The Application of Lean Tools Using the Plan-Do-Check-Act Cycle

Felix R. Rodriguez Muñoz
Manufacturing Competitiveness
Rafael Nieves, Pharm D.
Industrial Engineering Department
Polytechnic University of Puerto Rico

Abstract *—— This kaizen event is going to illustrated how to apply Lean principles and tool using the PLAN-DO-CHECK-ACT methodology. Throughout the project it will be demonstrated how important the Lean principles are for the medical device industry in general. The labor cost, efficiency and the quality of the product are the most important aspects of production. This project was design to targets this areas of the manufacturing environment. The Next Generation Balloon cell was set up to produce certain quantity of units with the require demand at the time of it develop. At this moment the demand has change and some changes need to be made. After a team was build and all the data was recollected a new Takt Time was calculated and from that result many changes were executed. It will be demonstrated that not only the pre determined goals are achievable but how new goals were developed throughout the event. The benefits of this project will help the company to maintain it cost in control and to be more competitive in the market of the medical devices. The result will show how the PDCA help the implementation of Lean techniques.*

Key Terms *— Lean manufacturing, Medical Device, PDCA, Space Maker Balloon.*

INTRODUCTION

In the new global economic market competition for the lowest cost in the manufacture of medical devices has made the first priority of corporations. The implementation of methods to improve or take advantage of modern production has led companies to innovate and evolve. Today competition comes from companies not only from without but also from the same internal branches located in countries where the cost of the work of operators is much lower than in Puerto Rico (PR) meaning that the local market have and are obligated to seek ways compete with these countries that are as close as the Caribbean or the companies would leave PR as have many of them. The techniques of Lean Manufacturing (MFG) developed for the car industry have been modified and adapted to be implemented in all types of operation including medical devices. These implementations provide a mechanism to improve quality and maintain low operating costs including labor and cycle time.

RESEARCH DESCRIPTION

This project will illustrate the implementation of these tools and how they seek to improve the cost of labor and the productivity of a production cell. The PLAN-DO-CHECK-ACT (PDCA) cycle is a methodology that is applied in Lean Manufacturing projects to effectively direct Kaizen events in the medical device environment of cell production. The importance of the PDCA is to advance and maintain the improvements that are implemented throughout the Kaizen.

RESEARCH OBJECTIVES

A Value Stream Map (VSM) was created to determine the Value Added (VA) and Non Value Added (NVA) activities this of the production cell. From this VSM is where the goals of this project are taken. The purpose of this project is to reduce labor costs, improve productivity and implement a materials management system using the tools of Lean MFG. When the company made the approach to the MFG group of the concerns of how the labor cost is too high the group come to the concluded that every employee need to contribute with

something that help the company to stay competitive. Every aspect of cost of production in the process was examined and came to the conclusion that the labor cost and material allocation are the two characteristic of the cell that can be improve with less effort and investment of money. Also the education of the operators in maintaining low cost and an improvement culture was one of the targets of the project.

RESEARCH CONTRIBUTION

A project like this is implemented and the benefits are immeasurable, the main target of the transformation is the productivity of the operators that is expected to be increase from 5 units per operator per hour to 7 units per operator per hour. The inventory of raw material on hand is also one of the areas that are going to be improved, the reduction in inventory estimated in a 40% base on the quantity of raw material existing in the cell at the moment of the plan. By adding visual aids and a cross training matrix the quality of the line is anticipated to improve as well, the cell yield is to be increased by 3% in comparison to the base line. What the team think is one of the mayor impacts is in the culture of the operators of the company because the knowledge that is pass to the people in the production floor is incredible. Every time that there is something that is causing issues everybody is thinking on how to fix it, the flow of ideas in the project hopper is more likely to increase every month after the fact. The solution to problems and potential problems in the day to day operation is anticipated to be running flawless and the horizontal deployment of the PDCA program in projected to be spreading trough out the company in the coming months. The program has brought expectation to the company management to gain growth but with the contribution of more profitability in the production operation.

LITERARURE REVIEW

The medical device product that we are going to work in this project is a balloons endoscopic instrument. The Space Maker Balloons (SMB) is use in the abdominal area and is design to first explore and then give the surgeon access the peritoneal cavity. See Figure 1. The instrument consists of combinations of 2 dissectors and 2 access devices integrated into a single, modular device. Once the surgeon gain access to the interior of the patient he can introduce different kinds of laparoscopic instruments in to the cavity, to staple, to cut, to grasp, to take specimens, etc. See Figure 2. [1]

