Complaint Reduction Project of Infant Heel Incision Lancets of a Medical Device Manufacturing Plant

José G. Rodríguez González
Master of Engineering in Manufacturing Engineering
Edgar Torres, Ph.D.
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *— The purpose of this project was to identify key factors affecting the complaint rate of the infant heel stick lancet related to insufficient blood flow from the incisions and no activation of the lancet after triggered. These two defects drive the complaint rate of this product thus overshadowing other minor complaint categories or defects. The results of this project directly affect the complaint rate of the lancet and therefore increase the product quality and manufacturer's efficiency. The anticipated outcome of this project was the identification of areas of the assembly process with high potential of incorrect assembly of parts due to process variation, which ultimately leads to customer complaints. Following the DMAIC methodology, it was possible to reduce customer complaint rate from 4.82 to 0.47 CPM.*

Key Terms *— Complaints per Million, DMAIC, Lean Principles, Regulation Classification.*

INTRODUCTION

The demand of the domestic and international catalogs of an infant Heel Incision Lancet is dropping due to quality opportunities in the product. Currently the device manufacturing plant is receiving a total of 4.82 complaints per millions of units manufactured with the top offender defects being, insufficient blood flow and no activation. Clients refer to insufficient blood flow as the lack of blood collected from one lancet's incision. No activation is when a Lancet is activated but there was no incision performed when the device is triggered against the baby's heel. The plant has requested an initiative to reduce these complaints and drive the actual rate of 4.82 CPM to a six-sigma level (3.4 CPM) or lower.

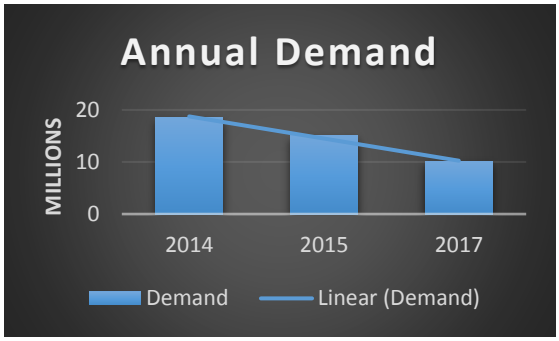

Figure 1
Lancet Device Annual Demand Trend

Research Description

The purpose of this project is to investigate the root cause of these defects and implement robust corrective and preventive actions to reduce customer complaints related to insufficient blood flow and no activation. This investigation will help shed some light in any problems present in the assembly or packaging process of the Lancets.

Research Objectives

The plant has requested an initiative to reduce these complaints and drive the actual rate of 4.82 CPM to a six-sigma level (3.4 dpm) or lower. By reducing the top offenders (insufficient blood flow and no activations) this goal can be achieved.

Research Contributions

If the established goal is reached a significant positive impact to product quality will be attained and sales volume will increase. The plant will not need a dedicated resource performing investigations to each complaint received resulting in lower indirect cost of the manufacturing process. Additionally, the company will have a lower regulatory exposure and a reduced risk of receiving a more critical complaint.

LITERATURE REVIEW

A critical step in the manufacturing process of this Heel incision device is the welding of the top and bottom plastic covers. The joining of these parts is done with Ultrasonic Welding technology. Ultrasonic plastic welding is the joining or reforming of thermoplastics through the use of heat generated from high-frequency mechanical motion. It is accomplished by converting high-frequency electrical energy into high-frequency mechanical motion. That mechanical motion, along with applied force, creates frictional heat at the plastic components' mating surfaces (joint area) so the plastic material will melt and form a molecular bond between the parts [1].

A common powerful tool used in the manufacturing environment when choosing the operating parameters of a certain process/equipment is the Design of Experiment or "DOE". A DOE is very useful when determining the relationship between some input parameters or factors with some output parameter or responses. In performing a designed experiment, we will intentionally make changes to the input process or machine variables (or factors) in order to observe corresponding changes in the output process. The information gained from properly planned, executed and analyzed experiments can be used to improve functional performance of products, to reduce scrap rate or rework rate, to reduce product development cycle time, to reduce excessive variability in production processes, etc. [2].

