

## Section 1.2 Intended Use and Indication for Use

### Intended Use

The AmiCORE Apheresis System is an automated blood cell separator intended for use in the collection of blood components.

### Indications for Use

The AmiCORE Apheresis System is an automated blood cell separator indicated for the collection of blood components. AmiCORE is indicated to collect:

Platelets Pheresis, Leukocytes Reduced

- May be stored in the platelet storage containers with an appropriate volume of storage fluid for up to five days at 20° C to 24° C with continuous gentle agitation.
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single or double units)
  - May be stored in a mix of 65% InterSol/35% plasma for up to five days at 20° C to 24° C with continuous gentle agitation.

Platelets Pheresis (single or double units)

- May be manufactured from products that do not meet leukocyte reduction product standards. This does not apply to Platelet Pheresis, Platelet Additive Solution (InterSol) (single, or double units).

Plasma

- Fresh Frozen Plasma (FFP)
  - Must be prepared and placed in a freezer at - 18° C or colder within eight hours after phlebotomy.
- Plasma Frozen Within 24 Hours After Phlebotomy (PF24)
  - Must be stored at 1 - 6° C within eight hours after phlebotomy and placed in a freezer at - 18° C or colder within 24 hours after phlebotomy.
  - Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Plasma Frozen Within 24 Hours After Phlebotomy Held at Room Temperature Up to 24 Hours After Phlebotomy (PF24RT24)

- Can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at - 18° C or colder within 24 hours after phlebotomy. Indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Source Plasma

### **Apheresis Kits**

AmiCORE apheresis kits are the only apheresis kits that are to be used with the AmiCORE Apheresis System.

## **Section 1.3 Adverse Effects**

This section discusses possible adverse effects donors may experience during apheresis procedures. Processing of the donor's blood should be temporarily slowed or halted if such symptoms occur.

A donor may experience adverse effects similar to those experienced during routine blood collection.

- Dizziness/lightheadedness, pallor, nausea, hyperventilation, sweating, fainting, vomiting, rapid heart rate, tiredness/fatigue, or low blood pressure may occur.
- Due to venipuncture, the donor may experience pain, bruising/hematoma formation, or skin irritation at the site of phlebotomy. In rare cases, local or venous infection, arterial venipuncture, or peripheral nerve injury may occur.

Reactions unique to apheresis collection procedures may also occur.

- Reinfusion of saline or donor blood may induce chills or cause infiltration.
- Infusion of anticoagulants containing citrate may lead to donor symptoms of moderate hypocalcemia due to chelation of calcium by unmetabolized citrate. Such donor reactions are usually manifested by a "tingling" feeling, often around the mouth or fingers. Allergic symptoms including skin redness, itching, hives, etc., may be seen. Other manifestations may include muscle discomfort, muscle twitching or spasms, hypotension and/or headache, or the presence of an unusual taste or smell sensation. In the rare case that severe hypocalcemia occurs, symptoms may include muscle cramps, tetany,