Incorrect Band Spacing Cost Reduction

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SUMMARY

The purpose of this project is to identify factors and the root cause that are causing the Band Spacing Incorrect defect in Model 5F CS. Through this investigation, the DMAIC methodology was used with the intent of reducing the defect rate in a 25%, representing a cost saving of approximately $33,000 in the third quarter of Fiscal Year2015. The optimization and improvement of the processes and the introduction of a new improved tooling to measure band space will guarantee the reduction and control of the defect. This investigation will contribute, as a reference, to other defects to implement similar solutions among other manufacturing areas.

Key Terms - 5F CS model, Band Spacing Incorrect, Diagnostic Catheter, Process Improvement

PROBLEM STATEMENT

An investigation arose in a catheter manufacturing area to propose solutions to an increase of rejected units related to incorrect band spacing in catheter model 5F CS. The bands of the catheter model 5F CS are measured using a band spacing template to confirm the catheter has maintained its space between bands per specification. Incorrect band spacing is a defect presented in model 5F CS when the bands are measured using a band spacing template and do not maintain their space between them as per specification. During two consecutive months, the reject rate percentage reported was of 54% and 34% respectively, impacting important metrics of business unit.

The incorrect band spacing defect became one of the business top offenders with a total of 111 units rejected in two months. All the rejected units with this defect belonged to a catheter family which is divided into two models: 5F CS and 6F. The defect was found only in model 5F CS and not in 6F. Model 5F CS is characterized for having a different diameter and for having more electrode bands than model 6F. Model 5F CS has a 5 French diameter and has 9 bands and 1 electrode tip resulting in 10 circuits passing inside its body. Because of having so many bands, this model is more likely to present the defect.

Figure 1
5F CS Catheter Model

Figure 2
Modelo 6F Catheter Model

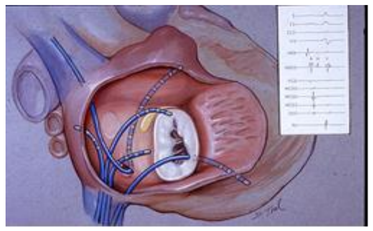

Figure 3
Cardiac electrophysiology Exam

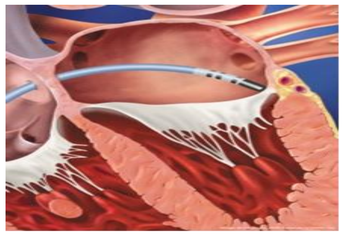

Figure 4
Ablation Treatment using RF Catheter

METHODOLOGY

As part of understanding the Incorrect Band Spacing defect, the DMAIC methodology was chosen in order to have a complete analysis of the defect step by step and perform the project. The DMAIC tool has five stages which are Define, Measure, Analyze, Improve and Control.

Define

During two consecutive months, the defect of Incorrect Band Spacing was presented in the Model 5F CS affecting the yield and performance of this catheter family. Also, important business unit metrics were being affected for this condition resulting in a scrap amount of $11,000 monthly.

Measure

The defect became one of the business top offenders with a total of 111 units rejected in two months belonging to the model 5F CS. Important measures were evaluated in order to collect data to get to the root cause and the possible causes of the defect and they are the following:

- Analyze the manufacturing processes.
- Evaluate the current method to measure band spacing.

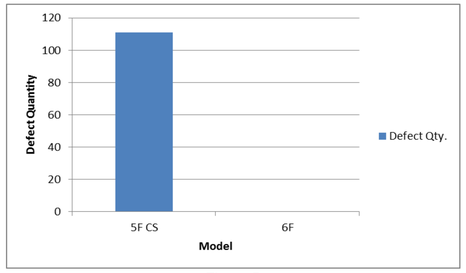

Figure 5
Defect Quantity per Model

Analyze

As part of the analyze phase, a fishbone diagram was performed in order to determine the possible causes triggering the defect. Band Spacing template was evaluated under the measurement category and it was determined that it could be improved since the template, as per drawing design, considers tolerances that the catheter do not has. A new prototype was designed and tested and it worked. Also, as part of the manufacturing flow, the swaging process was analyzed. In this process the catheter is passed through a swager machine with the intent of compressing the bands in the catheter. Once the bands are compressed, the band spacing template is used along with a microscope to verify if the space between bands is maintained. This same verification is also performed but with naked eye in a final device process and a discrepancy was found between the two processes; therefore, a change order was generated in order to align and standardize inspections across both processes.

