

# MAXIMIZER:

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## **Maximize the Use of Your Operation Footprint and Assets to Reduce Costs**

Most Medical Device Manufacturers (MDMs) have a manufacturing facility that is not utilizing its resources 168 hours a week. In an environment where MDMs are under constant pressure to reduce costs, there is an alternative to maintaining under-utilized operations or establishing larger operations and footprints. Medical device manufacturers (MDMs) can maximize their current assets.

This paper will examine a solution to dramatically reduce total operational costs by changing the ownership of cost of goods sold. It includes a case history of a top-5 orthopedic medical device company that successfully executed this strategy.



## REDUCE TOTAL PRODUCTION COSTS BY 25 PERCENT OR MORE

Medical device manufacturers (MDMs) are under constant pressure to reduce costs. They respond by adjusting their manufacturing processes in various ways to be more efficient. They also modify designs, use less expensive materials and reduce material waste. Other options include outsourcing certain manufacturing steps to contract manufacturers that are more experienced, better equipped and can leverage economies of scale. Another approach is reducing the length of the supply chain, which improves communication and decision-making and gets the product out faster.

Many MDMs feel comfortable making these kinds of changes because they are easy to understand and relatively small in scale. In general, MDMs are conservative in nature and don't like to stray too far from what has worked for them in the past. Change represents risk; MDMs are uneasy about larger-scale changes because they seem more complicated, expensive and risky.

Small changes can certainly have a positive impact to the bottom line: 2 percent here, 1 percent there. But what if there was a way to reduce costs by 25 percent or more?

Reducing cost in big ways requires innovative thinking. A major drain on MDM capital is brick-and-mortar manufacturing facilities that are not fully using their resources. For example, a factory that is not using its resources 168 hours a week is having a negative impact on the bottom line. Instead of maintaining that operation, and/or trying to fix it, what if the MDM outsourced the entire process to one select contract manufacturer, which then takes the MDM's complete value stream into its own facility to maximize efficiency and reduce operational costs?

This is exactly what Orchid Orthopedic Solutions (Orchid) does with its **Maximizer** solution. Maximizer facilitates the change of ownership of cost of goods sold, from the MDM to Orchid. This process covers everything from production through quality control, packaging and shipping. MDMs that partner with Orchid through Maximizer have the potential to dramatically reduce their total costs by 25 percent or higher, giving them more money to reinvest in their operations. Once the transfer of ownership is complete, Orchid has the capability of managing the ongoing product life cycle.

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## How MAXIMIZER WORKS

Maximizer allows MDMs to get the best return on the assets they own and operate. In manufacturing, return on investment (ROI) is often an underutilized key performance indicator which can greatly impact profitability.

$$\text{ROI} = \frac{\text{Gain from Investment} - \text{Cost of Investment}}{\text{Cost of Investment}}$$

One of the fastest ways to improve **ROI** is to shrink the denominator on equipment and facilities that show considerable variability in their operational expenditures. If a facility experiences variability, there may not be enough product demand to compensate for these fluctuations. Highly experienced contract manufacturers like Orchid know how to control these fluctuations to reduce costs in certain categories, creating long-term operational savings.

Maximizer, however, is not for every company, or every product. It can start with one process and others can be brought in later, as the gains (greater efficiency, lower-cost production and faster speed to market) are recognized. Maximizer is a very proactive way for MDMs to maximize their ROI on their current assets.

### Ideal candidates for Maximizer are companies that:

- Have too many rooftops and want to divest a footprint (for example, after an acquisition)
- Don't want to integrate a new manufacturing process into their systems (for example, after an acquisition)
- Have under-utilized capacity and high costs to maintain that capacity
- Make room for a core value stream by moving a less-critical value stream out

The process starts by assembling a leadership team consisting of MDM and Orchid representatives to define the goals of the project and determine a plan of action. The teams include project management, high-level technical talent and general management from both Orchid and the MDM. Fluent and ongoing communication among team members at all levels enables rapid decision-making. In healthcare today, the largest delays are often related to stalled approval queues—this is not the case with Maximizer because the executive

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team makes decisions together and can deploy the necessary resources to move the project forward.

