Coronary Guide Wires
Abbott Vascular

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Abstract — *Abbott Vascular produces guide wires which are designed to navigate vessels to reach a lesion or vessel segment. Once the tip of the device arrives at its destination, it acts as a guide so that larger catheters can rapidly follow for easier delivery to the treatment site. Guide wire manufacturing consists of diverse steps to obtain the final product. These manufacturing steps are upheld in two areas (Sub-Assembly [SA] and Finish Goods [FG]) where diverse types of metals are processed into becoming sub-parts of the whole wire to later be assembled. After being assembled and packed, they are delivered to the customer, which in this case they are doctors specialized in cardiology who utilize these guide wires.*

Key Terms — *Assembly, Guide Wires, Manufacturing, Metals.*

RESEARCH

There is a variety of guide wire models manufactured within Abbot Vascular known as Balance, Whisper and Universal. Therefore, different manufacturing processes are required. Balance Manufacturing, which is the focus of the project, has three different zones utilized to assemble and deliver the whole wire, which are: Soldering Zone, Adhesive Zone and Packaging Zone in that order.

Balance Manufacturing's input is equal to Sub-Assembly's output. The output contains sub-parts to be assembled and inspected in Soldering Zone, which are: Shaping Ribbon, Distal Wire, Tip Coil and Intermediate Coil.

Within Balance Soldering Zone, there are four lines with six manufacturing stations in a specific order, as seen in Figure 1, where each one has a different task to complete:

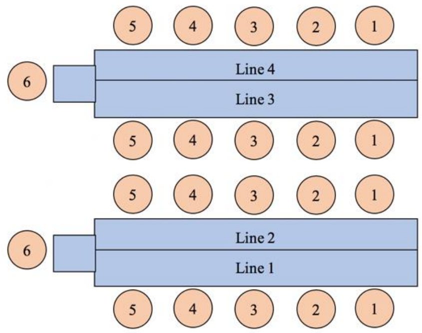

Figure 1
Balance Soldering Zone Process Diagram

- **Tack Solder (1)**: operator solders shaping ribbon together with distal wire.
- **Tip Attach (2)**: operator attaches tip coil with intermediate coil to then insert previously soldered shaping ribbon & distal wire within the two coils attached.
- **Tip Solder (3)**: operator solders the inserted shaping ribbon aligned with the end part of the tip coil.
- **Center Solder (4)**: operator solders the attachment of the tip coil with the intermediate coil.
- **Proximal Solder (5)**: operator solders the end part of the intermediate coil with the distal wire.
- **Wire 100% Inspection (6)**: operator performs a Tip Pull Test, a Proximal (Intermediate) Pull Test and a visual inspection of the whole wire seen in Figure 2.

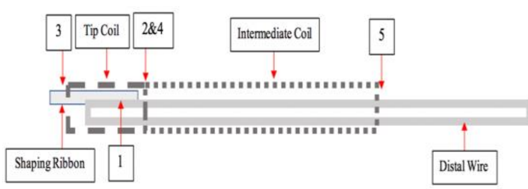

Figure 2
Final Assembled & Soldered Wire

DMAIC

To follow a structured process, DMAIC methodology was utilized, as seen in Figure 3. The DMAIC methodology is a rigorous and proven problem-solving approach that includes both a set of tools and a road map or sequence of applying those tools [1].

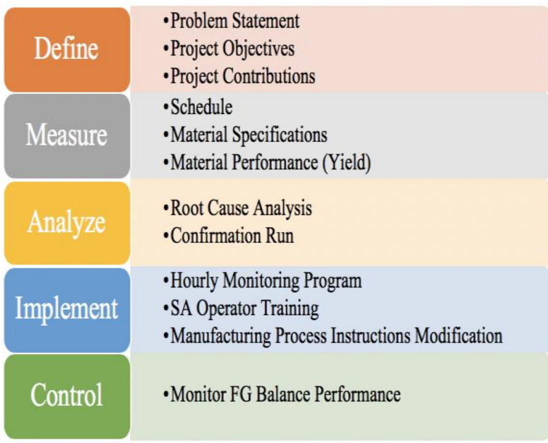

Figure 3
DMAIC Brakedown

DEFINE

The main focus of the define stage is to identify the problem in terms of critical to quality (CTQ) parameters [2].

Problem Statement

Balance Manufacturing yield has been lowered due to defects of coils identified at Soldering Zone Tip Attach station.

