Degradable Staples and Delivery Device

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Degradable Staples and Delivery Device

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Abstract—The development of the Degradable Staples and Deployment Device has been documented in a Design History File (DHF) and summarized in this report. The device underwent the Design Control Guidance for Medical Device Manufacturers of the Food and Drug Administration (FDA). The User Needs, Design Inputs, Design Process, Design Outputs and Medical Device Stages are described with supporting documentation.

I. INTRODUCTION

A. Clinical Problem

Some of the most common methods to secure skin grafts to healthy tissue include sutures, skin glues, and staples. Of these three methods, stapling is usually preferred. Grafts require many anchoring points, so suturing is often time-consuming. Skin glues have limited use, and they have a short cure time, which makes them impractical since larger areas of application exceed the adhesives cure time. Therefore, staples are the most convenient method to secure skin grafts.

Staples are quick to use, saving time during the procedure. They function well and secure the graft in place. The main disadvantage of using staples is that they are not absorbable by the body, meaning a second procedure must take place, 5–7 days after the staples are placed, in order to remove them. Small cases use roughly 30–40 staples, and larger cases can use as many as hundreds of staples. Removing each staple one at a time makes the procedure tedious, time-consuming, and painful. Sometimes, staples can be missed, and a patient may retain them, which leads to more pain and discomfort. Physicians and technicians may encounter challenges accessing and working with the staple if these are located in complex areas of the body. Staples can cause pigmentation in the skin, damage to the skin, bleeding on the skin, and/or scarring. Once secured, skin grafts start healing into the healthy skin. It usually takes about 5–7 days for the graft to hold itself in place, so a method of tacking the graft down during the initial period is needed. Additionally, the need to physically remove the staples must be eliminated.

B. Research of Existing and Alternative Solutions

Medtronic is the manufacturer of the V-Loc™ Wound Closure Device – Barbed Suture. This product is a device that facilitates the closure of wounds while eliminating the need to tie knots. Through eliminating knots, any complications associated with knots are also eliminated. This product evenly distributes tension throughout the wound and takes less time to suture. Anchoring is present through the pattern of the barbs on the suture [1].

The barbed design of the suture reduces the occurrence of infections. This is because there are not any internal pores present in the suture. Additionally, there is lower risk of an immune response upon application. Another advantage of the product is the cost due to efficiency. In the same surgical procedure, fewer barbed sutures are required than conventional sutures. Although this product has many advantages, there is also a disadvantage present. A disadvantage is that the mechanical properties of a barbed suture are lower than conventional sutures [2].

Medtronic is also the manufacturer of Velosorb, which is a braided suture. The suture consists of an absorbable synthetic polyester with glycolide and lactide. An advantage of this product is its predictability. Additionally, due to its strength and absorption, it yields a lower response from tissues. A disadvantage of this product is the limitation of the duration of use. Since it is absorbable, it cannot be used for more than seven days. However, this could also be an advantage depending on the desired absorption period. It also has limitations regarding application sites. It should not be used in ligation, ophthalmic, cardiovascular, or neurological procedures [3].

Arthrex is the manufacturer of the Collagen Coated FiberWire® Suture. The suture is a multi-strand long-chain polyethylene with an ultra-high molecular weight core. It is also composed of a braided sheath of polyester and ultra-high molecular-weight polyethylene. An advantage of this product is that it has a softer coating, which yields easier handling of the product. The material is high in strength and resistant to abrasion, which is beneficial. Additionally, the suture breaking during tying is eliminated due to the strength of the product. A disadvantage may be that the suture is not absorbed within the desired timeframe, which could result in time, resources, and potential pain for the patient during suture removal [4].

Baxter is the manufacturer of ARTISS. This is designed for burn and face-lift patients with a healing process dictated by tissue approximation. This product is a fibrin sealant with many advantages. ARTISS takes 60 seconds to complete initial polymerization, which allows time to position the graft accurately. ARTISS has adhesive properties that enable adherence of the entire surface of the skin graft to the wound. Additionally, ARTISS eliminates staple application and removal, which is beneficial. A disadvantage of ARTISS is that it cannot be used in individuals who have hypersensitivity to...
Cooper Surgical is the manufacturer of Insorb, which is a stapler and absorbable skin staple. The staple consists of a copolymer that has been sourced from polylactide-polyglycolide, which is commonly used in wound closure applications. This product has many benefits compared to a suture. The product increases the occurrence of skin eversion, which improves healing. It also reduces the time during operation and hand fatigue from the individual applying the product. Additionally, the risk of needlestick injuries is eliminated. The product has many benefits compared to metal staples. The pain associated with metal staples is eliminated as well as the potential for "railroad track" scars to occur. The product also eliminates the cost, inconvenience the patient experiences, and discomfort during the removal of metal staples [6]. There are also some disadvantages associated with this product. It is contraindicated with metal staples. The product shall secure the skin graft is the main purpose of our product. Therefore, it has the highest weight as a 5. The user requirement of “reduction of pain” was assigned a weight of 5 since the clinician wants to reduce the amount of pain that the patient experiences when the product is removed. This can be achieved if the removal procedure is removed as a whole. The user requirement of “versatility” has a weight of 4. The product needs to be able to be used on various anatomical sites. Application based on size or size should not be a limitation. The objective is one standard product that can be used for various applications. The user requirement of “biocompatibility” has a weight of 5 because it is very important. If the product is not biocompatible, it cannot be implanted in the body, and it will cause allergic and immune responses to develop. Next, in phase 1 of the QFD, the user needs were converted into engineering requirements. Then, the relationship between user needs and engineering requirements was determined. The strength of these relationships is demonstrated in the technical matrix of the QFD. Target values were also established for each engineering requirement. Also in this phase was the completion of customer competitor evaluations. Competitor products were evaluated on how well they fulfilled each user requirement. They were ranked on a scale of 0 (worst) – 5 (best) based on how well they met each user requirement.

### III. DESIGN INPUTS STAGE

#### A. Phase I of Quality Function Deployment (QFD)

Phase 1 of the quality function deployment (QFD) involves planning the function of the product based on the customer’s needs. First, the user requirements were implemented into the QFD. Then, the importance of each user requirement was identified, and weights were assigned based on the scale, 0 (least important) - 5 (most important). The user requirement of “quick application ability” was weighted as a 4. The clinician would like the application of the product to yield a time-convenient and feasible procedure. Although, if it takes longer for the product to be applied and still accomplishes the goal of securing the skin graft, that is acceptable. The user requirement of “absorbability” was weighted as a 5. The clinician wants to eliminate the need to remove staples. If the product is absorbable, it saves time and minimizes the pain experienced by the patient during removal. It also reduces the risk of the product being accidentally left behind. The user requirement of “securing of skin graft” was assigned a weight of 5 since securing the skin graft is the main purpose of our product. Therefore, it has the highest weight as a 5. The user requirement of “reduction of pain” was assigned a 5 since the clinician wants to reduce the amount of pain that the patient experiences when the product is removed. This can be achieved if the removal procedure is removed as a whole. The user requirement of “versatility” has a weight of 4. The product needs to be able to be used on various anatomical sites. Application based on size or size should not be a limitation. The objective is one standard product that can be used for various applications. The user requirement of “biocompatibility” has a weight of 5 because it is very important. If the product is not biocompatible, it cannot be implanted in the body, and it will cause allergic and immune responses to develop. Next, in phase 1 of the QFD, the user needs were converted into engineering requirements. Then, the relationship between user needs and engineering requirements was determined. The strength of these relationships is demonstrated in the technical matrix of the QFD. Target values were also established for each engineering requirement. Also in this phase was the completion of customer competitor evaluations. Competitor products were evaluated on how well they fulfilled each user requirement. They were ranked on a scale of 0 (worst) – 5 (best) based on how well they met each user requirement.

#### TABLE 1. USER REQUIREMENTS

<table>
<thead>
<tr>
<th>Number</th>
<th>User Needs Title</th>
<th>Statement</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Quick Application Ability</td>
<td>The user shall deploy two staples into the skin in less than one minute.</td>
<td>Clinician</td>
</tr>
<tr>
<td>2</td>
<td>Degradability</td>
<td>The product shall degrade in mass between 40-57% within 4 days of implementation, which is the required degradation for the staple to completely dissolve in the 7 – 10 days requested by the physician.</td>
<td>Clinician</td>
</tr>
<tr>
<td>3</td>
<td>Securing of Skin Graft</td>
<td>The product shall secure the skin graft to healthy tissue within a range of 11 - 21 psi. This range was calculated from studies completed with metal staples.</td>
<td>Clinician</td>
</tr>
<tr>
<td>4</td>
<td>Reduction of Pain</td>
<td>The product shall not cause the patient discomfort after 5-7 days of implementation.</td>
<td>Clinician</td>
</tr>
<tr>
<td>5</td>
<td>Versatility</td>
<td>The product shall be able to be applied in three different anatomical locations (primarily over soft flat tissue, primarily over soft curve tissue, and primarily over bony protuberances)</td>
<td>Clinician</td>
</tr>
<tr>
<td>6</td>
<td>Biocompatibility</td>
<td>The product shall be composed of materials compatible with the human body.</td>
<td>Clinician</td>
</tr>
</tbody>
</table>
B. Engineering Requirements

The engineering requirements that were derived from our user needs were sterility, biodegradable materials, simple usability, versatile application, biocompatible materials, and tissue grip strength. The formal engineering requirements are below:

1. Sterile: The product should have a SAL level of $1 \times 10^{-6}$.
2. Biodegradable Material: The product shall have a mass (g) reduction of at least 50% by the seventh day of implementation while maintaining structural integrity.
3. Simple Usability: The product's delivery system should be applied to 1 in² of the skin within two minutes.
4. Versatile Application: The product shall be able to be applied in a variety of different anatomical locations such as bony structures like hands, feet, and chin; soft curved structures like thighs, calves, and buttocks; and soft flat surfaces male chest and abdomen.
5. Biocompatible Material: The product shall be biocompatible.

