AUTOMATION OF IVUS CATHETER BONDING PROCESS AT TELESCOPE ASSEMBLY

A Project Report

Presented to

The Faculty of the Department of General Engineering

San Jose State University

In Partial Fulfillment

of the Requirements of the Degree

Master of General Engineering – Biomedical Devices Concentration

by

Andrew Chen

Sheelvrat Pathak

Samir Shah

May 2010

SAN JOSE STATE UNIVERSITY

The Undersigned Project Committee Approves the Project Titled

AUTOMATION OF IVUS CATHETER BONDING PROCESS

AT TELESCOPE ASSEMBLY

by

Andrew Chen

Sheelvrat Pathak

Samir Shah

APPROVED FOR THE DEPARTMENT OF GENERAL ENGINEERING

Sri Vungutur,	Senior Manufacturing Engineer	Date
Dr. Maryam Mobed-Miremadi,	General Engineering Department	Date
Dr. Leonard Wesley,	Computer Engineering Department	Date

ABSTRACT

At Boston Scientific Corporation (BSC), certain manual manufacturing processes would benefit from decreased cycle times and reduced product variability. In order to address these issues, our project has implemented an automated system in place of a manual process.

The new automated system will be introduced in the Telescope Assembly subsection of the Intravascular Ultrasound (IVUS) Catheter manufacturing process. Currently, the Flush Port Housing is bonded to the proximal end of the catheter using a manual process that involves an operator applying UV-cured adhesive with a foot-controlled dispensing needle. The operator then slides the two pieces into a UV curing machine and waits a specified amount of time for the assembly to properly cure. The new automated system will speed up this manufacturing step while eliminating variability in the amount of adhesive applied.

The project covered the entire development cycle of the automated system, including the planning, specification, design, and construction phases. Within these phases, specific protocols were followed in order to mitigate risk and ensure the system would meet specification. At this point, system construction is complete. Future work will involve validation tests and installation into the assembly line.

ACKNOWLEDGEMENT

We would like to take this opportunity to acknowledge the advice, support, and patience of all of our advisors, without which this project would never have reached fruition.

To Garvin Leon, Program Manager at Boston Scientific: Thank you for trusting a bunch of graduate students with your money.

To Sri Vungutur, Senior Manufacturing Engineer at Boston Scientific: You have been a pivotal source of advice and information--thank you for taking the time to mentor us.

To Professor Maryam Mobed-Miremadi: Your dedication to students is admirable--thank you for the valuable feedback on all our reports.

Last but not least, to Professor Michael Jennings and Professor Leonard Wesley: You have helped us become better project engineers who deliver great presentations--we will take this with us to industry.

Andrew Chen

Sheelvrat Pathak

Samir Shah

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1: INTRODUCTION

1.1 Project Overview

Perhaps the biggest surgical breakthrough of the preceding two decades has been the shift from open surgical procedures to less invasive alternatives. The rationale for this shift is obvious: minimally-invasive surgery imparts less trauma to the patient, allows for shorter recovery times, and results in smaller scars. Overall, survival rates are higher during minimally-invasive surgery than during open surgery [1].

With the growth of minimally-invasive procedures comes the need for new, often drastically different tools. For instance, traditional open cardiac surgery required tools that could spread apart the sternum and rib cage in order to reach the heart. Today, cardiovascular disease can often be treated with devices such as balloon angioplasty catheters and cardiac stents, shown in Figure 1. In addition, there is the need for new types of external monitors and diagnostic systems that can provide physicians a view inside the body while working externally.

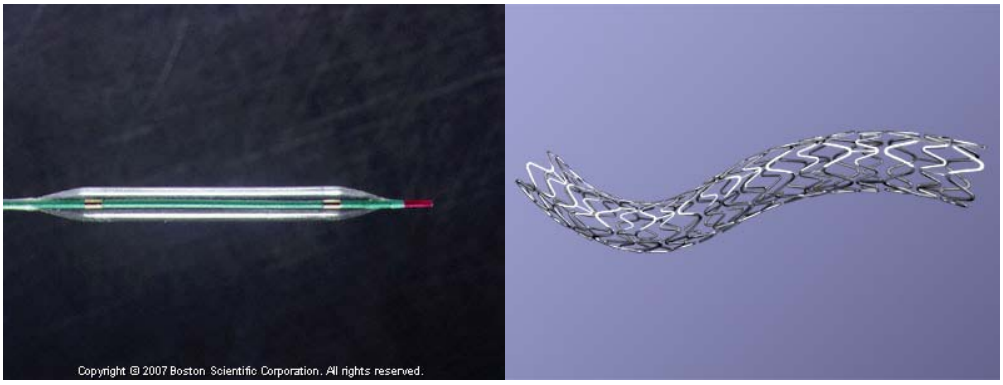

Figure 1: Balloon Angiography Catheter (left) and Cardiac Stent

Boston Scientific Corporation (BSC) is the largest minimally-invasive medical device company in the world, producing 13,000 products across multiple medical divisions, including cardiology, gynecology, urology, radiology, oncology, and gastroenterology. Examples of products made by BSC include various forms of defibrillators, catheters, coronary stents, pacemakers, and diagnostic tools.

Our project is being conducted within the interventional cardiology division of Boston Scientific. This division is responsible for devices that diagnose and treat cardiovascular disease, the leading cause of death in the United States. Cardiovascular disease is caused by narrowed or blocked coronary arteries, which limit the amount of blood that reaches the heart. Examples of devices produced by the interventional cardiology division include balloon angioplasty catheters, coronary stents, and ultrasound imaging tools.

1.2 Intravascular Ultrasound Catheters

Our project deals specifically with Coronary Intravascular Ultrasound (IVUS) Catheters. These are diagnostic tools used to image the inside of the coronary arteries, providing a more useful internal view of the vessel than older technologies such as angiography, which cannot visualize plaque deposits. An illustration of the IVUS Catheter device is shown in Figure 2.

Figure 2: IVUS Catheter Illustration

IVUS catheters are inserted into the femoral artery and guided through the vascular system to the coronary arteries. Once in place, a small ultrasound transducer transmits and receives an ultrasonic signal that is used to create a cross-sectional image of the vessel walls. This real-time image allows for plaque build-up in the coronary arteries to be visualized so that treatments can be more precisely targeted. Figure 3 provides example images of vessels, both healthy and blocked by plaque, produced by an IVUS catheter.

