International Journal of Engineering Applied Sciences and Technology, 2025
Vol. 9, Issue 12, ISSN No. 2455-2143, Pages 135-141
Published Online April 2025 in IJEAST (http://www.ijeast.com)

DEFECT REDUCTION IN MEDICAL CATHETER LINE USING LEAN SIX SIGMA

Jesus Lisea
Master Degree Student
Tecnológico de Chihuahua II, Chihuahua, Chihuahua, México

Rosa Amaya
Department of Engineering
Tecnológico de Chihuahua II, Chihuahua, Chihuahua, México

Patricia García
Department of Engineering
Tecnológico de Chihuahua II, Chihuahua, Chihuahua, México

Manuel Baro
Department of Engineering
Instituto Tecnológico Superior de Nuevo Casas Grandes

Abstract—**This study applies the Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology to reduce defects in the production of medical catheters. In the Define phase, the scope of the project was established, identifying critical defects (such as bubbles, irregular diameters, and contamination) that impact product quality. In the Measure phase, historical data were collected, and key metrics (DPU, DPMO, and initial Sigma level) were calculated. During the Analysis, tools such as Pareto diagrams (to prioritize defects), Ishikawa (to identify root causes), and ANOVA (to validate significant factors) were used. The main problems detected were variability in extrusion parameters, lack of process standardization, and environmental pollution. In the Improve phase, solutions were implemented, such as adjustments in molding temperatures, training in good manufacturing practices, and cleanliness controls in the clean room. Finally, in Control, procedures were standardized, control charts were established (SPC), and an audit plan was designed to ensure sustainability. The results showed a 60% reduction in defects and an increase in the Sigma level from 3.2 to 4.5, demonstrating the effectiveness of Six Sigma in optimizing critical medical processes.**

Keywords—**Defect, Improvement, Six sigma, DMAIC**

I. INTRODUCTION

Medical devices are instruments, apparatus, machines, implants, in vitro reagents, software, and other items used to prevent, diagnose, treat, and monitor diseases and health conditions. These devices vary widely in their complexity, from simple bandages to complex medical imaging systems ([1]

The production of medical devices globally has grown significantly in recent decades. According to a report by the Medical Device Industry Association (AdvaMed), the global medical device market reached approximately $450 billion in 2020, with a growth projection that could exceed $600 billion by 2025. This growth is due to technological innovation, an aging population, and an increase in chronic diseases[2].

The quality of medical catheters is important in all types of production to avoid complications such as infection, thrombosis, or perforation.

Some measures that have been taken to improve the quality of medical catheters are the use of biocompatible materials, coating with antimicrobial substances, sterilization control, and compliance with official Mexican standards[3].

Quality can be improved by implementing a quality management system, such as the ISO 13485:2016 standard. This establishes the requirements for a quality management system for medical devices. Implementing a quality management system can help ensure that medical devices are safe and effective[4]

The production of medical devices, which includes medical catheters, is a critical process that requires rigorous attention to quality, which is important to ensure their safety, efficacy, meet regulatory requirements and thus maintain customer confidence [5]

In terms of market growth, the global medical devices market is estimated to grow at a CAGR of 5.4% between 2021 and 2028 (Grand View Research, 2021). The medical device

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industry employs more than 2 million people in the United States alone (AdvaMed, 2020). Innovation: Approximately 60% of medical devices on the market are innovative, meaning they have been developed within the last five years [6]

II.PROPOSED METHODOLOGY

A. Problem Statement

The company under consideration had a deficit in the production of infant catheters, model K840, due to a high rate of rejection. This rate of rejection was considered waste or scrap, as the product was non-recoverable[7].

