



Overcoming Medical Device Production Challenges With an End-to-End Automation Solution

Scaling Production to Meet Supply Demands for a Legacy Medical Device

In 2021, a major medical device manufacturer faced a production challenge for a market-leading device. The existing production line could no longer keep up with the constantly increasing demand – and throwing additional labor at the problem was not a cost-effective solution. In addition to these concerns, even minor product alterations were out of the question in order to maintain the integrity of the medical device.

In partnership with Tessy Plastics, Tessy Automation accepted the challenge, drawing on creativity and deep experience to develop and deliver a new production line in less than a year. The new line seamlessly integrates a complex set of advanced machines, expanding capacity by a factor of two without any alteration to the manufactured device. Tessy's customer will enjoy continued profits from device sales, with supply assured and costs contained.

COMPANY

Tessy Automation

LOCATION

Meadville, PA

FOUNDED

1983

WEBSITE

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Delivering on a Leap in Production Volume Without Product Changes

In 2009, our team built the original automated production line to replace a completely manual assembly process. It reduced line operators from nine to three while boosting annual capacity to over 10 million units. However, the medical device has several sizes, and manufacturing change over between sizes was time-consuming, reducing order response flexibility and overall capacity. In addition, as the production line machines aged, more maintenance was needed, further reducing capacity.

From 2009 to 2021, the client's forecasted production volume grew, requiring the team to start up the original, manual assembly line in addition to the automated one to meet demand — causing a significant impact on unit costs. By 2021, they needed additional aspects beyond the capability of the existing automation to meet the forecasted volume. The line was running three shifts a day up to seven days a week, but orders still often exceeded capacity. With device demand continuing to grow, the business needed a leap in production volume while simultaneously keeping labor costs under control.

New manufacturing technology could deliver that leap, but the Tessy Automation production engineers faced a huge constraint: the medical device design could not be altered. Originally designed for manual assembly, the device was subject to government regulations that demand an extensive testing and approval process for virtually any change. To the customer, avoiding the costs and uncertainty of that years-long process was a non-negotiable requirement. That meant the device material and dimensions could not be modified, prohibiting even small adaptations that could help enhance manufacturing efficiency.

A Fully Automated, High-Capacity Production Line

The Tessy Automation team developed a solution that incorporates a complex set of advanced manufacturing technologies into a completely new production line, with three injection molding presses playing a key role. A final product is created by snapping together three separate components to feed an asynchronous part buffering system. Six 6-axis and two SCARA robots from EPSON Robots manage the assembly, part handling and processing system. These precise and programmable machines operate in concert with other fully automatic machines, including vision inspection and an auto-bagger. The only human involvement is for machine tending and packaging bagged components. The manufactured medical devices are, quite literally, not touched by human hands.

The new line provides the customer with a production capacity of 25 million units per year using the same number of workers. This level of production volume, combined with the old, still functioning production line, will meet current and future sales demands while maintaining a consistently low unit cost.

Producing 25 million devices each year would have required 100 line workers using the original manual process from two decades earlier. The manufactured device is still precisely the same, with no need for regulatory approval of any change.



From Concept to Operational in Less Than a Year

The new production line was operational in only 49 weeks, beating the project's original projection of 56 weeks. Tessy met this tight schedule despite supply chain issues and COVID-based shutdowns that totaled six weeks. The rapid development of the new manufacturing solution was critical to the customer's business, allowing them to meet growing demand with controlled costs. Every year without the new line would have burdened the customer with added labor costs estimated at \$350,000.

