

Recycling pacemakers could save lives in needy countries

December 20 2010, By Michele Munz

In the United States, pacemakers cost \$10,000 to \$50,000 to implant. About 100,000 Americans undergo the surgery each year. These lifesaving devices, however, are mostly discarded in medical waste or buried with people when they die.

"We just throw it away," Don Paluczak, a funeral director at Kutis Funeral Home's Affton location.

Meanwhile, in poor counties, about 1 million people die each year from not having access to <u>pacemakers</u>, according to Heartbeat International, a nonprofit group that delivers expired devices from pacemaker manufacturers to countries in need.

Instead of throwing the devices away, University of Michigan researchers are asking people to drop them in the mail.

They say they plan to sterilize the devices, ship them overseas and show that recycling pacemakers is feasible and ethical.

"It is our hope with this project to once and for all prove that this is safe and effective therapy for those who can't afford the device," said Dr. Timir Baman, cardiac electrophysiology fellow at the University of Michigan Hospitals and co-founder of Project My Heart-Your Heart.

The silver-dollar-sized device is implanted to correct a slow or <u>irregular</u> heart beat that can lead to fatigue or fainting. Depending on how hard



the device has to work, it can last up to 10 years.

Baman said the idea for Project My Heart-Your Heart came from one of his patients who told him she wanted her pacemaker donated for reuse after she died. Baman chuckled at the thought, but she persisted. He looked into it and found that while the FDA forbids the implantation of used pacemakers within the U.S., prohibitions on sending them abroad are fuzzy.

He found that a number of little-known charitable organizations have done it with great success. <u>Sterilization</u> and battery-life testing procedures were well-established, and more than a dozen studies across the world have shown reuse to be safe.

Bill Daem, a retired firefighter in Billings, Mont., has been sending postmortem pacemakers abroad since starting Heart Too Heart in 1994. Daem had come across an undertaker with a drawer full of pacemakers because he couldn't bear throwing the expensive devices away.

When a person is buried, so is the pacemaker. But if the deceased is going to be cremated, pacemakers must be removed because the devices can explode. Most funeral workers ask the family if they would like to keep the device or have it discarded.

Some funeral directors in the St. Louis area say they occasionally have family members who, without explanation, want to keep the device. If the family doesn't want it, they dispose of it. They keep no records on the numbers, the said.

Paluczak said Kutis Funeral Homes has participated in eyeglass and hearing-aid recycling programs, but he has never heard of one for pacemakers, "To our knowledge, there's no program here we could give them to," he said. "I've never been able to find anyone who handles and



takes the pacemakers."

The National Funeral Directors Association advises against shipping the devices.

The association consulted with the FDA and issued a legal advisory three years ago warning funeral directors that if they shipped pacemakers, they would be considered medical device distributors subject to federal and state legal requirements, such as licensing and record keeping. "Funeral directors that ship devices to a charitable organization are violating device distribution laws and are at risk for sanctions," the advisory stated.

Researchers at the University of Michigan are in the process of seeking FDA approval to ship and export the devices to remove any legal concerns, Baman said. Once they have approval, they plan to conduct a clinical trial testing the safety of the collection process and long-term success of the implantation surgery.

"We are trying to create a model that can be reproduced on a larger scale," Baman said. "There's been a lot academic institutions who have expressed interest in what we are doing. They are following us to see what kind of model we set up, which is we why we are being extremely diligent."

Funeral directors can request free postage-paid shipping boxes through www.myheartyourheart.org, and with the families' consent, ship pacemakers to the researchers. Baman said they hope to collect 250 pacemakers with a battery life greater than 70 percent.

Once FDA approval is gained, researchers will partner with World Medical Relief Fund, a Detroit-based nonprofit that specializes in the delivery of used medical equipment, to send the pacemakers to hospitals



in Manila, Philippines and Hanoi, Vietnam.

Baman was with a group of doctors who visited the hospitals to ensure the implantations could be done safely. They also saw the need firsthand.

"There were individuals being turned away from clinics who needed pacemakers," Baman said. "Some were in the hospital on temporary pacemakers and waiting for a donation to come." Temporary pacemakers are outside the body and require patients to stay in the hospital.

Demand is great, Baman said. Poor countries suffer high rates of cardiovascular disease. And in some Latin American and African countries, many people suffer from parasitic infections such as Chagas, which can disrupt the heart. Even though some foreign pacemaker manufacturers have reduced the cost of the device to \$800, the price can still be out of reach.

To determine how well Project My Heart would be received, the scientists conducted a survey of 100 patients and 90 funeral home directors in the Ann Arbor area. A resounding 87 percent of patients said they would be willing to donate their device to people in need in other countries, and 89 percent of funeral directors said they would be willing to send the devices to charity of given the chance. The survey also showed the directors retrieve an average of 27 devices a year.

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