

Revolutionizing the Orthopaedic Supply Chain

Using 21st Century Technology to Solve the Toughest Challenges

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Watching American Idol in Grainy Black and White

You've got everything at the office wrapped up and you rush to get home before American Idol starts. This week is the quarter finals and your favorite contestant is on the verge of elimination. You don't want to miss a minute of the show. You and your spouse settle into the couch, with Pad Thai from your favorite restaurant in front of you on the coffee table. You realize you need to move closer to the TV and get up to wiggle the rabbit ear antenna, pulling closer to the small screen. Then you wonder – what color is Simon's shirt? Finally your wife says "Honey this 13" grainy black and white TV has to go. I know it's been in your family for 30 years but enough is enough!"

Not the scene at your house?

Odds are very good that you are watching American Idol on vibrantly colorful flat panel TV in high definition. That's 21st Century Technology. If you are using the latest technology to watch a bunch of strangers sing, do you wonder why your company is still using technology that's 40 plus years old to run your supply chain? Your future, and your company's success, depend on squeezing every advantage possible out of today's hyper-competitive marketplace. That means 21st Century Technology in the warehouse as well as in the living room.

In the following pages you'll learn what the latest technology is for the orthopaedic industry, how you can be a hero to your CEO, get a promotion and a nice raise so you can buy a new flat panel HDTV to watch next year's American Idol series.

In the orthopaedic industry the two critical business processes challenges are:

- Reducing inventory cost
- Improving customer service through better fulfillment

Attaining those goals can be extremely stressful on an organization because reducing inventory costs generally means lower stock levels. Timely customer fulfillment requires readily available inventory which implies higher stock levels. It's a stress on the supply chain that can make or break an organization because the implications go to profit, sales success and even employee retention. Smart companies have cut that tension with technology.

The intent of this paper is to illustrate why RFID 2.0 is the choice of automation visibility technology for the leading medical device manufacturers and how the top companies have lowered inventory costs, increased customer service, and improved employee happiness and productivity by eliminating mindnumbing tasks.

The processes utilized to deal with problems encountered in the management of consigned orthopaedic inventories will be covered and show the efficiency gains. In order to lower inventory while maintaining or actually improving customer fulfillment a company must have a hyper efficient supply chain. An effective and automated inventory management system is essential to a hyper-efficient supply chain operation and a good inventory management system is accurate, timely and requires minimal labor to maintain.

Consigned inventory is very difficult to manage and one of the most challenging to manage is orthopaedic surgical implants. Implants are expensive and it is critical that the correct items are available and intact when shipped for a

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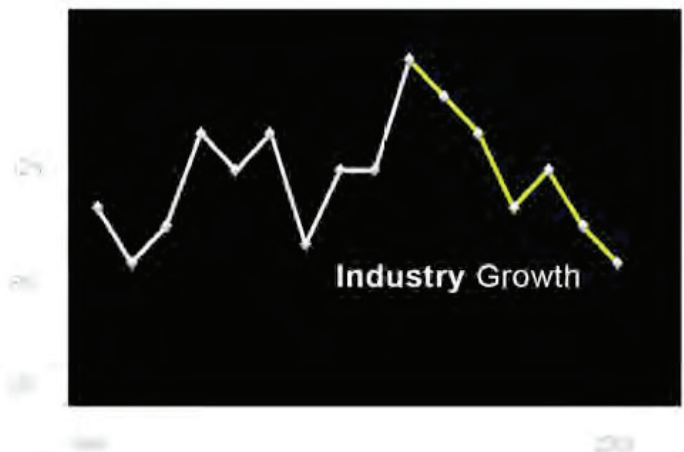
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procedure. This means there is a substantial opportunity for value creation – value from reducing inventory and value from being more responsive to client needs. The demand for orthopaedic products has been growing as the global population ages. Currently almost 40% of the US population is over the age of fifty. Globally the population of those over the age of sixtyfive is expected to triple in the next fifty years. These factors will help to drive the demand for orthopaedic surgical implants and make it all the more incumbent on suppliers and manufacturers to effectively manage their supply chains.

The problem, however is that the industry is using brute force to react to this demand. Inventory levels in the orthopaedic industry are at record highs according to a recent Goldman Sachs report. This means that to provide the right devices to a surgeon at the right time, more inventory is being added to companies warehouses and stock.

This might make sense if the industry growth was keeping pace with the inventory growth, but it's not. Over that same period (highlighted in yellow) growth has slowed from a high of about 17% annually down to 6% in 2009. Yet inventory has steadily grown. This pattern is not sustainable for the entire industry. If this continues and the cost of capital keeps increasing several medical device companies will be bankrupt in the next decade. Is yours one of them?



The accurate tracking of consigned orthopaedic surgical implants is critical to hospitals, surgeons and of course patients. Manufacturers consign these products to hospitals, clinics or their own sales representatives with the intent that they will be available for a procedure when required. The products are shipped in kits with the knowledge that only a small portion of the kit may be used for a procedure. This is due to the variety of sizes of patients and once a procedure begins it is essential that the correct piece in the correct condition is available to the surgeon. This requires that a full range of sizes be available in a kit. This also ensures that the majority of a kit's contents are not utilized for a procedure.

