Application of Lean Six Sigma Methodology to Optimize Fixation Device Assembly Line in the Medical Devices Industry

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Abstract *— The research project was focused in the line optimization of a Fixation Device assembly line in a Medical Devices Industry. The Fixation Device is called ProTack™. The Covidien Company is the manufacturer located in Ponce, Puerto Rico. The medical device has application in endoscopic surgery procedures for fixation of prosthetic material and approximation of tissue for various surgical specialties, such as repair of hernia defects. The Ponce facility of Covidien has identified improvement areas within the assembly process of ProTack™. The Lean Six Sigma (LSS) Philosophy was used to identify Non-Value Added (NVA) activities in order to be eliminated or reduced. The implementation of Lean Six Sigma Philosophy results were line output was optimized as per customer requirements, labor costs were reduced and line performance improved. This research demonstrates that the Lean Six Sigma Philosophy is a robust methodology for continuous improvement and optimization.*

Key Terms *— Lean Manufacturing, Process Optimization, Six Sigma, U-shape Manufacturing Cell.*

INTRODUCTION

The dominant sectors of the Puerto Rico economy in terms of production and income are manufacturing and services. Manufacturing is the largest sector of the Puerto Rico economy in terms of gross domestic product and the second largest in terms of gross national product. During fiscal year 2011, payroll employment for the manufacturing sector was 85,558, a decrease of 3.1% compared with fiscal year 2010.[1]

The manufacturer of the medical device of this research has been through lot of changes and challenges during the past decades. U.S. Surgical was always been a pioneering company since it was founded in 1964, when it introduced the world's first practical surgical stapler. And with the introduction of the world's first endoscopic clip applier in 1990, U.S. Surgical's EndoClip Applier revolutionized the surgeon's ability to remove a diseased gallbladder laparoscopically.[2] In 1998, a major milestone took place when Tyco Healthcare Group LP, purchased the then-U.S. Surgical Corp.[2] Covidien was founded on January 2007 when Tyco International LTD separated their Tyco Healthcare division and decided to name it Covidien as independent, publicly traded company.

The research project will be focused in the optimization of the ProTack™ Fixation Device assembly line at the Covidien facility in Ponce Puerto. The medical devices company organized a Lean Six Sigma team from multiple departments to work on this optimization. As part of the continuous improvement culture of the company, the goal of this project is to give continuation to some previous improvements implemented in the assembly line.

During previous improvements, the major goal was to convert the assembly line layout to a manufacturing cell. Prior to this improvement the assembly line ran in a conveyor type layout. A multi-departmental team found areas of improvement and decided to convert the assembly line to a manufacturing cell. That project resulted on lots of benefits at the moment of the implementation. However, the project team recognized that the manufacturing cell principles were not fully utilized; therefore, future improvements were identified and documented.

This research project will fully apply the manufacturing cell principles to optimize the manufacturing cell production. The Lean Six Sigma team has followed recognized improvements of the past project but also identified some wasteful activities of the current manufacturing cell. The team has identified the opportunity to reduce the labor cost. The team goal is the rebalance of the manufacturing cell and the reduction of wasteful activities in the assembly process. Once the project is finished, the team expects the increase of the production output of the line in terms of parts per person and a reduction in labor cost.

Research Description

The Fixation Device assembly process occurs in a manufacturing cell arrangement. After analyzing the process, the current balancing of the line shows wasteful activities that can be removed. A reduction of four employees, two on each shift, will provide the opportunity to reduce the labor cost in the assembly line. In addition, the line efficiency, productivity (PPMH) and process flow are affected with the current layout. The ProTack™ assembly process will be optimized with the use of the Lean Six Sigma Methodology.

Research Objectives

The Fixation Device optimization project will start with the current state analysis including takt time analysis and the assembly time study.The team will be working with the cell re-balance and re-configuration of the manufacturing cell. In addition, some other techniques from the Lean Six Sigma methodology will be used. The team will analyze all improvements; the "U" shape cell will be implemented in the Clean Room I A. This event is aimed to reduce non-value-added activities and optimizes line productivity. Once this phase is finished, then some final adjustments will be evaluated; for example, a 5S event will be performed after the re-layout.

Research Contributions

The improvement of the Fixation Device assembly process at the Ponce facility of Covidien will contribute in the whole value stream. The lean six Sigma methodology will be integrated for continuous improvement. The assembly process will met the customer requirements, balancing the different operations at takt time. New cell layout will be implemented for man power flexibility by demand fluctuations (Shojinka). Moreover, the correct use of process balance will increase productivity. Production costs will be reduced more than $60,000 with the re-balance and productivity improvements. The most important contribution is that the customer will benefit with more dependable product and improved lead times.