It has been acknowledged that, due to SA operator-related manufacturing procedures, the two coils (tip coil and intermediate coil) are arriving with defects and unwanted specifications making the operator's task difficult and occasionally causing wasted material (scrap). Therefore, Balance Manufacturing yield is lowered due to the amount of scrap being registered at Soldering Zone. The most coil-related scrap registered at Soldering Zone is known as "Coil Damage". A target yield was already determined to be at 97.5% for Balance Manufacturing, 99.1% for Balance Soldering Zone and 0.2% for Coil Damage. The current Balance Manufacturing yield is 95.3%, current Balance Soldering Zone yield is 96.4% and current Coil Damage percentage is 1.0%.

Project Objectives

To obtain an improvement within Balance Manufacturing, defects related to the coils that are coming from SA should be decreased. To evaluate in quantified terms, Coil Damage was targeted to decrease to 0.2%. In addition, Balance Line Yield and Balance Soldering Zone Yield were targeted to increase by 1% individually. All coil specification preferences should be determined and standardize within in-house Manufacturing Process Instructions (MPI).

Project Contributions

Once the objectives are accomplished, there is a noticeable productivity improvement while maintaining a continuous high yield. Along with high yield, there is a decrease in scrap units and operator variances.

MEASURE

The main objective during this stage is to establish the current performance of the process and measure the gap in the process performance and set target for improvement [2].

Table 1
PERT Breakdown

Task	*Letter*	*Predecessor*	*Start Date*	*End Date*	*Duration (Days)*
Determine Variables	A	-	1/21/19	1/25/19	4
Determine Coil Related Defects	B	-	1/21/19	1/25/19	4
Inspect Incoming Units	C	A, B	1/26/19	2/19/19	24
Collect Operator Feedback	D	A, B	1/26/19	2/19/19	24
Collect Coil Related Scrap Data	E	B	1/26/19	2/19/19	24
Confirmation Run Planning	F	C, D, E	2/20/19	3/14/19	22
Confirmation Run Execution/Analysis	G	F	3/15/19	3/20/19	5
Collect Production Impact Data (Universal vs Balance)	H	G	3/21/19	3/25/19	4
Collect Production Impact Data (Current Spec vs Rec. Spec)	I	G	3/21/19	3/25/19	4
1st Shift Training	J	G, H, I	3/26/19	4/4/19	9
2nd Shift Training	K	J	4/4/19	4/13/19	9
MPI Modification	L	J, K	4/13/19	4/30/19	17
Monitor Balance FG Performance	M	J	3/26/19	5/20/19	55

Schedule

Per Table 1, it is noticeable that the most time-consuming tasks would be C, D and E. These tasks can also be considered high-risk because of the importance of inspecting the units to know exactly what defects are arriving to FG Balance Manufacturing, know what these defects cause the operators trouble and determining what scraps are exactly related to the coil defects. Otherwise, the project might pursue a different resolution hunt rather than rapidly confronting the correct problems.

Material Specifications

In the initial evaluation of the Tip Attach station, the operator's task will be dependent of the tip and intermediate coils variables, seen in Figure 4 and Table 2. Each variable has its own specification already established in current Manufacturing Process Instructions (MPI).

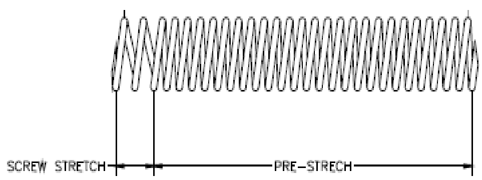

Figure 4
Coil Diagram

Table 2
Tip/Intermediate Coil MPI Specifications

Tip Coil		
Variable	**Specification**	**Tip Attach Comments**
Number of Turns: number of significant spaces in screw stretch.	0.5-2	If 0.5, attachment will cause waviness *Desired Spec: 1-2*
Pitch: amount of space in the screw stretch.	0.0058 in	No major issues
End Cut: finishing of the end of the stretch.	Diagonal Cut	Causes overlap of coils *Desired Spec: Perpendicular Cut*
Intermediate Coil		
Variable	**Specification**	**Tip Attach Comments**
Number of Turns: number of significant spaces in screw stretch.	0.5-3	If 0.5, attachment will cause waviness If 3, overlap of coils or waviness occurs *Desired Spec: 1-2*
Pitch: amount of space in the screw stretch.	0.0050 in	No major issues
End Cut: finishing of the end of the stretch.	Diagonal Cut	Causes overlap of coils *Desired Spec: Perpendicular Cut*

Material Performance (Yield)

Once acknowledging the coil variables and issues, collecting incoming lots to FG Balance from SA and segregating the ones with desired specifications from the ones with troublesome specifications was initiated. This task lasted 24 days (Collect Coil Related Scrap Data, per Schedule) and during this period, as seen in Figure 5, 29 lots were captured with undesired specifications along with 37 lots with desired specifications, as seen in Figure 5.

