

VI. ADDITON OF Calcium Chloride 10% (CaCl₂) FOR GRAFT HANDLING (OPTIONAL)

CaCl₂ 10% may be added to the PRP and applied to (or mixed with) with autograft and/or allograft bone, prior to application to a bony defect for improving handling characteristics by creating a Platelet Rich Fibrin Matrix (PFRM). See Figure 4 below for depictions of the steps.

- Determine the amount of PRP to be used. Each mL of PRP requires 0.05 mL of CaCl₂ as listed in the Figure below. Aspirate the proper amount of CaCl₂ 10% with the 1 mL syringe (I) using a hypodermic needle to withdraw the CaCl₂ from the glass vial using aseptic technique.
- Remove and discard the hypodermic needle. Attach the 1mL syringe to the female/female connector (J). Attach the PRP syringe to the connector and transfer 0.05 mL of CaCl₂ 10% for each mL of PRP. Gently mix the syringe containing the CaCl₂ and PRP. Apply the supplied patient identification label to the syringe and cap with the white syringe cap (H). Apply the PRP + CaCl₂ into the autograft and/or allograft. Repeat for each PRP tube.

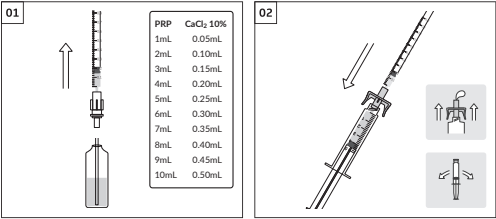


Figure 4. Addition of CaCl₂ 10% for graft handling

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For product inquiries, please call
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November 2024

SYMBOLS GLOSSARY

Symbol	Meaning
	Catalogue Number
	Batch number
	Use by
	Sterilized with ethylene oxide
	Single Use. Do Not Reuse
	Do not resterilize
	Not made with natural rubber latex
	See instructions for use
	Do not use if package is damaged
	Nonsterile protective packaging with sterile barrier system inside
	Keep Dry
	Protect from sunlight

RICHPLAT ORTHO®

Platelet Rich Plasma System

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Instructions for Use for the 20 mL and 40 mL Kit

RX Only

INTENDED USE

The RICHPLAT ORTHO® Platelet Rich Plasma System 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 bony defect for improving handling characteristics.

ENVIRONMENT

The RICHPLAT ORTHO® Platelet Rich Plasma System is intended for use at the patient's point of care.

CONTRAINDICATIONS

- The product should not be used in patients with problems of hypersensitivity to any of its components.
- Patients with active infections.

WARNINGS AND PRECAUTIONS

- Prior to using this device, carefully read the instructions for use and make sure that the required accessories are available, and the components are correctly connected.
- Only trained and authorized professionals must use this device.
- Inspect packaging. Do not use if packaging is damaged, opened or expired.
- Use the device immediately after opening the sterile pouches.
- For single use only. The reuse of any of the components of the kit would involve the risk of cross contamination for the patient or the user.
- Use the recommended volume of ACD-A. Note that ACD-A is not for direct intravenous use.
- The information in this Instructions for Use is not intended to establish any kind of medical or surgical procedure.
- Aseptic technique must be used when handling reagents, obtaining blood sample, processing, and administration, as applicable.
- Use universal precautions for bloodborne pathogens when handling blood and fluids.
- The PRP kit includes a blood collection safety needle with built-in safety features that help minimize the incidence of accidental needlesticks. After the blood draw is complete, the safety mechanism should be engaged. There is a click which ensures that the safety mechanism is correctly (and irreversibly) activated.
- Discard all the blood collection needles in a biohazard container approved for their disposal.
- Use the patient identification label at the time of the blood draw and place one on the PRP tube to maintain accuracy to the correct corresponding patient.
- Immediately after collection, the blood should be transferred from the syringe into the PRP tube and processed.
- PRP prepared using this device is not intended for transfusion. The safety and effectiveness of PRP for clinical use outside of its cleared indication has not been established.
- Note: PRP volume and PRP yield may vary with each patient.
- Do not use samples that are clotted or hemolyzed (pink or red plasma).
- Use the PRP within 4 hours after the blood has been drawn.
- Components in contact with blood must be disposed of as medical waste in accordance with local requirements.

Possible Adverse Events

- Allergies and other reactions to device materials.
- Damage to blood vessels, hematoma, nerve damage, delayed wound healing and/or infection may be associated with blood draw procedure.