Figure 1
Spacemaker Balloon

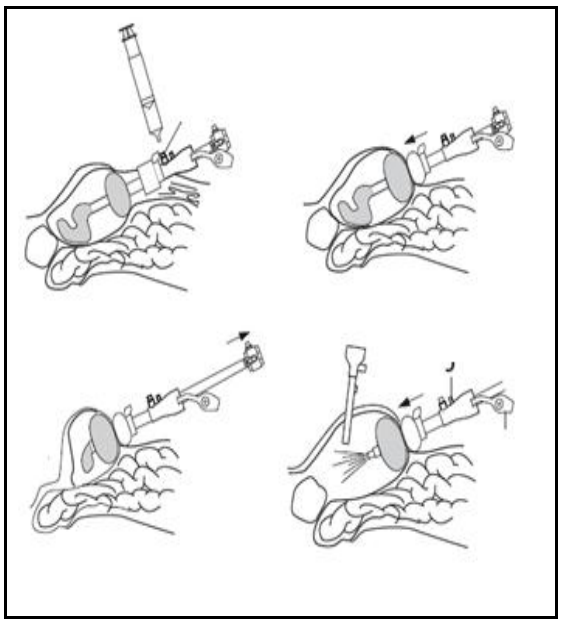


Figure 2
Source: Product Info Book

Product Application

The product is runs in a cell that uses 20 operators, with a production output of 100 pieces per hour and a 36 seconds Takt Time (TT). TT is the measurement that lean apply to the production cell that tell us when the costumer is pulling inventory from our warehouse (WH). One of the problems that the cell is showing is that the output of the cell by hour is more than the actual TT is asking. The lot size of the product is 500 units and when the line reaches that number a changeover is needed to start with the next lot. The down time (DT) of the changeover is about 30 minutes and at the end of the shift the lot remains open to be finishing in the next day and that is a problem because the operators need to be transfer to other production cells causing more DT. When the Team Charter (TC) was created only two areas were target. See Table 1.

Table 1
Targets for Improvements

Metric	Baseline	Target
Yield	90%	93%
Inventory	$12K	50% reduction
Labor Cost	$2.65 per unit	$2.25 per unit
Productivity	5 units per hour x operator	7.5 units per hour x operator

The industrial revolution of the 1880's gives birth to mass production systems that started by Henry Ford in the production of cars and later develop in Japan by Toyota. Lean Manufacturing is a technique that was developed by Toyota in the 1940's after the World War II (WWII). Japan was confronting difficult economic problems after the WWII and they can compete with countries like United States (US). Japan was passing through difficult times after WWII and the philosophy was making more with less. The elimination of *MUDA* or waste apply by lean techniques is the heart and soul of Lean. The introduction of Quality System develops by W. Edward Deming, Kauro Ishikawa, Genechi Taguchi, Shigeo Shingo and others started a revolution that changes the production industry not only in cars but in every aspect of production and still transforming the way that we produce in the modern world. In the 1990's was the decade were Lean kind of took of around the world and spread in every country that was producing in mass quantities, not only cars but everything. Lean evolved in to every industry including the medical device industry. Our company started introducing lean techniques in the mid 1990's by outsourcing experience people that have work with lean especially in Japan with Toyota. From that point the company has establish its own lean department that is call Operational Excellence (Opex). In this department is where the employees of the company learn to use and implement lean techniques thought out the production areas in principle. Opex has adopted the PDCA methodology to apply lean across the company. Once you plant the seed of lean it will flourish to every corner of the company. [2]

The PDCA cycle first created by Walter Shewhart while working for the Bell laboratories company in the 1930's and then develop by Dr. Edward Deming in the 1950's referred as the Shewhart cycle or the Deming wheel is a corrective action tool to troubleshoot processes.

METHODOLOGY

In this project the team is going to use the PDCA cycle to implement the Lean Tools pursuing the company lean system in four stages as follow:

1. Plan stages (This is performed during the two weeks previous to the event):
   - Building a team.
   - Kaizen logistics.
   - Quality and safety prevention.
   - Stakeholder analysis.
   - Startup metrics.
2. Do stage (This is performed during the week of the event) see Table 2:
   - Baseline understanding.

Table 2
Week Event Agenda

	Day 1 Current State	Day 2 Future State	Day 3 Heavy Lifting	Day 4 Bring It Together	Day 5 Sharing Actions and Plans
AM	**Review Agenda - Day 1** Review Stakeholder Analysis and Communication Plan Measure the Current Process as it exists today: – Review existing VSM (do not create a new map) – Discuss existing baseline metrics – Current Layout – Spaghetti Diagram – 5S Audit, including pictures – Waste Walk Observations Go and See	**Review Agenda - Day 2** Identify Gaps between the process today and the future state Develop new standard work for cell balance that addresses waste observations, spaghetti diagram observations, 5S audit, etc. Create Implementation Plan Simulate improvements with minor change and work aids	**Review Agenda - Day 3** Layout to new cell design Create standard work Train operators on new standard work Stabilize new process Collect time observations for new process Create new balance chart Make refinements	**Review Agenda - Day 4** Final Change is made Measure the improvements – 5S Audit – After Pictures – Compare with baseline metrics Develop Control Plans: – Standard Work – Visual Management – Communication Plan Discuss final metrics with facilitators and Financial controllers	Present Results to Leadership Celebrate
PM	Review Current Standard Work or SOP For each operator: – Determine Work Sequence – Time Observation Construct Balance Chart Create NVA/VA Analysis Create Standard Work Combination Sheet for semi-manual operations Create Agenda for Day 2	Run new standard work, measure new conditions Did you achieve One Piece Flow? Identify Gaps and develop new implementation plan Order supplies, Enter work orders for transformation Create Agenda for Day 3 Team Report Out to Staff and Class	Physical Change has been completed Running new process to make assessments of future state Pursue Perfection by improving on the new ideas Assess improvements for EHS, and Quality Concerns Create Agenda for Day 4 Team Leader Report Out to Staff	Develop Control Plans: – Standard Work – Visual Management Create 30 Day Action List Begin Final Report Presentation Practice Report Out	

- Identifying solutions.
- Plan implementation.
- Celebrate success.

3. Check stage (This is performed during the two weeks following the event):
   - Verify implementation.
   - Verify effectiveness
   - Monitor tendencies.
   - Communicate.
4. Act stage (This is performed throughout 3 month following the event):
   - Create countermeasures.
   - Look for new opportunities.
   - Continuous improvement.
     - PDCA again.

