF™ Protocol

(Please read carefully)

IntraSpin™ System Centrifuge Installation

REVIEW CENTRIFUGE MANUAL PRIOR TO USE
DO NOT ACTIVATE CENTRIFUGE UNTIL YOU HAVE REMOVED THE TRANSPORT BOLTS USED FOR SHIPPING AND PROTECTING THE ROTOR

1. Remove and save transport bolts from bottom of centrifuge
2. Attach AC cable and plug into electrical outlet
3. Turn power on using the rocker switch in back of centrifuge
4. Select speed and time
5. Ready for use

IntraSpin™ System Indications for Use

The IntraSpin™ System is intended to be used for the safe and rapid preparation of autologous platelet rich fibrin (PRF) from a small sample of blood at the patient’s point of care. The PRF is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.
**IntraSpin™ System Instrumentation**

- **IntraSpin™ Centrifuge - 1**
- **IntraSpin™ Blood Collection Tubes- 9 ml plastic tubes (single use) - 100**
- **Vacuette® Blood sample collection set (single use) - 24**
- **Tourniquet - 1**
- **Test tube rack - 1**
- **Surgical scissors and forceps – 1 each**
- **Round & rectangular trays – 1 each**
- **L-PRF™ dual biomaterial/fibrin matrix carrier - 1**
- **Biomaterial dual packer - 1**
- **Xpression™ Fabrication Kit - 1**

**Sterilization:** Sterilize clean wrapped instruments by using a full cycle pre-vacuum steam sterilization cycle at a temperature of 132°-135° C (270°-275° F) for an exposure time of 4 minutes. Dry for 30 minutes.

In order to offer patients the highest level of clinical safety, **Intra-Lock** products are made with materials that are biocompatible with human plasma.

This product is not authorized for sales in every market and it may not be available in your market. Please consult with your local Intra-Lock representative for additional information.

**CENTRIFUGE PARAMETERS**

1. **Electricity (AC) =** rear black swivel switch: Activate
2. **Speed = 2700 RPM**
3. **Timing = 12:00 minutes**
4. **Press START**
5. **The centrifuge cover will open automatically at the end of each cycle.**

After the first procedure, the timing and speed are recorded in the centrifuge memory unless the settings are changed (reference the centrifuge specific user manual).
BLOOD SAMPLE COLLECTION

The blood collection must be made as quickly as possible, since the there is no anticoagulant in the collection tube. The blood sample will begin to coagulate immediately.

DO NOT USE A SYRINGE FOR BLOOD SAMPLE COLLECTION.

Insert the needle into the vein. Insert the evacuated tube into the tube holder until the needle on the tube holder penetrates the rubber membrane of the cap and blood begins to flow into the tube. The tube will fill automatically. When the tube is full, remove it and insert tube number two. Once the second tube is full, remove it and place the first and second tubes into the centrifuge on opposite locations to counterbalance the rotor, close the cover of the IntraSpin™ centrifuge and press the “START” button allow it to spin for 12 MINUTES.

ALTERNATIVE PROCEDURE

If more than two tubes of blood are required, please follow this alternative procedure:

After the first two tubes of blood are collected, immediately place them into the IntraSpin™ centrifuge, opposite each other to ensure the centrifuge is properly balanced. Close the cover and set the timer to “1” Minute. Press the START switch and allow the centrifuge to run for one minute. Will come to a full stop and the cover will pop open.

3-4 Tubes of blood

While the centrifuge is spinning for 1 Minute, collect the third and fourth tubes of blood.

Upon completion, set the timer to 12 MINUTES and conduct the final centrifugation.

ANTI-COAGULANT THERAPY

When patients are on any type of anti-coagulant therapy (aspirin, heparin, Coumadin, Plavix, etc.), they have a longer coagulation time. For this reason, centrifuge the blood 18 MINUTES.
**IMPORTANT POINTS TO REMEMBER**

- **ALWAYS CENTRIFUGE TUBES IN PAIRS:** Always place the tubes in pairs and place them in opposite positions to balance the centrifuge rotor. The tubes must always be balanced in the rotor before pressing the START switch or this may cause serious damage to the centrifuge, improper coagulation and/or separation. If the tubes are not properly balanced, one will have too much vibration during centrifugation and a poor clot for L-PRF™ will result.

