



PLATELET RICH PLASMA (PRP) PREPARATION SYRINGE

INSTRUCTIONS FOR USE

INTENDED USE

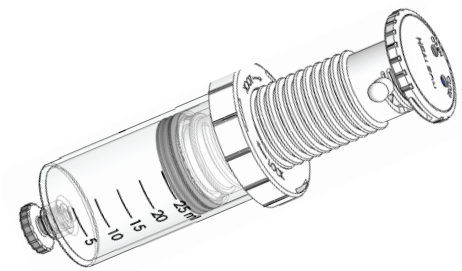
Healeon Duet™ is indicated to be used for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of peripheral blood at the patient point-of-care.

PRODUCT DESCRIPTION

A syringe assembly in a blister tray used for platelet rich-plasma preparation from peripheral blood. The product is provided sterilized and non-pyrogenic. This Product may be used in a medical office or hospital setting.

CAUTION

- **European Reporting Requirements:** Any serious incident that has occurred in relation to the device should be reported to Bimini Health Tech and the competent authority and the Member State in which, you as the user and/or patient, are established.
- For Single Patient Use Only. Reuse may cause infection. Once used, the item must be discarded following the protocol for biohazardous waste disposal, as required by the facility where it was used.
- PRP must be used on the same patient from which blood was drawn.
- Do not use PRP if any foreign matter is visible.
- Do not use if the Healeon Duet™ appears to be cracked or damaged.
- Do not use after its sterilization expiration date.
- Do not re-sterilize or attempt to clean after use.
- Once prepared, use PRP within 4 (four) hours after drawing blood.
- Practice Universal Precautions to protect from blood spatter,



- blood leakage, to minimize potential exposure to blood-borne pathogens.
- Handle all biologic samples and blood collection devices per the procedures established by your facility.
 - Appropriate medical attention is required in the event of any exposure to biologic samples.
 - Use sterile technique.
 - Follow manufacturer's instructions on the use of the centrifuge at your facility.
1. Centrifuge carriers and inserts should be of the size of the Healeon Duet™. Duet dimensions: 40mmx145mm
Insert dimensions: 40mmx 60mm
 2. Always allow the centrifuge to come to a complete stop before removing Healeon Duet™ devices.
 3. Counterbalance tubes will be required to balance the weight of the Healeon Duet™ during centrifugation. When using a counterbalance, place the balance with the same weight as the filled Healeon Duet™ with whole blood, opposite of the Healeon Duet™ with whole blood.
 4. Once the centrifugation spin cycle has stopped, open lid of centrifuge and examine for any breakage or leaking prior to use.
 5. Do not attempt to remove any broken devices or other debris with your hands. Use some type of hemostat or forceps to remove damaged items. Follow centrifuge manual provided by manufacturer for disinfection instructions.

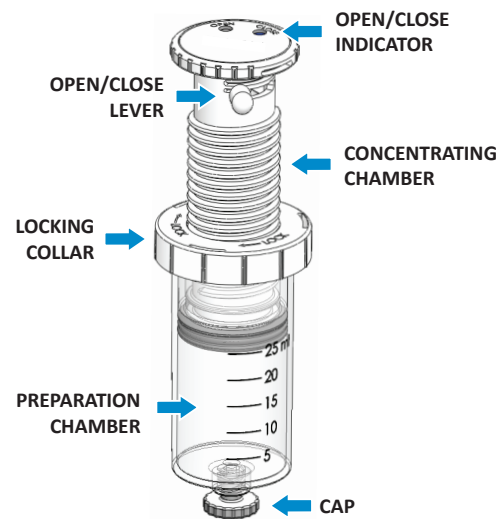
RECOMMENDED STORAGE TEMPERATURE

Store Healeon Duet™ between 15- 25° C.

REQUIRED ITEMS NOT PROVIDED FOR SPECIMEN ACQUISITION AND PROCESSING

Have these items assembled and ready prior to drawing blood:

1. Swing out rotor centrifuge capable of generating 2300 G Force.
2. Use gloves, eye protection, gowns, other apparel and disposable items to protect from exposure to blood-borne pathogens or other potential harmful materials. Follow the policies and procedures of your facility for venipuncture and blood draw procedures.
3. Alcohol swabs for cleansing draw site.
4. Sterile gauze.
5. Tourniquet.
6. Sharps disposal container for needles, syringes, needle/ holder device.
7. FDA Approved Anti-coagulant, Citrate Dextrose Solution, Solution A, U.S.P.