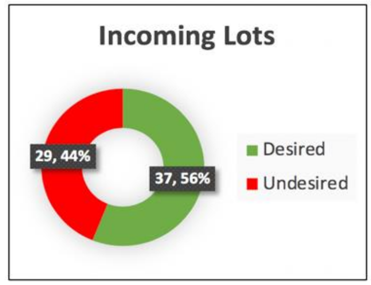

Figure 5
Lot Distribution of Desired/Undesired Specifications

Each lot was identified with the operator who performed the coil cutting and, as seen in Figure 6, there is a distribution of 10 operators from SA. There is a tendency by 3 operators (A, B and C) who are more common to perform the coil cutting with undesired specifications than the other 7 operators.

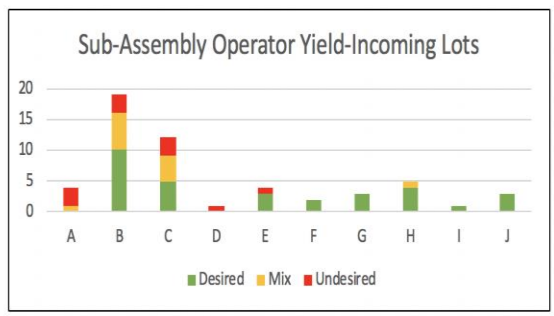

Figure 6
SA Operator Lot Distribution

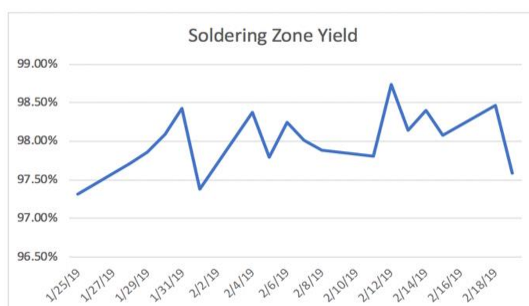

Figure 7
Soldering Zone Yield (Jan-25 to Feb-19)

During this period, Soldering Zone Yield and Balance Line Yield were monitored as seen in Figure 7 and Figure 8. The Balance Line Yield only met its target of 97.5% twice having an average of 96.1% and Soldering Zone Yield never met its target of 99.1% having an average of 98.0%. As for Coil Damage percentage, during this period, it never met its target of 0.2% as seen in Figure 9.

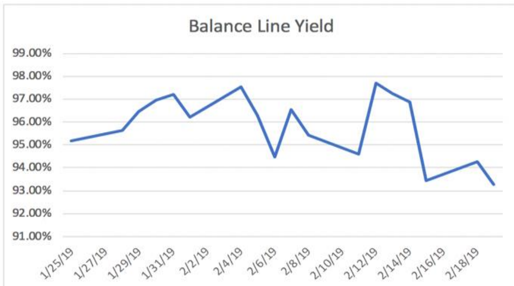

Figure 8
Balance Line Yield (Jan-25 to Feb-19)

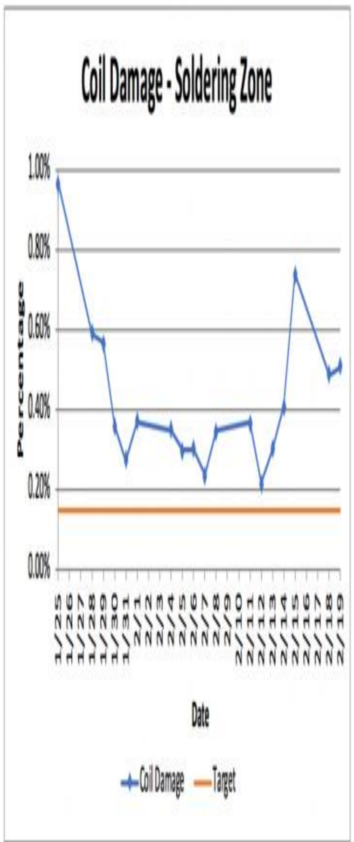

Figure 9
Coil Damage Percentage (Jan-25 to Feb-19)

ANALYZE

The causes for performance gap measured in terms of CTQs are identified and solutions to the problems are generated [2].