Each engineering requirement was derived with the consideration of the clinician, patient, and safety necessities. Sterility is a requirement that relates to the customer requirements of “Degradability” and “Biocompatibility” as the product needs to be sterile if it will be in contact with the skin to avoid infection. Ideally, the product should have an SAL level of $1 \times 10^{-6}$ because it will provide a greater assurance of sterilization for a product that will be in contact with exposed skin [8]. Due to limited resources, sterility is an objective for the product. Biodegradable material is a necessary requirement as it satisfies the customer requirements of “Degradability,” “Reduction of Pain,” and “Biocompatibility.” With a biodegradable material, the product would degrade in the skin and will aid in eliminating additional pain in burn patients as there is no need for product removal. The biodegradable material will need to be biocompatible to reduce the possibility of the body rejecting the product and ensure the safety of the patient. The product must decrease in mass by a minimum of 50% to ensure that it is biodegradable and will maintain its strength as the skin heals with the skin graft within the first week of product implementation. Simple Usability is a requirement that is applicable with the user need of “Quick Application Ability.” The product should be easy to use in order to facilitate quick use. Therefore, the objective of the product’s delivery system is to allow the staple to be applied to a square inch of skin graft within two minutes. Another requirement is a versatile application, which satisfies the customer requirement of “Versatility.” If the product is applicable in at least three different anatomical sites of the body (e.g. bony structure such as a hand, curve soft structures like the calf, and flat soft structures such as the abdomen), it proves that the product is adaptable to different locations. A biocompatible material is a necessary requirement as it is applicable to the customer requirement of “Biocompatibility,” which will confirm that the product is safe and will not cause allergic reactions in the body. Several tests would need to be conducted to verify the biocompatibility of the product, but this is a necessary requirement as the product cannot be used on the patient if it doesn’t pass the biocompatibility tests. Lastly, tissue grip strength is a requirement that fulfills the customer requirement of “Securing of Skin Graft.” This requirement is necessary as the skin graft needs to be secured by the product to meet the minimum capability of current solutions available in the market. Since the product will adhere to at least a square inch of tissue, there should be a skin graft pull-out force between 11 to 21 psi to observe the strength of the product on the tissues while still being able to remove the product easily during testing [9].

C. Preliminary Risk Assessment – FMEA

At this stage of the project, a failure mode and Effect Analysis (FMEA) was completed to identify and evaluate potential risks associated with the intended final product. Six ideal functions were generated and used to derive potential failure modes. Twelve potential failure modes and fifteen potential causes of failure were identified and derived at this stage of the design process.

For evaluation purposes, three different parameters were generated: severity, occurrence, and detection. All three graded parameters were evaluated from one to three. All parameters and respective grade levels were defined in further detail, as shown in Table 2.

<table>
<thead>
<tr>
<th>TABLE 2. FMEA PARAMETERS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severity</strong></td>
</tr>
<tr>
<td><strong>Level</strong></td>
</tr>
<tr>
<td>Description</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td><strong>Occurrence</strong></td>
</tr>
<tr>
<td><strong>Level</strong></td>
</tr>
<tr>
<td>Description</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td><strong>Detectability</strong></td>
</tr>
<tr>
<td><strong>Level</strong></td>
</tr>
<tr>
<td>Description</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
</tbody>
</table>

Each failure mode identified on the FMEA was evaluated and assigned a severity, occurrence, and detectability level. Risk priority numbers (RPNs) were calculated for each failure
mode and failure effect. Appendix D includes the full assessment table. For the purpose of this project, RPNs one through three are considered acceptable risks. RPNs four through nine are identified as risks that require a justification, and levels 10 through 27 are identified as unacceptable risks.

Twelve out of fifteen failure modes and effects were identified as requiring justification with RPNs ranging from four to nine. The remaining failure modes and effects were identified as acceptable with RPNs of either two or three.

D. Industry Standards

There are several industry standards that are relevant and applicable to ensure that the derived engineering requirements consider safety and efficacy. The standard for sterility is ISO 11137-3:2017: Tests for Sterilization, which requires sterilization tests to prevent infection and maintain patient safety [10]. The standard for biodegradable materials is ASTM F2902-16e1: Guidance for the assessment of absorbable polymeric implant, which verifies the mechanical properties of a biodegradable polymer that will be implanted in the body [10]. For biocompatible materials, the regulatory standard would be ISO 10993: Biological evaluation for medical devices [10]. This standard will ensure the safety of the device that will go into the body and has many tests that are applicable to the device, such as tests for sensitization and skin irritation, tests for local effects after implantation, and tests for cytotoxicity in the body. Other standards that can be applied to our device include ISO 14971:2019: Application of risk management to medical devices and ISO:13485: Quality Management Systems, which could be used for the engineering requirements of simple usability and versatile application as these standards investigate potential threats and mitigation and ensure the manufacturing process is safe, respectively [10].

IV. DESIGN PROCESS STAGE

A. Brainstorming

A brainstorming session was conducted to generate possible solutions to solve the clinical need. The engineering requirements and user needs were used as guidelines for the brainstorming session. A total of six solution categories was generated: a staple that falls out on its own, a self-dissolving staple, a self-dissolving suture and a rapid application device, a band-aid or patch, a device or external agent that initiates the dissolving or removal of the staple, and an adhesive. The specifics of these brainstormed and proposed solutions are documented within the DHF file and can also be found in Appendix E.

B. Primary Down Selection – Solution Selection Matrix

The team evaluated and analyzed each solution generated during the brainstorming sessions through two selection matrices. The first matrix evaluated the material that would be used for the device, and the second matrix evaluated the method through which the device would be applied to the skin and the graft. Both matrices are documented in Appendix F.

The following attributes were used for the first matrix to evaluate the solution concepts.

1. Material can be effectively sterilized.
2. Material has strong mechanical properties.
3. Easy to prove material is biocompatible.
4. Estimated money to acquire or develop material.
5. No extra time will be required to develop material.
6. Team's knowledge and familiarity with the material.

The following attributes were used for the second matrix to evaluate the solution concepts.

1. Procedure time is not extended when compared to regular staples.
2. The application method does not increase the potential for infection.
3. Application method guarantees that the skin graft is securely attached to healthy tissue.
4. Low severity risk.
5. Low occurrence risk.
6. Estimated money to develop.
7. Estimated time to develop.
8. Team’s knowledge and capabilities.

After analyzing and evaluating all the possible solutions, the team selected a self-dissolving staple as the primary solution and a suture device as a secondary solution.

C. Proof of Feasibility and Concept Generation

Once the primary down selection was completed with all of the proposed solutions from the brainstorming session, proof of feasibility was conducted in order to ensure that the primary solution concept would meet the user needs. Extensive research was done to analyze whether it is feasible to approach the device design. Through this task, we gained confidence in finding a biodegradable material to make our staple out of and designing a delivery device suitable for our application – the research and claims made are documented in Appendix G. Next, concept generation was done within the primary solution concept selected. For the dissolvable staples project, the primary solution concept selected was a self-dissolvable staple with a delivery device. Further brainstorming and research were conducted in order to elaborate on the possible designs that the self-dissolvable staple and delivery device can approach. Design ideas were laid out for the material composition of the staple, the delivery device, and the shape of the staple. The concept generation table with all the generated design approaches is documented in Appendix H.

D. Secondary Down Selection – QFD Matrices

After the team demonstrated that the self-dissolvable staples were a feasible idea and completed the concept generation, two QFD matrices were generated to evaluate the different engineering approaches that could be implemented through the solution. Three main components were identified for the final device: staple shape, staple material, and delivery device. These three components were analyzed and evaluated in terms of the user needs and engineering requirements. These two matrices are documented in Appendix I.

The secondary down selection matrix was used as a tool to determine the most effective approach for the device design. Through this down selection, the team selected a Poly Lactic-co-Glycolic Acid (PLGA) copolymer as the staple material, a
nail shape with a barbed tip design for the staple shape, and a tissue puncturing and staple deploying mechanism for the delivery device.

E. Parts Design Matrices and Critical Design Specifications

A secondary down selection yielded the top design choices within the primary solution concept. For the self-dissolvable staple and delivery device, parts design matrices were generated for five components: staple, housing to store staples, handle, staple deployment mechanism, and tissue puncturing tool. For each of these parts, the component specifications were listed and their relationship with the engineering requirements was analyzed. Weightage of the strong, medium, and no relationships allowed the component’s critical design specifications to be determined. Lastly, with additional research, design considerations, time limitations, and budget restrictions, the target values for each component specification were decided. With the completion of the parts design matrices, the initial primary solution concept that was started off with ended as a fully designed solution concept where the device design and specifications have all been identified. The design specifications have been documented and a SolidWorks model shows the device’s appearance and function; it can be found in Appendix K. The individual parts design matrices with the specifications and target values listed for each component can be found in Appendix J.

F. Risk Assessment with dFMEA for Major Components/Parts

A design Failure Mode and Effect Analysis (dFMEA) was completed in this stage of the project to improve the design and evaluate the risk associated with each component. Potential failure modes were identified for the staple, housing to store the staple, handle, staple deployment mechanism, and tissue punching tool. 32 failure modes and 44 potential causes were identified for all the components of the design.

The causes of each potential failure mode were evaluated for severity, occurrence, and detectability. Each level was evaluated based on the descriptions in Table 3 below.

<table>
<thead>
<tr>
<th>Severity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Inconvenience, Minor Pain</td>
</tr>
<tr>
<td>2</td>
<td>Moderate to Severe Pain, Increase Procedure Time</td>
</tr>
<tr>
<td>3</td>
<td>Additional Procedure Required, Hospitalization (&gt;1 day)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rare</td>
</tr>
<tr>
<td>2</td>
<td>Occasionally</td>
</tr>
<tr>
<td>3</td>
<td>Often</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Detectability</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Almost Certain, Instant Detection</td>
</tr>
<tr>
<td>2</td>
<td>Probable, Detection hours after product application</td>
</tr>
<tr>
<td>3</td>
<td>Almost Impossible, Detection days after product application</td>
</tr>
</tbody>
</table>

Risk Priority Numbers (RPNs) were created by multiplying the severity, occurrence, and detectability values. Levels were created and assigned based on the RPN level. RPN values one through three are acceptable risks, values four through nine are classified as needing justification and values 12 through 27 are unacceptable risks. Six failure modes had acceptable levels of risk, 29 failure modes had levels of risk that required justification, and nine failure modes had unacceptable levels of risk. Suggested mitigations were created for each cause of failure, and verification methods were created for each mitigation. The severity, occurrence, detection, and RPN values were reassigned based on the levels after mitigation and verification had occurred. Based on the new RPN values, one cause of failure needed justification, and 43 were acceptable.

V. DESIGN OUTPUTS STAGE

A. 3D Models and Drawings

Based on the determined specifications, 3D part models were generated for each individual component of the device. The respective part models were then combined in assembly files to show subassemblies and a complete assembly of the device. Drawings were generated for each part and assembly with the models. All the models and drawings can be found in the project’s DHF file.

B. Major Components, Bill of Materials, and Specifications

The device design was evaluated to identify its major components and specifications. The following components were identified, and a table is shown in Appendix M.