Also, the Fixation Device research project is a team effort in which employees will be benefit of the knowledge of Lean Six Sigma. Last but no less important, the research project will maintain the employment of manufacturing cell personnel as the assembly process prove to be more robust and efficient than before which warranty clients demand, product quality and stable productivity.

LITERARURE REVIEW

The ProTack™ is a sterile, single use device. The instrument has application in endoscopic surgery procedures for fixation of prosthetic material and approximation of tissue for various surgical specialties, such as repair of hernia defects. The instruments contain 30 titanium helical fasteners. The helical fastener design provides a secure fixation of a prosthetic material to various types of tissues. The helical fastener is made of titanium to minimize interference with imaging technologies, such as MRI. The instrument has a diameter of 5.0mm used in conjunction with a 5.0mm ports, minimizing the size of the insertion site. The overall length of the shaft is approximately 35.5 cm.[3]

The fixation device assembly line runs in manufacturing cell. The labor required are 12 operators. The manufacturing cell has 12 assembly stations: Coil welder; Helix test & lubrication; Helix loader 1; Helix loader 2; Leak test / X-ray inspection; Sub-assemblies for Builders; Builder 1, Builder 2; Builder 3; Weld body / Dry fire; Blister Pack & Sealed of unit and Packaging. Each operator is assigned to one station accordingly to assembly sequence. In addition, a material handler / coordinator assist team leader for material distribution, inventory accuracy and defects disposition. The line team leader is assigned to maintain line organization, provide training, documentation and production effectiveness.

During the research process, to measure the opportunities of the line, some Key Process Inputs KPI's were measured (Table 1):

Table 1
Fixation Device production line KPIs

Input	*Baseline*
Efficiency	88%
Operators qty.	12
Overall operators qty.	13
Availability	79.27%
PPMH	3.98

Due to these KPI's many opportunities were identified to improve efficiency and part per man hour. The line efficiency is 88% instead of 95% acceptable by the industry. These situations results on a poor PPMH of 3.98 instead of 4.71 required for an optimal process with the current line configuration. The implementation team will analyze the value stream from receiving to shipping, for better comprehension of the activities that effects productivity. In addition, a demand analysis will be needed to know customer needs.

During the demand analysis, it was determined that the current line had an overproduction, takt time is 43 seconds vs. cycle time of 35 seconds. This is an overcapacity of 19 units per hour, more than 65,968 in a year, this represent a overcapacity of 22%. To view all the non value added activities that affects the whole value stream to the customer.

Current State Value Stream Map (CSVSM) for the Fixation Device line show a significant opportunity to improve Lead Time vs. Total Cycle time. At the time of this map, non-value-added activities accounted for >99% of the total L/T, while value-added activities accounted for <1%. The team divided the VSM into 4 loops: the Pacemaker Loop, the Customer Loop, the Communication Loop and the Supplier Loop. For this event, the Pacemaker Loop is the team's area of focus. The team's objective is to reduce non-value added activities in production area: labor cost, overproduction, inventory and over processing.

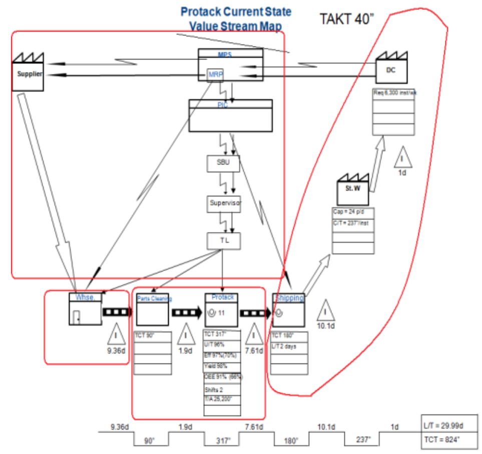


Figure 1
Current State Value Stream Map

Lean Six Sigma Methodology

Lean Six Sigma is a management approach for problem solving and process improvement based on a combination of the different tools of Lean Manufacturing and Six Sigma.

Lean Manufacturing provides mechanisms for quickly and dramatically reducing lead times and waste in any process, anywhere in an organization. Six Sigma provides the tools and organizational guidelines that establish a data-based foundation for sustained improvement in customer-critical targets. Together, Lean Six Sigma (LSS) is a powerful, flexible and proven cost and waste elimination method that has been used successfully in both private and public organizations.

As a combined entity, Lean Six Sigma has been on the scene since the 1990s. Since then, Lean Six Sigma has been shown time and again to enable organizations to reduce total costs by 25% by eliminating wasted time and activities from operations. This waste reduction effort has also served to increase the quality of the organization's products. Most importantly, Lean Six Sigma builds foundations within organizations that stimulate and nurture cultures of continuous improvement; thus providing these benefits both today and into the future.

