SICD Terminal Ring Cracks Reduction

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Abstract *— A medical device manufacturing line of cadioverter/defibrillators utilizes a mechanical process called staking to join two metal components as part of the electrode manufacturing process. The staking process exerts a vertical force into the metal components to deformed them and join them together. In some instances, the deformation experienced during the staking process causes small cracks or fractures on the metal component ring. The objective of this project is to reduce crack yield fallout at the staking process. Utilizing process improvement methodology from six sigma Define, Measure, Analyze, Improve and Control (DMAIC) permanent solution was implemented by reducing variation on metal ring component being staked which resulted in 95% yield improvement on crack defect. The project provided financial benefit to the medical device company reducing annual scrap of manufacturing product.*

Key Terms *— cracks, DMAIC, wall thickness, yield fallout*

INTRODUCTION

Process Improvement six sigma DMAIC is a very common methodology use nowadays in manufacturing companies looking to take processes into next level. The uniqueness of DMAIC is that is an organize methodology that obligates structure, data analysis and implementation of permanent solution which required monitoring to confirm effectiveness. Implementing projects utilizing DMAIC methodology guarantees improvements on manufacturing processes. The Boston Scientific (BSCI) SICD Emblem Electrode is experiencing a higher final yield fallout due to the terminal ring component cracks. This research project redesigned the terminal ring metal component to decrease final yield fallout.

Research Description

The terminal ring wall thickness dimension has no direct callout on the design drawing causing higher standard deviation after the manufacturing of the component. This project reduced variation on wall thickness; therefore, reduction on yield fallout turning out on scrap savings to BSCI.

Research Objectives

The main objective of the research is yield fallout reduction. After implementing the design drawing changes on the terminal ring the final yield fallout improves by more than 50%.

Research Contributions

The research provided great contributions to the Dorado BSCI site by utilizing very detail statistics and analysis on material components and deformation. The overall business saw a financial benefit after research complete.

LITERATURE REVIEW

The EMBLEM S-ICD Electrode (“Electrode” or “lead”) is intended for chronic implantation as an integral part of a Boston Scientific Subcutaneous Implantable Cardioverter/Defibrillator (S-ICD) System [1]. The EMBLEM S-ICD Electrode conducts sensed intrinsic cardiac electrical signals to an S-ICD pulse generator and delivers to the heart, as necessary, artificial stimulation from the S-ICD pulse generator. EMBLEM S-ICD Electrode is designed for subcutaneous application only. It is equipped with an SQ-1 connector which contains both high and low voltage connections. During the terminal staking process performed, two high voltage (HV) cables and a sense cable (senses heartbeat) are joined into the terminal ring. As part of the process, the lumens (open space inside the terminal in which the high voltage and sense cables are introduce) are filled with medical adhesive

(MA). Then, the cables are assembled into the lumens in the terminal ring. Finally, the cables are staked to the terminal ring. Staking is a mechanical process that joins two components by deforming them. Two of the lumens in the terminal ring are empty. The empty lumens are filled with MA as part of the MA backfilling process. To perform the staking process, force is applied to deform the terminal ring and join the cables with the terminal ring. In some instances, the deformation experienced by the empty lumen causes a small crack along the edge.

For the past few months an increase in yield fallout for cracks on the terminal ring had been seen on the manufacturing line after the staking process. After cross functional problem-solving investigation and research, the terminal ring dimension variation had been identified as the main cause of the problem. "Of all the influence factors for fracture toughness test, specimen thickness is a most important factor" [2]. That study helped the team to identify that increase variation on terminal ring wall thickness (just on the pocket that is deformed for the staking process) is the main root cause for the increase in cracks yield fallout. Study showed that the smaller the wall thickness the higher scrap rate due to cracks [2]. Physically the smaller the wall thickness the less material between the stake; therefore, increasing stress which eventually causes higher crack incidence. The terminal ring component drawing specification does not have a direct callout for this wall thickness; in the other hand, it requires (callouts) a specific dimension for six other dimension that correlate to the wall thickness. This research done showed that by setting a specification limit to the wall thickness of the terminal ring less variation would be found on the dimension resulting in less probability of creating a crack on the component after the staking process.