RESULTS AND DISCUSSION

In this chapter we will see how the Lean Tools are applied using the PDCA cycle in the Balloon cell and the results at the end of the project.

Plan stage

The project started by performing a startup meeting in wish the main objective is to plan the logistics of the Kaizen Event. The team goes through out a series of topics that include the safety prevention taking in to consideration that the team is going to be handling heavy machinery in the event. The quality of the product is the most important issue to be discussed because that is the main subject that cannot be jeopardize. An essential objective of the meeting is defining the team members and the tool that we use to do that is a Project Team Charter. In this document is stated mainly the team members, objective, scope, baseline and goals. See Table 3. Also a stakeholder analysis and communication plan document is created to have a better understanding of the impact of the event to the different support areas of the business.

Once the team is build a series of Lean MFG topics are discuss so they have a better understanding of what are the responsibilities and what is expected of them.

Table 3
Kaizen Event Team Charter

Value Stream/Focus Factory Owner	**Juan Lloveras**	**Contact Details**	**787-844-4526 ext.3615**
Kaizen Leader	**Felix R. Rodriguez**	**Contact Details**	**787-844-4526 ext.3576**
Champion	**Juan Lloveras**	**Contact Details**	**787-844-4526 ext.3615**
OpEx Facilitator	**Andres Rodriguez**	**Contact Details**	**787-844-4526 ext.3505**
Team Members	**Yahaira Roman MFG Assembler 2, Maritza Soto MFG Assembler, Lazaro Velez MFG Eng., Naida Luciano MFG Clerk, Jonathan Torres Q.A. Senior, Eluid Velazquez Eng. Mech., Mariela Arroyo Q.A. Eng., Evelyn Santiago PIC**		
Business Unit	**FF Endo/Acc**	**Site / Location**	**Ponce**
Kaizen Event Dates	**6/20/2011**	**Charter Rev Date**	**4/20/11**

Element	Description	Details	
1. Kaizen Event Name	**Unique identifier for event**	**Next Gen Balloon cell rebalance**	
2. Value Stream	**Identify which Value Stream the kaizen event supports**	**FF Endo/Acc**	
3. Kaizen Event Objective	**What improvement is targeted? ie: L/T or C/O Reduction, Productivity Increase, etc…**	**Productivity Increase**	
4. Kaizen Event Scope	**Start & end points of Kaizen Event.**	**Optimize the flow of codes (4) trough the cell operations.**	
5. Benefits of improving the Value Stream	**What is the rationalization for the Kaizen Event?**	**Reduce cycle processing time, set standard work, reduce labor cost and increase productivity.**	
6. Metrics	**Baseline metrics and targets so that improvements can be tracked**		
	Metric	**Baseline**	**Target**
	Yield	**90%**	**93%**
	Inventory	**$12k**	**50% reduction**
	Labor cost	**$2.65 per unit**	**$2.25 per unit**
	Productivity	**5 units per hr x operator**	**7.5 units per hr x operator**

For example 5'S, value stream mapping, waste walk observations, non-value added and value added analysis, time observations and task combinations, etc. The baseline metrics and main goals are conversed with the team so they can work with one thing in mind, the success of the project.

Do stage

Following the Kaizen agenda and to achieve the goal stated in the team charter a cell rebalances would be necessary in combination with other lean techniques. First we discuss the cell layout (Table 5) to get the team familiar with how many operators are in the cell. The cell at this moment has 18 operators for BTT Balloon and 20 operators for SBT Balloon assembly with a production standard of 100 units per hour. See Figure 3.

A spaghetti diagram is visual representation of movement or travel that is represented in units of measure, in this case feet. See Figure 4.

The diagram was draw to determine the travel distance that the cell team leader has to walk to the star up of the line to recollect machines parameters. In the processes there are 10 different machines or equipment that need to be document for parameters.

Even though the cell has a 5's system in place an audit was performed as part of the Kaizen event a three average were found. The founding's been collected in the line with the 5S methodology; See Table 5. [5]

- Seiri – Sort
- Seiton – Straighten
- Seiso – Cleaning
- Seiketzu – Standardize
- Shitzuke – Sustain

To identify the "Muda" (Japanese word for waste) a Waste Walk was performed using the Waste Walk Worksheet in the production cell were different types of waste were identified. The 8 forms of down time method was use and the following wastes were found. [4]

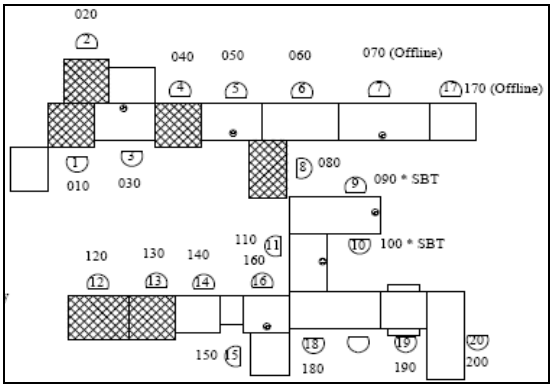


Figure 3
Cell Layout

Each letter of the word 'DOWNTIME" has a meaning for waste, see waste walk observations below:

Defect

- UV glue excess
- Leak Test
- Excess of glue on foams

Over Processing

- Obturators sub assembly
- Bulb sub assembly
- Foam sub assembly
- Check Valve sub assembly

