



A M E D I C A®

## BUSINESS PROFILE

THE LEADING PROVIDER OF MC<sup>2</sup>™ SILICON NITRIDE SPINAL IMPLANTS

## BUSINESS CHALLENGE

- NEW COMPANY WITH NO ERP SOLUTION IN PLACE
- NEEDED TO SUPPORT PRODUCT MANUFACTURING AND SALES PROCESSES
- LOT TRACEABILITY WAS A KEY REQUIREMENT

## SOLUTION

- MICROSOFT DYNAMICS NAV
- TECTURA LIFE SCIENCES

## BENEFITS

- AMEDICA CAN NOW TRACE LOTS FROM THEIR USAGE OR FROM THEIR ORIGIN
- TIME IMPACT FOR MANUFACTURING COSTING REDUCED BY 80% EVERY MONTH
- INVENTORY ADJUSTMENTS ARE NOW FULLY VERIFIED
- QUARANTINE CONTROL GIVES CONFIDENCE IN THE QUALITY OF THE IMPLANTS BEING SHIPPED
- ACCESS TO INFORMATION SPEEDS UP BUSINESS DECISIONS

## IMPLANTING QUALITY LIFE SCIENCE PROCESSES

### BUSINESS PROFILE

Utah-based Amedica Corporation has established itself as the leader in supplying MC<sup>2</sup>™ silicon nitride spinal implants. These products represent a new standard of care based on durability, performance, unique imaging characteristics, and hydrophilicity. These implants are radiolucent with clearly visible boundaries which is a major advantage for inter-operative implant placement and post-op assessment.

The long term performance and satisfaction of Amedica's implants is the driving force behind its comprehensive manufacturing process, and the company's end goal is to deliver a unique product for their distributors that hospitals and surgeons will want to use.

The organization has grown considerably since their first sale in 2008. Their products are now used in surgeries throughout the US. Amedica is looking at increasing their business year over year and are looking towards continued growth.

### CHALLENGE

Amedica is a new company, with no previous legacy ERP system in place to track manufacturing, sales, accounts receivable or payables. "Given the nature of Amedica's business, Lot Traceability was a key requirement, as we will always need to trace any Lot back to original production times," emphasizes Jordan Fuller, Amedica's Application Manager.

Historically, the company was running the finance department using QuickBooks. This was always a short term solution while Amedica went through the process of commercializing their products. Once the commercialization process was completed, the pressure was on to find a suitable solution to run the business. "Needless to say, QuickBooks did not provide any ERP or manufacturing capability, and the pressure was on to find a suitable solution," continues Fuller. "We needed to move quickly to establish a business suite that would support our future product manufacturing and sales success."

### SELECTION

Amedica looked at a number of alternatives when selecting a product to run their business. "We selected Tectura® Life Sciences built on Microsoft Dynamics® NAV as it was a strong contender for manufacturing, low cost and was easy to customize. Tectura's life sciences functionality was seamlessly integrated into Microsoft Dynamics NAV," says Fuller. Working with the right partner for Amedica was very important and Fuller goes on

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Jordan Fuller  
Amedica  
Application Manager

to say, “Tectura had the life science expertise, and had the additional advantage of a product that matched the industry Amedica operated in.”

### IMPLEMENTATION APPROACH

Amedica successfully advanced their implementation in a “Waterfall” style approach. With a planned program of project activity, the business roll out started with Finance followed in order by Manufacturing, Warehouse Management, Sales and Receivables and finally the Tectura Life Sciences module. “This was a logical order, as it followed the process of making the product, warehousing it and then taking it to market,” explains Fuller.

Amedica brought the implementation in house, using Tectura when needed, and leveraging existing Tectura and Microsoft documentation. Fuller continues, “They knew the possible pitfalls and shortcuts to implementing Microsoft Dynamics NAV and Tectura Life Sciences.”

### THE SOLUTION

Amedica leveraged departments when needed, bringing in key people and expertise at the right time. “The advantage of being a start-up is the system needs to be in place to sell, and this focuses individual departments, from Manufacturing, Warehouse Management through to Customer Services,” explains Fuller. “Their dedicated efforts meant we had a system fit for purpose.”

When Amedica brought in Tectura experts to facilitate specific elements of the project, such as Manufacturing Costing, the project became a lot less stressful. Fuller says, “Tectura talked with knowledge of our industry, as well as demonstrating technical and accounting understanding. This clearly helped.”

Starting in June 2006, the implementation from start to finish was eighteen months, including six months getting up to speed. Working across two sites, Amedica uses Tectura Life Sciences extensively, from Financial Management to complete ERP and Life Sciences functionality.

The Operations Manager really likes the manufacturing specification function and Fuller goes on to say, “We have increased the speed of production orders and aligned with product routing. It has facilitated the end to end process.” The Warehouse Management team is using the full extent of the product. With the implementation, and the software being functionally rich, Amedica is now exploring the supply chain planning functionality.