Being a plant that distribute product to United States of America (USA) and internationally the Medical Device plant that manufactures the Infant Heel Incision Lancet is regulated by the local government agencies which establish minimum regulatory standards for any company that distributes product in their regulated territory. These agencies which regulate the products of this particular plant are: The Food and Drug Administration (FDA) which regulates product distributed in the US and The International Organization for Standardization (ISO) which regulates product distributed internationally.

Regulatory agencies establish standards and guidelines, at a very high level, of how these manufacturing companies must operate from a product quality perspective and in some aspects of the operation at a not so high level. These guidelines are segregated into segments or parts which some parts may or may not apply to the companies depending on the type of product they manufacture and distribute in the territory which the agency regulates.

The segment or part of the FDA that is applicable to Medical devices distributed in the US is called CFR 21 Part 820 Medical Devices Quality System Regulation. FDA Part of 820 establishes guidelines for good manufacturing practice that Medical Device companies must follow in order to meet the regulation. Failure to meet said manufacturing practices will render the affected medical device or devices adulterated as described by the FDA. There is a wide range of characteristics that can rend a product adulterated per FDA regulation, in short, any device that did not meet any standard to which it is subjected, is considered an adulterated.

FDA CFR 21 Part 820 is divided in subparts which cover a great range of aspects of the manufacturing practices for Medical devices, from facilities, personnel and equipment to storage of the records, control of documents and management of customer complaints.

The subpart that targets the management of customer complaints is the Part 820 subpart 198 Complaint Files (Part 820.198). This subpart states the following: (a) each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) all complaints are processed in a uniform and timely manner; (2) oral complaints are documented upon receipt; and (3) complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part

803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary. (d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event. (e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include: (1) The name of the device; (2) The date the complaint was received; (3) Any device identifications(s) and control numbers(s) used; (4) The name, address, and phone number of the complaint; (5) The nature and details of the complaint; (6) The dates and results of the investigation; (7) Any corrective action; and (8) Any reply to the complaint. (f) When the manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either: (1) A location in the United States where the manufacturer's records are regularly kept; or (2) The location of the initial distributor [3].

As can be gathered from the above citation, the FDA regulation standard for complaints in the Medical Device segment is very robust.

The FDA Europe counterpart, ISO regulates Medical Devices with standard ISO 13485 Medical Devices Quality Management Systems Requirements for Regulatory Purposes. Similar to FDA's standard for Quality System, ISO 13485 establishes standards for a wide variety of aspects from the quality perspective.

The following citation is a summary of the applicable parts of this standard related to customer complaints:

The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. The organization shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained (see 4.2.4). If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1). If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4). If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures for such notification to regulatory authorities [4].

As can be gathered from the previous citation, ISO does not seem to be as restrictive as its US territory counterpart (FDA).

For the business wellbeing, it is important that the business meet all the standards applicable which includes the complaints standards. Failing to meet said specifications can prohibit the distribution of the affected product in the affected territory. Therefore,

it is critical that complaints are adequately handled in order to meet said standards.

It can be understood the importance of this Medical Device plant that manufacture the Infant Heel Incision Lancets to investigate in a robust manner the complaints related to a product that is targeted at infants.

In order to tackle the customer complaints problem, the DMAIC methodology will be used. DMAIC is a basic Six Sigma methodology component aimed to improve processes by eliminating defects. The DMAIL methodology takes a problem and utilizes a set of tools and techniques in a logical fashion to arrive at a sustainable solution(s). The resultant solution(s) will minimize or eliminate the problem, placing the organization in a competitive position [5]. This Six Sigma methodology is widely used in many corporations around the world.

The DMAIC methodology consist of the following phases or steps:

Define: In this step, it is important to define specific goals for achieving outcomes that is consistent with the customer's demands. In essence, one is laying down a road map for accomplishment.

Measure: In order to determine whether defects have been reduced, the user needs a base measurement. In this step, accurate measurements must be made and relevant data must be collected so that future comparisons can be measured to determine whether defects have been reduced.

