The Food and Drug Administration (FDA) gave approval in November for the sale of a radiofrequency identification (RFID) tag nurses can attach to patients like a Band-Aid to prevent wrong-site surgery.

The tag, developed by Bruce Waxman, MD, president and founder of SurgiChip Inc, Palm Beach Gardens, Fla. is the first surgical marker system to be approved by the FDA using RFID technology. The tag system marks an anatomical site for surgery. “Hopefully, SurgiChip will focus everybody’s attention on the patient, site, and procedure. It is hard to ignore when surgeons come in (to the OR), use the RFID scanner to read the chip, and know that the site is correct,” says Dr Waxman, an orthopedic surgeon who practices in Palm Beach Gardens, Fla.

SurgiChip is an added safeguard against wrong-site surgery on any body part or head area, Dr Waxman says.

In July, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) began requiring accredited facilities to follow its Universal Protocol for preventing wrong surgery. The protocol requires marking the surgical site and having a “time-out” immediately before the procedure to confirm the patient’s identity, site, and procedure. “You still have to follow the Universal Protocol and sign the site,” Dr Waxman says. “If people did that, there would be fewer errors. People forget sometimes.”

The JCAHO has identified about 350 cases of wrong-site surgery in its database, although some experts believe dozens of wrong-site surgery mistakes occur each year that are not reported.

How does SurgiChip work?

According to the FDA, the patient’s name and site of surgery are printed on the SurgiChip tag. Inside is a chip encoded with the type of surgery, date of surgery, and the surgeon’s name. Before surgery, the tag is scanned, and the patient is asked to confirm that the information is correct. On the day of surgery, the tag is scanned again and reconfirmed by the patient before the patient is sedated.

The patient helps stick the tag, which has an adhesive backing, near the surgical site. OR nurses scan the tag again to compare that information with the patient’s chart. Before surgery, the tag is removed.

The SurgiChip system is expected to cost $20,000 to $60,000, depending on the size of the facility, and each tag will cost about $2 to $3, Dr Waxman says. The system consists of a tag, labeled with an integrated passive transponder; an encoder; a device that can read the chip; and a printer that encodes the tags. AMTSystems, Cheshire, Conn, developed the system’s software and will provide marketing assistance, says Dr Waxman. The software would be downloaded by each facility.

Using SurgiChip “will take a little longer for nurses” than the current surgical site confirmation system, but from the standpoint of safety, he says, “it will be well worth the time.” He estimates the whole process takes about 4 minutes.

“The surgeon reads the tag, positions the patient, scrubs, goes back to the OR, and instructs the assistant to take the tag off,” Dr Waxman says. “You can take the tag off before (final surgical) prep, but I recommend after.”

He says he has tested the equipment in his office and found the process works well. He now will do studies at 156-bed Jupiter Medical Center in Jupiter, Fla, to compare the efficacy of the chip and handheld readers. Dr Waxman, who is in a
group of 13 orthopedic surgeons, says, “Some think it is wonderful, and some think it will slow things down. The majority feel it is a good idea.”

Tags catch on

SurgiChip’s FDA approval is the latest in a flurry of efforts to use RFID technology in health care for tracking medications, supplies, and equipment. Patient tracking can be done by wristbands, tags, and a chip inserted under the skin.

Earlier this year, the FDA approved RFID to track pharmaceutical drugs. By 2007, the FDA will require pharmaceutical companies to place bar codes or RFID chips on all hospital drugs.

The FDA also approved VeriChip for use in humans. The chip, made by Applied Digital Solutions, Delray Beach, Fla, is implanted under the patient’s skin to provide health care workers with medical record information, says spokesman Len Hall.

Later this year, a pilot study using RFID wristbands is expected to begin at 300-bed Valley Presbyterian Hospital in Van Nuys, Calif. Surgical nurses will use readers to scan patients with RFID wristbands before surgery to ensure the correct body part is operated on, says Irwin Thall, manager for RFID in health care with Precision Dynamics Corp, a San Fernando, Calif-based company.

—Jay Greene

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