During the root cause analysis, different tools were utilized such as a cause-and-effect diagram, correlation and design of experiment. The cause-and-effect diagram has several names such as the Ishikawa diagram and is a tool that graphically represents all inputs related to an output. "To determine possible root causes of rejection, Cause and-Effect Diagram (CED) is also a very useful tool. It helps to identify, sort, and display causes of a specific problem or quality characteristic. It graphically illustrates the relationship between a given outcome and all the factors that influence the outcome and hence to identify the possible root causes i.e. basic reasons for a specific effect, problem, or condition" [3]. Correlation was one of the different statistical tools used. Correlation is a tool for understanding the relationship between two quantities. Regression considers how one quantity is influenced by another [4]. Finally, design of experiment was critical tool used for process improvement during this research. Design of experiments (DOE) is a powerful data collection and analysis tool that can be used in a variety of experimental situations. It allows for multiple input factors to be manipulated, determining their effect on a desired output (response). By manipulating multiple inputs at the same time, DOE can identify important interactions that may be missed when experimenting with one factor at a time. All possible combinations can be investigated (full factorial) or only a portion of the possible combinations (fractional factorial) [5].

METHODOLOGY

The DMAIC (Define, Measure, Analyze, Improve, Control), it is a five-phase strategy for improving a wide variety of organizational processes, whether it's software development, manufacturing, or some other process [6].

This research process improvement methodology was as follow:

- Define
    - Definition of the goals
    - Identify Stakeholders
    - Outline project milestones and completion
- Measure
    - Historical Data: terminal ring component. Dim A and yield per manufacturing lot
    - Perform data analysis
    - Descriptive Statistic

    - Normality Analysis
    - Correlation Dim A and yield
    - Process capability for Dim A
- Analyze
    - Terminal Ring Root Cause Analysis
    - Improve Wall Thickness Variation
- Implement
    - Identify Best Solution
    - Develop solution test and plan
    - Inform stakeholder about solution
    - Implement permanent solution
- Control
    - Develop quality control plan to monitor solution effectiveness
    - Confirm final yield fallout reduction
    - Communicate lessons learned

RESULTS AND DISCUSSION

As part of the define phase, the main goal of the research was yield fallout reduction at Boston Scientific SICD Emblem Electrode manufacturing line. The yield fallout reduction was achieved by improving the terminal staking process which was causing cracks or fractures on the terminal ring metal component. Utilizing DMAIC process improvement methodology, the terminal ring component incoming wall thickness dimension was optimized to achieve a maximize yield output at the terminal staking process. Yield calculated thru this section is solely based on terminal staking process crack defect. The project stakeholders were identified as part of the kickoff and update of project status was reported monthly.

Moving into the measure phase, a mapping of the current process was done. The terminal ring is a metal component that is supplied from a third-party vendor to Boston Scientific per design print. Critical dimensions on the design print are monitored and measured by the vendor. Process monitoring sample measurement per each batch are registered by the vendor and must be compliant with design specification.

The material wall thickness is dimension between HV Cables and bottom of stake pocket (Dim A). The wall thickness of the terminal ring is the part that is deformed by the staking pin to mechanically join the terminal ring with the HV cables (figure 1). There is a current gap on the drawing in which no direct callout for wall thickness is shown. However, other dimensions indirectly affect the wall thickness dimension. Based on supplier feedback and previous investigation, other dimensions on the terminal ring are very consistent and do not change significantly from lot to lot. Therefore, as part of this investigation, Dim A was taken as direct relationship with the wall thickness. The higher the Dim A is the less wall thickness between HV cables and ring. The less thick the wall is, the higher the probability of causing cracks on the terminal ring after the staking process. It was proven that the most and only significant factor on a 4-factor design of experiment was the Dim A. The design of experiment was designed at 95% confidence (figure 2).

