Missing Magnet Defect Rate Improvement Project at the Cement Unit at Stryker Puerto Rico

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Abstract

At Stryker Puerto Rico, there was a growing of customer complaints for the new Prep+ Cartridge. The complaints were generated due to units found without a component. This is a magnet that is placed on the back of the product that allows a connection that makes the product work. Without the magnet, the product is useless. Based on the recognized problem in the organization, an analysis with the application of DMAIC was done to identify the root cause. It was found that the cause of the problem was during the assembly process. Nevertheless, some opportunities were also found in the design of the product. Propositions of Quality Control and Fixtures/Equipment improvements for production process were considered to decrease the defect rate for the missing magnet.

Introduction

There is a huge pressure on Stryker Puerto Rico organization to improve the customer satisfaction and quality due to a complaints generated by customers for the new product Prep + Cartridge launched on January 24th ,2023,. The customer annoyance arises from the fact that the product has been found inoperable in the field. This has been transferred to a big loss to the company and is affecting the sales for the new product. The purpose of the project is to identify the root cause of the missing component, robust quality controls during process and implement improvements that will allow to eliminate the complaints from customers.

Background

The Prep+ Cartridge product, to be manufactured at Stryker Puerto Rico is a device used for automated bone harvesting. Current methods consist of removing tissue from the bone manually with rongeurs, electrocautery or scalpel. These methods add inconsistency to the bone cleaning process when considering the potential of different staff performing these operations, or if the cleaning is not done thoroughly. The new Stryker's Prep+ will allow the customer to improve the bone cleaning process by automated bone harvesting which will free up staff time, promote additional safety practices by avoiding the manual use of scalpel and other sharp instruments for the harvesting, maintain a sterile environment, reduce bone cleaning time, and produce a higher quality bone graft. It is one of its kind and is the first on the market to do this function.

This product was launched on the market on January 24th, 2023. During stock build production, around 800 units were made. A month after it was launched, some complaints by customers began to be generated against the said product. The complaints are not related to patient harm but rather customer annoyance. The annoyance arises from the fact that the product has been found inoperable in the field due to a missing component. This component is a magnet that is assembled in a pocket on the bottom of the unit. By not having this magnet the product is totally useless and will not have functionality. From stock build units, 9.13% have been found with the defect of not having the magnet present in the Baseplate component. If it is not known if there are more units with this defect in the distribution center. This product is sterilized and cannot be reworked since double sterilization has not been proven for this product, so the rest of the units found would be losses assumed by the business since they would not work.

To solve this situation, the DMAIC tool was put in practice. The acronym of the words Define, Measure Analyze, Improve, and Control, DMAIC is a methodology based on process improvement [1]. The Define stage concentrates on determining the goal and the requirements of the project. The Measure stage gathers information about processes. This information is needed to better understand the possible places where a problem may occur. In the Analyze stage, the measurements are analyzed. In this stage "it is needed to define process capability, clarify the goals based on real data gained in the measure phase and start root cause analysis which has impact on process variability. By calculating process capability, which is defined as sigma of the process, ability of the process to meet customers' requirement is measured. Process capability will be a key point for planned improvements" [1]. Once the root causes are identified, then the process of addressing and fixing those gaps starts. The objective of the Improve stage is to create an action plan with possible solutions to the causes identified. After the improvements were completed, a stage of confirmation of the changes implemented starts. This stage is called Control. The purpose of this stage is to monitor the results of the improvements in a continuous way.

Problem

Customer complaints increased drastically on Q1 on the Prep+ Cartridge product manufactured at Stryker Puerto Rico due to escapes of defective units. A 9.13% of manufactured units for stock build has been found with the defect of not having the magnet present in the Baseplate component. This product is sterilized and cannot be reworked since double sterilization has not been proven for this product, so the rest of the units found would be losses assumed by the business since they would not work. Each unit has a cost of $675.00 on the market. The company loss in the first quarter was $49,275. Figure 1 shows the number of units found without the magnet component during the first quarter.

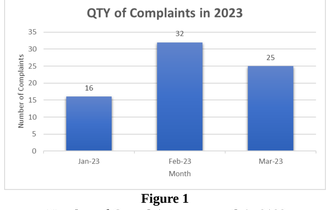

Figure 1
Number of Complaints per month in 2023

Methodology

The methodology to follow and make an approach to identify the root cause for this problem will be DMAIC from Lean & Six Sigma tools.

- First defining the problem and the scope of the project will be the initial step.
- Next create a project charter to identify the stakeholders, champion, scope, defining the goals and objectives for this project, defining any capital assigned for the project and expected results.
- Planning Session to start investigating the root cause. Create a plan to gather manufacturing data, lot information of raw material used, identification of the associates related to the manufacturing dates, certifications of the associates in the processes, quality controls per processes (inspections methods and polarity measurements), investigation of the equipment and fixtures used during process, incoming inspections, etc.
- A Cause-and-Effect Diagram (Fishbone) creation to start taking a detailed picture of the possible defects.
- Analyze data collected and create reports to identify the root cause.
- Once identified the root cause, create a Filtering Matrix to organize and prioritize each of the variables affecting the processes.
- Brainstorming and try-storm sessions to improve the processes and eliminate the defect.
- Update control plan to include new metrics and measurements identified during investigation to monitor the improvements.

