



ELIMINATION OF PEEL OFF UV ADHESIVE ON UV SHOULDER RMA DEFECT IN CATHETER ASSEMBLY

Lyka Mae D. Quillosa
Jaime Miguel C. Agustin

Medical Device Assembly Business Unit- Engineering Department
P.IMES Corp., Block 16 Phase 4, CEZ Rosario , Cavite
quillosa@pimes.com.ph, jagustin@pimes.com.ph

ABSTRACT

For FY2021, the top Return Merchandise Authorization (RMA) visual defect is **Libero SG model peel off UV adhesive on UV Shoulder**.

This catheter model, UV Adhesive plays an important role on the unit since it supports the other parts to be intact with each other and enables to complete the whole function of Libero SG Catheter in identifying the location inside the heart that causes *arrythmia*. Catheter Assembly production ensures that the UV Adhesive applied on the single lumen side and UV Shoulder must be in good condition with **no flakes** and **damage** that causes peel off during heart operations. Using basic QC tools and techniques, the team identified the potential root causes that have a major contribution on the said defect occurrence, And observed significant effect on eliminating RMA occurrence related to peel off UV Adhesive defect after series of verification and implementation of actions.

1.0 INTRODUCTION

Cardiac catheterization is a procedure used to diagnose and treat cardiovascular conditions. During cardiac catheterization, a long thin tube called a catheter, see fig. 1, is inserted in an artery or vein in the groin, neck or arm and threaded through the blood vessels to the heart. Each catheter product has different or specific functions, such as for detection, for reviving and for treatment of arrhythmia. Wire and ring terminals are one of the major part of the device since it serves as the passageway of electrical signals for treating and diagnosing heart diseases.

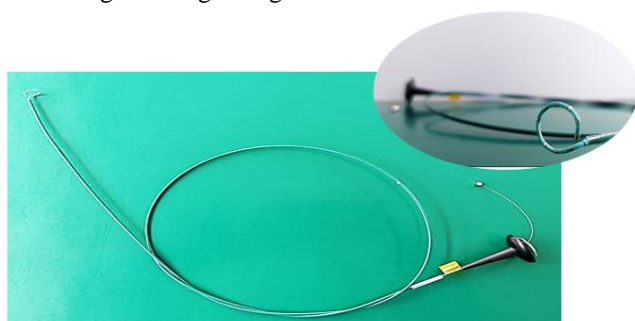


Figure 1. Cardiac catheter – Libero SG Model

1.1 Problem Statement

The company's target is to reduce the Highest Return Merchandise Authorization (RMA) quantity and the defects that can impact mostly to the patient's health if occurred.

In regards to the above company's target, shown in Figure 2, Visual Related Defect has the highest RMA defect occurrence feedback by customer JLL (Japan Lifeline), with **41.45%**.

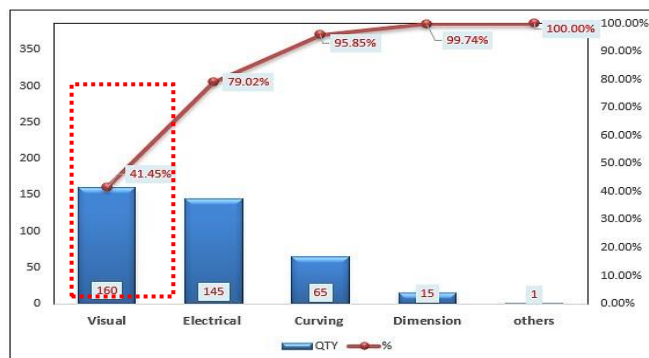


Figure 2. Visual Related Defect Trend

With the graph being presented, Based on the Visual defect per model (shown in Figure 3), **Libero SG** model has the highest visual defect quantity with **102 pieces** from **December 2020 to November 2021**.