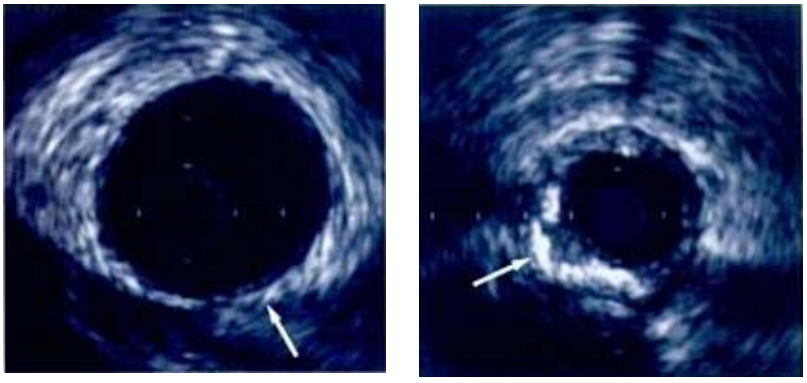

Figure 3: Images Produced by IVUS Catheter. The image on the left depicts a healthy coronary artery with open lumen, while the image on right depicts a blocked vessel with smaller opening

Boston Scientific IVUS catheters are single-use devices that operate at 40 Mhz. They are constructed of several parts: the transducer, the catheter shaft, and the Telescope Assembly, which is made up of the Flush Port and the Small Tube. The Flush Port is used by the physician to inject the catheter with saline solution to prevent clogging. The flush clears blood and other debris from the inside of the catheter so clotting or blockage does not occur. The IVUS catheter shaft has a 135cm usable length and the telescope assembly is 15 cm long.

Boston Scientific IVUS catheters are manufactured across a production line in a clean room environment. The assembly line format allows manufacturing personnel to become experts in one specific area of catheter assembly, allowing for quick and reliable production of devices. Our project is being conducted within the Telescope Assembly portion of the production line, specifically where the Small Tube is bonded to the Flush Port. These pieces, as mentioned earlier, are used to flush the catheter with saline solution during surgical procedures, and so a strong bond is necessary at this joint to prevent leakage. UV-curable adhesive is used to form the bond.

1.3 Automation of IVUS Catheter Manufacturing

Previously, in order to bond the Small Tube to the Flush Port, the Product Builder was required to perform a manual sequence of steps. Though the Product Builders are well-trained and highly competent, the increased need for human involvement led unavoidably to an increased possibility of human error. An outline of this manual process is listed in Table 1.

Table 1: Manual Flush Port to Small Tube bonding procedure

Step	Task
1	Small Tube and Flush Port are loaded and aligned on fixture
2	UV adhesive is applied using foot-controlled dispensing needle
3	Assembly is moved into UV Curing Box and cured for a predetermined amount of time
4	Assembly is removed from UV curing box and unloaded from the fixture

There are various areas in the manual process where human error can arise. Most critically, either insufficient or too much adhesive may be applied to the bond by the Product Builder, as this is controlled by an inexact dispensing needle. Other potential errors can arise from misalignment of parts or insufficient curing time. Any of these

errors can result in weakened bond strength and the possibility that the device does not meet specifications.

In order to reduce the possibility of human error in manufacturing, automation can be used to decrease the amount of human involvement necessary. The purpose of our project was to build such an automated system. This system would be positioned in the assembly line, where it would replace the majority of the manual steps that were used to bond the Small Tube to Flush Port. Of course, the resulting bonded parts would have to meet or exceed current specifications. Furthermore, the automated system would have to operate more quickly than the manual process. Finally, the system had to fit within a predetermined space in the line, be safe to operate, and work reliably with limited maintenance.

A general outline of the operation of the automated system is shown in Table 2. Operation of the system in more detail, including specifications and schematics, can be found in Chapter 3.

Table 2: Automated Small Tube to Flush Port Bonding Procedure

Step	Task
1	Small Tube and Flush Port are manually loaded on fixture
2	Automation system is started with button press, which begins rotation of pieces
3	Adhesive dispensing gun slides forward, applies predetermined amount of adhesive to the rotating parts, then slides back and out of the way
4	Clamshell doors close around the assembly and UV light is used to cure adhesive and permanently bond the pieces
5	UV light shuts off after predetermined amount of time, the clamshell doors open, and the bonded assembly can be removed by the Product Builder

In order to develop this automated system and incorporate it into the assembly line, we would have to progress through four development stages: planning, specification, design, and construction. Within each of these stages, it would be necessary to complete

certain documentation and reach certain milestones. More detail on each of these stages can be found in Chapter 3.

1.4 Project Objectives

Our project encompasses the entire life cycle, from planning to construction, of an automated system to be placed in the IVUS catheter production line. Our primary goal was to mitigate risk in order to ensure that the system would be validated for use; we did this by making certain that all proper protocols were followed at every stage of the project. When managing the vendor, we engaged in constant feedback and multiple design reviews. When determining functional specifications, we made sure that all user requirements were met. Likewise, when performing a site acceptance test, we ensured that all functional specifications were addressed and met by the system.

There are three main objectives in converting a manual process to an automated process: improve quality, increase productivity, and reduce costs. We will improve the quality of finished parts and decrease the probability of defects by reducing variability in adhesive usage and its application. We will be able to increase productivity at this portion of the line by reducing the amount of time it takes to complete each part. Finally, we anticipate that reduced work content will allow for increased personnel flexibility and lower costs for the company.

In addition to the main objectives listed above, there are other variables that we have addressed during the course of this project. The full list of variables that we addressed, as well as how they were intended to be optimized, are listed in Table 3.

Table 3: Variables addressed by project and intended optimization: smaller, nominal, or higher

Project Variables	Intended Optimization
Adhesive Usage Quantity	Nominal
Adhesive Usage Variability	Smaller
Tensile Strength Value	Nominal
Tensile Strength Variability	Smaller
Cycle Time	Smaller
Production Rate	Higher
Material Costs	Nominal
Operating Costs	Nominal
Labor Costs	Smaller
Operator Job Satisfaction	Higher

Once again, our primary focus was on adhesive usage variability, cycle time, production rate, and labor costs. While we would monitor the other variables, we would not base project success on improvements in those areas. For instance, whether the automated system uses slightly more or less adhesive per cycle than the manual method was inconsequential as long as it was using an appropriate amount to meet specification. Similarly, we did not intend to increase the strength of the bond; as long as finished parts met current specifications we would be satisfied.