Table 1 KITS CONTENTS AND REQUIRED ACCESSORIES

KIT CONTENTS	20 mL Kit	40 mL Kit
Blood Collection Set with Tray	1 - 20 mL*	1 - 50 mL*
Blood Collection Safety Needle	1 - 21G	1 - 21G
Concentrating Kit	1 - 20 mL	2 - 20 mL
Counterbalance Tube	1	Not required

*Note: Depicts the size of the syringe

The following accessories are required and not included in the kit and must be made available before you open the kit:

Table 2 REQUIRED ACCESSORIES NOT INCLUDED IN THE KIT

REQUIRED ACCESSORY	20mL Kit	40mL Kit
Anticoagulant Citrate Dextrose Solution, A solution, U.S.P (supplied separately)	2 mL	4 mL
10% Calcium Chloride (CaCl ₂ 10%) solution for bone graft handling (supplied separately upon request)	1 mL	2 mL
Hypodermic needle for ACD-A	1	1
Hypodermic needle CaCl ₂ 10%	1	2
Alcohol swab and tourniquet for blood draw	1	1
Bandage/dressing to cover needle puncture site	1	1
A general-purpose centrifuge. See below for centrifuge requirements	1	1

CENTRIFUGE REQUIREMENTS

- General-purpose Centrifuge with the following requirement:
Type of Rotors: Swinging (with adaptors to fit centrifuge buckets)
Bucket configuration: Round
Bucket Dimensions: Diameter 40 mm/Height 80mm
Relative centrifugal force*: 435g
Temperature: Room temperature
Spin Time: 8 minutes

*Recommended Relative centrifugal force for commercially available centrifuges:

- Drucker Boost2/Boost 2 Flex: 600g (2000 rpm)
- Drucker Flex 12: 640g (2000 rpm)
- Eppendorf Model 5702: 435g

Note: The RICHPLAT ORTHO® Platelet Rich Plasma System was tested using the Eppendorf Model 5702 centrifuge.

INSTRUCTIONS FOR USE

I. PREPARATION PRIOR TO BLOOD DRAW

The accessories listed in Table 2 above must be available prior to blood draw.

II. BLOOD COLLECTION

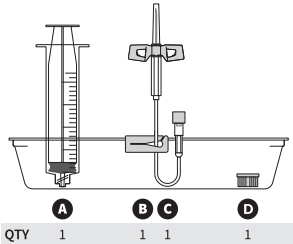


Figure 1. The Blood Collection Set

* Needle packaged separately. See needle packaging for expiration date.

1. Open the Blood Collection Set (Figure 1)
2. ACD-A preparation - A hypodermic needle must be used for glass vials with stoppers using aseptic technique to draw the ACD-A into the syringe. Discard the needle after use.
 - a. For the 20 mL Kit, fill Syringe (A) with 2 mL of anticoagulant.
 - b. For the 40 mL Kit, fill Syringe (A) with 4 mL of anticoagulant.

Note: For 20 mL kit, Syringe A will be a 20 mL syringe.

Note: For 40 mL kit, Syringe A will be a 50 mL syringe.

3. Open the safety needle package and place the clamp (B) on the needle tubing (C) before attaching it to Syringe (A). Attach the syringe (A) with the anticoagulant to the tube hub of the blood draw safety needle (C). Purge the needle tube with the anticoagulant.
4. Apply the tourniquet to the patient's arm. Disinfect the skin with an alcohol swab and puncture a medium/large vein holding the needle by its folded wings. Always wear gloves.
- ⚠ **CAUTION: Observe blood flashback in the chamber to confirm vessel entry.**
5. Apply a gentle negative pressure to draw the blood until the syringe is filled up to the appropriate level:
 - a. For the 20 mL kit, fill the syringe up to the 20 mL mark with 18 mL of blood.
 - b. For the 40 mL kit, fill the syringe up to the 40 mL mark with 36 mL of blood.
 - c. Once the blood draw is completed, clamp the needle tube.
- ⚠ **CAUTION: Carefully mix the syringe for every 5 mL of drawn blood to ensure a full blood anticoagulation.**
6. Release the tourniquet. Remove the needle from the patient's arm and activate its safety mechanism until it clicks. Remove the syringe and cap it with the Syringe Cap (D). Gently mix the syringe by inverting several times. Discard the needle.
7. The blood draw puncture site should be covered by an appropriate dressing or bandage or as per proper phlebotomy protocol of the facility.

*Needle must be disposed after use as medical waste

See figure 3 below for depictions of the procedure for blood collection, processing and centrifugation.

III. PROCESSING AND CENTRIFUGATION

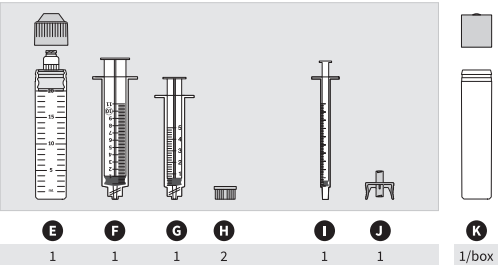


Figure 2. Concentrating Kits

Note: The 40mL kit includes 2 Concentrating Kits
Only the 20mL kit includes the counterbalance tube (K).