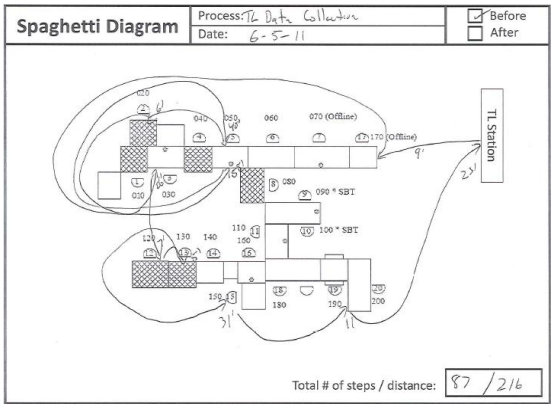
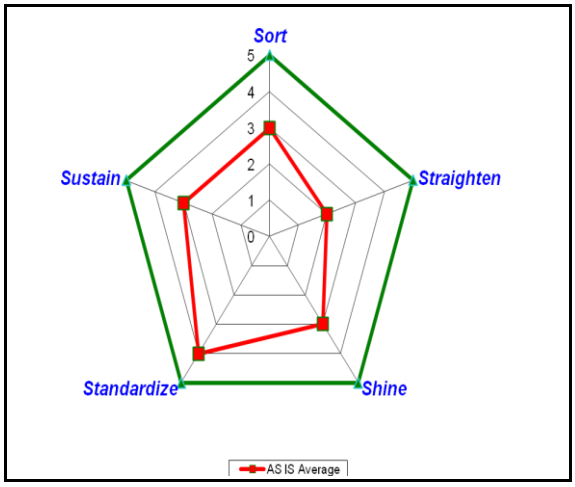


Figure 4
Spaghetti Diagram

Table 5
5's Radar



Waiting

- UV station
- Cannula Leak Test station
- Dissector Leak Test station

Non Utilize Personnel

- N/A

Transportation

- Packaging instruments

Inventory

- $9,000 inventory

Motion

- Bins too far away from the operators
- Foam gluing station

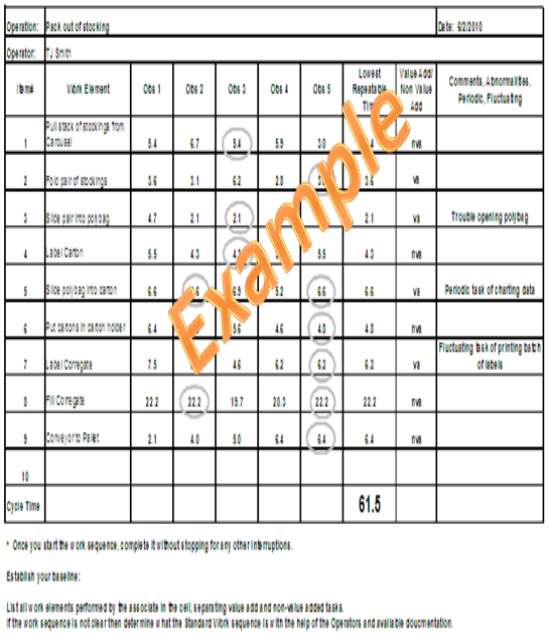
- Packaging operator

Extra Processing

- Locking collar operation – difficult to assemble
- Lubrication station

The team went to the cell and video tape each operator sequence for ten repetitions of its processes. This is to take the time observation without making the operators hesitant and put in question the time sequence of the operation and also to revise the Standard Operation Procedure (SOP) again the process. Once the videos are taken haft of the team went to a room to watch the video to take times of each operation and break them in elements. Out of the ten repetitions only five are selected, normally the selected ones are between the four and the eight, one team member watch and dictate the time and the other take notes. See Table 6.

Table 6
Time Observation Sheet



Operation:	Pack out of stocking								Date: 6/2/2010
Operator:	T. Smith								
Item#	Work Element	Obs 1	Obs 2	Obs 3	Obs 4	Obs 5	Lowest Repeatable Time	Value Add/ Non Value Add	Comments, Abnormalities, Periodic, Fluctuating
1	Pull stack of stockings from Carousel	5.4	6.7	5.4	5.9	5.0	5.0	nva	
2	Pick pair of stockings	3.6	3.1	6.2	2.0	3.6	3.6	va	
3	Slide pair into poly bag	4.7	2.1	2.1			2.1	va	Trouble opening poly bag
4	Label Carton	5.5	4.3	4.7		5.5	4.3	nva	
5	Slide poly bag into carton	6.6	6.6	6.9	5.2	6.6	6.6	va	Periodic task of charting data
6	Put cartons in carton holder	6.4		5.6	4.6	4.8	4.8	nva	
7	Label Corrugate	7.5		4.6	6.2	6.2	6.2	va	Fluctuating task of printing batch of labels
8	Fill Corrugate	22.2	22.2	19.7	20.3	22.2	22.2	nva	
9	Conveyor to Pallet	2.1	4.0	5.0	6.4	6.4	6.4	nva	
10									
Cycle Time							61.5		

* Once you start the work sequence, complete it without stopping for any other interruptions.

Establish your baseline:

List all work elements performed by the associate in the cell, separating value add and non-value added tasks.
If the work sequence is not clear then determine what the Standard Work sequence is with the help of the Operators and available documentation.

