Implementation of Innovative Automated Coating Technology in a Medical Device Facility

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Abstract *— As part of new products development in a medical device plant, an innovative coating technology known as Physical Vapor Deposition (PVD) will be implemented for the electrode coating process. Current process is performed by dip coating parts manually and exposing to high temperatures for pre-defined time. This process has a high cycle time from 8 to 10 hours per batch. Additionally the process results in not uniform coating thickness and high variability between parts. The new process to be implemented will be automated where the operator will load and unload parts in the system and press one button to start the process. The PVD technique is performed by sputtering atoms that make up the coating via bombardment of a plate of the coating material by energetic ions. Testing results showed more uniform coating thickness and less variability between parts as well as reducing the cycle time per batch to 45 minutes.*

Key Terms *— Automation , Electrode Coating, Physical Vapor Deposition, PVD*

INTRODUCTION

Implantable pacemakers are medical devices that use electrical impulses, delivered by electrodes contacting the heart muscles, to regulate the beating of the heart. These electrodes require a special coating in order to enhance its functionality. Currently the electrode components coating process is performed manually by operators dipping the components in a prepared solution and baking at high temperatures in ovens for a pre-determined time, this is repeated a number of cycles depending on the product, resulting in a high cycle time from 8 to 10 hours per batch, not uniform coating and a process with a high variability.

RESEARCH OBJECTIVES

The main objective of this design project is the implementation of the new automated coating technology, physical vapor deposition (PVD), to be used for components coating process in new products of a medical device manufacturing plant. This will result in a process with less variation, higher quality and lower cycle times.

RESEARCH CONTRIBUTIONS

This project will improve the components coating process by providing an automated process technology that will replace the current manual dipping process for next product generations. By implementing this new technology, the cycle time for the batch process will be reduced dramatically; therefore a reduction in manufacturing costs will be reflected. Additionally a reduction in variation of the coating surface of the components will be achieved. This reduction in variation of the coating surface will result in improvement in the electrochemical performance of the components, provide a more uniform coating thickness and provide a controlled process.

RESEARCH BACKGROUND

The development and manufacturing of a medical device is an increasingly difficult endeavor as competition grows stronger and regulatory constrains broaden [1]. Medical device companies must look for ways to increase efficiency in their processes so as to remain competitive and in compliance with the various regulatory bodies governing the worlds markets.

IrOx coatings have been utilized in a variety of electrode applications to provide enhanced electrochemical performance and stability of components. The use of the coating for the base metal is known to reduce polarization, sensing impedance, and voltage threshold, while increasing charge injection capacity, corrosion resistance, and capacitance [2].

Currently the process used for electrode coating in a medical device manufacturing plant is performed by preparing a solution and exposing it to high temperatures to create the required coating (thermal decomposition). This process is performed mostly manually by dipping the components in the prepared solution. After each dipping, the components are dried on a 1st oven and then oxidized on a 2nd oven. This process can be repeated from 4 to 7 times depending on the product specifications that will use the coated component. These activities result in a cycle time of 1 to 2 shifts per batch. Additionally, results have showed high variation in the coating surface of the components.

Various coating technologies were assessed in order to select and implement a new process that would provide more consistent results and reduce the operator process dependency for new products to be developed. Among the technologies evaluated were the following:

- Electrodeposited Irox Film (EIROF)
- Spray (Electro-spray & Nozzle spray)
- Physical Vapor Deposition (PVD)

From these options, the PVD process was selected because it is a proven technology used for in other medical devices components within the organization. There was available prototype system that could be used for the process development and testing during the investigation phase.

Physical Vapor Deposition is a process to produce a metal vapor that can be deposited on electrically conductive materials as a thin highly adhered pure metal or alloy coating. The process is carried out in a vacuum chamber at high vacuum (10-6 torr) using a cathodic arc source [3].

Physical deposition processes are a class of material deposition methods that do not require a chemical reaction for the deposition process to occur. The process utilizes plasma formed by a large voltage in a low pressure gas (0.1 torr) across a closely spaced electrode pair. The target material (source material to be deposited) is on the cathode. The ions come from an inert gas within the chamber. Bombardment of the cathode by energetic ions gives rise to the sputtering process.
When ions strike a material surface, several things can happen, depending on the energy of the ions:

- Bouncing off the surface
- Absorption by the surface to produce heat
- Penetration of the surface to deposit the energy within the material
- Ejection of surface atoms from the cathode (sputtered)

Sputtered atoms have more energy than evaporated atoms, which increase the surface mobility of the sputtered atoms. Increased surface mobility produces better step coverage that is attainable with the evaporation process. Because of ions collisions give rise to the sputtering of the target material, a gas with a high atomic weight is advantageous. Argon is frequently used inert gas in a sputtering process. The sputter deposition does not depend on the substrate temperature; however, substrate may be heated to promote adhesion or prevent firm cracking. [4]

Sputtering is the preferred vacuum deposition technique used by manufacturers of semiconductors, CDs, disk drives, and optical devices. Sputtered films exhibit excellent uniformity, density, purity and adhesion. It is possible to produce alloys of precise composition with conventional sputtering, or oxides, nitrites and other compounds by reactive sputtering.

