

# ***Design and Implementation of Laser Marking with OCR/OCV Vision Inspection System***

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**Abstract** — *The laser marking process is aimed to create a permanent identification and/or descriptive information on the surface of metallic spinal implants to provide full traceability for the products being manufactured at Medtronic Spinal Humacao. The process, as its name implies, utilize a laser equipment to produce the required reference marks. Products are marked with their respective size, lot number and part number. Identification tags are also laser marked for product identification. In addition, products are 100% inspected during routine manufacturing activities to guarantee that marking information, location and legibility are met per print specifications. The DMAIC methodology was used as part of this research project to improve and optimize the Laser Marking and Inspection manufacturing process. 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 Words** – *DMAIC, Inspection, Laser, Metallic Spinal Implants, Surface, Traceability.*

## **INTRODUCTION**

The laser marking process [1] is aimed to create a permanent identification and/or descriptive information on the surface of metallic implants to provide full traceability for the products being manufactured at Medtronic Spinal Humacao. The process, as its names implies utilize a laser equipment to produce the required traceability such as the part number identifier, the lot number, size, material and Medtronic Raising Men (where applicable).

Cobalt Chrome (CoCrMo) and Titanium (Ti) products go through laser marking process using multiple Laser Marking systems, such as Laser Telesis, which uses fiber laser technology and Electrox Cobra which uses lamp diode pump technologies. In addition, products identification tags are also marked using Rofin Marking System. All marks are 100% visually inspected during routine manufacturing activities as required per prints specifications which guarantees that marking information, location, and legibility requirements are met.

This research project was focused in designing and implementing an integrated Laser Marking and Inspection System.

## **PROBLEM STATEMENT**

Current marking and inspection system are performed separately in different equipment under different processing stages. This requires more equipment, location space, processing time, different operators and multiple transactions in the manufacturing system. In addition, actual laser marking equipment requires several adjustments for the processing of different products and generate high processing scrap for the instability they present. There is a high number of units scrapped daily in these equipment's for incomplete laser, laser illegible and laser mark out of position. The goal of this project is to reduce this scrap and have an integrated system that performs both Marking and Inspection. In order of achieve this goal, the DMAIC project methodology will be used to evaluate the current process and determine optimum process improvements along the process.

## **RESEARCH DESCRIPTION**

This research is focused on the design and implementation of a Laser Marking System with Optical Character Recognition and Optical Character Verification (OCR-OCV) Vision Inspection that will perform laser marking and laser marking inspection operation for multiple products among Humacao Spinal products. System will be able to mark and inspect products for which processing will require a fixture design to accommodate the part and provide consistent and repeatable positioning during the process. Laser Marking and Marking inspection will be performed with OCR-OCV algorithms from their integrated machine vision solution within the same laser marking equipment. The integrated machine vision solution also provides the system the capability to perform axis adjustments or marking pattern orientation (rotation and displacement) to always mark the part at the specified location. To accommodate different products and different geometries the machine will have an X, Y and Z linear motion axes, will provide a docking for rotation capabilities to accommodate the variability of products currently manufactured at Humacao Spinal.

## **RESEARCH OBJECTIVES**

This project aims to achieve implement an integrated laser marking and inspection system. This system will allow more precise marking location and contribute towards laser scrap reduction. In addition, it will reduce equipment, reduce manufacturing usage space, reduce operators and processing time.

## **RESEARCH CONTRIBUTIONS**

This project seeks to increase laser processing output by reducing scrap transaction and processing time. In addition, reduce equipment space, which could further on be used for increasing manufacturing processing capacity.

## **LITERATURE REVIEW**

The laser marking process [1] is aimed to create a permanent identification and/or descriptive information on the surface of metallic spinal implants to provide full traceability for the products. The process, as its name implies, utilize a laser equipment to produce the required reference marks. Products are marked with their respective size, lot number and part number, among others. In some cases, laser marking may be used to create reference marks or measurement graduations on products to facilitate use by the customer. Laser marking process [2] occurs when a beam interacts with the surface of a material and slightly alters its properties or appearances without engraving the material. This process is performed by moving a low-powered beam slowly across the material using the method of discoloration. The discoloration is a method that creates high-contrast marks without penetrating the material. Then the laser heats the material and causes oxidation under the surface and turns the material black. The laser then applies low temperatures to metal to anneal the surface. This process is done without penetrating the surface of the metal.

