# *SICD Manufacturing Scrap Yield Improvement*

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***Abstract*** *— Defects that occur during the manufacture of a product are consider a problem that affects the yield rate of all manufacturing lines around the world. The Subcutaneous Implantable Cardioverter Defibrillator (SICD) Manufacturing Line productivity is being impacted by quality events who caused nonconformance investigation who negatively impacted the line performance. As outcome investigation, the SICD product center cable damage and fray cable defect were identified as the root cause of the performance reduction. Also, the swaging machine at SICD Manufacturing Line was identified as causal factor of both quality defects. Once identified, the defects and main causal factor, a special run was executed with the intent to test the swaging machine with the implemented adjustment. In addition, Lean Six Sigma methodology was followed to implement improvements and mitigate identified defects reoccurrence. As preventive control, new instructions, and frequencies to the preventive maintenance of the swaging machine were included. In addition, as process improvement, new inspections steps were added to the manufacturing process with the intend to capture the defect as soon as it appears in order to proceed with the mechanical failure correction. Since the implementation of all improvements, the defects reoccurrence was mitigated and the SICD Manufacturing Line productivity improved allowing to achievement a 84% of yield goal by the end of fiscal year 2021.*

***Key Terms*** *— Yield; Lean Six Sigma; Production Line; Swaging*

## INTRODUCTION

Manufacturing lines around the world constantly suffer from defects that affect their yield rates. The biggest challenge for the leaders of the production lines is to identify the root cause of each defect and to make the necessary adjustments to improve the performance of each line. Upon establishing and implementing the required activities for improvement, the line increases its performance and obtains a favorable term of cost.

This behavior is currently reflected in the manufacturing line of the product named Subcutaneous Implantable Cardioverter Defibrillators (SICD) at Boston Scientific. An SICD is a novel electronic device that protects the user from Sudden Cardiac Arrests (SCA) by analyzing their heart rhythms and generating pulses accordingly. The yield rate from the SICD manufacturing line is 83.37% and needs to be improved to comply with the business goal of 84% by the end of FY2021. By a yield analysis evaluation, it was observed that the defects of fray cable and center cable damages reflect the heist percentage of the unit rejected that represent 1.36% of the yield rate. Basically, these defects are defined as protuberances in the center cables of the SICDs, meaning that they are broken, thus preventing the processing of the units.

As an objective, this article is based on the activities developed and executed to increase the yield rate of the manufacturing line in charge of producing and assembly all the necessary parts to create SICD product. This paper begins by explaining what yield is and various challenges manufacturing lines face to improve their corresponding yield rates. It then depicts the analysis of how the SICD Manufacturing Line's yield was improved by successfully implementing the manufacturing engineering essentials, which are methodologies that help manufacturing engineers to detect defects that affect the outputs of the finished SICD products, and to implement changes to mitigate them. Lastly, the article presents the results of implementing the necessary changes for improving the yield of the SICD Manufacturing Line.

## LITERATURE REVIEW

Yield is a measure that is used by manufacturing lines to monitor the behavior of their process outputs. This yield represents the rate of non-defective units against all the units manufactured. “The rate of the manufacturing line is the result of the goods units produced divided by the number of total units that went through the process” [1].

There are companies that help manufacturing industries and contribute as advisers to improve the yield rates. Companies like ASC International reveal that “studies that show an average first pass yield is 80% for electronics manufacturers” [2]. As consequence, since manufacturing lines are constantly monitored for capacity, performance, and quality reasons, each manufacturing line must include a manufacturing yield goal.

There are challenges every day that could impact the manufacturing rate. For those professionals that are growing inside the manufacturing business, improving a yield is an opportunity to grow as professional in a business. “Whosoever can achieve this difficult target can expect rapid career growth with handsome rewards” [3]. Therefore, for employees who are hungry to learn and spend more within the manufacturing industry, it is a benefit to get involved in this type of project.

There are methods and techniques that individuals use to improve the yield rate of a manufacturing line. A way to mitigate a constant manufacturing fallout defect is to brainstorm about it [4]. Many individuals just go directly to the production line and interview the operators that are responsible of executing the process, receive their inputs, and look for a solution. That solution may not be permanent, and the defect could even be mitigated for a period of time, but in the future, it could resurface.

In manufacturing environments, engineering essentials that are used for the benefit of the manufacturing engineers are integrated. Those essentials are used as tools following the Lean Six Sigma techniques. Under Lean Six Sigma methodology, the DMAIC process is integrated. This process is defined as a quality improvement and problem-solving method used to enhance business performance. This method contains “five phases: Define, Measure, Analyze, Improve and Control” [5]. It is necessary to execute these phases in the exact same order as they are defined. If any of the phases are omitted, the investigation could be compromised, and the implementation activities may not be optimal.

As defined, “DMAIC refers to a data-driven quality strategy for improving processes” [6]. Essentially, the DMAIC process is a tool to guide teams involved in a project in an efficient way. Executing the DMAIC process results in the ability to observe variables that are not considered regularly, and the implementation of permanent solutions that emerge because of this process represents a positive impact on any company’s costs.