Substrates are placed into the vacuum chamber, and are pumped down to their process pressure. Sputtering starts when a negative charge is applied to the target material (material to be deposited), causing a plasma or glow discharge, refer to Figure 1.

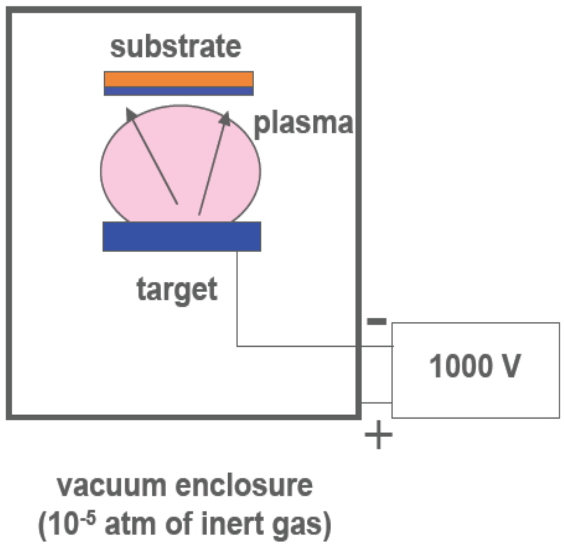

Figure 1
PVD Representation

Positive charged gas ions generated in the plasma region are attracted to the negative biased target plate at a very high speed. This collision creates a momentum transfer and ejects atomic size particles from the target. These particles traverse the chamber and are deposited as a thin film onto the surface of the substrates. [5]

As part of the new process implementation, new equipment was developed and built to our customized needs. Therefore, the main objective of this project is the implementation of this new system for production environment. The implementation covers equipment testing, Pilot builds readiness, process characterization, manufacturing instructions development, traceability requirements and process testing

RESEARCH METHODOLOGY

In order to implement the new coating process, the company process development and Pilot Readiness procedures were followed. System Life cycle methodology is the best that can be used to describe the process that will be followed in order to implement the new sputtering system. System Life Cycle includes the following phases:

- Definition – to define the process needs and develop system requirements and specifications.
- Development – Equipment development as per system requirements and specifications. As part of the development and definitions phases, a risk analysis is developed. Process risk analysis is an activity that progresses throughout process development and validation. The process risk analysis will identify failure modes and causes that must be evaluated during process characterization. It will link process inputs to process outputs to help establish the basis for validation work.
- Testing – the Testing phase includes the following:
    - Master Validation Plan development – The Master Validation Plan establishes the validation strategy for a process and provides a reference for validations performed.
    - Equipment Testing – Intended to demonstrate that the equipment is properly identified, installed and documented and that it meets its intended use.
    - Process Characterization – Intended to determine proven acceptable range and nominal settings for use in production. During process characterization methods such as range finding experiments, screening experiments, DOE’s, etc. are used to identify variables that have a significant impact on the process outputs within their controlled range of variation.
- Release for Production or Pilot A Readiness – The pilot production process defines the operation requirements for manufacturing production-equivalent devices for use in design verification and validation testing. Among the operation requirements are the following:
    - Assembly Materials and Design Documents need to be at pre-production status

- Master Validation Plan approved
- Manufacturing Documentation developed and approved.
- Manufacturing Traceability defined and implemented
- Operators trained and certified.

RESEARCH RESULTS

Using the system prototype in the Minnesota R&D area, the PVD process was tested in order to determine the feasibility of implementing the technology to be used for IROX coating of the next generation devices. The following tests were performed:

- Verified electrical performance. The PVD coated parts were compared with the dip coated parts using dv/dt testing. The results showed that PVD coated parts performed as well as dip coated parts (Refer to Figure 2).