Results and Discussion

DEFINE

The objectives of this project were to:

- Reduce the escape of non-magnet units.
- Improve quality controls to capture 100% of the non-magnet units manufactured.

MEASURE

A process flow map was created to understand the possible places in which the defect was generated. Also, a Failure Mode and Effect Analysis (FMEA) was conducted to understand the possible risks. The process map shows all the possible points of cause and failure inspections.

The Magnet to Baseplate Assembly is identified as a point of cause for the defect generation. If the defect is generated in that step, it will be carried over to the other processes. Therefore, this begins by evaluating the raw material and the equipment. For this process, a manual press is used to make the assembly at the magnet to baseplate. The components used for this process are the prep Baseplate and the detection magnet. The intention of the process is to insert the detection magnet in the baseplate pocket using the manual press. The press shaft is magnetized which will hold the detection magnet and make it easier for the operator at the assembly. Figure 2 shows the inputs for the Magnet to Baseplate Assembly process.

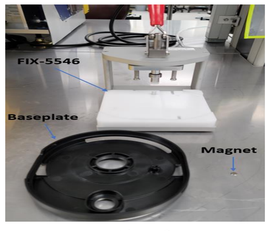

Figure 2
Inputs for Magnet to Baseplate process

After process execution, the magnet must be inserted in the baseplate pocket with the right polarity facing the visible surface. The assembly output for this process will be the magnet fully inserted in the pocket and the visible surface polarity should be south (green light). A polarity tester is used to make this process check. Figure 3 shows the process outputs.

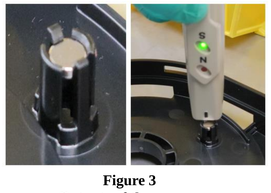

Figure 3
Outputs of the process

The baseplate and detection magnets component were measured to determine if the critical quality attributes (CQA's) and key features are within specification range as per respective part drawing. Table 1 shows the specs range for the features for the baseplate pocket component, while Table 2 shows the specs range for the features for the detection magnet component.

Table 1
Baseplate CQA's specs range

Diameter (in)			Tab to Tab distance (in)		
Low	Nom	High	Low	Nom	High
0.254	0.2600	0.263	0.167	0.172	0.185

Table 2
Detection magnet CQA specs range

Diameter (in)		
Low	Nominal	High
0.246	0.250	0.254

The parts were measured with the current inspection method as per Attribute Charts. Also, the same parts were measured in a different method to create a correlation analysis to challenge the current inspection method against others to discard the measuring system from the possible causes. This allowed to understand if there were parts within spec, and if the supplier was providing good parts. The current inspections methods (caliper and pin gage) for the baseplate were challenged against Keyence microscope and optical gage.

For the detection magnet, 30 samples were measured to understand if the magnets are within specification.

After measuring the raw material, the assembly fixture was investigated. In this analysis, 30 samples were evaluated before and after the assembly. The purpose of this study was to identify if the fixture or any of the two components was affecting the process output previously mentioned. The baseplate pocket diameter and tab-to-tab distance were measured before and after placing the magnet.

On the other hand, it was evaluated if all the associates who worked during those manufacturing dates were properly trained and certified in the process. Turns out all the associates were certified. It was also evaluated if the environment was a factor or possible cause. The environment was discarded since it has no relation to the defect.

ANALYZE

After measuring evaluation, the baseplate samples were measured in optical gaging products and Keyence microscope to create a correlation and see if the method used were capable to provide reliable results. As per acceptance criteria from procedure, for a CQA of low risk, the average tolerance range and the individual tolerance range must be equal or less than 30% to be acceptable. The overall tolerance was 27%, which is acceptable, but the individual tolerance range for the diameter dimension in the baseplate pocket is above the acceptance value for sample four, five and six. This will not comply with the procedure.

Also, a T-Test was created to analyze if there any significance between means for both samples. Figure 4 demonstrates that the hypothesis of equal means is rejected since the P-Value is equal to zero. This means that the test is statistically significant since there is a great difference between means. An opportunity in the inspection method for the baseplate pocket diameter CQA was found since the P-Value is zero (0).

