



**SYSPRO**<sup>TM</sup>  
Simplifying your Success

Medical Devices Vertical



Enterprise Software Solutions  
for Manufacturers & Distributors



## A Healthy Approach to Ensuring Success

SYSPRO for Medical Devices has been developed from over 30 years of implementation experience with manufacturers operating under increasingly strict government regulated controls. Medical device manufacturers today are forced to comply with stringent standards in quality, safety and traceability, and must provide documentation to substantiate procedures.

While the manufacturing process remains consistent with other industries, the additional overhead of rules and regulations is forcing medical device manufacturers to look for business partners to facilitate a lean, efficient environment, enabling them to produce the right product at the right time. It is imperative that these companies have visibility and control of their entire supply chains in order to assist fully comply with laws, regulations and guidelines while providing high levels of customer service.

SYSPRO offers medical device manufacturers a sophisticated enterprise system that supports a broad set of activities to help manage and coordinate business functions, including production planning, purchasing, inventory maintenance, lot tracking, bar-coding, orders management, customer relationship management and service in a single or multi-site environment.

The system is designed and constructed to help medical device manufacturers manage the five key components of a medical manufacturing business: Design, Manufacture, Distribution, Maintenance and Service.



Configured to  
**Deliver**



# Complete Control

SYSPRO strives to provide affordable focused solutions to facilitate and alleviate the operational bottlenecks and issues facing the Medical Manufacturer. Some of these include:

- Reduce costs of compliance related to manufacturing in this regulated environment
- Facilitate meeting the laws, regulations and guidelines laid out by the FDA and other regulatory bodies
- Customer satisfaction through faster responses and order tracking
- Increase market share and revenues
- Control, minimize and track operating expenses
- Shorten order-to-delivery cycle times
- Reduce costs to convert raw materials to finished goods
- Lower capital expenditures via reduced work in process and inventory levels
- Improve yield and product quality while conforming to specifications
- Increase the accuracy and effectiveness of plant floor data
- Traceability from source to ultimate destination
- Improve overall asset utilization
- Improve supply chain interoperability and effective integration with disparate internal and external systems

## ERP Enterprise Resource Planning

SYSPRO for Medical Manufacturers is a fully integrated business solution that delivers control over the planning and management of all facets of an operation, including accounting, manufacturing, distribution, customer relationship management, advanced planning and scheduling, e-commerce and warehouse management.

The component-based architecture is designed to provide a highly cost-effective way for SYSPRO customers to integrate best-of-breed applications, maximize business-to-business trading and leverage wireless connectivity. It also provides the framework for a new generation of Web-based applications. These new applications developed using the Microsoft .NET architecture are fully customizable to meet customer requirements. The Document Flow Manager, a SYSPRO e.net solutions™ tool, enables electronic processing of inter-company and business-to-business transactions.

The SYSPRO Customer Relationship Management (CRM) module closes the gap between the front office and the back office by integrating key activities without duplicating input. SYSPRO CRM allows sales, marketing and customer support operations to work collaboratively to achieve total customer satisfaction.

The SYSPRO Advanced Planning and Scheduling (APS) application suite enhances existing manufacturing operations, effectively closing the loop between Material Requirements Planning (MRP)/Enterprise Resources Planning (ERP) business functions and the shop floor. SYSPRO APS provides managers with real-time information on current shop floor activities and also offers a powerful “what-if” capability, facilitating the most effective use of resources. Additionally, the rapid scheduling and order tracking power of SYSPRO APS provides flexible, efficient management of volatile changes in demand and pinpoints individual customer preferences in the production schedule.

# Business Benefits



## **SYSPRO Has a Large Number of Medical Manufacturing and FDA Regulated Customers:**

### **Chase Scientific Glass, Inc.** FDA Approved /ISO

Chase Scientific Glass, Inc., manufactures specialty glass products for science, industry and laboratories

### **Stratagene**

Stratagene is a worldwide leader in developing innovative products and technologies for life science research.

### **Refractec, Inc.** FDA Approved

Refractec, Inc., develops and markets proprietary NearVision Conductive Keratoplasty for the treatment of visual errors.

### **Waldman Lighting** FDA Approved /ISO

Waldmann Lighting is a leading manufacturer of medical lighting systems and workplace lighting for many industries and applications.

### **American Medical Sales** FDA Approved Class 1

American Medical Sales manufactures and distributes a complete line of high quality X-Ray illuminators and the most innovative digital and film viewing products, networking solutions and sophisticated dental tomography equipment.

