HAEMONETICS®
THE Blood Management Company

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RE: Particulates in HS bowl collection sets

Dear Haemonetics Customer:

Haemonetics is advising our U.S. customers of a situation regarding particulate matter in HS-core collection sets: The issue has only been observed in Europe.

Problem Statement:

1) There are particulates being generated in rare instances during collection with the 625-HS plasma collection sets; 2) The incidence of these particulates is 1:1000 or less; 3) The composition of these particles is proteinaceous material and non-biological matter; 4) We believe that the size of the particulates is larger than 170 microns.

Current Status:

1. The particulate generated is a rare event. The incidence is 71 defects per million (29 reports since September 2010).
2. The composition of the particles has been confirmed to be primarily protein. Spectral analysis has confirmed this. Non-biological matter consisting of carbon particulate is also identified.
3. The black particulates, consisting of protein, are larger than 170 microns. Smaller particles, the vast majority 20 microns or less have been identified (many between 1-2 microns), consisting of protein and/or carbon.

Considerations:

1) Donor risk is mitigated by on-line filtration during the collection procedure; 2) Plasma fractionation process mitigates risk due to the manufacturing steps. 3) If the material is proven to be generated from the seal, it has been shown to be biocompatible; 4) the particulate incidents have not been observed with other plasma collection sets.

Current Status:

1. Donor risk is negligible. The risk is mitigated by the filtration during the collection procedure. Smaller particles would be processed by the body. Given the studies that concluded that plasma is safe for patient use, even if containing particles, we consequently conclude that donors are not at risk (see References).

2. Plasma collected from HS-core sets for fractionation is safe, given the rigorous filtration processes that are used in the manufacturing process.
3. The carbon particulate is being generated from the seal in the bowl. Tests on the seal meet biocompatibility standards. Test of the particles for cytotoxicity are negative (no cytotoxicity) and are negative for hemolysis.
4. We have found that a manufacturing process change in the bowl manufacture of 0.03" (0.76 mm) is a contributing factor in the generation of carbon particulates.
5. Tests of the coagulation activity in plasma collected by the HS-core shows no abnormalities, as demonstrated by PTT, ATIII, fibrinogen, factor VIII and D-dimer assays.

Ongoing Investigation:

Current Status:

1) As stated above, tests have confirmed the composition of the particulates and the size.
2) Studies are on going to mitigate the generation of the particulates.
3) Studies pertaining to complement activation are ongoing.
4) Further studies are being done to understand the contribution of other possible factors to the generation of particulate.

Recommendations:

1. Plasma collection may continue using the 625-HS for purposes of fractionation.
2. Plasma collection for therapeutic use should be suspended with the HS-core.
3. Plasma currently in storage and intended for transfusion should be transfused with filters with a maximum pore size of 170 microns.

Current Status:

1. We believe that plasma collection may continue for fractionation, given the safety of the manufacturing process.
2. We advised a cessation of collection of plasma for therapeutic use as a precautionary step. We believe that the plasma is safe for therapeutic use. We are maintaining our recommendation until we have corrected the manufacturing problem.
3. For Plasma for therapeutic use currently in inventory, we recommended the use of 170 micron filters as a precautionary step. We recommend standard filtration practices, 170-260 micron filters, and visual inspection of the plasma. If black particulates are visualized, we recommend that the unit will not be used for transfusion, in line with good clinical practice.

The smaller particulates meet industry pharmaceutical standards for particulate. The US Pharmacopoeia allows 5 particles greater than 20 microns per ml. (See References).

We will update you on a regular basis with our corrective action investigation and work. Your patience is greatly appreciated.

Regards,

Mark A. Popovsky, M.D.
Vice President and Chief Medical Officer

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