

RFID for Medical Device and Surgical Instrument Tracking

Ensuring patient safety and quality of care has become an increasingly technology-reliant process for most healthcare providers. In addition to electronic medical records (EMRs), automated medical administration systems, and other solutions, many hospitals are turning to automatic identification technology such as RFID to track assets, medical devices, and surgical tools.

Automated asset tracking helps improve efficiency and save costs for hospitals, which are tasked with managing hundreds of pieces of equipment across large facilities. Nursing staff may waste precious minutes searching for a wheel chair or IV pump. Surgeries may be delayed because a critical piece of equipment can't be found. Automated tracking saves time and helps organizations avoid unnecessary purchases to replace hard-to-locate equipment.

But this type of tracking also improves patient safety. Because of human error, it can be difficult to accurately account for all of the required surgical tools before, during, and after a procedure. Accuracy can also be compromised by incorrect instrument lists, untrained personnel, or time constraints. Hand counting these instruments can affect turn-over time for the operating room, and compromise quality of care.

Accurate medical device tracking also plays a role in accreditation and compliance with government regulations. For instance, in an effort to improve patient safety, the Joint Commission (JCAHO) developed the Universal Protocol to avoid wrong site, wrong procedure, and wrong person surgery errors. Part of the protocol includes verifying the items and surgical tools required for the procedure using a standardized list.

Those items should be checked before and after the procedure to ensure that everything necessary is already in the operating room before the procedure starts, and to make sure that no surgical instrumentation is lost or left inside the patient after surgery. To prevent these types of errors, all surgical items are recounted and inventoried after a procedure. If an item is missing, staff must locate it before the procedure can be completed, at a cost of hundreds of dollars per minute of clinical time.



In the case of medical device manufacturers, automatic identification technology can help meet the U.S. FDA's new Unique Device Identification (UDI) tracking requirements in a matter of seconds. The UDI program was developed to provide more accurate tracking of medical devices in the healthcare industry in order to speed product recalls and improve patient safety. Starting in 2014, different classes of medical devices are required to include a permanent mark containing a unique identifier and manufacturing information. The number of devices that fall under UDI will be expanded each year through 2020.

The information on from the device labels will be centrally managed via the Global Unique Device Identification Database (GUDID), making it available to stakeholders across the healthcare supply chain. In addition to improving safety, UDI can help manufacturers better manage and track inventory. Healthcare organizations such as hospitals could also use the UDI to manage inventory or to track devices internally.

FDA UDI INFO
UNIQUE DEVICE IDENTIFICATION (UDI)

The UDI information can be encoded on the device using 2D bar codes, direct part marking, or via RFID tagging.

RFID: Solving the Medical Device Tracking Challenge

Rugged RFID tags that are designed to withstand the rigors of the healthcare environment, as well as harsh sterilization processes, can be used to automate aspects of the Joint Commission's Universal Protocol, as well as meet FDA UDI requirements.

For medical device manufacturers, RFID tags can be used to identify each device uniquely. More importantly, RFID does not require line-of-sight scanning (like bar code labels or direct marks would), so items can easily



be scanned even when the UDI tag or label is not visible. RFID tags can also store additional information, and provide other stakeholders in the healthcare supply chain (like distributors or hospitals) to manage these assets using RFID portals in their own facilities.

RFID tagging individual surgical instruments allows hospitals to document each instrument's vital statistics (image, name, manufacturer, manufacturer's ID number, date of purchase, number of sterilization cycles, repair history, and location). This provides safety, asset management, and cost savings benefits for the health care institutions, both in and out of the surgical suite.

So Much More than Asset Tracking: The Surgical Safety Scanner

There are already RFID solutions in existence targeted at solving these tracking and identification challenges. For example, the Surgical Safety Scanner system from Surgical Scanner LLC was designed to help healthcare organizations achieve automated, accurate surgical counts and billing for surgical services, as well as complete inventory tracking of instrumentation. To meet UDI requirements, the solution contains a 32-bit device identifier (DI), along with the capability to encode the image, name, manufacturer, manufacturer's ID number, date of purchase, number of sterilization cycles, repair history, and location on an RFID tag.

The core of the system lies in unique RFID tagging of instrumentation. The Xerafy RFID tags used for the application are unique for their ability to withstand the decontamination and sterilization processes with no damage to the RFID tag. An easy to use hand held scanner is utilized to identify and view the instruments individually or in groups (sets/trays) within seconds on a screen rather than only by an individual's visual assessment. After scanning, the user can find additional information for each instrument in the operating room, decontamination area, central sterile supply, or throughout the facility as needed by multiple departments. For customers that are already utilizing a 2D scanner system, the company offers an RFID scanner with a 2D bar code scanning option to list the tools on the screen in the same way, making the transition to RFID very easy and simple.