### **Frank Stubbs Company** FDA Approved

Since 1968, Frank Stubbs Co., Inc., has been a leader in the medical industry with innovative design and manufacturing of quality orthopedic supports and braces, as well as a complete line of compression garments for the plastic surgery market.

### **Imaging Associates** FDA Approved

Imaging Associates is a developer and distributor of technology tools for the medical imaging specialist.

### **Juzo Julius Zorn, Inc.** FDA Approved

Juzo Julius Zorn, Inc., has been a leading provider of compression therapy products for over 90 years. Juzo's products are successfully used with diseases requiring compression therapy.

### **Sigvaris** FDA Approved/ISO

Sigvaris is a leader in providing compression therapy products for patients confronted with chronic venous insufficiency.

### **Richards Medical Equipment** FDA Approved

Richards Medical Equipment is a distributor of medical products, primarily in the disposable anesthesia area.

# Leveraged Solutions



## Traceability Across the Extended Supply Chain

Lot traceability for medical device manufacturers is a supply chain issue, not just a manufacturing issue. SYSPRO has full backward and forward lot traceability across the extended supply chain. The system manages, tracks and documents all the changes of a product from the time raw material is received through product manufacture and storage, until it is delivered to the customer site. Because SYSPRO is an integrated enterprise solution, the lot traceability is tightly integrated to all supply chain aspects, not just to one manufacturing plant.

SYSPRO allows medical device manufacturers to assign both lot and serial numbers to one item for more efficient traceability, if required. Serial numbers, by default, are within a lot number.

Medical device manufacturers are sometimes required to pre-allocate component lots to work-orders to adhere to strict specifications. Likewise, lot numbers for medical devices may be determined when the work order is created or upon receipt into inventory. SYSPRO provides the flexibility required to meet these manufacturing requirements within the confines of compliance.

SYSPRO offers inspection at the time of receipt from either a purchase order or a work order. Non-conforming parts failing inspection from a supplier may be tracked using the Return to Vendor capability. Non-conforming parts that have failed inspection in Work in Progress (WIP) may be rejected or sent back to the same job or a new job for rework. If applicable, the part could be received into a different warehouse or even received into inventory as a different product.

SYSPRO supports multi-warehouses, providing the option to create a quarantine warehouse that may have different levels of security to prevent the incorrect usage of the items placed in this location.

Through pro-active exception inquiries, reporting and automatic notification functionality, both operational and management personnel have full visibility throughout the supply chain.

## Complete Customer Service

Customer service is increasingly influencing the bottom-line of Medical Device manufacturers. The comprehensive SYSPRO Customer Relationship Management (CRM) solution lets users track and manage all customer and supplier touch points. Customer correspondence, status, vendor relationships, marketing campaigns, service issues, product returns, warranty and repair histories, quotes and sales order information are monitored and recorded. SYSPRO CRM enables sales, marketing and customer support operations to work collaboratively to achieve total customer satisfaction.

A 360 degree view of internal or external business relationships is delivered, providing full visibility into inquiries, complaints, corrective and preventative action. Because all CRM information is recorded in a central repository, data mining tools can provide insights into customer service experiences. As a result, pro-active changes in business processes can be implemented to improve overall customer experience levels.

SYSPRO CRM provides real-time visibility with advanced tools for establishing account-specific service level agreements, tracking service tickets and managing warranty programs, renewals and defects. Users can control all aspects of the customer management and sales cycle from a single screen, improving effectiveness and empowering employees with the tools to deliver effective and profitable products and services.

# Industry Focused

## Controls and Compliancey

Laws, regulations and guidelines require that medical device manufacturers establish and maintain controls and procedures from the design phase through to the delivery of the finished goods. The level and stages of controls must satisfy the safety and performance needs of a specific manufacturer, product and user-market. SYSPRO has many FDA regulated customers that rely on the functionality of the SYSPRO enterprise solution to facilitate compliance with these rules. SYSPRO, through a focused reseller channel and industry experience can provide consulting and implementation expertise to assist customers in their quest to fulfill these regulated obligations.

Over the past five years, there has been a strong focus on CAPA (Corrective and Preventive Action) recording and patient device tracking in medical manufacturing. The ever-increasing demands for real-time information and analyses, and the need to involve customers and suppliers in the quality assurance process have caused organizations to refocus their efforts to include CAPA capabilities within their enterprise business systems. By doing this, an entire organization is able to respond to critical situations within minutes or hours, and issues can be identified, analyzed and addressed from any location. The automation of CAPA ensures complete visibility when deviations, potential discrepancies or non-conformances are discovered.

