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Doctor's invention aims to prevent surgical mishaps

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Surgeries performed on the wrong organ or limb, or even on the wrong person, are rare, but a Washington University School of Medicine physician thinks he has a solution to prevent them.

Dr. Richard Chole's CheckSite System is being used in six health care centers across the United States, including Center for Advanced Medicine, a partnership between Barnes-Jewish Hospital and Washington University.

The system uses a patient wristband with a microchip, and two sensors near each operating room door. If the operating team does not mark the proper spot to operate on a patient and fails to place a sticker on the wristband to deactivate the microchip, the sensors sound an alarm.

"Wrong-site" surgery is "unacceptable but rare," according to a 2006 study funded by the federal Agency for Healthcare Research and Quality. Last year, 77 cases of wrong-site surgeries were reviewed by The Joint Commission, a nonprofit group that accredits health care organizations nationwide and sets patient safety standards. That's down from 88 operations reviewed in 2005.

Chole got the idea for his system after a discussion at a medical staff meeting in 2004 centered on wrong-site surgeries. Shortly afterward, Chole saw security sensors in Home Depot and hatched a way to track the pre-operation procedure. He initiated the patent process in spring 2004 and launched CheckSite Medical Inc., a Town and Country company formed to develop and distribute the product.

The system was developed in several months and testing was completed by spring 2005, said Stephen Chole, Richard Chole's brother and the president of CheckSite Medical. Parts of the system are manufactured by suppliers in the United States and Shanghai. The patent on the system was approved in July.

With the CheckSite System in full production for about six months, six health care facilities have adopted the system, five more have pledged to buy it and about 50 are considering the product, Stephen Chole said.

Other technologies similar to the CheckSite System exist. One of them is SurgiChip, a device that uses radio frequency identification, or RFID, to encode patient information on a tag. The tags are then electronically read by handheld machines before surgery to verify identification.

Bruce Waxman, president of Palm Beach Gardens, Fla.-based SurgiChip Inc. and the inventor, said launching the product in a hospital costs about \$50,000. A tag costs about "\$4 to \$5," he said.

Stephen Chole said SurgiChip Inc. is an "indirect competitor." Chole said his product is cheaper, simpler and more effective.

Wristbands for the CheckSite System cost hospitals \$2.50 per patient, Stephen Chole said. The sensors cost about \$3,000 per pair, but hospitals that perform

more than 10,000 surgeries a year receive the sensors on loan for free, Stephen Chole said.

Marigrace Clarke, a perianesthesia nurse who works in the Center for Advanced Medicine, said the CheckSite System "has proven helpful" in the last two years.

"There have been cases of where the alarm went off," she said, adding the detectors aren't the last safety barrier. The Joint Commission requires doctors and nurses to stop just before surgery and agree that the site to be operated on is accurately marked.

Clarke said she hopes "for patient safety reasons that (the CheckSite System) would spread to other hospitals."

But the Chole brothers said marketing and distribution has been difficult. It can take months for a hospital to decide to buy the system because changes in procedures and products must be approved by doctors, nurses and hospital administrators, Stephen Chole said. Still, Stephen Chole said his goal is to have 150 hospitals using the system by the end of next year.

Richard Chole was optimistic about his invention's usefulness: "If you were having surgery on your knee, and you knew ... (for \$2.50) you could have a wristband that would change your (wrong-site) risk to zero, which would you choose?"

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