### **ILT Laser Marking System with OCR-OCV**

The ILT Laser Marking System with OCR-OCV Vision Inspection will perform laser marking and laser marking inspection operation for multiple products among Humacao Spinal products. The system will be able to mark and inspect products for which processing will require a fixture design to accommodate the part and provide consistent and repeatable positioning during the process. The Laser Marking and Marking Inspection will be performed with OCR-OCV algorithms from their integrated machine vision solution within the same laser marking equipment. The integrated machine vision solution also provides the system the capability to perform axis adjustments or marking pattern orientation (rotation and displacement) to always mark the part at the specified location. To accommodate different products and different

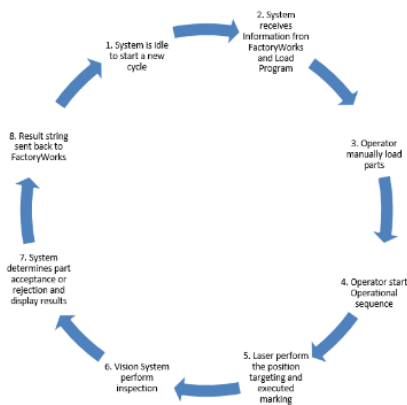
geometries the machine will have an X, Y and Z linear motion axes, will provide a docking for rotation capabilities to accommodate the variability of products currently manufactured at Humacao Spinal.



**Figure 1**  
ILT System

System is required to laser mark and inspect parts as required. In general system is required to be able to:

- Provide Means to Verify Part Presence
- Provide Means to Laser Mark Part and Inspect
  - Provide Operator Interface by Means of HMI, PC or any other visual mean
  - Provide Safety features for Operation (Guards, Interlocks, Emergency Stop, etc.)
  - Provide Access Levels for Protection (User-Password Controlled)
  - Provide Means to Make Program/Job Files per Part Number/Model or family.



**Figure 2**  
ILT Process Summary

### DMAIC Methodology

DMAIC is a methodology used for process improvements and process optimization using Six Sigma. It is a data-driven quality strategy used for process improvements. DMAIC is an acronym that stands for the five phases of this process: Define, Measure, Analyze, Improve and Control (See Figure 3).



**Figure 3**  
DMAIC Methodology

In the Define phase, the customer, team, plan and charter are defined. The problem/opportunities are stated, and the projects expectations are also defined. In addition, the requirements to achieve the desired output are established. In the Measure phase, data is collected of the process and document in order to have a baseline data narrow for the project focus. The analyze phase, the data collected is analyzed to determine possible root causes and identify and remove wastes from the process. In the Improve phase, solutions are generated and evaluated to optimizes and improve the opportunities identified. Finally, the Control phase, the projects benefits are validated.

### METHODOLOGY

In order to achieve the goals for this project a systematic approach will be used. This project seeks to increase laser processing output by reducing scrap transaction and processing time. In addition, reduce equipment space, which could further on be used for increasing manufacturing processing capacity. Since the purpose of the project is to improve the output of laser marked units, the DMAIC methodology will be used. DMAIC is a methodology used for process

improvements and process optimization using Six Sigma. It is a data-driven quality strategy used for process improvements. DMAIC [3] is an acronym that stands for the five phases of this process: Define, Measure, Analyze, Improve and Control.

For the define phase, a project charter will be used to preliminary define the scope of the project, goals, objectives, personnel involved, roles and responsibilities, timeline, stakeholders, and structured the project. In the Measure phase scrap unit's data will be collected from December 2017 the start-up of the New Product Introduction up to May 2018, to be representative of the process, using the different laser marking defects reject codes, such as incomplete laser, laser illegible and laser mark out of position. For the Analyze phase, the data collected will be analyzed to determine top offender reject code and compared with the data from the new laser system. This process data will be continually evaluated throughout the improvement and control phase to determine the project's success.

## RESULTS AND DISCUSSION

For the Define Phase of this project, a project charter was used to define all the deliverables, focus and goals of the project (See Table 1).

