

CASE STUDY—MEDICAL DEVICE COMPANY SUPPORTING NEW SYSTEMS AND 3RD PARTY LABELING WITH SEAMLESS INTEGRATION

BACKGROUND

The company in this case study is a multinational medical device manufacturer, specializing in surgical care. Their challenge was twofold:

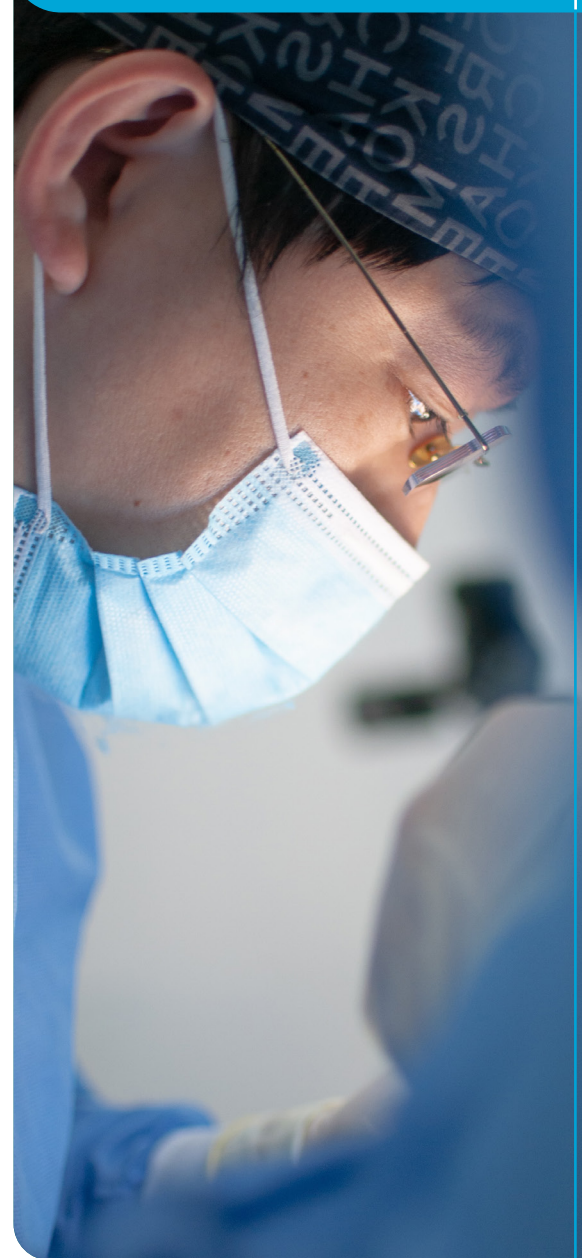
- Ensuring their labeling solution integrated seamlessly with a new ERP (SAP) and Quality system.
- Maintaining design and content control while extending print functionality to a 3rd party contract manufacturer.

They needed to accomplish this while adhering to all Medical Device Regulations (MDR) and complying with the FDA's Unique Device Identifier (UDI) regulations for labeling.

PRAGMATYXS' SOLUTION

An efficient, reliable, and scalable solution was designed and implemented to make critical production order information such as lot numbers, product descriptions, manufacture and expiration dates available for label printing. This solution ensured data efficiently and accurately flowed between ERP, Quality and Labeling systems. While the manufacturing would be managed by a 3rd party, the product owner needed to maintain control of the product label data and design.

In the new system, label printing is initiated through the system remotely by the 3rd party manufacturer to their local printers. The labeling system is an off-the-shelf solution combined with Pragmatyxs' tailored extensions, both of which are fully supported by a "Pragmatyxs Critical Care plan". By splitting data and design control from print execution, Pragmatyxs was able to assist the customer in delivering an efficient and high performing solution while ensuring compliance with all quality and regulatory requirements.



COMPANY OVERVIEW

A multinational medical device company producing surgical devices for more than 100 years. Their surgical technology and solutions have revolutionized surgery with minimally invasive procedures.

Pragmatyxs is a trusted advisor for this customer and has continued to provide full range support of their labeling solution for more than 15 years.

✓ **TRACKING**

✓ **COMPLIANCE**

✓ **ACCURACY**

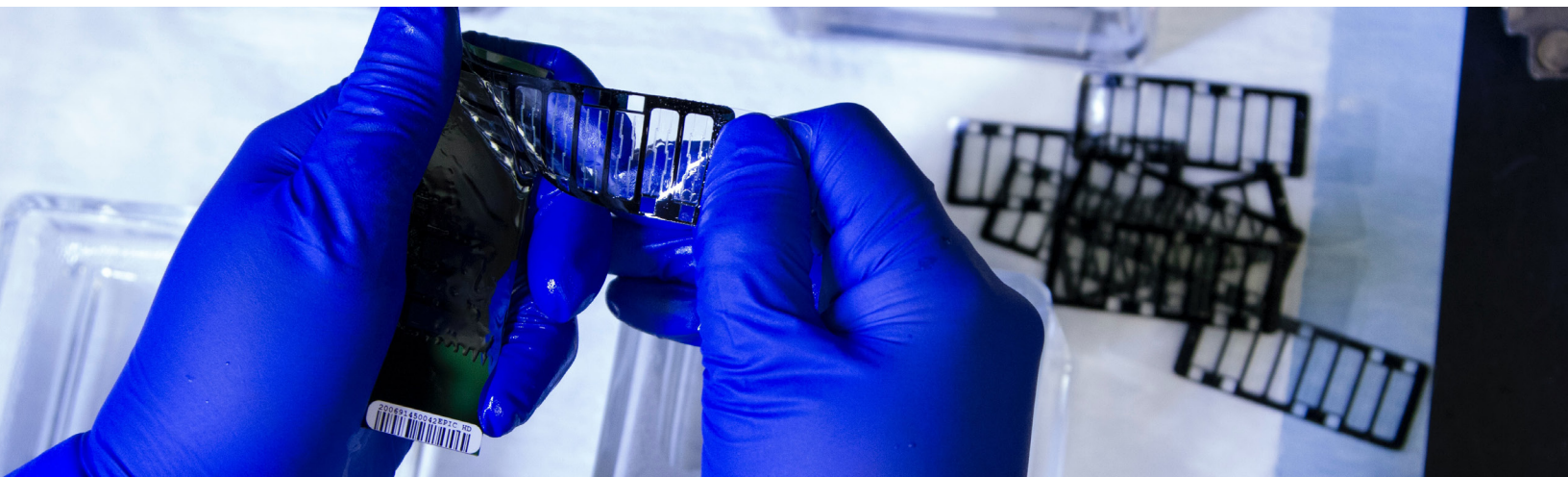
✓ **SECURE**

RESULTS

Strong system integration and stringent labeling controls were non-negotiables for our customer. The medical device industry continues to face recalls which are time consuming and costly to remediate. Mislabeling is a primary driver.

This project provided the company the ability to:

- Ensure accurate and consistent product labels
- Adhere to strict labeling compliance regulations
- Quickly react to labeling changes, decreasing cost, time to market, and avoiding recalls due to labeling defects
- Ability to remotely print new product label revisions on-demand immediately after change
- Expertise to support 3rd party manufacturing within the current infrastructure, data, and designs



Pragmatyxs, Inc. provides fully integrated solutions for companies of any size. With 25+ years of experience and the ability to solve some of the medical device industry's more complex issues, we consistently meet or exceed the customer's quality, timeline and budget expectations.



pragmatyxs.com

Sales@pragmatyxs.com

253-638-7740

**20415 72nd Ave. South
Suite 250
Kent, WA 98032**