TiMesh Product Transfer to MPROC Humacao

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***Abstract* —** *The objective of this project is to ensure that the machining, electropolishing, product testing and packaging processes; manufacturing control methods; and product specifications are properly installed, qualified and validated for the TiMesh product at Medtronic Spinal Humacao. The TiMesh product is being transferred from Medtronic Goleta in California, where is has been manufactured for the last 15 years. The transfer of the TiMesh product will be implemented in a Cell Operating System with a Product ID Equipment to ensure the best control of the product during the final inspection and packaging steps of the product. The products will be 100% inspected during routine manufacturing activities. The TiMesh will be distributed worldwide due to its small size and use in operating rooms.*

The DMAIC methodology was used for this research project for the product transfer of TiMesh surgical screws at Medtronic Spinal Humacao from the sister company Medtronic Goleta in California. DMAIC is a methodology used for process improvements using Six Sigma. DMAIC is an acronym that stands for the five phases of this process: Define, Measure, Analyze, Improve and Control.

Key terms *— DMAIC, inspection, product ID, TiMesh product*

INTRODUCTION

Medtronic plc is a medical device company that generates most of its sales and profits from the US healthcare system. However, for tax purposes, it is based in the Republic of Ireland. The Humacao operations deal with spinal products, especially for degenerative disc disease, spondylolisthesis, trauma (i.e., fracture or dislocation) spinal stenosis, curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumors, pseudarthrosis and/or failed previous fusions.

There is a small internal Brain Division operation in Humacao that produces surgical instruments intended for use in neurosurgery, including craniotomy and spinal surgery, as well as ear, nose and throat (ENT), orthopedic and general surgical applications, including maxillofacial, craniofacial and sternotomy surgeries.

The TiMesh System is intended for use in any reconstructive oral-maxillo-cranio-facial surgical procedure, either orthognathic or trauma, wherein rigid or semirigid internal fixation is utilized as a means of holding bone fragments together. Alternatively, the TiMesh System is also indicated for use in reinforcing weak bony tissues in orthopedic surgical procedures such as pelvic reconstruction, acetabular reconstruction, and cement restriction. This product is not intended for spinal use. The TiMesh screws are designed and labeled for single use only. All devices are supplied non-sterile in sealed packaging.

This research project focuses in the implementation of the TiMesh on the cell system with the Product ID equipment to eliminate any product mix during execution and to have a better quality-controlled product for the customer. Every lot will be 100% inspected during routine manufacturing activities in the cell.

PROBLEM STATEMENT

Currently, the TiMesh product has a different/difficult process that gives the screw a higher price to the consumer. (See different representations of the screw in figure 1.) The product is manufactured in the Medtronic facility in California, is sent to undergo electropolishing, is sent to a Medtronic vendor that will pack the product

in a legacy process, and then is finally sent to Medtronic in California to be distributed. The legacy process is based on individual procedure, large processing time, poor handling, loss of quantity in the lot, different operators and multiple transactions that could impact the final product. Because of the smaller sizes and the legacy process, the TiMesh product has a large incident incidence of mixed product in the operating room. The goal of this project is to reduce product mix by using new inspection equipment and integrating the CELL OPERATING SYSTEM, in order to have constant product workflow and better inspection of products of every size, to implement the new product in Humacao with all the inspections necessary to have a better-quality product out the door. Because the screw is self-drilled, a new inspection in the incoming area will be evaluated during the implementation.

