Strategies for Ensuring Integrity for Medical Tissues and Devices

RFID technologies offer near-real time safe and secure item-level visibility

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Recent advances in medical device technology, surgical procedures and tissue preservation are revolutionizing the health care industry. Most experts agree that we have just scratched the surface of the potential that this new medicine offers. However, this expanded capability requires an equally sophisticated system to track devices, prosthetics and tissues as they move through the supply chain. A mistake or shortfall at any point can have serious consequences both to the patient and the provider.

Although the demand for supply chain integrity applies to all aspects of medical technology, its apex is in human tissues. The growing network for harvesting, storing and distributing viable cells and organs brings significant new safety concerns and requirements for tissue banks, hospitals and surgical facilities. Defining the processes by which these materials are collected, stored, distributed and used is a cooperative and collaborative effort of many oversight entities. Among the key players are the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the American Association of Tissue Banks (AATB). In addition, various state and local agencies as well as the human tissue industry itself, also contribute.

The extraordinary degree of scrutiny that's been applied to the supply of human tissues is certainly merited. This network clearly requires the highest standards of accuracy, accountability and control. Concurrently, the number of agencies involved adds a significant measure of complexity to the regulatory environment. Thus, if challenged to develop a system for tracking items from origin to use, one could not find a more complex or demanding model than human tissues. How can RFID technology be applied in this demanding environment?

Human Tissues — The Critical Case

Recognizing the unique requirements of this industry, the FDA issued guidelines in 2005. These covered everything from donor eligibility to inspection protocols. Here, the FDA also established Good Tissue Practices (GTPs) as they relate to human cells, tissues, and cellular and tissue-based products. The materials covered include skin, eyes, musculoskeletal tissue, eggs and sperm, veins, blood stem cells, and membranes, among others.

The FDA tailored its regulations to the degree of risk posed by each product. Like blood and other body fluids, these are living materials that can provide life-saving benefits. However, these tissues can also transmit disease. When you consider that one human donor can affect many patients, the complexity of tracking all these cells, tissues and organs as they move through the supply system becomes apparent.

The goal of the FDA and the other aforementioned groups is to make human tissues safer, and to verify that their sources of supply and delivery are fully documentable and accountable. This effort aims to protect the public health while not imposing unnecessary restrictions on research, development or the

availability of new or existing transplant and grafting products. The level of documentation demands a new standard of precision in tracking and inventory control.

The industry is exploring a variety of methods for meeting these tracking standards. One of these, Radio Frequency Identification (RFID), offers certain unique benefits and advantages over other methods. These include ready applicability, efficiency in achieving the required supply chain precision, minimal associated labor and reduced likelihood of human error. Although most people understand RFID, the scope of its application here requires further elaboration.

RFID Overview

The foot soldier in RFID is the chip or tag. Generally, this is a small, read-only device that can transmit its stored information without an internal power source. RFID tags can easily be incorporated into conventional labeling systems such as those that carry bar coded delivery and tracking data. However, unlike bar codes, RFID tags do not require line-of-sight scanning.

The second element in the system is the RFID reader. This is a transmitter that broadcasts a tuned frequency signal. When an RFID tag comes within range, its circuitry is activated by the energy of the reader's signal. The tag responds by transmitting its stored data back to the reader. The information gathered by the reader can then be logged into a local network and subsequently stored or uploaded to the Web or other wide-area network.

RFID chips are available in a variety of read formats. Some rely on narrow bandwidths that can offer a measure of security against unauthorized access.

This may be an important consideration if the tag must carry sensitive information. However, there's a trend to use RFID systems that are based on global standards such as UHF Gen 2. This allows various inventory management systems in the item's supply chain to log its presence.

If sensitive information needs to be included, encryption technologies can offer protection against unauthorized access. Alternately, the tag can carry ID numbers only and have any additional information stored in a secured database that's accessible to authorized users via the Web or other network.