At the conclusion of the production line for this specific catheter is the quality station, or final inspection, an activity that is manually executed by the operators in charge. At this station, the length of the catheters is meticulously measured with a scale and then compared with the corresponding design specifications[8]. A recent investigation revealed that the K840 model exhibited deficiencies in meeting customer specifications. These shortcomings stemmed from a series of defects pertaining to the catheter length, which fell short of the parameters delineated in the design drawings. Specifically, the catheters were found to be significantly shorter than the minimum specification limit.In case of two-dimensional image, after a DWT transform, the image is divided into four corners, upper left corner of the original image, lower left corner of the vertical details, upper right corner of the horizontal details, lower right corner of the component of the original image detail (high frequency). You can then continue to the low frequency components of the same upper left corner of the 2nd, 3rd inferior wavelet transform[7,9].

Fig. 1.Medical catheter production line. Own elaboration.

As a way of graphically representing the problematic situation presented by the company at the time the case was taken for study, Figure 1.2 presents the gap calculation and cost analysis graph of SCRAP, of 2 types of medical catheters that present the problem of shortages, from the year 2021 to 2023[10].

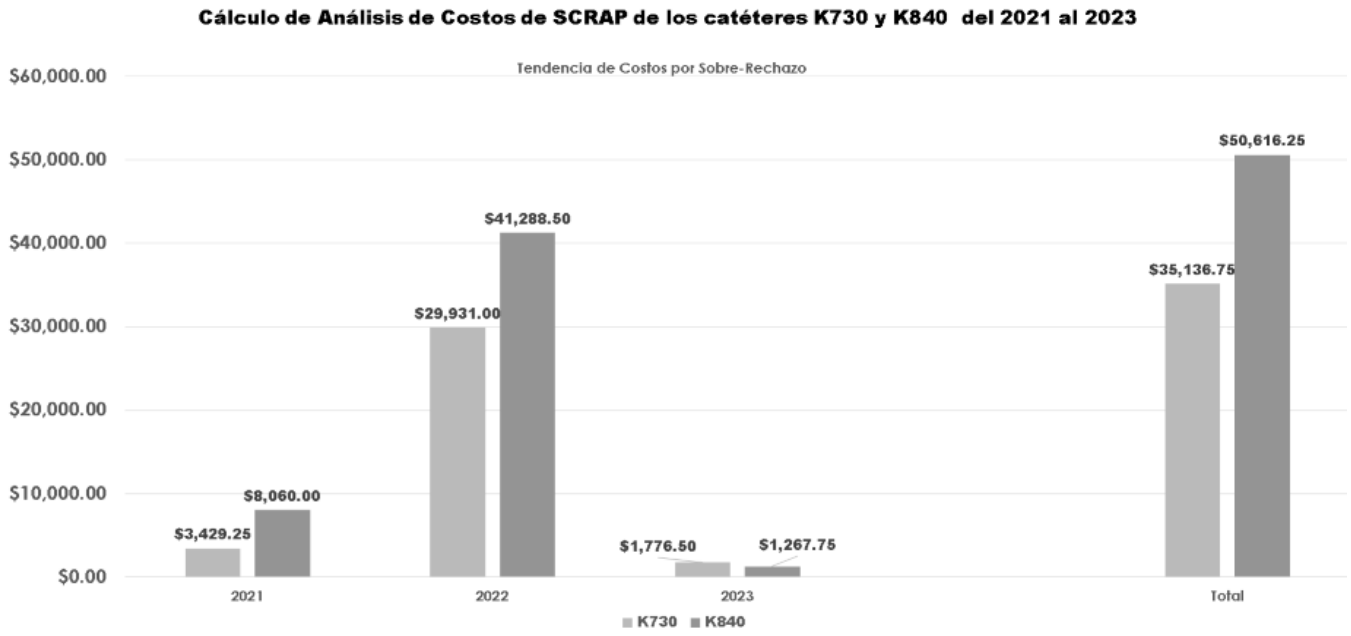

Fig 2. SCRAP Gap Calculation and Cost Analysis Chart

Figure 1.2 shows that the K840 model (infants) had higher costs per SCRAP than the K730 model (adults) in the period from 2021 to 2023. The K840 model generated a total cost of $50,616.25, while the K730 model generated a total of $35,136.75, so the study will focus on the K840 model, which had the highest costs for the company[11].

