Neuromodulation Leads Yield Fallout Improvement due to Fallen Segment

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Abstract

Neuromodulation Leads used for Deep Brain Stimulation (DBS) is an elective surgical procedure in which electrodes (that generates electrical impulses that control abnormal brain activity) are implanted into certain brain areas. The leads consist in Ring Electrodes and a combination of Ring and Segmented. The electrodes are welded to the conductive wires using Resistance Welding technology. Epoxy adhesive is used at the electrode arrays to hold the electrodes in place and to provide stiffness for lead handling during implant. After each Epoxy Adhesive bonding process, the leads are Grinded to reduce the outside diameter. A failure is observed at the grinding process of the distal electrodes array when the segment electrodes detached from the assembly. An increase in Yield Fallout was observed during the implementation of a new Epoxy Adhesive. The objective of this project is to improve the yield performing a Resistance Welding Study that is expected to reduce the electrode detachment.

Introduction

The Neuromodulation DBS Lead required a Medical Adhesive material change that resulted in lower adhesion between the Epoxy and the distal segmented electrodes increasing the yield fallout due to fallen segments. This project intends to evaluate different process changes that could mitigate the impact of the new Medical Adhesive therefore resulting in scrap savings to BSCI. The objective of this study is to reduce the yield fallout due to segment electrodes detaching from the assembly during the Grinding process back to the original reject rate of 2%. The reduction of the reject rate will reduce product scrap dollars and increase line Final Yield and efficiency that will allow to meet production plan output.

Background

The DBS distal electrode array is a composite joint design where the segmented electrodes are held in place by the cable to electrode resistance weld and the Epoxy backfill applied under the carrier that contains the segmented electrodes. After Backfill process is completed the lead go to Oven Cure.

The resistance welding process used for the DBS Neuromodulation leads uses a Copper Chromium Electrodes to weld the Platinum Core cables to the Platinum Iridium segments. Resistance welding is a thermo-electric process in which heat is generated at the interface of the parts to be joined by passing an electrical current through the parts for a precisely controlled time and under a controlled pressure, also called force.

The current Copper Chromium Electrode design has a Tip of 0.030" to perform the weld. Current Segment electrode design allows for a material contact interface of 0.048". Therefore, part of this research will focus on how the increase in contact surface of the welded area impact the weld strength potentially improving the chances of the segment electrode to hold in place when exposed to the stresses caused during the Grinding process. Grinding is machining process that's used to remove material from a workpiece via a grinding wheel. As the grinding wheel turns, it cuts material off the workpiece while creating a smooth surface texture in the process.

Problem

The historical yield fallout with the previous Epoxy Adhesive was about 2% and the new Epoxy adhesive showed yield fallout of 16.92%, resulting in a $20K increased in monthly scrap. Since no other process was changed as part of the Epoxy raw material implementation, it is believed that the adhesion of this new adhesive is causing the increased in yield fallout.

Methodology

Resistance Welding Investigation Research

The first step of the research was to manufacture two full leads, one of them had all the segments welded to cables using the current resistance welding process and the other one had the segments welded to the cables. Since practical difference was found in the grinding performance during the inspection of these leads, a secondary part of the research was done. The second part focused on how to improve the resistance welding strength expecting to overcome the reduction in the bonding strength caused by the change in the adhesive epoxy.

To increase the resistance welding strength an investigation was performed increasing the effective welding area between the cable and the segmented electrode. Increasing the effective welded area increases the maximum shear strength that the joint may be able to hold which would result in a better yield performance during the grinding process. These samples were welded with the new welding electrode design with the optimized resistance. The pull strength results from this samples were used to compare them to the pull strength results obtained from the previous Process Validation testing when the old design of the welding electrode was used. Also, the results were verified to meet the current axial strength product specification of minimum 0.5 lbf and the minimum Ppk of 0.69 required by the Boston Scientific Global Sampling plan procedure for the sampling size selected of N=15.

After it was ensured that the product specification was met with the new electrode design and its performance was better than the older electrode design, 30 full leads were manufactured and grinded using the new electrode design. The grinding operation induces shear forces to the lead while removing material via the grinding wheel. The intent of this test was to verify if the increased in the effective welded area had an improved performance during the grinding operation overcoming the yield fallout caused by the change in Epoxy adhesive. The sample size of N=30 was selected taking in consideration the Internal Procedure for Sampling plan for Attribute that suggest a minimum of 22 samples, also the manufacturing constraint and high cost of the Neuromodulation Leads were part of the rationale. Refer to table 1 for Test Objective and Evaluated Parameters summary.

