Incorrect Band Spacing Cost Reduction

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Abstract *— 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*

INTRODUCTION

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 (shown in Figure 1) 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. However, the defect is not presented in model 6F (shown in Figure 2) because this model has a bigger diameter of 6 French and has only three electrode bands and one electrode tip and measuring less bands is easier since this model tends to maintain its space between bands.

Figure 1
Model 5F CS

Figure 2
Model 6F

A considerable quantity of units is being rejected for this condition impacting the business unit with a scrap amount of $11,000 monthly. With this project the intent and main scope is to reduce the reject rate in a 25% representing a cost saving

of $33,000 for the end of the third quarter of Fiscal Year 2015.

The main contribution of this project is to optimize and improve the current processes and redesign the current band spacing template to make it more robust eliminating the band spacing incorrect defect.

LITERATURE REVIEW

Before entering into the defect, it is necessary to understand the purpose of a catheter and its band and how it is used in a patient.

Non –Steerable Diagnostic Catheter and its purpose

The Non-Steerable catheters are diagnostic catheters with a fixed curve. The purpose of the Non-Steerable Catheter is to be use in diagnostic electrophysiologic procedures. The catheter is designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies. Cardiac electrophysiology is the science of diagnosing and treating the electrical activities of the heart shown in Figure 3. The study of cardiac electrophysiology (EPS) normally measured the response of injured myocardium.

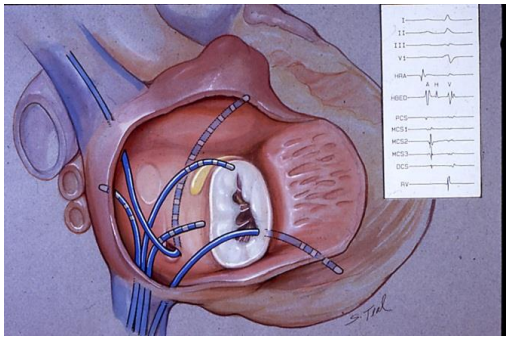

Figure 3
Cardiac electrophysiology Exam

"Catheter ablation is a medical procedure used to treat some types of arrhythmia. An arrhythmia is a problem with the speed or rhythm of the heartbeat. During the ablation catheter or catheters are put into a blood vessel in his arm, groin or neck. Cables are guided through the blood vessels in his heart. A generator sends power to your heart through catheters. Power to destroy small areas of heart tissue where abnormal heartbeat can cause an arrhythmia start. Catheter ablation is often involves radio frequency (RF) energy. This type of energy uses radio waves to produce heat that destroys the heart issue. Studies have shown that the RF energy works well and is safe". [1] Figure 4 shows an ablation treatment using RF catheter.

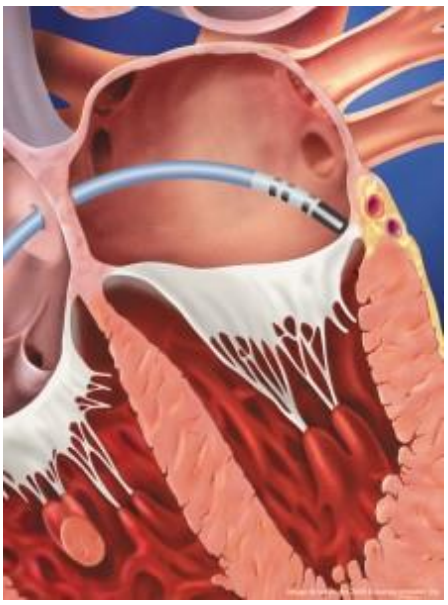

Figure 4
Ablation treatment using RF Catheter

"Advances in catheter design, x-ray equipment and radiographic contrast agents have improved the safety of diagnostic cardiac catheterization and have enabled the development of therapeutic procedures trans-catheter. These advances allow a cardiac catheterization to apply to patients more severely ill and have also allowed that the procedure that is often a less expensive outpatient treatment. Cardiac catheterization can be done through any brachial, radial or femoral artery vascular access. Most centers prefer the technique femoral, reserving alternative techniques for patients with severe aortic or iliac disease. When the catheter is removed, vascular repair in the site of the incision is required. Because of the reduced caliber compared with femoral artery brachial

artery, vascular occlusion is a most common complication with this technique. Cardiac catheterization can also be performed via the brachial artery using a percutaneous approach without vascular incision" [2].

