2017 Global RFID Surgical Instrument Tracking New Product Innovation Award
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Background and Company Performance

Industry Challenges

With standard medical procedures typically stipulating triple counts for surgical instruments, a hospital's staff typically spends three or more hours per day on inventory management. Frost & Sullivan research estimates that 20% of the time, staff members are unable to find equipment, leading to additional wasted time and loss of the instrument itself. Additionally, instruments left inside a patient after surgery can cost a hospital more than $200,000, including legal defenses, indemnity payments, and the additional surgery needed to remove the instrument. Furthermore, if the clinical staff is unable to find an instrument after surgery, the patient must remain under anesthesia until the instrument is located, resulting in lost time in operating rooms (OR) and staff time.

Outside the OR, it is estimated that 20% of hospital supplies, devices, or equipment are lost or misplaced due to inefficient supply chain management, leading to the OR working at about 50% decreased efficiency due to poor equipment flow.

Some hospitals recognize the inefficiencies of this process and choose to use auto-identification applications such as barcode scanning, optical recognition, and biometrics to track medical supplies. While more efficient than manual counting, these systems have many disadvantages including being slow and unreliable, requiring line of sight, and depending on human intervention — all reducing hospital return on investment (ROI).

To overcome these specific challenges, surgical instrument manufacturers have begun to develop smart solutions relying on radio-frequency identification (RFID). These systems are cost-effective methods for automated tracking and tracing, reducing OR errors, avoiding surgical equipment loss, and improving patient safety.

RFID systems scan surgical instruments before and after surgical procedures, through sterilization and storage, ensuring no instruments are left behind during surgery and that hospital staff can find instruments when needed. The systems can store large amounts of user data and track individual instrument location, history, and sterilization processes. This increases instrument visibility, allowing hospitals to efficiently track the life cycle of individual instruments to ensure optimal instrument utilization.

Frost & Sullivan recognizes a growing demand for RFID technology, as hospitals see fast ROI and increased patient safety from properly prepared and managed surgical trays. Furthermore, Frost & Sullivan estimates that cloud-based RFID systems with integrated analytics accessed through web-based applications will see a greater demand, as the Internet of Things’ influence increasingly affects the healthcare industry.

New Product Attributes and Customer Impact of Xerafy

Xerafy’s Surgical Instrument Tracking system integrates software, hardware, and RFID tags to uniquely meet OR and CSSD needs, particularly regarding:
• Improving patient safety by reducing infection risks and RSI (retained surgical items)
• Fast and accurate unique instrument identification in support of UDI regulatory compliance
• Tracking throughout the whole workflow, leading to optimized processes
• High performance on metal and in contaminated environments
• Automatic real-time identification and effective reconciliation between OR and CSSD
• Capable of withstanding repeated sterilization and chemical cleaning procedures, ensuring reliability and effectiveness over time

Where previous technologies would be hindered by operational limitations, healthcare providers are able to use Xerafy’s technology to monitor the lifecycle of their surgical instruments, to ensure they undergo proper sterilization processes, and to determine when instruments need to be replaced, eventually unlocking further big data benefits.

Intuitive Software

Xerafy designed its software to deliver critical and actionable information regarding asset tracking and traceability. Its intuitive user-interface created with healthcare end-users and environments in mind, reducing training requirements and ensuring an fast implementation process. Finally, the company designed its software to be used with a variety of mobile devices for easy integration into existing workflows and systems and allowing customers to track and find assets on the go throughout their organization.

Hardware Products and Flexible Configurations

Hardware available in various configurations with form factors adapted to blend into existing workflow processes, e.g., antennas embedded in devices, manual or stationary readers. It is adaptable to fit seamlessly in any operational environment and add value throughout the workflow. Xerafy extensively test different configurations for when it comes to speed and accuracy, and have them field-proven for different applications.

RFID-Ready Instruments, Devices, and Equipment

The Xerafy family of UHF autoclavable RFID tags includes market leading devices like the Roswell, XS and XXS tags. They have been designed to specifically meet healthcare requirements. Where other technologies experience drastic limitations, Xerafy’s tags have unique features and capabilities:

• Size - Smallest of tags adapted to fit even the most limited of available surfaces (For instance, the XXS Dash measures 0.26 by 0.08 by 0.08 inches, while the XXS Dot is about half the size of a grain of rice and measures 0.16 by 0.008 inches)
• Metal - Developed to be fully functional in the presence of metal
• Temperature - Tags and glue have been tested thoroughly over the years well above the 1,000 sterilization cycles the industry considers as the lifespan of surgical instruments
• Accuracy - Accurate scanning from three to four feet
• Compatibility - With any ISO:18000-6C reader, allowing providers to use equipment they already operate in their workflow

• Availability - Integrated by leading medical manufacturers, source tagging at point of manufacturing, or instrument retrofit using Xerafy’s FDA-approved glue.

**Review of Implementations of RFID Surgical Instrument Tracking at the Point of Care**

Xerafy’s technology has a track record of successful deployments globally. The following selection presents specific challenges and highlights the uniqueness of Xerafy’s technology.

