



Research of Anterior Cervical System using different materials



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Abstract

With the continuous worldwide demand for anterior cervical systems, Medtronic Spinal Division decided to make changes in the manufacturing process in order to meet this demand. Therefore, various prototypes were developed to accomplish the US Food and Drug Administration (FDA) requirements and the market. All the prototypes were evaluated in order to give the company more alternatives to match the specific customer needs with the best technology and engineering management techniques in the industry. In this paper, the PEEK and TTN implants were compared. PEEK resulted to be the best choice.

Introduction

The purpose of this study is to understand the process of manufacturing a new product using poly-ether-ether-ketone (PEEK) material versus Titanium (TTN), the requirements needed for the manufacturing a new product, and management techniques used in one Medtronic Company Plant.

The objectives are to evaluate the engineering management tools implemented, analyze the project cost, determine the risk during the development and the manufacturing process, identify opportunities for improvement, and analyze the Timeline.

DMAIC method is used for the evaluation of actual and planned manufacturing process, risk assessment, project cost, and Timeline. This document is intended to investigate the implemented procedures, analyze the findings or results, and propose recommendations to improve the new product manufacturing process.



Define

Anterior Cervical System can be manufactured using two (2) different materials. Both materials have different physical and chemical properties. Based on that, in this paper the properties and processes to manufacturing both materials are analyzed to identify the best choice.

Measure

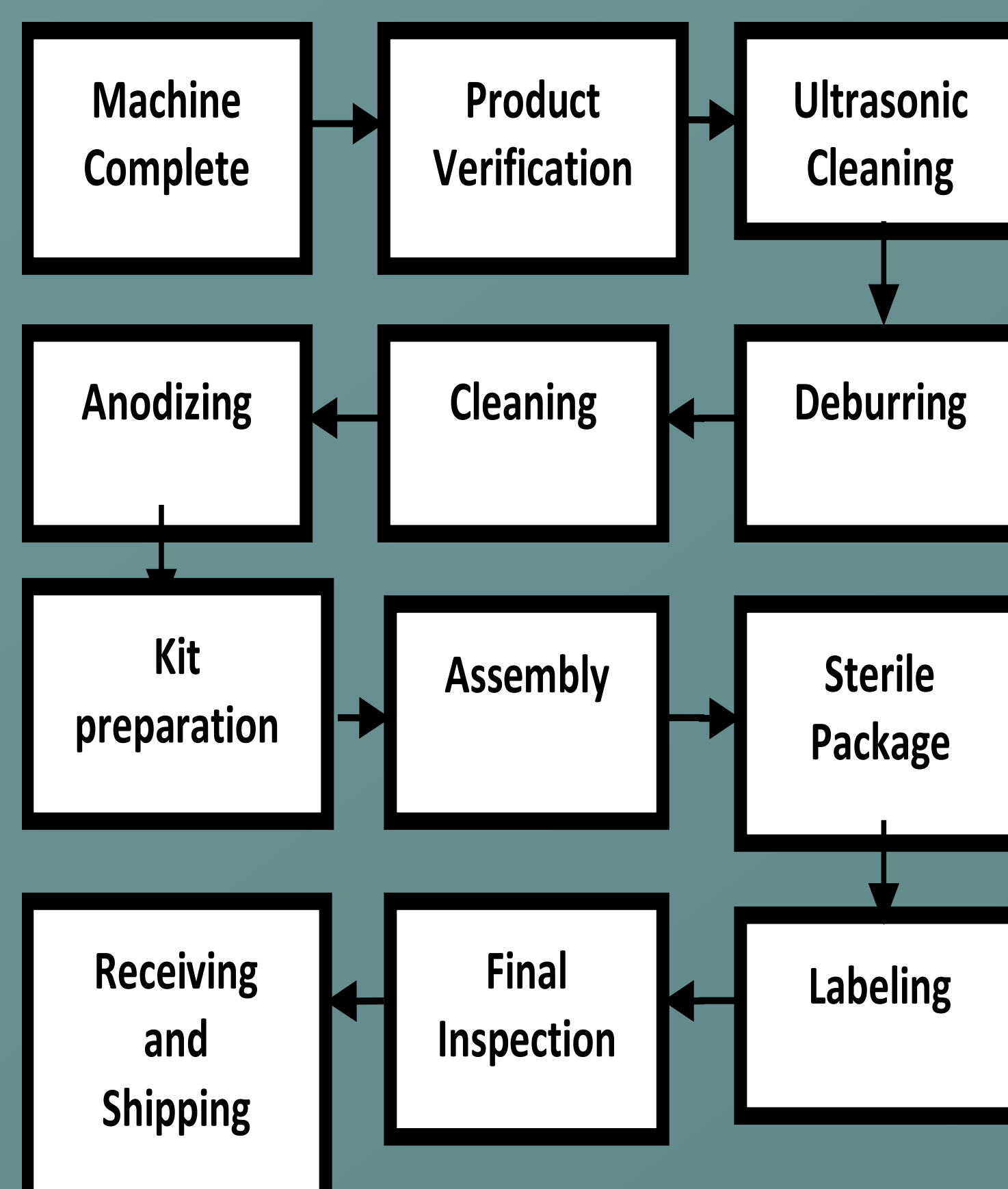
Some tools used to measure the properties and the manufacturing process were the flowchart, baseline, project cost, and risks for both materials. During the project, data was collected, some field visits were performed, and other essential information was collected to proceed with the analysis of the data.