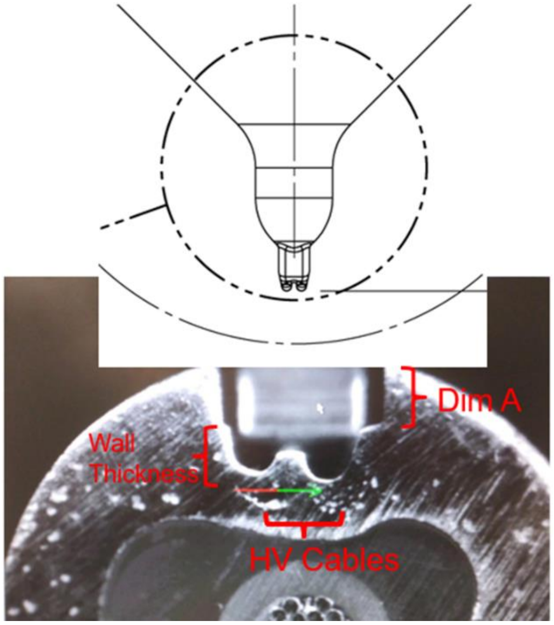


Figure 1
Terminal Staking Process

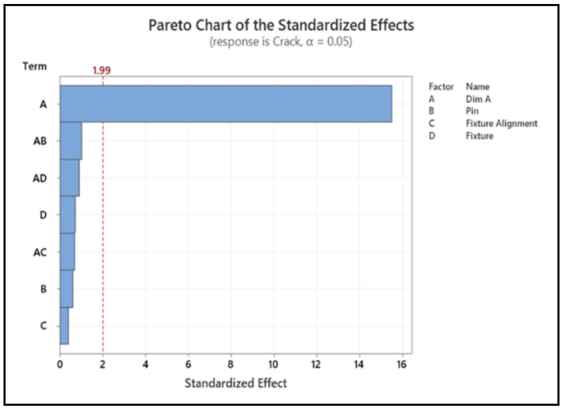


Figure 2
Design of Experiment (DOE)

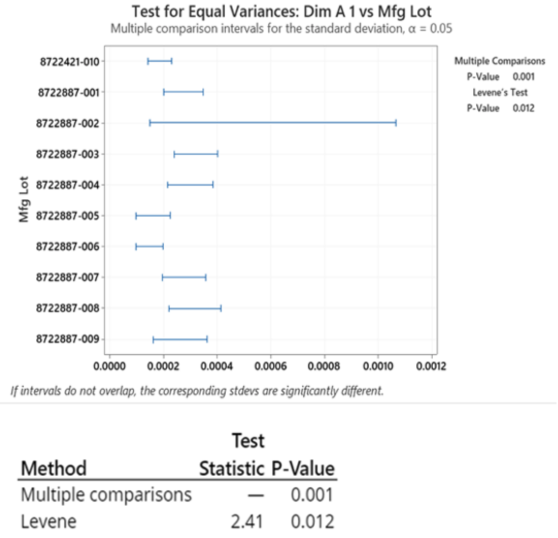
To understand current behavior of the process, historical measurements from the supplier were analyzed. For each terminal ring component batch, the supplier takes a validated sample size and measures critical dimension per design print. The Dim A measurement data from the supplier was analyzed with a 95% confidence multiple sample ANOVA to determine if the difference of the means of Dim A is statistically significant between each manufacturing lot (Mfg lot) (table 1).

Table 1
ANOVA Dim A per Mfg Lot

Mfg Lot	N	Mean	StDev
8722421-010	45	0.013096	0.000173
8722887-001	25	0.013236	0.000246
8722887-002	22	0.013100	0.000368
8722887-003	29	0.012972	0.000293
8722887-004	26	0.012923	0.000270
8722887-005	21	0.013057	0.000136
8722887-006	36	0.013183	0.000132
8722887-007	19	0.013053	0.000241
8722887-008	25	0.012916	0.000282
8722887-009	27	0.013030	0.000227