8. Open the Concentrating Kit (Figure 2). For the blood transfer step:
 - a. For the 20mL Kit, remove the sterile drape and place on a flat working surface. Uncap Syringe (A) with blood and screw it onto the PRP tube (E). Slowly transfer the 20 mL of anticoagulated blood into the PRP tube (1mL/s) keeping it upright. Unscrew and discard the empty syringe as medical waste. Put the PRP cap back on the PRP tube (E).
 - b. For the 40 mL kit, open the second Concentrating kit. Repeat Step 8.a to transfer the remaining 20 mL blood into the second PRP tube.
9. Centrifugation Step:
 - a. For the 20 mL Kit, place the PRP tube and the counterbalance tube (K) in the centrifuge unit following manufacturer's instructions. Close the lid.
 - NOTE for the 20 mL kit: Place the counterbalance tube on the opposite side to the PRP tube. Fill the counterbalance tube with a matching volume of saline solution (e.g. 20mL) and put the counterbalance cap on the tube prior to placing it in the centrifuge.
 - b. For the 40 mL Kit, place both PRP tubes in the centrifuge unit following manufacturer's instructions. Close the lid.
 - NOTE for the 40 mL kit: Place the both PRP tubes containing anticoagulated blood opposite to each other into the centrifuge. Check matching volumes in the tubes to ensure they both contain 20mL of volume of anticoagulated blood.

For the Centrifuge:

NOTE: To ensure an aseptic procedure, the manufacturer's instructions must be followed for the cleaning/sterilization of the centrifuge and its components.

10. Spin the tubes at the following parameters:

Spin Time: 8 minutes
Temperature: Room Temperature
Relative centrifugal force*: 435g

*Recommended Relative centrifugal force for commercially available centrifuges:

- Drucker Boost2/Boost 2 Flex: 600g (2000 rpm)
- Drucker Flex 12: 640g (2000 rpm)
- Eppendorf Model 5702: 435g

11. Once the centrifugation of the PRP is complete, withdraw the PRP tube(s) carefully. Avoid shaking or tilting the tube. Place the tube(s) in an upright position on a flat surface and remove the PRP cap from the PRP Tube(s).

IV. PRP PREPARATION

12. Push down the plunger of each syringe before connecting it to the PRP tube to ensure there is no air in the syringe. Use the 10 mL (F) and/or 5 mL (G) syringe onto the PRP tube, based on the amount of PRP required to be drawn up. Draw out the PRP by pushing down on the tabs of the connected syringe letting the plunger of the syringe move freely, keeping a rate of descent of approximately 1 mL/s. DO NOT PULL UP ON THE PLUNGER. STOP as soon as the plunger touches the red fraction. All the plasma drawn is concentrated PRP. Once the desired amount of PRP is collected into the syringes(s), carefully unscrew the syringe from the PRP tube and place the syringe cap (H).
- For the 40 mL Kit, repeat this step for the second PRP tube.

⚠ **CAUTION: The PRP mixture must be used immediately. The PRP must be used within 4 hours after the blood has been drawn.**

V. ADDITION OF PREPARED PRP TO BONE GRAFTING MATERIAL

The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. See Section VI for the optional step of mixing the PRP with CaCl₂ 10%.

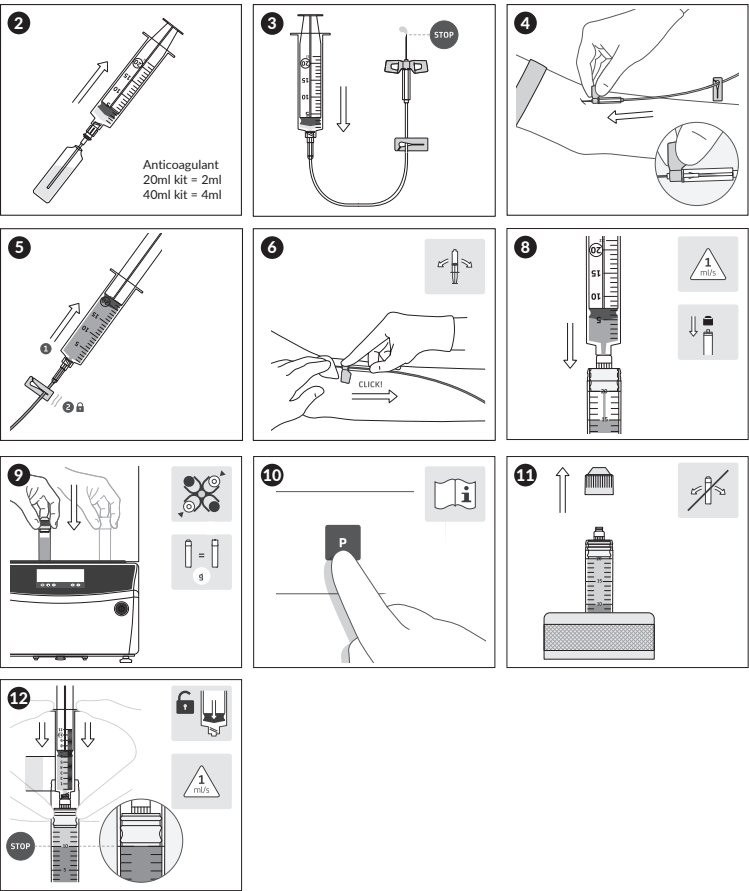


Figure 3. Procedure for blood transfer, processing and centrifugation