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Search on for users of faulty heart valves

250 deaths linked to broken device

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Officials are trying to locate 23,000 people in Canada and the United States who received artificial heart valves that may be defective.

The manufacturer says that once a valve breaks a patient can die within hours if it is not replaced.

The valves, manufactured by Shiley Inc., a subsidiary of the giant pharmaceutical company Pfizer Inc. of Irvine, Calif., were implanted between 1976 and 1986.

About 250 deaths worldwide have been linked to the device, known as the Bjork-Shiley Convexo-Concave (C-C) heart-valve implant. The company has already faced numerous lawsuits, some of which have been settled out of court for a reported $1-million each.

The company says it wants to get in touch with heart-valve recipients so they will be able to recognize the signs if something goes wrong and seek immediate medical care.

For the search, the manufacturer has recruited the help of Medic Alert Foundation, a non-profit group that has begun a registry of individuals with artificial implants.

Kenneth Harms, Medic Alert president, said that between 1,500 and 2,000 people living in Canada received the implant. About 1,400 of them are already registered with Medic Alert.

"So we have a big leg up on locating these people," he said, adding that many Canadian hospitals encourage patients to register with Medic Alert.

In the United States the job will be much tougher because many hospitals have not maintained current addresses of patients, he said. Nor are a majority of U.S. patients registered with Medic Alert.

Usually, manufacturers send warning notices to physicians and hospitals when they realize something is wrong with one of their devices. It is then left up to the doctors to notify patients. Seldom do manufacturers try to contact all the patients directly.

"We've never been involved in anything like this before," said Mr. Harms, referring to the massive search for implant recipients.

Brian Evans, a lawyer from Whitby, Ont., who has been representing Canadian patients in lawsuits against Pfizer, said the company "will be seen to be doing the right thing" with its notification effort.

"My concern is that it is too little too late. We've been urging them to do this for some time," Mr. Evans said.

Even when the patients are warned of the potential implant defects there is little they can do except wait, because the risk of dying in surgery to replace the valve is greater than the chance of the implant breaking, said Dr. Roger Sachs, a spokesman for Pfizer.

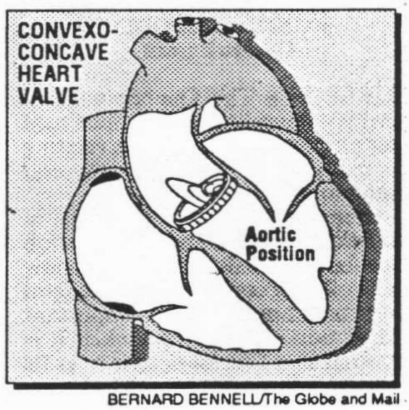
Each year, on average, seven out of every 10,000 implants fail. By contrast, 5 per cent of patients who undergo open-heart surgery die as a result of the operation.

"There is no way to tell in advance if a valve is going to break," he added. So the patients are being urged to watch for the warning signs of a problem and then rush to a hospital when it occurs, Dr. Sachs said. The warning signs can include chest pains, shortness of breath, dizziness and unusual sounds from the device. Some patients may even become unconcious.

Mr. Sachs added that no artificial implant is risk free, and that the artificial heart valves have been responsible for prolonging thousands of lives.

The valves in the heart are designed to keep blood flowing in one direction. In individuals with heart disease, the valves may not open up fully and thereby prevent enough blood from flowing through. Or else they may not close properly, resulting in a backflow of blood.

The artificial valve, which allows the blood to flow normally, was first developed in the 1950s.



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