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Abstract

In the medical device industry, particle matter in products is a problem. Recently, a medical device company noticed that, for the last three months, rejection of product due to particle matter was in an increasing trend. The problem was analyzed by evaluation of manufacturing process, storage area, personnel training and inspections performed on product. Additionally, to boost employee engagement and moral, a rewards system was implemented. Evaluation identified areas of improvement in manufacturing process, storage area cleaning, implementation of new inspections for product as well as new inspection equipment. Data collection after improvements demonstrated a better control for particulate matter. Rejection quantity was reduced from 25% to 14%, there was a profit increase of \$165,000 and the rewards system implemented improved employee engagement to target the particulate matter problem.

Introduction

In the medical device industry, having particulate matter in products is a risk companies don't have the luxury to take. Particulate matter can create problems such as product recall, negative financial impact and, in a worst-case scenario, be the cause of death of a patient.

A manufacturer of medical devices performed internal audit on one of the manufacturing lines and identified a high defect scrap rate related to particle matter inside a tube which is part of the product. As explained before, having particle matter inside the tube of the product is very critical for patient safety. The product provides suction and irrigation via the different tubes attached to it. Particle matter can be a cause for infection in patients if it is introduced to the inside of the body, so it is important that medical device products manufactured by medical device companies are free of particle matter.

This project was executed at the manufacturing line for the suction and irrigation product, where the particle matter is generated and introduced to the products. With this project, it was intended to mitigate, as much as possible, the particle matter inside tube defect from the manufacturing line. The particle matter inside the tubing defect has an increasing trend from 15% of total produced products to 25% in the past three months. An increase in this defect is translated to \$375,000 lost in sales which represents a 10% of the gross profit of the medical device company.

The project objective is to reduce the particle matter inside tubing defect and increase gross profit for the medical device company.

introduction is a general foreword of what the research is about. It presents a brief introduction of the research, explaining the problem or situation that originated this work.

Methodology

The methodology followed for this project was :

- Interview of Operators - All operators were interviewed for their inputs about where the particle matter could be generating from. This gives them participation and creates engagement with the issue at hand.
- Implementation of Rewards System - To help motivate the operators further, a rewards system was implemented to provide incentive to those that participate, and a group reward was also presented to promote team unity.
- Manufacturing Process Evaluation - The engineering team was tasked with performing evaluation of the entire manufacturing process to help determine where in the process particulate matter was being generated (input from operators help guide engineering team).
- Evaluation of Product Inspections - Inspections performed during manufacturing were evaluated to understand if there were deficiencies in the inspections performed or if additional inspections were required.
- Storage Evaluation - Since particulate matter can be generated from multiple sources storage area was evaluated.
- Operators Training - To ensure all operators manufacture the product in the same standard way as established, re-certification of all operators was performed.

Results and Discussion

The interview with all operators was a good technique to utilize since it is them who perform the manufacturing of the product day to day. This knowledge greatly helped the engineering and quality teams determine what areas on the manufacturing line they should be focusing on. This reduced time spent on evaluation and allowed for a faster implementation of solutions.

Implementation of a rewards system was well received by the operators and as expected, it boosted operator performance and engagement in the overall efficiency of the manufacturing line. Manufacturing re-training of all operators was achieved successfully and helped to eliminate the variability that can happen when different operators perform the same task differently. From the evaluation of the manufacturing line, inspections of the product and component storage performed, it was determined the following:

- New inspections were required.
- New equipment for inspections was required.
- Validation of new inspections and equipment was required.
- Additional cleaning was implemented during line clearance for component storage locations.

After completion of all validation activities and implementation of additional tasks, data collection was started. This data was evaluated at the end of each manufacturing shift in order to provide constant monitoring of the defect and help correct any deficiencies that could arise. The data is presented graphically on Figure 1. The graph presents a clear trend for particle matter reduction.