**Table 1**  
**Project Charter**

<b>PROJECT TITLE</b>
Design and Implementation of Laser Marking with OCR/OCV Vision Inspection System.
<b>BUSINESS CASE</b>
This project has the intent to potentially decrease the scraps in manufacturing due to laser marking defects and increase process output.
<b>GOAL STATEMENT</b>
The goal for this project is to reduce manufacturing laser marking scraps by June 2018.
<b>SCOPE</b>
In Scope: Laser Marking Process, Out of Scope: All other Processes.
<b>PROBLEM/OPPORTUNITY STATEMENT</b>
Current marking and inspection system are performed separately in different equipment under different processing stages. This requires more equipment, location space, processing time, different operators and multiple transactions in the manufacturing system. In addition, actual

laser marking equipment requires several adjustments for the processing of different products and generate high processing scrap for the instability they present. There is a high number of units scrapped daily in these equipment's for incomplete laser, laser illegible and laser mark out of position. The goal of this project is to reduce this scrap and have an integrated system that performs both Marking and Inspection. In order of achieve this goal, the DMAIC project methodology will be used.

### TEAM MEMBERS

Key Stakeholders	Members Names
Project Manager	Carlos Curet
Manufacturing Manager	Luis Colon
Quality Engineer	Stephany Serrant
Manufacturing Engineer	Jonatan Rosario
SME	Carlos Gonzalez
Project Sponsor	Alberto Rivera
Additional Resources	Members Names
Environmental, Health & Safety Representative	Mildred Pizzaro

### PROJECT RISKS

Risk	Low	Medium	High
Location Restrictions		X	
Equipment Availability		X	

### PROJECT TIMELINE

Key Milestone	Target Date
Start Date	15-MAY-16
Purchase of Equipment	31-JAN-18
Installation of Equipment	25-FEB-18
Modification of Procedures	1-APRIL-18
Training	15-APRIL-18
Completion Date	30-APR-18

### PRELIMINARY BUDGET

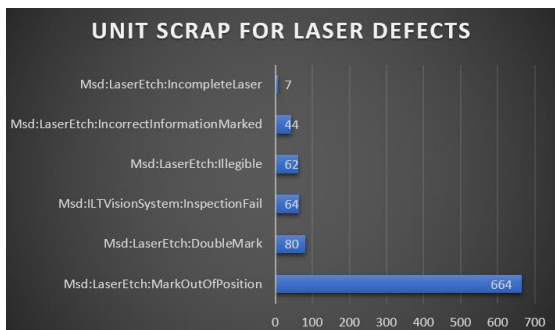
The preliminary budget for this project is of 500K.

In the Measure phase scrap unit's data will be collected from December 2017 the start-up of the New Product Introduction up to May 2018, to be representative of the process, using the different laser marking defects reject codes, such as incomplete laser, laser illegible and laser mark out of position (Refer to Table 2). This data will be analyzed to determine the mayor offender of the laser marking defects. In addition, the process output will be compared from the actual process to when the new implemented system is incorporated into the Manufacturing operations. For the new

implanted system, the scrap reject code for defects associated to the Laser Marking is “Msd:ILTVisionSystem:InspectionFail”. Since this new equipment is dedicated to a New Introductory Product, the data was filtered for that specific product. All other reject codes shown in Table 2 are associated to the Legacy Laser Machines. Figure 4 shows that the top offender reject code associated to the Laser Scrap is Mark out of Position. This reject code is mainly seen associated to the setup and adjustment made to the equipment when changing from different part numbers or product families. Current Laser Equipment are sensitive to parameter changes, and when changing from part number or product families, several adjustments need to be made for the parts to meet with their print specifications. This causes an increase in Mark out of Position of the parts.

