



Wrap-Up



Your Full Service Medical Device Contractor

2005



VISIT US AT MD&M WEST

at the Anaheim Convention Center in Anaheim, California
from January 10-12, 2005 in Booths 2470 & 2472

Visit us at MDM West in Anaheim this January at the Anaheim Convention Center to see first hand our wide selection of outsourcing services and OEM opportunities. We are always excited to see our customers and have a chance to discuss your business needs and how our services can help you grow and achieve your goals.

A Message From Joe...

This last year has been a great and exciting year for our company. STI and McLean Medical continue to work with our customers to provide the world with new and innovative medical products and we are part of the health care stream that helps save lives and improves the quality of life for many...what a wonderful thing to be a part of!

As we look forward to the coming new year we can see definite trends in the medical device manufacturing market.

Trends

- More outsourcing
- More pressure on product cost/overhead
- Higher Standards for quality systems
- More pressure regarding time to market
- OEMs sticking to their core competencies
- More company acquisitions and consolidations
- More start up virtual companies

Because of these trends we at STI and McLean Medical have seen tremendous growth in the last year. We are a seamless extension of the companies that we provide our services to. This enables our customers to do what they do best, sell, market and develop their products. We meet and exceed their expectations by providing:

- QUALITY
- TRUST
- EXPERIENCE

STI and McLean Medical's commitment to quality is a fundamental component of our mission. Our quality systems interface with the world's leading medical device manufactures. We have vast experience in managing the regulatory requirements for Class I, II and III medical devices.

Trust is the reason we see our largest area of growth is with our current customer base ...the top global medical device manufactures.

Many of our customers have been with us for 20 years or more and as they have grown so have we!

Experience is provided every step of the way...from initial design concept to manufacturing, supply chain management, and active, continuous improvement programs. We have over 24 years of experience in medical device outsourcing and our customer base ranges from startup companies to Fortune 500 medical device companies.

We are in a fantastic industry that will continue to grow and excite. All of us at STI and McLean look forward to a year of innovation and growth in our industry.

Joseph F. Scanlan
Vice President/Business Development

Quality at Surgical Technologies, Inc.



A person once said something to the effect that the road to assuring a good quality product does not have a destination and that the trip is a never ending journey.

That is and has been the quality life at STI. The improvement process is never ending and the process involves everyone in the building (quite a full bus).

For years people have tried to define what quality means and what a quality product is. The most recent definition I have heard is: The acceptable quality of the product is what your customer tells you it is.

STI is in a very regulated industry. We not only need to adhere to FDA regulations, we are also ISO certified which gives us another set of regulations that must be adhered to. None of the agencies will tell you how to run your business but they will tell you what the rules are in order to continue business. We must keep this in mind while orchestrating the activities required to ship a product.

Being a contract manufacturing

organization STI has many customers that all deal with manufacturing, engineering, documentation and communications in different ways but they all expect the same thing, a good quality product.

The introduction of a new quality product at STI begins with our Quality Plan, lovingly referred to 028 internally. This document describes all the activities required to complete a well defined and controlled introduction of a new product. The Plan assures that all required activities are completed prior to the release of the product. The activities begin with Customer Service. From there all areas, Sales, Engineering, Materials, Manufacturing, Microbiology and Quality all have their vital inputs. When "028" is completed we know that we will deliver what the customer wants.

Once underway with the manufacturing, other internal systems kick in for quality improvement. We have a very active internal Corrective Action/Preventative Action system. These can be generated by anyone in the company. The completion and implementation is closely monitored by

Quality. Our external Corrective Action system is used to improve supplier quality and delivery performance. These are also monitored by Quality. Quality and Engineering also conduct meetings with suppliers to assure the requirements are understood. You must have high quality components to build high quality product.

Another simple tool used at STI is internal communications. Each week meetings are held by Manufacturing and Quality to openly discuss concerns, schedules and improvement opportunities. Minutes are taken and distributed. Requested actions are monitored to assure follow thru and completion. To assure upper managements involvement, a meeting is conducted each week to discuss the events and activities from the past week and the plans for the next week.

While the rest of us are busy assuring a quality product is shipped on time, Sales and Customer Service are in constant contact with the customer to assure all needs are met. Most of our customers provide us with a report card, which indicate how we did on quality and delivery for a given time frame. This is very important data for a manufacturing company. To aid improvement, meetings are held to review the report and discuss how we can do better. Another continuous activity.