Analyze: Analysis is extremely important to determine relationships and the factors of causality.

Improve: Making improvements or optimizing processes based on measurements and analysis can ensure that defects are lowered and processes are streamlined.

Control: Control ensures that any variances stand out and are corrected before they can influence a process negatively causing defects.

Six Sigma has been around for more than 20 years. In its methodology, it asserts that to achieve high quality manufacturing and business processes, continued efforts must be made to reduce variations.

The Six Sigma system strives to reduce these variations. To do so, processes must be measured, analyzed, controlled, and improved upon. To improve upon these processes, the Six Sigma system requires sustained commitment from an entire organization.

It should be noted that the Six Sigma system derives its name from the high-quality output that it strives to achieve. Six Sigma refers to a defect level of lower than 3.4 defects per million opportunities. This methodology has saved businesses around the world billions in dollars due to its low defect output.

METHODOLOGY

To achieve the research objectives, the DMAIC Six Sigma Methodology will be used and consist of the following steps:

Define: The purpose of this phase is to establish specific goals or objectives, therefore the define phase for this project will be to establish the goal of achieving a six-sigma level (3.4 per million) or lower of customer complaints for the Heel Incision Lancet.

Measure: The goal of the Measure phase is to establish an accurate base of measurement for the defects. The measurement base for this project will be the total volume of parts produced by the manufacturing plant divided by the total customer complaints received by the manufacturing company for any given month.

Analyze: The intent of this phase is to perform the analysis of the data gathered by measurements or metrics. For this project, an analysis of the defects reported by the customers will be performed in order to identify all possible causes in the process that can result in customer complaints.

Improve: In this phase, the goal is to make the improvements to the process based on the data gathered and the analysis performed which will ultimately drive the customer complaints rate down.

Control: Once all improvements have been made to the process, the next step is to establish proper controls to maintain the improvements effective. In this phase, the two manufacturing lines will be potentially validated in order to demonstrate

that the changes made does not impact the process adversely and that the manufacturing line can consistently produce product that meets any new predefined requirements. T

The following figure represents the project schedule:

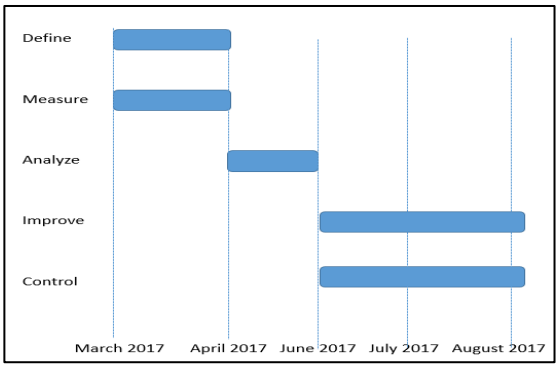

Figure 2
Project Time Line

RESULTS AND DISCUSSIONS

Following the DMAIC methodology, the following step is the measure phase. For the measure phase, it was decided to maintain the current metric that the plant uses, the complaints per million (CPM) metric since the baseline is established in CPM. This metric is calculated by the Quality Specialist located at the plant. This calculation is performed by dividing the number of complaints received during a certain period by the units manufactured during that same period expressed in millions.

Analyze

In order to complete the analyze phase, a multidisciplinary team was formed in order to tackle all possible aspects of the manufacturing process that could be potentially contributing to the customer complaints defects. After an extended evaluation of the manufacturing process for both machines, the following items were observed:

Inconsistent Welding - There was inconsistent welding between the top and bottom cover of the devices. This is attributed to the welding process. The welding method used was not helping the process maintain constant welding quality.

Incorrect Assembly – It was observed that even though there was a vision system inspecting 100% of the components after assembly, there was a high risk of the spring component to move to an incorrect position after the vision system inspection due to vibration created by seceding stations, after this vision system inspection there was no additional controls to inspect for correct position of components other than in-process testing.

Inconsistent Equipment Setup – Engineering studies were performed in order to compare the impact of different machine alignments within the process Operating Procedure and it was found that there was too much variation allowed in the alignment of four of the machines stations that could potentially affect product performance. These stations consist of high precision grippers therefore, alignment is critical to the correct placement of the internal parts of the heel stick device since there is a very small window of error allowed before the part is incorrectly installed.

