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the way you imagined

RFID for Med Devices: Identifying a Partner

A GUIDE FOR OEMS

Introduction

More and more forward-looking OEMs are integrating RFID technology into their medical devices at the manufacturing stage, thus increasing value throughout the supply and use chain. From easier tracking within the factory to the creation of features that enhance patient safety, embedded RFID leads to significant benefits for all stakeholders.

Of course, integrating an RFID tag into a product begins with sourcing the RFID tag itself. There are two ways to do this. The first option is to invest internal resources into engineering, R&D and building of an RFID solution from the ground up. For most organizations, this proves extremely cost-prohibitive. As a consequence, leading medical device OEMs typically turn to an RFID partner with the experience and track record to do the job correctly in an efficient, cost-effective manner.

This guide is designed to help OEMs find such a partner. It will outline what manufacturers should look for in an RFID supplier, present case studies detailing successful engagements and detail proprietary technologies that make true RFID integration a reality.

What Problem Are You Trying to Solve?

Of course, before you begin the RFID integration process, you must first determine what you want to achieve. Will your onboard RFID system be used primarily for configuration management? Chain of custody tracking? Managing the distribution chain? "Pairing" parent devices with child devices? Authenticating genuine consumables? Will it be primarily end-user focused, allowing hospitals and practices to track product lifecycle data, improve loss prevention and easily locate devices? All of the above?

The answer to this question drives not only the tag vendor you choose, but also the rest of the RFID "team" you must assemble. An RFID tag by itself, after all, is not an asset management system; it is the *core* of one, but not a system unto itself. The OEM (and/or the OEM's customers) must deploy proper data collection and information management systems, as well as processes to guarantee the ongoing efficacy of the new RFID-based asset management solution.

This can be accomplished with the help of a qualified RFID consultant (some of which are also tag vendors) or a healthcare-focused system integrator. Once these high-level factors are well established, it is time to begin looking for a vendor that offers the versatile technology necessary to successfully integrate RFID into your medical device product.

What to Look For in an RFID Partner

All RFID providers are decidedly not the same.

Many of the most prominent RFID suppliers are high-volume makers of commodity, off-the-shelf tags. While they often make fine products, they are not in tune with the demands of highly regulated healthcare applications, or with volumes smaller than the millions their overseas factories are designed to produce. In addition, these larger firms have long development cycles, often in far-flung locations, that hinder rapid response to – and close integration with – medical device product development teams.

How can you avoid problems like these? Ask these questions of your supplier before entering into any engagement.

Is their technology "one size fits all"?

Integrating RFID into medical devices is not as simple as affixing an off-the-shelf tag. The technology must be configured to exacting specifications – physical dimensions, environmental tolerances, material properties, read ranges, use cases, etc. At Vizinex RFID, for instance, we handle embedded RFID projects using our proprietary ViziCore™ technology – our patented tag construction methodology used as the basis for low-cost solutions that can withstand the rigors of the manufacturing process, including injection or compression molding, enamel curing and autoclave cycles. This combination of repeatable processes and custom construction means that every project gets an RFID feature set that meets the exact need.

Where are they located?

Integrating RFID into a medical device requires an expert hand – both from the manufacturer and the RFID provider. U.S.-based OEMs, then, are highly advised to turn to a U.S.-based RFID vendor; time zone differences, language barriers and the difficulty of global collaboration can have significant negative impacts on the finished product and the ease and speed of the development process.

What is their experience level?

May RFID tag vendors may boast that they've done "embedded" RFID. In some cases, however, it might only mean that they've affixed an off-the-shelf tag inside a product's case. Vizinex, by contrast, has a long history of successful RFID integrations. Our ViziCore™ tags, customized to meet the exact needs of the customer have been deployed in surgical devices, analytical instruments, oil field equipment, IT devices and returnable containers. These custom tags have been used to store configuration information, for machine to machine communication and to track life cycle and sterilization history, among other functions.

What Does Successful Medical Device RFID Integration Look Like?

By definition, every embedded RFID project is different. This section, however, presents two examples of successful engagements – the problem faced by the OEM, the solution and the results.

Case Study #1

The medical device manufacturer profiled here produces systems that include high-precision end effectors, like endoscopes, that touch or are inserted into patients' bodies. These end effectors must be cleaned and sterilized prior to use in another procedure.