Analyze

The company has to create a plan to achieve the market of over 60 million of patients. The company strategy need to be done base on market demand, new products manufacturing capacity and deliverables, finance, and other high level corporate decisions.

The advantage and disadvantage could be found in the design, material, and cost. The density of the material is a critical element to be considered when an apparatus is selected. Other implications in the manufacturing process are evaluated and analyzed to comply with the good manufacturing practices.

In this analysis, a correlation of cost was analyzed to objectively have an idea of the production cost. Moreover, it is important in the development of the new product the qualification of the equipment, facilities, and the process. Therefore, the Timeline and actual tasks were analyzed and compared to measure the progress.



Manufacturing screw process



PEEK comparison to metals		
Steel	Bronze	Aluminum
PEEK has cheaper manufacturing cost	PEEK has a better mechanical properties	PEEK has cheaper manufacturing cost
PEEK has fewer leachable	PEEK is harder	PEEK is better
PEEK has better dry wear properties	PEEK has better wear & friction	PEEK has a better wear & friction
PEEK has better chemical resistance	PEEK has better chemical resistance	PEEK has better chemical resistance
PEEK has 83% Lower Density	PEEK has 85% Lower Density	PEEK has 50% Lower Density
PEEK has less "memory" / chemical absorption & release	PEEK has low outgassing	