Chapter 2: Literature Review

2.1: Equipment and materials

There are several key components to the automation of the assembly process for the IVUS catheter. These parts include the epoxy used to seal the housing, the dispensing system, the curing system, and Programmable Logic Circuit (PLC).

When choosing the epoxy, there are many grounds for the choice. First, the team has to consider the compatibility with the surfaces [2]. The two bonded parts are made of different material. The epoxy needs to be tested to ensure that it does not corrode either of the materials. The glue must also be able to bond to the two surfaces. If the glue is unable to mechanically or chemically hold the two surfaces together, the flush port housing will fail and fall apart.

The epoxy must also have the appropriate bonding strength [3]. The bonding must be able to pass internal specifications by Boston Scientific. If it does not, there might be leakage or failure of the assembly. The two tests are well-connected to the functionality of the the device. The epoxy must be fit for the method of application and the method of curing [3]. Lastly, the epoxy must be capable of withstanding sterilization [3].

There are many methods to cure glue: localized heating, overall heating, hot plate heating, infrared, laser, microwave, and ultraviolet [4]. For Boston Scientific's proprietary systems and logistics, UV-cured epoxy seems to work the best. Care must be taken into consideration for possible shrinkage of the epoxy [4]. It is also one of the few

epoxies accepted by BSC as a method for assembly. Table 4 lists the properties of UV-cured epoxy.

Table 4: Properties of UV-cured Epoxy

Surface compatibility	many grades available giving good compatibility with most plastics and metals
Bond strength	good (up to 16 Nmm^2 shear glass to metal)
Environmental factors	inert when cured
Method of application	low-volume dosing system
Cure mechanism	driving of crosslinking reaction by light energy
Cure time	surface a few seconds up to a few minutes for deeper sections
Completeness of cure	can remain uncured in deep sections
Toxicity	low in cured and uncured states
Sterilization compatibility	good with all methods, but cannot withstand temperatures above 135 °C
Shelf life	several years
Handling precautions	often an irritant in unreacted form, vapour can cause headaches, requires extraction

The dispensing system must operate in such a manner that it dispenses the correct amount of epoxy. The system must also be able to prevent curing of the adhesive within the dispensing point. The system must also be able to have the power to dispense a high viscosity fluid. The epoxy will not flow like water. Lastly, the dispensing system must have the ability to dispense in a continuous fashion as oppose to squirting method (lines vs. dots).

The curing considerations include the wavelength of the light, the power of the lamp, and the degradation of the lamp. There is still a user component to this process. If the wavelength of the light is in a harmful spectrum, such as ultraviolet, there needs to be

consideration for user. The power of the lamp is important because it affects the speed of the curing process. This is illustrated in the Figure 4.

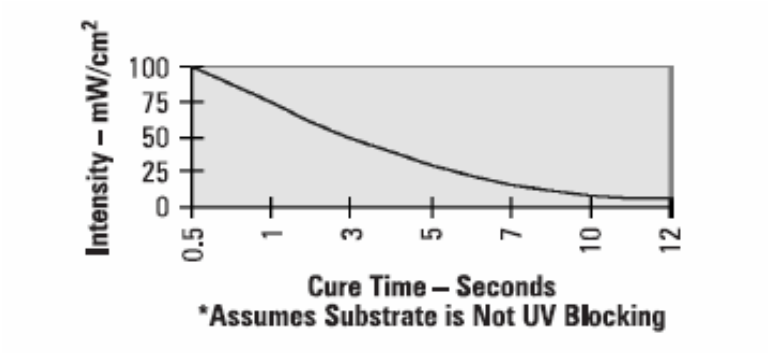

Fig 4: Typical Time to Cure Epoxy Through Clear Surface

The degradation of the lamp is important for overhead costs and waste that is produced. The intensity of the lamp can be a function of the degradation, so a proper balance must be determined. This is illustrated in Figure 5.

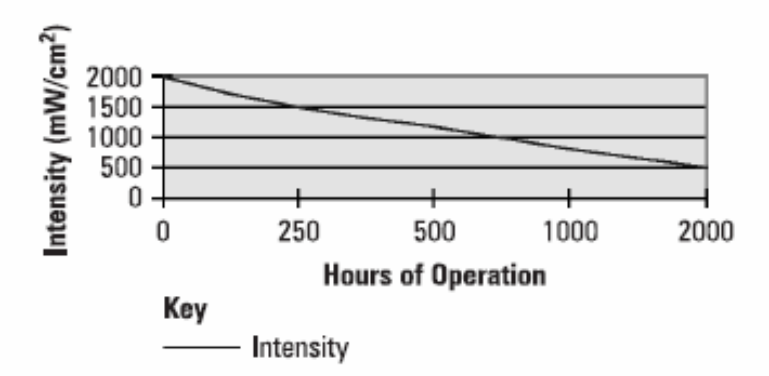

Figure 5: Degradation of Intensity of UV Lamp Over Time

Another part of the system is the programmable logic circuit (PLC). This portion of the automated system will control the functions and the diagnostics of the system. Normally this system is programmed with ladder-logic scripts, but it may also be programmed via some proprietary language [5]. The vendor will use their own methods.

2.2 FDA Regulation of Medical Devices

The Food and Drug Administration (FDA) was started in 1906. The goal of this agency is to monitor all food, pharmaceuticals, and medical-related products for quality and efficacy in the United States. The FDA has many guidelines that cover the the entire development and production of medical devices. From research and development, to manufacturing, to quality, the FDA has documentation that needs to be carefully read by engineers.

For the purposes of this project, the FDA regulations related to the manufacturing of medical devices is under the Quality Systems Regulations (QSR) requirements for manufacturers. Originally, the requirements were under its own section known Good Manufacturing Process (GMP) [6]. The FDA strictly enforced and defined the processes by which medical devices were produced. However, a motion was passed to move all GMP requirements under the QSR rules [7]. Unlike many of the other FDA systems, QSR varies and is highly dependent on the manufacturers.

2.3 Six Sigma

Six Sigma was a program started in 1987 by Bill Smith with the backing of Motorola CEO Bob Galvin. The goal of the system was to lower the number of defects found. The name comes from the notion that if a product is made to six sigmas, or standard deviations, of the specification limit on a normalized graph, there should be no failures or defects.