B. Methodology

This research employs a case study approach, characterized by its exploratory and correlational scope. The objective of this methodology is to identify the underlying causes of short defects in the SAF line, which are considered scrap, and to determine their associated factors. The primary aim is to

correct these defects and prevent their recurrence[12].The methodology to reduce the level of scrap consists mainly in the design of a system of periodic measurements with statistical and process tools, capable of monitoring and controlling the dimensional tests that are performed, in addition to the establishment of a plan of timely actions for the moment in which the shorts occur in the length of the catheter, and thus reach an acceptable Cp and Cpk index in the SAF line[13].The case under study was a type of medical catheter (K840) intended for infants, as it represented the greatest economic burden for the company, attributable to the high scrap rate[14]. To address this issue, several LEAN tools were implemented in accordance with the stages of the DMAIC methodology. The DMAIC methodology comprises five stages: Define, Measure, Analyze, Improve, and Control. The subsequent section will delineate the first stage of the Define phase[15].

Define stage of the project are delineated.

Critical Quality Tree. Utilizing the Critical Quality Tree (CTQ Tree) depicted in Figure 4.1, the quality indicator employed for the quantitative assessment of product quality is illustrated. This indicator signifies the non-rejection tolerance of the K840 model.

Kano Model. The Kano Model was used as a method of analysis to determine the relationship between product characteristics and the level of satisfaction they provide to the customer, in order to determine product quality.

SMART Objectives. Project objectives with SMART characteristics must comply with being: specific (S), measurable (M), achievable (A), realistic (R) and time-bound (T). The objective is to increase the capability index (Cpk) of the process, through its measurable in the SAF line of medical catheters, which the programmed achievement was for April 2024, whose reality is the current value of the Cpk of -0.56 and the desired value is 0.30.

Business Case. The business case model illustrates the advantages of addressing the catheter length problem for this particular business case, thereby reducing scrap, as a means to substantiate the project's acceptance.

Business Benefits: The elimination or reduction of high scrap costs for the K840 model due to short length problems is a key benefit.

Customer Benefits: The elimination of downtime in final processes, attributable to material shortages.

Rationale for project attendance: Opportunity in financial objectives of the company (quality, delivery/service and productivity).How the strategy is aligned: Achieved by the successful implementation of a strategy that aims to attain an acceptable Cpk in the SAF line.

SIPOC Model. The SIPOC model depicted in Figure 4.3 was utilized to illustrate the interrelationship among the components, namely suppliers (S), inputs (I), process (P), outputs (O), and customers (C)[16].

Measurement

The following instruments were utilized during the measurement stage. Time Series Graph. The production data for the K840 model was recorded for the months in which the model was operational. The monthly data, in addition to the production totals, production losses, and costs incurred in the model where the shortage problem was present, were examined. The production of the K840 model totaled 21,809 units, falling short of the projected output of 29,900 units by 24,730 units. This discrepancy, referred to as production losses, resulted in financial implications amounting to $54,900.

Measurement System Validation. The validation of the measurement system involves the demonstration of the quality indicator, which serves as a reference for the scale measurements and plane measurements at each station. This process enables the quantitative determination of the product's quality, thereby indicating the non-rejection tolerance in the K840 model. As illustrated in Figure 4.11, the validation of the measurement system is instrumental in determining the non-rejection tolerance.

The process FMEA depicted illustrates the measurement of the failures that give rise to the length problem of the SAF line. The potential failure modes identified in the preceding analyses, along with their potential consequences, including severity, occurrence, and detection, are demonstrated. The respective RPN values are also provided. It is noteworthy that the failures with the highest RPN values (315 and 210) were attributed to parts with incorrect measurements, misalignment, improper methods, and design tolerances that were out of range.

Analysis

The following tools were selected and developed in the production runs to identify the quality problem of short catheters in the stations and the different models.