**Table 2**  
**Scrap Data**

FISCAL MONTH	REJECT CODE	UNIT SCRAP QUANTITY
FY2018 DEC	Msd:LaserEtch:MarkOutOfPosition	138
FY2018 JAN	Msd:LaserEtch:MarkOutOfPosition	67
FY2018 MAR	Msd:LaserEtch:IncompleteLaser	1
	Msd:LaserEtch:Illegible	33
	Msd:LaserEtch:MarkOutOfPosition	87
FY2018 APR	Msd:LaserEtch:MarkOutOfPosition	158
	Msd:LaserEtch:DoubleMark	40
	Msd:LaserEtch:Illegible	5
	Msd:ILTVisionSystem:InspectionFail	33
FY2019 MAY	Msd:LaserEtch:IncorrectInformationN	8
	Msd:ILTVisionSystem:InspectionFail	31
	Msd:LaserEtch:MarkOutOfPosition	214
	Msd:LaserEtch:Illegible	24
	Msd:LaserEtch:DoubleMark	40
	Msd:LaserEtch:IncorrectInformationN	36
	Msd:LaserEtch:IncompleteLaser	6



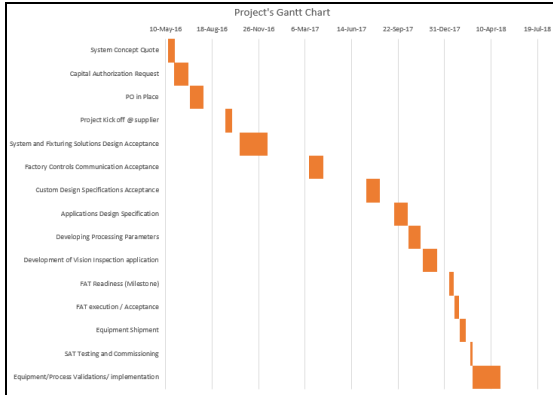
**Figure 4**  
**Top Offender Laser Scrap**

For the implementation phase of this project a Gantt Chart was developed to define all the

deliverable of the project’s implementation tasks and deadlines (See Table 3 & Figure 5).

**Table 3**  
**Gantt Chart Data**

No	Action Items	Start Date	End Date	Duration (Days)
1	System Concept Quote	5/15/2016	5/30/2016	15.00
2	Capital Authorization Request	5/29/2016	6/28/2016	30.00
3	PO in Place	7/1/2016	7/31/2016	30.00
4	Project Kick off @ supplier	9/15/2016	9/30/2016	15.00
5	System and Fixturing Solutions Design Acceptance	10/17/2016	12/16/2016	60.00
6	Factory Controls Communication Acceptance	3/15/2017	4/14/2017	30.00
7	Custom Design Specifications Acceptance	7/15/2017	8/14/2017	30.00
8	Applications Design Specification	9/13/2017	10/13/2017	30.00
9	Developing Processing Parameters	11/5/2017	12/20/2017	45.00
10	Development of Vision Inspection application	11/5/2017	12/15/2017	40.00
11	FAT Readiness (Milestone)	1/10/2018	1/20/2018	10.00
12	FAT execution / Acceptance	1/21/2018	1/31/2018	10.00
13	Equipment Shipment	2/2/2018	2/15/2018	13.00
14	SAT Testing and Commissioning	2/25/2018	43160	4.00
15	Equipment/Process Validations/ implementation	3/1/2018	4/30/2018	60.00



**Figure 5**  
**Project's Gantt Chart**

From the data presented in the DMAIC Measure Phase, shows a significant reduction in the scrap from the Laser Marking Operation performed under the ILT System. Since new ILT System was implemented on April 2018, there is not much data presented in order to compare with past data. Although, from when it was implemented up to May 2018, only sixty-four (64) units were detected to be scrapped from the new laser system (Refer to Figure 4). All units were physically inspected to determine potential root causes for these scrap transactions. Units presented Laser Marking that met with print specifications, but the Vision System required to be trained and expand the Vision Field and failed the inspection. They did not present a product laser mark defect, but operators still performed the scrap transactions. As a mitigation, awareness was generated to operators in order for Engineering to be able to perform the training transactions required by the system on the Vision Inspection System. This data presents, that when laser mark is being performed under this new system, the scrap transactions present to be in control and they have been significantly decrease. This is due to that the ILT system is a more precise Laser Marking System.

## CONCLUSION

Since this project is has been recently implanted on site, there are not much data results for the improvement and control phases. Although, the expected result from this project is to increase

laser processing output by reducing scrap transaction and processing time, so far from the data obtained, the ILT System has demonstrated to be capable for its intended used and fulfil the business desired output. In addition, reduced equipment space, which could further on be used for increasing manufacturing processing capacity.

## REFERENCES

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