1. Staple
   a. 50/50 PLA and PGA Co-polymer
2. Tissue Puncturing Mechanism
   a. Stainless Steel Rod – 2.5mm diameter and 90mm length
   b. ABS Deployment Button – 13mm diameter
   c. Stainless Steel Spring – 25mm length
   d. 18 GA Stainless Steel Needle
3. Staple Deployment Mechanism
   a. Stainless Steel Rod – 2.5mm diameter and 120mm length
   b. ABS Deployment Button – 13mm diameter
   c. Stainless Steel Spring – 25mm length
   d. Butyl Rubber Staple Pusher
4. 3D Printed (Clear Resin) Staple Housing
   a. Staple Capacity: 15 staples
5. Handle with Guide for Tissue Puncturing and Staple Deployment Mechanism
   a. 3D Printed (Clear Resin), Maximum Diameter: 55mm

To put together the bill of materials (BOM) list for the device, all instruments and materials used in the fabrication process were considered and considered. The breakdown and quantity specifications can be found in Appendix N. Based on prototype iterations, a few dimension and feature modifications
were made to some of the device’s components. The final specifications can be found in Appendix O.

C. Purchase Orders and Assembly Plans/Procedures

Once all of the device’s components were modeled, assembly plans were outlined for manufacturing the entire device. Smaller subassemblies are built first; then the full device is fabricated. The detailed steps and procedures are shown in flowchart diagrams in Appendix P.

D. Risk Management Report

In order to analyze and assess the hazards and/or risks associated with the use of the Degradable Staples and Delivery Device, all the components used in the device were identified and the potential failure modes associated with them. This was completed mostly through research and clinician interviews. Once all failure modes were identified, multiple effects for these failure modes were derived. To classify each failure mode into a risk category, the team used the following table to assign a severity, occurrence, and detection value to each failure mode, which was later used to identify the Risk Priority Number and classify the failure mode into its hazard category: Acceptable, Justification Needed, Unacceptable (reference Appendix D, Table 5 and Table 6).

<table>
<thead>
<tr>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Risk Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Inconvenience, minor pain</td>
<td>Rare</td>
<td>Almost Certain</td>
<td>Acceptable 21</td>
</tr>
<tr>
<td>2 Moderate to severe pain, increase procedure time</td>
<td>Occasional</td>
<td>Almost Certain</td>
<td>Acceptable 4</td>
</tr>
<tr>
<td>3 Additional procedure required, hospitalization (&gt;1 day)</td>
<td>Rare</td>
<td>Probable</td>
<td>Acceptable 18</td>
</tr>
<tr>
<td>Moderate</td>
<td>Rare</td>
<td>Probable</td>
<td>Justification Needed 1</td>
</tr>
</tbody>
</table>

A total of 32 potential failure modes were identified based on the device's intended use. They were further analyzed in the Design Failure Modes Effects Analysis.

All preliminary hazards and potential failure modes of the device were analyzed. In total, 44 potential failure mode effects were identified. The hazardous situations and harms that they could lead to were analyzed, including intermediate probabilities.

Risks were reduced as far as possible. If a risk was classified as “unacceptable” based on the Risk Table, Risk Control Measures were implemented. The following categories of Risk Control measures were implemented in priority as follows: inherent safety by design, protective measures and information for safety. In total, 15 different control measures were implemented.

Some mitigation methods used to reduce risks as far as possible, include but are not limited to:

1. Material selection and inspection of the product once it arrives from the vendor.
2. Conducting additional testing (biocompatible or sterilization).
3. Addition of critical tolerances.
4. Incorporating calibration and maintenance procedures into production equipment.
5. Changing original design specs to allow for better usability and less user error.
6. Addition of instruction manual
7. Incorporation of bonding agent to increase bond strength between components.

Once Control Measures were incorporated, the Risk Priority Number of each risk was recalculated. The values for each potential failure mode effect have been summarized in the table below.

### TABLE 5. RPN LEVELS AFTER CONTROL MEASURES

<table>
<thead>
<tr>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Risk Level</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inconvenient</td>
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As noted in the table above, one potential failure mode remained in the Justification Needed category. This failure mode effect was identified as the staple breaking within the tissue of the patient after its deployment. This would cause the strength that would hold the skin graft down against the skin to be lost. This failure mode effect has the possibility of increased procedural time when applying the staples on the patient and even infection since the skin graft wouldn’t be securely attached to the patient’s tissue. Although this risk can have adverse outcomes, the benefits of adding the Dissolvable Staple into the market outweigh the risks. The main benefit expected from this device is a significant decrease in pain since metal staples won’t have to be mechanically removed by a physician. This also means that the procedure time will be reduced, and patient comfort will increase since they won’t require a second visit to the physician for the removal of the staples.

Risk Mitigation's future focus will be on the continuous development of the staple design and material. The aim is to take advantage of the many advances continuously completed in the biomaterials and copolymer fields and use those to develop a stronger staple that dissolves faster. Another activity expected to be completed is physician and technician training to ensure that the device is being used appropriately and, in doing so, reducing user error.
VI. DESIGN VERIFICATION

Verification plans, procedures, and reports were all completed in the design outputs phase to show whether the device’s design outputs were meeting the design inputs (engineering requirements). The step-by-step procedure followed to conduct this testing can be found in the device’s DHF file.

A. Sterility

Sterilization is the process by which microorganisms are eliminated or killed. It is crucial for a medical device to be sterilized if it is intended to contact the body. Sterilization is essential to prevent the transmission of infections and diseases. In our application, sterilization will decrease the possibility of pathogens entering the body and the possibility of contamination spreading from components of the device when they touch skin [11].

The sterility verification test passed for stainless steel, butyl rubber, and Formlabs Biomed clear resin. The test passed with exception for the PLGA 50:50 because the argon plasma sterilization technique is shown to alter the material properties of PLGA; however, the properties are altered in such a way to improve the topography of the material that in-vivo integration in improved post-sterilization. Due to the enhancement of in-vivo integration, this sterilization technique will be acceptable for our application.

B. Biodegradable Material

Biodegradable materials are capable of either degrading within the body or becoming integrated as a part of the body. Degradation characteristics and degradation rate vary from material to material and play a role in the material's mechanical strength [12]. Finding the perfect balance between degradation time and mechanical strength can be challenging since there are many limitations. The convenience of using biodegradable materials is that they do not need to be removed from the body after the healing process is complete [13]. In our device, the staple component stays in the body, so incorporating a biodegradable feature within it is necessary to eliminate the need for a second operational procedure where the physician must physically remove the staples one at a time after the skin graft is healed to the healthy tissue.

The biodegradable material verification test passed. Low molecular weight 50:50 PLGA degrades in the body within 1-2 weeks. We used a FEM model to determine if our staple can be made out of this polymer to ensure that it will be capable of withstanding an applied load.

C. Simple Usability

Procedure time is always something that wants to be minimized to make processes easy and efficient. The complexity of the device should not get in the way of the quality or standard of care. The device must be easy, quick, and easy to understand.

The simple usability verification test passed. The skin graft was secured successfully within the allocated time limit in all three trials.

D. Versatile Application

The intention of the device is to use it across a variety of anatomical locations and not constrain it to only being applicable to one site. Allowing the device to be versatile will show its adaptability. In our set-up, the table surface represents flat surfaces on the body, such as the palm and thighs; the Lysol wipes canister surface represents curved surfaces like the arms and legs, and the edge/ corner of a wall represents surfaces like the ear and face.

The versatile application verification test passed. The staple was successfully deployed, and it secured the skin graft on all three types of surfaces.

E. Biocompatible Material

Biocompatibility is an important safety element of medical devices. Utilizing biocompatible materials prevents the body from developing harmful biological reactions [14]. The PLGA staples used in our device will be inserted into layers of skin and left in the body for at least 7 days. PLGA must be biocompatible to ensure the body safely accepts the foreign object being inserted and absorbed.

The biocompatible material verification test passed. Literature research shows that PLGA is a biocompatible material.

F. Tissue Grip Strength

Smooth staple deployment is not enough to say the skin graft is held down securely. The staple must sit in the punctured hole strongly to ensure the skin graft is held down and cannot be dislodged. This requirement is essential for an effective healing process.

The tissue grip strength verification test passed. The pressure our staple can apply to hold the skin graft is 16.28 psi, which falls within the desired range of 11.38 psi – 21.34 psi.

G. Report

The verification report, along with testing pictures, can be found in Appendix Q.

VII. DESIGN VALIDATION AND MEDICAL DEVICE STAGE

The team has created a validation plan to ensure that the medical device created meets customer requirements. A validation plan and an overview description were generated that listed each validation method corresponding to the customer requirements. All validation methods are considered for feasibility in terms of an academic project. If feasible, the methods can be conducted within budget, time constraints, and with available resources.

Throughout the validation process, the team went through an unforeseen challenge. It was revealed that the PLGA 50:50 intended to be used for validation would not be able to meet the user requirements. The low-molecular PLGA 50:50 staple would degrade within the time frame needed to meet the user requirements; however, it did not have the mechanical strength to maintain the shape of a staple. This means that this wouldn’t be able to be used to test the other requirements, such as “Quick Application Ability,” “Securing of Skin Graft,” and
“Versatility.” On the other hand, the high-molecular PLGA 50:50 staple was able to be created. However, the results do not meet the degradation time needed to meet the clinician’s needs. A new material was needed to validate the product with the user's needs, and the team chose to use gelatin and beeswax as materials to create the staple.

A. Quick Application Ability

“Quick Application Ability” was based on the verification procedure for “Simple Usability”, except the final prototype is used to validate our device meeting the user requirements. The device failed this test due to the staple continuously being jammed in the device’s housing. To improve this, further reiterations would need to be made to the housing so that the staple can be easily deployed from the device.

B. Degradability

To test the degradability of gelatin and beeswax, two members of the team tested gelatin/beeswax staples on their arms and secured the staples with a Band-Aid for 36 hours. One of the gelatin/beeswax staples was dryly secured to the Band-Aid, while the other contained a few drops of salt water to mimic the properties underneath the skin. The staples were measured on an analytical balance scale before and after 36 hours to measure the percentage of mass loss. After 36 hours, results showed that the gelatin/beeswax staple with salt water had a mass loss of 20%, meaning that within 7-10 days, the staple would be completely degraded.

C. Securing of Skin Graft

The “Securing of Skin Graft” test is based on the verification procedure of “Tissue Grip Strength,” except the test is validated with the final prototype of the medical device. The results for this procedure passed with exception due to the fact that the staple had shrunk in size after it was created. However, when the staple was freshly out of the mold, it was the same size as the dimensions originally designed in SOLIDWORKS. In the future, this could be improved by adding additional components to reduce the amount of shrinkage from the gelatin/beeswax staples.

D. Reduction of Pain

To ensure that our device meets the patient's pain reduction requirement, a literature search was conducted to prove that our device meets this requirement. Because our product completely removes the need for removal of staples and biodegradable staples are painless, our device meets this requirement.

