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Heading: Baptist Heart Institute Investigates Early Heart Attack Detection Device
By ANN METZ

Morristown resident Darlene Bell, 61, calls the AngelMed Guardian® system her lifesaver.

"I have an extensive history of heart disease, and I have spent a lot of time in the hospital," she explained. "I am also a very active and busy person… This early warning device gives me peace of mind."

Bell, who works for the Jefferson County Baptist Association, was the first person in Tennessee to be enrolled in the DETECT Feasibility Study at the Baptist Heart Institute at Baptist Hospital of East Tennessee, Knoxville. She was successfully implanted with the device on November 19, 2007, by Dr. Stephen Hoadley, a board-certified interventional cardiologist with East Tennessee Heart Consultants, PC.

Baptist is the only hospital in Tennessee, and one of just three medical facilities nationwide, to implant the new internal monitoring system that checks for signs of an impending heart attack.

"I didn't have a family history of heart disease and I didn't smoke," Bell said. "Yet I started experiencing chest pain. I was diagnosed with coronary artery disease in 2002 and had three stents placed. I continued to have chest pain and was in the hospital every six months or so. I had more stents placed, followed by angioplasty and triple bypass surgery in 2006. Today, I have aggressive coronary artery disease.

"Heart disease had hindered my ability to function as a normal human being," Bell said. "I was a perfect candidate for this device. Since it was implanted in my chest, I have traveled out of town for my job, which I was hesitant to do before. For me, it was an easy procedure with no side effects. The device does stick out a bit, but I'm not so concerned with looks anymore."

According to Dr. Malcolm Foster, a board-certified interventional cardiologist and principal investigator for the DETECT Feasibility Study, the AngelMed Guardian® system was developed to help reduce the time it takes patients to get to the emergency room when they have a heart attack. The objective of the 36-month study is to provide a preliminary assessment of the safety and effectiveness the experimental device.

"There is no other device like it with rival technology," Foster said. "It is far more sensitive than EKG in the diagnoses of a heart attack. And because it is implanted, it is much more precise, sensitive and specific."

Components of the diagnostic monitor include a pacemaker-sized device that is implanted under the skin in the upper left side of the chest; an endocardial lead and lead adapter; a pager-sized portable external alarm device; and a laptop computer that is used by the cardiologist to program the device.

The device works by continuously monitoring the heart's electrical signals for changes that may indicate a heart attack. If the monitor detects an abnormality,

it will alert the person to seek immediate medical attention by vibrating gently underneath the skin—similar to a cell phone vibration. It will also send a signal to the external alarm device, which will then start beeping. A light on the external alarm device also will flash to indicate what type of alarm is being signaled.

The system can also warn the patient if the device detects problems that prevent it from working properly. In these situations, the patient will be alerted to visit their physician for an evaluation of the device.

For Bell, the device has already done its job. Soon after it was implanted, Bell experienced pain in her left arm and left jaw. The device also registered a "call doctor" alarm. Her cardiologist was able to quickly review the data from the device, which indicated that Bell's medications should be adjusted.

"This reassured Darlene and her doctor that she was not having a heart attack," Foster said.

"This device is amazing," Bell added. "I am happy to make my contribution by participating in this study."

Even though the device is implanted in the same manner and resembles a pacemaker, the use and implantation of the system is considered experimental.

"If the AngelMed Guardian proves to be safe and effective, we may have a paradigm shift in the early detection and warning of heart attacks for high risk patients," Dr. Foster said. "After the feasibility study, we look forward to participating in a large, multicenter pivotal trial."

The Baptist Heart Institute has enrolled three patients in the DETECT Feasibility Study, and hopes to enroll three to five more patients. A total of 20 patients nationwide will be part of this initial study.

According to Foster, the Baptist Heart Institute has five full-time research coordinators and has participated in 30 clinical trials since its inception seven years ago. "We are among the top sites in the nation for cardiovascular studies," he said.

For more information on the study and the AngelMed Guardian system, call the Baptist Heart Institute at (865) 549-7535.

[PHOTO NOTES: Mug shot of Dr. Malcolm Foster and photo of Dr. Stephen Hoadley implanting the device in Morristown resident Darlene Bell.]