

**PLATELET CONCENTRATOR KIT** 

## NOTICE: SINGLE USE DEVICE ONLY

IMPORTANT: US Federal Law (U.S.A.) restricts the sale and use of this device by or on the order of a physician.

### **DEVICE DESCRIPTION**

The ProGen<sup>™</sup> Platelet Concentrator (PC) Kit is designed to provide an easy to use device for collecting Platelet Rich Plasma (PRP) at required concentration levels.

• CAUTION: The blood products from this device are not to be used for transfusion.

#### **INTENDED USE**

The ProGen<sup>™</sup> PC Kit is indicated for 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 / or allograft bone prior to the application to a bony defect for improving handling characteristics of the graft.

► CAUTION: Venipuncture, collection and processing of the patient's blood should occur under aseptic conditions. The disposable ProGen<sup>TM</sup> PC, syringes and accessories, must be properly discarded following standard biohazard guidelines after each use. Sealed sterile packages containing the ProGen<sup>TM</sup> PC Kit must be inspected before opening. If seal is broken, contents may not be sterile.

► CAUTION: Verify soft brake setting to prevent remix of blood components. See centrifuge manual for instructions.

#### CONTRAINDICATIONS

The ProGen<sup>™</sup> PC Kit may be contraindicated when used in a non-sterile environment, patients taking aspirin within 72 hours, drugs that affect platelet function, patients with any serious medical conditions that would make them unable to safely tolerate the extracorporeal blood components and/or blood volume required for the procedure.

 CAUTION: The platelet rich plasma should be used within 4 hours of collection.

## **ProGen™ Platelet Concentrator Kit**

Quantity	ProGen™ PC Kit Component	Part Number
1	60mL Syringe	CELL-56820
2	30mL Syringe	CELL-56830
1	20mL Syringe	CELL-56840
2	Centrepid™ PC	CELL-80180-AA
1	Patient Label	BELL-22390
2	Alcohol Wipe	NASP-70740
4	Female Luer-Lok™ Cap	CELL-57200

ProGen<sup>™</sup> PC Kit Part Number: BELL-82380-A

NOTE: ACD-A USP and a 1.5 inch 20 gauge needle are NOT supplied as part of the ProGen<sup>™</sup> PC Kit. Clinical Grade ACD-A USP and 1.5 inch 20 gauge needle must be purchased separately.

#### **CENTRIFUGE INFORMATION**

The centrifuge, swing out rotor and carrier (50mL or 85mL) assembly must be rated for 1900rcf. The centrifuge must have a soft brake feature (Minimum brake time of 120sec). The proper adapter must be used with the Platelet Concentrator, i.e. BELL-22000 (Druck-er/Eppendorf only) centrifuge carrier, BELL-21990 (Drucker/Eppendorf only) and BELL-22010 50ml carrier (ELMI CM-7S only). The centrifuge must have a 30-min. timer. For additional centrifuge information please contact Customer Service at 888.372.3982.

► CAUTION: A venipuncture must be made by a trained medical person using standard blood collection procedures

# **INSTRUCTIONS FOR USE**

Manufactured For: Bellus Medical, LLC 5005 Lyndon B Johnson Fwy, Ste 370, Dallas, Texas 75244

Made in the USA by: NASP 19 Park Drive Franklin, NJ 07416 PATENT# 6,835,353 BELL-21960 Rev. D

**1.** Using a 1.5 inch 20 gauge needle, fill the 60mL syringe with 9mL of ACD-A USP (needle and ACD-A not are not supplied in ProGen<sup>™</sup> PC kit). Secure the pre-filled 60mL syringe containing the 9mL ACD-A USP to the donor site, and draw 41mL of the patient's blood at a rate of 1mL per second for a total volume of 50mL. Gently mix the blood/ACD-A USP solution for one (1) minute. Connect the 60mL syringe to the ProGen<sup>™</sup> PC cap Luer-Lok<sup>™</sup> (Figure 1).

▶ CAUTION: Insufficient mixing may cause the blood to clot

2. While holding the paired syringe and ProGen<sup>™</sup> PC in a vertical position, very gently to avoid cavitation, dispense 50mL of blood/ACD-A USP mix at a rate of 1mL per second Figure 1 into the PC (Figure 1).

and may cause a reduction in outcome.

CAUTION: Dispensing the blood too fast may activate the platelets and may cause a reduction in outcome.

3. Remove 60mL syringe from the ProGen<sup>™</sup> PC Luer-Lok<sup>™</sup> cap and apply a female Luer-Lok™cap, (Figure 6). Dispose using standard biohazard protocol. Wipe the cap valve area of the ProGen<sup>™</sup> PC with alcohol wipe. Rotate ProGen<sup>™</sup> PC cap until cap tab is firmly against the 'RBC' stop position (Figure 2).

CAUTION: The ProGen<sup>™</sup> PC cap tab MUST be turned firmly against the 'RBC' stop position. Failing to complete this step successfully may prevent the RBC aspiration.

**4.** Place the ProGen<sup>™</sup> PC , using the proper adapter, into centrifuge carrier. If equipped, install aerosol cap and place into centrifuge rotor. Fill the second ProGen<sup>™</sup> PC with 50mL of water, and turn the cap to the 'RBC' position until cap tab is firmly against the 'RBC' tube stop position. Place the counter balance, using the proper adapter, into centrifuge carrier. (Figure 3). If equipped, install aerosol cap and place into the opposing centrifuge rotor position. Following the centrifuge manual instructions, set the speed for 1900rcf Figure 3 and the timer to 5 minutes.

5. At the end of the centrifuge first spin cycle, prior to removing the ProGen<sup>™</sup> PC, collapse one (1) 30mL syringe. Remove the ProGen<sup>™</sup> PC from the centrifuge, always / maintaining a vertical position to prevent blood component separation and remix.

6. Connect the 30mL syringe to the ProGen<sup>™</sup> PC cap female Luer-Lok<sup>™</sup>, while maintaining a vertical position to prevent blood component separation and remix (Figure 4).

▶ CAUTION: Syringes must be fully seated.



8. Wipe the valve area of the ProGen<sup>™</sup> PC Luer-Lok<sup>™</sup> cap with alcohol wipe and place the ProGen<sup>™</sup> PC counter balance, using the proper adapter, into centrifuge rotor. Readjust the counter balance weight water volume to match the new blood volume, using the 50mL scale. Place the readjusted counter balance, using the proper adapter into the carrier and place into the opposing centrifuge rotor position (Figure 3). Following centrifuge manual instructions, set speed for 1900rcf and timer to 8 minutes.

9. At the end of the centrifuge second spin cycle, prior



Figure 6

Figure 5

to removing the ProGen<sup>™</sup> PC, collapse one (1) 30mL syringe. Figure 7



Figure 8



CAUTION: Not turning the cap firmly against the tube stop may prevent PPP aspiration.

second until air begins to enter the inner tube. Apply a female Luer-Lok<sup>™</sup> cap to the PPP filled syringe and dispose

using the standard biohazard disposal procedures (Figure 9).



Figure 4



12. Collapse the supplied 20mL syringe, connect to the Figure 10 ProGen<sup>™</sup> PC Luer-Lok<sup>™</sup> cap and draw the remaining PRP at a rate of 1mL per second (Figure 11).

13. Apply female Luer-Lok<sup>™</sup> cap to protect PRP collection during handling and transport, (Figure 12) and complete the Patient Label with the PC lot number and expiration time (4 hours after PRP collection) /date.

Figure 12

Figure 11









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