SYSPRO includes the following key features to help with CAPA compliance:

- Integrated document/content management
- Enterprise collaboration
- Flexible custom report generation
- 21 CFR Part 11 Electronic Signature capabilities



# Specialist Environment

## Engineering Change Control

SYSPRO Engineering Change Control (ECC) module enforces controls in product design with a user-defined workflow that can supplement or replace the paper trail that usually accompanies any product design or changes to product design. Groups or individuals are electronically notified of required actions, accompanied by instructions, comments, documents and drawings. Specific actions or responses are required before the change order can move to the next step in the design and ultimate approval process. Existing orders (sales, purchase or work orders) can optionally be locked by the system, when a change order request is accepted. Prior revisions of an item are archived and can be accessed for manufacturing or for investigative purposes.

## Audit Trails, Documentation, Reporting and Metrics

Laws, regulations and guidelines can often stipulate that medical device manufacturers have audit trails for every step of their procedures. SYSPRO provides detailed audit reports of all transactions, including changes to static data. The operator making the change is recorded, along with the old and new value of the changed information. SYSPRO provides multiple facilities for additional notes, and the technology platform facilitates the fluid development of custom requirements.

SYSPRO archives specific data as XML, which can be viewed as HTML pages. The open system architecture of XML is easily transported between systems, as required. SYSPRO provides an easy-to-use, intuitive Report Writer for custom reporting requirements. The Report Writer's functionality extends beyond producing reports; it can be used to extract data in Excel format or even as XML for storage or for communicating with suppliers and/or customers.

Medical device manufacturers can attach up to 50 objects (Word documents, Excel spreadsheets, PDF documents, CAD drawings, etc.) to any static record or order (sales, purchase or work order) in SYSPRO. Standard or specific notations can also be attached to any inventory item for automatic printing on documents sent to customers, suppliers or to the shop floor.

SYSPRO Analytics uses the Microsoft SQL Server enabled data warehousing functionality, which allows medical device manufacturers to track trends and perform data mining and analytics in all areas of the business. SYSPRO Analytics is an end-to-end solution which comes standard with the most common Key Performance Indicators (KPI) ready to use in an internal viewer. SYSPRO Analytics is designed to facilitate easy customization of the existing KPI's and with OLAP or MDX knowledge, the generation of additional KPI's.



# Total Visibility



## Security

Security is important to medical device manufacturers, and SYSPRO offers multiple levels of security. Sophisticated security is defined at group and operator levels, where custom menus can be defined and/or access control can be specified right down to module, program, function and field level. SYSPRO ERP passwords are rules-based and can force change after a pre-defined period, limit number of retries when logging in and auto-logout users when they are dormant.

ECC institutes its own level of security by controlling the workflow of engineering change orders, therefore preventing the next step until certain actions have occurred.

SYSPRO CRM has the ability to initiate automated processes as a result of an activity, improving internal and/or external communications. SYSPRO integrates closely with Microsoft Office, and all the document security within Microsoft Office can be utilized to control Design History Files and Design Master Files.

Leading Edge

# Technology

## Low-Cost Manufacturing

SYSPRO for Medical Devices enables manufacturers to keep finished goods in inventory at an absolute minimum through demand and inventory planning. SYSPRO Forecasting takes the guess work out of generating forecasts by producing realistic forecasts based on actual usage. SYSPRO Forecasting will automatically select the most suitable algorithm to use for each item, thereby facilitating demand-driven manufacturing. The forecasts feed the Requirement Planning module, which uses many tools to further facilitate a lean environment.

SYSPRO Advanced Planning and Scheduling (APS) provides more sophisticated functionality for the manufacturer to determine where to make product, on which resource. The system will generate a plan, using the company defined rules of which products need to be run in which sequence to facilitate compliance to regulations. Changeovers and clean-outs of production equipment can also be planned and scheduled through SYSPRO, resulting in higher productivity and reduced costs.

SYSPRO enables efficiencies by maximizing throughput and resource utilization by leveling off production peaks and troughs. Improved decision-making is based on what's scheduled and what's running. Capacity, resources, labor, work orders, overloads, skills, potential problems, set-up, tear down and pegging are all considered.

SYSPRO APS for Medical Devices incorporates a strong finite capacity scheduling capability, further facilitating a lean, cost-effective manufacturing environment. Data is recorded in real-time, highlighting bottlenecks immediately, delivering the flexibility to dynamically and cost-effectively reschedule operations to accommodate constraints. This results in a lower cost of operations.



