

MEDICAL DEVICE MANUFACTURING

Application Case Study - Terumo Medical Corporation

Global Medical Product Manufacturer Error-Proofs Its Packaging Line with Automated Labeling and Track-and-Trace Solution

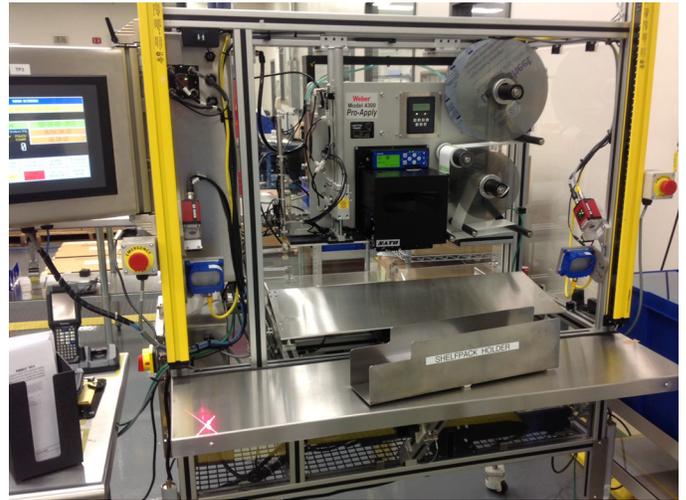
Company Profile

The name Terumo has been synonymous with high-quality, innovative medical devices for more than 90 years. Terumo Medical Corporation (a subsidiary of Terumo Corporation) develops, manufactures, exports, imports, markets, distributes, and sells a diverse portfolio of products worldwide, including guiding sheaths, syringes, catheters, and other medical products. As stated on the Terumo Medical website, “In the world of medical devices and supplies, the cornerstones of excellence are dependability, predictability, and consistency. To ensure that every item they manufacture meets these criteria, Terumo Medical Corporation applies strict standards of quality control. By developing innovative, high-quality medical products that the healthcare community can rely on, Terumo Medical Corporation realizes its goal of ‘Contributing to Society Through Healthcare.’”

The Challenge

Terumo’s Elkton, Maryland manufacturing facility spans over 321,000 square feet and specializes in the production of introducer kits - entry site management devices for interventional medical procedures, such as the placement of stents or balloons in arteries - as well as insulin syringes, IV catheters, and other medical accessories. After the manufacturing process is complete, products are sealed into a sterile barrier package, and then labeled to identify the product.

Terumo recognized that the manual labeling process was susceptible to human error. A simple mistake could result in the wrong label being placed on the wrong product,



Two QX Hawk Imagers on each packing line in Terumo’s Elkton, MD facility read and verify every product label.

using a poorly printed or damaged label, or inability to account for every printed label.

Always proactive in its quality measures, Terumo sought out an error-proofing solution that would eliminate these risks while ensuring compliance of labeling and artwork with all applicable medical device regulations and standards, including the FDA Quality System Regulation and ISO 13485 standard.

The Solution

Terumo contacted Matrix Systems & Solutions, Inc. of Sanborn, NY, a software provider with integration and custom equipment capabilities and a Microscan partner, to develop

■ **Objective:** Error-proof labeling of medical products to ensure that each device receives a correct and readable label that is traceable and compliant with all industry requirements.

■ **Project:** Replacement of manual batch labeling process with automated labeling & track-and-trace system.

■ **Solution:** An integrated system based on a Weber labeler with Microscan’s QX Hawk Industrial Imagers and the Matrix Packaging Execution System software to print, place, validate & verify labels.

■ **Result:** No labeling errors since implementation. Flexible software is reconfigurable for changing requirements.

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a solution for them. Matrix specializes in centralized printing, track & trace, inventory control and automated pallet labeling systems. Terumo had preselected a Weber label dispensing system, but required a more specialized software configuration than the labeler's standard package in order to meet all of their requirements.

Matrix provided Terumo with a turnkey solution that includes Microscan's QX Hawk Industrial Imagers and is tied together by the Matrix Packaging Execution System (MPES) IT system. Integrated with the existing ERP system, the MPES unifies the label marking and track-and-trace process to enforce a one-piece work flow and ensure traceability at the item, carton, and case level. Compliant with all software validation requirements, including the FDA's CFR 21 Part 11, the Matrix software package can be configured rather than customized, which enabled Terumo to use an off-the-shelf computer solution. Software changes can be reconfigured if business requirements change through settings instead of hard coding - a major benefit in the medical device industry, where any changes to software need to be revalidated to ensure compliance.

The system includes two Microscan QX Hawk Industrial Imagers on each line to read and verify every label. The first imager reads a Data Matrix code on the label containing serialization data to ensure that each pouch receives a label and that the label is legible. "The codes on the labels are quite small and there is not a lot of quiet zone around them", explains Matrix VP, Dan Hare. "We were still able to get robust decoding from the QX Hawk. In addition, the imagers have unique visual indicators for good reads, native Ethernet connectivity, and integrated lighting with an autofocus lens, so manual adjustment by operators is not required."

A second QX Hawk reads the serialized label again, counting the product as a finished good, and associating it to a carton, called a "shelf pack". A shelf pack label will be generated and applied as each shelf-box receives the defined number of devices. Once the full process has been repeated to fill the defined case quantity, a case label will be generated by an Intermec Smart Printer, which includes a built-in processor, enabling direct communication with the scanner and eliminating the need for an external PC. The case label is applied by hand. Every product package is associated to a shelf pack and a case, providing lot traceability at a very granular level. A count variance is run prior to the end of the run, enforcing label accountability; the run cannot be ended without accounting for all labels in the system.

"One of the key deliverables for us was the enforced one-piece work flow", says Terumo's Sr. Manufacturing and Industrial Engineering Department Manager, Rick Stapleford. "The earned label system requires that a label is scanned and verified before another can be printed. No two labels can occupy the same space, which means that there are no excess labels that could inadvertently be put on the wrong product."



The automated labeling process helps to ensure a one-piece work flow.

Conclusion

After passing all software validation requirements to ensure compliance, the system went live in January of 2013, and Terumo has not experienced a labeling error since its implementation. The system is also capable of helping to achieve compliance with the FDA's proposed Unique Device Identifier (UDI) rule for medical devices in the future. The integrated solution ensures labeling accuracy and "cradle-to-grave" traceability that not only exceeds the stringent requirements of the medical device industry, but meets the high standards of dependability, predictability, and consistency for which Terumo Medical Corporation is known.



Microscan's QX Hawk Industrial Imager features robust decode algorithms for reading both 1D and 2D codes.

Overview

- **Customer:** Terumo Medical Corporation
- **Industry:** Medical Device Manufacturing
- **Application:** Data Matrix Code Reading for Label Verification & Reconciliation
- **Product:** Microscan QX Hawk Industrial Imager
- **Reseller/Integrator:** Matrix Systems & Solutions, Inc.

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