E. Versatility

This test was based on the “Versatile Application” test on verification testing, with the exception that the final prototype was used for validation testing. The device successfully deployed the staples to tack down the skin graft to artificial skin at three different surfaces to represent different anatomical sites; therefore, our product proves it can deploy biodegradable staples on different parts of the body.

F. Biocompatibility

A literature search was conducted to ensure that new materials, gelatin and beeswax, are biocompatible in the body. Gelatin and beeswax have both been used in medicinal applications and are known to be biodegradable, meaning that gelatin and beeswax can be safely used in the body.

VIII. DISCUSSION AND FUTURE WORK

Current design constraints include complications when deploying more than one staple due to the vertical stacking of staples inside the housing and the bulky large handle design, which makes the device not user-friendly. To eliminate these constrains, an evaluation of the handle will be completed. The aim is to develop a method of deploying staples in an independent manner and designing a more ergonomic handle.

The ideal balance between the mechanical strength and degradation time of the staple material must continue to be researched and developed since it is an important element in fulfilling the user and engineering requirements of the project.

IX. ACKNOWLEDGEMENTS

The team would like to thank the Department of Biomedical Engineering for providing us with the resources necessary to fulfill the objectives of our project. We appreciate the expertise and knowledge that the clinician, Dr. Khandelwal, at Akron Children’s Hospital, provided. Additionally, the guidance from Dr. Baker, Steve Paterson, and Dr. Yun was valuable throughout the process of designing the degradable staple and delivery device.

X. REFERENCES

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Selection of an appropriate sterility assurance level (SAL) for Medical Devices: Techtip. STERIS AST. (2023, April 3). https://www.steris-ast.com/techtip/sterility-assurance-levels-sal-irradiation/#:~:text=This%20probability%20is%20referred%20to,quantitative%20value%20to%20assure%20sterility.


XI. Appendices

A. Appendix A – Gantt Chart

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Figure 1: User Needs Stage – Problem Statement and Background Research Tasks

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Figure 2: User Needs Stage – Customer Requirements and Validation Plan Tasks

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Figure 3: User Needs Stage – Final Report Draft and Gate Review Tasks
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### Figure 7: Design Inputs Stage – Gate Review Tasks

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Figure 8: Design Process Stage – Project Plan and Ideation Tasks

Figure 9: Design Process Stage – Phase 2 of Quality Function Deployment (QFD) Tasks

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**Figure 12:** Design Process Stage – Gate Review Presentation Tasks
### Figure 13: Design Outputs Stage – Project Plan and Design Outputs Tasks

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### Figure 14: Design Outputs Stage – Risk Management Report, Final Report Draft Tasks, and Gate Review Presentation Tasks

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<td>4/8/24</td>
<td>4/8/24</td>
<td>Makayla</td>
</tr>
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<td>Final Report</td>
<td>4/9/24</td>
<td>4/15/24</td>
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</tr>
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<td>241</td>
<td>Edit Final Report</td>
<td>4/9/24</td>
<td>4/13/24</td>
<td>Meha</td>
</tr>
<tr>
<td>242</td>
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<td>4/18/24</td>
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<td>Capstone Day and Preparation</td>
<td>4/9/24</td>
<td>4/15/24</td>
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<td>255</td>
<td>Demonstration</td>
<td>4/9/24</td>
<td>4/15/24</td>
<td>Jessica, Kareemati</td>
</tr>
<tr>
<td>278</td>
<td>Poster Submission</td>
<td>4/9/24</td>
<td>4/9/24</td>
<td>Meha</td>
</tr>
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<td>256</td>
<td>Capstone Day</td>
<td>4/16/24</td>
<td>4/16/24</td>
<td>Jessica, Kareemati</td>
</tr>
<tr>
<td>257</td>
<td>Gate Review</td>
<td>4/19/24</td>
<td>4/21/24</td>
<td></td>
</tr>
<tr>
<td>258</td>
<td>Prepare Presentation Slides</td>
<td>4/19/24</td>
<td>4/21/24</td>
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</tr>
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<td>277</td>
<td>Project Description Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Makayla</td>
</tr>
<tr>
<td>266</td>
<td>Project Plan Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Makayla</td>
</tr>
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<td>264</td>
<td>Purchase Order Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Jessica</td>
</tr>
<tr>
<td>262</td>
<td>Assembly of Device Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Meha</td>
</tr>
<tr>
<td>263</td>
<td>Completion of 3D Printed/Fabricated Parts</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Jessica</td>
</tr>
<tr>
<td>259</td>
<td>Validation Plan Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Kareemati</td>
</tr>
<tr>
<td>260</td>
<td>Validation Procedure Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Meha</td>
</tr>
<tr>
<td>261</td>
<td>Validation Report Slides</td>
<td>4/19/24</td>
<td>4/19/24</td>
<td>Kareemati</td>
</tr>
<tr>
<td>265</td>
<td>Summary/Takeaway Slides</td>
<td>4/19/24</td>
<td>4/21/24</td>
<td>Makayla</td>
</tr>
<tr>
<td>267</td>
<td>Present Gate Review</td>
<td>4/22/24</td>
<td>4/22/24</td>
<td>Jessica, Kareemati</td>
</tr>
</tbody>
</table>

Figure 15: Medical Device Stage – Medical Device Prototype, Validation, Capstone Poster, Final Report, Gate Review Tasks
## Appendix B – Expense Report

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description and why this part is needed. Did you do shop around? Use more than one line or separate page if needed.</th>
<th>Unit Price</th>
<th>Qty.</th>
<th>Discount</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>75165A121</td>
<td>This part is needed for the puncturing tool in the device. The needle needs to puncture the skin first before the staple is inserted into the skin.</td>
<td>$10.97</td>
<td>1</td>
<td></td>
<td>$10.97</td>
</tr>
<tr>
<td>1265K26</td>
<td>This part is needed for the puncturing tool and the staple deploying rod of the device. We will buy one 400mm rod and cut it to length for both components.</td>
<td>$28.43</td>
<td>1</td>
<td></td>
<td>$28.43</td>
</tr>
<tr>
<td>2006N291</td>
<td>This part is needed for the staple deploying rod and puncturing tool. One package of five springs will satisfy our need of two springs.</td>
<td>$12.18</td>
<td>1</td>
<td></td>
<td>$12.18</td>
</tr>
<tr>
<td>9545K37</td>
<td>This part is needed as a stopper for the staple deploying rod. The 7/64”-9/64” is ideal for our device.</td>
<td>$5.76</td>
<td>1</td>
<td></td>
<td>$5.76</td>
</tr>
</tbody>
</table>

**Professor's Approval**

**Total:** $57.34

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Description and why this part is needed. Did you do shop around? Use more than one line or separate page if needed.</th>
<th>Unit Price</th>
<th>Qty.</th>
<th>Discount</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7510A807</td>
<td>These luer lock syringes are needed for inserting silicone into the mold that will create a negative for the staples.</td>
<td>$6.28</td>
<td>2</td>
<td></td>
<td>$12.56</td>
</tr>
</tbody>
</table>

**Professor's Approval**

**Total:** $12.56

<table>
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<th>Description and why this part is needed. Did you do shop around? Use more than one line or separate page if needed.</th>
<th>Unit Price</th>
<th>Qty.</th>
<th>Discount</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>B0013IZSDM</td>
<td>CRC Silicone Mold Release is for releasing the silicone from the mold.</td>
<td>$16.49</td>
<td>2</td>
<td></td>
<td>$32.98</td>
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</tbody>
</table>

**Professor's Approval**

**Total:** $32.98
C. Appendix C – QFD Phase 1

Figure 16: Quality Function Deployment (QFD) Phase 1
## Table 4: Failure Modes Effect Analysis (FMEA) Risk Assessment

<table>
<thead>
<tr>
<th>No</th>
<th>Ideal Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sterile</td>
<td>The product has a SAL level of less than (10^{-6}).</td>
<td>The product could cause contamination to the wound or result in an infection.</td>
<td>Sterilization procedure is not conducted properly. Sterilization was not done in a closed system, for the correct amount of time, and in a controlled environment, at the correct constant temperature. The autoclave sterilization machine was not calibrated and serviced regularly to ensure proper function.</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>9</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>2</td>
<td>Bioabsorbable Material</td>
<td>The product has the same mass (g) after the seventh day of product application.</td>
<td>The product remains in the patient and there is no signs of it getting absorbed within the body. This could cause uncomfor to the patient and a second procedure must be done by the clinician to remove the product.</td>
<td>The product was not made out of bioabsorbable materials.</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>3</td>
<td>Simple Usability</td>
<td>The product's delivery receives a rating of less than 3 out of 5 stars.</td>
<td>The skin graft will not heal properly and there is a risk it could fall off.</td>
<td>The device is too complicated to use, and/or requires very precise deployment of the product. The clinician needs special training to learn how to use the device correctly.</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>4</td>
<td>Versatile Application</td>
<td>The product's deployment mechanisms is not intuitive.</td>
<td>The product is not deployed in the intended location, it is very difficult to deploy the product, or if used incorrectly, the product might deform when being released from the delivery device.</td>
<td>The device takes too much time to set up.</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>5</td>
<td>Biocompatible Material</td>
<td>The product is made with non-biocompatible materials.</td>
<td>The patient's body will not accept the product and will create allergic reactions or immune responses against it.</td>
<td>The product is made out of materials that are not biocompatible and not safe for the human body - materials that cause harmful reactions.</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>6</td>
<td>Tissue Grip Strength</td>
<td>The product has a pull out force under 0.967 psi.</td>
<td>The skin graft is too tightly secured to the healthy tissue and too much pressure is being applied along the edges to hold the skin graft down. This could cause body responses to develop. If the product is sitting too tightly in the skin, then skin irritation can arise. The product will be very difficult to remove if it needs to be. Blood flow could be compromised.</td>
<td>The product's composition is made up of materials that are too strong and rigid. The shape of the product might be too flexible or easily deformable.</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>Justification Needed</td>
</tr>
</tbody>
</table>

**Table 4: Failure Modes Effect Analysis (FMEA) Risk Assessment**

<table>
<thead>
<tr>
<th>No</th>
<th>Ideal Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
</tr>
</thead>
<tbody>
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<td>1</td>
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<td>3</td>
<td>1</td>
<td>3</td>
<td>9</td>
<td>Justification Needed</td>
</tr>
<tr>
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<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>3</td>
<td>Simple Usability</td>
<td>The product's delivery receives a rating of less than 3 out of 5 stars.</td>
<td>The skin graft will not heal properly and there is a risk it could fall off.</td>
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<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>4</td>
<td>Versatile Application</td>
<td>The product's deployment mechanisms is not intuitive.</td>
<td>The product is not deployed in the intended location, it is very difficult to deploy the product, or if used incorrectly, the product might deform when being released from the delivery device.</td>
<td>The device takes too much time to set up.</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>5</td>
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<td>The product is made with non-biocompatible materials.</td>
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<td>3</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>Justification Needed</td>
</tr>
<tr>
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<td>The product's composition is made up of materials that are too strong and rigid. The shape of the product might be too flexible or easily deformable.</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
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Table 5: RPN Score Level Calculation