For better knowledge, the manufacturing lines, or production lines, consist of a series of processes that are configured in specific ways to assemble a product [7]. Within the medical devices industry, there exists a plentiful list of products that contain lead cables in charge of transporting drugs or transmitting a signal to a predetermined area; this depends on the therapy applied to the patient using said device.

For the products that transmit signals, multiple kinds of technologies are implemented inside the manufacturing process. One of the implemented technologies are the swaging processes that are also used to manufacture pipes, plastics, and others. The swaging process is used to compress material, and there are models of technologies that contain swaging die that slowly “reduce the diameter of a ductile, thin-walled, metal bands onto plastic catheter shafts” [8]. In short, the intent of the swaging process is to compress and shape an object with the help of a swaging die with a tampered cylindrically, thus reducing his diameter.

## ANALYSIS APPROACH

On Fiscal Year 2020, the SICD Manufacturing Line reported 83.37% (versus a total of 83%) of scrap yield target to reduce the rejection of bad units and increase the yield rate. For this reason, the business set a goal of 84% of yield by the end of FY2021 based on the continuous improvement mindset to help the business, and as consequence, gain more cost-efficient processes that save costs in terms of materials, labor, and at the same time, increase the capacity of the line.

Based on the manufacturing engineering essentials, a scrap yield analysis was developed to identify the reject rate per defects by prioritizing the improvement tasks by the highest reject rate to achieve the yield goal. During the analysis executed in mid-Q1 of FY2021, a 23% of the rejected units were identified as Center Cable Damage or Fray Cable defects, which represents an impact of approximately $400.00 per unit. This defect was analyzed and, as a result, it represented a total of 1.36% of scrap yield rate reported on FY2020.

During the investigations, activities using the DMAIC process from the Lean Six Sigma methodology were executed, and it was detected that the defects were caused by the effects reflected from the output of the swaging process. This process consists of compressing the center cable diameter from 0.018" to 0.0140" ± 0.005". Therefore, the units processed through the swaging machine passed through the swaging die part to compress the center cable of the unit and reduces its diameter.

DEFINE; the outputs of the process were analyzed and the defects that cause the fallout of units were defined as units damaged by Fray Cable Defect and Center Cable Damage.

MEASURE; with the use of normalized data, the fallout was statistically evaluated comparing the fallout quantity of the defined defects within the total of completions units. As a result, the rejected rate evaluated in mid Q1 of FY2021 reflect a total of 3.53% for January 2021 and 8.95% for February 2021 (refer to Figure 1).

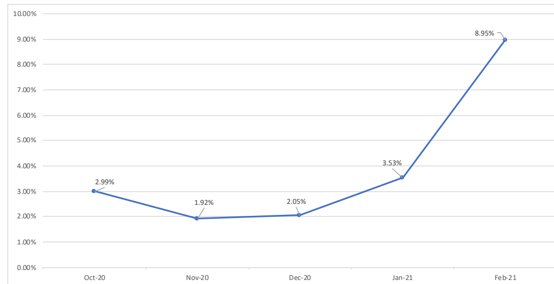


**Figure 1**

**Scrap Percentage of Center Cable Damage and Fray Cable Defect**

Therefore, it was identified that the fallout reject rate of the defined defects were increasing drastically, as noted in Figure 1.

ANALYZE; a fishbone diagram was constructed to identify variables by considering the concepts of Materials, Man, Machine, Method, Measurement, and Mother Nature. Under the analysis of the concepts, all the variables that could provoke the defects on the units were properly identified. The variables were analyzed and tested. As a result of the tests, the variables that caused the highest percentage of defects were identified as:

- Machine vibration caused by a swaging hub part that was not adjusted inside the machine.
- Swaging die wear.
- Handling of the units through the process flow.

## RESULT

IMPROVE; once the variables that caused the defect were identified, multiple conversations were carried out to stablish the changes required to improve to the swaging process. Interim actions that only require to be documented and not to be approved were executed. Those actions were identified as a) replace the swaging die, and b) adjust the part of the hub that was identified as not adjusted.

As part of the established tasks, two additional preventive maintenance frequencies were implemented. The first maintenance contains a monthly frequency verification of the internal diameter of the swaging die with the intent to identify any kind of wearing on the area that interacts with the center cable of the unit. If the die does not comply with the diameter criteria established per design, the part will be replaced with new one. In addition, a second maintenance was established with an annual frequency verification throughout the hub part area of the swaging machine. If any component of the hub is loose, the manufacturing technicians must adjust the part. In the case that any part could not be adjusted or fixed, it is required for the component to be replaced. As a last technical maintenance task, ensembled materials were verified in the last swaging machine, and all the pieces in the replacement area were bought and stored.

Regarding the process changes, a Go / No Go Gauge was initially designed and built based on the dimensions of the product in order to identify if the center cable was compressed correctly after being processed by the machine. Therefore, a new process change was established on the manufacturing procedure to include a new inspection of the center cable. This inspection consists in using the Go / No Go Gauge to confirm if the compression of the swaging die to the center wire achieved the goal of reducing the center wire to 0.0140” ± 0.005” per product specification. Refer to Figure 2.