# Internet Power

## Internet Power

In today's competitive business environment, the integration of systems and processes is at the heart of effective business-to-business trading. Software tools such as ERP and CRM can help improve customer and supplier relationships, but not if they are used in isolation. A customer placing an order over the Internet expects a fast response and this requires full integration. The Internet is easily the most powerful business tool of the new millennium. It has altered business methodologies and dramatically impacted the way organizations relate to their customers. From the ordering process to customer support and customer service, the Internet offers limitless opportunities to those companies with access to Web-enabling technologies. SYSPRO for Medical Devices ushers in a new era of Web services. SYSPRO leverages Microsoft® .NET component architecture to deliver SYSPRO e.net solutions, an open component-based software framework.

SYSPRO e.net solutions provides a highly cost-effective way to trade across the Internet by integrating best-of-breed applications, maximizing business-to-business trading and leveraging wireless connectivity. SYSPRO e.net solutions not only allows users to interact with the SYSPRO system over the Internet, but also remotely from their handheld device or cell phone, so they can enter purchase orders or check inventory in the field. SYSPRO's e.net solutions allows your customers to access catalogs or manuals online, search for and order items and then track their progress, from order to delivery, in real-time – all this via a standard Web browser.

SYSPRO delivers B2B (Business to Business) or B2C (Business to Consumer) trading functionality to the medical manufacturer either through a fully integrated offering or by providing the tools to integrate disparate customer facing Internet application with the back-end SYSPRO enterprise system.

# Proven ROI



## **Document Flow Manager & Electronic Document Interchange**

In business, sharing data with trading partners is essential. SYSPRO Document Flow Manager provides a powerful way of automating business processes and forms a key part of facilitating collaborative commerce.

The SYSPRO Electronic Document Interchange (EDI) module is geared towards manufacturers and distributors who must accommodate complex transactions among a community of suppliers in standardized formats. EDI is an invaluable tool that enables the rapid, electronic transmittal of transactions and notifications between trading partners, thereby speeding the entire order/shipping cycle. EDI also increases accuracy by eliminating unnecessary manual entry.

## **Lower Cost of Ownership**

Medical device manufacturers operate in very competitive marketplaces with significant financial and human resource constraints. Companies need flexible solutions that fit their business and which enable their people to grow and adjust to changing requirements very quickly. SYSPRO contains the essential functionality for medical device manufacturing to compete effectively. The fully integrated, industry-focused system will stimulate a lower cost of ownership by speeding up the implementation cycle and providing an expedited time-to-benefit.



## **Implementation Methodology**

The SYSPRO STARS (Structured Technique to Achieve a Rapid Solution) Implementation Methodology is a highly structured, business-centric methodology that guides implementers through the implementation process and provides a framework by which business practices can be examined and re-energized to maximize overall operational efficiency. STARS is provided as a two-volume, high quality printed set for reference purposes with a template-based electronic CD-ROM containing an extensive array of documentation, implementation information and project management tools.



Canada  
Syspro Software Ltd.  
4400 Dominion Street, Suite 215  
Burnaby, BC  
Canada V5G 4G3  
Tel +1 (604) 451 8889  
Fax +1 (604) 451 8834  
Toll free (888) 259 6666  
Email [info@ca.syspro.com](mailto:info@ca.syspro.com)

USA & Americas  
Syspro Impact Software, Inc.  
959 South Coast Drive, Suite 100  
Costa Mesa  
California 92626 USA  
Tel +1 (714) 437 1000  
Fax +1 (714) 437 1407  
Toll free (800) 369 8649  
Email [info@us.syspro.com](mailto:info@us.syspro.com)

Africa and the Middle East  
Syspro (Pty) Ltd.  
Block A  
Sunninghill Place  
9 Simba Road  
Sunninghill 2157 South Africa  
Tel +27 (0) 11 461 1000  
Fax +27 (0) 11 807 4962  
Email [info@za.syspro.com](mailto:info@za.syspro.com)

United Kingdom and Europe  
Syspro Limited  
Baltimore House  
50 Kansas Avenue  
Salford Quays  
Manchester M5 2GL UK  
Tel +44 (0) 161 876 7771  
Fax +44 (0) 161 876 4502  
Email [info@uk.syspro.com](mailto:info@uk.syspro.com)

Asia Pacific  
Syspro Software Pty Limited  
Level 5  
113 Wicks Road  
North Ryde  
NSW 2113 Australia  
Tel +61 (2) 9889 5600  
Fax +61 (2) 9889 5566  
Email [info@au.syspro.com](mailto:info@au.syspro.com)



Go to [www.syspro.com](http://www.syspro.com)

**Microsoft**  
GOLD CERTIFIED

Partner

Copyright © 2006 SYSPRO. All rights reserved.  
All brand and product names are trademarks or registered trademarks of their respective holders.