The following list enumerates the production models. Information was extracted from the database, and the production process of the 48 models that presented the problem of short catheters was reviewed. The results are shown in the following tool.

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Number	Medidas (in)	Medidas corte	Medidas Lugin	Medida Molde	Rev		Description	Part Class	Lifecycle Phase
L-07080-001C	31 3/4 +3/8	32 + 1/8	31 3/4 + 3/8	31 1/2 -5/8 -5/8	17	ECO-055779	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07511-001B	5	4 7/8 ± 1/8	4 5/8 ± 3/8	4 3/8 - 1/2 + 3/8	17	ECO-055196	SHEATH EXT ASSY W/DILATOR: 5 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07045-001D	18 3/8	18 1/4 ± 1/8	18 ± 3/8	17 3/4 -5/8 + 3/8	20	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07865-001D	25 7/8 + 3/8	26 1/8 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 + 3/8	19	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07880-001D	31 3/4 +3/8	32 ± 1/8	31 3/4 ± 3/8	31 1/2 - 5/8 +3/8	19	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07900-001B	39 5/8 +3/8	38 7/8 ± 1/8	39 5/8 ± 3/8	39 3/8 -5/8 +3/8	17	ECO-068318	SHEATH EXT ASSY W/DILATOR: 9 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07511-001B	4 5/8 +3/8	4 7/8 ± 1/8	4 5/8 ± 3/8	4 3/8 - 1/2 +3/8	18	ECO-055196	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07024-001B	9 5/8 +3/8	9 7/8 ± 1/8	9 5/8 ± 3/8	9 3/8 -1/2 +3/8	18	ECO-055758	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07035-001C	14 +3/8	14 1/4 ± 1/8	14 ± 3/8	13 3/4 -1/2 +3/8	18	ECO-055778	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07065-001C	25 +7/8+3/8	26 1/8 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 +3/8	18	ECO-055196	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07811-001B	4 5/8 +3/8	4 7/8 ± 1/8	4 5/8 ± 3/8	4 3/8 -1/2 +3/8	21	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07824-001C	9 5/8 +3/8	9 7/8 ± 1/8	9 5/8 ± 3/8	9 3/8 -1/2 +3/8	20	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07835-004	14 3/8	14 1/4 ± 1/8	14 ± 3/8	13 3/4 -1/2 +3/8	18	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
K-07007-003	3 1/4 +3/8	3 1/2 ± 1/8	3 1/4 ± 3/8	3 -1/2 +3/8	14	ECO-067397	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Obsolete
L-07524-001B	9 5/8 +3/8	10 1/8 ± 1/8	9 5/8 ± 3/8	9 3/8 -1/2 +3/8	19	ECO-055758	SHEATH EXT ASSY W/DILATOR: 5 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07545-001D	18 3/8	18 3/4 ± 1/8	18 ± 3/8	17 3/4 -5/8 +3/8	13	ECO-055197	SHEATH EXT ASSY W/DILATOR: 5 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07565-001B	25 7/8 +3/8	26 3/4 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 +3/8	14	ECO-055778	SHEATH EXT ASSY W/DILATOR: 5 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07590-001B	35 3/4+3/8	36 7/8 ± 1/8	35 3/4 ± 3/8	32 1/2 -5/8 +3/8	13	ECO-055779	SHEATH EXT ASSY W/DILATOR: 5 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07611-001C	4 5/8 +3/8	4 7/8 ± 1/8	4 5/8 ± 3/8	4 3/8 -1/2 +3/8	18	ECO-055196	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07624-001C	9 5/8 +3/8	9 15/16 ± 1/8	9 5/8 ± 3/8	9 3/8 -1/2 +3/8	21	ECO-055758	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07635-001C	14 3/8	14 15/16 ± 1/8	14 ± 3/8	13 3/4 -1/2 +3/8	20	ECO-055196	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07645-001C	18 3/8	18 1/4 ± 1/8	18 ± 3/8	17 3/4 -5/8 +3/8	20	ECO-055195	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07665-001C	25 7/8 +3/8	26 1/8 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 +3/8	21	ECO-055196	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07690-001C	35 3/4 +3/8	36 7/8 ± 1/8	35 3/4 ± 3/8	35 1/2 -5/8 +3/8	20	ECO-055197	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07700-001C	39 5/8 +3/8	39 7/8 ± 1/8	39 5/8 ± 3/8	39 3/8 ± 3/8	18	ECO-055779	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07711-001C	4 5/8 +3/8	4 7/8 ± 1/8	4 5/8 ± 3/8	4 3/8 -1/2 +3/8	18	ECO-055192	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07724-001C	9 5/8 +3/8	9 7/8 ± 1/8	9 5/8 ± 3/8	9 3/8 -1/2 +3/8	18	ECO-055758	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07735-001C	14 3/8	14 1/4 ± 1/8	14 ± 3/8	13 3/4 -1/2 +3/8	17	ECO-055197	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07745-001C	18 3/8	18 1/4 ± 1/8	18 ± 3/8	17 3/4 -5/8 +3/8	17	ECO-055196	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07765-001	25 7/8 +3/8	26 1/8 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 +3/8	17	ECO-055778	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07780-001C	31 3/4 +3/8	32 ± 1/8	31 3/4 ± 3/8	31 1/2 -5/8 +3/8	18	ECO-055197	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07800-001D	39 5/8 +3/8	39 5/8 ± 1/8	39 5/8 ± 3/8	39 3/8 ± 3/8	19	ECO-068330	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07911-001B	4 5/8 +3/8	4 7/8 ± 1/8	4 5/8 ± 3/8	4 3/8 -1/2 +3/8	19	ECO-068318	SHEATH EXT ASSY W/DILATOR: 9 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07924-001B	9 5/8 +3/8	9 7/8 ± 1/8	9 5/8 ± 3/8	9 3/8 -1/2 +3/8	18	ECO-068318	SHEATH EXT ASSY W/DILATOR: 9 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07965-001C	25 7/8 +3/8	26 1/8 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 +3/8	17	ECO-068318	SHEATH EXT ASSY W/DILATOR: 9 FR	SHEATH EXTENSION ASSEMBLY	Production
L-07980-001B	31 3/4 +3/8	32 ± 1/8	31 3/4 ± 3/8	31 1/2 -5/8 +3/8	17	ECO-068318	SHEATH EXT ASSY W/DILATOR: 9 FR	SHEATH EXTENSION ASSEMBLY	Production
L-71165-001	25 7/8 +3/8	26 1/8 ± 1/8	25 7/8 ± 3/8	25 5/8 -5/8 +3/8	17	ECO-055197	SHEATH EXT ASSY W/DILATOR: 11 FR	SHEATH EXTENSION ASSEMBLY	Production
L-71180-001	31 3/4+3/8	32 ± 1/8	31 3/4 ± 3/8	31 1/2 -5/8 +3/8	16	ECO-055196	SHEATH EXT ASSY W/DILATOR: 11 FR	SHEATH EXTENSION ASSEMBLY	Production
P-07511-001	4 5/8 +3/8	3 15/16 ± 1/8	3 3/16 ± 3/8	2 15/16 -1/2 + 3/8	17	ECO-055779	SHEATH EXT ASSY W/DILATOR: 5 FR	SHEATH EXTENSION ASSEMBLY	Production
P-07611-001	4 5/8 +3/8	3 1/2 ± 1/8	3 3/16 ± 3/8	2 15/16 -1/2 +3/8	18	ECO-055579	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
R-07645-001	18 3/8	18 3/4 ± 1/4	18 ± 1/16	17 3/4	08	ECO-040124	SHEATH EXT ASSY W/DILATOR: 6 FR	SHEATH EXTENSION ASSEMBLY	Production
R-07745-001A	18 1/16	18 3/4 ± 1/4	18	17 3/4	09	ECO-040124	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
R-07745-007	18 3/4 +1/4	18 1/4 ± 1/8	18 ± 3/8	17 3/4 -5/8 +3/8	14	ECO-055779	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
R-07780-001	35 3/4 +3/8	36 1/2 -1/2 +1	35 3/4 ± 3/8	32 1/2 ± 1/2	10	ECO-050265	SHEATH EXT ASSY W/DILATOR: 7 FR	SHEATH EXTENSION ASSEMBLY	Production
T-07860-001	24 3/8	25 ± 1/4	24 3/8	24 1/8 ± 1/8	15	ECO-058214	SHEATH EXT ASSY W/DILATOR: 8 FR	SHEATH EXTENSION ASSEMBLY	Production
K 730	G 3/16 +1 1/8	G 3/16 +1 1/8	G 1/4 ±1/8	Gt 1/8	07	ECO-051417	SHEATH EXT: 8 FR X 6"	SHEATH EXTENSION	Production
K-00040-001	G 3/16 +1/8	G 3/16 ± 1/8	G 1/4 ± 1/8	G ± 1/8	06	ECO-073160	SHEATH EXT: 9 FR X 6"	SHEATH EXTENSION	Production
L-07045-001E	18 3/8	18 1/4 ± 1/8	18 ± 3/8	17 3/4 -5/8 +3/8	09	ECO-055779	SHEATH EXT ASSY W/DILATOR: 10 FR	SHEATH EXTENSION ASSEMBLY	Production