Once the time of the operations is determined we needed to calculate the actual Takt Time (TT) for the production cell. Using the product monthly demand and the time available for production during the same period of time to calculate the TT we use the following. See Table 7. [3]

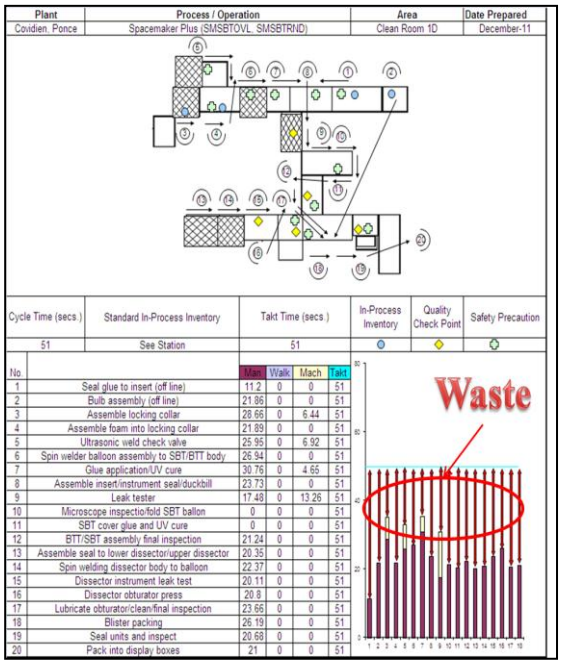
Table 7
Takt Time Calculation Template

8	Hrs per Shift x 60 Min. =
480	Minutes per Shift less
30	Minutes Lunche & break less
15	Minutes for clean up less
15	Minutes for other *planned* activities =
420	Sub total x __2__ shift =
420	Availables minutes per day
8	Working days per month
3,360	Available minutes per month x 60 sec./ min. =
201,600	Available seconds divided by __4,000__ monthly demand =50.4

Takt Time = __51__ sec/piece

Knowing now the real TT, a standard balance work sheet was created with the actual time of the operation to know the gap between the TT and the time of each operation to determine the waste of time that need to be deal with. See Table 8.

Table 8
Standard Balance Sheet



Using the time observations and the waste walk of the process 46 activities with VA and 56 activities with NVA where identified. Also a 90% yield of output was founded in the data that was collected for the product in the Defects per Million (DPM).

A gap analysis of the findings was created with the team and we came up with the followings recommendations. The most significant impact that needed to be developed was the line rebalancing. See Table 9.

Table 9
Gap Analysis and Recommendations

Metric	Baseline	Target	Key Action or recommendation
Yield	**90%**	**93%**	**Total Preventive Maintaines/ Work Instructions**
Inventory	**$12K**	**50% reduction**	**Pull System**
Labor Cost	**$2.65 per unit**	**$2.25 per unit**	**Line Rebalance**
Productivity	**5 units per hour x operator**	**7.5 units per hour x operator**	**Line Rebalance**
5's	**3**	**4.5**	**Audit form**
Spaghetti Diagram	**87 step/216 travel distance in feet**	**0 steps/0 travel distance**	**Line Rebalance**
Operators	**SBT 20/BTT 18**	**SBT 11/BTT 10**	**Line Rebalance**
NVA	**56 Activities**	**0 Activities**	**Line Rebalance/Pull System**

The team analyzed the recommendations and decided to start with the line balancing first by combining the process operation that were break in to elements. Here is an example of the combination processes, the operations 20 and 30 were combined in to one operation (operation 20) using a time study sheet. See table 10 (old operation) and figure 11 (new operation). By doing this combination the quantity of operator goes down from 20 to 11 in the SBT and from 18 to 10 in BTT.

The second technique implemented by the team was the Total Preventive Maintenance (TPM). See Figure 4.

Configurations that empower operators to performed by them self-maintenance and cleanings. This tool helps the yield of the process because the lack of TPM allows equipment to damage devices that at the end are accounted as scrap.

Table 10
Old Time Study Sheet

Spacemaker Plus Next Generation
Time Study Analysis

Current Balancing

Takt Time:	36	secs
Std. Prod.:	100	pcs/hr
Oper. Qty.:	20	ops.

Oper. #	Element Description	Time	Mach. Time	Perfor-mance	Allow.	Std. Time	Opers.
020	Separate the screen filter	3.92					
	Place the filter onto the Check Valve	4.55					
	Place the Check Valve with the filter into the BTT/SBT Body (10K-32911)	4.02					
	Place the BTT/SBT Body into welding machine and secure	2.28					
	Activate/Machine time		6.92				
	Remove from the machine	3.67					
	Place body assembly into Testing fixture	2.78					
	Test for air	2.50					
	Remove from fixture	2.23					
	Total	**25.95**		**100%**	**5.00%**	**27.24**	
030	Place Collar tube assembly onto the aligment post	2.97					
	Apply glue over the collar tube	6.57					
	Slide foam onto the aligment post	4.06					
	Slide onto the aligment post	2.39					
	Remove assembly from the fixture and Inspect foam	5.90					
	Total	**21.89**		**100%**	**5.00%**	**22.99**	

Also it allows the engineering personnel concentrate on other tasks such as predictive maintenance with precise facts of the top downtime issues in the cell.

Another tool implemented is the Visual Work Instructions. They were posted in each station of the cell. This tool reinforces operators' assembly understanding in each operation. This tool helps tremendously bringing down the defects of the production cell and in the training of operators. See Figure 5.

Table 11
New Time Study Sheet

Spacemaker Plus Next Generation
Time Study Analysis SBT

Current Balancing

Takt Time:	51	secs
Std. Prod.:	72	pcs/hr
Oper. Qty.:	11	ops.

