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BLUE BELT TECHNOLOGIES™

Blue Belt Technologies  
and MAX

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"I can rest easy knowing our inventory is accounted for and my traceability doesn't stop when products ship out."

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# MAX CONSIGNMENT MODULE HELPS BLUE BELT TECHNOLOGIES MAINTAIN FDA COMPLIANCE



Blue Belt Technologies manufactures computer assisted technology and advanced robotic systems for orthopedic surgery. The company's smart instrumentation enables surgeons to operate with repeatable accuracy and precision in even the most complex bone shaping procedures. Founded in 2003 by Anthony M. DiGiola III, MD, Craig Markowitz and Branko Jaramaz, PhD, the company's innovative products are based on research from Carnegie Mellon University's Robotics Institute. Blue Belt's Technologies allows surgeons to use advanced technology to tackle difficult procedures and apply formerly under-utilized treatments with superior results.

The company prides itself on its customer focus. Blue Belt Technologies puts time and effort into building strong relationships with surgeons and hospitals to understand their needs. They offer support and onsite training programs to ensure that each robotic assisted program is highly successful. As a result of their innovative products and dedication to customer and patient satisfaction, the company has received several awards, including Frost and Sullivan's 2014 and 2012 Global Orthopedic Surgery Enabling Technology Leadership Award, and they were number one in Outpatient Surgery's 2014 AAOS Innovations in Orthopedics. They were also nominated for Pittsburgh Technology Council's Tech 50 Innovator of the Year Award. The privately held company, and its Navio Surgical System

and Stride Unicondylar Knee System, are well respected in the medical technology community as well as the orthopedic community.

## **Business Needs**

Blue Belt Technologies experienced strong growth as its groundbreaking products began to reach critical mass with orthopedic surgeons. As a medical device manufacturer, Blue Belt Technologies must adhere to strict compliance requirements laid out by the FDA, including the ability to track and trace components and finished units in the field quickly and accurately. In order to meet FDA standards and to maintain control of the manufacturing process as they hit a critical growth point, Blue Belt needed to streamline inventory tracking systems.

Around this time, Blue Belt Technologies brought on Robin Gonzales as Director of Logistics, who immediately identified the company's need for ERP software. Robin has worked with several medical device manufacturers, specifically startup companies. She manages logistics for these small startups as they grow to the point where digital systems become absolutely necessary to keep track of burgeoning orders and inventory. Gonzales has implemented MAX at four out of the five medical device start-ups she's worked with over the last two decades. She stresses the importance of ERP software in fast-growth startups, saying "The first thing we need to think about in a small company as it grows larger is inventory control."

Gonzales has identified MAX's ability to customize reports and access information with ease as two main reasons for her loyalty to MAX over the years. Due to her past experience with MAX and MAX implementations, she has been able to help get the system up and running fast at each of the medical device manufacturing companies she's worked with. Once MAX is live, Gonzales says it's easy to access the information necessary to do her job with just the touch of a button.

### Business Solutions

Traceability is central to Blue Belt Technologies' manufacturing operations. As a leader in the robotic orthopedic surgery community, Blue Belt Technologies is a quick adopter of new industry standards. For example, when the FDA began to roll out Unique Device Identification number [UDI number] requirements in 2013 Gonzales knew MAX could help Blue Belt Technologies adhere to the stricter tracking requirements. She immediately called a MAX Consultant and set up reporting to make sure she was able to access the right information to keep Blue Belt Technologies in compliance and ahead of the curve, as UDI number regulations continue to roll out over the next several years.

Gonzales says that in the event of a recall, the degree of traceability within MAX is a lifesaver. At another company where

Gonzales worked and used MAX, she faced a recall situation. As she says, "One time there were 100 bad devices and I was able to locate 99 of them within five minutes using MAX." That kind of traceability is what helps Gonzales feel at ease knowing product is accounted for at all times, potentially saving lives if, for example, medical device implants must be recalled from within patients.

However, consigned product presented a unique concern when it comes to inventory management. Prior to using the Consignment Module, traceability essentially stopped when product left the plant. For companies like Blue Belt Technologies that need to know where product sits at all times, this is problematic. The Consignment Module in MAX solves this concern by accounting for consigned product. Blue Belt Technologies implemented MAX's Consignment module in August, 2015. Using the module, product lot numbers and the manufacturer's lot number show up in a consigned location so the company knows exactly where all their consigned product sits.