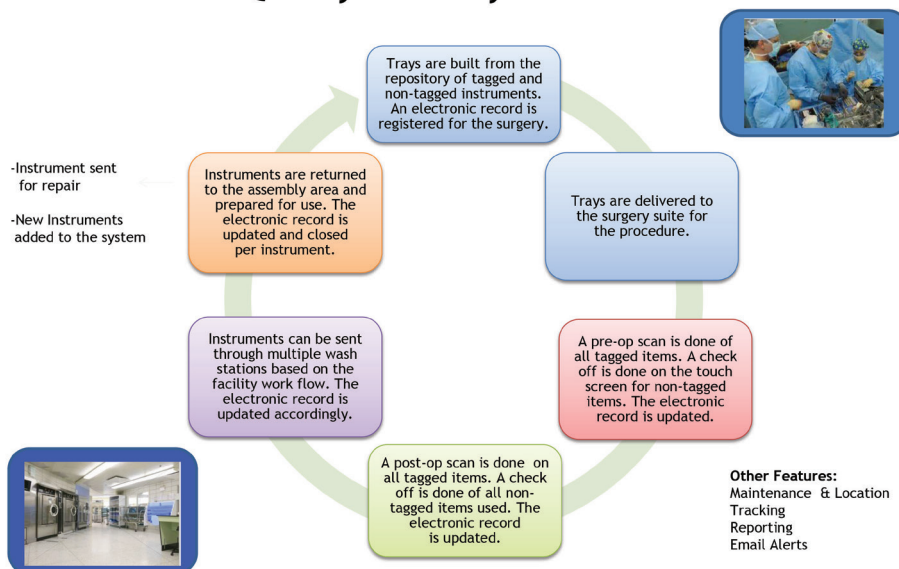
Xerafy Autoclavable Dash XS attached on a surgical instrument

The implementation of the Surgical Safety Scanner System begins with the attachment of an RFID tag to each instrument. This is accomplished using a FDA approved method that does not compromise the function of the instrument. As each instrument is tagged and counted, a master list of instruments called the repository is created. Instrument lists for sets/trays are built from the repository. Instruments can be grouped together or listed separately with the required level of specificity. For example, the instrument list requirement for compliance with the Joint Commission can be fulfilled by including the correct number and generic type of instruments, rather than the specific instrument(s). For example, six baby allis (a type of forceps) would fulfill the requirement; not six specific baby allis with their specific RFID tags.

Prior to sterilization, staff scans the instruments within a set/tray to confirm 100 percent accuracy of the list and actual instrument match. Any instruments not present would be highlighted in red on the screen of the handheld reader until the discrepancy is corrected. Once instrument trays/sets are built and sterilized, a scanner is used by OR personnel to complete required counts instead of requiring the staff to visually match instruments against a list.

JASPIR'S CYCLE OF SURGERY

Quality & Safety Innovations



Scanning over the instruments provides a visual count on the screen as well as documentation of the time and place of the count. Again, missing instruments would be highlighted in red. The count is verified as complete or incomplete in seconds instead of minutes. Completing rapid, correct, and well-documented surgical counts provides immeasurable patient safety improvements, as well as cost savings related to turnover time. Another component of the system allows non-scannable items to also be tracked in the OR suite for preference list building, counting, re-stocking of supplies, pricing, and billing purposes.

Post procedure, an institution may also choose to account for instruments at various stages of decontamination and set assembly prior to re-sterilization by scanning. Utilizing this feature may further assist with loss prevention cost savings. The system can also provide staff with the ability to immediately locate instruments within a facility. A further consideration for implementation is the capability of tracking the life cycle of an instrument. This feature includes tracking when an instrument is sent for repair or when sets/trays are loaned out. Additionally, when instruments are retired, all information necessary for replacement is readily available.

Conclusion

By utilizing Xerafy's autoclavable RFID tags and surgical tracking management solutions designed for the healthcare environment, organizations can automatically track critical equipment, ensure the correct tools are available for each surgical procedure within seconds instead of hours, and improve patient safety and outcomes. Medical device manufacturers can also meet the requirements of the FDA UDI program via RFID, in addition to providing a means to enable additional tracking applications up and down the supply chain—including within the hospital.

*Track all of your tagged and non-tagged
instruments and miscellaneous supplies
in and out of the suite.*

About Xerafy

Xerafy's innovations have changed the price performance ratio for RFID tags and made it possible for customers to track assets in a wide range of harsh environments. Xerafy provides read-on-metal tags that can be embedded directly into assets to meet a full range of needs for RFID asset tracking in the aerospace, industrial, data center, healthcare, energy and other industries. Xerafy is headquartered in Hong Kong and maintains U.S. sales and support offices in Dallas and Houston, and additional offices in the U.K. and China. Learn more about Xerafy's Healthcare expertise by visiting www.xerafy.com/en/application/healthcare and on Twitter at @Xerafy.

About Surgical Scanner LLC

Surgical Scanner LLC, of Brighton MI, has spent the last four years doing research development and testing for the Surgical Safety Scanner system. The system is a multifaceted solution for the problems encountered by hospital surgical suites, surgery center and dental offices when striving to achieve accurate surgical counts, and instrument history. Utilizing RFID unique identification tags for each instrument, the system is able to track instruments with vital statistics (image, name, manufacturer, manufacturer ID number, date of purchase, number of sterilization cycles, repair history, and location). This is the ultimate safety, asset management, and cost savings solution for health care institutions, and dental offices, that are looking to increase patient safety and improve patient outcomes. More information on Surgical Safety Scanner system may be found at www.surgicalscanner.com



SURGICAL
SAFETY SCANNER