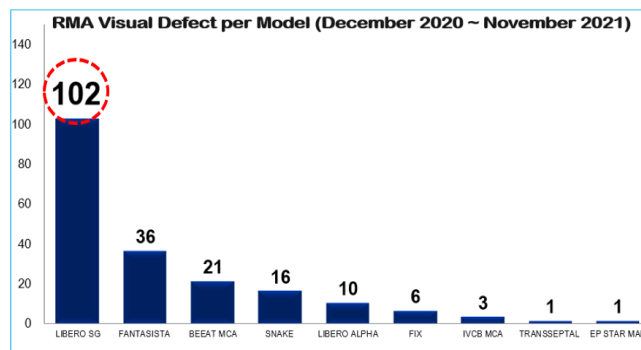


Figure 3. Visual Related Defect per model

Upon presenting above graph's, all the visual related defect in model Libero SG in RMA, Peel off UV Adhesive on UV Shoulder has the highest defect rate with **61 out of 102 pieces - (0.61%)** being feedbacked.

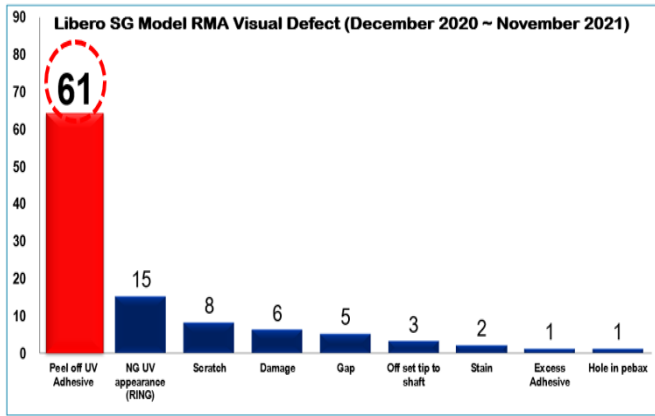


Figure 4. Libero SG Visual Related Defect

Based on the gathered data, this project will focus on **Libero SG Peel-off UV adhesive on UV Shoulder**.

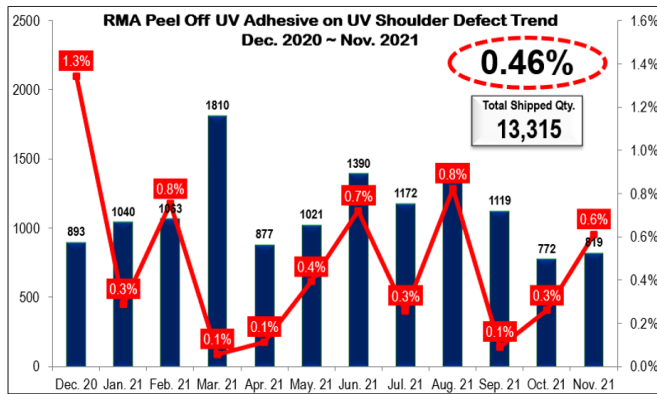


Figure 5. RMA Peel Off UV Adhesive on UV Shoulder Defect Trend (Dec. 2020 ~ Nov. 2021)

Upon identifying the highest RMA Defect for FY2021, Figure 5 shows, the Peel Off UV Adhesive on UV Shoulder Monthly Trend with varying defect rate of 0.1% to 1.3% defect rate with an overall rate of **0.46%**.

Therefore, RMA defect rate of **0.46%** of Peel-off UV Adhesive on UV shoulder of Libero SG encountered in FY2021 from Dec. 2020 to Nov. 2021.

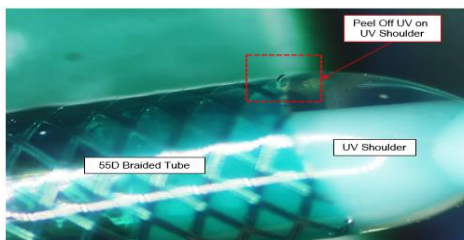


Figure 6. Peel Off UV Adhesive on UV Shoulder of Libero SG model

1.2 Problem Scope

This technical project intends to eliminate the Highest Return Merchandise Authorization (RMA) quantity of **Libero SG Peel-off UV Adhesive on UV Shoulder** RMA defect by the end of October 2022.