Additional Advantages

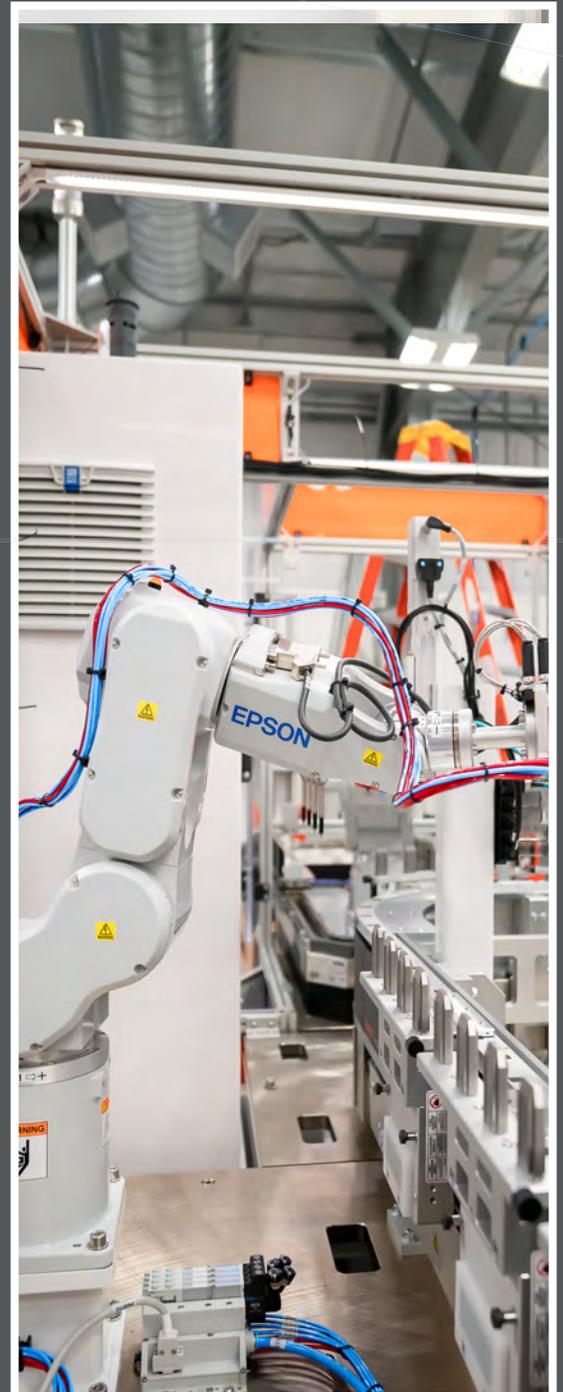
In addition to meeting the essential customer requirements, the new production line comes with multiple additional advantages. First, an Ethernet communications system between machine controllers, developed by Tessy Automation, means improved flexibility and easier upgrades to future machine technologies. The messaging structure of this system was designed by Tessy to support effective communications between a range of machines from various vendors.

By designing the production line to seamlessly switch between product sizes, order-filling flexibility was increased without compromising quality. Tessy Automation was able to accomplish this by restricting alterations to the injection molds and leaving the existing process untouched. This made product size changeover for the line efficient, fast and less costly.

The line also includes a secondary unload capability that can be used to support the manual addition of value-added items to product shipments. A current example is adding LED lights to the bags for some orders. This occurs without interfering with the automatic production operations.

The already high level of product quality was enhanced further by an automated vision system. This system, integrated into the production line, is used to make a detailed inspection of two small hinge points in the device where defects sometimes appear. Defective units are removed by machine and never affect end-user satisfaction.

Perhaps most importantly, the new line enhances worker safety. Tessy developed a standardized machine frame base platform and guarding system. This flexible platform will also be applied to future production systems for other clients, with expanded or reduced sizes to meet specific needs.





Engage With Tessy

Tessy Automation designs and manufactures custom electromechanical automation solutions to include build-to-print, build-to-spec and complex automation assemblies. Our team of Automation Architects provides customers in the medical, consumer, consumer healthcare and energy industries with a clear vision of custom automation projects. Founded in Meadville, PA, Tessy Automation has earned a reputation for innovation, quality and efficiency that traces back to the production of the famous Talon Zipper.

Tessy Plastics, the parent company of Tessy Automation, is a global contract manufacturer headquartered in Skaneateles, NY, specializing in injection molding and custom automated assembly solutions. All Tessy facilities are FDA/GMP compliant and add up to more than 1.6 million square feet, including 135,000 square feet of ISO Class 7 & 8 clean room manufacturing. Through comprehensive engineering and research & development, Tessy provides superior quality and speed to market. Contributing to both Medical and Consumer markets allows Tessy to leverage their expertise over a wide range of products. Capabilities include everything from product concept development and prototyping to manufacturing, packaging and global distribution.

Our team is ready to apply what we learned to upgrade manufacturing for other products. We would welcome the opportunity to discuss your production capacity and cost challenges. To learn more about Tessy Automation, visit our website at <https://tessyautomation.com> or call us directly at 814-724-6336 to discuss how a turnkey automation system could benefit your company.

EPSON Robots

Tessy maintains a close and highly valued partnership with EPSON Robots. Their state-of-the-art products, including 6-Axis and SCARA robots, are renowned and highly respected for their ease of use, reliability, performance and overall value. Our production line design engineers consult closely with EPSON Robot's experts to select the optimal models for each unique situation.



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