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<th>Occurrence</th>
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<th>Severity 3</th>
<th>Detection</th>
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<tr>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
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<tr>
<td>1</td>
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<td>3</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>8</td>
<td>12</td>
<td>2</td>
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<td>3</td>
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<tr>
<td>3</td>
<td>9</td>
<td>18</td>
<td>27</td>
<td>3</td>
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</table>

Table 6: RPM Score Level Classification

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<th>Risk Level</th>
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</tr>
<tr>
<td>6</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>8</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>9</td>
<td>Justification Needed</td>
</tr>
<tr>
<td>12</td>
<td>Unacceptable</td>
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<tr>
<td>18</td>
<td>Unacceptable</td>
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<tr>
<td>27</td>
<td>Unacceptable</td>
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</table>
E. Appendix E – Solution Concepts from Brainstorming Session

Table 7: Solution Concepts Generated from Brainstorming Session

<table>
<thead>
<tr>
<th>Staple - Falls Out on Its Own</th>
<th>Staple - Self-Dissolving</th>
<th>Suture - Self-Dissolving and Rapid Application Device</th>
<th>Band-Aid / Patch</th>
<th>Device / External Agent that Initiates Dissolving or Reseed</th>
<th>Adhesive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automatic staple dispenser; staple is attached to skin and when 5-7 days are up, automatically disinfects and falls out</td>
<td>Staple with hydrogel (KM)</td>
<td>Dissolvable sutures with extra healing ability (KM)</td>
<td>Glass &amp; compression sock - a material that would compress the graft against the skin to ensure it sticks - could be used in combination with glue (KM)</td>
<td>Device that can be placed on skin on to dissolve at once, e.g. gel or spray (KM)</td>
<td>Teady material - not a glue, more thick like cellulose paste, but better (MS)</td>
</tr>
<tr>
<td>Nominal staple coated in collagen, releases pain from metal staples, collagen yields absorption (MS)</td>
<td>Dissolvable staple that will not fall out on its own (KM)</td>
<td>A device that applies a dissolvable scaffold-like to the skin that does not cause the liquid to leak (KM)</td>
<td>A staple that will be used to reattach tissue to healthy tissue (KM)</td>
<td>Various staple options that can be placed on skin or graft that are not absorbed by body (KM)</td>
<td>Spray on skin (shape version) (IC)</td>
</tr>
<tr>
<td>Staples that are in the body, flattens out when dissolving, healing properties (KM)</td>
<td>Dissolvable staple - staple is filled with a liquid that will initiate the dissolving of it (KM)</td>
<td>Absorbable sutures - using an off-the-shelf, absorbable scaffold and developing a deploying device that will allow the surgeon to quickly secure the graft, electronic needle (KM)</td>
<td>Sticky tape - adhesive strips that would connect the graft to the skin tissue (KM)</td>
<td>A material that can comprise a suture and a anchor (brushed over it), the degradation occurs, the solvent must only impact suture, not skin (KM)</td>
<td>Fiberglue (MS)</td>
</tr>
</tbody>
</table>

F. Appendix F – Primary Down Selection Matrix

Table 8: Primary Down Selection Matrix with Solution Concepts

<table>
<thead>
<tr>
<th>No</th>
<th>Decision Making Attribute</th>
<th>Suture Device</th>
<th>Adhesive</th>
<th>Band-aid/Patch</th>
<th>Dissolved by external agent device</th>
<th>Self-dissolving Staple</th>
<th>Staple that falls out on its own</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Procedure time is not extended when compared to regular staples</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>2</td>
<td>Application method does not increase the potential of infection</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>Application method guarantees that skin graft is securely attached to healthy tissue</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>4</td>
<td>Low Severity risk</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>5</td>
<td>Low Occurrence risk</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<td>+</td>
</tr>
<tr>
<td>6</td>
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<td>-</td>
<td>+</td>
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<td>7</td>
<td>Estimated time to develop</td>
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<td>-</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>Team’s capabilities and knowledge</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No</th>
<th>Decision Making Attribute</th>
<th>Suture Device</th>
<th>Adhesive</th>
<th>Band-aid/Patch</th>
<th>Dissolved by external agent device</th>
<th>Self-dissolving Staple</th>
<th>Staple that falls out on its own</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Material can be effectively sterilized</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
<td>Material has good mechanical properties</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>3</td>
<td>Easy to prove material is biocompatible</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>6</td>
<td>Estimated money to acquire or develop material</td>
<td>-</td>
<td>-</td>
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<td>No extra time will be required to develop material</td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>Team’s knowledge and familiarity of material</td>
<td>-</td>
<td>-</td>
<td>+</td>
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<td>+</td>
<td>+</td>
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<td>No Go</td>
<td>Go</td>
<td>Go</td>
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## Table 9: Proof of Feasibility

<table>
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<tr>
<th>Need</th>
<th>Feasible?</th>
<th>Proof of Feasibility</th>
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</thead>
<tbody>
<tr>
<td>Claim 1</td>
<td>We will need to obtain materials that are bioabsorbable by the human body. This is essential for the self-dissolving nature of the staple.</td>
<td>Yes</td>
</tr>
<tr>
<td>Claim 2</td>
<td>We will need a delivery device to deploy the stapler. The staple is mechanically strong enough to grip tissue, and the delivery device will only need to be able to deploy the staple at the intended location. If the staple is not mechanically strong enough, the puncture tissue, then the delivery device will need to incorporate a pre-puncturing tool so that the staple can be inserted into tissue and will not need internal force.</td>
<td>Yes</td>
</tr>
<tr>
<td>Claim 3</td>
<td>Bioabsorbable materials need to have the ability to be shaped into a form that does not allow it to fall out of tissue. The shape can either be done in the manufacturing process or after manufacturing using the shape of the staple.</td>
<td>Yes</td>
</tr>
<tr>
<td>Claim 4</td>
<td>The bioabsorbable material will need to be compatible with a distribution process. The material shall not lose its mechanical strength or chemical properties when it is sterilized.</td>
<td>Yes</td>
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### Concept Generation: Self-Dissolving Staple with Delivery Device

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<th>Staple Material Composition</th>
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<tr>
<td>1</td>
<td>Magnesium alloy</td>
</tr>
<tr>
<td>2</td>
<td>Polylactide (PLLA) - Polyglycolide (PGA) copolymer</td>
</tr>
<tr>
<td>3</td>
<td>Fibers that line animal intestines</td>
</tr>
<tr>
<td>4</td>
<td>Polycaprolactone (PCL)</td>
</tr>
<tr>
<td>5</td>
<td>Chitosan</td>
</tr>
<tr>
<td>6</td>
<td>Hydrogel</td>
</tr>
<tr>
<td>7</td>
<td>Polydioxanone</td>
</tr>
<tr>
<td>8</td>
<td>Polyhydroxybutyrate (PHB)</td>
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<table>
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<td>1</td>
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</tr>
<tr>
<td>2</td>
<td>Staple deploying and shaping device</td>
</tr>
<tr>
<td>3</td>
<td>Tissue puncture, staple deploying device</td>
</tr>
<tr>
<td>4</td>
<td>Tissue puncture, staple deploying and shaping device</td>
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<table>
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<tr>
<th>Staple Shape</th>
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<tbody>
<tr>
<td>1</td>
<td>Open Base Rectangle with Legs that Bend Inward</td>
</tr>
<tr>
<td>2</td>
<td>Open Base Rectangle with Barbed Legs</td>
</tr>
<tr>
<td>3</td>
<td>Open Base Trapezoid with Legs that Bend Inward</td>
</tr>
<tr>
<td>4</td>
<td>Open Base Trapezoid with Barbed Legs</td>
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<td>5</td>
<td>U-Shape with Legs that Bend Inward</td>
</tr>
<tr>
<td>6</td>
<td>U-Shape with Barbed Legs</td>
</tr>
<tr>
<td>7</td>
<td>Nail Shape with Barbed Tip</td>
</tr>
<tr>
<td>8</td>
<td>D-Shape</td>
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### I. Appendix I – Secondary QFD Down Selection Matrices

#### Table 11: Secondary QFD Down Selection with Concept Generation of Primary Solution Concept

<table>
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<th>User Needs</th>
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<tr>
<td></td>
<td>Staple Deploying Device</td>
<td>Staple Deploying and Shaping Device</td>
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<tr>
<td>1 Quick Application Ability</td>
<td>3</td>
<td>4</td>
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<tr>
<td>2 Absorbability</td>
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<td>1</td>
</tr>
<tr>
<td>3 Securing of Skin Graft</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>4 Reduction of Pain</td>
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<tr>
<td>5 Versatility</td>
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<td>3</td>
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<tr>
<td>6 Biocompatibility</td>
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<td>1</td>
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<tr>
<td>Upside-down rectangle with barbs on legs</td>
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<td>Applied to one squared inch of skin within two minutes</td>
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<td>Applicable in at least 3 anatomical sites</td>
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<td>Skin graft pull-out force between 0.967 - 2 psi.</td>
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### Appendix J – Parts Design Matrices

#### Table 12: Parts Design Matrix for Staple Component

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<td>Maximum Beak Strength</td>
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<td>4</td>
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<td>1.5 mm</td>
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#### Table 13: Parts Design Matrix for Housing to Store Staple Component

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Target Values
### Table 14: Parts Design Matrix for Handle Component

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<td>Tissue Grip Strength</td>
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<td>&lt; 2 lbs</td>
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### Table 15: Parts Design Matrix for Staple Deployment Mechanism Component

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<th>11</th>
<th>12</th>
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</tr>
<tr>
<td><strong>Target Values</strong></td>
<td>Grip</td>
<td>13 mm</td>
<td>5 mm</td>
<td>ABS</td>
<td>90 mm</td>
<td>2.5 mm</td>
<td>26 mm</td>
<td>2.7 mm</td>
<td>Grip</td>
<td>1.5 mm</td>
<td>4 mm</td>
<td>5 mm</td>
<td>4 mm</td>
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</tbody>
</table>