2.0 EXPERIMENTAL SECTION

2.1 Materials and equipments

- > UV Irradiation Machine
- > UV 9014 Adhesive
- > Microscope
- > Syringe

2.2. Identification of Root Causes

Ishikawa diagram in Figure 7 was used to identify the potential root cause of **Peel Off UV Adhesive on UV Shoulder**.

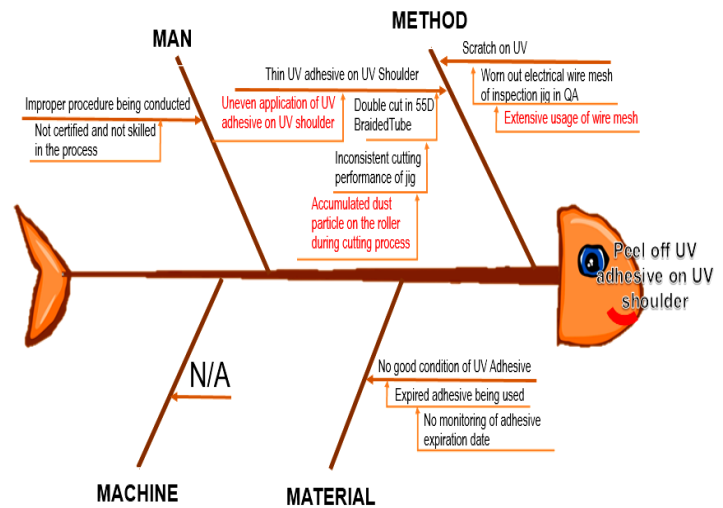


Figure 7. Ishikawa Diagram for Peel Off UV Adhesive on UV Shoulder

2.3 Verification of Potential Root Cause

After the verification of the potential root causes it is found that the possible cause of Peel Off UV Adhesive on UV Shoulder has a relation with **UV application, electrical jig and a jig used in cutting the 55D Braided Tube**. (See Figure 8 for the 4M Analysis).

4M	Possible Cause	Cause Validation	Remarks
MAN	Not certified and not skilled in the process	Skilled and certified operator	Not true Cause
METHOD	Uneven application of UV adhesive on UV shoulder	No defined standard appearance of overlap UV on 55D.	True Cause
	Accumulated dust particle on the roller during cutting process	Observed that the cutting jig produces double cut on 55D Braided tube when the roller part is dirty	True Cause
	Extensive usage of wire mesh	No monitoring of wire mesh replacement – Worn out wire mesh has a direct contact to the UV Shoulder that can cause UV peel Off	True Cause
MATERIAL	No monitoring of adhesive expiration date	Manufacturing has a monitoring in adhesive expiration date	Not True Cause

Figure 8. 4M Analysis

2.4 Selection of Best Alternative Solution

2.4.1 Action Formulation Method

Upon identifying the root causes of the problem, Below are the analysis and action for each cause validation.

A.) ANALYSIS: Uneven spread of UV adhesive on UV Shoulder to 55D braided tube

ACTION: Evenly spread UV adhesive on UV shoulder to 55D braided tube

Implementation Date: April 19, 2022

Illustration:

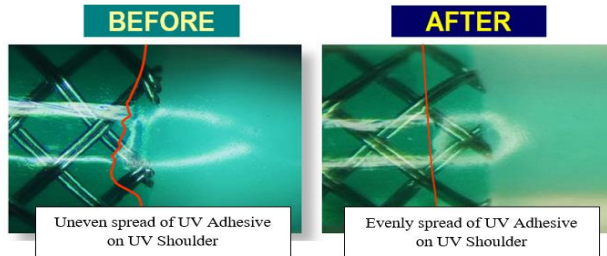


Figure 9. Uneven vs. Even spread of UV Adhesive on UV Shoulder

B.) ANALYSIS: Accumulated dust particle on the roller During cutting process.