Six Sigma insists the operations follow the DMAIC sequence. DMAIC stands for Define, Measure, Analyze, Improve, and Control. Define is to make sure the problem

and boundaries and customer requirements are stated clearly. Measure refers to determining the process capabilities, stability and evaluation of the measurement systems. Analyze refers to identifying potential issues and sections of improvement. Improve refers to establishing measures, figure out the correlations between results and causes, implement mistake proofing, and verify process improvement. Control signifies monitoring of the outputs, controlling key inputs, and finalizing the project charter.

At Boston Scientific, many of the tools used to help achieve the Six Sigma guidelines are statistical tools. These tools measure and test for capability, normality, comparisons, fit, and population characteristics. Three of these tools are Gage R&R, Mini-tab, and ANOVA.

CHAPTER 3: DEVELOPMENT OF AUTOMATED SYSTEM USING EA&S

The Equipment Automation and Systems (EA&S) is the project life-cycle used by Boston Scientific to define the development, maintenance, and retirement of validated systems [8]. For the purposes of this project, we will refer strictly to the development stage as applied to our automated system. The development stage consists of five phases: Planning, Specification, Design, Construction, and Installation & Testing [8]. In addition, risk management is a constant priority throughout the project life cycle, often referring to the pFMEA (Process Failure Modes and Effects Analysis) as a means for control. What follows is a description of each phase, the documentation covered, and the activities surrounding each phase.

3.1 Planning Phase

The planning phase was used as a period to define the intended use of the system and plan for the deliverables needed to implement the system on the line. These deliverables depend predominantly on the risk associated with the process. The base patient risk and base compliance risk involved with the flush port housing to small tube process was gathered from the pFMEA and determined to be medium [9].

3.11 Initial Tests

To date, there have been a number of tests carried out on the manual process during production to fully characterize it. This testing has been the basis for defining process inputs and process parameters in the URS (User Requirements Specification) and the IU (Intended Use), documents the vendor uses to design a system to meets its original requirements [8]. The IU document defines the components and functions of the system

and places it in context. It also answers questions regarding user interaction, interfaces, and automated control. Lastly the IU document assesses the base risk associated with this particular process. The URS specifies the process inputs, raw materials, and the sequence of events required to build the system. Following the final construction of the system, engineering studies will be carried out as functional verification. Described below are the details of three initial tests conducted during the planning phase.

3.12 Time Study

A time study was conducted on the Flush port housing to small tube bonding procedure to detail each job element as performed by the product builder. For this particular operation, cycle time was broken down into the loading time, the machine time, and the unloading time. The loading time consists of three steps: alignment of the flush port housing to the small tube using a mandrel, placement of the two parts within the UV fixture, and the application of adhesive needed to create a bond between the two parts. The machine time here is simply the time it takes for the bond to be fully cured. Lastly, the unloading time represents the time it takes the product builder to remove the finished assembly from its holding fixture. Table 5 outlines each step and its representative cycle time [10].

Table 5: Small Tube to Flush Port Housing Time Study Results

Job Element	Manual Load	Machine Time	Manual Unload
Insert Flush Port on UV box	7.20 seconds		
Place small tube on UV box and inside flush port	5.20 seconds		
Add adhesive and close UV box	6.30 seconds		
Machine time		20 seconds	
Add loctite and secure			10.60 seconds
Inspect and remove mandrel			1.20 seconds

3.13 Tensile Tests

The current manual process has been validated to a standard destructive test per ISO 10555-1, Annex B, which describes the true tensile force at break for any particular bond. Non-standard material requests (NSMRs) were made for previous OQ/PQ validations and the tensile force met the required acceptance criteria of ≥3.37 lbf [11]. These sample units were tested on a calibrated INSTRON using a standardized pull-test. Similarly, the acceptance criteria mentioned above will be subjected to our automated system once it's ready for validation. It must be noted that while meeting the acceptance criteria is required for validation, it is not necessarily deemed advantageous to exceed the minimum force at break.

3.14 Adhesive Usage

In order to accurately estimate the adhesive used to bond the Flush Port housing with the small tube, deviations due to operator technique and time of day were taken into consideration. The materials planning department at Boston Scientific has monthly data

on the materials usage of any given process. To determine adhesive usage at our operation, we divided the amount of adhesive used in a month by the number of catheters built during that month. The resulting amount of adhesive used per application is meant to be calibrated and fixed within our automation system.

3.2 Specification Phase

The goal of the specification phase is to define the functionality of our automated system and to fulfill the user requirements detailed in the planning phase. Topics including system alarms, sequence of operations, security, and safety were documented in the FS (Functional Specification). Furthermore, a Requirements Traceability Matrix (RTM) document was drafted to verify that each user requirement was addressed by one or more associated functional specifications [11]. The IU, URS, and FS documents together consisted of a package given to the vendor to help develop an initial design. Below is an example of the system start-up and initialization section as seen in our FS document:

[FS-01]	The system shall operate using a standard electrical connection of 220V (± 10%), 20 Amps single phase, with neutral 50/60Hz [URS-01]
[FS-02]	The system shall launch the default software application when commanded. [URS-02]
[FS-03]	The system shall initialize using configuration values when the system is powered on. [URS-03]

3.3 Design and Feedback

Using the documents mentioned from the previous two development phases, the vendor created concept designs for our team to review. The goal during the design phase was to ensure system conformance to defined requirements and risk mitigation through proper controls. Two iterations of the design are shown in Figures 6 and 7 [12]. Figure 6 shows the system within a large enclosure – to inhibit UV light from escaping its confines. The flush port housing is placed onto a flexible mandrel and sits on top of a rotating platform (teal). The small tube and strain relief follow and are aligned using the same mandrel. The two UV light guides are positioned laterally; such that they cure the site of adhesive application. Lastly, the adhesive dispensing unit sits on a pneumatic slide that comes in and out of the bonding area. After conducting a design review with manufacturing engineers and quality engineers, our team wanted something simpler that allowed greater accessibility to the catheter sub-assembly. The second iteration of the design, Figure 7, shows a clam-shell design that meets those needs. After receiving cross-functional approval on this concept, a 'design freeze' was put in place. Describing the operation of the system, the product builder loads the parts in place and presses the green start button to initialize the process. This signals the adhesive dispensing unit to position itself near the bonding site for adhesive application. The entire assembly rotates on the platform while adhesive is applied at a volumetric rate. Next, the dispensing unit retracts back into position while the clam shells close over the bonding site. The UV cycle commences and cures the bond for 20 seconds while it is hidden from view.

