

Push plunger in downward position to dispel the remaining hematocrit in chamber A into a biohazard bag or basin. Place the cap back on. (Figure K)

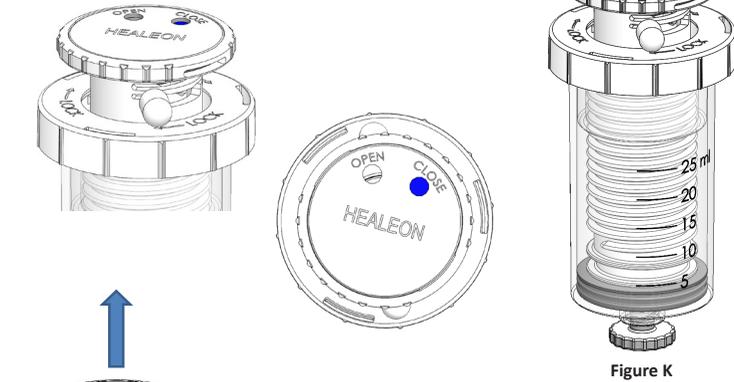


Figure K

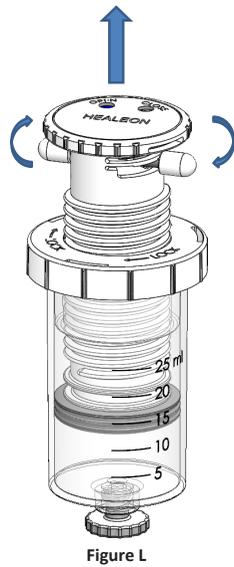


Figure L



Figure M

Turn lever into 'open' position, confirmed by blue dot in the open window, and pull back on plunger to allow the 11ml of PRP to fill chamber A. (Figures L, M, N)



Figure N

4) PRP TRANSFER

While keeping the Healeon Duet™ vertical, remove cap and attach a 5ml standard syringe to the Healeon Duet™ using a standard leur-leur connector. Transfer the bottom 5ml of PRP to the syringe. Detach the 5ml syringe, and with a separate 10ml standard syringe, with the remaining 7ml of PRP.

Please refer to table below for appropriate PRP volume using a single spin or double spin protocol.

Volumes are accurate +/- 0.5mL

| BLOOD DRAW VOLUME | PRP VOLUME |
|---------------------|------------|
| 25 ml - Single Spin | 12 ml |

5) PRP USE

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

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
8. 1-5ml syringe, 1-10ml syringe, leur-leur transfer device.
9. Blood draw items: 21ga butterfly needle with leur-lock hub connection

RECOMMENDED STORAGE TEMPERATURE

Store Healeon Duet between 15-50° C.

MANUFACTURER: Bimini Health Tech
420 Stevens Ave, Suite 220
Solana Beach, CA 92075, USA
Tel: +1-858-348-8050
www.biminihealthtech.com



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



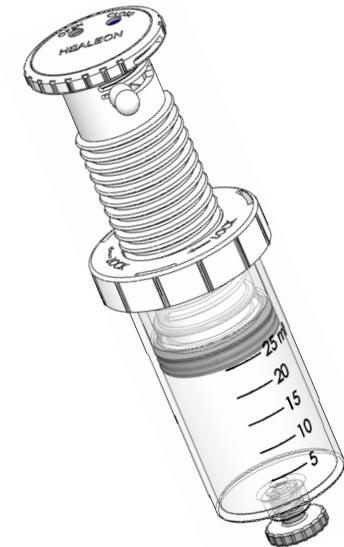
GLOSSARY OF SYMBOLS

| | | |
|------------------------------------|---|---|
| Consult Instructions for Use | LOT Batch Code | STERILE EO Sterilized using Ethylene Oxide |
| Do Not Reuse | Do Not Use If Damaged | Manufacturer |
| REF Catalog Number | Expiration Date | Temperature Limit |
| Keep Out of Sunlight | Keep Dry | Sterile Barrier |
| MD Medical Device | Rx ONLY Caution: Federal law restricts this device to sale by or on the order of a physician | Non-Pyrogenic |
| Not made with natural rubber latex | Do Not Resterilize | Date of Manufacture |
| EC REP EC Representative | CE CE Mark with Notified Body Reference # XXXX | |

INSTRUCTIONS FOR USE



PLATELET-RICH PLASMA (PRP) PREPARATION SYRINGE



HEALEON
REGENERATIVE RESOURCE

BIMINI HEALTH TECH
420 STEVENS AVE, SUITE #220
SOLANA BEACH, CA 92075 USA
TEL: +1-858-348-8050
www.biminihealthtech.com

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.