Lean Six Sigma develops effective employees within your organization as employee involvement is one of the key elements. It promotes active participation and results in an engaged team and helps to building trust. Basically, Lean Six Sigma develops a sense of ownership and accountability for your employees. This increases their effectiveness at delivering results for any improvement project they are involved in.

Lean Manufacturing Philosophy

The Lean Manufacturing philosophy involves never ending efforts to eliminate or reduce 'muda' (Japanese for waste or any activity that consumes resources without adding value) in design, manufacturing, distribution, and customer service processes. Developed by the Toyota executive Taiichi Ohno (1912-90) during post-Second World War reconstruction period in Japan, and popularized by James P. Womack and Daniel T. Jones in their 1996 book 'Lean Thinking.' Also, it is called lean production.

Lean Manufacturing identifies 7 key muda.[4] They are: Transportation, Inventory, Motion, Waiting ,Overproduction, Over Processing and Defects.

Lean tools in manufacturing, such as Value Stream Mapping, Quick Changeover/Setup Reduction, Single Minutes Exchange of Dies (SMED), Kaizen, Cellular/Flow Manufacturing, Visual Workplace/5S Good Housekeeping, Total Productive Maintenance (TPM), and Pull/Kanban Systems, are used to produce change.

Lean in short terms means "eliminating waste" (The Toyota way), using the continuous improvement philosophy. The lean manufacturing philosophy uses 5 important principles: Identify value; Map the value stream; Create flow; Establish pull and Pursue perfection

Six Sigma Methology

Six Sigma is a systematic approach to reducing variation within processes. It was originally developed in 1986 by Motorola as an attempt to reduce the costs of poor quality that resulted from rejected material, rework, inspection processes, lost revenue, and other hidden costs associated with "not doing it right the first time". This business management strategy is now used in many different industries in an effort to improve the quality of products or services produced by the business through the removal of defects and errors.

A six sigma process is defined as one in which 99.99966% of products created are expected to be statistically free from defects. Six Sigma can therefore be also thought of as a goal, where processes not only encounter less defects, but do so consistently (low variability). Basically, Six Sigma reduces variation, so products or services can be delivered as expected reliably.

The Six Sigma methodology follows the DMAIC process, where project teams work to: *Define* the problem as perceived by the customer, *Measure* the performance of the process, *Analyze* data to determine root causes of problems, *Improve* the process and *Control* the improvements.

METHODOLOGY

The Lean Six Sigma methodology will be used for the Fixation Device production process. Given the principles and tools of Lean Six Sigma, the objective of this research project is to reduce all the non- value added activities and implement a continuously improved process. The Lean Manufacturing methodology is divided in 5 phases.

Phase I. Define

What problem would you like to fix? The Define Phase is the first phase of the Lean Six Sigma improvement process. In this phase, the leaders of the project create a Project Charter, create a high-level view of the process, and begin to understand the needs of the customers of the process.

Phase II. Measure

How does the process currently perform? Measurement is critical throughout the life of the project and as the team focuses on data collection, initially they have two focuses: determining the start point or baseline of the process and looking for clues to understand the root cause of the process. As part of eliminating waste of the process, a value stream is necessary to be mapped. In short term, the value stream is all the activities required to procure a product or service that pass through similar process steps and over common equipment. The most common value stream used is the raw material to finish product.[5] This specific will be used to study the Fixation Device process. Once the value is draw, the team will identify all the waste in the process.

Phase III. Analyze

What does your data tell you? This phase is often intertwined with the Measure Phase. As data is collected, the team may consist of different people who will collect different sets of data or additional data. As the team reviews the data collected during the Measure Phase, they may decide to adjust the data collection plan to include additional information. This continues as the team analyzes both the data and the process in an effort to narrow down and verify the root causes of waste and defects.

Phase IV. Improve

How will you fix the problem? Once the project teams are satisfied with their data and determined that additional analysis will not add to their understanding of the problem, it's time to move on to solution development. The team is most likely collecting improvement ideas throughout the project, but a structured improvement effort can lead to innovative and elegant solutions.

Phase V. Control

How do you sustain the newly achieved improvement? This phase is a mini version of process management. The team has been building a form of infrastructure throughout the life of the project, and during the Control Phase they begin to document exactly how they want to pass that structure on to the employees who work within the process. This final and most important principle means that the Lean Six Sigma is a continuous journey of process improvement. To corroborate that the purpose and results met customers' requirements, new metrics and audits will be implemented to identify new opportunities. The new metrics and audits will be designed to ensure that any potential improvement to prioritize by costumer needs.

RESULTS AND DISCUSSION

This section collects all the implementation activities for the ProTack™ Line Optimization process using the Lean Six Sigma methodology.