Finally, the clam shells open and the product builder is able to unload the finished sub-assembly.

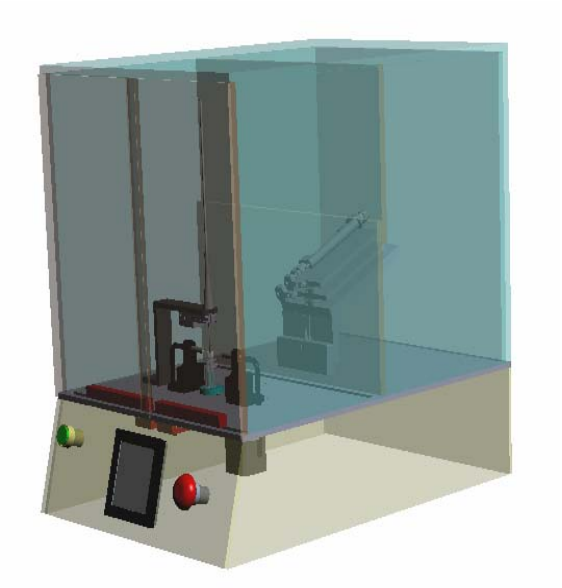

Figure 6: Initial Concept design from Vendor

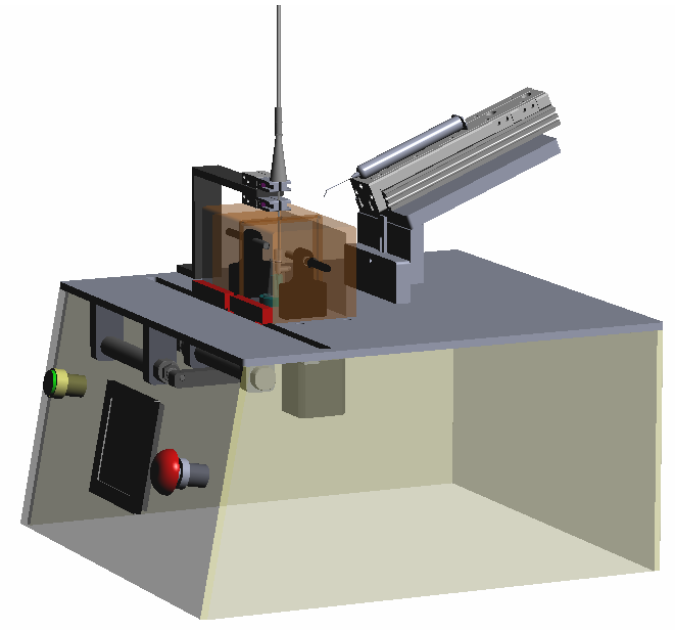

Figure 7: Final Concept design from Vendor

3.4 Construction of System

The ultimate goal during the construction phase is to build the system according to the defined design. All the software and equipment needed to build the system are laid out in the SCS (Software Configuration Specification) and SDS (Software Design Specification). It is at this stage that another trace analysis is conducted on the system—to ensure that system requirements have been accompanied by appropriate design and testing. Once all design deliverables are set in stone, an IV/OT (Installation Verification and Operational Testing) document is drafted [8]. These protocols are drafted during construction phase so they are ready in time for validation efforts once the system is in house. Additionally, we held talks with industrial engineers to determine the layout of the system and how the work content will be balanced. Furthermore, consideration in changes to equipment, documentation, guarding and safety requirements, facility requirements, and calibration requirements will be addressed in this phase. Generally, addressing these topics and optimizing their affects on our process will help us realize our full savings.

CHAPTER 4: ECONOMIC JUSTIFICATION

4.1 Executive Summary

Most analysts predict that medical device growth will outpace all other industries in the coming years and decades. In order for medical device companies to keep up with growing demand, they must optimize manufacturing. When manufacturing systems are not properly planned and managed, defects can arise in parts and production can be delayed. This is a critical issue for companies to address.

SCP Consulting oversees the entire life cycle of manufacturing optimization, from design to construction to installation. We develop automated systems to be placed in the production line. These automated systems can decrease scrap, increase production, and reduce costs. Our knowledge of both manufacturing and the intricacies of the medical device industry differentiate us from our competitors.

Our services can be applied at any of the numerous medical device companies around the United States. Based on the size of the medical device market and its projected growth, we can estimate that the market for our services is between $750 million and $1.0 billion. This number will grow in line with growth of the industry as a whole.

There is a great deal of competition in the consulting space, though firms that focus solely on medical devices are more rare. Most large firms employ consultants who are familiar with manufacturing operations, though they tend to have knowledge that is more broad than specialized. In addition, there is competition from within medical

device companies themselves, as many companies avoid hiring outside contractors that will need access to proprietary information.

In order to cover salaries and overhead, we will need capital investment of $750,000 for three years. This investment will be used to pay the salaries of three consultants at $75,000 each per year, as well as overhead costs of $10,000 per month. A three year investment will allow us to establish our business and build a reputation in the industry.

Based on our projected profits and losses over the next three years, we estimate that we will break-even early into our third year. By this third year, we expect revenues of approximately $500,000.

4.2 Problem Statement

The medical device industry is poised for exceptional growth. An aging population and the expectation of longer, healthier, more active lives means medical device manufacturers must prepare to meet this demand. In order to keep up, companies have to ensure that manufacturing is operating as efficiently as possible. This means parts have to be produced reliably with little scrap, production lines have to move quickly, and costs need to be reduced. Manufacturing systems that are not properly optimized, that are rushed, or that are not well-planned and supervised, lead to inconsistency and possible defects in the resulting parts.

In order to optimize production, many companies are introducing automation into the assembly line. However, this is a complicated process that must be properly managed in order to reap the benefits that automation provides. If all risks are not mitigated during

design and construction of the system, the resulting parts will not meet specification and the entire investment will be a waste. In addition, when any new system is implemented, a period of inefficiency arises due to the learning curve. If not properly supervised, declining performance can lead to a "Valley of Despair," which leads to fewer parts being produced and decreased profits for the company.