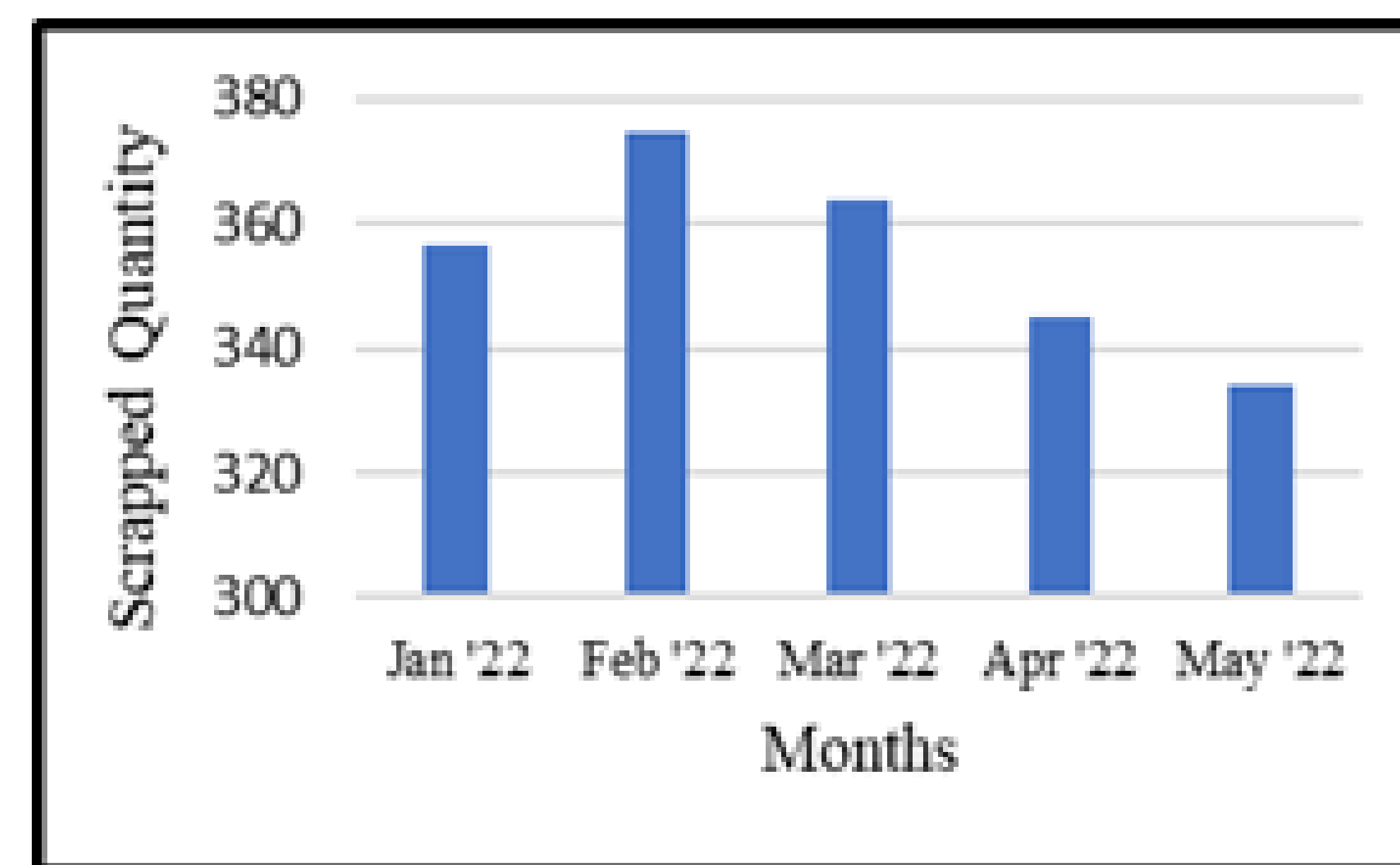


Figure 1
 Scrapped Units for Particle Matter Inside Tubing

In addition to the defect monitoring as presented in Figure 1, a profit trend analysis was performed to translate the reduction in defect creation into a monetary value that management could easily understand the output of the project. The data reported is presented on Table 1 and the profit trend analysis is shown on and Figure 2.