### Table 16: Parts Design Matrix for Tissue Puncturing Tool Component

<table>
<thead>
<tr>
<th>Specifications</th>
<th>Columns #1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<th>11</th>
<th>12</th>
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<tbody>
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<td><strong>Input Requirements</strong></td>
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<tr>
<td>Sterile</td>
<td>4</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Biodegradable Material</td>
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<tr>
<td>Simple Usability</td>
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<td>Versatile Application</td>
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<tr>
<td>Biocompatible Material</td>
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<td></td>
</tr>
<tr>
<td>Tissue Grip Strength</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Target Values</strong></td>
<td>12 Gauge</td>
<td>From</td>
<td>Circle</td>
<td>11 mm</td>
<td>4 mm</td>
<td>ab</td>
<td>120 mm</td>
<td>Spring</td>
<td>4 mm</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
<td>Stainless steel</td>
</tr>
</tbody>
</table>

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### Appendix K – Design Specifications

**Table 17: Design Specifications**

<table>
<thead>
<tr>
<th>Component</th>
<th>Critical Design Specification</th>
<th>Function</th>
<th>Model</th>
<th>Assembly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staple</td>
<td>Material</td>
<td>Secures the skin graft to the wound site.</td>
<td><img src="image1" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Housing to Store Staple</td>
<td>Material</td>
<td>Stores 15 staples in a vertical position so that they are ready for deployment. It is within the handle component.</td>
<td><img src="image2" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Handle</td>
<td>Material, Length, Diameter, Weight, Finger Grooves</td>
<td>Allows the user to grasp the device and connects the internal drive member components (staple deployment mechanism and tissue puncturing tool).</td>
<td><img src="image3" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Staple Deployment Mechanism</td>
<td>Pusher Material</td>
<td>To push out the staple from the housing component one at a time.</td>
<td><img src="image4" alt="Image" /></td>
<td></td>
</tr>
<tr>
<td>Tissue Puncturing Tool</td>
<td>Sharpness</td>
<td>To poke a hole in the tissue for the staple to easily get inserted into the skin.</td>
<td><img src="image5" alt="Image" /></td>
<td></td>
</tr>
</tbody>
</table>
Table 18: Dissolvable Staple dFMEA

<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Cause(s)</th>
<th>Potential Effect(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>TPIN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Actual results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple is not absorbed into the body too slowly.</td>
<td>The staple is not absorbed within the body at a quick enough rate and, as a result, must be removed or the patient must wait the entire length of time for the staple to be fully absorbed.</td>
<td>The ratio of the composition of materials does not allow for absorption to occur quickly enough.</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>6</td>
<td>Justification Needed.</td>
<td>Selecting materials and a composition ratio that allows for a sufficient absorption rate in a biological system and ensure the ratio is in the desired range.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple is not absorbed into the body too quickly.</td>
<td>The percentage of the skin graft is compromised. The skin graft will not be held firm in place if the staple is fully absorbed within 5 days.</td>
<td>The ratio of the composition of materials causes an absorption rate that is too high (quick degradation).</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>Justification Needed.</td>
<td>Selecting materials and a composition ratio that is not absorbed too quickly by the body.</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple is not absorbed by the body.</td>
<td>The staple must be physically removed. This will require a second procedure.</td>
<td>The ratio of the composition of materials does not allow for absorption to occur or the staple is made out of absorbable materials.</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Acceptable.</td>
<td>Select absorbable material to make the staples out of.</td>
<td>Consult the bill of materials of the staple for absorbable materials and conducting testing to measure the rate of absorption in a biological system and ensure the ratio is in the desired range.</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple breaks.</td>
<td>The staple is composed of materials with weak material properties.</td>
<td>The staple is made out of materials that are not absorbable.</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Justification Needed.</td>
<td>Selecting absorbable materials that have high mechanical strength properties.</td>
<td>Consult the bill of materials of the staple for absorbable material composition and conduct tensile testing to evaluate rupture strength for break strength properties.</td>
<td>2</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Cause(s)</th>
<th>Potential Effect(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>TPIN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Actual results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple is not biocompatible.</td>
<td>The patient’s body may not have an adverse reaction to the staple. The staple could develop allergic reactions or immune response.</td>
<td>The staple is not sterility because the staple is made out of materials that are not biocompatible.</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>12</td>
<td>Unacceptable.</td>
<td>Conduct biocompatibility testing to ensure the staple is safe for the human body.</td>
<td>Refer to ISO 10993 in order to assess the biocompatibility of the staple after manufacturing.</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple is not sterility.</td>
<td>The patient’s body may have an adverse reaction to the staple. The staple could develop allergic reactions or immune response.</td>
<td>An error occurs during the sterilization process. The sterilization equipment is not placed in a closed system or the correct amount of time. The staple is not viewed prior to sterilization. The packaging of the staple is broken during shipment. The sterilization machine was not calibrated.</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>18</td>
<td>Unacceptable.</td>
<td>Checking the sterilization level of the staple prior to shipping and reaching the hands of the customer.</td>
<td>Refer to ISO 14644-1 in order to assess the sterilization level of the staple after it has been sterilized.</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple is not biocompatible.</td>
<td>The patient’s body may not have an adverse reaction to the staple. The staple could develop allergic reactions or immune response.</td>
<td>The staple is not sterility because the staple is made out of materials that are not biocompatible.</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>14</td>
<td>Unacceptable.</td>
<td>Conduct biocompatibility testing to ensure the staple is safe for the human body.</td>
<td>Refer to ISO 10993 in order to assess the biocompatibility of the staple after manufacturing.</td>
<td>1</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Cause(s)</th>
<th>Potential Effect(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>TPIN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Actual results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Staple</td>
<td>Secures the skin graft to the wound site.</td>
<td>The staple fails out of the skin, and the skin graft loses its attachment.</td>
<td>During the sterilization process, the staple loses its strength.</td>
<td>A manufacturing error that resulted in the incorrect dimensions of the staple (head, shaft, leg, inner dimensions) could affect the sterility of the staple, the deployment, and how firmly the staple sits in the skin.</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>Lethal Failure.</td>
<td>Incorporate a tolerance of dimensions to allow room for error while maintaining the desired range of dimensions.</td>
<td>After manufacturing, measure the dimensions of the staple to check for error through a quality control inspection.</td>
<td>1</td>
</tr>
<tr>
<td>No.</td>
<td>Part / Component</td>
<td>Function</td>
<td>Potential Failure Mode</td>
<td>Potential Effect(s) of Failure</td>
<td>Potential Cause(s) / Mechanism(s) of Failure</td>
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<td>OCC</td>
<td>DET</td>
<td>RPN</td>
<td>Level</td>
<td>Suggested Mitigations</td>
<td>Verification</td>
<td>Action Result</td>
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<td>------------------------</td>
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<td>--------------</td>
</tr>
<tr>
<td>2</td>
<td>Housing to Store Staples</td>
<td>The staples are not in the housing.</td>
<td>The staples do not adhere to the housing, which could prevent deployment and limit the function of the deployment mechanism. Prolonging could also cause the staples to be released and become inert. This will also take up time during the procedure.</td>
<td>The staples are not properly aligned within the housing.</td>
<td>Add more profound dots along the inner walls of the housing in order to position each staple independently.</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>Unacceptable</td>
<td>Inspect the staple alignment within the housing.</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>The housing is not aligned with the staple deployment mechanism, so the two components collide and the housing breaks.</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Justification Needed</td>
<td>Select materials that are not so rigid that the housing is more resilient to breaking. Incorporate a tolerance of dimensions to allow room for error while maintaining the desired range of dimensions.</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The housing material has weak material properties. The housing can crack if dropped or external impact is applied.</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Justification Needed</td>
<td>Select materials that have high mechanical strength properties to withstand the mechanical forces.</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The patient may have an adverse reaction after the staple has been deployed. An allergic reaction could also make the staples useless.</td>
<td>An error occurred during the sterilization process. The sterilization was not done in a closed system or for the correct amount of time. The housing is not sterilized prior to sterilization. The packaging of the housing is not compatible with the sterilization system.</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>18</td>
<td>Unacceptable</td>
<td>Refer to ISO 11137:2006 in order to assess the sterilization level after the housing has been sterilized.</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Acceptable</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Handle</td>
<td>The handle is not sterilized.</td>
<td>The handle is not sterilized. The patient may have an adverse reaction if the handle touches the skin.</td>
<td>An error occurred during the sterilization process. The sterilization was not done in a closed system or for the correct amount of time. The handle is not sterilized prior to sterilization. The packaging of the handle is not compatible with the sterilization system. The sterilization machine was not calibrated. The sterilization packaging was not compatible with the sterilization process.</td>
<td>Incorporate regular calibration and maintenance services of the 3D printer.</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>Justification Needed</td>
<td>Inspect the product after 3D printing to assess for warping.</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>The sterilization process, storage conditions, or environmental conditions cause the housing to deform shape.</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Justification Needed</td>
<td>Select materials whose mechanical properties are not affected by the sterilization process.</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The handle cracks.</td>
<td>The internal components will not be secured within the housing. If the internal components are not secured, the staples, housing deployment mechanism, and puncturing tool may fail, resulting in incorrect application of the staples.</td>
<td>Excessive force is exerted on the handle from being dropped or other external impact.</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>13</td>
<td>Unacceptable</td>
<td>Incorrectly sterilized.</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Acceptable</td>
</tr>
<tr>
<td></td>
<td>The handle is not comfortable for the user to hold.</td>
<td>Application force is increased since the user will be inclined to adjust the positioning of the device as to not hold it firmly. This may result in the staples being applied incorrectly if the user is holding the device incorrectly.</td>
<td>The handle’s diameter does not align with the average dimensions of an adult hand.</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>Justification Needed</td>
<td>Select materials that have high mechanical strength properties to withstand the mechanical forces.</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Acceptable</td>
</tr>
<tr>
<td></td>
<td>The handle does not align with the average dimensions of an adult hand.</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>Justification Needed</td>
<td>Adjust the size of the handle to align with the average dimensions.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Acceptable</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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| No. | Part / Component | Function | Potential Failure Mode | Potential Effect(s) of Failure | Potential Cause(s)/Mechanism(s) of Failure | SEV OCC DET RPN Level | Suggested Mitigations | Verification | Activity Time |
|-----|-----------------|----------|-----------------------|--------------------------------|-------------------------------------------|-------------------------|---------------------|--------------|----------------|----------------|
| 3   | Handle          | Allows the user to grasp the device and inserts the internal driver member (staple deployment mechanism) tool. The internal driver member components are not secured to the housing. The internal components are not secured to the staple, housing, deployment mechanism, and puncher unit (punching tool). | The user may have to spend more time accessing the buttons, which will increase application time. Also, in order to access the buttons, they may hit the device incorrectly, causing incorrect application of the staples. | A manufacturing error results in the buttons being replaced on the stapler, making the buttons more difficult to access by the user. The 3D printing process creates warping within the material. | 2 | 1 | 1 | 4 | Justification Needed | Change the location of the buttons to make them more easily accessible by the user. Incorporate regular calibration and maintenance services of the 3D printer. | 1 | 1 | 2 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | Select in relation to the actual location of the stapler. | Conduct a test regarding the mechanical properties of the housing before and after the sterilization process to ensure the properties are the same. |                         | 1 | 1 | 2 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | Inspect the product after 3D printing to assess for warping. |                         | 1 | 1 | 1 | Acceptable |
| 4   | State Deployment Mechanism | The staple deployment mechanism dispenses more than one staple at a time. | The staple deployment mechanism cannot be inserted into the staple outlet of the housing component. | There is a blockage within the housing, resulting in the internal staple being ejected from the stapler. | 1 | 2 | 3 | 12 | Unacceptable | Add more of the staple in the inner wall of the housing in order to prevent each staple independently. | 1 | 1 | 2 | Acceptable |
|     |                 | To push out the staple from the housing component at a time. | The staple is not dispensed into the hole created by the punching tool. This skin graft cannot be effectively secured to the wound site. | The user does not release the button on the deployment mechanism hard enough. | 1 | 2 | 3 | 6 | Justification Needed | Determine the appropriate amount of force needed to push the button and aid in creating a feature that guides the user include an instruction manual with the device to provide to the user. | 1 | 1 | 2 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | The staples are jammed within the housing, which prevents the deployment of the staple. | The device will be used to ensure the new control feature is working within the specifications and the instruction manual is clear to understand by the user. | 1 | 1 | 1 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | Staples alignment within housing. |                         | 1 | 1 | 1 | Acceptable |
|     | State Deployment Mechanism | The staple is damaged by the puncher piece or the staple deployment mechanism. | The staple is damaged when it returns to the housing, which could compromise the structural integrity of it, resulting in the loss of the staple deployment mechanism. | The user pushes the button on the deployment mechanism too hard and applies too much force. | 2 | 2 | 3 | 12 | Unacceptable | Add more of the staple in the inner wall of the housing in order to prevent each staple independently. | 1 | 1 | 2 | Acceptable |
|     |                 | To push out the staple from the housing component at a time. | The staple deployment mechanism is not used. | An error occurred during the sterilization process. The sterilization was not done in a humidified system or for the correct amount of time. The puncher is not cleaned prior to sterilization. | 2 | 3 | 3 | 18 | Unacceptable | Check the sterilization level of the puncher prior to clipping and releasing the handle of the customer. | 1 | 1 | 1 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | The button and the rest are not connected to a sensor. | Conduct a basic test to ensure the button has been used. | 1 | 1 | 1 | Acceptable |
|     | State Deployment Mechanism | The staple falls off of the staple deployment mechanism. | The staple does not get deployed due to the spring not getting stuck within the housing without the spring. The deployment mechanism cannot be controlled for operation. | The spring component of the staple deployment mechanism is not secured to the housing. | 1 | 2 | 3 | 6 | Justification Needed | Incorporate a strong binding agent that can maintain the strength over time to connect the button and the handle. A mechanism locking feature will also be added. | 1 | 1 | 1 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | Determine the appropriate amount of force needed to push the button and add a control feature that does not allow the user to exceed that force. | The device will be used to ensure the new control feature is working within the specifications. | 1 | 1 | 2 | Acceptable |
|     |                 |          |                       |                                |                                           |                         | The staple deployment mechanism is not used. | Conduct a basic test to ensure the button has been used. | 1 | 1 | 1 | Acceptable |