Table 1

Test Objective and Evaluated Parameter

Test Name	Test Objective	Samples Qty	Evaluated Parameter
Segment Welded vs Non-Welded	Evaluate interaction of the weld joint with the Epoxy adhesion to segment	2 Full Leads	Welded segments and segments non welded
Weld Joint Axial Strength	Verify if the new electrode met Product Spec of 0.5lbf	15 Samples	New Electrode
Yield Fallout	Yield Fallout Comparison	30 Full Leads	Fallen segments reject rate

Cure Time Study (Epoxy Curing Time)

The research will study the effect of oven cure time increase using both old epoxy called Hysol (as baseline) and New called BSC, that could reduce the amount of segment electrodes detach during the grinding operation. This study was performed as exploratory test, for that reason the amount of sampling was limited due to the cost of the total study, each sample cost $1.6k, the total cost for all samples was close to $60k. The groups were as follows:

Table 2

New vs Old Epoxy Group by Cure Time hrs

Group	Samples	Epoxy	Ambient Cure	Oven Cure Time
1	1-10	Hysol	1 hr	3 hrs
2	11-20	Hysol	1 hr	5 hrs
3	21-30	BSC	1 hr	3 hrs
4	31-40	BSC	1 hr	5 hrs

Results and Discussion

15 samples were compared with 45 older samples created during process validation at Valencia and Dorado Site. In the previous process qualifications (PQ) the capabilities values (Ppk) for Dorado site were 1.74, and for Valencia site were 1.60. In the Capability Analysis for New Electrode Design show in Figure 1, it is observed that Ppk was 3.67 which shows an improvement when compare with 1.74 (Dorado Ppk) and 1.60 (Valencia Ppk). Also, it demonstrated that the process with the new electrode design can consistently meet product specification of 0.5lbf and it met the Ppk of 0.69. In Figure 2 a lower pull strength variation was observed when comparing the group of the data of the new electrode design against the older groups.

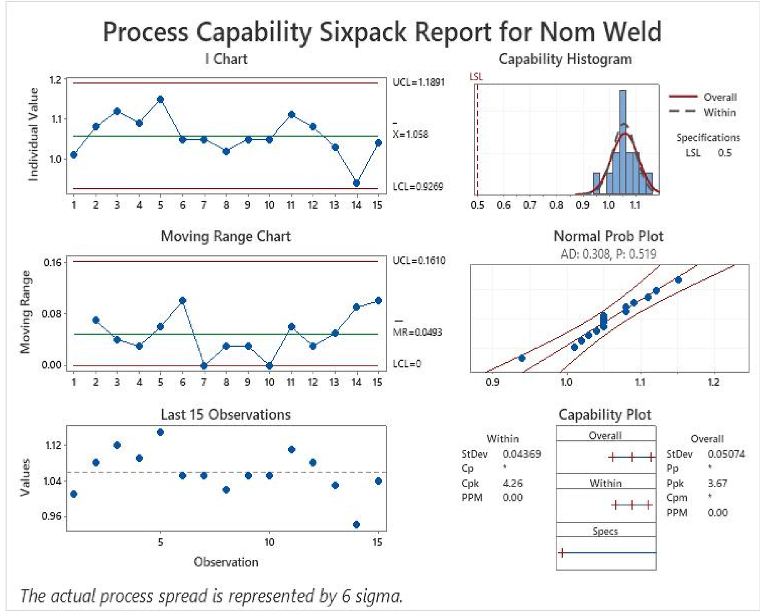

Figure 1

Capability Analysis for New Electrode Design

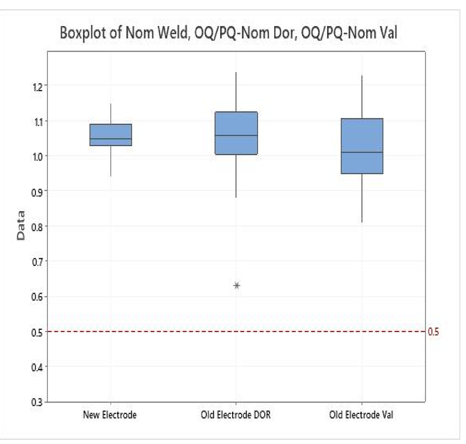

Figure 2

Pull Strength Boxplot for New Electrode vs DOR vs Val Old Electrode

In Figure 3, it can be observed a table containing the information regarding Yield fallout of older and newer electrode weld design from week 1 to 21 of the year 2021. The 30 full leads manufactured with the new electrode design were process at Grinding in the week 21.

