Scrap Reduction of Ventral Hernia Product in Foil Pouches for Manufacturing Line #7

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Abstract

Scrap generated in finished products is one of the top contributors that negatively impact the production goals and budget in most of the production industries. This paper shows a scrap reduction project conducted in a medical device company. The aim of the project was to reduce the scrap generated in the final seal operation, specially scrap in foil pouches for the ventral hernial repair product. The project was worked by focusing on finding the source of scrap and implementing corrective actions based on the findings. It was found that the cause of the scrap was a combination o of equipment and training opportunities. The procedures were updated, and corrective actions were taken in the sealing equipment. This corrective action leads to achieve the goal of reducing the scrap and increase the production output

Background

As part of the cost savings project identification process, the fiscal year 2020 scrap report was verified to identify the top offenders scrap generators among the products in the plant. In the report it was noticed that the ventral hernia repair mesh product was one of the major sources of $50,000 worth of scrap.

The ventral hernia product is designed to repair the intraabdominal tissue disruption caused by abdominal hernias [1]. The product consist of a polypropylene mesh combined with a coating designed for better adhesion of the device into the muscular tissue. the mesh is placed in a foil pouch to keep the integrity of the sterile product. Figure 1 shows the finished product and the foil pouch used to place the mesh.

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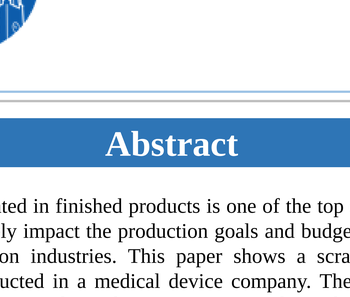

Figure 1
Product and Packaging Illustration

Problem

The project aimed to identify the sources of scrap, the root cause of scrap, implement corrective actions that reduce the scrap and the verification of the effectives of the implementation measures. The tangibles objectives of the project are the following:

- Reduce the scrap of foil pouches by 80%
- Scrap reduction resulting in $40k in savings
- Increase production output by 10%

Methodology

The project was worked using a similar approach of the DMAIC (Define-Measure-Analyze-Improve- Control) methodology which allows study and analysis of the problem, as well as the approach for the possible solutions.

The first step was the data collection and consisted of collecting 6 weeks of scrap units. A pareto chart was plotted visualize the frequency of defects and the cumulative impact. This was used to identify the major offenders as well as to select the defects that will be part of the scope of the project. In Figure 2 it can be observed that Marks and Particulate accounts for 81.5% of the total scrap data for the data collected period, so these two defects turned into the focus of this project.

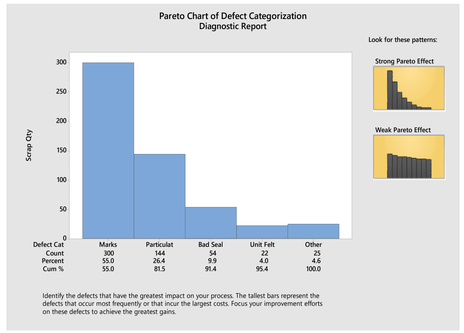

Figure 2
Pareto Chart of Defects

As observed in the fishbone diagram in Figure 3, there are multiple possible causes for the scrap generated, however, due to the time constraint and resource availability, the following causes were the selected for further analysis:

- Visual Standard
- Manufacturing Procedures
- Preventive Maintenance
- Seal Bar Teflon

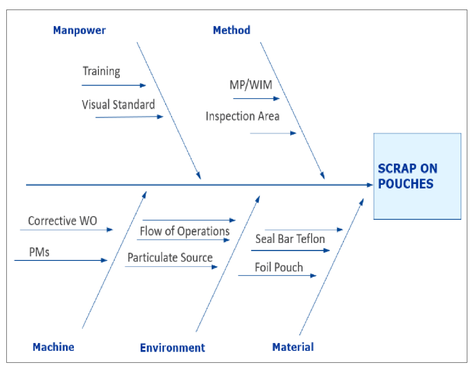

Figure 3
Fishbone diagram

Results and Discussion

Seal Strength Pouch Testing Results

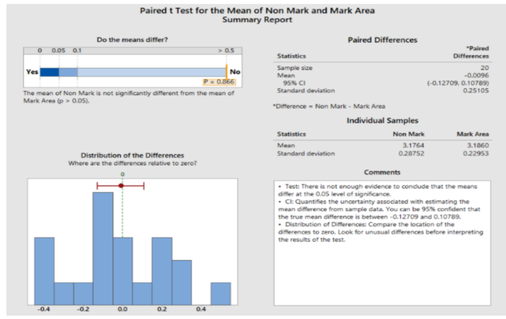

Figure 4
Paired T Test mark area on pouch vs non mark on pouch

- **Visual Standard Procedure Changes**: The visual standard procedure was updated to include specific details regarding acceptable marks on pouches. This procedure change will ensure that there will ne no scrap on acceptable units.
- **Sealing Procedures changes**: The procedure was updated to clarify the instructions regarding the inspection of pouches. The procedure now allows to place the aside and perform an inspection using the chart that measures the particulate dimension and decide to accept or reject units.
- **Sealer Preventive Maintenance Update**: The preventive maintenance frequency for the sealer machine was updated from each 2 weeks to 1 week in order to reduce the particulate residual in the sealing bar.
- **Seal Bar Teflon Sheet Change:** The bar sealers Teflon sheet used for mitigating the impact on the sealer bar was changed for a thicker sheet to reduce the marks on the pouches caused by the impact of the sealing.

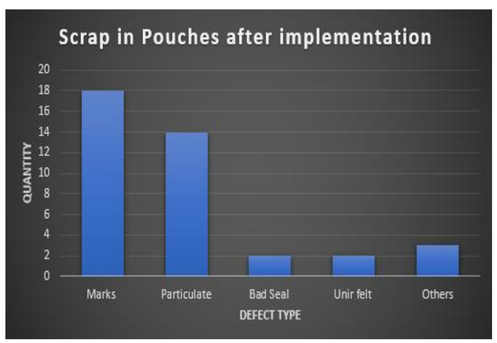

Figure 5
Scrap in Pouches after corrective actions

Benefits

As observed in Figure 5 and Table 1, the scrap was significantly reduced for both marks and particulate defects. Since the defects for marks is the one with more frequency, the principal goal of reducing the scrap by 80% was considered achieved.

Table 1
Scrap Reduction Percent Comparison

Defect Type	Before	After	Reduction	Reduction %
Marks	100	18	82	82
Particulate	53	13	40	75.47

Conclusions

It can be stated that the objectives and main purpose of project were achieved. The main sources and causes of scrap on foil pouches were identified and corrections actions were implemented. These corrections actions will ensure the achievement of the goal of reducing scrap by 80%, leading to an estimated annual savings of 40k in materials and labor as expected. Additionally, it will improve the line yield and reduces the rework activities. The implementation of the project provides additional opportunities to extend the project corrective actions to all the manufacturing lines in the plant. Management is looking forward to this since it can provide additional savings for higher cost products.

Future Work

The implementation of the project provides additional opportunities to extend the project corrective actions to all the manufacturing lines in the plant. Management is looking forward to this since it can provide additional savings for higher cost products.

References

[1] Ventrio, TM, Hernia, Patch. (n.d.). BD. Retrieved May 16, 2021, from https://www.bd.com/en-us/offerings/capabilities/hernia-repair-and-fixation/hernia-repair-mesh/synthetic-mesh/ventrio-hernia-patch