The final element needed in this application is called an RFID cabinet. This is where the individually tagged product or material is stored until use. The cabinet's built-in readers record a tag as it enters or leaves. Access to the cabinet can be restricted to authorized personnel who must use an RFID-based pass key or even biometric identification. Thus the person accessing the cabinet and the event involving the tag are documented in the system.

If a special storage environment is required, such as temperature or humidity control, the cabinet can be designed to maintain those conditions. Through continuous feedback from sensors, the cabinet monitors storage environment and provides a documented record of storage conditions.

A Web-based system can simplify communication between all elements of the system by eliminating the need for a special dedicated network. Current security protocols offer more than adequate protection for transmitted data. These systems can also be designed so that hardware, software and services combine as a turnkey solution for consignment supply with vendor-managed inventory control, or host-site internal inventory control of tissue products.

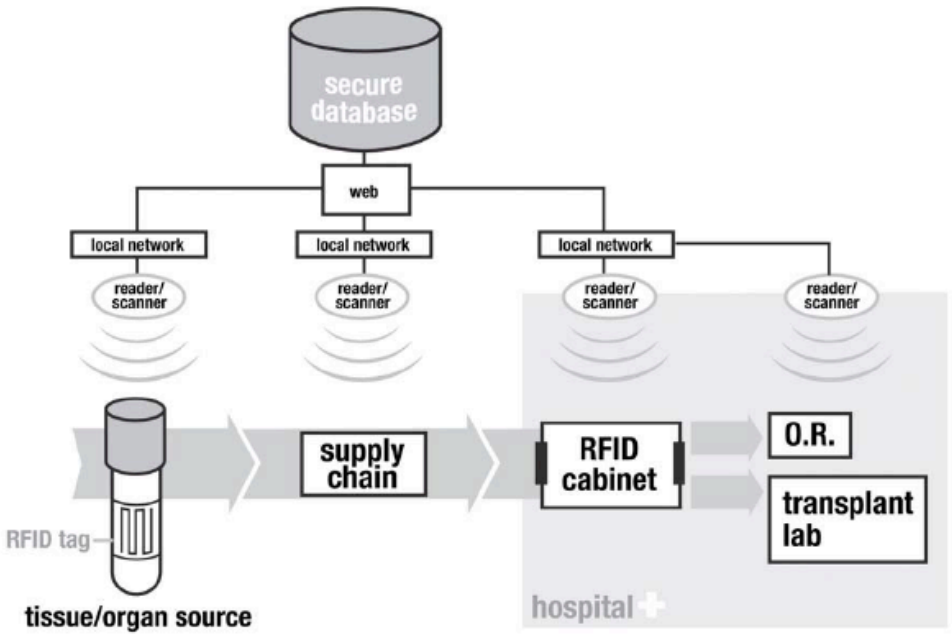

Figure 1. How RFID technology can be implemented in the human tissue supply chain

Application Scenario

A tissue bank receives an order for 10 pieces of tissue that need to be sent to a hospital with an RFID cabinet. The tissue bank pulls the requested items from its inventory and attaches an RFID tag to each tissue package. In addition to the RFID tag, the tissue bank gives each tissue product its own bar code label

containing information about the product—the batch number, the unique ID of the product, the expiration date, as well as any additional relevant data needed to meet federal, industry and state tissue-handling requirements. All the critical information is then uploaded to the secure database controlled by the system provider. This sequence of events is depicted in Figure 1.

As the tagged items travel through other steps in the supply chain, they are logged by the local inventory control and tracking systems. The events are subsequently uploaded to the database, thus providing Web-based tracking and status reports to authorized users. Keep in mind that once the data has been initially entered into the system, the remaining steps in the process can be fully monitored and recorded using automated methods.

Once delivered to the final location, the tag is logged as it enters the RFID storage cabinet. An operationally live cabinet would read its entire inventory, both new and existing stock, with each transaction and send the information back to the database.Through the user interface, the system registers that the cabinet has received 10 new products with individually dedicated RFID tags and all associated data. When called for use, the item is logged as it leaves the cabinet and, if readers are present, when it arrives in the operating room or transplant lab.