Phase I. Define

The Project Team Charter (Table 2) was filled to understand all the variables that affect the production in order to eliminate or reduce the non-value added activities. The Project Charter contains all the metrics to be impacted with the line optimization implementation. In addition, the Project Charter specifies all the requirements, scope, resources that were identified to facilitate tasks delegation and teamwork. The implementation dates discussed by the team prevent project delays and help with time management. Due to the information presented by the Project Charter, many opportunities exist with the current line configuration.

Table 2
Project Team Charter

Project Title	**ProTack™ Line Optimization**
Total Saving Identified	$ 60,000
Project Leader	Elmer A. Lopez Colon
Project Start Date	January 2010
Project End Date	May 2010
Element	**Team Charter**

<table>
<tr><td>Process: The process in which the opportunity exist</td><td colspan="3">ProTack™ assembly process.</td></tr>
<tr><td>Problem Description: Describe the problem that need to be solved, or the opportunity to be addressed</td><td colspan="3">The opportunity to reduce the labor cost in assembly line. After analyzing the process, the current balancing of the line shows wasteful activities that can be removed. Reduction of four employees, two on each shift.</td></tr>
<tr><td>Objective: What improvement is targeted?</td><td colspan="3">The team will target productivity improvements. The goal is to balance the line to Takt time and reduce the amount of wasteful activities in the process. This will, in turn, increase productivity of the line in terms of parts per person, and reduce labor costs.</td></tr>
<tr><td rowspan="4">Metrics: What are the measurements that quantify program process and success?</td><td>Metric</td><td>Baseline</td><td>Goal</td></tr>
<tr><td>Labor HC</td><td>24</td><td>20</td></tr>
<tr><td>Efficiency</td><td>90.92</td><td>95</td></tr>
<tr><td>PPMH</td><td>3.98</td><td>4.47</td></tr>
<tr><th>Element</th><th colspan="3">Team Charter</th></tr>
<tr><td>Team Members: Names and Roles of Team Members</td><td colspan="3">Rafael Rodríguez — Process Owner, Luis D. Rivera — Lean Support, Elmer López — Mfg. Engineering, Ivelisse Cotto — QA Support, Gladys León — Line Team Leader, William Veguilla — Lean Mfg. Manager & Advisor, Victor Nazario — Champion, Lemuel Guisao — OpEx Support, Ricardo Ortiz — Finance</td></tr>
<tr><td>Benefit to External Customers:</td><td colspan="3">Customers will benefit from a more dependable product with improve lead time</td></tr>
<tr><td>Schedule: Give the key milestones and dates</td><td colspan="3">Key Project Dates
Define: February 2010
Measure : February 2010
Analyze: March 2010
Implement: March 2010
Control: April 2010</td></tr>
<tr><td>Budget: What financial resources are required for the team?</td><td colspan="3">Financial analysis assistance</td></tr>
</table>

Phase II. Measure

The goal of Measure phase is to establish a clear understanding of the current state of the process you want to improve. A base line measure is taken using actual data. This measure becomes the origin from which the team can gauge improvement.

The team started to collect data considered necessary. The data collection process was divided in two sub-phases. The first sub-phase collected the data of previous months of the project. During the first sub-phase, the team coordinated meetings with Assembly Line management group including the Manager, Supervisor, Line Team Leader, Line Coordinator, Quality Control technician dedicated to the line, among others.

The second sub-phase was the process evaluation in which the team visited the assembly line during normal operation. This sub-phase was completely dedicated to work in the manufacturing line. The team interacted with assembly line employees in order to involve them in the process.

The team started by getting the information related to the customer requirements during meetings with the Manager of the Assembly area and the Finance specialist. The ProTack™ demand report was provided and revised by the team. Additional reports such as Downtime Report / Metrics, Product-Quantity Analysis, Product Efficiency Report, and Overall Equipment Efficiency (OEE) Report were also revised.

In addition, the current manufacturing cell layout was provided (see Figure 2). This layout shows some principles of a manufacturing cell however this layout does not take advantage of manufacturing cell characteristics.

During the assembly line runs the team performed a time study of the line. The time study took time samples from three different employees at each assembly workstation.

With the collected data, the team developed a Current State Value Stream Map (CSVSM). Once finished, the team realized that the lead time of the assembly line is 29.99 days while the Total Cycle Time is 824 minutes.

Phase III. Analyze

The Analyze phase identifies the critical factors of a “good” output and the root causes of defects or “bad” output. This phase is often intertwined with the Measure Phase.