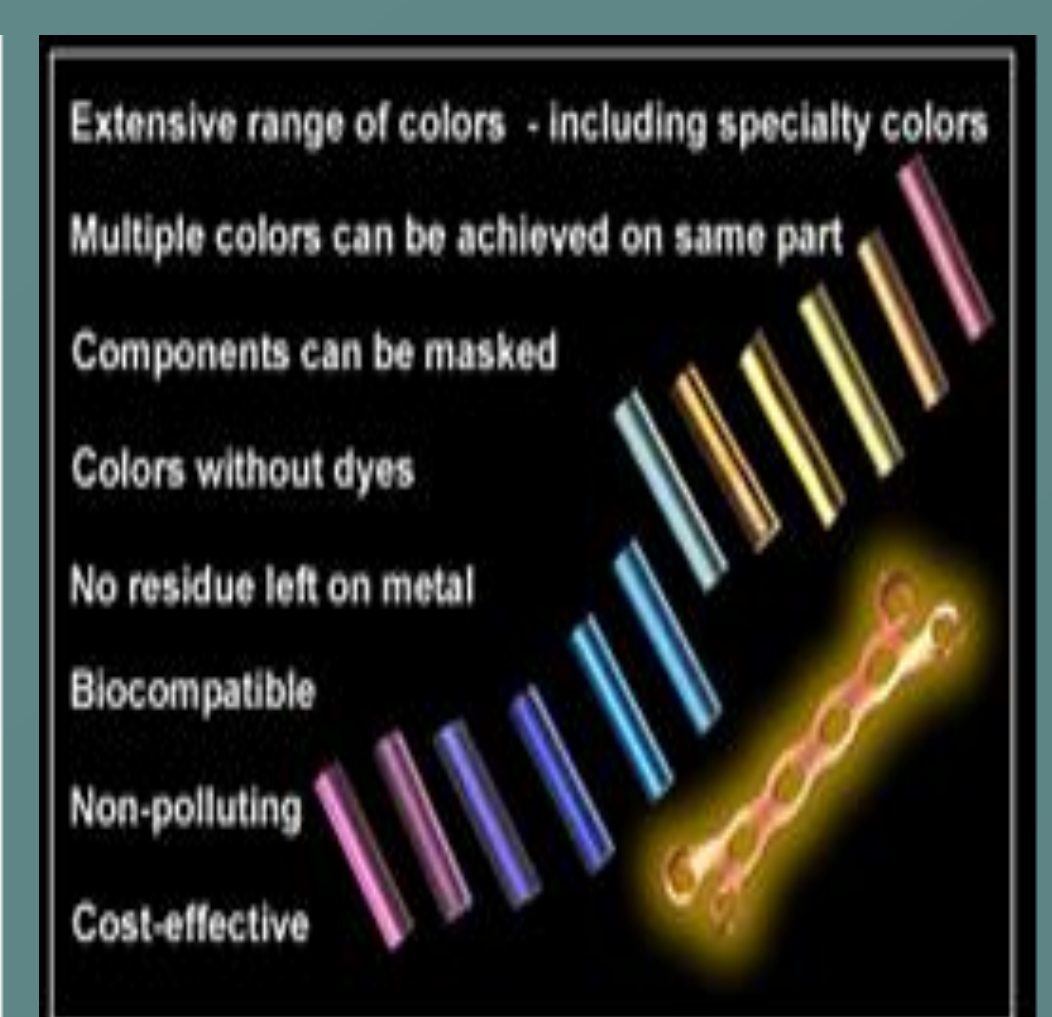
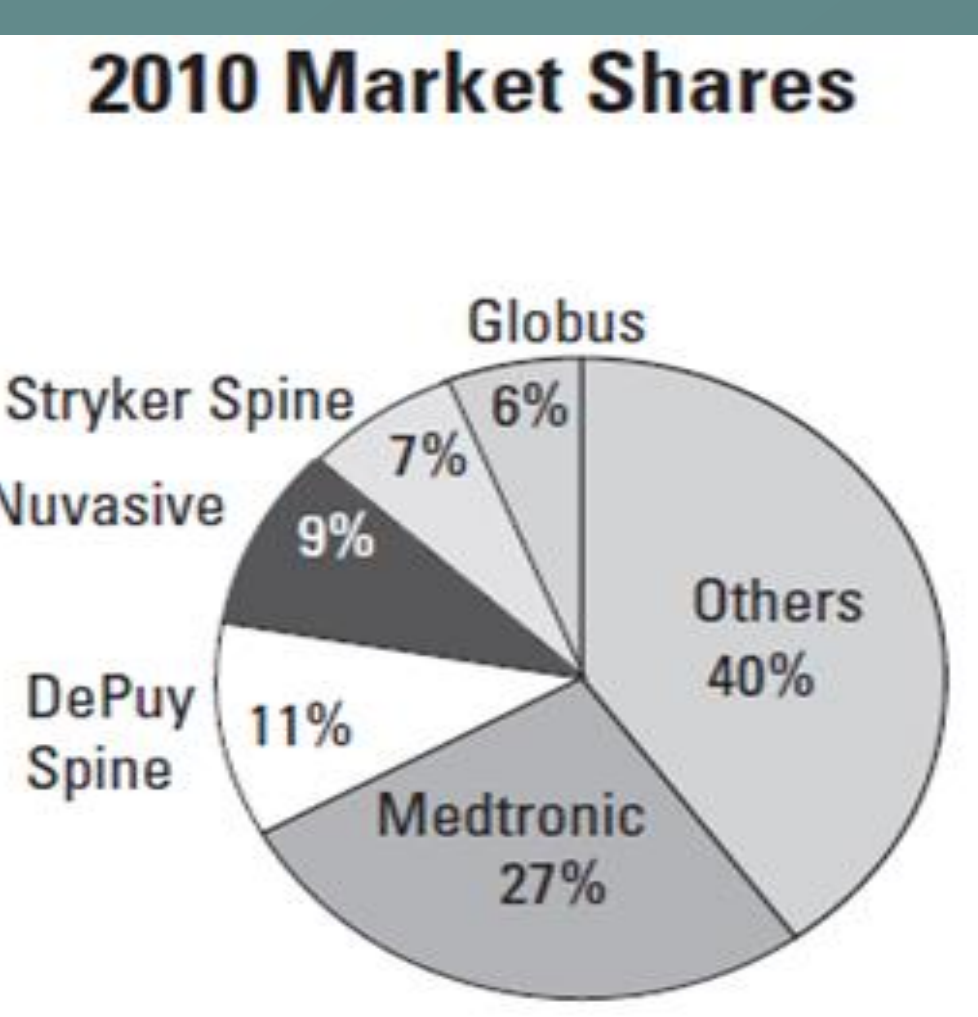
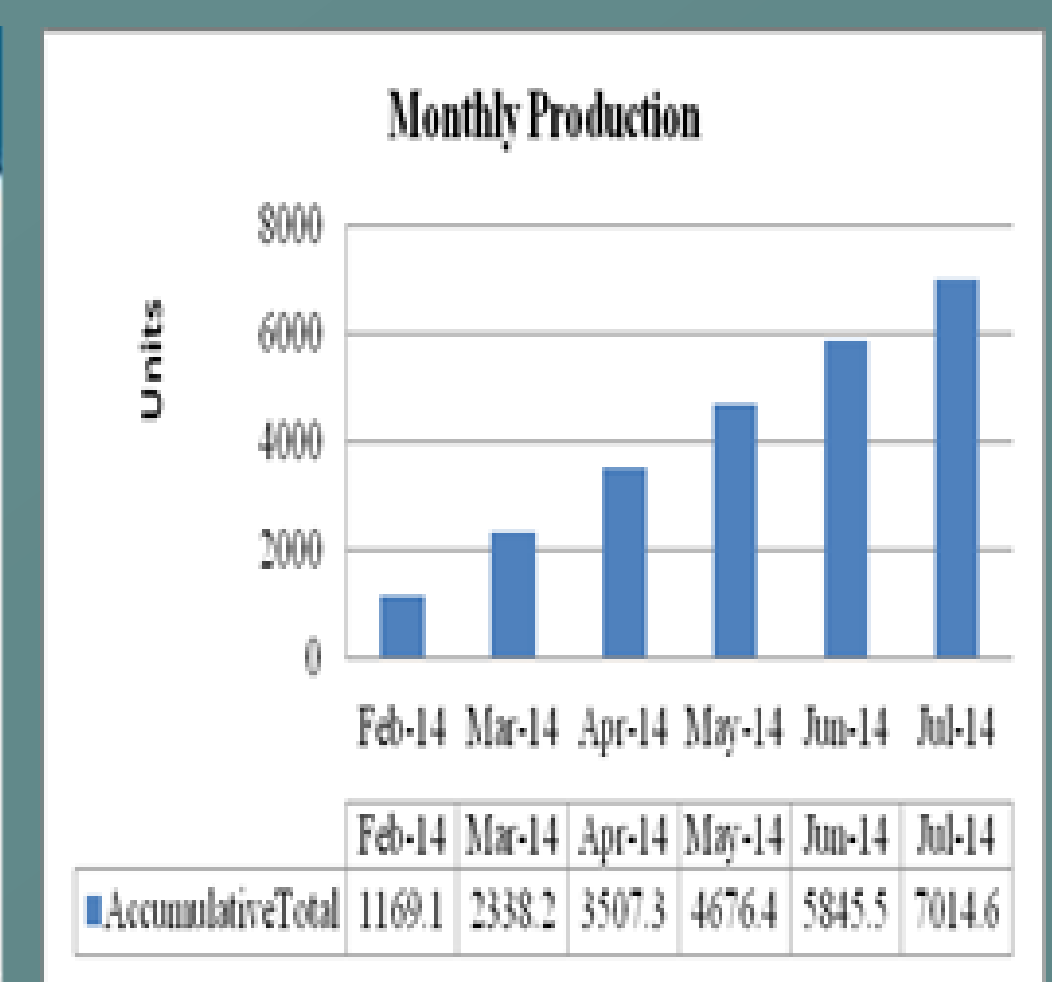
Results

