



WARNING!

This symbol advises the user of serious danger for the patient and the user.



CAUTION!

This symbol informs the user that particular care is required for safe and efficient operation of the system.



IMPORTANT NOTE

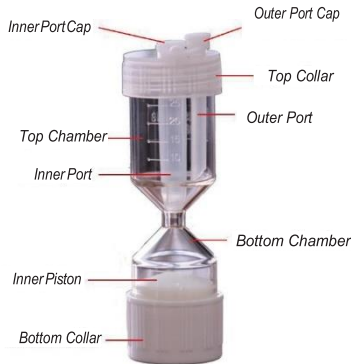
This symbol provides the user with useful or additional information.

Symbols for warnings, Cautionary Measures, and Notes

Product Description

The bioGELx PRP™ hourglass tube is a single-use, sterile device that is used for separating blood. The components are outlined in Figure 1.

Figure 1: Components of the bioGELx PRP™



Description of bioGELx PRP™ device components

Outer Port cap: used to insert collected blood sample through outer port into the top chamber. Also where plasma is collected after centrifugation.

Inner port cap and inner port: opening for 1mL syringe to be inserted at the surface of the buffy coat for its removal by aspiration from the neck of the device. Inner port acts as a separator between top and bottom chamber.

Top collar: Opens or seals the connection between the top chamber and the bottom chamber when turned either clockwise or counter clockwise.

Bottom Chamber: After centrifugation, red blood cells are separated into the bottom chamber with the buffy coat on the surface.

Bottom Collar: When turned counterclockwise, bottom collar moves inner piston up, pushing buffy coat into the neck and top chamber of the device.

Indications for Use

The bioGELx PRP™ tube is indicated for use in the rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Contraindications

The bioGELx PRP™ is not to be used under the following contraindications:

1. Critical thrombocytopenia (low platelet count)
2. Hypofibrinogenaemia
3. Haemodynamic instability (collapse)
4. Sepsis (infection)
5. Acute and chronic infections
6. Chronic liver disease
7. Anti-coagulation therapy (warfarin, dabigatran, heparin)



WARNING!

- ONLY use the PRP mixture into the patient from whom the PRP was derived
- Process only one patient's blood per disposable bioGELx PRP™ device
- Do NOT use for direct intravenous infusion
- Do NOT re-use the used bioGELx PRP™ device
- Do NOT re-sterilize
- Do NOT use expired products
- Ensure patient is aware of general risks associated with treatment and possible adverse effects
- The PRP is ONLY for use in the patient from which it is derived.



CAUTION!

- ONLY use certified blood collecting equipment
- Always store the device in clean state
- Ensure device is not contaminated
- Ensure Identify tag is affixed to the bioGELx PRP™ (containing donor's name or registration No.) to avoid contamination
- Ensure drawn blood is not exposed to other people
- Discard disposable device in biohazard container after use
- PRP treatment is to be carried out by trained Health Professional

How to Use

Prior to use

1. Check the expiry date of the product.
2. Check for any damage on the packaging and product.



WARNING!

- Do NOT use if product date is expired
- Do NOT use if inner package seal is broken as it is no longer sterile
- Do NOT use if damaged



CAUTION!

- Read all instructions prior to use.

Blood Draw

1. Using butterfly blood collection kit, draw **23 mL** of whole blood from patient.
2. Following blood draw, Slide yellow protective cover on butterfly to shield needle for safe disposal.
3. Remove butterfly from 30mL syringe and discard all biological matter as per regulation.
4. Note: The end user must provide an FDA approved anticoagulant; one is not included with the kit.

Transferring Blood to bioGELx PRP™ tube

1. With gloved hands, unpack the bioGELx PRP™ tube from the sterile packaging.
2. Confirm top chamber is open to the bottom chamber. Close top collar and re-open. Hold output facing you and turn the collar counter clockwise one and a quarter turn. See Figure 2.
3. Confirm bottom chamber is open to 15mL mark. Rotate bottom collar clockwise until top of internal piston is at 15mL mark. See Figure 3.