**2016 - Charité-Universitätsmedizin Berlin (Germany):** “We were able to test all the treatment processes that were used throughout the usual life cycle in test scenarios. There were no problems.” - Sadmir Oasmancevic, CFM Department Head

**Challenges:**

- Recognized as Germany’s best hospital
- Time and costs of tracking and tracing 300,000 surgical instruments are increasing
- Need for support when it comes to instruments’ servicing and documenting their lifecycle
- Finding a technology that bypasses the identification and reading limitations inherent to contaminated instruments
- How to ensure seamless operation throughout the Central Sterile Supply preparation process as well as in-packaging, prior to sterilization

**Results:**

- Usability of retrofitted instruments not affected, as validated by medical staff, while manufacturers were able to confirm existing certifications
- Tags’ durability and performance established over 1,000 sterilization cycles with rigorous testing including chemicals, mechanical stress during transport, material expansion during high temperatures
- Tests on biocompatible glue employed show no risk of dislodgement, while withstanding contact with blood, saline and iodine-containing substances
- Xerafy’s technology will be at the heart of the new Charité Facility Management building scheduled to open in 2017
2016 - HRAEI Regional Specialty Hospital of Ixtapaluca (Mexico): “We urgently needed a solution for the high cost of managing our surgical instruments and operation workflow.” - Jorge Mario Lopez Arango, General Manager

Challenges:

• 246-bed hospital with 13 surgical rooms, serving a community of five million people
• Visual counting procedures result in miscounts and missing items
• Sterilization procedures involve sandblasting in order to remove any deposit due to high mineral content in the water.

Results:

• 97% of the surgical tools in use at the hospital are tracked
• Extensive successful tests through 1,000 autoclave cycles
• Handheld RFID readers and Android tablets in use during sterilization processes, during the building of surgical kits, and prior to each procedure
• Instruments counted within seconds, while remaining in their sterile packaging

2015 - Columbia University's College of Dental Medicine (USA): “Using RFID, we will be able to prove that an item went into an autoclave for a certain amount of time and at a certain temperature.” - Phil Jennette, Assistant Director of Special Projects

"This type of technology allows for complete and accurate tracking of each instrument we use from the time it is dispensed through its utilization, processing, sterilization and return to storage.” - Steven M. Erde, PhD, MD, Chief Information Officer

Challenges:

• A leading dental school and a recognized leader in the use of technology
• Up to 300 instruments kits processed daily by central sterilization
• Need for a reliable and cost-effective solution to improve patient safety by ensuring proper sterilization procedures are followed, and to manage dental instruments
• Looking for a technology that is durable and works well with steel and small instruments, while overcoming the limitations of solutions such as barcoding when it comes to manual scanning

Results:

• 20,000 dental instruments and 1,700 dental instrument cassettes tagged with UHF RFID tags
• Sterilization data are maintained for each instrument and cassette
• Strategically positioned automated readers alert staff and prevent cassettes with missing instrument or not properly sterilized from being used

• Maintenance and sharpening schedules for the instruments are now automatically managed

2013 - Rigshospital Copenhagen (Denmark): “RFID UHF technology provides unparalleled speed and accuracy advantages compared to barcode and other RFID technologies for tracking surgical instruments.” - Dr. Henrik Eriksen, Project Director

Challenges:
• 75,000 surgeries performed each year
• Free up time for better treatment and improve service to patients
• Optimize workflow at central sterile supply departments (CSSD) and surgical theaters
• Finding RFID tags small enough for use on surgical instruments while providing good read range around metals

Results:
• Up to 80 instruments can be counted at once, in seconds, with full accuracy
• Balance of instruments and how surgeons use them are not impacted by the addition of RFID tags
• Tags withstand over 1,000 autoclave sterilization processes, surviving temperatures, harsh chemicals and pressure
• 31,000 hours saved per year in OR procedures alone, based on comprehensive 18-month trial
• First hospital in the world to pilot ultra-high frequency RFID tags for tracking surgical instruments
• First time that all functions related to surgical instruments in a hospital, from the operating room to cleaning and storage, are tracked and traced through a single system
Xerafy’s Commitment to Meeting Customers’ Needs

Xerafy understands the healthcare industry’s specific challenges: focus on patient care and safety, the impact of UDI regulation, the need for effective inventory management, and the drive for growth. While constraints abound, Xerafy’s technology delivers beyond the typical industry constraints and allows hospitals to unlock value and take advantage of new opportunities.

Working closely with an ecosystem of partners, software providers, medical manufacturers, regulatory agencies, and others, we work closely with our customers around the globe with a focus on ensuring each deployment fits into existing workflow processes to minimize change, while meeting all their process needs. Our passion to relentlessly deliver solutions for these challenges has led to focusing on continuous improvement and investing in innovation, including: healthcare regulations-compliant glue, machine-automated instrument retrofit, source tagging at point of manufacture, working with manufacturers to include RFID into the very design of surgical instruments.

Future Advancements and Innovation

Xerafy is among a number of technology healthcare players constantly pushing for patients and hospitals to benefit from technological innovations, and eventually helping deliver the vision of Manufacturer to Patient traceability at the very core of UDI.