Critical in the success of a company is the velocity of inventory. How quickly can the same kit go out to a surgeon and be returned back in to be fulfilled? How quickly can a warehouse operation react to an order received the same day? The process and market are creating unique problems.

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The Problems

There are several issues with consigned orthopaedic inventory including:

- Transactions include both shipping and return back to stock.
- The end user is not financially accountable for the use of the entire kit.
- Inventory turns need to be extremely fast, in many cases same day.

Consigned inventory implies that once a kit is delivered to a customer, part of it will be returned. This means that consignment transactions require twice as much effort to administer as standard transaction. An order needs to be picked, packed, quality checked and shipped. The kits that are tracked against return dates which are often used to forecast availability. This establishes an expectation that kits and components will be available the day they are returned to the manufacturer. That is easier said than done.

Just as there is process associated with shipping a kit there is an equally arduous one involved with its return. Kits require a thorough item-by-item inspection. Each item is barcode scanned and visually inspected. Depending on the size of the kit it takes somewhere between ten and forty-five minutes to check-in a kit when returned. This does not include rebuilding the kit; generating a pick ticket; replacing items consumed while consigned. Warehouse workers are often numbed into a state of diminishing quality by the repetitive scanning of hundreds of bar codes per kit. It's the most arduous part of their job. The pick function and manual scan to associate the item to the kit has been refined over the past several years, many companies have implemented JD Edwards or SAP to make those associations – that's like getting cable instead of relying on the rabbit ear antennas, but the visibility – the small black and white screen is still manual and error prone.

The time required to process a return kit creates several problems. Most operations require two to three shifts at least five days a week, sometimes more, with overtime a normal occurrence due to the manual inefficiency of the process. The manual processes used require a significant amount of labor with backlogs occurring as bottlenecks develop at bar code scanning areas. The impact of backlogs and bottlenecks is compounded by demand for individual kit components to complete other kits that are outbound. This leads to cannibalization of in-bound kits to fulfill demand for those out-bound kits. These factors impact inventory forecasting and planning and drive up labor costs. Delays processing returned kits also have a negative impact invoicing for consumed parts which adversely affects cash flow. The biggest hit on cash flow is resolution dispute with clients because those cannibalized kits were not properly recorded as items were taken out of kits before they were fully checked in for billing.

While the patient is the end user of orthopaedic implant products it is the surgeon who determines which products are used. Orthopaedic surgeons determine the time and place for a procedure to take place. The surgeon is the one who has to be pleased with not only the quality of the product but perhaps more importantly the quality of the service provided with those products. They want what they need when they want it and are not particularly concerned about the condition of the kit when it is sent back to the supplier. The sales person needs to develop a strong relationship with the surgeon in order to maintain their loyalty and continued business. The sales person will often, if not usually, put the surgeon's interests and preferences, above requirements of their employer whether they work for the manufacturer or distributor. Distribution models of course vary. The sales person cannot be counted on to effectively track consigned

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inventory or ensure that kits are returned properly. These factors add to the difficulties in accounting for kit contents when they are returned.

The orthopaedic implants industry is both competitive and unique. The market players have a lot of challenges in optimizing the service to their customers while maximizing profitability to shareholders. Those who position themselves to meet these challenges will gain greater market share and customer loyalty while driving greater entity value. Time to look at the solution which allows companies to do just that.

The areas where there are opportunities for process improvement include:

- Reduction in processing time for receiving kits and items.
- Improved billing and receiving accuracy.
- Improved ability to find items and service orders on the fly.
- Reduced time to assemble and ship kits.
- Improved kit accuracy outbound.
- Shortened order to cash cycle.

The RFID 2.0 Solution - HD for Supply Chain

Visibility is as key in the supply chain as it is enjoying your favorite TV program. RFID provides unprecedented visibility without needing people to take action. Many people have heard about radio frequency identification (RFID) in the context of Wal-Mart for tracking cases in the warehouse. That type of RFID was the foundation for RFID 1.0. The second generation of RFID is based on newer chip technology and more advanced reader functionality with software agents providing reader management directly on the readers. The function of the RFID tag is similar to the barcode although data can be retrieved and processed significantly faster and more accurately, without any human interaction.

RFID 2.0 is solving significant problems within global supply chains for many Fortune 100 companies in 2010. It can increase productivity and efficiencies through hands-off data collection and verification of many items at once, even inside a container. Assets can be tracked and scheduled more effectively. Inventory accuracy and availability can improve which will lead to fewer missed sales due to out of stocks. RFID can solve specific problems that managers encounter every day.

Specific situations that may be suited for an RFID solution include:

- Labor requirements and time constraints cause bottlenecks in a data collection or product identification process
- High error rate associated with the data collection process
- Difficulty in tracking assets critical for production causing delays

Situations like these confront managers in orthopaedic implant supply chains daily. RFID can solve these types of

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problems. A unique solution has been architected that can potentially make managers within an orthopaedic product supply chain more effective and sleep better at night.