- **ODD NUMBER OF BLOOD SAMPLES:** If you have an odd number of blood samples to centrifuge, then place a tube of the same size as the blood samples, filled with water opposite to the un-paired tube in the rotor. This will allow for proper balancing of the centrifuge.

- **START CENTRIFUGATION:** Begin centrifugation immediately after collecting the blood samples. Delays affect the blood separation procedure and result in a poor clot for L-PRF™.

- **AFTER CENTRIFUGATION:** Remove the cap from each tube and place the tubes onto the sterile rack.

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**L-PRF PREPARATION**

After centrifugation, three segments are visible:

1. **Upper Segment**
   - platelet poor plasma (PPP).

2. **Middle Segment**
   - fibrin clot: L-PRF™.

3. **Lower Segment**
   - red blood cell clot.

- L-PRF™ fibrin matrix must be prepared relatively quickly: 0-15 minutes after centrifugation or the clot will shrink in volume by releasing the trapped serum.
- Remove L-PRF™ clot from the tube with forceps.
- Cut the L-PRF™ clot just below the union with the red blood cell clot. This will leave a very small portion of red blood cells and large platelets attached to L-PRF™ clot.
The Xpression™ Box

The Xpression™ Box enables the fabrication of fibrin matrixes of constant thickness with ease. The Xpression™ Box has a cover to maintain hydrated fibrin matrixes for several hours and if desired, the exudate can be collected under the tray.

The Xpression™ Box includes wells and piston to fabricate L-PRF™ cylinders that easily fit post-extraction sockets.

Xpression™ Components

Xpression Cover

Xpression Press

Xpression Tray

US and Foreign Patents Pending
Fibrin Matrix Preparation

The Xpression™ Tray
Placing each of the fibrin clots on the perforated surface of the tray. Once the clots to be converted into fibrin matrix are placed on the perforated surface, place the Xpression™ Press over the fibrin clots without exerting any pressure over the clots. Allow the weight of the tray to slowly PRESS down the fibrin clot while the exudate is filtered to the bottom of the tray. Do not apply pressure to the weighted plate. Gravitational force on the weighted plate will gently compress the clot and express the serum from the PRF clot without damaging the fibrin network.

Place the cover of the Xpression™ Box on top of the tray. Wait at least 5 minutes before removing and using any fibrin matrix. Do not remove any fibrin matrix until actual time of use. The fibrin matrix may remain in the Xpression™ Fabrication Kit for a period of up to 3 hours.

Preparing L-PRF™ for extraction sockets
Place a fibrin clot inside the white cylinder. Use the piston to slowly press the clot inside the white cylinder. Continue to press until the top edge of the piston is flush with the top edge of the white cylinder. With this technique, one will be able to form a thick, round fibrin matrix or plug for the extraction socket. For a single tooth, one L-PRF cylinder may be sufficient. Pre-molars may need two L-PFR cylinders, and three L-PRF cylinders may be needed for molars, depending on the size of the extraction socket and the size of the fibrin clot created.
Recommended Instructions for mixing small fragments of L-PRF with bone graft material

1. Place the predetermined amount of bone graft material into a sterile bowl or tray.
2. Dip the expressed L-PRF clot(s) or pieces of the L-PRF clot into the graft material covering the entire surface area of the L-PRF clot or pieces with graft material.
3. Alternatively, the graft material may be sprinkled onto the L-PRF clot or pieces of the clot, covering the entire surface area with graft material.

   Note: Wetter L-PRF may retain slightly more graft material than dryer PRF.
4. The graft material should cling to the surface of the L-PRF, however, if desired, gently press the graft material into L-PRF.
5. Forceps can be used to place this mixture into the defect.

Recommended Instructions for mixing large L-PRF fragments or entire L-PRF Clot with bone graft material

1. Gently cut the L-PRF fibrin matrix into small pieces in a sterile dish.
2. Add the desired amount of bone graft material.
3. Thoroughly mix the L-PRF and bone graft material. This mixture can be placed into defects using a spatula.

IntraSpin™, Xpression™ & L-PRF™ are trademarks of Intra-Lock International Inc.; Vacutette® is a registered trademark of Greiner Bio-One International AG.; US and foreign patents pending.

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