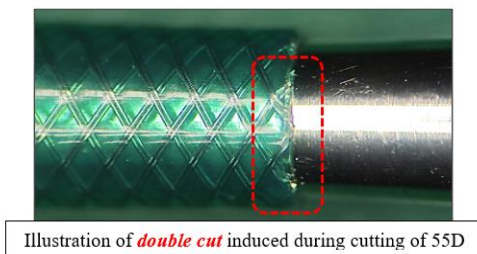


Illustration of **double cut** induced during cutting of 55D

ACTION: Cleaning the roller part of cutting jig using air gun and cotton swab before and after use.

Implementation Date: April 09, 2022

Illustration:

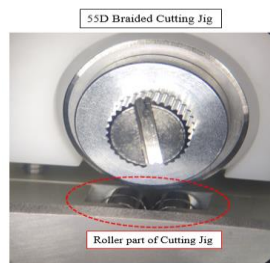


Figure 10. 55D Braided Tube Cutting Jig



Figure 11. Dirty vs. Cleaned roller part of Cutting Jig

C.) ANALYSIS: Extensive usage of wire mesh

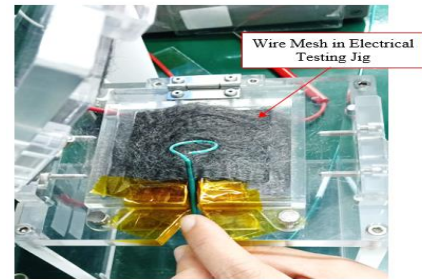


Figure 12. Wire Mesh in Electrical Testing Jig

ACTION: Replacement of wire mesh if worn out

Implementation Date: May 09, 2022

Illustration:

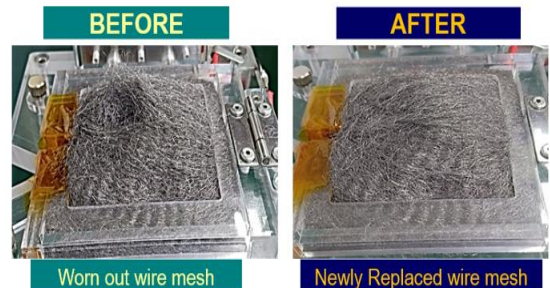


Figure 13. Worn Out vs. Newly Replaced wire mesh

However, by replacing new wire mesh on the electrical jig:

- Observed **scratch** on UV adhesive and Single lumen on shoulder part, that may potentially cause peel off through continuous process
- **7** out of **13** pcs of catheters found scratch on UV adhesive on UV Shoulder and Single Lumen with the average of **53.8%**.

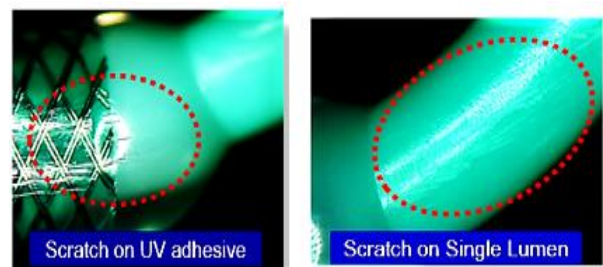


Figure 14. Scratch on UV Shoulder and Single Lumen

It was observed that the cause of scratch on UV Adhesive on single lumen was the **porous and rough** material of *Extra Fine Wire Mesh*.



Figure 15. Extra Fine Wire Mesh

- This mesh has porous and rough that used for smoothing the wood surfaces, polishing stainless steel and copper.

EXTRA FINE WIRE MESH SIMULATION				
MODEL	CATHETER LOT #	Before Appearance of UV Adhesive	Number of Reading Positioning	FINAL Judgement
PVI1015-110	P22D306-1	ok	3	ok
	P22D306-2	ok	3	ok
	P22D306-3	ok	2	ok
	P22D306-4	ok	2	ok
	P22D306-5	ok	3	ok
	P22D306-6	ok	3	ok
	P22D306-7	ok	3	ok
PV2020-110	P22D296-S-2	ok	3	ok
	P22D296-S-3	ok	2	ok
	P22D296-S-6	ok	2	ok
	P22D296-S-9	ok	2	ok
	P22D296-S-10	ok	3	ok
PV2017.5-110	P22D296-S-6	ok	3	ok

Figure 16. Extra Fine Wire Mesh Simulation

Results: Yellow highlighted portion are the catheters with **2 ~ 3** times **re-positioning** conducted on the jig.