Because the end effectors have particular characteristics and life cycles, information about the effectors is stored in an IC embedded in the chip. This allows the host instrument to correctly identify the effector and its characteristics, and to know the life cycle status of the effector. Each effector has an effective life, and if the device goes beyond the planned life or number of autoclave cycles, it must be retired from service. This is facilitated by the on-board chip.

In early generations of the system, the chip was hard-wired to a connector on the effector, which mated to a connector on the host. Unfortunately, repeated autoclave cycles oxidized these connectors – occasionally causing unreliable connections between the host instrument and the end effector. For safety's sake, any device with this communication error would have to be removed from service, causing operational problems for the customer and imposing

warranty costs on the manufacturer

The demanding life cycle and reliability standards and data integrity requirements are tailor-made for a non-contact secure data link such as that enabled by certain RFID technologies.

Vizinex worked with the manufacturer to develop a solution that eliminated all hard wiring and interconnects between the host and effector. This was accomplished by mounting a reader antenna at the connection point between the system and the end effector and placing a high-memory HF RFID tag in each effector.

The host can now read and write to the effector's RFID's memory wirelessly, and critical information can be read and stored without an unreliable electrical connection. The RFID chip includes a powerful encryption engine, so the wireless communication is secure – even through dozens of autoclave cycles, thanks to Vizinex's extensive experience with high-temperature applications.

The newfound reliability isn't the only benefit of the RFID program. There is potential to develop RFID enabled device storage cases, which could automate inventory management for end customers – telling them continuously and in real time the number of devices on hand, the life cycle status of each device and whether more effectors need to be ordered.

Case Study #2

Another major medical device manufacturer provides – though a network of distributors – joint replacement kits used by thousands of hospitals nationwide. Each kit contains a number of components, one of which is chosen individually by the surgeon to create the proper fit for each patient.

The unused portion of each opened kit is returned to distributors who must re-stock the unused items quickly and accurately. Tracking the parts moving to and from customers and then back into available inventory stocks required a precise and automated identification method. RFID provides a high throughput, low error solution for these distributors.

The manufacturer needed to provide distributors with a streamlined method of inventory tracking. The process needed to:

- Not require kits to be shipped to distributors, then opened and counted
- Consistently provide accurate, up-to-date results
- Utilize components capable of withstanding multiple autoclave cycles

The manufacturer turned to Vizinex RFID and its software partner to provide an asset tracking solution meeting all of the above criteria. In turn, Vizinex produced a durable,

autoclavable RFID tag solution integrated with a scale, capable of determining which components were present in each kit, based on weight.

The Vizinex RFID tag itself – hardened to withstand steam, chemicals and elevated temperatures – is mounted to the metal tray housing each kit. Vizinex tags have proven both reliable and durable in this demanding application.

RFID technology helped the manufacturer create significant efficiencies, saving money and reducing non-value-add work both internally and at partner distributors. Perhaps most importantly, the RFID-based asset tracking system helps ensure patient safety and reinforce the trust hospitals and surgeons place in the manufacturer's solution.

About ViziCore™ Embedded RFID Technology

ViziCore™ embedded RFID technology utilizes a unique, patent-pending tag construction methodology as the basis for low-cost solutions that can withstand the rigors of the manufacturing process, including injection or compression molding, enamel curing and autoclave cycles. ViziCore™ implementations are maintenance-free, last the life of the product and – because they're passive RFID tags – require zero maintenance.

Vizinex's team of RFID experts works closely with manufacturers to develop custom ViziCore™ solutions that can be embedded directly within products, offering a unique level of connectivity and intelligence. Our experience developing embedded technologies allows us to operate extremely efficiently and cost-effectively; we can typically create specialized RFID tags that meet the most exacting requirements in time frames that please even the most demanding customers.

About Vizinex RFID

Vizinex RFID was established in 2001 to provide leading edge RFID solutions to businesses and governments to help them overcome problems associated with tracking, security, and authentication. Staffed with experienced leaders in manufacturing, quality and product development, Vizinex focuses on providing complete RFID consulting and RFID tag solution services, using proven development methods and patented manufacturing processes.

The success of an RFID solution is only as good as the RFID tag deployed for the application. The tag is the single most critical component for data collection. Too often, readers and software are configured for each individual application but little effort is put into the tags. Vizinex's experience has shown that same level of attention must be focused on the tag design to achieve optimal performance from an RFID system. Vizinex knows that RF performance, environmental robustness and tag positioning are critical factors in the reliability and effectiveness of any RFID system.

For more information about Vizinex RFID, contact us at sales@vizinexRFID.com or 215.529.9440.