



Implant Tracking Integrated Into Everyday Processes

Summary Statement:

This custom designed web-based software combines mobile computing (via super phones) and process engineering to create a revolution in medical device logistics through a net centric real time platform that links field sales from the operating room with back office support and management. Users realize an unprecedented combination of flexibility and speed of use with secure access to historical archives.

The Need:

Medical device sales and distribution in 2008 continues to rely extensively on severely dated management tools such as the fax, pen and paper and dry erase boards. The complexity and dynamic nature of these supply chains compounds the inefficiency and inaccuracy of these manual methods.

Historically a large orthopedics distribution company conducted their business via manual methods such as phone, fax and forms. They manually tracked inventory of over 100,000 implants, and numerous sets of instruments for the support of hundreds of surgeries weekly. The correct combinations of implants and instruments for a wide variety of types of cases had to be available for each surgical case while providing the best possible patient care and service to surgeons. Manually accomplishing this volume of high pressure tasks exacted excessive costs as well as extreme stress on the people charged with unfailing support for surgical cases. It became apparent that this manual-analog tool box of business processes had long passed into obsolescence.

At the point of patient surgical care, systems to record details of devices implanted vary from hard copy files to EMR systems. Current systems and processes retain the shortcoming of not facilitating flexible and fast retrieval of implant data to feed joint registry input or even to support a surgeon's desire to research their own historical implant use. Current systems are patient centric and do not readily support a health care provider with interest in searching archived data by implant. For more than a decade the US health care system has lagged behind numerous developed nations which have established joint registries due to myriad concerns of feasibility and liability. The NY Times reported that "the risk in the US that a patient will need a replacement procedure because of a flawed product or technique can be double the risk of countries with databases," (Meier 2008/07/29). This risk has manifested itself in major withdrawal from the market of many thousands of implants as patient risk is assessed.

This shortcoming across the US health care system was acknowledged in the launch of The Sentinel Initiative by the US FDA to create a joint registry in the Summer of 2008. Sentinel is intended as "a long-term effort by the U.S. Food and Drug Administration (FDA) to create a national electronic system for monitoring medical product safety. It will strengthen FDA's ability to track how drugs and other medical products perform once they go on the market and, ultimately, facilitate the development of tools to strengthen the agency's ability to communicate safety information to the public." (Sentinel Fact Sheet, US FDA)

Sentinel foresees joint public-private partnerships to populate a national database for its purposes. How individual contributors to the database maintain their own records in accessible archives remains an open question. Close to one million hip and knee replacements implant approximately four million implants in the US each year and the surgeons using those devices, have limited tools at their disposal to drill down into their implant usage data. *WebOps provides a state of the art tool to capture and archive this essential information integrated into the routine processes of the implant supply chain through point of actual implantation.*

Development Summary:

WebOps, LLC developed its software in collaboration with one of the largest implant distributors in the US and a custom software developer in order to automate medical device sales and distribution business processes. The solution required a web-based platform to integrate sales and operating processes with full spectrum connectivity via handheld devices that were not dependent on wireless hot spots. The priorities of WebOps were user adoption, visibility and real-time speed across all functional teams.

Speed Developers worked closely with teams of users at medical device distribution companies to map each interconnected business process from when the sales representatives first learned of a surgical case, through fulfillment of the implants and instruments to the hospital, to the usage tracking for billing purposes. Technological options were considered to maximize the maneuverability, productivity, and efficiency of sales representatives and support personnel (customer service, warehouse, and inventory personnel). Central to the success of the project was empowering the field sales force that worked in hospital and surgeons' offices with a handheld device that did not depend on classic hot spot WiFi. From the revolution of cellular technology, solutions were found.

The ubiquitous nature of the World Wide Web allowed surgeon's offices to post cases directly to their own WebOps case schedule, instantly visible to the vendor's staff. This surgical case

record would then provide the surgeon a portal to access historical implant usage data in seconds.

Visibility Handheld applications were developed for the new class of super phones running Palm OS, Windows Mobile and the Blackberry operating systems. Surgeon's, or their Sales representatives using these devices could schedule their surgeries directly to a web based back end platform that instantly became visible and actionable to all support staff and management, in real time, 24 x 7, anywhere in the world. The sales force could then see all the details of all products being sent to them for their surgeries as soon as the items were shipped; likewise, backend operations personnel had 100% visibility of each item, ultimately allowing for pinpoint tracking and accountability of each item.

Surgeons or their sales reps can access their entire history of implant usage searching WebOps records with broad search criteria. As joint registries require, information on the patient and implants used is available from a secure database.

Precision During surgery, the sales force could directly input the actual products used through their phones due to WebOps being a web based application. This data could be entered into the surgical case record by scanning the bar codes for part and lot number of the products used with a variety of blue tooth scanners or by keying the information. Upon

completion of this activity, the sales rep had the ability send his back office a short survey about the accuracy of products sent to support his case; this ensured 'excellent customer satisfaction'.