Due to the above observation, the formulated action plan is to replace the variant Extra Fine Wire Mesh into **Super Fine Wire Mesh** type.



Figure 17. Super Fine Wire Mesh

- This mesh has a gentle abrasiveness that used for polishing glasses without use of water

SUPER FINE WIRE MESH SIMULATION				
MODEL	CATHETER LOT #	Before Appearance of UV Adhesive	Number of Reading Positioning	FINAL Judgement
PV2015-110	P22E186-S-1	OK	1	OK
PV2015-110	P22E186-S-2	OK	1	OK
PV2015-110	P22E186-S-3	OK	1	OK
PV2015-110	P22E186-S-4	OK	1	OK
PV2015-110	P22E186-S-5	OK	1	OK
PV2015-110	P22E186-S-6	OK	1	OK
PV2015-110	P22E186-S-7	OK	1	OK
PV2015-110	P22E186-S-8	OK	1	OK
PV2015-110	P22E186-S-9	OK	1	OK
PV2015-110	P22E186-S-10	OK	1	OK
PV2015-110	P22E186-S-11	OK	1	OK
PV2015-110	P22E186-S-12	OK	1	OK
PV2015-110	P22E186-S-13	OK	1	OK
PV2015-110	P22E186-S-14	OK	1	OK
PV2015-110	P22E186-S-15	OK	1	OK
PV2015-110	P22E186-S-16	OK	1	OK
PV2015-110	P22E186-S-17	OK	1	OK
PV2015-110	P22E186-S-18	OK	1	OK
PV2015-110	P22E186-S-19	OK	1	OK
PV2015-110	P22E186-S-20	OK	1	OK
PV2015-110	P22E186-S-21	OK	1	OK
PV2015-110	P22E186-S-22	OK	1	OK

Figure 18. Super Fine Wire Mesh

Results: Conducted **one time positioning** of unit due to stable resistance reading

Evaluated 40 pcs Input Quantity:

- ✓ NO peel off UV adhesive
- ✓ NO scratch on UV adhesive
- ✓ NO scratch on Single Lumen

3.0 RESULTS AND DISCUSSIONS

3.0.1 COUNTERMEASURE #1

ACTION PLAN: Evenly spread UV adhesive on UV shoulder to 55D braided tube

Evaluation Results:

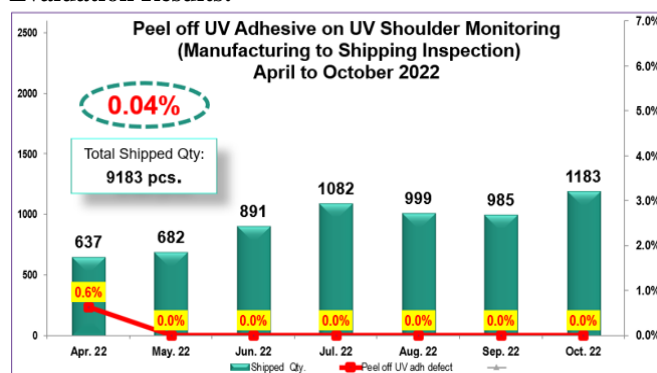


Figure 19. Peel Off UV Adhesive on UV Shoulder Monitoring

Based on the graph given in Figure 19, it shows that we have only found **0.04%** Average defect rate from April to October 2022 after the implementation of controlled UV Application on the shoulder part.

*Data based on actual monitoring of units from manufacturing to shipping inspection.