Improve

As part of the improve phase a number of actions were implemented in order to address the sources of variation and sources of negative impact to the product. For inconsistent welding, the same welding equipment was change from “Collapse mode” to “Energy mode” which demonstrated to produce consistent welding during an engineering study which included a screening DOE to determine the new welding parameters under this new welding mode. As for the incorrect assembly potential, a new vision system camera was installed at the end of the assembly process which inspects through the device’s front slot in order to determine whether the spring component is located in an incorrect position. This implementation was challenging since a high performance LED light had to be setup in order to illuminate the interior of the assembled device to provide adequate and consistent lighting for the camera. Finally, for the inconsistent machine alignments, a set of fixtures were created in order to aid the operators in the machine setup process. This resulted in a much more consistent machine setup

and alignment. For these fixtures, an engineering study was performed in order to confirm that the product performance was not negatively affected and resulted in satisfactory results.

After a period of approximately three months after the implementation of the improvements, the CPM went down to 0.47 from the baseline of 4.82 CPM.

Control

As a result of the control phase, al changes were implemented through the plant's change control process which is the way of changes implementation. As part of this change control process some of the changes, like the implementation of the new vision system and the change in welding mode, had to go through a full validation consisting of Installation Qualification (IQ) with Measurement System Analysis (MSA), Operational Qualification (OQ) and Performance Qualification (PQ). For the implementation of the fixtures, an engineering study having destructive testing was enough to comply with the plant's change control system. All changes were also required to be reflected in each machine's Standard Operating Procedure which is the machine's operator guideline for operation.

CONCLUSIONS

As part of this project, the manufacturing and inspection process for the Infant Heel Incision Lancet was studied in order to reduce the customer complaints rate related to insufficient blood flow and no activation defects. At the time of the beginning of this project (March 2017), the customer complaint rate was found at 4.82 complaints per million of unit manufactured. During this study, Lean approach was used in order to investigate all possible root causes of the customer complaints rate related to insufficient blood flow and no activation defects. DMAIC methodology was used through this project to follow a structured problem solving or improvement process. This methodology helped to clearly define the problem, establish a baseline measurement of the problem in order to perform an analysis of the possible causes of the defects, implement improvements identified and establish robust controls to ensure that improvements are kept in place and executed as established. By analyzing the sources of the insufficient blood flow and no activation defects, corrective/preventive actions were implemented which resulted in a significant decrease of 90.25% in the customer complaints rate received by the manufacturer.

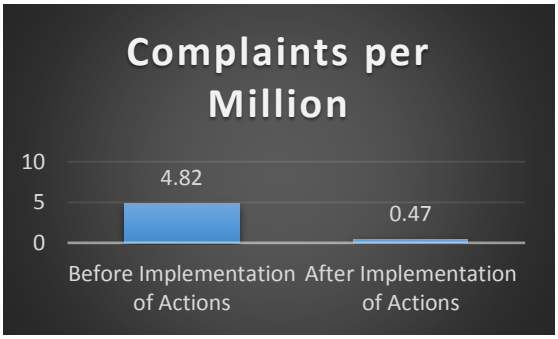

Figure 3
Complaints Data

REFERENCES

[1] L. Dukane IAS. (2016). DUKANE Intelligent Assembly Solutions [Online]. Available: https://www.dukane.com/us/PPL_whatisUPA.htm. [Accessed 15 April 2017].

[2] J. Antony, Design of Experiments for Engineers and Scientists, 1st Edition, Elsevier, 2003.

[3] U. S. Food & Drug Administration. (2017, April 1). "CFR - Code of Federal Regulations Title 21," in *U.S. Department of Health & Human Services* [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=820.198. [Accessed 13 April 2017].

[4] ISO, ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes, Switzerland: ISO, 2003.

[5] R. Shankar, *Process Improvement Using Six Sigma: A DMAIC Guide*, ASQ Quality Press, 2009.