Maximizer does whatever is needed to streamline the transfer of assets. Equipment is purchased from the client (or purchased new, if needed) and installed in an Orchid facility to create a dedicated operation—all in-house under Orchid's roof. Orchid can move large amounts of capital equity and has invested \$1 million or more for the right project. By reducing variations and improving efficiency, Orchid creates an operational environment that has the potential to reduce costs by 25 percent or more. The MDM meanwhile, no longer has to worry about expenses (especially if there is a fall in demand) and can take those savings and reinvest them in R&D and product development.

## A CASE HISTORY

A top-five orthopedic medical device company had acquired a production facility that had been underperforming for the last several years. The facility only operated 60 hours a week with 20 support staff. The cost of goods sold (COGS) variance was high and did not meet the company's network optimization strategy. After meeting with Orchid executives and discussing several Maximizer options, the company decided to have Orchid build a redundant factory. The company transferred all production from the acquired plant to Orchid, including all equipment and the majority of the business office assets.

The leadership team worked together to oversee the transfer of assets and the building of the redundant factory. The goal was to close the acquired facility, move the equipment and set up the product line in an Orchid facility in Michigan, thereby freeing the company from dealing with negative variances and trying to maintain predictable costs.

The entire manufacturing facility was moved to Michigan in three months. This included machining centers, three large capacity laser cutters with all ancillary equipment, a CNC cutter grinder, wire electrical discharge machining (EDM) equipment, water recycling system and all finishing equipment included blasting, sonic cleaning and passivation systems. The Orchid team worked closely with the company to determine what equipment would be purchased and moved by Orchid and what equipment would be sold or donated on site, resulting in a seamless move.




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Orchid transferred the entire product line of 600 SKUs. This included used customer models and prints to create manufacturing drawings, CAD models, CNC machining programs, inspection data and DMR (device master records) for all the products. Orchid created packaging bills of materials and developed a method for FDA-compliant, completely sterile packaging. All rigging and trucking contracts and communication were handled by the Orchid team.

Twenty-six validations were completed on major pieces of capital. Additional new equipment was also purchased and validated by Orchid, including new machining centers, laser welding equipment, precision CNC laser cutters and a complete line of packaging systems.

Orchid also executed a sterilization validation for the products. Orchid used the MDM's existing validations for guidance in selecting worst-case challenges for each piece of equipment or process. Customer acceptance criteria and sampling plans were used for all validations. Using existing validations as templates greatly reduced the turnaround time on receiving customer approval and accelerated production.

Now, instead of managing the entire shop, with its problematic and expensive variances, the company simply oversees its product by providing forecast data to Orchid, placing purchase orders and communicating any needed expedites; the large manufacturing facility is no longer needed. Day-to-day management (production and quality, purchasing requirements, inventory management) is handled by Orchid.

“The most surprising part of the project was the ability to validate so many new pieces of equipment in a relatively short amount of time,” said the associate director of network optimization for the company. “Also, over the course of a year or so, other machines/processes were added to the shop floor and validated.”

The MDM is pleased with the outcome of the project. “We were able to reduce our COGS to the expected value and reduce most of the burden of managing the other facility,” added the associate director. “Of the 700+ SKUs, approximately 90 percent transferred, with just the low-priority ones remaining to be approved. We have achieved the goals we set forth at the beginning of the project. Orchid has also had to ramp up production levels considerably, due to increases in demand.”



## A BETTER WAY TO MAKE DEVICES

Maximizer is an innovative approach that improves quality, minimizes risk and reduces operating costs for medical device manufacturers. Orchid has the deep resources to take ownership of production lines of various sizes and bring them in-house to manage. It can quickly transfer/purchase and validate equipment and even handle regulatory requirements, if needed. By taking advantage of this alternative to expensive brick-and-mortar infrastructure, MDMs can reinvest more money in their products, take advantage of market opportunities and accelerate growth.

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“Our level of communication with Orchid has greatly improved,” said the associate director from the company. “They also now have a much more in-depth knowledge of our processes and procedures, which will help us as we move forward with sourcing future products with Orchid.”