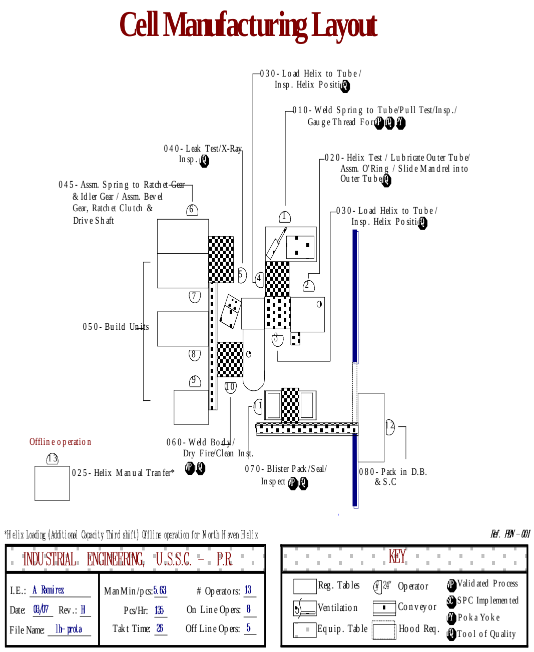


Figure 2

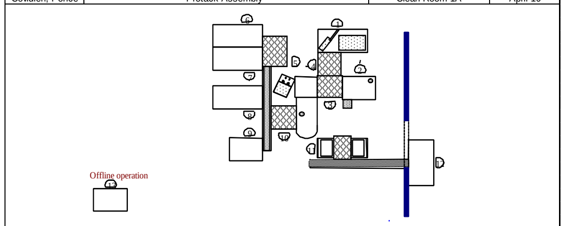
Current Layout with 12 Operators

The current efficiency of 88% tells us that the operations are unbalanced and the employees don't have the expertise to work in the line. In addition, the machines poor performance, specifically the Coil Welder and Helix Loader affect availability and efficiency. The PPMH of 3.98 instead of 4.47 reflects the opportunities to be improved in the line. This information is shown in the Table 1 on Page 3.

These metrics in combination with the PQ / Demand Analysis and Current State Value Stream Map (Figure 1) were used to analyze and improve the line. In addition, in order to verify the current line balance, a Standard & Balanced work was developed to identify gaps between takt time vs. cycle time (Figure 3).

This current Standard & Balanced Work shows a big gap between the takt time vs. cycle time. The chart showed some potential improvements for employee's optimization in order to eliminate and/or reduce NVA activities. This helped the team to focus on labor reduction to meet customer requirements.

Plant	Process / Operation	Area	Date Prepared
Covidien, Ponce	Protack Assembly	Clean Room 1A	April-10



Cycle Time (secs.)	Standard In-Process Inventory	Takt Time (secs.)	In-Process Inventory	Quality Check Point	Safety Precaution
40	See Station	40	○	◇	✚

No.	Operation Description	Man	Walk	Mach	Takt
1	Weld Spring to Tube / Pull Test/Insp. / Gauge Thread Form	36.52	0	26.34	24.9
2	Helix Test / Lubricate Outer Tube / Assm. O'Ring / Slide Mandrel into Outer Tube	35.83	0	0	24.9
	Helix Manual Tranfer	12.87	0	0	24.9
3	Load Helix to Tube / Insp. Helix Position	32.33	0	37.29	24.9
4	Load Helix to Tube / Insp. Helix Position	32.33	0	37.29	24.9
5	Leak Test/X-Ray Insp.	17.85	1.2	0	24.9
6	Assm. Spring to Ratchet Gear & Idler Gear / Assm. Bevel Gear, Ratchet Clutch & Drive Shaft	21.33	0	0	24.9
7	Build Units	34.85	0	0	24.9
8	Build Units	34.85	0	0	24.9
9	Build Units	34.85	0	0	24.9
10	Weld Body / Dry Fire/Clean Inst.	24.03	1.2	2.5	24.9
11	Blister Pack / Seal / Inspect	26.75	0	8	24.9
12	Apply Patient Label to lid / Pack in D.B. & S.C	32.55	3.2	0	24.9

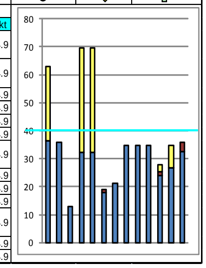


Figure 3

Before Improvements Standard & Balanced Work

During the MEASURE phase some NVA activities were identified by the team: **Transportation,** 70,000 Ft² delivery space; **Inventory,** 29 days of inventory; **Waiting,** machine downtime, lack of raw material and line clearance; **Overproduction,** 35" cycle time vs. 43" takt time; **Over Processing,** Coil Welder; **Defects,** Jams on Helix loader (rework).

The team focused the line optimization to the following activities: Line Balancing, Coil Welder downtime, Helix loader time study, Balance Builders workstations and TPM.

The comparison of cycle time vs. takt time shows the overproduction and the imbalance of the line. The Pareto chart in Figure 4 shows the Coil Welder contribution to the downtime of the line.

