



New labeling system enables regulatory compliance and unprecedented systems efficiencies at medical device manufacturer Zimmer Biomet

As medical device manufacturer Zimmer Biomet grew through merger and acquisition, they sought to harmonize different labeling systems across their global facilities with two goals in mind: to gain the efficiencies that standardized labeling processes offer; and to enable global compliance, especially with the pending European Medical Device Regulation (EU MDR). Zimmer Biomet chose ROBAR software from Innovatum, with label design and print powered by BarTender®.

The challenge

Zimmer Biomet, headquartered in Indiana, USA, ranks among the world's largest medical device companies, designing, manufacturing and marketing orthopedic implants and other musculoskeletal technologies and services with operations in more than 25 countries. They partner with numerous healthcare providers across the globe.

The company was built through merger and acquisition, and with each new acquisition came new legacy systems leading to dissimilar capabilities across facilities.

Labeling was a particular concern. Legacy systems were limited in design and data structure, and not scalable. Many of the systems could not generate some of the newer barcodes essential to medical device labeling, like the 2D Data Matrix. The situation was compounded by inadequate vendor support and internal attrition. The company experienced print latency, system-generated outages and had to expend significant effort maintaining accuracy.

The inefficiencies impacted business profitability and made it much harder to maintain regulatory compliance with the US FDA and their global counterparts.

We were unable to process some of the newer barcodes," said Aimee Wright, Zimmer Biomet's Manager for Global Labeling. "We had to hard code symbologies into our printers. We were managing thousands of SKUs in our system, and every new label design required work from our IT team."

Additionally, Zimmer Biomet had to address the tsunami of requirements from the European Union's impending Medical Device Regulation (EU MDR).

The solution

Selecting a labeling system

In 2009 Biomet had deployed ROBAR, which includes BarTender, for enterprise labeling at the company's dental facility in Florida, followed by additional instances at facilities in New Jersey and company headquarters in Indiana.

When Zimmer and Biomet merged in 2015, the company required a system that would scale to their rapid pace of growth and provide process efficiencies, while at the same time enabling compliance with emerging regulatory standards. After a comparison between existing systems, their experience with ROBAR was the differentiator.

The company's decision was based on the best-in-class user experience of the ROBAR platform, the impeccable support provided by the ROBAR team, and BarTender's adaptability. "The system's user-friendliness, audit readiness, scalability and design capabilities were a differentiator. It included everything we need to handle regulations" said Ms. Wright.

ROBAR delivered a resilient and agile platform that included redundant server architecture and 99.99% uptime performance. "It was remarkable, for example, that we could print labels for 30,000 different SKUs, using a single template. We printed this one template at 75 different corporate and contract

manufacturing locations to about 50 different models and brand of printers of various resolutions.” said Ms. Wright.

Label translation and localization — ROBAR Destination Labeling

At their Dutch distribution facility, Zimmer Biomet deployed ROBAR’s Destination Labeling module in 2019. ROBAR manages intelligent SAP-guided picking, the printing of Instructions for Use (IFUs) and generation of any required supplemental language labels based on the shipment’s ultimate destination. With a single UDI barcode scan at the packaging line, ROBAR determines what languages are already on the product label, evaluates the languages required at the destination, and in less than one second, prints out the supplemental languages on the label. If needed, it also prints the other required non-label documents. To ensure accuracy, the barcode on the label and IFU are then scanned to verify the right documentation is being included with the right product.

Unprecedented agility, regulatory compliance and automated change management

Due to limitations of existing systems, the company previously used many static elements on label files, requiring a hard-to-manage number of label templates. Now, labeling is connected with dynamic data stored in ROBAR’s embedded database management system. Integrations with at least twelve different PLM and ERP systems allow for appropriate sources of critical label content and manufacturing data. Leveraging BarTender’s conditional printing features, ROBAR merges data into label templates, generating samples for review and approval using an integrated workflow module.

The system is built to process and automate changes at scale, a requirement to efficiently operate across multiple regulatory environments. ROBAR provides the agility to manage mass updates, generate required PDFs, automate redline version comparisons and electronic label approvals. Zimmer Biomet has the ability to process very large change controls, such as the Brexit CE change, in an instant, across more than 125,000 labels.

Presently, over 800 users process approximately 9,000 multicopy label requests every day, including users from over 70 outside vendors, ensuring that Zimmer Biomet always receives

components labeled to their requirements. The vendors access ROBAR through the internet using a simple browser-based interface with no local client or app installed on the vendor’s system — vendors don’t need access to Zimmer Biomet’s network to print Zimmer Biomet labels. ROBAR’s database management system captures the full audit trail for both internal and external print operators, maintaining regulatory compliance and operational efficiency.

The system provides first label out in about three seconds, worldwide, with 99.99% uptime achieved through ROBAR’s redundant, load-balanced, automatic failover architecture. And for those times when the company needs additional support, the ROBAR support team is available around the clock, all day, every day, with response time measured in minutes.

Complex labeling, simplified

Rather than relying on expensive, customized, tailored coding to design labels, ROBAR and BarTender provide a configurable, user-friendly experience. “ROBAR and BarTender have allowed us the control over our labeling challenges,” said Ms. Wright. “We handle all the label content management and format design work in our department with minimal assistance from our IT team. The solution has allowed us to apply data governance and structure to this mission critical function.”

BarTender provides Zimmer Biomet the flexibility to explore expanded use cases. Encoding RFID for a smart label is no more complicated than creating a barcode. And for cases that may need special attention, VB scripting is available.

Preparing for future growth

“I don’t think you can get a more user-friendly, responsive labeling and design system than this,” said Ms. Wright. “We’re able to streamline our processes with layers, Visual Basic scripting and other functionalities that come as a standard in BarTender. Printing is mission critical for Zimmer Biomet, and the response time we are experiencing is nothing like we’ve ever seen before. Moving to ROBAR and BarTender has given us endless opportunity that we didn’t see with any other solution. It’s allowed us to think strategically about the future. It’s been a game changer for us.”