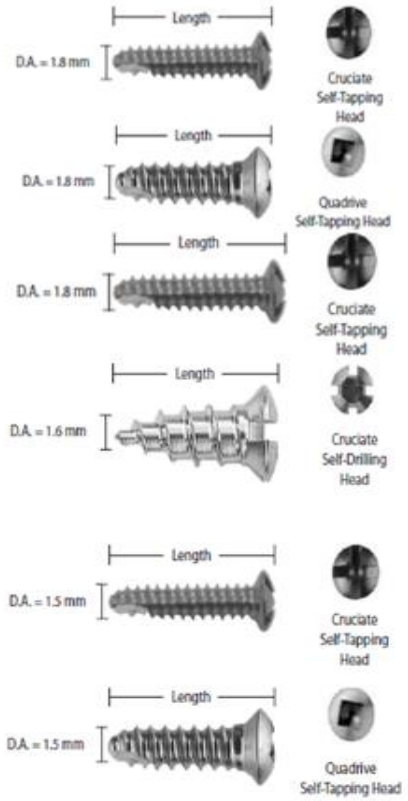

Figure 1
Different representations of the screw

RESEARCH DESCRIPTION

This Research is focused on the transfers and implementation of the TiMesh product on a Cell Operation System with the installation of the Product ID equipment system to inspect the screw by size in Medtronic Humacao. The Product is being transferred from the sister Medtronic company in California to our facility in Humacao. The TiMesh product used is manufactured in California and packaged at a vendor company (that uses a legacy process) that will themn return the product to the Medtronic facility. The transfer to Medtronic Humacao ensures that TiMesh will have a continued flow on a cell operation system and inspection equipment that will eliminate product mix in the final packaging step. TiMesh is a difficult product to handle because of the size of the different screws; the smallest sized screw is 3.5 mm and the largest size is 4.0 mm. As an example, figure 2 shows a screw next to a small item. The cell system will reduce packaging time, multiplier operator handling, poor inspection of the final product and supervisor of the product in every step. Also, manufacturing and packaging the TiMesh product at the same building will help in reducing product cost and increase gains for the company.

Figure 2
TiMesh product next to a penny

RESEARCH OBJECTIVES

The TiMesh transfer product aims to achieve the implementation and better the inspection of the product during the packaging steps. The TiMesh product will be the smallest product produced at Medtronic Humacao, to implement the product with all the tools necessary for the operator to continue doing quality work in the final packaging area. In addition, the implementation in Medtronic Humacao will reduce manufacturing and packaging costs, provide better quality control of the product and control its processing time. Also, the TiMesh product will be the company's most important project this year because it will open the company's Brain division to new products. The company is moving into the future of health care for all patients and this new product is the beginning.

RESEARCH CONTRIBUTIONS

The research project aims to implement a cell system to have a better control of the packaging process, eliminate product mix, decrease cost of product, decrease self-drill testing and poor handling of product, and have better quality control. Also, the TiMesh product is the beginning of the Brain product that will be implemented in Medtronic Humacao to expand the company into the future.

LITERATURE REVIEW

For this research project of the implementation of TiMesh, two of its most important components will be the Cell Operating System (figure 3) and the product ID [1]-[2]. The Cell Operating System is designed to have a continued workflow of a product, integrate everybody and everyday improvement where the operator can express any idea, they have to upgrade the process and help the cell system. The Cell Operating System has been shown to improve quality, productivity, lead-time, work-in-process, space, and employee engagement.

Figure 3
Cell Operating System

The Product ID Vision Inspection System (figures 4 and 5) is used to inspect screws and components using a four-camera vision technology arrangement. The Product ID is used to make attribute decisions (Pass/Fail) on the screw unit features such as Overall Diameter based on an image setting (using pixel resolution) created as part of programming activities. This image is used to perform a comparison with the screws to be inspected as part of the manufacturing process. The use of this system will minimize product mix-up and increase product segregation during regular manufacture. The Product ID uses four cameras with a resolution of 123 mm/2592 pixels (0.047mm/pixel) to make attribute decisions (Pass/Fail) on the TiMesh screw. Each TiMesh part number will be configured using a tolerance of ± 3 pixel of nominal value calculated by the system to detect product mix-up during manufacturing process.

Figure 4
Product ID

What are a pixels? A pixel is defined as a unit of measurement derived from combined functions of the cameras, lenses and distance from the object to be measured. Programming of the part is based on a combination of product specifications and physical part image grabbed by the system. By using a threshold and background color, the Product ID sees the difference among sizes and detects a product mix-up because it performs a comparison with the screws to be inspected as part of manufacturing process.

The DMAIC Methodology

DMAIC is a methodology used for process improvements and process optimization using Six Sigma [3]. Most companies use it to improve their processes, have a more streamlined process and eliminate any waste and defects. DMAIC uses a real-time data strategy for process improvements. DMAIC is an acronym that stands for the five phases of this process: Define, Measure, Analyze, Improve and Control (figure 5).

Figure 5
The DMAIC methodology

On the Define phase of DMAIC, the project charter is defined, and it includes the customer, team members, expectations and the plan moving forward [4]. The Measure phase is where data is collected to be analyzed for the project focus. The Analyze phase uses the data to determine any possible root cause to be eliminated from the process. The final two phases are Improve and Control, which will optimize the process and identify any opportunities.

METHODOLOGY

In the Define phase of the research project, a project charter (table 1) will be created to define the project's scope, objectives, team members, responsibilities, stakeholder and timeline. In the Measure phase, where lot process through the cell system will be evaluated to collect product mix or scraps. The Analyze phase will use the data collected to analyze whether the improvement of the cell and PID is working [1]. The Improvement and Control phases will determine whether the project was successfully implemented.