8. 5ml syringe, 10ml syringe, luer-luer transfer device.
9. Blood draw items: 21G butterfly needle with luer-lock hub connection.

PROCEDURE STEPS TO OBTAIN PRP

1. STARTING MODE /POSITION

Remove Healeon Duet from the blister tray. Confirm the top lever is in the closed position as indicated and twist the locking collar in a counter-clockwise direction to ensure it is unlocked prior to the blood draw. (Figures A & B).

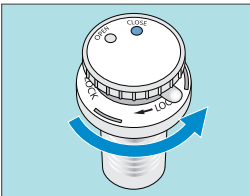


FIGURE A

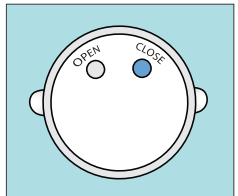


FIGURE B

2. DRAW BLOOD

Remove Healeon Duet from tray. Attach an 18G standard needle to withdraw 2.5 ml of an FDA approved anti-coagulant for the preparation of PRP directly into the Healeon Duet by pulling back on the plunger.

Following accepted blood collection guidelines, draw 22.5 ml of the patient's blood (Figure C) for a total of 25 ml fluid, into the Healeon Duet syringe assembly and replace the cap.

Invert Healeon Duet syringe 7 (seven) times to thoroughly mix anti-coagulant with patient blood.

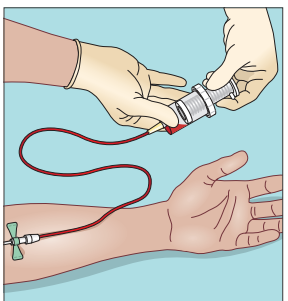


FIGURE C

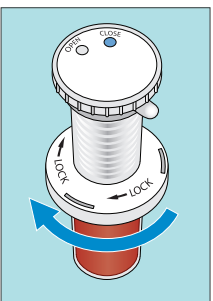


FIGURE D

Turn locking collar in clockwise direction, as indicated on the device, to lock the collar into place (Figure D).

3. SPIN PRP

Turn on centrifuge and unlock lid. Place Healeon Duet into individual sleeves across from each other to achieve a balanced

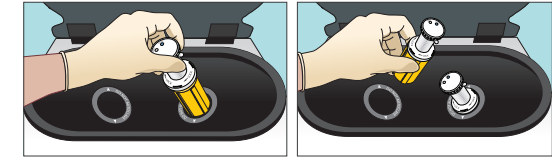


FIGURE E

FIGURE F

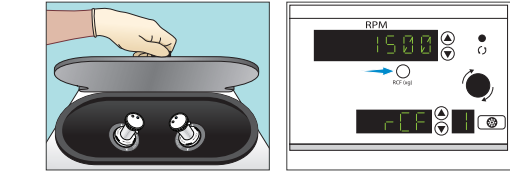


FIGURE G

FIGURE H

load in the centrifuge or use an appropriate counterbalance. Lock the lid. Spin for 2 (two) minutes at 1500 G Force (Figure E, F, G, H).

4. PRP EXTRACTION - FIRST SPIN:

Unlock centrifuge lid and keep Healeon Duet in the upright

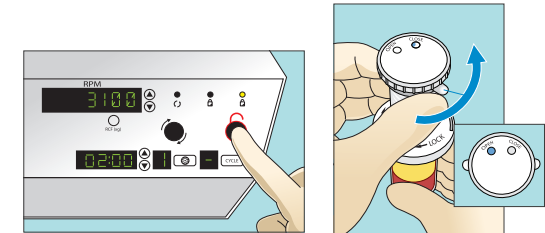


FIGURE I

FIGURE J

position (Figure I). Turn the lever under the plunger head to the 'OPEN' position, confirmed by the blue dot in the open window. (Figure J).

