

New products

Baxter announces European approval of Isolex™ 300 Magnetic Cell Separator system for stem cell transplant

Baxter Healthcare Corporation's Biotech Group has announced it has received European regulatory approval of its Immunotherapy Division's Isolex™ 300 Magnetic Cell Separator system for stem cell separation and purification. Infusing purified stem cells after high-dose chemotherapy has the potential to lower the risk of cancer relapse and to reduce some of the side effects patients experience with stem cell transplantation. The Isolex™ 300 system is the first such medical device to be awarded the CE Mark of conformity, which allows a company to market its product in all countries of the European Union.

Stem cell selection from blood or bone marrow increasingly is used as a key component of blood stem cell or marrow transplant therapy for cancer, as well as in some types of experimental gene therapies. Approximately 10 000 high-dose chemotherapy treatments requiring blood stem cell or marrow transplantation were performed in Europe in 1994 and this number is growing rapidly, according to the International Bone Marrow Transplant Registry.

In the process of destroying tumor cells in the patient, high-dose chemotherapy also destroys the patient's stem cells, which are located in bone marrow and blood. Because stem cells are the progenitors of all blood cells, they must be replaced after high-dose chemotherapy in order for the patient's blood and immune cells to return to their normal numbers and function. Replacement requires a blood stem cell or bone marrow transplant.

In autologous blood stem cell or marrow transplantation, a large sample of the patient's blood or

marrow is frozen and stored prior to the high-dose chemotherapy treatment. After chemotherapy is completed, the sample is thawed and reinfused into the patient.

The Isolex™ 300 system separates the patient's stem cells from the rest of the cells in the bone marrow or blood sample. The purified stem cells are stored and frozen, while the remaining cells are either saved for other purposes or discarded. This purification allows stem-cell-transplant material to be stored in much smaller volumes.

Aside from the economic benefits of reduced storage space and less need for expensive storage solutions, smaller reinfusion volumes may result in certain medical benefits.

The Isolex™ 300 system consists of three separate components, each manufactured under GMP guidelines. The basic cell separation device, known as the Isolex™ 300 Magnetic Cell Separator, contains powerful magnets and other hardware and software required for performing the stem cell purification procedure. The Isolex™ 300 Disposable Set comprises a biocompatible tubing set and chamber where the stem cell purification takes place. Lastly, the Isolex™ 300 Stem Cell Reagent Kit contains murine antibody to mark stem cells expressing the CD34 antigen; Dynabeads® (manufactured by Dynal, Oslo, Norway) immunomagnetic beads, which are coated with sheep anti-mouse antibody to bind and capture the CD34⁺ cells; and an enzymatic agent for releasing the captured CD34⁺ cells from the Dynabeads prior to their collection as a purified population of stem cells.