Fig. 3. List of the 48 models run that present the problem of short catheters. Own elaboration.

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Utilizing the FMEA as a point of reference, the two items with the highest RPN values of 315 were identified, corresponding to the initial two failures: components exhibiting inaccurate measurement and misalignment. Consequently, this identified an opportunity for improvement in the out-of-dimension catheter problem of the K840 model. Therefore, the Hypothesis Testing Plan was carried out[17].

Hypothesis Testing Plan Following the identification of the areas of opportunity with the FEA that had the highest RPN values and the subsequent allocation of preferential attention to the failures that presented these high values, the following research questions were generated: First, it was determined whether the SAF line process of the K840 model was within the lower specification limit. Second, it was investigated whether temperature and baking time affected the length of the parts of the K840 model in the SAF area. From these inquiries, the following hypotheses were formulated to address the short catheter problem. The objective of hypothesis testing is to determine whether the model K840 falls outside the lower specification limit[18].

Improvement

In the improvement stage, tools were implemented to verify that short catheters are no longer appearing in the quality measurables of the production line. The implementation of three inspections in the process, the modification of the supplier's technical sheet, and the changes in the drawing limits by the design personnel resulted in a reduction of the RPN values in the AMEF. Action Plan. The action plan used to initiate the opportunities identified as an improvement plan is presented below.

A verification run was conducted using the initial cut-off limit settings and data collection during the entire production process of the K840 model. It was proposed to adjust the lower and upper limits to 6.187 +/- 1/8, thereby ensuring that the subsequent data obtained would remain within these parameters. This adjustment was made by modifying the cut-off length of the catheter in the plane. A validation run was subsequently conducted to verify that the issue of short catheters no longer manifested during the molding process. It is observed that most of the data are within the lower and upper limits, therefore, in the cutting process it is increased 1/8 to the dimension at the upper limit of 6 3/16 +/- 1/8 (based on the historical statistical study) and after performing the K840 model run of 1000 pieces, which due to length problems were detected 10 with a FTT=98.90 %[19].

III. EXPERIMENT AND RESULT

The results obtained from the study are presented in two sections. The initial section delineates the proposed guide, which is an integral component of the methodology devised to minimize scrap in the SAF line. The subsequent section offers a synopsis of the findings. The proposed methodology for reducing scraps due to shorts on the SAF line is outlined, and guidance is provided for its implementation. Following the design and implementation of the proposed methodology for the study, which is based on the establishment of a system of periodic measurements and a plan of timely actions, favorable results were obtained for the company, the client, and the operator of the SAF line.