3.0.2 COUNTERMEASURE #2:

ACTION PLAN: Cleaning of roller part using air gun and cotton swab before and after use

Evaluation Results:

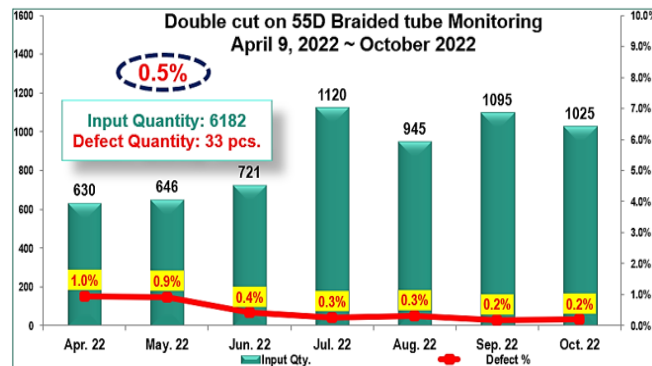


Figure 20. Double cut on 55D Braided tube Monitoring

As observed, by cleaning of roller part of Cutting jig, the double cut **decreased** after the action implementation

Overall, Figure 21 shows Peel off UV Adhesive occurrence was **eliminated** after the implementation of actions

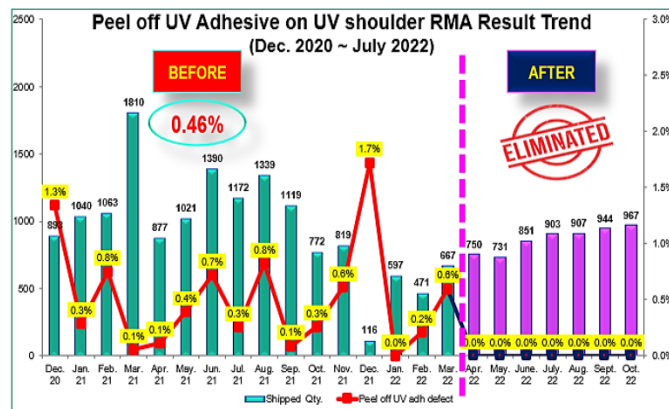


Figure 21. Peel off UV Adhesive on UV Shoulder RMA Trend Before and After Implementation of Actions

BEFORE ACTIONS: 0.46%
AFTER ACTIONS: ZERO (0)

4.0 CONCLUSION

Based on the results, implementation of action plan of evenly applying the UV on UV Shoulder, cleaning the accumulated dust particles on the roller part of jig during cutting and changing variant of mesh from Extra Fine to Super Fine Wire mesh helped to eliminate the defect of Peel Off UV Adhesive on UV Shoulder from its original defect rate of 0.46% from April ~ October 2022 can gain a high quality and cost efficient catheter products not just for customer's satisfaction, but also for P.IMES credibility and integrity.

5.0 RECOMMENDATIONS

With the presented graphs of Action and result being implemented, it is recommended to standardize the usage of super fine wire mesh variant of the electrical test jig in shipping inspection process (QA) and even application of UV adhesive on UV shoulder and lastly, cleaning of Roller part of 55D braided tube cutting jig

6.0 ACKNOWLEDGMENT

The authors would like to express their deepest gratitude to our Almighty God for giving us the knowledge to make this Technical paper possible. And also a warm and heartfelt appreciation to all our colleagues, department managers and Medical Device team for supporting us through this journey.

7.0 ABOUT THE AUTHORS



Lyka Mae D. Quillosa is graduate of Bachelor of Science in Computer Engineering from Lyceum of the Philippines University-Cavite Campus. She's been working with P.IMES Corp. for 2 years under Engineering Department of OEM Medical Device Assembly Business

Unit and currently holding a position as Product and Process Engineer.



Jaime Miguel C. Agustin is a licensed Mechanical Engineer and graduate of Bachelor of Science in Mechanical Engineering from Technological University of the Philippines -Manila. He has been working for P.IMES Corp. since January 2015 and also currently

holding the position of Process and Product Engineer under the Engineering Department of OEM Medical Device Assembly Business Unit.