Source	DF	F-Value	P-Value
Mfg Lot	9	5.19	0.000
Error	265		
Total	274		

It is observed thru this ANOVA test that means difference between manufacturing lots is significant since null hypothesis was rejected due to p value less than 5%. It is important to understand mean variation between each manufacturing lots as a baseline for this investigation to evaluate its impact if any to yield fallout. In addition, 95% confidence test for equal variances was done to expand understanding the difference in standard deviation per each manufacturing lot. Results show that there the difference in standard deviations per each manufacturing lot is significant because null hypothesis is rejected with a p value below 5% (figure 3). Standard deviation or variation within each lot causes a higher range of measurements for Dim A; therefore, impacting the manufacturing process output.



Method	Test Statistic	P-Value
Multiple comparisons	—	0.001
Levene	2.41	0.012

Figure 3
Test for equal variances Interval Plot Dim A per mfg lot

Normality Test was done per each manufacturing lot before performing any other statistical analysis. All the normality tests resulted in that all of them are normal.

As part of the analyze phase, correlation analysis was performed between Dim A and yield of the staking process. The average yield at terminal staking process was calculated per each manufacturing lot for the last year and analyzed with respect to the mean of Dim A and standard deviation. Two correlation analysis were made: correlation between mean and yield and correlation between standard deviation and yield both per each manufacturing lot. Based on the data obtain there is weak negative correlation between yield and mean of Dim A with correlation R-value of -0.061; however, there is a higher negative correlation between standard deviation of Dim A and yield with a correlation R-value of -0.332. R-value below absolute value of 0.5 is considered weak (figures 4 and 5).

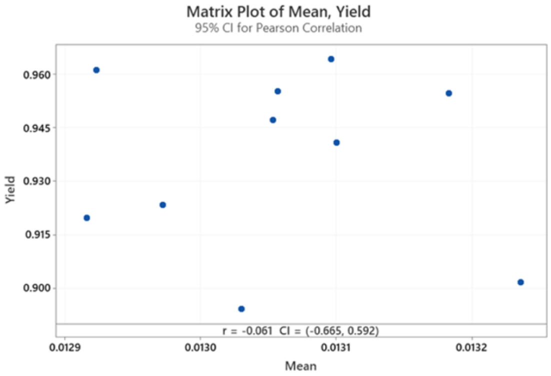


Figure 4
Correlation Yield and Mean of Dim A

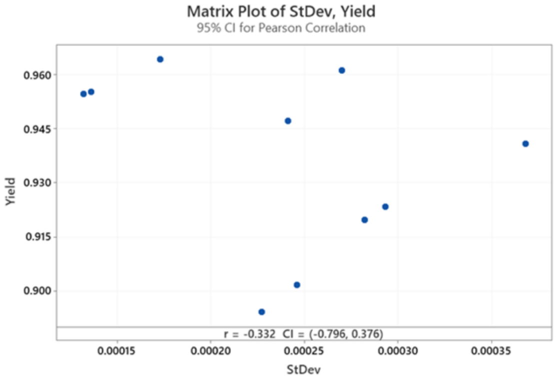


Figure 5
Correlation between std dev of Dim A and Yield

Even though correlation between Dim A and Yield resulted in weak correlation the team decided to take further analysis into Dim A. Process Capability (from supplier data) analysis was made to understand capability of the supplier to meet design specification for Dim A. Process capability results for Dim A measurements taken by the supplier with respects to design specification of 0.0132 +0.0010/-0.0015. Process capability resulted in Ppk ranging from 1.00 to 2.92 for all manufacturing lots.

