

convulsions, or cardiac arrhythmia which, if untreated, could lead to death.

- In rare cases, there is a potential for platelet loss, which may lead to increased risk of bleeding and/or bruising; plasma clotting factors may be damaged, causing an increased risk of bleeding after donation; kidney function may be impaired; activation of cells returned to the donor may shorten platelet survival and/or result in the development of clots.
- Improper operating conditions may result in excessive citrate infusion, blood loss, damage to blood (e.g., hemolysis or clotting), and air infusion, which may lead to serious adverse reactions, such as dyspnea. Improper operating conditions that may be prevented or mitigated by operator action are included in applicable warnings.



**Warning:**

The physician or operator responsible for the operation of the separator should refer to the package insert accompanying each drug product used during blood processing procedures, for full drug product information.

## Section 1.4 Product Claims and Specifications

### WBC Counts

The AmiCORE Apheresis System provides processed leukoreduced platelet products.

Platelets Pheresis, Leukocytes Reduced:

- <  $5 \times 10^6$  95% of the time with 95% confidence\*
- <  $1 \times 10^6$  90% of the time

\* For collections under  $9.0 \times 10^{11}$ , this value is per collection. For collections greater than or equal to  $9.0 \times 10^{11}$ , this value is per platelet dose.

### Yield and Volume

The platelet yield range per storage container is  $1.5 \times 10^{11}$  to  $4.7 \times 10^{11}$  platelets. Volume and yield requirements are specified in the Appendix section, "Number of Leukocytes Reduced Platelets and Minimum Storage Fluid Volumes, Including AC".



**Note:**

Concentration of platelets/mL = platelet yield/volume.

Actual plasma product volume should be within  $\pm 10\%$  of target plasma product volume.

Plasma collected, processed, and placed in a freezer at  $-18^{\circ}\text{C}$  or colder within eight hours after phlebotomy may be used as Fresh Frozen Plasma.

Plasma collected for use as PF24 must be stored at  $1 - 6^{\circ}\text{C}$  within eight hours after phlebotomy and placed in a freezer at  $-18^{\circ}\text{C}$  or colder within 24 hours after phlebotomy.

Plasma collected for use as PF24RT24 can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at  $-18^{\circ}\text{C}$  or colder within 24 hours after phlebotomy.

## Section 1.5      **Contraindications**

The AmiCORE Apheresis System is contraindicated in those cases where adequate anticoagulation cannot be achieved.

## Section 1.6      **Donor Requirements and Care**

### **Donor Requirements**

Donors should be selected based on the requirements of the appropriate state, federal, or national health-regulating agencies as well as institutional standard operating procedures (SOPs) for the individual blood collection center.

### **Donor Care**

Follow institutional guidelines and SOPs for venipuncture site and donor care.



**Note:**

The donor should be informed of the basic procedure and understand the potential adverse reactions associated with apheresis.