Sterilizer Temporal Service Shutdown Project

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Abstract

Sole sourced sterilization company announced a one-year shutdown affecting adjustable valves manufacturer. The identified root cause was the sole sourcing strategy action taken by a medical device manufacturer that is already experienced on required sterilization ETO technique for adjustable valves. The manufacturing process of adjustable valves, as well as inventory levels and future requirements, were studied to understand current situation and possible solutions. It was found that by relinquishing inhouse sterilization sutures capacity to sterilize adjustable valves, not only ensured business continuity, but also was a costs and lead time saving opportunity.

Introduction

CST (Cerebrospinal Technologies), the most renowned manufacturing division of an American multinational medical device company, oversees the manufacture of adjustable valves for hydrocephalus treatment. Located on the Dominican Republic along with Sutures, Endo mechanical devices, Laboratory services and sutures sterilization divisions.

In the face of an impending one-year shutdown of their exclusive sterilization partner based in the United States, a comprehensive strategy was devised to sustain their operations, meet product demand, and uphold our commitment to delivering life-extending medical devices. The following objectives were established:

- Ensure sterilization of at least 65% of product demand in the calendar year 2024.
- Maintain inventory levels with a maximum overstock monthly allowance of 10%.
- Implement a solution that will keep sterilization cost equal or lower than actual cost.
- Reduce costs of operations that will compensate for a higher sterilization cost than current.

Literature Review

Adjustable hydrocephalus valves, vital in shunt systems, utilize a mix of materials like silicone, metal, magnet, ruby, and polypropylene. Ethylene oxide is the preferred sterilization method, adhering to FDA standards to control carcinogenic emissions [1]. Careful inventory management is essential, balancing the risk of stockouts and overstock situations [2]. Multiple supplier relationships mitigate stockouts, offering resilience and potential cost savings [3]. While overstocking ensures continuous client deliveries, its cost efficiency is debatable due to associated expenses [2]. Recognizing the probabilistic nature of demand, proves crucial in overcoming deterministic inventory control limitations [2]. Striking this balance is vital to avoid backorders and ensure a steady supply of these critical medical devices [4].

Methodology

The methodology encompassed current state measurement, demand plan analysis, proposed solutions with economic evaluations, solution selection, process validation, implementation, and ongoing objective checks for valves therapy delivery.

The medical device manufacturer ships adjustable hydrocephalus valves, totaling approximately 1,378 units, to the sterilizer after one week of production. The entire lead time to the distribution center is condensed to 3.25 weeks. Figure 1 shows process flow diagram for Adjustable Valves Delivery.

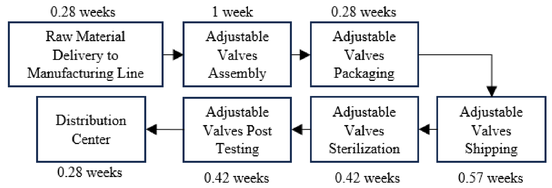

Figure 1
Adjustable Valves Delivery Flow Chart

Table 1 for September 2023 indicates an 18% overstock at the distribution center, surpassing company policy. Fluctuations in the valve assembly line performance are the main cause, as shown in Figure 2, where yield variations beyond the anticipated 60% contribute to exceeding safety allowance.

Table 1
Inventory Metrics Distribution Center, September 2023

Metric	Result
Available Inventory	9,233 EA
Ordered Units	7,200 EA
Service Level	100%
End to End Lead Time	3.67 weeks
Safety Stock Policy	10%
Overstock	18%

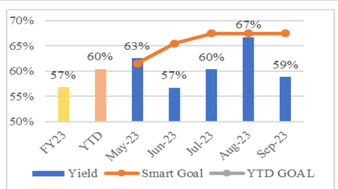

Figure 2
Adjustable Valves Manufacturing Yield

Figure 3 highlights a significant 48% operational efficiency loss in hydrocephalus valve production, using almost half of the productive time. With an expected 60% yield, the tight margins are evident, as the takt time for one unit (204 seconds) and cycle time (210 seconds) offer no room for contingencies during manufacturing.