The human step of having to physically go into the hospital's storage unit and count each individual package is time-consuming and error-prone. The RFID system can perform this function, as well as others, automatically in near-real time and create an instant record. When supported with adequate redundancies, the system can provide a near-perfect archive.

The system can update itself at the time of an event, i.e., every time the cabinet is accessed. The Web-based data services system displays a complete snapshot of inventory visibility as of the last transaction. In this context, near-real time data capture:

- Provides absolute accountability by tracking every transaction, virtually eliminating shrinkage and maximizing revenue, especially for consignmentbased products.
- Reduces the need for physical inventory counts, which lowers overhead costs and eliminates human error.
- Reduces stock-outs, which ensures product availability.
- Reduces expired product, thereby ensuring tissue viability and the prospect of improved patient outcomes.

The near-real time data capture also promotes GTPs by continuously monitoring the temperature inside each cabinet. If there is an incident where the temperature exceeds a set limit, the cabinet can be programmed to send an alarm, regardless of the time, and appropriate notification steps are enacted to inform the host facility and ensure compliance.

RFID cabinets provide a much more accurate view of inventory status. These systems offer a way of protecting against unauthorized tissue entering the supply chain. If a hospital uses such a system, it reduces the likelihood of tissue coming from an unauthenticated tissue bank. The ability to better identify full chain-of-custody for tissue products—where something came from, who supplied it, how was it handled, how was it inventoried and where did it go—is vital.

Records Requirements

People make mistakes. The more steps and processes you force people to follow, the more likely that errors will occur, even under the most rigorous controls. Computers, on the other hand, excel at executing routine, repetitive tasks. This is not to say that humans should be removed from the equation. Rather, the advantages and benefits of RFID technology should be leveraged to take full advantage of the speed, precision and reliability they offer. This also frees medical personnel to focus more of their time and efforts on patient care.

Documenting every detail in the process is an essential element of GTPs, and virtually all other guidelines set by the aforementioned oversight agencies. In general, the record-keeping requirements are rigorous. One of the primary assets of an RFID cabinet system is its ability to follow and document these data retention policies and protocols. For example, a transplant facility could be required to download all data at prescribed times throughout the year with all the transactions and temperature recordings provided in digital and hard copy. In the event of such an audit, the necessary documentation exists in an accessible and accepted format.

To ensure reliability for data recording and communication, the system needs to be engineered with the highest possible degree of validation performance as well as redundancy. Again, this capability is a proven strength of digital technologies. The primary objective is to make sure no data are lost, that all transactions are recorded when they occur, and that the information is promptly and precisely communicated to the data center.

The goal must be to ensure the system is completely reliable in terms of the data capture and communication. Once data enters the system, a robust hardware and data center infrastructure is necessary to ensure its retention. The system must operate under rigorous retention procedures for backup and archival protocols established by the oversight agencies.

Conclusion

Industry standards, coupled with social responsibility, ethics and the consequences of error, act as strong primary motivations for deploying RFID cabinets at the point-of-use for human tissue. Not only does RFID technology provide a currently effective and efficient means of ensuring integrity, it offers the scalability and ongoing security necessary to remain viable well into the future. Above all, RFID stands ready to play a key role in bringing the enormous potential benefits promised by medical science into the daily realities of life and business.

About Terso Solutions

Headquartered in Madison, Wis., Terso Solutions is a wholly owned subsidiary of the Promega Corporation, which develops innovative solutions and technical support for the life sciences industry. Promega began developing RFID-enabled cabinets and freezers, as well as a Web-hosted business application, in 1999 in order to automate product distribution and inventory management of its own high-value products. Terso was spun off from its parent company in 2005 and is committed to bringing emerging RFID technology solutions to new markets. All of Terso's products are certified by the Federal Communications Commission for EMC emissions and have received CE, C-Tick and UL certifications.