Root Cause Analysis

- **Balance Operator Mishandling:**
  - Situation: In occasions, the operator might damage the coil if they are in a hurry to meet the hourly demand.
  - Solution: create an Hourly Monitoring Program to identify when it is more likely to find a high volume of Coil Damage or any other scrap data.
- **SA Operator Technique**:
  - Situation: It has been identified that the most problems with the coil specifications come from the coil cutting performed by operators of the 2nd shift. The technique used by operators of the 1st shift is more effective.
  - Solution: Create a Cross-Training Dynamic between the 1st and 2nd shift operators where the operators from the 1st shift share their knowledge and technique onto the 2nd shift operators.
- **Tip/Intermediate Coil Specifications:**
  - Situation: The specifications established in current MPIs is not the most efficient instructions and coil specifications for the operators to follow.
  - Solution: Modify the current MPIs with the desired coil specifications (Number of Turns & End Cut) and add more visuals/figures to make it error-proof.

Confirmation Run

A Confirmation Run was performed to be certain that the undesired and desired coil specifications are correct. In order to perform this Confirmation Run, 100 units of tip and intermediate coils with desired specifications were separated and inserted into the Soldering Zone for processing. Likewise, 100 units of tip and intermediate coils with undesired specifications were inserted in into the Soldering Zone to also be processed. As expected, the units with desired specifications performed with a higher yield and better processing time at Tip Attach, as seen in Table 3.

Table 3

Confirmation Run Specifications and Results

Confirmation Run			
Desired Specs (1-2 Turns)		Undesired Specs (0.5 & 3 Turns)	
Units	100	Units	100
Scrap	0	Scrap	5
Tip Attach Time	27min	Tip Attach Time	37min
Theoretical Tip Attach Rate	220	Theoretical Tip Attach Rate	160
Current Rate	170	Current Rate	170

Having confirmed that the desired specifications have a more efficient performance, the solutions for the Root Cause Analysis can be initiated.

Implement

The main focus during this stage is to implement the solution to the problem identified during the define stage and target set during the measure stage [2].

- **Hourly Monitoring Program**

To avoid operator mishandling the units during the soldering process, an Hourly Monitoring Program was created to observer information of how the soldering zone behaves. If an operator registers to the program a Coil Damage or any other scrap, the manufacturing engineer will receive this information. In addition, the manufacturing engineer can identify which soldering line has a poor performance and be more watchful of this specific soldering line.

Furthermore, by accumulating these hourly data, the manufacturing engineer will have a better understanding of which hour the operators are more likely to register Coil Damage or any other scrap data. With this information, the manufacturing engineer can react in a timely matter to solve why there was a Coil Damage registered by knowing the peak hours of scrap data.

After viewing the Hourly Monitoring Program, the hours where the operators are more likely to have a low yield performance is at the 4^{th} and 8^{th} hour. Therefore, the manufacturing engineer should be more watchful during these hours.

- **SA Operator Training**

As previously mentioned, 1^{st} shift operators have better performance than 2^{nd} shift operators. However, certain discrepancies in their technique to cut coils were noticed between them, such as how to count the number of turns within the screw stretch. Therefore, after a counting alignment was performed with the 1^{st} shift operators, pre-planned Cross-Training between both shifts was initiated.

One operator from the 2^{nd} shift was brought down to 1^{st} shift to establish a learning dynamic with the 1^{st} shift operators. They shared techniques, suggestions were given, and test runs were performed by the 2^{nd} shift operator to be evaluated by the 1^{st} shift operators.

After successfully training one 2^{nd} shift operator, this operator shared all the acquired knowledge with the other 2^{nd} shift operators. Hence, Cross-Training was completed.

- **Manufacturing Process Instructions (MPI) Modification**

All SA operators follow a specific MPI to know how to perform their tasks, in this case a coil cutting MPI for Balance Manufacturing. The feedback provided by SA operators is that such MPI has uncertain instructions and figures. Other than that, the format provided throughout the MPI is not easy to follow.

To make coil cutting MPI for Balance Manufacturing error-proof, the format was reconfigured, instructions were modified, and figures were added to make the instructions more graphic. After implementing all these changes, the approval of the operators was received to make the new MPI an official document and possibly adapt the same changes to other models.