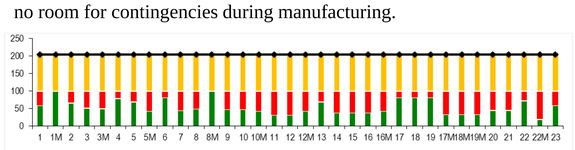

Figure 3
Adjustable Valves Line Balancing Graph

Methodology

An analysis of historical data and trends from the SAP ERP System, using the Min-Max method, revealed forecasted demand results (Table 2). The adjustable valves market is divided 30% in the US and 70% internationally. Table 2 projections, segmented by market percentages, are depicted in Figure 4. Without intervention for the sterilization company's temporal shutdown, backorders were estimated to reach 1.78M units internationally and 0.76M units in the US, totaling 2.54M units by the end of 2024. Addressing this potential backlog is crucial.

Table 2
Adjustable Valves Forecast and Inventory Requirements 2023 - 2024

Period	Forecasted Requirement
October 2023	8,670
November 2023	5,720
December 2023	6,700
January 2024	2,100
February 2024	1,500
March 2024	2,430
April 2024	4,910
May 2024	4,820
June 2024	4,310
July 2024	4,420
August 2024	4,090
September 2024	2,270
October 2024	2,840
November 2024	1,770
December 2024	550

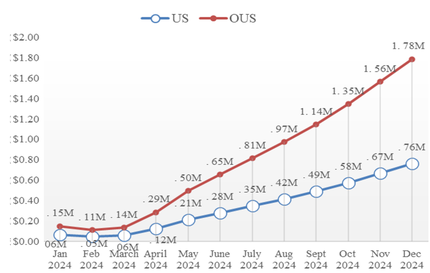

Figure 4
Adjustable Valves Market's Backorder Projection

The identified challenges led to the formulation of three proposed solutions:

- S1- Manufacturing Capacity Increase.
- S2 - Inhouse Sterilization.
- S3 - Subcontract Sterilization Company.

Table 3's cost-benefit analysis indicates that the most economically favorable option, with the highest cost/benefit ratio, is S3: subcontracting the sterilization process.

	S1	S2	S3
Total Costs	$1,899,322	$2,690,662	$820,931.8
Benefits (sold units)	$8,900,535	$9,018,223	$7,922,084
C/B Ratio	4.68	3.35	9.65

Table 3
Economic Evaluation of Proposed Solutions

Solution Selection

The Analysis Hierarchy Process matrix (Table 5) guided solution selection for the sterilizer shutdown impact. Constraints, including Economic Evaluation (EE), Implementation Lead Time (ILT), Overstock Levels (OL), and Transportation Lead Time (TLT), were considered. Table 1's 18% overstock and the directive to maintain or improve Transportation Lead Time were critical factors in decision-making.

Table 5
Normalized Comparison Matrix and Overall Score

	S1	S2	S3	Weights
ILT	0.571	0.286	0.143	0.5115
EE	0.159	0.252	0.589	0.0986
OL	0.088	0.669	0.243	0.2433
TLT	0.069	0.426	0.506	0.1466
Overall score	0.3395	0.3961	0.2644	

S2 (Inhouse sterilization) was selected with a leading score of 0.3961. Despite sacrificing 30% of sutures product sterilization, its implementation, approved by management, resulted in reduced lead time for product delivery and cost savings in shipping and inhouse ETO sterilization.

Table 2 shows a peak forecasted monthly requirement of 4,910 EA for 2024. The manufacturer ensures 100% sterilization with current capacity. In-house sterilization eliminates overstock by reducing lead time. Average lead time for delivering 1,378 EA was reduced from 3.25 to 1.40 weeks with the in-house sterilizer, as depicted in Figure 5.

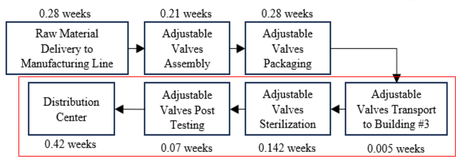

Figure 5
Adjustable Valves Delivery Flow Chart In-House Sterilization

Conclusions

The temporary shutdown of the sterilizer no longer jeopardizes the medical device manufacturer's product delivery, thanks to the validated in-house sterilizer. This experience has provided valuable lessons on sole sourcing, highlighting the risks associated with increased lead time and costs. The in-house sterilizer has proven to be a success, offering the convenience of reduced lead time and improved inventory management through continuous sterilization. This approach has not only reduced sterilization costs but also granted the medical device manufacturer enhanced quality control over its products being sterilized in-house.

References

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[2] R. a. A. Khairunisa, "Integration of deterministic and probabilistic inventory methods to optimize the balance between overstock and stockout," IOP , Yogyakarta, 2020.

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