Types of Non-Steerable catheter

There are difference types of Non-Steerable catheters. They are characterized for having different fixed curved which are Damato, Josephson, Cournand, Josephson Cournand and CS. Also the non-steerable catheters, depending on the model, have different quantity of bands. The 6F and the 5F models have three bands and one tip and the 5F CS model has nine bands and one tip.

The Non-Steerable catheters have different type of spacing. The standard spacing are measured in millimeters and is the spacing between the edges of the bands. Some spacing specifications are 2mm/5mm/2mm, 2mm/8mm/2mm, 2mm/2mm/2mm, 5mm/5mm/5mm and are used to perform the mapping.

5F CS Diagnostic Catheter

The catheter family series of model 5F CS provide various curve shapes designed for easy advancement and precise tip placement to match different heart anatomies. The benefits are:

- Curve shape may avoid inadvertent placement into side branches of the CS, but still allows easy placement into the Coronary Sinus.
- 5F size may allow catheter to advance further into the Coronary Sinus.
- Specifications;
- Fixed curve, braided stainless steel shaft.
- Decapolar (10) electrodes.
- 2/2/2, 2/5/2, 2/8/2 electrode spacing.
- 65 cm and 90 cm lengths.

Types of testing to the bands in a catheter

The bands are measured through the electrical band testing and the band spacing testing verification. Through the electrical band testing the catheter is placed into an electrical Tip Clamp and is connected to the Verification Test Box, so if the band spacing is correct the pins will make contact with the tip and the band electrodes and the continuity will be tested.

Through the band spacing testing the catheter is placed in a band space template and the bands must be within the slots in the template.

Incorrect Band Spacing Defect

As mentioned before, incorrect band spacing incorrect 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 and the unit is discarded. The consequences of incorrect band spacing could be a wrong diagnostic or bad band reading.

A. Types

- Diagnostic catheters
- Ablation (therapeutic) catheters

B. Applications

- The Diagnostic catheters are used in diagnostic electrophysiologic procedures. These catheters are designed for recording intracardiac electrograms and temporary pacing associated with electrophysiology studies.
- Ablation (therapeutic) catheters are used with the RF generator to deliver RF energy for intracardiac ablation of atrioventricular (AV) conduction pathways associated with tachycardia for the treatment of AV nodal re-entrant tachycardia and for creation of complete AV block in patients with a difficult to control ventricular response to an atrial arrhythmia.

C. Potential Complications

- Diagnostic catheters

"Perforation of the vasculature is an inherent risk of any catheter placement. Additional potential complications are those attending any intracardiac catheterization procedure including, but not limited to: cardiac tamponade, thromboembolic episodes, hematoma, pneumothorax, local or systemic infection, and death".

- Ablation (therapeutic) catheters

"Potential complications include, but are not limited to, pulmonary embolism; myocardial infarction; cerebrovascular accident; cardiac damage, perforation, and tamponade; perforation of the vasculature; partial or complete AV block; and death. Due to the x-ray beam intensity and the duration of the fluoroscopic imaging during ablation procedures, patients and laboratory staff may be subjected to acute radiation injury and increased risk for somatic and genetic effects. Catheters with distal pair electrode spacing greater than two mm should not be used in the ablation of septal accessory pathways or in the treatment of AV nodal re-entrant tachycardia because of the potential for creating inadvertent complete AV block. Implanted devices such as pacemakers and implantable cardioverter-defibrillators (ICDs) may be adversely affected by RF energy. Catheter materials are not compatible with magnetic resonance imaging (MRI)". [3]

"Catheter ablation is a heart catheterization like procedure in which a small catheter is placed inside the heart (via a leg vein). The catheter has a 4-8 mm metal tip through which radio-frequency energy is skillfully delivered to selected parts of the heart. (The area to ablate is selected primarily by two simple strategies: vector analysis of the how thearrhythmia activates the heart for example north to south, east to west) and secondly, by moving the ablation catheter in a "warmer-colder" trial-and-error manner.) The 4-8 mm ablations lesions can eliminate rogue cells that have electrically run amok, or in the case of AF, isolate entire areas of the heart into quadrants". [4]