Remember the busload of people I talked about earlier? Each person on that bus is important to this quality journey.

And so it continues each and every day. The process never stagnates, if it does we will not succeed.

Outsourcing Services Offered

Surgical Technologies, Inc. (STI), McLean Medical & Scientific, Inc., and Scanlan Group, B.V., (SGBV), offer you experienced outsourcing services for your medical products manufacturing and regulatory needs. As ISO certified and FDA registered suppliers, we offer:



McLean Medical & Scientific, Inc.

Specializing in manufacturing the finest surgical instrumentation to customer's exact specifications, McLean Medical combines superior materials and skilled craftsmanship to produce the highest quality OEM surgical products.

- Instruments and tools for surgical, medical, and production environments
- Tooling for over 5,000 instrument forgings
- Design consulting



Surgical Technologies, Inc. (STI)

Offering dependable contract packaging and responsive service, STI combines state-of-the-art technology with the most dedicated, energetic experts in the industry.

- Assembly, packaging, and sterilization
- Class 10,000 Clean Room - Class 100 Conditions
- Complete packaging and sterilization validation protocol development
- Design consulting

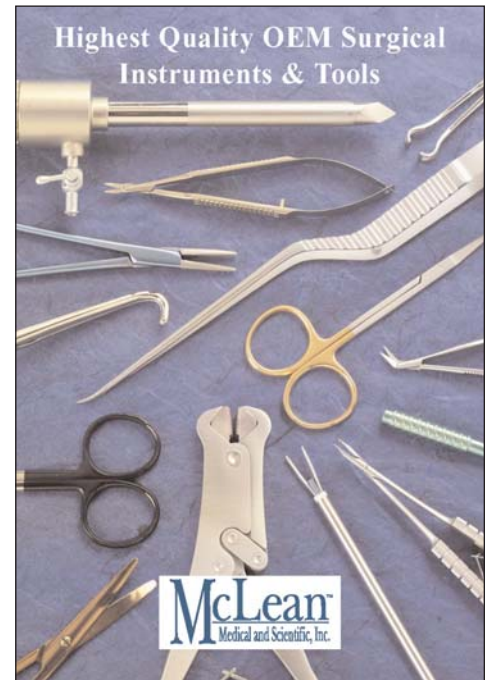


Scanlan Group, B.V. (Amsterdam, The Netherlands)

Providing a "launch pad" for companies entering the European or U.S. markets, the Scanlan Group offers essential services needed to establish a satellite office in Europe or the United States — virtually overnight.

- MDD-compliant European Authorized Representative for U.S. manufacturers
- FDA U.S. Agent services for European manufacturers
- Complete logistics / distribution / virtual office services
- Consulting

McLean DVD Now Available!



Custom instrumentation is a large percentage of the market for McLean and we are now offering a new DVD to assist customers with their design control. The new DVD offers approximately 75 base product patterns for OEM customers and potential customers to modify to meet their specific and unique design requirements.

These base patterns, designed by McLean's expert artisans, will save time in the design process and assist in providing quicker turn around time with quotes and proposals. This process will also help move products into production more quickly.

If you would like to receive a copy of the DVD please contact: scanlanj@surgicaltechnologies.com or call: 800-777-9987



Ken Blake, Vice President/General Manager of STI / McLean at the recent MDM Minneapolis

Meetings Schedule

MD & M West
Jan. 10-12, 2005
 Anaheim, CA
 Anaheim Convention Center

Design of Medical Devices
 April 13-15, 2005
 Minneapolis, MN
 Radisson Hotel

MD & M East
 June 13-15, 2005
 New York, NY
 Jacob Javits Center

MD&M Minneapolis
 Nov. 2-3, 2005
 Minneapolis, MN
 Minneapolis Convention Center

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Senger and Associates will offer our full array of medical Outsourcing services, including...

- Assembly, packaging and sterilization
- Class 10,000 Cleanroom - Class 100 conditions
- Complete Sterilization Validation Protocol Development

- Design and Development services
- OEM of surgical instrumentation
- Regulatory Affairs Consulting

For more information, contact Steve Senger of Senger & Associates at 651-633-6040 / www.senger-assoc.com

UNDER CONSTRUCTION: New Dry Room with Controlled Environment

STI is in the process of building a new controlled environment room for certain types of medical devices and pharmaceuticals. The room will be a dry room with 5% or under relative humidity and class 10,000 clean room conditions.