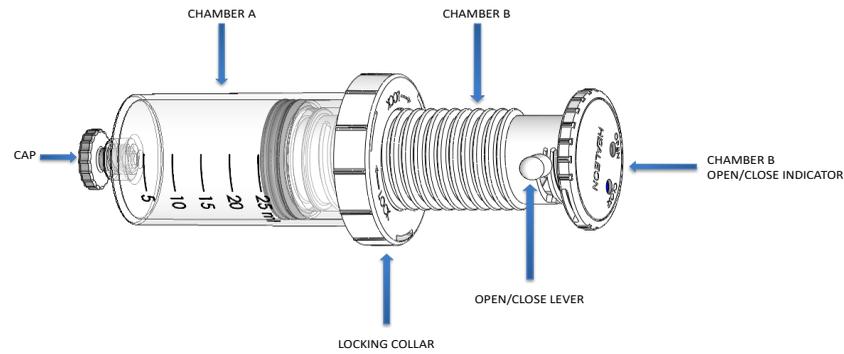
PRODUCT DESCRIPTION

A syringe assembly in a blister tray used for Platelet Rich Plasma (PRP) 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

- For Single Patient Use Only. 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.
- Follow manufacturers instructions on the use of the centrifuge at your facility.

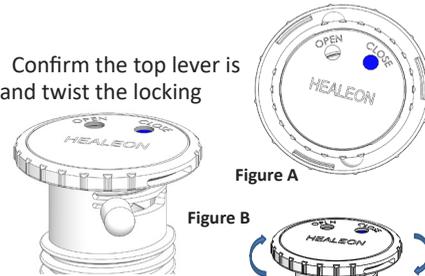
- Centrifuge carriers and inserts should be of the size of the Healeon Duet™. Duet dimensions: 40mmx145mm Insert dimensions: 40mmx 60mm
- Always allow the centrifuge to come to a complete stop before removing Healeon Duet™ devices.
- Counter-balance tubes will be required to balance the weight of the Healeon Duet™ during centrifugation. When using a counter-balance, place the balance with the same weight as the filled Healeon Duet™ with whole blood, opposite of the Healeon Duet™ with whole blood.
- Once the centrifugation spin cycle has stopped, open lid of centrifuge and examine for any breakage or leaking prior to use.
- 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.



PROCEDURE STEPS TO OBTAIN PRP

1) STARTING MODE / POSITION

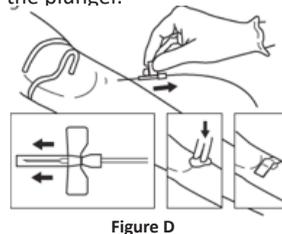
Remove Duet from the blister tray. Confirm the top lever is in the closed position as indicated and twist the locking collar in a counter-clockwise direction to ensure it is unlocked prior to the blood draw. (Figures A, B, C)



2) DRAW BLOOD

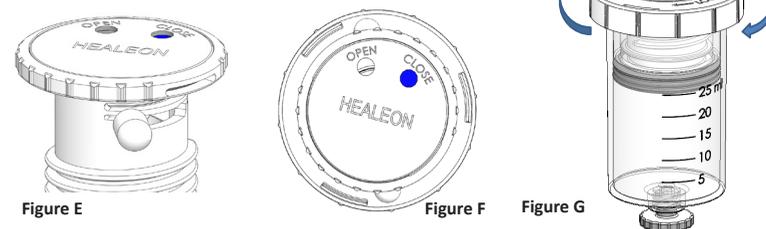
Remove Healeon Duet™ from tray. Attach an 18-gauge standard needle to withdraw 2.5ml of an FDA approved anti-coagulant for the preparation of PRP directly into the Healeon Duet™ by pulling back on the plunger.

Following accepted blood collection guidelines, draw 22.5ml of the patient's blood (Figure D) for a total of 25ml 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.

Turn locking collar in clockwise direction, as indicated on the device, to lock the collar into place. (Figures E, F and G)



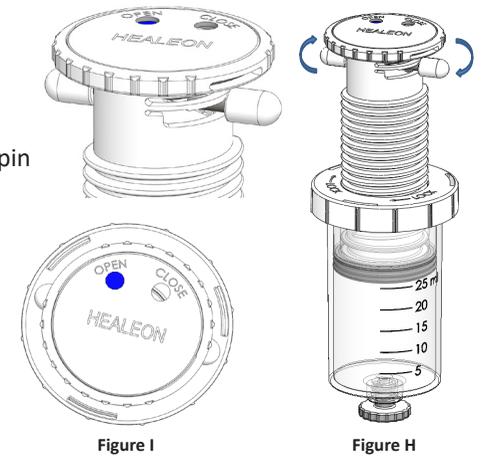
3) SPIN PRP

Turn on centrifuge and unlock lid. Place Healeon Duet™ into individual sleeves across from each other to achieve a balanced load in the centrifuge, or use an appropriate counter balance. Lock the lid. Spin for 10 (ten) minutes at 400 G Force.

4) PRP EXTRACTION - First Spin

Unlock centrifuge lid and keep Healeon Duet™ in the upright position. (Figure H)

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



Screw the plunger in a downward clockwise direction to enable plasma to enter into Chamber B, until you capture the white buffy coat (approximately 12ml of plasma). (Figure J)

Turn the lever back to the 'closed' position to close Chamber B. Unlock the collar and remove the cap. (Figures K, L, M)