Figure 2: Opening Top Collar

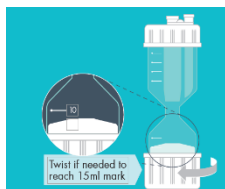


Figure 3: Opening bottom chamber to 15mL

- Open outer port by lifting cap. Leaning the tube at less than a 45° angle, transfer the whole blood sample into the bioGELx PRP™ tube using the syringe (without a needle) and inserting into outer port.
- Reseal the outer port after the transfer by closing cap.



WARNING!

- Do NOT push plunger with strong force when using the bioGELx PRP™ tube.

Centrifugation

- Using a digital scale, ensure that the weight of the bioGELx PRP™ tube and the counter weight are equal ($\pm 5g$). Place the fully prepared World PRP tube and counter weight tube into the centrifuge, aligned across from each other. Close the lid and lock the centrifuge.
- Fill up the counterweight with 68 grams of tap water, approximately 25ml syringe of water. Please make sure that the counterweight is open to 1 ¼ turns
- Place the bioGELx PRP™ tube and counterbalance into the centrifuge. Set the centrifuge to the following settings: Rotation speed 3,000 rpm, Operation time: 3 minutes.

*For additional centrifuge information, please refer to the user manual.

If spin cycle is incomplete, verify that:

- The centrifuge is on a stable, level surface
- Top chamber of the World PRP tube is open to 1 ¼ turn, allowing blood to flow between both chambers
- Weight of the counterbalance provided in the kit and whole blood sample are equal within a 5 gram variance.



Follow the Instructions provided with the centrifuge regarding how to set the required settings.

Collecting Plasma

Following centrifugation, plasma will be in the top chamber, red blood cells and buffy coat in the bottom chamber. See Figure 4.

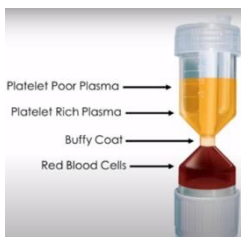


Figure 4: Location of blood components following centrifugation

- Remove bioGELx PRP™ tube from centrifuge.
- Raise the red blood cells and buffy coat by turning bottom collar counter clockwise until buffy coat had reached neck of the PRP tube. Continue to turn bottom collar until buffy coat has been transferred into top chamber, leaving red blood cells in the neck of the tube. See Figure 5.
- Turn collar clockwise to seal off connection between top and bottom chambers.



Figure 5: Red blood cells in neck of tube, Buffy coat in top chamber.

4. Collection: 6-7ml with PRP, without PPP

- For PRP, immediately after sealing the RBCs in the bottom chamber, tilt the hourglass towards you 45° with outer port at 6 o'clock position. Aspirate half of the contents using a syringe (no needle). The aspirated contents are the Platelet Rich Plasma and Buffy coat. The platelet poor plasma will remain in the hourglass. See figure 6.
- Before use,, the PRP and the graft must be mixed with autograft or allograft bone in order to improve bone handling characteristics prior to application to a bony defect.

Collection option 1: 6-7 ml of PRP without PPP

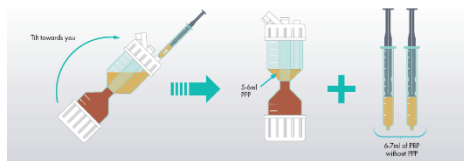


Figure 6: Collection of PRP

Storage and Management of Syringe with Mixed Plasma and Buffy Coat

- Attach and identification tag to 5cc syringe with mixture to prevent accidental contamination of blood products.
- To prevent contamination, store products/syringes containing PRP in a clean, cool, dry place until ready to use.
- PRP should be used within 4 hours.

Disposal

Dispose the used product and all biological materials to institutional guidelines for biohazardous medical waste.

Additional Packaging Symbols

Symbol	Description
	Manufacturer
	Model
	Manufacture Date
	Lot Identifier
	Do not use if package is damaged
	Sterilized with Gamma radiation
	Prescription Only
	Fragile
	Keep away from sunlight
	Keep dry
	Single Use

Manufacturer Information

LBL-00139 revA

LUVO MD
125 Fleming Drive
Cambridge, ON
N1T 2B8

LUVO MD

For any questions, contact LUVO MD authorized Representative.