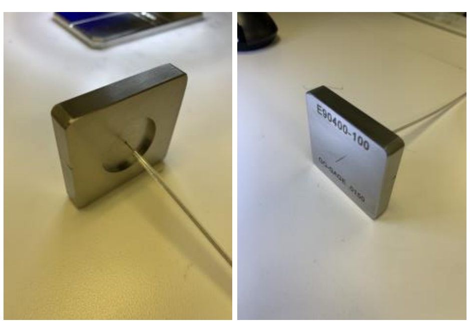


**Figure 2**
**Inspection of the center cable by the Go/No Go Gauge**

As a second process change, a pin gauge capable of holding a material called heat shrink was designed and built; it is assembled over the center cable of the lead as protection (refer to Figure 3). This protection mitigates the damage that the center cable suffers during handling of the unit throughout all the processes within the manufacturing flow. The intent of the pin gauge is to maintain the heat shrink material fixed while heated air is transmitted in order to be compressed. After the material has been compressed, it is then removed from the pun gauge and then assembled into the unit to protect the center cable.

**Figure 3**
**Heat Shrink protection to center cable**

Once the Go/No Go Gauge and the Pin Gauge were built, there were executed special productions orders developed by the engineering members with the purpose of challenging the integration of the parts inside the manufacturing process. As a result, all the tests were fully satisfied during the special runs.

Then a verification of the manufacturing procedures was executed to identify which documents were affected by the implementation of the new improvement change. Once the procedures were identified, the changes were generated and sent to the change management system for approval. Under this stage, the changes were reviewed by the manufacturing and quality engineer, the engineering and quality managers, document change resource, design engineer, and the members of the regulatory geography board.

Under the change management system, all the documentation required per regulations was included. The documentation contains the justifications of the changes, all the analysis developed, the results of the test, and the manufacturing procedures that were changed to include the improvements.

Currently, the defect is individually monitored for a period of one year by the manufacturing engineer and lead of the project. Since mid of

March 2021, when the interim actions were completed, the defect was fully mitigated. Basically, there is no fallout of units by center cable damage and fray cable defect, refer to Figure 4.

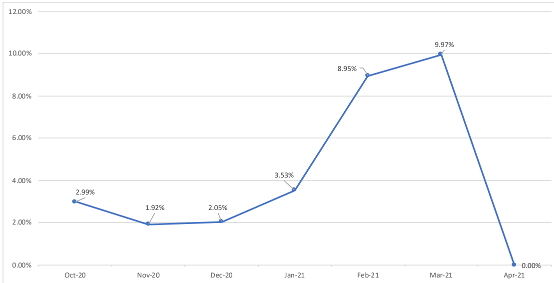


**Figure 4**

**Scrap Percentage of Center Cable Damage and Fray Cable Defect**

## Discussion

As noticed, during the analysis of scrap yield, the defect that was causing the highest percentage of fallout was defined. As mentioned before, the scrap yield basically represents the behavior of the manufacturing line. That allows the leaders of the manufacturing line to be more organized and focus on the tasks that require urgency or have higher priority.

Monitoring the behavior of manufacturing lines helps leaders notice those details that weaken the performance. This consequently causes individuals to stay busy and committed to implement continuous improvement changes.

Those implementations that have good results as consequences, are noticed by the executive leaders and consequently help the people involved to be considered for projects with greater visibility and, in return, obtain promotions that help their individual professional growth.

The DMAIC technique is used by individuals as a guidance tool to analyze, identify, and mitigate the defects that affect the output of the process, as positive results help to implement the required actions to mitigate the defects. As mentioned previously, the technique must be executed step by step to make possible the implementation of changes that mitigate the defects and not just controlled for an indefinite period.

It is important to mention that this work dynamic is executed better within a team, since the everyone's input aids when considering multiple theoretical angles. Those perspectives are considered as variables and possible root causes that are defined and discarded during the execution of tests.

In this case, the process that caused the impact on the performance of the line was identified using the scrap yield report for continuous monitoring of the performance of the line. It is for this reason that the DMAIC technique was used to analyze the process and identify all the variables that caused the defects when the center cable of the unit was compressed by the swaging die.

## Conclusion

Thanks to the tools and techniques executed during this investigation, the manufacturing line improved its actual yield to 84.36%, complying and exceeding the established goal of 84% by the end of FY2021.

However, the line is continuously monitored with the intent of identifying and mitigating any defect that may get out of control. For this reason, weekly meetings are held between all the leaders of the manufacturing line to discuss its behavior. Also, improvement projects are in continuity to improve the yield of the manufacturing line.

In addition, all the work carried out during the investigation and mitigation of the defect was carried out with success thanks to the efforts of the team members and leaders of the manufacturing line. The availability and collaboration of each member was extremely important to achieve the objectives of the project.

Thanks to the collaboration and dedicated effort, there were no implications that delayed the implementation and improvement tasks in the process. All changes implemented complied with the plan.

It is very important to mention that the line has not come to meet the requirements of a mature line. To achieve the objective, the goal of a 98% yield or more of must be met. Thus, it is ultimately important to continue increasing the yield goal annually to motivate the resources to invent new improvement changes.

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