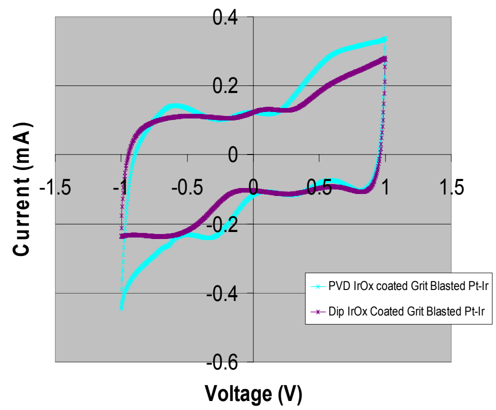

Figure 2
Electrical Performance Testing

- Axial load was tested to verify adequate adhesion of Irox surface to silicone parts using the PVD process. The results showed that PVD coated process met the axial load requirements (Refer to Figure 3).

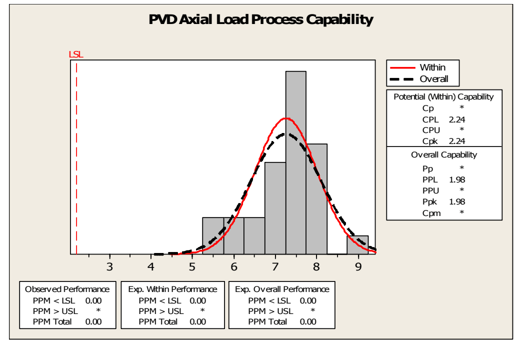

Figure 3
Axial Load Testing

- Coating thickness was tested by verifying consistent thickness throughout part. The results showed consistency and better coating thickness than dip coated parts (Refer to Figure 4).

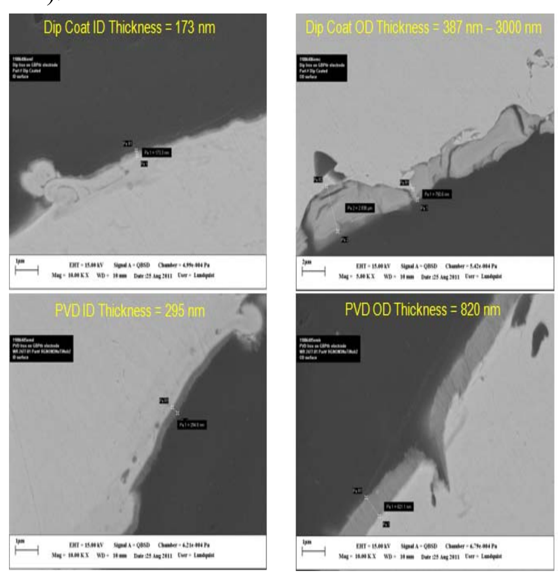

Figure 4
Coating Thickness Comparison

Based on these results the PVD process development was approved and capital budget assigned for the system to be acquired. A company specializing in PVD and vacuum systems was selected to design and built a customized system for our needs.

The system was designed taking into consideration besides the process requirements of performing an Irox coating process, it needed to meet the following system features:

- Rotary loading mechanism. This loading mechanism was designed to help the operator in the loading and unloading parts to the chamber with minimum human effort.
- Safety Requirements. All safety measures should be taken in consideration in order to guarantee the safety of all personnel operating the system and comply with the company requirements and policies.
- Compliance with the company's general equipment specification and ergonomics design guide.

After the system was built by the selected vendor, testing was performed before accepting the equipment. Factory Acceptance Testing (FAT) was performed at the vendor's site and parts were coated in order to fully test the equipment. Among the testing performed were:

- Inputs and Outputs testing
- HMI test
- Alarms & Interlocks Test
- Safety features test
- Startup and Shutdown process
- Functional test
- Assembly verification

During the testing and verification activities, all findings of the errors or problems in the system were corrected by the vendor before shipping the equipment to our facility.

In order to install the equipment in the plant, a new layout was designed and facility modifications were performed. This required coordination between different functional groups within the plant due to the size of the equipment and installation requirements. The system was shipped and installed as per plan successfully.

Once installed and all utilities were available, testing was performed in order to characterize the process and develop the recipe to be used for the PVD coating process. The parameters tested were: power, pressure, Gas/Air ration and time. The outputs measured were electrical performance, axial load and coating thickness. Based on the results obtained in these testing a process recipe was developed and implemented in the system.

As per process development procedures, the system needs to be release for Pilot A Production in order to build the units for design verification and validation testing. All Pilot A requirements were completed as per plan and the system was released for Pilot A production.

Additionally to all test results obtained and documented, a major result of this installation is the change or improvement of the process flow and cycle time related to the Irox coating process. As per Figures 5 and 6, the Irox dipping process requires more operator dependent steps than the new PVD process, resulting in a more uniform and less variable process with a dramatic reduction in cycle time per batch (Refer to Figure 7).