Fallen Segment Yield Trending						
Week	Qty Scrap Unit Hyso	Qty Scrap Unit BSC	Qty Unit Grind-Hysol	Qty Unit Grind-BSC	Fallout-Hysol	Fallout BSC
1	12	0	41	7	29%	0%
2	1	0	21	0	5%	0%
3	1	0	30	8	3%	0%
4	0	1	0	40	0%	3%
5	0	0	0	0	0%	0%
6	0	0	0	16	0%	0%
7	0	1	0	34	0%	3%
8	0	0	0	38	0%	0%
9	0	0	0	13	0%	0%
10	0	0	0	17	0%	0%
11	0	1	0	16	0%	6%
12	0	2	0	49	0%	4%
13	0	1	0	31	0%	3%
14	6	0	61	0	10%	0%
15	16	0	48	0	33%	0%
16	0	0	0	4	0%	0%
17	0	1	0	29	0%	3%
18	0	0	0	0	0%	0%
19	0	0	16	0	0%	0%
20	4	0	14	7	29%	0%
21	5	0	35	0	14%	0%
	45	7	266	309		
	Yield Fallout Total		16.92%	2.27%		

Figure 3

Fallen Segment Yield Trending Table

Table 3

Yield Fallout Hysol vs BSC Epoxy

	Hysol	BSC
Totals Scrap	45	7
Yield Fallout	16.92%	2.27%

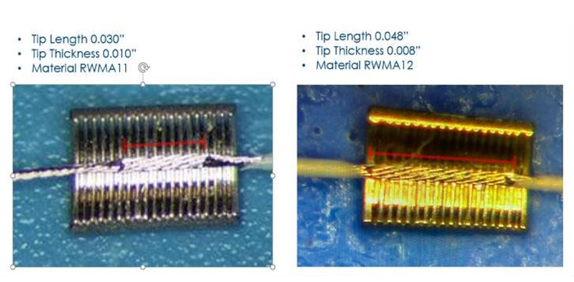

Figure 4

Old vs New Electrode Design

As it can be observed in Figure 3, none of the 30 units that were welded using this new electrode and Hysol Epoxy on week 21 resulted with missing or fallen segment electrode after grinding. Table 3 explain that 45 units scrap contain Hysol epoxy, and 7 units scrap contain BSC epoxy, corresponding to 16.92% vs 2.27% in yield fallout. As it can be observed in Figure 4 the new upper electrode design showed a significant increase in the effective welding area between the cable and the segmented electrode.

A cure time study was conducted using both Epoxy adhesives. The data collected showed that the cure time is not a significant factor since the number of failed units due to fallen segments from the units bonded with the New Epoxy was similar at both the 3hrs and 5hrs cure time. Two Proportion Test results for both cure times vs Hysol and BSC Epoxy were equal 0.000.

Conclusions

With the data collected through this study it can be concluded that the increased in the effective weld area between the cable and segment electrode increases the maximum shear strength that the joint can withstand during the grinding process. This improvement on the maximum shear strength that the new welding electrode provided proved sufficient to overcome the adhesion strength lost caused by the Epoxy material changed reducing the amount of unit scrap due to fallen segment at the Grinding operation. Also, the results from this study showed that the cure times of the different Epoxies is not as a significant factor as the Epoxy material change.

The contributions of this research project have been the sustained reduction in rejection rates, returning the yield fallout to below 2% (baseline of the process) instead of the 16.92% observed when the epoxy change. The study results lead to a more capable, repeatable, and reliable welding process. For that reason, less starts need to be made, giving the manufacturing line to be more flexible, having a better capacity to meet production plan output, this ultimately translate in a better net labor efficiency. After the change implementation a clinical build requirement of 236 units was performed, the result of yield fallout regarding fallen segment was 1.7% this represents a total of 4 scrap units for a cost of $6,400. If the process were having the previous yield fallout of 16.92% a total of 40 units should has been result in scrap for a potential total cost of $64,000.

Future Work

The increase in the welded area between the cables and the segment electrodes effectively increase the capability of the electrode joint to withstand the shear stress caused by the grinding process. For future development of similar resistance welding processes, the effective welded area between the components must be as important output to be study as any other variable being study as part of the characterization phase.

Acknowledgements

Ivan M. Aviles, Ph.D., P.E Project Advisor and Miriam Pabon, Ph.D. Dean Graduate School for assitance and mentoring. Carlos Morales Principal Engineering at Boston Scientific for mentoring.

All funds for this project came from engineering department of Boston Scientific Dorado, Puerto Rico manufacturing site.

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