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. With 4,000 reported Retained Surgery Items cases a year in the US alone, hospitals have turned to automatic identification technology such as RFID to track medical devices and surgical instruments. Leading hospitals like the Mayo Clinic's Saint Marys Hospital in Minnesota and Rush University Medical Center in Chicago have deployed RFID to track equipment, surgical instruments, and staff members.

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 with hard-to-locate equipment, including the all too elusive collections of $15,000-a-piece endoscopes.

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 instruments 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 instruments required for the procedure using a standardized list.

O.R. in China during onsite institution survey (Source: Xerafy)

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. When an item is missing, staff must locate it before the procedure can be completed, at an average cost of $1,800 per hour in the surgical suite.

Sterilization equipment at U.S. hospital (Source: Xerafy)

In the case of medical device manufacturers, automatic identification technology can help meet the U.S. FDA's 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.

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)

⬆ Assembly station at SPD department in hospital in Brazil (Source: Xerafy)

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.

⬅ Review of SPD process at U.S. hospital during onsite institution survey (Source: Xerafy)

So Much More than Asset Tracking:
Xerafy's Surgical Instrument Tracking (SIT) Solution

Xerafy's Surgical Instrument Tracking solution is targeted at solving these tracking and identification challenges in the surgical suite.

⬆ Review of SPD storage at U.S. hospital during onsite institution survey (Source: Xerafy)

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The core of the solution lies in unique RFID tagging of instrumentation. The Xerafy RFID tags and attachments methods used are unique for their ability to withstand the decontamination and sterilization processes with no damage to the RFID tag.. Fixed and hand held scanners are utilized to count and identify 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.


⬆ Xerafy Autoclavable Dash XS attached on a surgical instrument (Source: Xerafy)

The implementation of the Surgical Instrument Tracking solution begins with the attachment of an RFID tag to each instrument. This is accomplished using hospital-validated attachment methods that do not compromise the instruments. As each instrument is tagged and counted, a master list of instruments is created.. Instrument lists for sets and trays are built from the master list. Instruments can be grouped together or listed separately based on kits, count sheets and preference cards.. 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, Assembly personnel scan the instruments within a set/tray to confirm 100 percent accuracy of the list and actual instrument match. Any instruments not present would be flagged until the discrepancy is corrected. Once instrument trays/sets are built and sterilized, a scanner is used by OR nurses to complete required counts instead of requiring the staff to visually match instruments against a list.
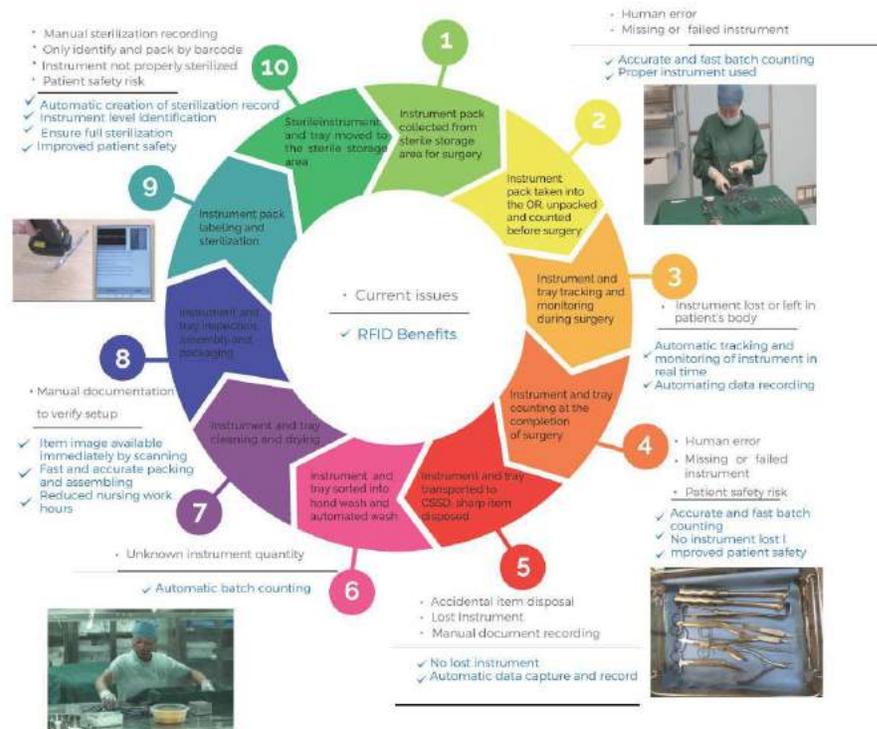
Scanning over the instruments provides a visual count on the screen as well as documentation of the time and place of the count. Again, missing instruments in the OR would be flagged. The count is verified as complete or incomplete in seconds instead of minutes. Completing rapid, accurate, and well-documented surgical counts provides immeasurable patient safety improvements, as well as cost savings related to OR 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.

Review of OR hardware options at Brazil hospital during onsite institution survey (Source: Xerafy)

Post procedure, an institution may also choose to account for instruments at various stages of decontamination and set assembly prior to re-sterilization. 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

Analyzing the data that RFID generates will be the next phase of IT innovation in hospitals according to Harvard Business Review. By deploying Xerafy's autoclavable RFID tags and surgical instrument tracking solutions designed for healthcare, institutions can automatically track critical equipment, ensure the correct sets 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.

About Xerafy

Xerafy's game changing technology enables real time traceability for the industrial market to drive safety, reduce costs and facilitate digital transformation. We power data through products and solutions in Healthcare, Aviation, Manufacturing and Oil & Gas. Over the years, Xerafy has been distinguished by many awards such as the Global Red Herring, EY and Frost & Sullivan. Headquartered in Singapore, Xerafy has offices and operations in U.S., U.K. and China.