Oper. #	Element Description	Time	Mach. Time	Perfor-mance	Allow.	Std. Time	Opers.
020	Separate the screen filter	3.92					
	Place the filter onto the Check Valve	4.55					
	Place the Check Valve with the filter into the BTT/SBT Body (10K-32911)	4.02					
	Place the BTT/SBT Body into welding machine and secure	2.28					
	Activate/Machine time		6.92				
	Remove from the machine	3.67					
	Place body assembly into Testing fixture	2.78					
	Test for air	2.50					
	Remove from fixture	2.23					
	Insert Foam Locking Collar over the Cannula/Place the Balloon (Cannula) sub-assy into locking fixture and Close Clamp Lever	11.18					
	Place BTT/SBT Body into Spin Welder driver	2.71					
	Activate Welder/Welder time	8.39					
	Total	**48.22**		**100%**	**5.00%**	**50.63**	

Seq	Area		Estado Ideal
1	Sensores de activación	Verificar [illegible] de la máquina.	Que este encendido.
2	Botón de emergencia	Verificar que detenga la máquina	Desactivado
3	Guarda de seguridad	Verificar que baje al activar la máquina	Hacia arriba
4	Válvulas de pega	Verificar que tire pega	Hacia arriba
5	Puntas de las válvulas	Limpiar el exceso de pega de las puntas	Libre de pega

Figure 4
TPM

The 5S audit is a gift the empowerments to the operators to maintained and keep the cell organized.

The 5S audits were developed to ensure direct participation in all levels:

1. Daily: Line operators and Team Leader
2. Weekly: Supervisor
3. Monthly: Section Heads
4. Quarterly: Managers

The involvement of all company members is very significant to visualize the area with different points of view because that allows for different form of problem solving techniques. The advantage of this tool is to recognize all the potential opportunities to upsurge productivity. See Figure 6.

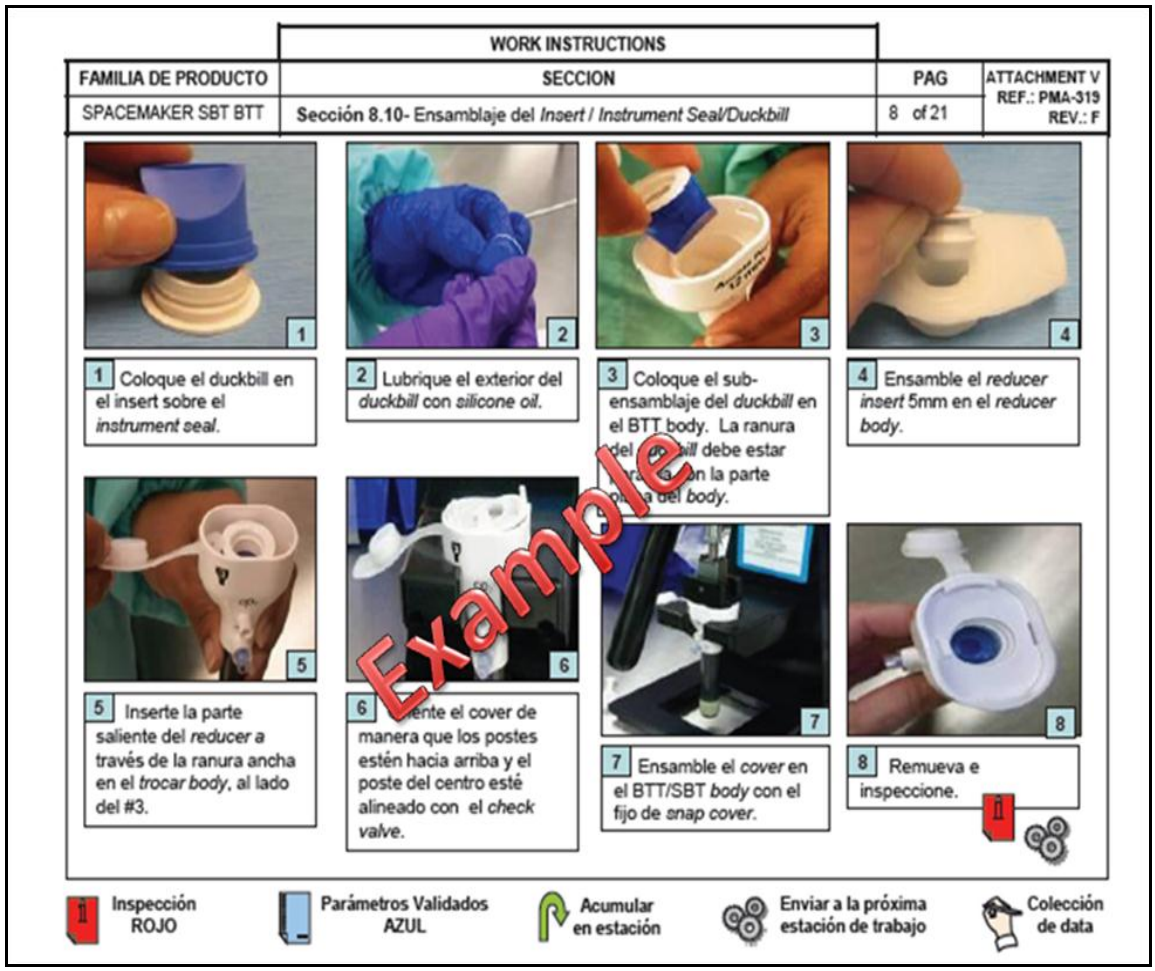


Figure 5
Visual Work Instructions

The first step to create an effective pull system is going through the process and use the VSM to see were the schedules, takt time, inventories, delays, transportation, waiting and lead time of the process are to determine what to change in order to implement the system. Then identify the possible areas were the opportunities are and the tools that can be apply. We also identify the quantities if the parts that the vendor are sending us to adjust then to our production quantities. Try to understand the materials flow of the product trough the company from the receiving of raw materials to the shipping of finished goods.