At the intersection of technology and healthcare, Xerafy is uniquely positioned to deliver the hardware and software capabilities that hospitals are looking for in solution providers in order to advance patient safety as well as to deliver on ROI, cost reductions, revenues and regulatory compliance, among others. Xerafy’s products are designed as critical building blocks for the Healthcare Internet of Things (HIoT), paving the way for the digital transformation of hospitals through Big Data.

Through selected technology and healthcare partnerships, Xerafy’s products are available in most markets as OEM or retrofit. Increasing adoption around the world provides industry-validation as well as critical insights for future innovation in hardware, software and tags. Xerafy believes its market share will continue to expand with the healthcare industry becoming digitized, as many developed and developing regions no longer ask “if” they will become digitized, but “when.”
Conclusion

Hospitals using manual counting methods or bar-code scanning technologies can waste up to 90 minutes per procedure merely counting instruments before, during, and after a surgical procedure. Xerafy’s Surgical Instrument Tracking delivers high-accuracy tracking and automatic processing, with hospitals typically achieving ROI within six months of deployment.

Xerafy’s innovation capabilities are behind the only RFID tags available in the market that are designed and tested with healthcare professionals to withstand the harshest and most demanding environments: small size, on-metal, autoclave temperatures, chemicals, biocompatibility. They are associated with hardware and software helping to further optimize a hospital’s workflow without the need for additional capital spent on a new compliant tracking system.

These unique technical characteristics allow Xerafy to tag up to 97% of all surgical instruments and allow typical average savings of over $3 million from increased staff efficiency while creating revenue-generation opportunities from additional surgeries conducted with the newly freed operating room time.

For these reasons, Xerafy is recognized with Frost & Sullivan’s 2017 Global New Product Innovation Award in the RFID Surgical Instrument Tracking market.
Significance of New Product Innovation
Ultimately, growth in any organization depends upon continually introducing new products to the market, and successfully commercializing those products. For these dual goals to occur, a company must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding New Product Innovation
Innovation is about finding a productive outlet for creativity—for consistently translating ideas into high quality products that have a profound impact on the customer.
Key Benchmarking Criteria

For the New Product Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—New Product Attributes and Customer Impact—according to the criteria identified below.

**New Product Attributes**

- Criterion 1: Match to Needs
- Criterion 2: Reliability
- Criterion 3: Quality
- Criterion 4: Positioning
- Criterion 5: Design

**Customer Impact**

- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

The Intersection between 360-Degree Research and Best Practices Awards

**Research Methodology**

Frost & Sullivan’s 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan’s research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan Awards follow a 10-step process to evaluate award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

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<tr>
<th>STEP</th>
<th>OBJECTIVE</th>
<th>KEY ACTIVITIES</th>
<th>OUTPUT</th>
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| 1 Monitor, target, and screen | Identify award recipient candidates from around the globe | • Conduct in-depth industry research  
• Identify emerging sectors  
• Scan multiple geographies | Pipeline of candidates who potentially meet all best-practice criteria |
| 2 Perform 360-degree research | Perform comprehensive, 360-degree research on all candidates in the pipeline | • Interview thought leaders and industry practitioners  
• Assess candidates’ fit with best-practice criteria  
• Rank all candidates | Matrix positioning all candidates’ performance relative to one another |
| 3 Invite thought leadership in best practices | Perform in-depth examination of all candidates | • Confirm best-practice criteria  
• Examine eligibility of all candidates  
• Identify any information gaps | Detailed profiles of all ranked candidates |
| 4 Initiate research director review | Conduct an unbiased evaluation of all candidate profiles | • Brainstorm ranking options  
• Invite multiple perspectives on candidates’ performance  
• Update candidate profiles | Final prioritization of all eligible candidates and companion best-practice positioning paper |
| 5 Assemble panel of industry experts | Present findings to an expert panel of industry thought leaders | • Share findings  
• Strengthen cases for candidate eligibility  
• Prioritize candidates | Refined list of prioritized award candidates |
| 6 Conduct global industry review | Build consensus on award candidates’ eligibility | • Hold global team meeting to review all candidates  
• Pressure-test fit with criteria  
• Confirm inclusion of all eligible candidates | Final list of eligible award candidates, representing success stories worldwide |
| 7 Perform quality check | Develop official award consideration materials | • Perform final performance benchmarking activities  
• Write nominations  
• Perform quality review | High-quality, accurate, and creative presentation of nominees’ successes |
| 8 Reconnect with panel of industry experts | Finalize the selection of the best-practice award recipient | • Review analysis with panel  
• Build consensus  
• Select winner | Decision on which company performs best against all best-practice criteria |
| 9 Communicate recognition | Inform award recipient of award recognition | • Present award to the CEO  
• Inspire the organization for continued success  
• Celebrate the recipient’s performance | Announcement of award and plan for how recipient can use the award to enhance the brand |
| 10 Take strategic action | Upon licensing, company may share award news with stakeholders and customers | • Coordinate media outreach  
• Design a marketing plan  
• Assess award’s role in future strategic planning | Widespread awareness of recipient’s award status among investors, media personnel, and employees |
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