Many companies, though brilliant at research and development, fail to understand the complexities of manufacturing. Without proper expertise, they will be unable to meet the growing demand for their products and will be unable to keep up with competition. Being able to produce devices that customers can purchase is the most critical duty of a company, and ranks as the most vital issue they will have to address.

4.3 Solution and Value Proposition

SCP Consulting develops detailed, specific optimization solutions for medical device companies of all sizes. We help companies meet the growing demand for their products by ensuring that their manufacturing operations are running as smoothly as possible. We develop automated systems for production lines and oversee the entire life-cycle of the project, from design all the way through to construction, testing, and installation. We take complete control of vendor management, conducting design reviews and ensuring work is progressing according to schedule.

In order to avoid the "Valley of Despair," we make certain that the workforce is properly trained and given detailed documentation on the operation of any new system. The systems themselves are designed to be as intuitive to use as possible, with multiple safety checks in place that mitigate the chances of incorrect operation. By carefully

overseeing every stage of development, we are able to ensure that our manufacturing solutions will not negatively affect overall production during ramp-up.

What separates SCP consulting from our competitors is our understanding of not only manufacturing, but also the medical device industry. We understand the FDA and the regulatory aspects of the industry. We understand how medical devices function, what their purpose is, and how they affect the human anatomy. And perhaps most importantly, we understand the risks involved with these devices and what can go wrong should one malfunction in or around the human body. This knowledge ensures that we place the utmost care in all of the work that we do.

4.4 Market Size

While companies do not publish how much they spend on automation and optimization of manufacturing, we can estimate the market size for our services by considering the size and growth of the overall medical device market. According to analyst Michael Rosen, the U.S. medical device market generated revenues of approximately $240 billion in 2008. Table 6 lists the leading U.S. medical device companies by revenue. According to Frost & Sullivan, the medical device market is poised for growth of 9.0 percent annually until 2013 [13].

Table 6: Leading U.S. medical device companies (2007)

Company	2007 Revenues ($ billions)
Johnson & Johnson	21.7
GE Healthcare	17.0
Medtronic	12.9
Baxter International	11.3
Covidien	10.0
Boston Scientific	8.4
Becton Dickinson	6.5
Abbott Labs	6.3
Stryker	6.0
Cardinal Health	5.0

Based on our discussions with a manufacturing project manager, companies such as those listed in Table 6 spend on average between 2% and 5% of revenues on operations, which includes manufacturing and related activities [14]. Extrapolating this number out over the entire industry, we can estimate that between $5 billion and $12 billion was spent on operations in 2008, with this number growing annually at a rate equivalent to the industry as a whole. While difficult to ascertain exactly, the market for our services can thus be determined to be a not insignificant fraction of the total amount spent on operations. We estimate this number to be between $750 million and $1 billion.

4.5 Competitors

There are numerous consulting firms, small and large, that specialize in manufacturing consulting. Most well known firms, including global leaders such as Deloitte and Bain, have divisions that concentrate on manufacturing operations. Consultants employed by these large firms, however, have a reach that is much broader than just medical devices. Because of this, their ability to fully understand all of the complexities of the industry, including all of the regulatory aspects, might be limited.

However, it is not the outside consulting firm that is our biggest competition. Most medical device companies prefer to handle all manufacturing activities in-house. Because these companies are sitting on large amounts of confidential information, they are often hesitant to let outside contractors work internally on their projects. In such cases, it is necessary for the outside consulting firm to have a strong reputation that breeds trust and confidence.

4.6 Customer

Because the services provided by SCP Consulting require serious investments of time, people, and money, it is necessary for our marketing teams to sell directly to senior-level management at medical device companies. While the need for manufacturing optimization is usually noticed and initiated by engineers who work on the production line, they do not have the authority to allocate resources, shift workload, and temporarily slow production while the new system is being installed. Manufacturing efficiency is vital to a company's success, so most manufacturing issues will be quickly escalated to upper management.

Our optimization solutions are usually implemented first within one specific product line, which might be just one part of a larger medical division. For instance, at Boston Scientific our automated system is to be installed within the IVUS Catheter assembly line, which is one product within the Interventional Cardiology division. If our system improves production in the product line, it may be implemented more widely.

4.7 Costs

As a consulting agency whose primary product is technical skill and manufacturing expertise, we have limited costs. All systems that we implement are funded by the company through which we are contracted; thus we do not have to bear any of that financial risk. We also do not need a research and development department. The majority of our recurring costs stem from salaries, overhead, and training. At this point we do not have a marketing department, sales, or administrative needs, though those might be necessary in the future.

Table 7 shows our estimated costs for the current year and two years into the future. We plan to hire additional marketing, administrative, and sales personnel in 2011 and 2012 to help grow our business. In addition, we will need to hire additional consultants to handle the additional workload and move into larger facilities with more space. Based on these needs, our costs will greatly increase over the coming years. Of course, we anticipate that increased future revenue will make this worthwhile.

Table 7: Estimated costs for next three years

	2010	2011	2012
Three Founders' wages (total)	180K	255K	300K
Rent	24K	48K	48K
Overhead	15K	25K	45K
Admin/Sales/ Marketing	0	180K	345K
Additional consultants	0	225K	450K
Total	219K	733K	1.2M

4.8 Price Point

The cost of our services varies based on the size and complexity of the project we are undertaking. We charge a rate of $90 per hour for our consulting services, which does not include any vendor or material costs. As an example, implementing the automated system at Boston Scientific took three consultants about 3 months to complete and required an investment of $150,000 by BSC. This included $130,000 for our consulting work and $20,000 that was paid to the vendor. The vendor costs were fixed at the beginning of the project and included both construction and materials.

4.9 SWOT Assessment

Table 8 lists the strengths, weaknesses, opportunities, and threats (SWOT) of SCP Consulting services and our business model.

Table 8: SWOT Assessment of SCP Consulting

Strengths	Weaknesses
We participate in a niche market: Manufacturing consulting services that focus solely on the medical device industry. We are a small, nimble organization that can address manufacturing issues at both large and small companies.	We do not have the reach or reputation of large, established consulting firms such as Deloitte, Bain, or BCG. Large firms can dedicate more resources to a project than we have available.
Opportunities	**Threats**
There are thousands of medical device companies, many of which are seeing rapid growth. These companies will need assistance in scaling-up their manufacturing operations.	Many companies prefer to keep manufacturing activity confidential in order to protect IP. These companies would be more likely to use internal teams when addressing manufacturing issues.