Table 1
Project charter

PROJECT TITLE
TiMesh Product Transfer to MPROC Humacao
BUSINESS CASE
The research project aims to implement the TiMesh product in a cell Operation System to have a continued flow to obtain a more quality-controlled product. Installing new inspection to the product during the packaging step.
GOAL STATEMENT
The goal is to reduce product mix and cost of the product during the manufacturing and packaging steps.
SCOPE
In scope: Cell Operation System, Product ID inspection: all other processes.
PROBLEM / OPPORTUNITY STATEMENT
Currently the TiMesh product have a different/difficult process that give the screw a higher price to the consumer. The product is manufacture in the Medtronic facility at California to them being sent to receive the electropolishing, for later be send to a Medtronic vendor that will pack the product on a legacy process and finally send to Medtronic at California to be distributed. The legacy process is based on individual procedure, large processing time, different operators and multiple transactions that could impact the final product. Because of the smaller sizes and the legacy process, the TiMesh product have a large incident report of mixt product in the operations room. The goal of this project is to reduce the product mix during using new equipment of inspection and the integrating the CELL OPERATING SYSTEM to have a constant workflow of the product.

Table 1

Project charter (continued from previous page)

TEAM MEMBERS			
Key Stakeholders	**Members' Names**		
Project Manager	Carlos Cotto		
Manufacturing Manager	Ranfel Vázquez Torres		
Quality Engineer	Natasha Ortiz Lugo		
Manufacturing Engineer	Anthony Rivera Aprico		
SME	Carlos González		
Project Sponsor	Alberto Rivera		
Additional Resources	**Members' Names**		
Environmental, Health & Safety Representative	Mildred Pizarro		
PROJECT RISKS			
Risk	**Low**	**Medium**	**High**
Location restrictions		X	
Equipment availability		X	
PROJECT TIMELINE			
Key Milestone	**Target Date**		
Start Date	FEB-19		
Purchase of Equipment	JUNE-19		
Installation of Equipment	OCT-19		
Modification of Procedures	JAN-2020		
Training	APRIL-2020		
Completion Date	June 2020		
PRELIMINARY BUDGET			
$87K			

In the Measure phase of the project, the data collected comes from the first six lots processed in the cell system. During the execution in the cell system, there are no scraps or product mix detected, because for TiMesh parts with a length of 4.0 mm, the Product ID was capable of detecting that the screws have a nominal parameter of 96.0 pixels, while those with a length of 3.5 mm will have a nominal parameter of 87 pixels. Both lengths were evaluated under a camera resolution of 123 mm/2592 pixels (0.047 mm/pixel). Because of the 0.5 mm length difference—which is equal to 9.5 pixels between part number and ± 3 pixels of tolerance—, the TiMesh screw will not overlap to cover the same area in the inspection process. Figure 7 shows that 87 pixels is equal to a length of 3.5 mm, while figure 8 shows that 97 pixels is equal to a length 4.0 mm in pixels.

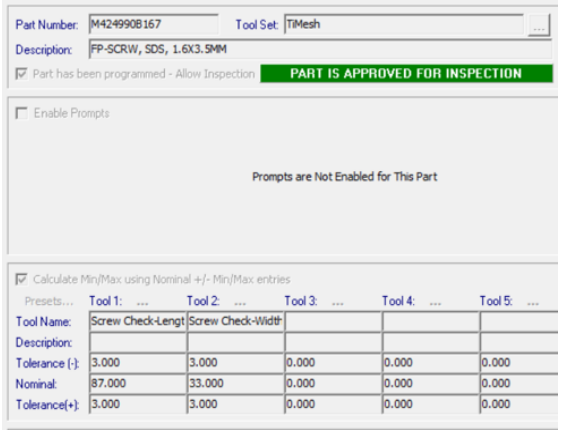

Figure 6

Length of 3.5 mm in pixels

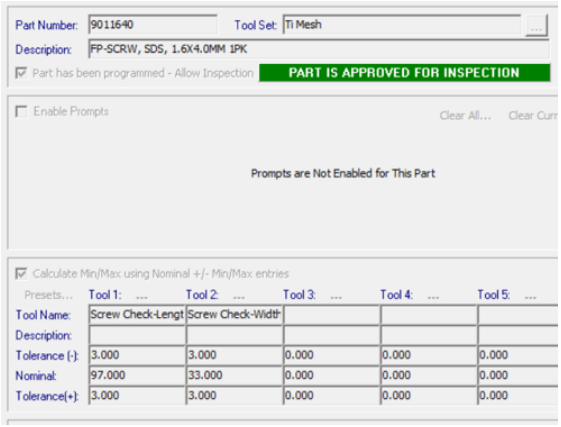

Figure 7

Length of 4.0 mm in pixels

In this phase, a Gantt Chart was created to define all the deliverables of the Cell Operating System's implementation of tasks and deadlines (table 2, figure 8).