04/19/2024
<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s), Mechanism(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Acting results</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>Tissue Punching Tool</td>
<td>The punching tool does not puncture the skin.</td>
<td>The needle is not sharp enough to penetrate the skin.</td>
<td>The needle is not sharp enough to penetrate the skin.</td>
<td>Include an additional manufacturing step to sharpen the needle prior to assembling to the tissue-punching mechanism.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Tissue Punching Tool</td>
<td>The button to push the needle free of the tissue punching tool</td>
<td>Not enough force is generated by the user on pushing the button to push the needle out.</td>
<td>The button to push the needle free of the tissue punching tool</td>
<td>Determine the appropriate amount of force needed to push the button and add a control feature that guides the user in an instruction manual, with the device to provide to the user.</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>3</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Tissue Punching Tool</td>
<td>The staple component of the tissue-punching tool breaks.</td>
<td>The spring is compressed too much or pulled out, experiencing too much tension and stress.</td>
<td>The spring is compressed too much or pulled out, experiencing too much tension and stress.</td>
<td>Replace the spring with a spring that is stronger and able to withstand the deployment mechanism.</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Tissue Punching Tool</td>
<td>The needle breaks.</td>
<td>Excessive force is applied on the needle from the button, rod, and spring parts.</td>
<td>Excessive force is applied on the needle from the button, rod, and spring parts.</td>
<td>Add a feature within the punching mechanism assembly that allows for a controlled deployment of the needle. This will help the needle be pushed out at a uniform speed and torque every time.</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>6</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s), Mechanism(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Acting results</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Tissue Punching Tool</td>
<td>The needle does not puncture the skin deep enough for the staple to be inserted.</td>
<td>There is a problem with the needle causing the staple to be inserted.</td>
<td>There is a problem with the needle causing the staple to be inserted.</td>
<td>Ensure a mechanism is in place for the needle to puncture the skin correctly.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s), Mechanism(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Acting results</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Tissue Punching Tool</td>
<td>The needle is not sterilized.</td>
<td>The needle is not sterilized at the site where the force was applied.</td>
<td>The needle is not sterilized at the site where the force was applied.</td>
<td>Check the sterilization level of the needle prior to storing and reading the hands of the customer.</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>18</td>
<td>Unacceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No.</th>
<th>Part / Component</th>
<th>Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Potential Cause(s), Mechanism(s) of Failure</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
<th>Suggested Mitigations</th>
<th>Verification</th>
<th>Acting results</th>
<th>SEV</th>
<th>OCC</th>
<th>DET</th>
<th>RPN</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Tissue Punching Tool</td>
<td>The needle is too thin and made of a material that is not suited for the intended application.</td>
<td>The needle is too thin and made of a material that is not suited for the intended application.</td>
<td>The needle is too thin and made of a material that is not suited for the intended application.</td>
<td>Ensure a mechanism is in place for the needle to puncture the skin correctly.</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>Acceptable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4/19/2024
### Table 19: Dissolvable Staples Device Major Components List

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staple</strong></td>
<td>50/50 PLA and PGA Co-Polymer</td>
</tr>
<tr>
<td><strong>Tissue Puncturing Mechanism</strong></td>
<td>Stainless Steel Rod – 2.5mm diameter and 90mm length</td>
</tr>
<tr>
<td></td>
<td>ABS Deployment Button – 13mm diameter</td>
</tr>
<tr>
<td></td>
<td>Stainless Steel Spring – 25mm length</td>
</tr>
<tr>
<td></td>
<td>18 GA Stainless Steel Needle</td>
</tr>
<tr>
<td><strong>Staple Deployment Mechanism</strong></td>
<td>Stainless Steel Rod – 2.5mm diameter and 120mm length</td>
</tr>
<tr>
<td></td>
<td>ABS Deployment Button – 13mm diameter</td>
</tr>
<tr>
<td></td>
<td>Stainless Steel Spring – 25m length</td>
</tr>
<tr>
<td></td>
<td>Butyl Rubber Staple Pusher</td>
</tr>
<tr>
<td><strong>3D Printed (Clear Resin) Staple Housing</strong></td>
<td>Staple Capacity: 15</td>
</tr>
<tr>
<td><strong>Handle with Guide for Tissue Puncturing and Staple Deployment Mechanism</strong></td>
<td>3D Printed (Clear Resin), Maximum Diameter: 55mm</td>
</tr>
</tbody>
</table>
## Appendix N – Bill of Materials

### Table 20: Dissolvable Staples Device Bill of Materials

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Item Description</th>
<th>Quantity / Unit of Measure</th>
<th>Assembly Phase</th>
<th>Vendor / Source</th>
<th>Unit Cost</th>
<th>Total Part Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Dissolvable Staples Device</td>
<td>1,020 Lab-use units</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>2</td>
<td>3D Printing: Dissolvable Coil</td>
<td>3D printed components of the top and bottom of the device</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>3</td>
<td>Mold Release</td>
<td>Used as a release agent when making the 2D sheet of the device</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>4</td>
<td>Chitosan</td>
<td>Used as the dissolving agent when making the PVA sheets</td>
<td>Design Implementation</td>
<td>Non-Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>5</td>
<td>1/4-20 Bolt</td>
<td>To secure the PVA sheeting</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>6</td>
<td>1/4-20 Nut</td>
<td>To secure the PVA sheeting</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>7</td>
<td>70% Alcohol Prep Pads</td>
<td>To clean the device</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>8</td>
<td>75% Alcohol Prep Pads</td>
<td>To clean the device</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>9</td>
<td>10% Sodium Chloride</td>
<td>Used as a release agent when making the 2D sheet of the device</td>
<td>Design Implementation</td>
<td>Resourced</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>10</td>
<td>Scissors</td>
<td>Used to cut the PVA sheeting</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>11</td>
<td>Gloves</td>
<td>Used when working with the 2D sheet of the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>12</td>
<td>Pipettes</td>
<td>Used to measure and transfer parts A and D of the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>13</td>
<td>Disposable Plastic Cup</td>
<td>For transferring parts A and D of the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>14</td>
<td>Mixing Stick</td>
<td>Used to mix and combine parts A and D of the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>15</td>
<td>Vacuum Chamber</td>
<td>Used to hold the mixing vessel during the mixing process</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>16</td>
<td>50 mL Flask</td>
<td>Material composition of the staples</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>17</td>
<td>Roller Cutting</td>
<td>Used to cut the staples to the correct length</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>18</td>
<td>1/4-20 Ht. Tap And Die Set</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>Loca #40 Adhesive</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>50 mm Long Staples (Staple Card)</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>Base With 2 Holes</td>
<td>Used to hold the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>22</td>
<td>Bully Rubber</td>
<td>Used as a soft pad to provide a smooth surface to the staple upon insertion into the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>23</td>
<td>Stiff Wire</td>
<td>Used to provide the staple before the staple is released</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>24</td>
<td>17.7 mm Long Stainless Steel Rod</td>
<td>Used as one of the five screw components of the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
<tr>
<td>25</td>
<td>Nitrile Chair Mat</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>Distilled Water</td>
<td>Used to rinse the device</td>
<td>Design Implementation</td>
<td>Available In Lab Room</td>
<td>$28.40</td>
<td>$28.40</td>
</tr>
</tbody>
</table>
### Appendix O – Specifications