4.10 Investment and Capital Requirements

As stated previously, the majority of our fixed costs are due to salary and overhead. We currently have three engineers on salary, each earning $60,000 per year. In addition we have costs of approximately $3,250 per month on rent, utilities, and other miscellaneous expenses. These costs will increase in years two and three. In order to cover our expenses for the first three years, we will need $2,000,000 in total investment. This will provide us with adequate time to establish our business in the industry.

4.11 Personnel

SCP Consulting was founded by three engineers who understand not only manufacturing and how to make it more efficient, but also the ins and outs of the medical device industry. This specialized knowledge is what sets us apart from the numerous manufacturing consultants in business today. Though we are currently a small consulting operation, it will be necessary to expand in order to compete with the larger firms. This means hiring additional consultants who have the dual knowledge of manufacturing and medical devices that we find so important. It means hiring a sales team that can be in contact with senior-level management at medical device companies and can effectively pitch our services. It means establishing a marketing department that will able to find and target companies around the United States that are in need of our services. Eventually, once operations begin to grow, it will mean bringing aboard a CEO that can effectively handle a large business.

4.12 Business and Revenue Model

Growth of our consulting business will require a multi-phase approach. Initially, we have to leverage our contacts within the medical device industry in order to obtain contracts and build a reputation in the industry. From there, we can use these references and examples of our work to reach out to companies that we've had no prior contact with. By targeting upper management and clearly defining the benefits of manufacturing optimization, we will be able to take on additional projects of increased importance. As we become profitable, we will be able to establish a marketing department that can work full-time on researching companies and finding where our services would be needed.

4.13 Strategic Partners

The most likely strategic partnership that we will establish is with a vendor or group of vendors that specialize in system construction. Our ideal criteria for a vendor is at least ten years of experience, a track record of success in past projects, diversification to be able to handle different types of projects, and the floor space to handle projects of varying size. Once a vendor proves successful, it is advantageous to establish a partnership with that vendor so that both sides bear risk and reward.

4.14 Profit and Loss Statement

Table 9 shows our projected profit and loss over the next three years, as well as a calculated return on investment (ROI). We don't anticipate achieving profitability in the next three years due to increases in salaries and overhead.

Table 9: Return on Investment Calculation

Year	2010	2011	2012
Cost	$219,000	$733,000	$1,200,000
Revenue	$130,000	$390,000	$780,000
Profit/Loss	-$89,000	$-343,000	-$420,000
ROI	-0.41	-0.46	-0.35

4.15 Exit Strategy

As a consulting firm, our "asset" is essentially experience, knowledge, and skill. While we do not see ourselves exiting this business in the near future, there is the possibility that our company could be acquired by a larger consulting firm that wants to gain a foothold in the medical device market. Because of the incredible growth predicted in this industry, the specialized knowledge that we have would be valuable for many firms.

CHAPTER 5: PROJECT SCHEDULE

The project was essentially divided into two stages. Semester One was used to refine our topic, research the literature, and prepare project scopes and economic analyses. Semester Two was used to conduct the actual project itself, including determination of requirements and specifications, working with the vendor on finalizing design, and managing vendor performance. At the time this report was compiled, installation and performance qualifications had not yet been completed, though they will be performed over the course of the next two weeks.

5.1 Project Milestones

Table 10 lists the start dates, durations, and end dates of various project tasks.

Table 10: Milestones for Project

Tasks	Start Date	Duration (days)	End Date
Selection of topic	8/14/2009	14	8/28/2009
Assembly of committee	8/28/2009	7	9/4/2009
Literature search	9/7/2009	45	10/22/2009
Project scope report/presentation	9/14/2009	10	9/24/2009
Literature survey/presentation	9/28/2009	10	10/8/2009
Economic analysis/presentation	10/12/2009	10	10/22/2009
Final scope report	10/26/2009	10	11/5/2009
Final scope presentation	11/9/2009	10	11/19/2009
Define intended use	11/23/2009	7	11/30/2009
Define user requirements	12/1/2009	14	12/15/2009
Risk analysis	12/15/2009	7	12/22/2009
Define functional specifications	1/10/2010	25	2/4/2010
1st design review and feedback	2/15/2010	14	3/1/2010
2nd design review and feeback	3/1/2010	14	3/15/2010
Construction of system	3/16/2010	30	4/15/2010
Site acceptance test	4/15/2010	14	4/29/2010
Finalize documentation	3/1/2010	60	4/30/2010
Installation qualification	5/3/2010	5	5/8/2010
Performance qualification	5/10/2010	5	5/15/2010

5.2 Project Gantt Chart

Figure 8 depicts our project milestones graphically in Gantt Chart format.