"Cardiac catheterization is a procedure that allows the cardiologist to direct information about blood pressure and the flow of blood within your heart patterns. An angiogram is an x-ray film that is taken while injected special liquid (called contrast) That is visible by rays x in a Chamber of the heart or major blood vessels. Catheterization involves placing small tubes in the vein and the artery of a leg, arm, or neck. The catheter moves slowly through the movement until it reaches the heart. From there it can be passed to different chambers of the heart and the veins and arteries connected to the heart. The cardiologist can learn important information about their condition from heart of the samples of blood and blood pressure measurement through the catheter at different places in the circulation". [5]

Analysis of the Band Spacing Defect and Process Improvements

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.

Defining the project of Band Spacing Defect

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.

Measuring the Defect

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, as presented in Figure 5.

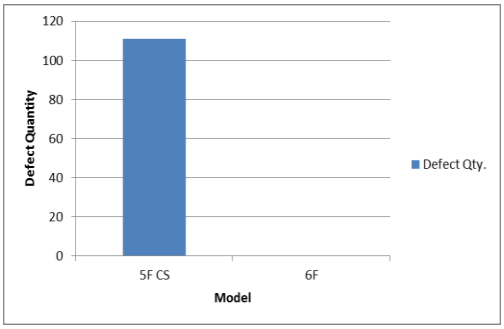

Figure 5
Defect Quantity per Model

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.

Analyzing the Defect

As part of the analyze phase, a fishbone diagram shown in Figure 6 was performed in order to determine the possible causes triggering the defect.

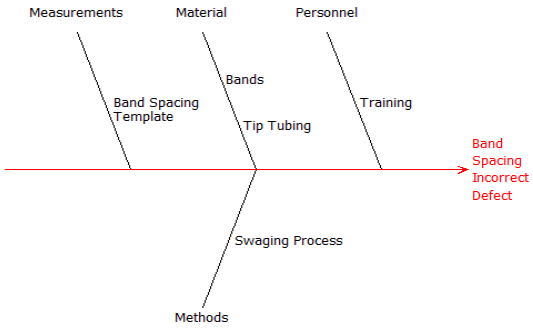

Figure 6
Defect Fish Bone Diagram

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.

In the material category, the bands and tip tubing were evaluated to know if the elongation of both materials when passing through the swaging operation process were influencing in the defect. No problems were identified.

In the personnel category, all the manufacturing team members trained in the operation where the bands are measured were evaluated and all were well trained. The swaging process was analyzed under the method category. 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, then the band spacing template is used to verify if the space between bands is maintained. This same verification is also performed in a final device process and a discrepancy was found between the two processes. In the swaging process, the verification of the band spacing is performed, as shown in Figure 7, using the template with an unaided eye and, in Figure 8, in the final device process the band spacing verification is performed using the template along with a microscope causing to magnify the defect. The catheter specification was reviewed and it was confirmed that the verification should be done only with the unaided eye. A change order was generated in order to standardize both processes verifications.

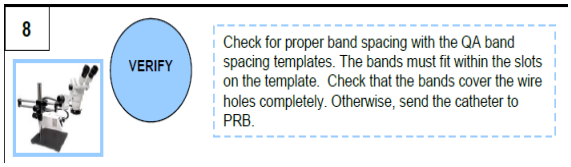

Figure 7
Verification in Swaging Process

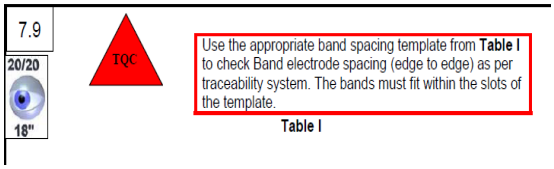

Figure 8
Verification in Final Device Process

Process Improvements

The improvements performed to the processes were divided in two phases and were made that way since the management wanted a fast solution to mitigate the defect. In 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 in phase 1 a change in the method of measuring the band space was made adding a caliper to be used along with the band spacing template, as seen in Figure 9. This change was made 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.