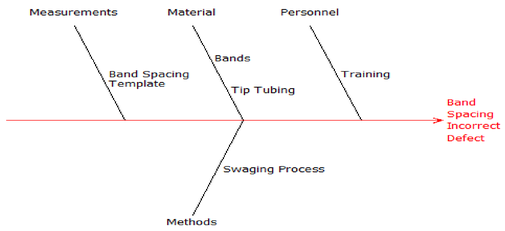

Figure 6
Defect Fish Bone Diagram

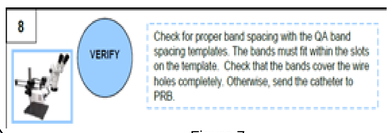

Figure 7
Verification in Swaging Process

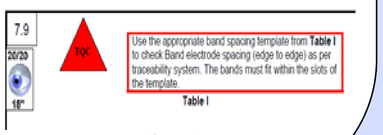

Figure 8
Verification in Final Device Process

Improve

The improvements performed to the processes were divided in two phases:

Phase 1 - A change order was generated in order to standardize and align the band spacing verification in the swaging process and in the final device process to use the band spacing verification with the template with an unaided eye. Also a change in the method of measuring band space was made adding a caliper to be used along with the band spacing template with the intent of confirming band space in the case of bands are found to be as close as possible in the slots in the template.

Phase 2 – Current template was improved reducing the tolerance of each hole to the half of what it currently had but first the tooling number had to be removed from the product specification to introduce the new one.

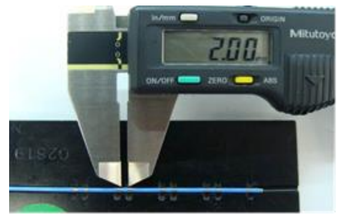

Figure 9
Verification with Caliper

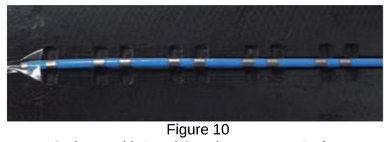

Figure 10
Catheter with Band Spacing Incorrect Defect using current template

Figure 11
Catheter using prototype template

Control

To confirm the effectiveness the defect rate trend was analyzed post improvements with a significant defect reduction seen in the months of December and January.

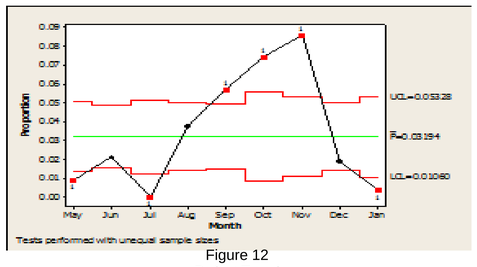

Figure 12
Defect Trend

CONCLUSION

Using DMAIC methodology, it was found that the causes for the Incorrect Band Spacing on the catheter model 5F CS were that in the execution of the process the inspection between swaging procedure and Final TQC procedure was not standardized because in one procedure microscope was used and in other it was performed by naked eye and process changes were implemented to align inspections across the manufacturing processes and have same inspection criteria.

A caliper was added, as a mitigation in Phase 1 of improvements, to work with the catheters which still presented the defect to confirm spacing. The major change was the improvement of the current band spacing template, in Phase 2, reassigning new tolerances which contributed to eliminate the band spacing defect when implemented.

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