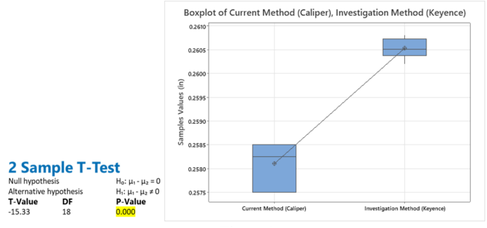

Figure 4
2 Sample T-Test between Caliper and Keyence Methods for pocket diameter

Regarding the other CQA of the baseplate (tab-to-tab distance), the correlation met the evaluation criteria with an overall 3.22%. All individual tolerances were also met. Therefore, the inspection method for the CQA is correct. It is assumed that the measurements are correct and are within specification. For the detection magnet, since the diameter of the magnet is not a characteristic measured because is an off the shelf component, as a conservative approach was decided to follow procedure to establish the Ppk profile for a low-risk component. With a confidence of 95% for a sample size of 30 units, the acceptance criteria shall be Ppk equal or higher to 0.89. Cpk for a low-risk component is 0.67. After analyzing the results with a process capability study, the diameter of the detection magnets appears to be within the nominal specification with a Ppk of 4.97. This study demonstrates that the detection magnets are not a possible cause. Figure 5 shows the capability analysis for the detection magnet diameter.

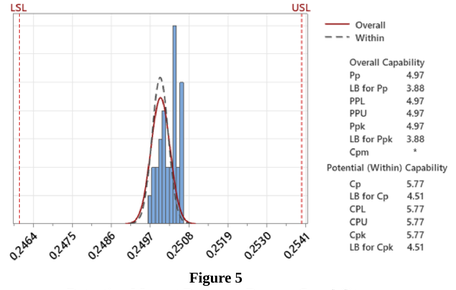

Figure 5
Detection Magnet Diameter Process Capability

To analyze the assembly fixture, 30 samples were evaluated before and after the assembly. The baseplate pocket diameter and tab-to-tab distance were measured before and after placing the magnet. The detection magnet diameter dimensions are not being taken for this step since it is a standard component and it was possible to prove that the dimensions do not vary much, so their process capability study came out high enough to be confident that it is not a variable that affects. A capability analysis was created to understand the behavior before and after the magnet assembly. The pocket diameter increased the dimension after the assembly (see Figure 6). This means that the magnet is creating a wear in the edge of the baseplate pocket. Also, PpK before and after the assembly do not comply with the acceptance criteria. The statistics show that 29% were out spec before the assembly and that 100% of the units were out spec after the assembly. Therefore, the supplier is providing out spec components or near to the upper spec.

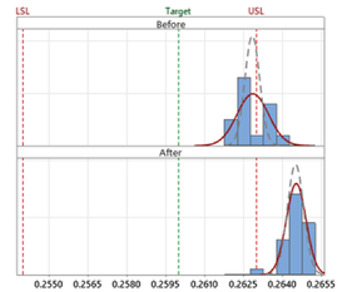

Figure 6
Before and After comparison for the Pocket Diameter dimension

IMPROVE

To eliminate the imperfections an implementation plan was created with Short-Term Solutions and Long-Term solutions. The flowing corrections are the Short-Term Solutions:

- Adding a new 100% polarity check inspection for the magnet before sealing as quality control.
- Update Attribute Chart with the new inspection method (Keyence Microscope) for the Baseplate CQA's.
- Quality Awareness to the supplier to verify the specifications of the Baseplate Pocket and inspect the units with other method.
- Improve the tip of the fixture to avoid holding the baseplate tabs and avoid marks after assembly.
- Blister sealing machine was improved with sensors to detect the presence of the magnets before sealing. If the machine detect that the magnet is missing it will not seal the blister.

As a long-term solution, a redesign of the baseplate pocket or a completely new design for the magnet and baseplate retaining technique was proposed.

CONTROL

For the past two months, fifteen (15) non-magnet units have been captured before sealing and zero (0) escapes. These fifteen (15) units has been reworked and be able to do not lose the whole unit. This is a cost saving of $10,125 for the last two months.

Table 3
Saved units for the past two months

April	May
9	6
Total	15
Cost per Unit	$ 675.00
Total Saved	$ 10,125.00

Conclusions

It was found that the fixture was causing certain marks on the component after assembly. However, the design still has an opportunity since the magnet diameter its greater than the tab-to-tab distance and it will exert an outward force in the assembly, which will make the baseplate pocket larger after assembly. The process of creating a new design will take time, so effective process controls were established in the processes determined by the Process Flow Map and FMEA assessment., to ensure that there are no escapes. The number of escapes could be reduced but the defect persists until the design is changed.

Future Work

A redesign of the baseplate pocket or a completely new design for the magnet and baseplate retaining technique

References

1. Monika Smętkowska & Beata Mrugalska. (2018, April 27). *Using Six Sigma DMAIC to Improve the Quality of the Production Process: A Case Study* [paper]. Available: https://reader.elsevier.com/reader/sd/pii/S1877042818300697?token=2669EBF2F9D39FEC2E6343E59D60B7559C1B351341E26916676CB566FE4612BC4A9CA5AD607B4732BBC0A650EFF4D187&originRegion=us-east-1&originCreation=20230516004156)