The subsequent section presents a synopsis of the findings derived from the implementation of the proposed methodology. The primary outcome of this approach was the elimination of elevated costs, amounting to $54,900 per rejection, attributable to length-related issues in the K840 model.

Furthermore, the elimination of overtime for personnel dedicated to this model was achieved.

Furthermore, the elimination of downtime in the final processes due to material shortages was achieved.

The company's financial objectives, namely Quality, Delivery/Service, and Productivity, were successfully achieved.

Notably, an acceptable Cpk of 0.45 (positive) was achieved in the SAF process.

The K840 model demonstrated an efficiency of 96.74%.

Furthermore, a substantial reduction in the RPN values of the FMEA was achieved through enhanced detectability, severity, and occurrence.

The results obtained reflect significant improvements in various operational and financial aspects of the K840 model. The key points are discussed below:

Cost Reduction 2.

The elimination of the high costs generated by rejects due to length problems, which amounted to $54,900, represents a substantial advance in terms of economic efficiency. This not only improves the profitability of the K840 model, but also reflects greater stability in manufacturing processes by minimizing critical defects.

Labor Time Optimization

The elimination of overtime in the personnel assigned to the K840 model suggests an optimization in the planning and execution of activities. This could be related to a better alignment of resources or improvements in process efficiency.

Downtime Reduction

The elimination of downtime, especially in end processes due to material shortages, is indicative of improved inventory and workflow management. This change contributes directly to increased productivity and greater delivery reliability.

Stage	Tools	Results
Define	Definition of the quality problem identified in the SAF line of medical catheters, Time Series Graphs, Scatter Plots, SIPOC Analysis and SMART Objective Statement.	High rate of SCRAP on SAF line, where medical catheters are produced.
Measure	In the Pareto painter chart, data was collected and quality problems were identified.	Data were obtained on a high SCRAP rate of 18% in short medical catheters in the SAF line with a total loss cost of $54,616.25 dollars, in 2 and a half years.
Analyze	Ishikawa Diagram, 5W2H Analysis, Cause-Effect Matrix, Pareto Chart of Root Causes, Failure Mode and Effect Analysis, Initial Process Capability Analysis (CTQ), Hypothesis Testing Plan, Dimensional Change Through the Process, and Original Drawing Analysis.	It was found that the largest contributor to SCRAP was the short catheters (18%) of the K840 model, in the critical inspection and cutting stations, with a dimension less than 1/8 inch in length from the lower limit of the drawing specification.
Improve	Daily monitoring of waste rates, daily data capture in OEE logs, statistical analysis, and monthly adherence impact assessment. OEE logs are added to critical inspection and cutting stations.	Reduced SCRAP of the short catheter to 0%. Plane update increased by 1/8 toward the upper limit of the catheter length and FMEA update.
Check	Control Charts and Internal Audits. Sustainability: Monthly review of the established process and KPIs.	SCRAP stable at 0% on the short catheter problem and 98% productivity

IV.CONCLUSION

Utilizing the designated LEAN instruments and adhering to the DMAIC framework, it was determined that during the procedure of reducing the catheter's length, its dimensions fell below the lower specification limit stipulated by the client as a benchmark for acceptability. Consequently, a decision was made to modify the design, extending the length slightly beyond the lower specification. This modification ensured that, upon completion of the process and the subsequent cutting step, the catheter would remain within the acceptable limits. This approach effectively addressed the initial problem.
The results obtained demonstrated significant progress in the efficiency, quality, and productivity of the K840 model, as well as a positive impact on overall profitability. However, the avenues for additional enhancement were identified, particularly regarding augmenting the Cpk to align with elevated quality control standards. This strategic approach is expected to ensure the sustainability and competitiveness of the model in the market.

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