Spinal Cord Stimulator Glassed Feedthrough Improvement Using DMADV Methodology

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Abstract

Chronic pain is an illness that affects more than 1.5 billion humans worldwide and can affect daily activities leading up to disability and despair. The goal of treating chronic pain is to reduce pain and improve function so that a person can resume day-to-day activities. The neurological device supplied by a private medical device company is a spinal cord stimulator therapy which masks pain signals before they reach the brain and produces relief to the patient. This investigation will analyze the manufacturing operation optimization using a Six Sigma framework to investigate ways to generate more revenue from a commercially released medical device.

Introduction

The primary focus of this investigation is to improve a currently marketed medical device from the spinal cord stimulation category supplied by a private company. This improvement consists of substitution of titanium raw material to glass in the feedthrough assembly used to manufacture the neurological device. The DMADV methodology will be used through this investigation to identify processes that are impacted by this change, determine design improvements, and mitigate any risks associated.

Background

Medical device companies worldwide work effortlessly every day to provide patients the best available technologies to treat thousands of conditions. In order for these companies to continue to invest in innovations and ways to improve their product, revenue from their market products needs to be obtained. A top ranked medical device company is currently focused on providing customers with the best quality products and continuing their research to promote reliability and consumer trust in their products. One of these products is the spinal cord stimulator product. This device is currently one of the best-selling devices for chronic pain relief marketed worldwide. Recently, this private medical device company as any other company feels the need to make a fair profit on current operations to meet obligations, sustain growth, and reach goals. Through this research and with the use of known manufacturing methodologies, an improvement in the neurological device will provide a substantial financial saving in raw material as well as manufacturing labor for increased revenue of the company.

Problem

This study will allow a pathway for higher profits from the neurological device as well as a higher efficiency during the manufacturing operation in the private medical device facility. A general improvement in the product's performance, reliability and quality will achieving company interests and allowing sustainability and growth for the company. This product improvement will not only allow the company to increase profits but will also allow the private medical device company to reconsider the device's cost making it more affordable to the 1.5 billion consumers who suffer from chronic pain and allowing additional capital for new technologies on future products

Methodology

This project will apply the DMADV methodology which is a Six Sigma framework for implementing new strategies in a current process. The DMADV approach also known as DFSS varies, of course, according to whether the design is of a product or of a process. This approach is especially useful when implementing new strategies and initiatives because of its basis in data, early identification of success and thorough analysis. The DMADV model is usually a five-step process:

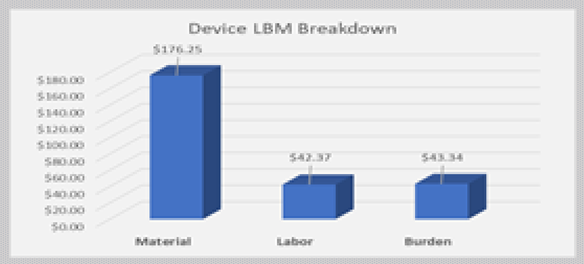
For any DMADV project, there may be more emphasis on certain components of the approach over others, though the goal remains the same: to address an identified issue and produce desired results in a way that can be maintained through normal operations. The investigation will propose a new technology in the existing market of the spinal cord stimulation device. The DMADV will help understand the critical factors that need to be assessed in order for the improvement to be successful.

Results and Discussion

DEFINE

The goal of this re-design is to decrease costs of raw material and remove components considered waste that add burden to the cost of production of this device. Keeping this in mind and top priority, a target of a two (2) million increase in revenue was established for the project to be successful.

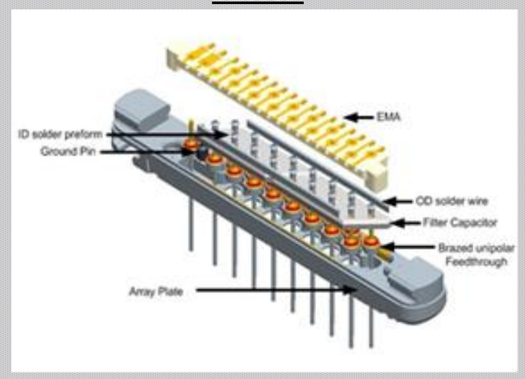
MEASURE



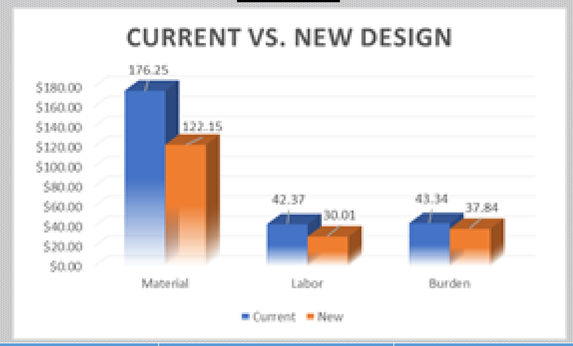
Results and Discussion (cont.)

ANALYZE

DESIGN



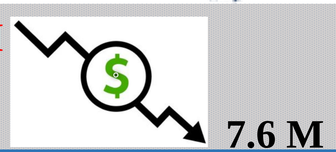
VERIFY



Process	Impact Description	Validation Activity
Trim and Form Feedthroughs	Evaluation of damage on new glass material	•Process Characterization
Apply Dadet and Cure	Inpsection on feedthroughs	•Test Method Validation
Stack Assembly	Internal Component Volume	•Process Characterization
RSW Front Weld	Evaluation of damage on new glass material	•Process Characterization
LW Cover Plate	Evaluation of damage on new glass material	•Process Characterization
Rework for Laser Weld Cover Plate	Evaluation of damage on new glass material	•Process Characterization
Injection Molding	Completely filled with LSR	•Process Characterization

Conclusions

After completing the improvement of the Connector Module Assembly for the spinal cord stimulator while applying the DMADV Six Sigma Methodology, it was determined that an improvement was feasible for the existing device where revenue could be gained. With the help of the engineering and design team, the implementation of this project will be completed once receiving confirmation from the FDA to commercially produce the device. The objective of this investigation was achieved by reaching and exceeding the target goal of a $2M revenue increase.



Future Work

This approach will serve as a guideline for future projects from the same product family within the medical device manufacturing facility. The scope of this work should also not be limited to only projects from this product family, but can also be implemented throughout the entire facility. This methodology can also be applied to other departments such as accounting, shipping, and administrative areas of the company. This project is another demonstration of how Lean Six Sigma methodologies can be applied for existing products in the manufacturing industry.

Acknowledgements

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