In this section, the materials properties and characteristics, the actual and planned project cost and the Timeline are described and are compared mutually. It is important to be analyzed and understand the results to select the best material, and maintaining the project cost without lost and a proper timeline.

PEEK maintains high mechanical strength, resists stress cracking, and hydrolytic stability in hot water, steam, solvents, and chemicals. Therefore, PEEK is considered a better product in biocompatibility, mechanical strength, and resistant to stress cracking.

Another finding was the new product amount was 7000 units. The machine performed only 67% of the require orders. If the company wants to complete the project in ten months, an additional machine should be considered to achieve the 7000 units

Cervical		2010 List 2010 ASP	
Cervical Non-Bone	Medtronic Sofamor Danek Cornerstone PSR	6277641	NA \$1,119
	DePuy Spine Bengal	1873-01-104	\$1,890 \$987
	Stryker AVS AS	48322074	\$3,190 \$1,304



Conclusions

In this study it was demonstrated that PEEK continue to be the leader in the implant markets. To avoid any risk before the product launch, an additional machine is required to be installed before February 2014. Also, more employees in the development of the project need to be hired.

The major findings are the manufacturing process was redesigned, the activities or tasks in the schedule was completely modified with a proper logic and terms, the resource pool was implemented with the best management practices, the project cost did not suffer any impact in the project implementation phase, and it is projected not impact at the end of the process.

There are potential risks associated with the use of the implants. The customer complaint needs to be analyzed to determine the cause of these implants post operatives situations.