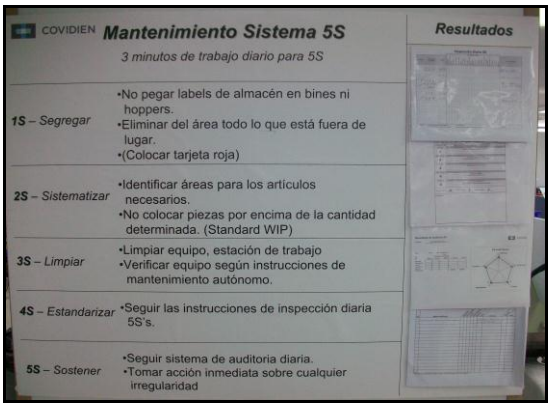


Figure 6
5's Maintain System

1. First we create routes, locations and reconciliation for the product families.
2. Determine the ideal quantities of parts needed to run the lines for a 10 days span.
3. Improve material requisitions time from warehouse to production.
4. New WIP zones for material storage in the production area.
5. Locate high volume materials in the low racks of warehouse.
6. Create pull systems standard works.
7. The use of cards to let the material handler what materials are going to be pull from warehouse to production.
8. The creation of standard WIP between cells.
9. Trained operators and materials on the importance and purpose of pull system.
10. Heijunka board to level the weekly demand.

The Results

After all the tools were applied this are some of the results and improvements of the process in the production cell;

This is the new layout with eleven operators. See Figure 7.

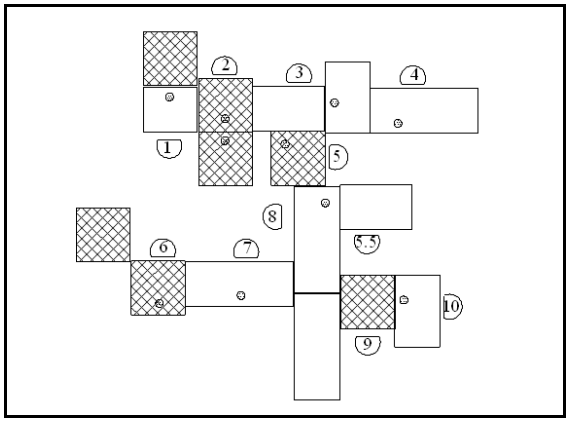
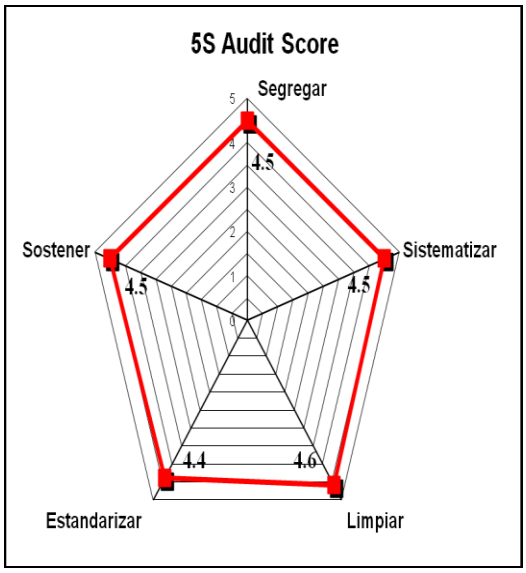


Figure 7
New Cell Layout

This is the new collection data sheet (see Table 9) for the equipment parameters for the production cell, this sheet is pass from one operator to another so the TL does not need to be walking through out production cell, reducing to cero the steps in the spaghetti diagram.

With the 5's audit form the average went up from 3 to 4.5. See Table 12.

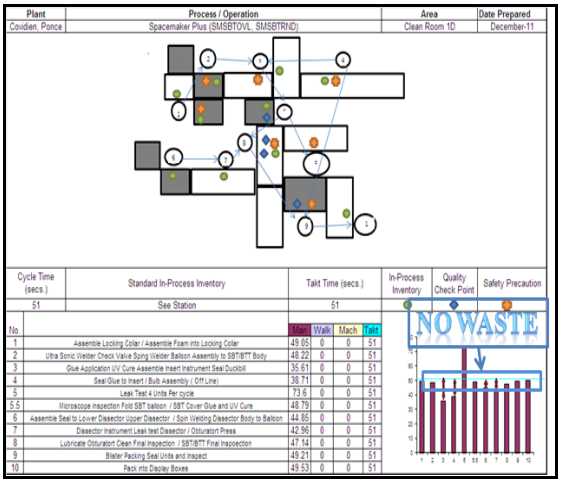
Table 12
New 5's Radar



As the new standard balance sheet shows the waste of the production cell in terms of time is reduced significally. See Table 13.