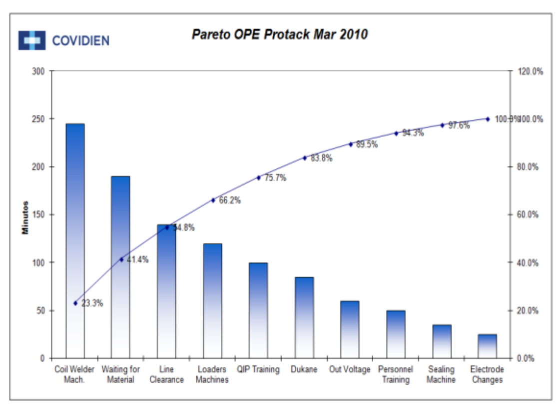


Figure 4

Pareto Chart for Downtime

Phase IV. Improve

In the Improve phase the best solutions to the problem are brainstormed, developed, selected and implemented. The effects of the solutions are measured and evaluated.

A new Value Stream Map, Future State Value Stream Map (FSVSM), was developed (refer to Figure 5 FSVSM). This FSVSM shows reduction in Lead Time from 29.99 days to 5.5 days and a reduction in Total Cycle Time from 824 minutes to 497 minutes. This FSVSM shows a more robust process which is capable to comply with customer demand.

After a thoughtful analysis, considering employees feedback, the team worked on improvements to the manufacturing cell. The manufacturing cell was arranged in a U-Shape cell taking advantage of the manufacturing cell characteristics. Figure 6 shows new implemented layout.

One observation during the Measure phase was the downtime in the Coil Welder machine. The team obtained some ideas from the assembly line employees. After the evaluation of the ideas, it was determined to perform a Kaizen event to work on this situation. The Kaizen event of the Coil Welder machine consisted of four proposals for improvement. The events were the following:

Re-layout of the Coil Welder station. It is required to perform two tests after the coil is welded to the tube. These inspections are the pull test and the coil depth measure. Before the Kaizen event, the fixture to measure the depth was in front of the employee while the fixture for the pull test was at the side of the Coil Welder machine. After the Kaizen event, both instruments were place in front of the employee in order to provide a more feasible way to perform the test.

Installation of a guide in order for the assembly operator to know where to place the beginning of the coil in machine. Prior to the Kaizen event, there was no guide, causing delays in the process. After the Kaizen event, the guide assists the employee to make it right the first time.

Installation of a Autonomous Maintenance System which provides a signal that indicates the time to change the welder tip. Prior to the Kaizen Event, the welder tip was used without any indicator that replacement was needed causing a continuous use and bad units due to broken welds in further processes. After the Kaizen event, it was determined an amount of welds that guaranteed no bad units. The system warns the employee and the team leader that the welding tip needs replacement. This replacement takes 5 – 10 minutes to be performed; therefore, it is coordinated to be performed during employee breaks so no downtime is recorded.

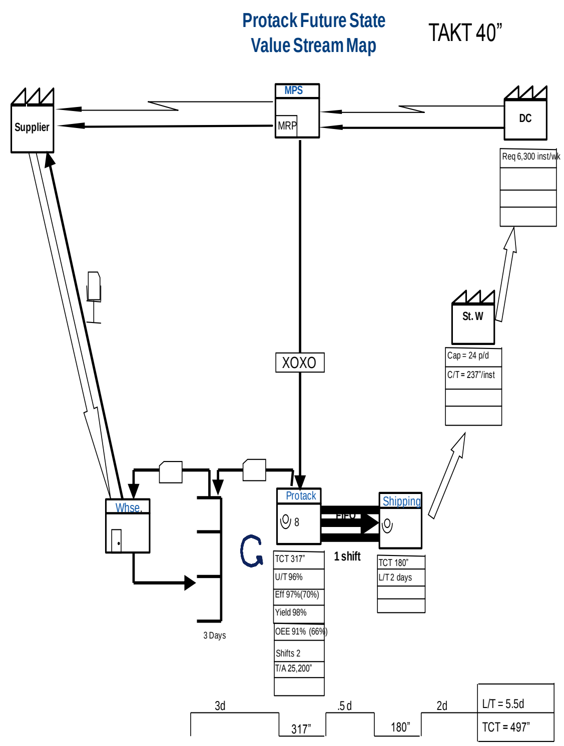


Figure 5
FSVSM

Safe guard installation. The safe guard has been provided with an interlock system to provide a safe work environment for the employees. This safe guard activates and deactivates the machine. Once the coil and the tube are ready, the operator closes the guard and the machine is activated by the safe guard. At the same time, when the machine finishes the weld, the operator opens the door and the weld stops.