Process capability of the current manufacturing process for Dim A of terminal ring is overall capable of complying with the design specification. Supplier data is just a sample size of the manufacturing lot and within lot variation may be a significant factor affecting yield. Even though the sample size measure by the supplier can comply with the design specification and with good process capability the team decided to ask for special builds with a specific dimension A for the terminal ring component. The current specification ranges from 0.0117” to 0.0142”. Two set of builds were specially constructed by the supplier for this investigation and 100% inspected; this will allow to have 100% of the data instead of sample size per each lot. Group 1 of special build was constructed with a specification of 0.0129”-0.0142” while Group 2 with a specification of 0.0117” to 0.0128”. The idea behind both groups is to have lower end of the specification compared with higher end of the specification. After receiving the special builds descriptive statistics was done first to get a baseline on each group and make sure they are compliant with the special build dimension per each group. Special Group 1 (higher end of the specification) mean was 0.0134” while special group 2 (lower end of the specification) mean was 0.0122”.

Afterward, the terminal staking process and crack inspection was performed using terminal rings from each special group respectively following normal manufacturing instructions. Special Build 1 (higher end of the specification) crack inspection resulted in 20 out of 30 with a 67% yield; in the other hand, special build 2 (lower end of the specification) crack inspection resulted in 29 out of 30 with a 97% yield. This analysis shows that lower end specification terminal ring Dim A from 0.0117” to 0.0128” resulted in significant higher yield at crack defect than higher end specification terminal ring Dim A from 0.0129”-0.0142”. The root cause identified for the increase yield fallout was that the increase in cracks was due to decrease in wall thickness for the staked component.

The remaining of the methodology was performed per project plan. The team proceeded to change the design specification of the terminal ring within the current specification limit but with a guard band. The terminal ring Dim A change FROM 0.0117”-0.0142” TO 0.0117”-0.0128”. This change required stakeholder approval and change notice to change all the documentation required.

A rigorous control plan was established to verify effectiveness of this change; monitoring on a weekly basis for 1 month the yield fallout. The average scrap rate or yield fallout due to cracks on the terminal ring before implementing change was 5% year to date (from first week of January [week 1] to first week of April [week 15]); after change implemented is 0.24% (reference table 2).

Table 2
Yield Fallout before and after change

Week Number	Final Yield Fallout	Final Yield
1 Total	0.00%	100.00%
2 Total	4.73%	95.27%
3 Total	3.45%	96.55%
4 Total	5.97%	94.03%
5 Total	9.33%	90.67%
6 Total	1.30%	98.70%
7 Total	8.71%	91.29%
8 Total	8.14%	91.86%
9 Total	4.37%	95.63%
10 Total	4.17%	95.83%
11 Total	2.98%	97.02%
12 Total	12.76%	87.24%
13 Total	1.93%	98.07%
14 Total	2.12%	97.88%
15 Total	4.51%	95.49%
16 Total	0.25%	99.75%
17 Total	0.18%	99.82%
18 Total	0.23%	99.77%
19 Total	0.34%	99.66%
20 Total	0.19%	99.81%

The implemented change was proved to be effective after one month of successful yield fallout reduction. The team proceeded on sharing official lessons learned from the project to other manufacturing lines at Boston Scientific Dorado.

CONCLUSION

The Boston Scientific SICD Emblem Electrode was experiencing a higher yield fallout at the terminal staking process which performs a mechanical joint between to metal components exerting a vertical force thru a pin into the metal ring. The wall thickness of the metal ring was too thin and having large variation and causing higher scrap rate due to cracks. An area of opportunity was found after statistical relationship between terminal ring components and yield fallout was identified; the less thick the wall is, the higher the yield fallout. Permanent solution was implemented by guard banding the specification limits of the terminal ring metal component within the current specification providing a more consistent and quality process which resulted in 95% yield fallout improvement.

This project benefited Boston Scientific Corporation by reducing scrap cost due to failed parts because of the terminal staking process causing cracks on the terminal ring. Considering 2021 volumes and standard cost per each SICD Emblem Electrode the annual saving estimated for this project are $332,000. Not only scrap cost saving but also the company benefited with a better-quality product with less waste.

In the future, other areas of opportunity to improve the manufacturing process capability and consistency is to re-design the staking pin. During this research project, it was found that the staking pin during the staking process gets misaligned due to its wiggle room inside the staking pocket. The staking pin tip shape should be redesigned to decrease its clearance inside the stake pocket; therefore, providing more consistency on the process.

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