Table 2

Gantt chart

Task	Start Date	Days to completed
Transfer Initiation Phase Completion	1-Feb-19	30
Goleta's PVA Approval	5-Feb-19	5
Quality Agreement Approval	23-Nov-19	45
Purchase of Equipment	10-Jun-19	10
Cleaning Qualification	8-Jun-20	13
Installation of Equipment	19-Oct-19	14
Modification of Procedures	25-Jan-20	15
Training	1-Apr-20	5
Packaging/Label FAIs completed	15-Jun-20	7
Manufacturing Procedures COs Completed	1-May-20	2
Transfer Report Closed	30-Jun-20	0

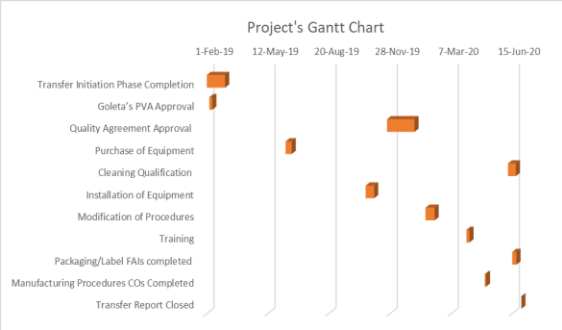

Figure 8
Project's Grantt chart

Note: all the activities in the Gantt chart will be for the implementation of TiMesh product in the Cell System. The implementation includes other machining activities that were not consedered in this research project.

RESULTS AND DISCUSSION

From the data and information present in the DMAIC it shows a significant improvement from the Legacy Process in the sister company [1]-[3]. The product apart from the 6 units used for the self-drilling testing in every lot, there are not scraps, mis handling of lot, correct quantity in lots and no product Mix during the packaging steps in the cell. Based on the results obtained as part of the first 6 lots process in the cell, it was demonstrated that the inspection process using the Product ID is capable to detect possible product mix-up during manufacturing process and to make attribute decisions (Pass / Fail) on the TiMesh screw sizes.

In the improve phase of the research project for TiMesh, a packaging problem was uncovered. The TiMesh screw will be pre-package in an Inner and Outer tube from rose plastic (refer to Figure 8 and 9) because the product has a single and Multi-part numbers. The single part number will have only one screw meanwhile the multi pack will have 6 screw in the final packaging. After the pre-packing is made the operator did not have any space to place the tube with the Screw. To improve the pre-Pack step, a new 3D holding fixture was created. The fixture is designed to help the operator to have a count of how many tubes they work and to have them in one place. Another improvement to the line will be to divide the lot in children of 96 screws to have a better movement in the cell system.

Figure 9
Single pack

Figure 9
Multi-pack

The final step in DMAIC is the Control Phase, a continues monitor of the process and take measurement to ensure all the solution are working. every implementation has to have a 3-month supervisor before passing the project to the manufacturing area, on those 3 month I will be monitoring every step. Give training to news operator and engineer in another shift, to understand

the process of the TiMesh in the cell system. The used of the new fixtures will be monitored to evaluate and modified if any operator have comments. The most important training for the engineer in the manufacturing floor will be in the Product ID. Different from other product in the final pack area where the screw or assembly have the length to modify the Tolerance in the inspection, TiMesh don't have that advantage. In the training of the product ID for TiMesh the tolerance can not be change, the slice change in tolerance can overlap product or send it to scrap because it didn't pass the inspection. Because of the length difference of 0.5 mm that is equal to 9.5 pixel between part number and ± 3 pixels of tolerance, the TiMesh Screw cannot be change. The used of the new fixture to hold and count is important, because the tube are moving from one table to another, having the fixture will help any poor handling or tube in the floor. The rest of the step is continuing, and any control or training will be necessary.

CONCLUSION

Since the implementation of the TiMesh product in Medtronic Humacao a more quality control product is being ship out to the Distribution center. The implementation of the cell operation system and the continues flow of the product have reduce significantly the mist handling, incorrect quantity lot and the installation of the Product ID have control and help identified product mix in the lots. The product ID equipment has demonstrated to be capable for its intended used and fulfill the desire output and because of the length difference of 0.5 mm that is equal to 9.5 pixel between part number and ± 3 pixels of tolerance, the TiMesh Screw will not overlap to cover the same area in the Inspection Process. The process of inspection and packaging will continue being updated to get the implementation to the best quality control process possible. In addition, by manufacturing and packaging the product on the same building the business have reduce the cost and have a gain in the finances. Every aspect of the objective of the project is met and every TiMesh process in the cell will have a 100% inspection to be a quality control product for the company.

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