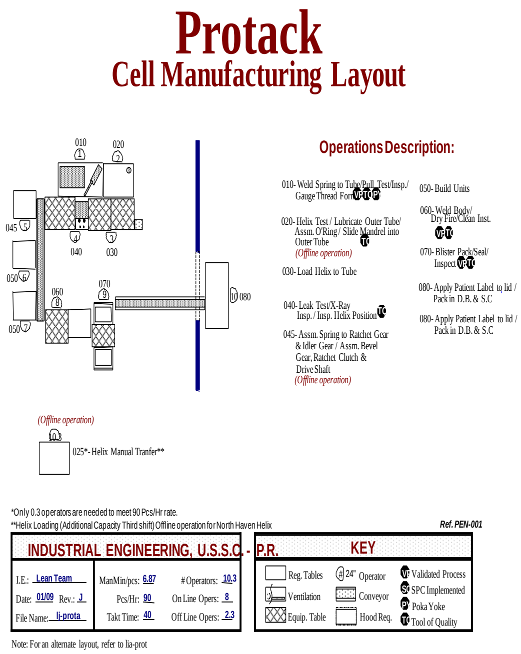


Figure 6
New Cell Manufacturing Layout

Other Kaizen events were done simultaneously in order to improve other areas of the manufacturing cell. These Kaizen events were: redesign of the O-ring tool at the Helix loader machines, Helix loader time study and the implementation of a TPM system for the whole manufacturing cell.

At the Helix loader workstation, an O-ring needs to be placed to keep helix in place. This was a safety concern as the tool had sharp edges. The tool was redesigned to prevent any safety risk.

Another Kaizen event consisted of the implementation of TPM system. TPM is a management process developed for improving productivity by making processes more reliable and less wasteful. The objective of TPM is to maintain the plant or equipment in good condition without interfering with the daily process. To achieve this objective, preventive and predictive maintenance is required. TPM was performed in the following machines: Coil Welder, Loader machines #1 and #2 and DUKANE/MU274 which welds body parts together.

Another area for improvement referred by manufacturing cell employees was the visual work instruction. This instrument was implemented in other assembly lines in the company and has been positively evaluated by the employees referring that the work is more feasible having the Work instruction in the workstation. The team and the employees developed the Work instructions which were installed at the workstations as recommended by ProTack™ manufacturing cell employees.

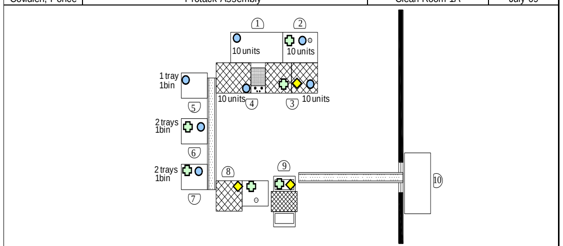
The work load operations balance of Fixation Device manufacturing was rebalanced to meet the customer requirements, improve productivity and reduce waste. The Helix Loader workstation was the most impacted.

The current workstation combines the two (2) Helix loader machines with one operator. The inspection task previously performed in this workstation was assigned to the next workstation. In the current layout, the workstation #4 performs the following inspection: Helix Position Inspection Leak Test, and X-Ray Inspection. In addition, due to the overproduction revealed in the manufacturing cell, a Builder workstation was eliminated. These changes were validated during the Control phase. In terms of space requirements, there was no much difference in utilization; however the new configuration provides better arrangement of the area such as the aisle next to the Coil Welder which is shared with another assembly line.

One final step prior going to the Control Phase, was a 5S exercise performed by the team and the line employees. **5S** describes how to organize a work space for efficiency and effectiveness by identifying and storing the items used, maintaining the area and items, and sustaining the new order. The decision-making process usually comes from a dialogue about standardization, which builds understanding among employees of how they should do the work.

The exercise is performed to make sure that after an improvement such as the implementation of the manufacturing cell of ProTack™, there are no organization issues. In addition, a 5s audit takes part of the Control phase which has been designed to be audited in different periods.

Plant	Process / Operation	Area	Date Prepared
Covidien, Ponce	Protack Assembly	Clean Room 1A	July-09



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	Helix Manual Tranfer	12.87			
3	Load Helix to Tube / Insp. Helix Position	20.33	0	37.29	24.9
4	Leak Test/X-Ray Insp.	29.85	1.2	0	24.9
5	Assm. Spring to Ratchet Gear & Idler Gear / Assm. Bevel Gear, Ratchet Clutch & Drive Shaft	21.33	0	0	24.9
6	Build Units	34.85	0	0	24.9
7	Build Units	34.85	0	0	
8	Weld Body / Dry Fire/Clean Inst.	24.03	1.2	2.5	24.9
9	Blister Pack / Seal / Inspect	26.75	0	8	24.9
10	Apply Patient Label to lid / Pack in D.B. & S.C	32.55	3.2	0	24.9

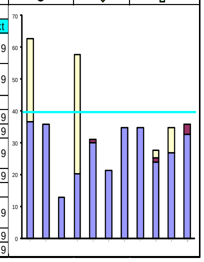

Figure 7
New Standard Balance Worksheet

Phase V. Control

The CONTROL phase is the conclusion of the team's journey. As part of the Fixation Device continuous improvement journey, the team implemented various tools: 5S Audits, Lean Audits and Kaizen Newspaper.