The added benefits to controlling product even when it is off location on consignment include the ability to generate reports on the consigned inventory, improved MRP accuracy, and improved accounting accuracy. All of these benefits are made possible by eliminating the need for manual tracking of consigned inventory and manual adjustments to financial accounting. With the MAX Consignment Module Blue Belt Technologies is able to maintain control of their groundbreaking devices throughout the entire product life cycle, even when that lifecycle includes consignment.

### Results/ROI

Medical device manufacturers, like Blue Belt Technologies, need to be able to track and trace inventory with precision in order to maintain FDA compliance. Gonzales reports a thirty percent increase in accuracy when using MAX to track inventory versus no ERP system. ERP software provides an advantage over a manual spreadsheet system because it helps to protect

## BENEFITS

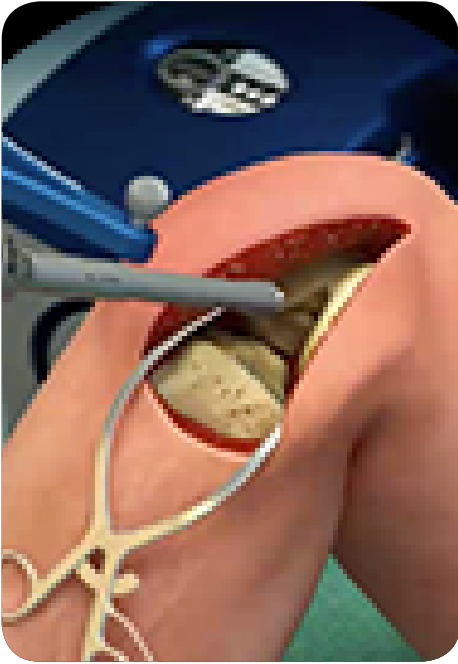
- Keeps on hand inventory balances accurate so MRP calculations stay on target.
- Tracks consigned inventory as a company owned asset, increasing inventory visibility and control.
- Generates simple and accurate reports, eliminating the need to track consigned goods manually.
- Automates sales order management, conveniently generating invoices when your customer accepts consigned goods.
- Increases accuracy of accounting for all assets and liabilities by automatically accounting for consigned goods.

### Blue Belt Technologies

Robin Gonzales, Director of Logistics



I know the company is protected and our customers are protected because I can always find what I need."



against transposition errors and forgotten transactions. As Gonzales says, "I always know what's going on with our inventory thanks to MAX." This visibility helps with every area of business, but most important for FDA compliance is traceability.

With the Consignment Module, Blue Belt Technologies has extended traceability to include consigned product. "I can rest easy knowing our inventory is accounted for and my traceability doesn't stop when consigned products ship out," says Gonzales. She describes the value in being able to know exactly which product and specifically which versions of product are at a location, as well as which are sitting on shelves and which have been purchased and are in use. The traceability allowed for by the MAX Consignment Module is reassuring to any manufacturer who must maintain high levels of compliance. With

MAX and the added Consignment Module, Gonzales says "I know the company is protected and our customers are protected because I can always find what I need."

#### Up Next for Blue Belt Technologies

Blue Belt Technologies is a fast moving company in a high speed industry. They see a need to be able to manage design changes as quickly and efficiently as they're able to track product. They expect to implement the MAX ECO Module in the near future to help streamline their Engineering Change Order Process.

MAX is the right solution for manufacturers who have to meet strict compliance regulations. For Blue Belt Technologies, the Consignment Module added to the already robust inventory management MAX has been providing.

## SEE MAX IN ACTION

Visit us at [max4erp.com/events](http://max4erp.com/events) to register for an upcoming webinar so you can see for yourself why so many manufacturers rely on MAX for ERP.

#### GET YOUR QUESTIONS ANSWERED BY A MAX EXPERT

Choosing the right ERP solution doesn't have to be a daunting task. Get in touch with a MAX Expert by calling 1.855.392.2862 to schedule an introductory consultation. You won't believe how easy it can be to use MAX to help you control your business.

If you have any questions about our products and services, please contact us at 1.855.392.2862 or visit us online at [www.max4erp.com](http://www.max4erp.com).