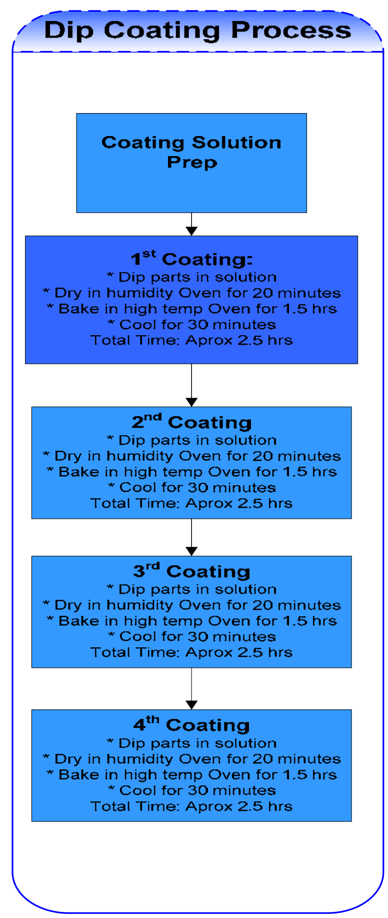

Figure 5
Current Irox Dip Coating process flow

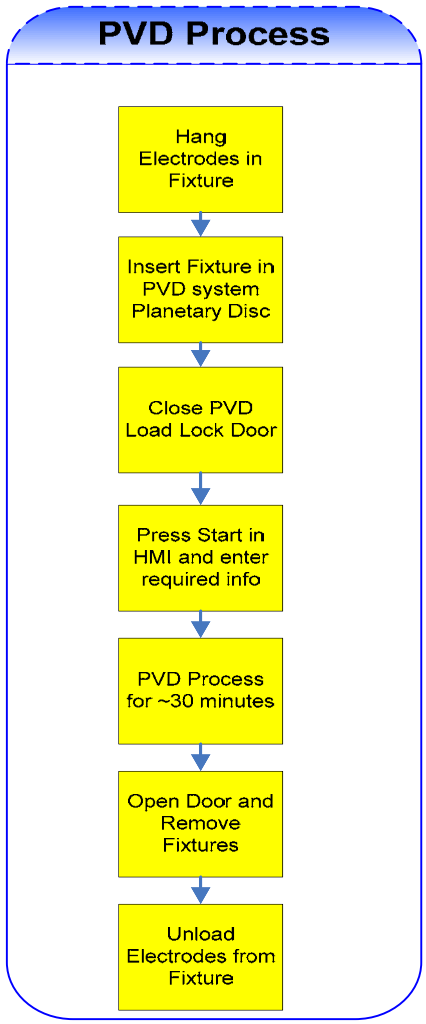

Figure 6
New PVD Coating process flow

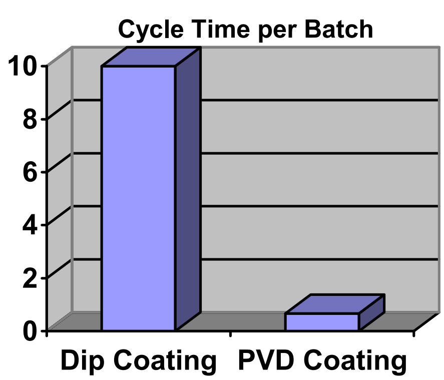

Figure 7
Cycle Time Comparison

CONCLUSIONS

When comparing the dip coating process versus the new PVD process, we can identify the following operation benefits (Refer to Figure 8 for comparison summary):

- Electrochemical performance is good with both processes.
- Coating thickness and variation is more controlled and with less variation using the PVD process
- Axial load requirements are met with both processes but the PVD system showed more consistency.
- Cycle time is dramatically reduced from 1 to 2 shifts to 45 minutes per batch.

	Dip Coating	PVD Coating
Electrochemical Performance	√ Good	√ Good
Coating thickness	Varies	√Good Control
Initial Equipment Cost	√ Low	High
Coating Surface Variation	High	√ Low
Process Complexity	Manual Coat, dry & bake cycles	√ Simple, one button operation
Cycle Time	1 – 2 shifts per batch	√ 40 – 45 minutes per batch

Figure 8
Dip Coating Vs PVD Coating

Although the initial investment with the PVD system is very high due to the complexity and customization required due to our business needs, the implementation of this process is justified with the proven results. The process is no longer operator dependent and provides consistent and controlled coated parts that comply with the design and process specifications in a reduced cycle time. These results provide long term benefits to our industry while maintaining the quality and compliance to regulatory and safety needs.

Future Projects

The next steps related to this project are the final release to Production of the new product coating process after validation and production release requirements are met. Once all requirements are met, the product will be submitted to the regulatory agencies for the Product approval for market sales.

Future plan is to replace the current dip coating process with this new technology in our legacy products.

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