The 5S audit is a tool in which the cleanness is created and maintained. The systematic 5S audits were developed to ensure direct participation in all levels: **Daily:** Line employees and/or Team Leader; **Weekly:** Supervisor; **Monthly:** Superintendent; **Trimestral:** Staff Members.

The Lean Audit is another powerful tool to visualize if the implemented tools are maintained or improved. The scores are tied to the process owner's performance (refer to Table 3). For all the metrics showed in the table, a criterion is determined to make an objective audit. This criterion is adjusted for the production areas, to make this simple and easy to follow. This tool is also used to measure the gap between current lines execution vs. optimal scores.

The Kaizen Newspaper is a collection table which contains all the opportunities identified by area. This is a powerful tool to prioritize the optimization activities at the line.

Table 3
Lean Audit Example

Auditoria Mensual para Celulas
Supervisor: **Rafael Rodriguez / Gladys Leon**

		PSC 130	Puntuación
		Si	
Herramientas	Evaluar		
Head count	Propuesto (Head count vs. Product quantity)		
Continuous Flow	"One piece flow" excepto en estaciones de acumulación con Std WIP		
	Estaciones acorde el layout (Sentado / De pie)		
TPM	Colocado en la estación o en la máquina		
	Checklist actualizado		
Work Instructions	En todas las estaciones		
Pitch Boards	Actualizado cada hora		
Standard WIP	En área del KANBAN		
	Cantidades acorde con las tarjetas		
KANBAN	Verificar tabla de piezas vs. inventario fisico (al menos 5 piezas)		
Eficiencia & OPE	Verificar "spreadsheet"		
Kaizen Newspaper	5S, TPM, Pitch Board, OPE/OEE, SMED y otros		
Follow up	5s		
	Eventos Kaizen		
	Entrenamientos		
	Binder		
Analisis de Demanda	PQ Analisis actualizado (Takt time)		
	Analisis de Demanda de Materiales		
Value Stream Map	Product / Process Matrix		
	Estado Actual VSM		
	VSM Futuro		
	Total		

CONCLUSION

This research demonstrates that the Lean Six Sigma philosophy is one of the strongest methodologies in the current industry environment. One of the advantages of the Lean Six sigma philosophy is the diversity of tools to address any opportunity no matter which type of process.

This project was focused in the integration of the lean philosophy to obtain better results in the optimization of the line. It demonstrates that lean fits on every activity of improvements. In this case, the team identified that the line needed a better layout to eliminate overproduction and reduce labor requirements.

The proposed objectives in the Project Charter were accomplished. The number of operators was reduced from 24 to 10 for two (2) shifts. Also, the PPMH was increased from 3.98 to 4.47, reducing the overproduction of the previous layout. In addition, the efficiency of the line was improved from 88% to 94%, 1% short to the goal, however, it is a great improvement.

Also, the utilization of the other tools, such as the Standard & Balanced Work, Autonomous

Maintenance and 5S Audits, helped to improve the line productivity by different angles. Most important in this process is the involvement of all level resources; the regular participation motivates all level employees to improve the production areas. This is the key of the lean philosophy and line optimization subsequent integration.

REFERENCES

[1] "COMMONWEALTH OF PUERTO RICO Financial Information and Operating Data Report June 8, 2012". Government Development Bank for Puerto Rico, Retrieved on June 20, 2012 from http://www.gdb-pur.com/spa/documents/commonwealthreport.pdf

[2] "Surgical Success", *Industry Today*. 2007. 8(2), Retrieved on December 21, 2012 from www.industrytoday .com/article_view.asp?ArticleID=827

[3] Autosuture Online (2012). ProTack™ Fixation Device. Retrieved on May 11, 2013 from http://www.autosuture.com/autosuture/pagebuilder.aspx?webPageID=0&topicID=7418&xsl=xsl/productPagePrint.xsl

[4] Womack, J.P., *et al*. (2003). "Lean Thinking", *Free Press, 2003, p. 352*

[5] Meyers, F E., *et al*. (2002). "*Motion and Time Study for Lean Manufacturing*". Columbus, OH: Prentice Hall.