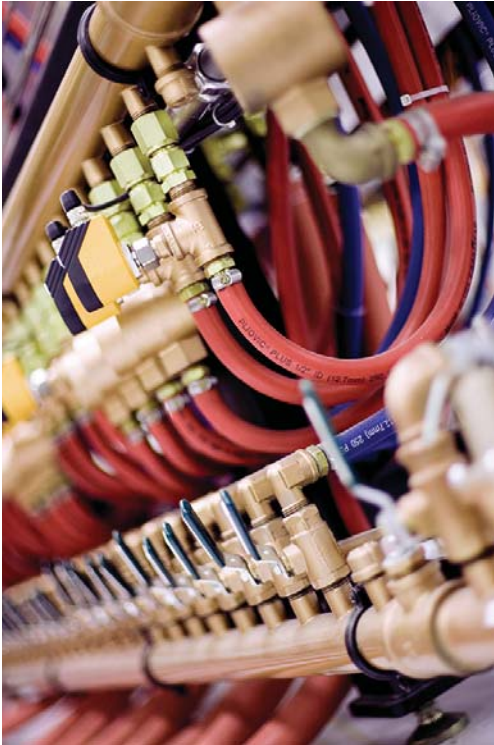
Already Tectura has taken Amedica through four successful upgrades. “We define the project two weeks in advance, and after providing the conversion, it is remotely installed ready for Monday morning,” highlights Fuller. “It’s always a quick process, and to date, we have had no problems.” Tectura also provides a help desk facility delivering a quick or an



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advanced resolution to any issue Amedica identifies. “Tectura is quick at getting back to us, and provides confidence with estimated times for completion.”

With reference to Tectura’s expertise, Amedica is still taking on board their initial recommendations. With particular reference to implementing bar coding, Fuller explains, “We have a bar code scanner connected to the thin clients on the manufacturing floor. Users can log in to Microsoft Dynamics NAV using a simple form. They can then process the product order at each routing step.” Fuller continues, “Tectura’s employees were extremely helpful, bringing with them many years of experience and knowledge of the product, both from the US and the EU perspective.” Amedica’s Operations Manager was able to easily deliver requirements and Tectura was responsive, providing valued insight into Microsoft Dynamics NAV.”

## BENEFITS

Looking particularly at the system highlights, item tracking and Lot traceability within Tectura Life Sciences means Amedica can always trace Lots from their usage or from their origin. “If we ever need to know where a specific Lot is, we can use the Tectura Life Science module to quickly find it,” highlights Fuller. “We have instant visibility of the Lots and which hospitals, surgeries or distributors the products have been sent to. Whatever batch or time period we need to trace, we

can do it. All movements and the origin of a Lot can be immediately reported.”

From an accounting costing perspective, Amedica used to run the process outside of the system, which was particularly labor intensive. “Manufacturing Costing is now automated, and we can see the information real time. The time impact for Amedica has been reduced by about 80% every month. This has enabled us to speed up reporting and analysis,” highlights Fuller.

The security function within Tectura Life Sciences has meant that inventory adjustments are now fully verified through password controls before they are allowed to be posted, ensuring the integrity of the data and authenticity of the transaction. Certification of manufacturing specifications are confirmed and fully audited with electronic signatures. The quarantine function allows Amedica to receive products, and ensure they are fully tested and approved before they are released for sale and manufacturing. Fuller goes on to say, “This level of quality control provides confidence in the quality of the implants being shipped, and supports Amedica’s long term performance and customer satisfaction goals.”

Order entry is also enhanced, and team members now only need to use a few keystrokes to have an instant view into manufacturing, with full visibility of when products are ready to ship. This reinforces

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Amedica’s customer satisfaction levels, as they are confident expectations will be met.

From a financial perspective, it used to be a painful process pulling data together for effective analysis. Fuller goes on to say, “It is now 70% quicker to write reports within Microsoft Dynamics NAV using SQL Reporting Services. These reports are also able to be published to Microsoft SharePoint. This is a huge benefit to the executive team as decisions that have a positive impact on the business are made faster.”

Reporting is also made easier by using the Dimensions feature in Microsoft Dynamics NAV. Amedica can combine business data from different dimensions, achieving a better understanding of how well the business is operating, where it’s going and where it needs help. Fuller continues, “Amedica now has the market intelligence to see which products are selling best, and can track sales by specific analysis dimensions that we can then use to slice and dice the data in a multiple of ways.”

With particular reference to regulation requirements, the system has the ability to be validated using Tectura’s pre-developed templates. Fuller highlights, “When we go down the path of validation, it will be easier with such templates already completed within the system.”

Tectura understands the Life Sciences industry, and brings relevant and detailed

experience to Amedica. “In particular, Tectura brings medical device experience and understands Amedica’s vernacular which has really made things easy,” concludes Fuller. “All we had to do was let them know our business process and they easily understood.”

## LESSONS LEARNED

Amedica did have a bumpy implementation process, managing the program themselves internally. They recognize that having Tectura more heavily involved throughout the program would have made the whole project a lot smoother. “It would have been a more successful experience,” explains Fuller. “Using expertise from the outset to ensure that any potential issues were short lived.”

In particular, Fuller highlights, “Bring Tectura in early in the process, continue to bring them in, and don’t be afraid to ask a lot of questions. Always make sure you’re connected to the right people and you are on your way.”



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