#### Table 21: Tissue Puncturing Tool – Specifications

<table>
<thead>
<tr>
<th>#</th>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sharpness &amp; Diameter</td>
<td>18 Gauge</td>
</tr>
<tr>
<td>2</td>
<td>Needle Length</td>
<td>6.35 mm</td>
</tr>
<tr>
<td>3</td>
<td>Button Shape</td>
<td>Circle</td>
</tr>
<tr>
<td>4</td>
<td>Button Diameter</td>
<td>13 mm</td>
</tr>
<tr>
<td>5</td>
<td>Button Thickness</td>
<td>5 mm</td>
</tr>
<tr>
<td>6</td>
<td>Button Material</td>
<td>Formlabs Clear Resin</td>
</tr>
<tr>
<td>7</td>
<td>Rod Shape</td>
<td>Circle / Cylinder</td>
</tr>
<tr>
<td>8</td>
<td>Rod Diameter</td>
<td>2.5 mm</td>
</tr>
<tr>
<td>9</td>
<td>Rod Length</td>
<td>117 mm</td>
</tr>
<tr>
<td>10</td>
<td>Rod Material</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>11</td>
<td>Button Connection Method</td>
<td>Spring</td>
</tr>
<tr>
<td>12</td>
<td>Spring Length</td>
<td>25 mm</td>
</tr>
<tr>
<td>13</td>
<td>Spring Diameter</td>
<td>ID: 2.8 mm, OD: 3.8 mm</td>
</tr>
<tr>
<td>14</td>
<td>Needle Travel Length</td>
<td>4 mm</td>
</tr>
<tr>
<td>15</td>
<td>Needle Material</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>16</td>
<td>Needle Attachment</td>
<td>Polypropylene Plastic Luer Connection</td>
</tr>
</tbody>
</table>

#### Table 22: Staple Deployment Mechanism – Specifications

<table>
<thead>
<tr>
<th>#</th>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Button Shape</td>
<td>Circle</td>
</tr>
<tr>
<td>2</td>
<td>Button Diameter</td>
<td>13 mm</td>
</tr>
<tr>
<td>3</td>
<td>Button Thickness</td>
<td>5 mm</td>
</tr>
<tr>
<td>4</td>
<td>Button Material</td>
<td>Formlabs Clear Resin</td>
</tr>
<tr>
<td>5</td>
<td>Rod Shape</td>
<td>Circle / Cylinder</td>
</tr>
<tr>
<td>6</td>
<td>Rod Diameter</td>
<td>2.5 mm</td>
</tr>
<tr>
<td>7</td>
<td>Rod Length</td>
<td>90 mm</td>
</tr>
<tr>
<td>8</td>
<td>Rod Material</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>9</td>
<td>Spring Length</td>
<td>25 mm</td>
</tr>
<tr>
<td>10</td>
<td>Spring Diameter</td>
<td>ID: 2.8 mm, OD: 3.8 mm</td>
</tr>
<tr>
<td>11</td>
<td>Pusher Shape</td>
<td>Blunt Cone</td>
</tr>
<tr>
<td>12</td>
<td>Pusher Diameter</td>
<td>3.5 mm Base Tapered Down to 3 mm Base</td>
</tr>
<tr>
<td>13</td>
<td>Pusher Material</td>
<td>Butyl Rubber</td>
</tr>
<tr>
<td>14</td>
<td>Pusher Height</td>
<td>3 mm</td>
</tr>
</tbody>
</table>

#### Table 23: Handle – Specifications

<table>
<thead>
<tr>
<th>#</th>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Length</td>
<td>150 mm</td>
</tr>
<tr>
<td>2</td>
<td>Diameter</td>
<td>55 mm</td>
</tr>
<tr>
<td>3</td>
<td>Shape</td>
<td>Circle / Cylinder</td>
</tr>
<tr>
<td>4</td>
<td>Material</td>
<td>Formlabs Clear Resin</td>
</tr>
<tr>
<td>5</td>
<td>Weight</td>
<td>&lt; 2lbs</td>
</tr>
<tr>
<td>6</td>
<td>Alignment Disk</td>
<td>55 mm in Diameter, 15 mm Thick, 2 holes: 6.20 mm and 2.75 mm in Diameter</td>
</tr>
<tr>
<td>7</td>
<td>Distal End Opening</td>
<td>4 mm</td>
</tr>
<tr>
<td>8</td>
<td>Lid</td>
<td>61 mm in Diameter, 5 mm Thick, 2 holes: 6.20 mm and 2.75 mm in Diameter</td>
</tr>
<tr>
<td>9</td>
<td>Distal End Shape</td>
<td>Cone - 45 mm Tall, 55 mm Base Tapered Down to 4 mm Opening</td>
</tr>
<tr>
<td>10</td>
<td>Finger Grooves</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Table 24: Housing to Store Staple – Specifications

<table>
<thead>
<tr>
<th>#</th>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Height</td>
<td>115 mm</td>
</tr>
<tr>
<td>2</td>
<td>Diameter</td>
<td>4.5 mm</td>
</tr>
<tr>
<td>3</td>
<td>Capacity</td>
<td>15 staples</td>
</tr>
<tr>
<td>4</td>
<td>Reloading Ability</td>
<td>Yes</td>
</tr>
<tr>
<td>5</td>
<td>Shape</td>
<td>Cylindrical with Extruded Barbs</td>
</tr>
<tr>
<td>6</td>
<td>Barb Extrusions</td>
<td>0.6 mm Thick, 0.75 mm Wide</td>
</tr>
<tr>
<td>7</td>
<td>Material</td>
<td>Formlabs Clear Resin</td>
</tr>
</tbody>
</table>

### Table 25: Staple – Specifications

<table>
<thead>
<tr>
<th>#</th>
<th>Specification</th>
<th>Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Height</td>
<td>5 mm</td>
</tr>
<tr>
<td>2</td>
<td>Head Diameter</td>
<td>3.5 mm</td>
</tr>
<tr>
<td>3</td>
<td>Head Thickness</td>
<td>1 mm</td>
</tr>
<tr>
<td>4</td>
<td>Shaft Diameter</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>5</td>
<td>Shaft Height</td>
<td>1.5 mm</td>
</tr>
<tr>
<td>6</td>
<td>Shape of Tip</td>
<td>Triangle / Cone</td>
</tr>
<tr>
<td>7</td>
<td>Tip Height</td>
<td>2.5 mm</td>
</tr>
<tr>
<td>8</td>
<td>Maximum Tip Diameter</td>
<td>3 mm</td>
</tr>
<tr>
<td>9</td>
<td>Distal Tip Diameter</td>
<td>0.1 mm</td>
</tr>
<tr>
<td>10</td>
<td>Mechanical Strength</td>
<td>2 GPa</td>
</tr>
<tr>
<td>11</td>
<td>Rate of Absorption</td>
<td>at least 50% Reduction of Mass in a Week</td>
</tr>
<tr>
<td>12</td>
<td>Material Composition</td>
<td>50-50 PLGA</td>
</tr>
<tr>
<td>13</td>
<td>Weight</td>
<td>23-27 mg</td>
</tr>
</tbody>
</table>
Figure 17: Assembly Plan – Staple Fabrication

Figure 18: Assembly Plan – Staple Housing Subassembly
Materials/Supplies:
1. Pusher
2. Spring
3. 117 mm Long Stainless Steel Rod
4. Button
5. 1/4-20 Drill, Tap, and Die Set
6. LocTite 401 Adhesive

Figure 19: Assembly Plan – Staple Deployer Tool Subassembly

Figure 20: Assembly Plan – Tissue Puncturing Tool Subassembly

Figure 21: Assembly Plan – Handle / Device Assembly
Q. Appendix Q – Verification

Table 26: Verification Report

<table>
<thead>
<tr>
<th>Requirement #</th>
<th>Requirement Description</th>
<th>Test #</th>
<th>Test Name Description</th>
<th>Method</th>
<th>Results</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sterility</td>
<td>1</td>
<td>Sterility Testing</td>
<td>Literature Inspection</td>
<td>Pass</td>
<td>N/A</td>
</tr>
<tr>
<td>2</td>
<td>Biodegradability</td>
<td>2</td>
<td>Biodegradability Testing</td>
<td>ANSYS</td>
<td>SolidWorks Analysis</td>
<td>Pass</td>
</tr>
<tr>
<td>3</td>
<td>Simple Usability</td>
<td>3</td>
<td>Simple Usability</td>
<td>Timer Test</td>
<td>Pass</td>
<td>See Verification SS</td>
</tr>
<tr>
<td>4</td>
<td>Versatile Application</td>
<td>4.1</td>
<td>Versatility on Tablettop</td>
<td>Demonstration</td>
<td>Pass</td>
<td>See Verification SS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2</td>
<td>Versatility on Lyso Wipes Canister</td>
<td></td>
<td>Pass</td>
<td>See Verification SS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.3</td>
<td>Versatility on Edge of a Wall</td>
<td></td>
<td>Pass</td>
<td>See Verification SS</td>
</tr>
<tr>
<td>5</td>
<td>Biocompatibility</td>
<td>5</td>
<td>Biocompatibility Testing</td>
<td>Literature Inspection</td>
<td>Pass</td>
<td>N/A</td>
</tr>
<tr>
<td>6</td>
<td>Tissue Grip Strength</td>
<td>6</td>
<td>Tissue Grip Strength</td>
<td>Tensile Test</td>
<td>Pass</td>
<td>See Verification SS</td>
</tr>
</tbody>
</table>

Figure 22: Ansys Model of Staple – Biodegradable Material Verification Testing

Figure 23: Simple Usability Verification Testing
Table 27: Versatile Application Verification Testing

<table>
<thead>
<tr>
<th>Validation #</th>
<th>Custom er Req #</th>
<th>Source</th>
<th>Validation Method</th>
<th>Overview Validation Description</th>
<th>Feasible</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Testing</td>
<td>Testing</td>
<td>Testing will be done to measure the time taken for the product to be applied to the skin.</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Inspection</td>
<td>Observation</td>
<td>Observation will determine if product was absorbable/dissolvable within skin after 5-7 days.</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>Demonstration</td>
<td>Demonstration</td>
<td>Demonstration will confirm that graft is secured starting from first day of product implementation throughout the 7th day (Ex: movements of patient, water spill, etc.)</td>
<td>Yes</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>Analysis</td>
<td>Analysis</td>
<td>A survey will be conducted to measure the patient's pain/discomfort after product implementation on a scale of 1-10.</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>Demonstration</td>
<td>Demonstration</td>
<td>Demonstration will confirm that product is adaptable to five anatomical sites of the body or size of the wound after implementation. (Ex: Applying skin grafts with the product to each part of the body)</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Testing can be performed on the skin after 5-7 days of application to ensure that product did not cause allergic reactions.

Figure 25: Tissue Grip Strength Verification Testing – INSTRON Tensile Test Results

Figure 26: Gelatin/Beeswax Staples