Control

In the control stage of the DMAIC cycle several statistical tools are used to sustain the quality improvement achieved using the previous four stages [2].

- **Monitor FG Balance Performance**

After successfully implementing all three solutions brainstormed during Root Cause Analysis, a re-evaluation of FG Balance was executed to determine if such solutions were effective.

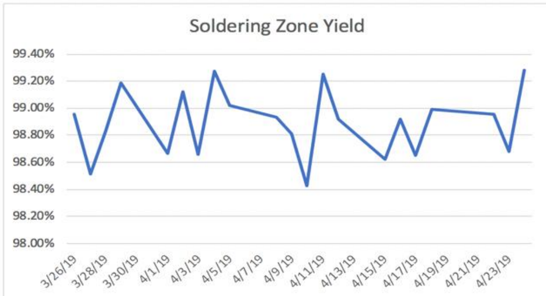

Figure 10
Soldering Zone Yield (March-26 to April-24)

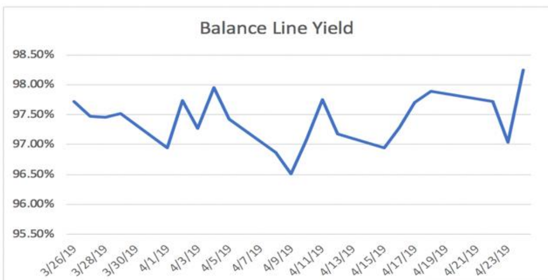

Figure 11
Balance Line Yield (March-26 to April-24)

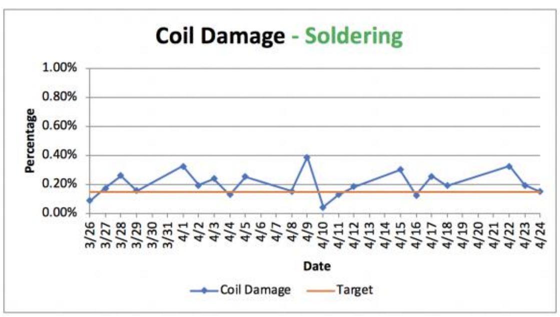

Figure 12
Coil Damage Percentage (March-26 to April-24)

Ever since 1st shift SA operator training began, an improvement was observed on all three evaluations of Soldering Zone, Balance Line and Coil Damage.

For the Soldering Zone, the target yield of 99.1% was met five times as seen in Figure 10 having an average of 98.9%. Comparing the average of the initial evaluation (98.0%) with the last evaluation (98.9%), an increase on 0.9% was accomplished. For the Balance Line, the target yield of 97.5% was met nine times as seen in Figure 11 having an average of 97.4%. Comparing the average of the initial evaluation (96.1%) with the last evaluation (97.4%), an increase on 1.3% was accomplished. For the Coil Damage, the target percentage of 0.2% was met nine times as seen in Figure 12 and maintaining a tendency closer to the target. Acknowledging all these improvements, it can be concluded that all project objectives were accomplished. Therefore, acquiring all project contributions for Abbott Vascular Balance Manufacturing.

RECOMMENDATIONS

At first, there is an urgency to solve the problem. This sensation might delay finding an actual solution since there is a procedure to be understood before realizing a response to how to solve the problem.

Analyzing operator complications requires the understanding of how and where the defects are found during the manufacturing process. Therefore, it is recommended to study the manufacturing process to later develop a root cause analysis.

FINANCIAL EVALUATION

The current target of units to be produced in Balance Manufacturing is 4,500 units along with a target yield of 97.5%. Based on the initial average yield (96.1%), 4,323 units were being produced. Having an increase of 1.3% in the final average yield (97.4%), 4,383 units were being produced. Therefore, Balance Manufacturing had an increase in production by 60 units. Each unit costs $3.39 to be produced. Consequently, Balance Manufacturing started saving $203.40 per day due to the 1.3% increase in yield. Assuming only 5 working days per week and continuous yield, it is equivalent to $1,017 per week and $52,884 annually.

CONCLUSION

Balance Manufacturing accomplished an efficiency improvement in three evaluations: Line Yield, Soldering Zone Yield and Coil Damage Percentage. Coil Specifications were standardized, which minimizes inconsistencies between SA and FG Balance. In addition, Cross-Training between SA 1st shift and 2nd shift also decreased inconsistencies between operators. Modifications to current MPI's will help future operators have a better understanding of the adequate manufacturing process. These improvements will continue to be monitored to avoid any possible rework.

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