Table 13

New Standard Balance Sheet



Check stage

After the event is completed the team put together a follow up plan using an agenda to check the performance of the lean tools implemented in the production cell. Daily sunrise and sunset meeting are conducted with the operators to discuss the lean metrics and to brainstorm about new improvements. Also Monthly Lean Audit (see Table 14) was implemented where the process owner is given a score in which different areas of the production cell are monitor. The first eight shop order were monitor by the finance department with acceptable results (see Table 15). All the event goals were updated and out of eight targets six of them were achieved or surpass. Two of them are expected to address on new PDCA Lean Tools implementations. See Table 16.

Act stage

In this stage we use the Kaizen newspaper to follow up all the findings of the audits, ideas from operators, supervisor, quality personnel and all the suggestions that are made to keep improvement on the production cell. Also the monitoring of the financial numbers are according to the accomplishments and see if some of the metrics are not meeting with the projects achievements.

Table 14

Monthly Lean Audit

AUDITORIA MENSUAL PARA CELULAS ESTANDARIZADAS			
Supervisor: Félix Rodriguez / Jessica Mercado			
		Balloons	Puntuación
Herramienta	Evaluar	Sí	
Head Count	Propuesto (Head count vs. Product quantity)	3	3.25
Continuous Flow	"One piece flow" excepto en estaciones de acumilación con STd. WIP	2	2
	Estaciones acorde el layout (Sentado/De pie)	4	4
TPM	Colocado en la estación o en la máquina	5	5
	"Check list" al día	3	3
Work Instructions	En todas las estaciones	5	5
Pitch Boards	Actualizado cada hora	4.5	4.4
Standard WIP	Cantidades acorde con las tarjetas	3	3
KANBAN	Verificar tabla de piezas vs. inventario físico (al menos 5 piezas)	4	4
Eficiencia & OPE	Verificar "spread sheet"	4	4
Kaizen Newspaper	5S, TPM, Pitch boards, OPE/OEE, SMED y otros	3	3
Follow up	5S	3.5	3.8
	Eventos Kaizen	4	
	Entrenamientos	4	
	Binder	4	
Análisis de Demanda	PQ-Análisis al día (Takt Time)	5	5
	Análisis de Demanda de Materiales	3	3
Value Stream Map	Product/Process Matrix	5	5
	Estado Actual VSM	4	4
	VSM Futuro	1	1
	TOTAL	3.7	3.66

Table 15

Finance Report

Shop Order#	Item Number	Variance $ Amount	Labor Efficiency
130383	SMSBTOVL	$110.80	127.10%
131168	SMBTTRND	$315.91	153.40%
131180	SMSBTRND	$1,018.82	128.40%
131506	SMBTTOVL	$1,218.96	111.00%
131507	SMBTTOVL	$1,281.51	122.70%
132812	SMBTTRND	$1,606.67	116.10%
132813	SMBTTRND	$908.45	130.80%

132814	SMBTTRND	$1,419.76	161.40%
		$9,347.95	124.60 %
		Yield	96%

Table 16
Event Targets Goals

Metric	Baseline	Target	Key Action or recommendation	Results
Yield	90%	93%	Total Preventive Maintance/ Work Instructions	96%
Inventory	$12K	50% reduction	Pull System	45% Reduction
Labor Cost	$2.65 per unit	$2.25 per unit	Line Rebalance	$2.2 per unit
Productivity	5 units per hour x operator	7.5 units per hour x operator	Line Rebalance	7.5 units per hour x operator
5's	3	4.5	Audit form	4.5
Spaghetti Diagram	87 step/216 travel distance in feet	0 steps/0 travel distance	Line Rebalance	0 steps/0 travel distance
Operators	SBT 20/BTT 18	SBT 11/BTT 10	Line Rebalance	SBT 11/BTT 10
NVA	56 Activities	0 Activities	Line Rebalance/Pull System	20 Activities

CONCLUSION

In this project it was demonstrated how to apply Lean principles using the PDCA. At the start of the event only four goals were identified, and during the process of the tools four more additional goals were discovered. Yield and cost of labor were the goals with the most financial impact. The yield exceeded our expectations by three percent, where the goal was too improved from 90% to 93% and was increase up to 96%, achieving a financial benefit of $ 9.347, on the other side the labor efficiency was accomplished improving the efficiency of labor up to 124%. These improvements were noted in the first eight lots built. On the other hand the influence of the tools in the manufacturing personnel is very valuable. Focusing all efforts of all departments involved in the production process on the end user that is the client, which should be the ultimate goal of Lean. According to the PDCA the cycle never ends, after completing the project the team with the cell personnel quickly began to develop a plan to attack the goals of the project that could not be met and evaluate new opportunities not only in this work cell, but in other production areas by horizontal development the tools. Lean was developed in the automotive industry but as we demonstrated in this event it evolved into all industries. The benefits brought to the medical device industry have been immense worldwide.

REFERENCES

[1] Auto suture. Space Maker Balloon. Covidien Surgical. Retreived July 22, 2011, from http://www.autosuture.com/autosuture

[2] Womack, J.P., Jones, D.T. & Roos, D. (2007). The Machine That Change the World. New York, USA: Free Press.

[3] Yasuhiro M. (1998 Third Edition). Toyota Production System. Georgia, USA: Chapman & Hall.

[4] Womack, J.P. & Jones, D.T. (2003). Lean Thinking. New York, USA: Free Press.

[5] Juran, J.M. & De Feo, J.A. (2010 Sixth Edition). Juran's Quality Handbook. USA: McGraw Hill.