



The Company

Terumo Cardiovascular Systems (Terumo CVS) is a global supplier of medical devices used in cardiac surgery. The company is headquartered in Ann Arbor, Michigan, with manufacturing operations in Ann Arbor, as well as Elkton, Maryland; Ashland, Massachusetts; and Tustin, California. Terumo CVS is a subsidiary of Terumo Medical Corporation, the U.S. subsidiary of Terumo Corporation of Japan. Terumo Corporation is a premier global medical company with 2000 annual sales of more than \$1.6 billion. Terumo Corporation manufactures, markets and sells a wide range of medical products including syringes, needles, catheters, and blood bags.

The Challenge

Terumo CVS was formed in 1999 when Terumo Medical Corporation purchased 3M's cardiovascular device business. Prior to that time, the company operated on the Sherpa product data management (PDM) system. With the formation of the new company, Terumo CVS now needed to replace the 3M licenses for Sherpa and begin an evaluation for a product lifecycle management system.

Medical Devices

The Success

- **Turnover Reduced**
eMatrix simplified procedures, enabling employees to work more efficiently and effectively.
- **Improved Product Quality**
By gaining tighter control over business processes through precise and deliberate definition, product quality and production schedules were improved.
- **Streamlined Document Distribution System**
eMatrix reduced the time required to locate and distribute designs and other documents from hours to minutes and also eliminated version control errors.

The Story

“eMatrix has proven particularly valuable in helping us model our business process, which it does very well. As a relational database, eMatrix enables our people to work through the details of a business process and apply it through an eMatrix schema.”

*Stephen Wells
Design and Documentation
Manager*

A primary consideration of the Terumo CVS evaluation team was to find a product lifecycle management (PLM) system that could effectively manage the vast amounts of information common in the medical device industry. Successfully documenting, vaulting and auditing information including approvals authorization, notification distribution, electronic document markup, and audit trails of the entire change process are necessary to comply with FDA 21 CFR Part 11 (commonly referred to as Part 11) regulations that pertain to electronic records and electronic signatures.

To speed production and improve quality, Terumo CVS needed a deeper, more informed understanding of when to accelerate products into production. Like most medical device firms, the company produces systems in small batches, releasing a major model change about every 10 years. Suppliers of the components in the systems have much shorter life cycles, requiring Terumo CVS to frequently replace components. Terumo CVS needed a way to track, implement and document component changes while ensuring the entire finished product remained essentially the same.

The Solution

Quick, Easy Changes

Terumo CVS selected MatrixOne's eMatrix™ product lifecycle management platform. With eMatrix, Terumo CVS can now make changes to any type of technical document in addition to bills of materials (BOMs), authorizations and notifications. Through eMatrix, Terumo CVS manages the device master record—a term used by the FDA and ISO certification bodies that encompasses the entire definition of what the product is, how it is made and what processes are used before releasing the product. This ensures consistency throughout the production process and reduces errors.

Whenever Terumo CVS initiates a new design or document, or changes an existing one, eMatrix displays a wizard for creating or changing this item, and then sends the change for review and approval to all necessary parties. The change can then be processed and distributed in the final form. An additional benefit to this, apart from the improved productivity, is the availability of a full audit trail from eMatrix that shows how a change was initiated, approved and implemented. The audit trail shows the full history of the design, which is particularly beneficial during regulatory audits.

Helping People Work Together

To keep up with the changes suppliers make to each product's component parts, Terumo CVS uses eMatrix to record and implement the changes. By getting the right people involved at the right time, eMatrix ensures all product designs reach production at the appropriate time with the correct components available. Terumo CVS intends to incorporate suppliers directly into the design process through eMatrix in the future.

Terumo CVS also plans to use eMatrix to manage the electronic approvals for other Terumo CVS processes—including those from HR and Web site content management. Using eMatrix in these non-technical areas enables several departments within Terumo CVS to more efficiently manage changes to the Web site, request vacation time, enroll for training and record progress, and other corporate-level functions.

The Bottom Line

"The ease, speed and range of use of our eMatrix implementation has been commented upon by some of our other software vendors," said Stephen Wells, design and documentation manager for Terumo Cardiovascular Systems. "By providing benefits to others in Terumo in addition to fulfilling its original mission to accelerate our product lifecycle proves the value of the eMatrix platform to our organization."

About MatrixOne

MatrixOne, Inc. (NASDAQ: MONE) is a recognized leader in delivering collaborative Product Lifecycle Management (PLM) solutions. Together with our partners, we provide flexible solutions that unleash the creative power of global value chains to inspire innovations and speed them to market. MatrixOne's more than 625 global customers represent the aerospace/defense, automotive, consumer products, general machinery, high technology, and life sciences industries, and include GE, Procter & Gamble, Philips, Siemens, Agilent Technologies, Johnson Controls, and Honda. MatrixOne is headquartered in Westford, Massachusetts with locations throughout the world.



210 Littleton Road, Westford, Massachusetts 01886 T. 978 589 4000 F. 978 589 5700 www.MatrixOne.com