The solution assumes a very low cost RFID tag is placed on the packaging of each item and that RFID tag has a unique electronic product code (EPC) which points to information in the corporate database. All the items in the kit are electronically associated with the kit conveyance or tote. The tote box carrying the contents can be cardboard, plastic, or composite materials. This creates a Kit identification and that Kit should always go out the door with a very specific bill of items in that box. The out-bound process for this Kit in the old process is to take out each of up to 200 items in the kit and manually bar code scan each item twice (lot code and item number) then put the item back in the shipping box. It's easy to miss an item or skip a barcode. And it is tedious mind-numbing work.

RFID 2.0 allows a solution specifically built to optimize the medical kit process. Quake Global's EasyKit™ ships as a complete solution that automates Kit or item receiving, building, replenishing and shipping. The solution consists of a tunnel affixed to a 10-12 foot conveyor. The tunnel covers most of the conveyor and has special RF properties which contain the RFID energy to inside the tunnel and an antenna array inside the tunnel to make sure each item in the Kit is read with 99.9% accuracy. The key to the 99.9% read rate is understanding the physics of radio frequency and designing a solution to take advantage of those physics. This is particularly important with items that are titanium, cobalt chrome and similar metallic surfaces.

The solution ensures that only the contents of the specific Kit in the tunnel are tracked, recorded and associated allowing for serialization at the kit and item level as well as delta reporting on shortages, overages or changes to the bill of material. Just as important, the solution operates at up to 12 times faster than traditional barcode solutions and can be configured to auto-generate pick lists or check against expiration dates. The throughput improvements enable a single operator to process as many as 80 kits per hour.

Additionally, EasyKit™ is a drop in solution, requiring no extra hardware, servers, or additional space that seamlessly integrates into any database, ERP or data acquisition program. The automation and visibility that can be found with the Quake Global EasyKit™ will reduce labor costs and work in process (WIP) delays while increasing inventory turns, accuracy and order throughput. The Quake Global EasyKit™ can significantly help improve supply chain efficiency with an orthopaedic implant supply chain.

The innovative solution allows operators to quickly add RFID to their system without a complicated integration and immediately realize the benefits of RFID. When products are shipped, the kit is automatically validated against the standard BOM. Any differences are noted in a delta report and the kit can be fixed so that it has a proper BOM. When the kit returns to the facility, any missing or extra items are quickly identified and summarized on a delta report where the HBIC barcodes are printed for easy data entry into existing systems.

The chart below shows the type of productivity improvements that can be realized through an implementation of Quake Global's EasyKit™.



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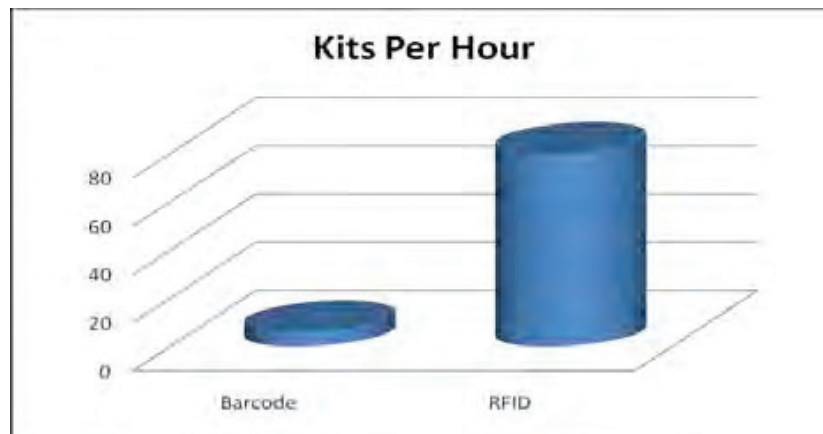
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Visibility is critical in the orthopaedic supply chain. There are two ways to get that visibility – pay a lot of people to put their hands on every single item that flows through your supply chain many times a day, or automate the entire data collection process with RFID and eliminate most of the manual counting and touching of products, and eliminate all the errors. You can watch American Idol on a 13" static washed black and white TV and you'll know who the winner is, but watching it on a 60" LCD screen with high-definition surround sound will change your experience dramatically. The difference between watching American Idol and optimizing the orthopaedic supply chain is that one is necessary to stay ahead in a hyper-competitive market, and can make you a star performer for you company – the other is just a way to kill time on Wednesday night.



RFID has the potential to solve significant problems within a supply chain. It can increase productivity and efficiencies through hands off data collection and verification. Assets can be tracked and scheduled more effectively. Inventory accuracy and availability improve; which improves order throughputs and customer satisfaction. RFID 2.0 makes your investment in ERP programs like JD Edwards and SAP much more valuable, because the increased real time visibility provides a wealth of data analysis possibilities.

The automation and visibility that can be found with the Quake global EasyKit™ can be the primary tool to reduce labor costs while increasing throughputs and improving customer satisfaction. The Quake Global EasyKit™ can significantly help improve supply chain efficiency within an orthopaedic implant supply chain and optimize your supply chain with 21st Century Technology. Contact Quake Global today to find out why 60% of the Top medical device companies are using Quake's solutions.

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