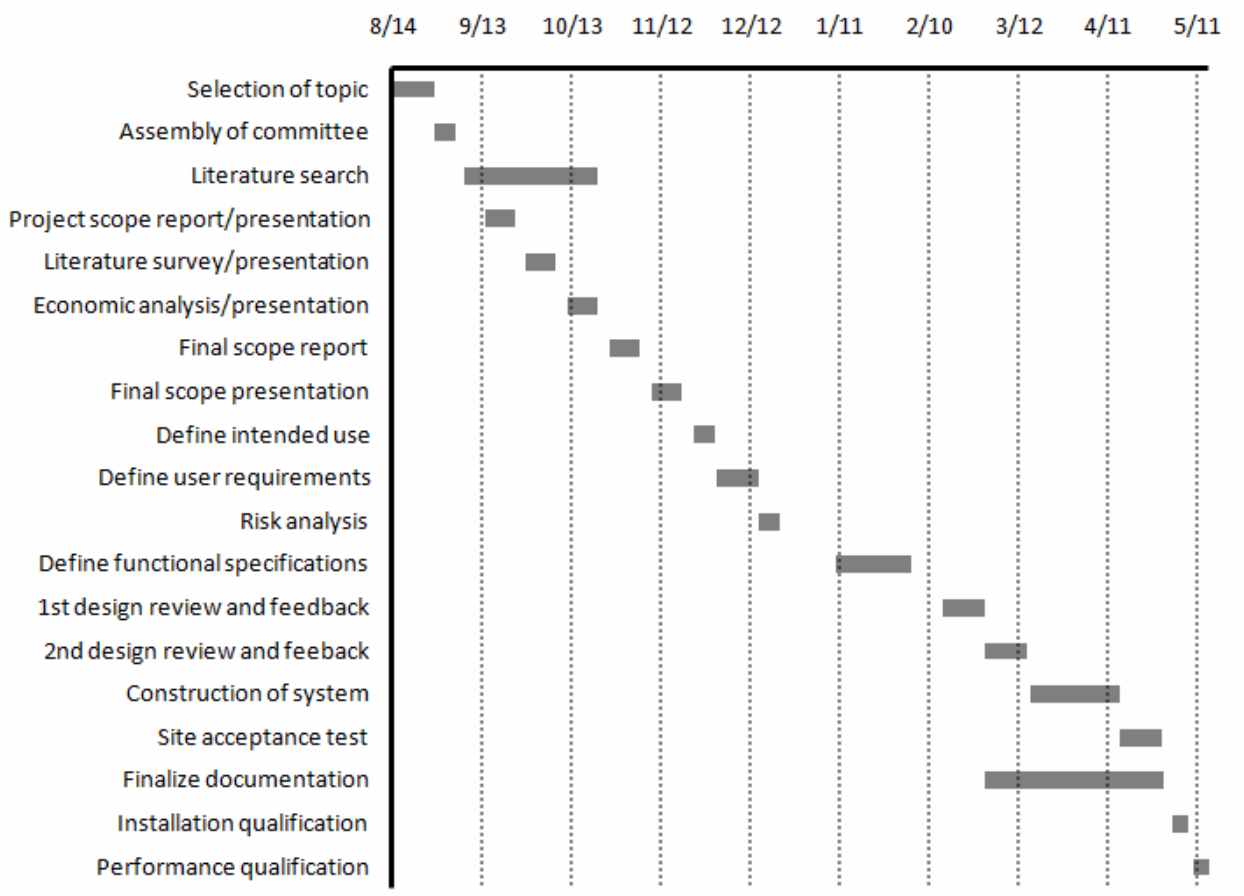

Figure 8: Project Gantt Chart

CHAPTER 6: FUTURE WORK

The future work for this project includes validating the system for production use. Process validations include the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). The IQ verifies that the system has been properly assembled and installed according to system drawings and specifications; it is embodied in the IV/OT document as completed in the construction phase [8]. The OQ tests the system within its minimum and maximum ranges of use and the PQ tests the system at its nominal conditions. Successful execution of an IQ, OQ, and PQ protocol will demonstrate that our system operating within the defined process parameters will consistently result in a Small tube/Flush Port bond that meets all pre-determined requirements.

In order to start validation, the risk priority number (RPN) must be determined to prescribe a minimum number of samples to be tested. The pFMEA document helps calculate the product of the failure severity, occurrence, and detection (SxOxD) scales to achieve a Risk Priority Number (RPN) [9]. The RPN value, as seen in Table 11 is ultimately correlated to Boston Scientific's corporate sampling plan.

Table 11: Risk Priority Number Chart

RPN Range	**Risk Index Level**	*Risk Index Decision Rule*
1 – 9	0	If severity is $\geq$4, a baseline Risk Index Level 2 will be assigned.
10 - 27	1	
28 - 59	2	
$\geq$60	3	N/A

The corporate sampling plan suggests a minimum number of samples to test in order to meet the minimum acceptance criteria with a certain confidence. Two ISO

certified tests need to be completed on our system: tensile tests and pressure tests. For tensile tests, units need to exceed a tensile force of >3.37lbf with a ppk>0.69 for a one-sided variable with 95% confidence and 5% LTPD (lot tolerance percent defective). For pressure tests, samples need to undergo 310kpa of pressure for 30 seconds or more with 95% confidence and 5% LTPD. The LTPD is the level of quality generally rejected by the sampling plan. If all our tests pass, we can say with 95% confidence that all our lots are equal to or better than the LTPD [11]. Essentially, the LTPD describes the risk associated with releasing bad lots or batches, which is seen as critical in the medical device industry. After the appropriate validation samples are built and tested for, a final report will list the results. These results will pass through cross-functional approval, after which they will validate our system for production use.

CHAPTER 7: CONCLUSION

In the course of implementing a new automated system in the IVUS Catheter production line, it was necessary to manage the entire life cycle of the project. This included: the planning stage, where user requirements and risks were determined; the specification phase, where functional specifications were established; the design phase, where design reviews were conducted with the vendor; and the construction phase, where vendor management became necessary as they constructed the system. Over the course of this life cycle, risks were mitigated by continually updating the necessary documents and ensuring no steps were overlooked.

At the time of this report, system construction is complete. Because we were careful when determining requirements and specifications, we can be fairly certain that our finished system will validate for use. Over the course of the next two weeks, we will be performing installation and performance qualification tests to ensure that the parts made by the system meet specification. Once the system passes these tests, we will install the system into the line.

REFERENCES

1. Iribarne, Alexander, et. al. (2010). Eight year experience with minimally-invasive cardiothoracic surgery. *World Journal of Surgery*, 34, 611-615.
2. Turner, M. (1999). Adhesives: A Selection Guide. Medical Device Technology, 29-33.
3. Bachmann, A. G. (2000). Light curing adhesives increase productivity. Assembly Automation, 20, 144-149.
4. Tavakoli, S. M., Pullen, D. A., & Dunkerton, S. B. (2005). A review of adhesive bonding techniques for joining medical material. Assembly Automation , 100-105.
5. Hu, W., Schroeder, M., & Starr, A. G. (2007). A Knowledge-Based Real-Time Diagnostic System for PLC Controlled Manufacturing Systems. London Department of Computing.
6. FDA. (2009). Current Good Manufacturing Practice.
7. FDA. (2009). Quality System Regulation.
8. E&AS Life Cycle Process Training, Participant Guide, rev. 10/3/07 (internal)
9. pFMEA spreadsheet--Boston Scientific (internal)
10. Work Content Graph--Telescope Assembly Line, Flush Port to Small Tube
11. Boston Scientific Corporate SOP---Validation Sampling Plans (internal)
12. Boston Scientific Design Review
13. Frost & Sullivan [http://www.financialservices.frost.com/]
14. Interview with Garvin Leon, Project Manager – 4/15/10