Screw the plunger in a downward clockwise direction to enable plasma to enter Concentrating Chamber until you capture the

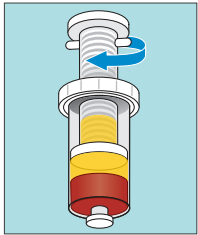


FIGURE K

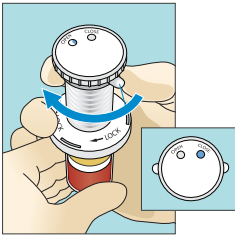


FIGURE L

white buffy coat (approximately 12 ml of plasma) (Figure K). Turn the lever back to the 'CLOSE' position to close Concentrating Chamber (Figure L).

Unlock the Collar and remove the cap (Figures M, N).

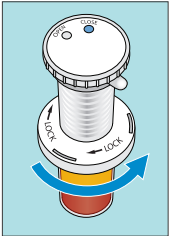


FIGURE M

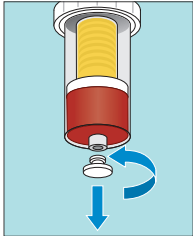


FIGURE N

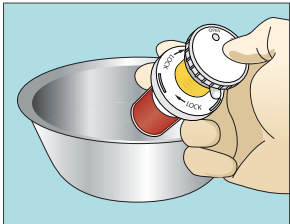


FIGURE O

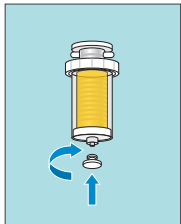


FIGURE P

Push plunger in downward position to dispel the remaining hematocrit in Preparation Chamber into a biohazard bag or basin (Figure O). Place cap back on Healeon Duet (Figure P).

5. PRP EXTRACTION - SECOND SPIN (OPTIONAL):

Return Healeon Duet to centrifuge with appropriate counter-



FIGURE Q

balance. Centrifuge for 3 (three) minutes at 1500 G force (Figure Q). Unlock centrifuge and remove Healeon Duet keeping in an upright position. With lever in the 'CLOSE' position remove cap from Healeon Duet (Figure R).

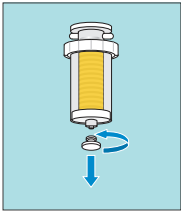


FIGURE R

6. PRP TRANSFER

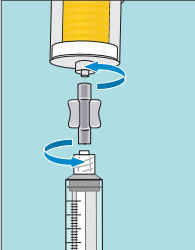


FIGURE S

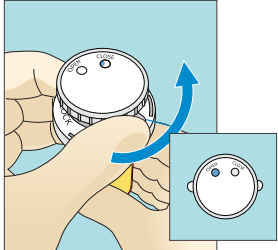


FIGURE T

Attach a 5ml standard syringe to the Healeon Duet using a standard luer-luer connector (Figure S). Turn lever to 'OPEN' position, confirmed by blue dot in the open window (Figure T). Pull back on 5ml syringe plunger to allow PRP to fill syringe

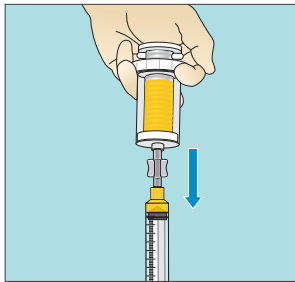


FIGURE U

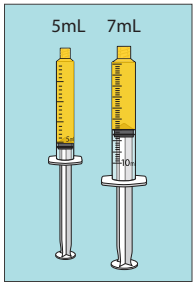


FIGURE V

(Figures U, V). Detach the 5ml syringe, and with a separate 10ml standard syringe, withdraw the remaining 7ml of PRP.

Please refer to table below for appropriate PRP volume using

a single spin or double spin protocol.

Healeon Duet contains approximate volume markings for user convenience. Final output volume is determined by Clinician-provided injection syringes.

Volumes are accurate +/- 0.5mL

BLOOD DRAW VOLUME	PRP VOLUME
25 ml Single Spin	12 ml
25 ml Double Spin	5 ml

7. PRP USE

The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

GLOSSARY OF SYMBOLS

REF	Catalog number	LOT	Batch code
	Do not use if package is damaged.		Do not re-sterilize
	Keep dry		Product is not made with natural rubber latex
	Temperature limit		Consult instructions for use
	Use-by date		Do not re-use
	Sterilized using ethylene oxide		Keep away from sunlight
	Single sterile barrier system		Medical device
	Non-pyrogenic fluid path		Manufacturer
	European authorized representative		CE Mark with notified body XXXX
	Federal (USA) law restricts the use of this device to sale by or on the order of a physician.		