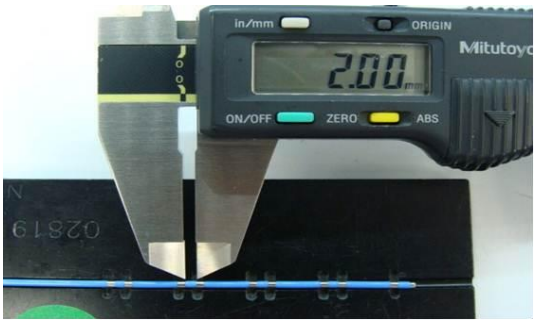

Figure 9
Verification with caliper

Phase 2 of process improvements consisted of improving the current band spacing template. The template with a designated tooling number was used as per specification but an opportunity was found in the tolerances it contains. Each hole in the template has the measure of the bands which is of 0.050 thousands of inch and an additional 0.010 thousands of inch at each side having a total space of .070 thousands of inch in each hole.

When the bands are compressed in the swager machine, as per material composition, it tends to expand more or less 0.02 thousands of inches so then the template has 0.018 of tolerance in excess. Figure 10 shows this excess of tolerance in the holes when a catheter is measured using the template. The bands that are out of the holes in the template look like they have moved to the left in the figure which is considered the band spacing defect.

Figure 10
Catheter with Band Spacing Incorrect Defect using current template

The improvement was basically to reduce 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. Meetings with the designer engineer were made in order to remove the current tooling number from the specification and in parallel the new prototype template was designed. In the new tooling each hole only consider the band size of 0.050 thousands of inches and only 0.05 thousands of inches to each side having a total of 0.060 thousands of inches per hole. Figure 11 shows the same catheter used in Figure 10 but using the prototype template to measure band space.

Figure 11
Catheter using prototype template

RESULTS

Based on all the investigation performed, it can be concluded that the solutions performed reduced the defect rate as expected specially when analyzing data post improvement. Once the improvements have been performed the next step is to analyze how the solution impacted the defect rate at the end of the quarter looking at the defect trend. Figure 12 shows the defect trend in which a significant defect reduction is seen in the months of December and January.

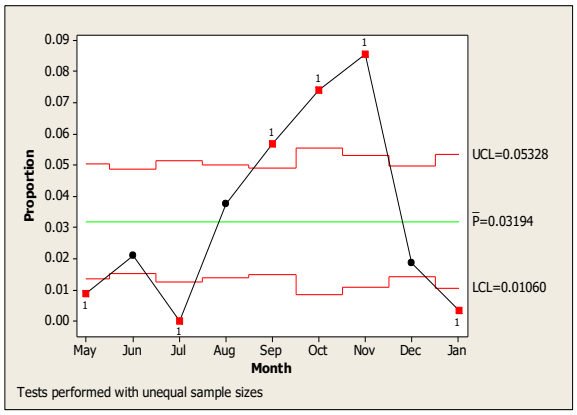

Figure 12
Defect trending

DISCUSSION

This project helped the business reduce the scarp rate controlling two important scorecard

metrics. The product availability and the conversion loss are two important business unit metrics that were being affected by this defect condition. With the investigation results both metrics improved since now the product is available when needed in the distribution center and the loss in dollars due to the defect decreased.

One of the biggest challenges during this project was the availability of the people involved in the changes outside the facility since the time for the approval of the proposed changes became more than expected and projected in the timeline. It was proposed to attend this situation by assigning more resources for prompt approvals. Timeline was affected a little bit but it was able to catch up. Overtime was necessary in order to be able to get back on proposed schedule.

CONCLUSION

Using the DMAIC methodology, it was found that the causes for the Incorrect Band Spacing on the catheter model 5F CS were the following:

- In the execution of the process the inspection between swaging procedure and Final TQC procedure was not standardize because in one procedure microscope was used and in other it was performed by naked eye.
- New process changes were implemented to align inspections across the manufacturing processes.

The swaging process and the final inspection process were aligned in order to have same criteria across the manufacturing line and a caliper was added, as a mitigation, 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 reassigning new tolerances which contributed to eliminate the band spacing defect when implemented.

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