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HEART NEWS: Feature Story

Infected Heart Valve Grafts Shake Leading Cardiac Tissue Supplier

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In response to an investigation of Cryolife, a major tissue processing company, by the Center for Disease Control (CDC), the Food and Drug Administration (FDA) has issued a recall for all Cryolife allograft tissue except heart valves. An allograft is a graft between genetically dissimilar members of the same species: in this case, the grafted tissue is removed from another living human or from a cadaver and transplanted into the patient. The recall of Cryolife allografts was the outcome of a several-month probe by the CDC, which began when a 23-year-old man in Minnesota died shortly after routine reconstructive surgery.

On November 7, 2001, a 23-year-old man from Minnesota underwent elective knee surgery using a femoral condyle allograft. Within a few days of surgery, the man developed severe abdominal pain, then went rapidly into septic shock. He died shortly thereafter. Blood cultures obtained premortem showed the presence of Clostridium Sordelii, a toxic anaerobic spore usually found in dirt and fecal matter. The spore was also present in the cadaver from which the tissue had been harvested. It was later discovered that the cadaver was not refrigerated by the tissue bank until nineteen hours after it had been picked up, well over the industry standard.

This occurrence was the first indication that routine knee surgery of this kind could have potentially fatal risks. The CDC eventually discovered 26 cases of similar allograft infections. Of these, twelve were infected with Clostridium septicum, and one with Clostridium sordelii. In at least eleven of these thirteen cases, additional evidence implicated the allograft as the cause of infection. All thirteen allografts infected with Clostridium had been used in orthopedic surgery, and eleven of those thirteen patients had received tissue processed by Cryolife.

Cryolife is currently being sued by at least nine families and a group of stockholders. The company continues to claim that the infections related to orthopedic tissues were in no way related to Cryolife products. In June, the company also issued a press release denying reports that it had provided infected heart valves to two patients; in July, it rescinded this denial. One of the heart valve patients in question was a Californian named Ken Alesescu, who reported to the CDC that he had developed a fungal infection after receiving a heart valve transplant. Alesescu, who suffered a hemorrhagic stroke, says he is wheelchair-bound and suffering from seizures. The other victim was a six-year-old girl from Albequerque, who died from a rare fungal infection after receiving an allograft heart valve. The fungus was identified as arthrographis kalray, which is usually found in soil and rotting vegetation. Her family is currently suing Cryolife.

In August, the FDA, responding to the findings of the CDC and the many reported cases of allograft-related infections, issued a recall of all Cryolife allografts except heart valves. Cryolife has been one of the dominant provider of cardiac tissues since it patented allograft heart valve production in 1984. Before the recall, it supplied over 70 percent of all allograft heart valves in the United States and 90 percent of all vascular tissue. It is not clear that the rest of the industry could provide enough cardiac tissue to meet national demands if Cryolife were forced to remove its supply from the market.

The events of the last year have caused many surgeons and medical professionals to call for higher standards of sterilization in the industry. The American Association of Tissue Banks, a self-regulating professional association, recently held a session titled “New Advances in Tissue Sterilization.” The CDC has also issued new recommendations to reduce the risk of allograft-associated infections: in particular, it advocates gamma irradiation and the consideration of new and developing technologies. Cryolife itself has responded to the recall by negotiating an agreement with the FDA, which will require the company to test tissue samples for infection and communicate with consumers about potential risks of infection. The company says that it plans to be ready for reinspection by the FDA in November or December.

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