Table 1
 Profit Increase Data Reporting

Month	Increase in Profit (\$)
Feb '22	0
Mar '22	45,000.00
Apr '22	120,000.00
May '22	165,000.00

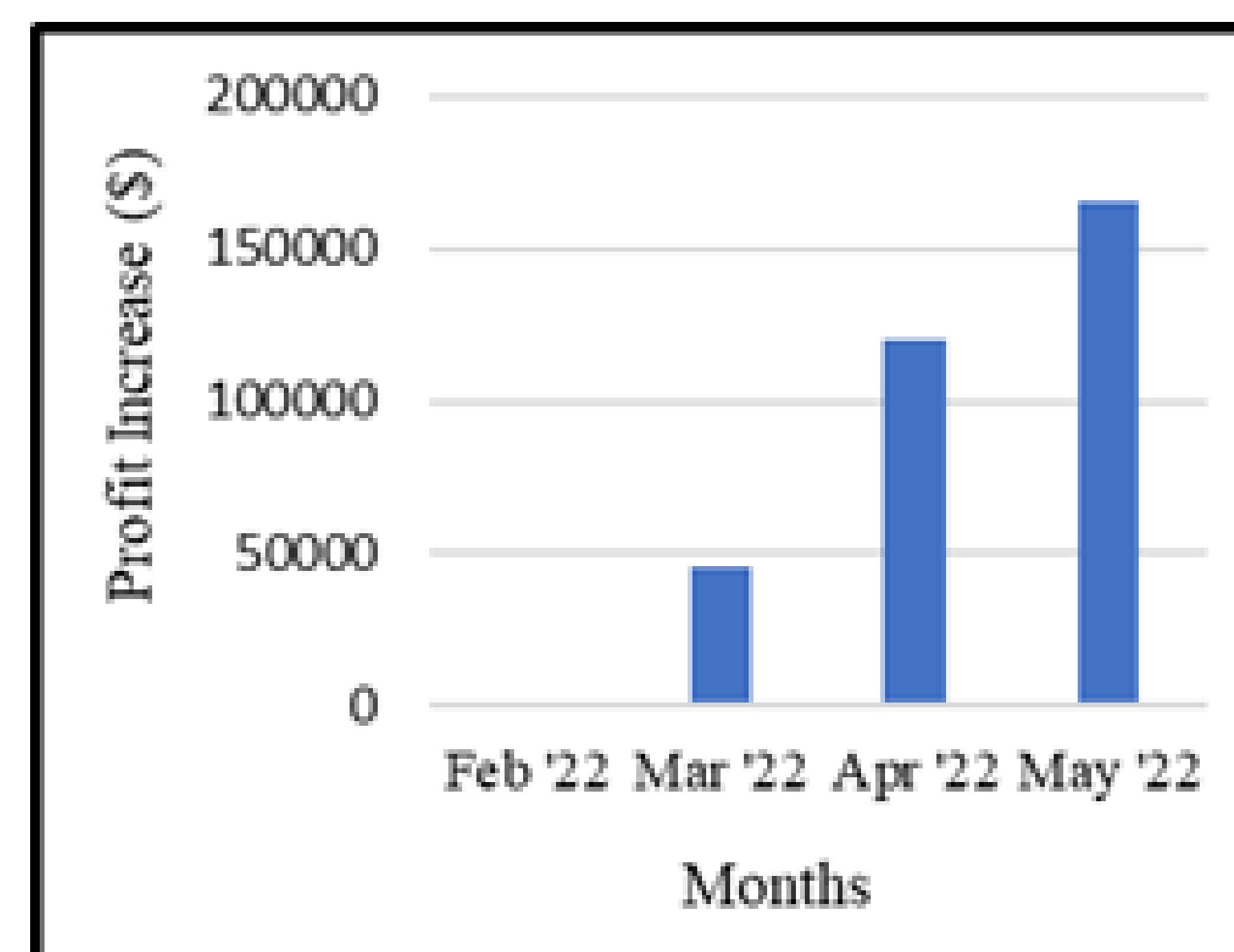


Figure 2
 Profit Trend Analysis

Conclusions

With implementation of all activities and from the data collected, it was confirmed through objective evidence that control of particle matter defect can be made possible if a complete evaluation of the process is performed. The total reduction in particle matter scraped product contributes to a 11% of a total manufacturing yield of \$1,500,000. This units which are now saved and can be sold to customers represent an increase in profit of \$165,000. Therefore, it can be concluded that the project for reducing particle matter in tubing component from a medical device was completed satisfactorily.

References

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