Upon the completion of the surgery, if their choice of phone supported signature capture, they could secure hospital signatures confirming products used to comply with Sorbanes Oxley revenue recognition rules. And if the circumstances of the operating room did not support or allow connectivity, the handheld application would work in "off line" mode, saving the usage data and signature and update the web based application as soon as phone signal connectivity was restored. The revolution was beginning.

Back office support staff could view the products used during surgery in real time, allowing for re-order and billing activities to occur as soon as purchase orders were secured and entered into the surgical case record in WebOps. All

of these tasks performed are recorded in the surgical case record in WebOps and the statuses of these tasks are visible to the sales representative and management with the permission to view them.

Additional revolutionary functionality was added to allow the sales staff to utilize the cameras on some of their devices to capture and attach pre-op or post-op X-rays to the surgical case

record for detailed templating and case planning.

The use of these super phones allowed sales representatives to consolidate all the equipment (phone, pager, and PDA) on their "Bat Belt" into one device. These users could stay in contact with office staff and managers by utilizing email server software and "push" email. This order of magnitude improvement in efficiency and accuracy drove rapid and enthusiastic adoption by field sales force staff, increased sales rep productivity, and created tremendous operational efficiencies.

Traceability This revolution in sales force automation and medical device logistics was matched by the revolution in back office support of the field sales force. Errors created when reps communicated surgery requirements via phone or fax would be virtually eliminated. Warehouse and inventory staff could rapidly track the location and status of inventory down to lot code detail across their territories. Decision support logic

improved support planning and service by recommending the product systems needed to correctly support. And inventory cycle counting functionality leveraged the speed and flexibility of a web based application with widely distributed super phones and blue tooth

scanners to feed in inventory count data.

This traceability capability enable rapid identification of implants used – who, when and where – in the event of FDA quality actions such as recalls and potential future joint registry actions.

Revolutionary Results

One of the largest orthopaedic device distributors in North America (\$100M+ sales), despairing of the waste and service quality issues inherent in their paper based business tools implemented WebOps in Q1 2005. This distributor was able to capture a 20 percent growth across 2005 and 2006 without adding any back office support staff due to back office productivity gains of 57%. By previous historical trends, this productivity improvement avoided the addition of six to eight additional support staff. And equally important, service failures for products sent to surgeries, considered at crisis levels, were virtually eliminated.

The experience of over 600+ users across the US who've tested this application since 2006 has mirrored these dramatic improvements.

Significant savings were recognized in the following areas:

- Inventory utilization- distributors/ manufacturers reduced field inventory up to 10%
- Support labor – headcount and overtime savings of 20%
- Freight expense – courier savings of 20-30% [visibility = planning and systematic execution]
- Supplies – copier/fax/paper savings of 61%

The radically improved visibility of all surgery requirements across their territories has enabled them to reduce freight costs through better planning and execution of delivery and retrieval of products. During FDA compliance product hold activity, they report lot code tracing and locating of affected products taking minutes rather than the hours required without the speed and visibility of their business that WebOps delivered.

Analysis across five distributors validated a Return on Investment ranging from 282% to 538%. These companies are realizing dramatically more efficient and profitable operations with game changing levels of service and product quality and compliance.

Testimonials:

"The WebOps software has changed the way that we do business. Products can be ordered well in advance of surgery, billing can be done quicker, and sales forecasts can be tracked more closely. All these and much more make WebOps an absolute must in the fast paced world

we live in today!"

- Shawn Everhart- Sales Representative

"WebOps has proved to be a huge asset to our company. It's helped us keep pace with growth while reducing paperwork and the risk of mistakes. Before, we relied heavily on transcribing phone calls. Now the sales rep can choose exactly what they want from their Treos. We no longer have to spend time writing down surgery postings, and trying to keep them organized. It's all computerized, which eliminates lost postings and miscommunications. Web Ops also gives us a clear outlook of the upcoming week, which makes planning easier and more efficient. And finally, WebOps gives us the tools to grade our performance so we can see where we need improvement"

- Scott Blackstone- Sales Support

"WebOps has been a very successful tool! From a case standpoint, once we enter a surgery (which has to be recorded somehow) everything else just falls together. We can add x-rays to the posting which is huge! We can let personnel know what is exactly needed for surgery. Once surgery has been done we can track the usage forever! This is huge! So many times we have to go back and check what was used on a patient 6 months, 1 year or 6 years before. This makes it easy. And once a surgery is posted we can find out what has been sent to the surgery through our hand held or PC and then follow the billing and receiving PO's process. This whole process helps out everyone from me the rep, to the warehouse, to the customer service who orders the replenishment. In the long run, it will prove to be an effective tool of the industry."

- Gene Dopson- Sales Representative

"WebOps gives me the ability to see all of my reps cases in one view. As soon as the sales rep finishes the surgery, the usage is right there in real time I don't have to go back and forth to a fax machine or shuffle through a stack of faxes. Also there is no more guess work trying to decipher tiny lot codes that are often hard to read on a fax copy. WebOps allows me to see which cases I've reordered, or not reordered, which ones I've billed/not billed and how many total cases my reps have scheduled so I can plan my day accordingly"

- Scott Goggans-Customer Service Rep