CoorsTek- Spine Discectomy

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Design Baseline Document

CoorsTek- Spine Discectomy

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# Project Roles and Responsibilities

<table>
<thead>
<tr>
<th>Project Role</th>
<th>Name</th>
<th>Document Role: Pages Covered</th>
</tr>
</thead>
</table>
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|                       |                    | Reviewer: Sec. 3.1-3.2, Appx. A  
|                       |                    | Compiler: Sec. 3, Appx. A |
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|                       |                    | Reviewer: Sec. 1.1-1.6, 2.1-2.7, 3.1-3.2  
|                       |                    | Compiler: Sec. 1-2, 8 |
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|                       |                    | Checker: Sec. 3.1-3.2 |
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| Faculty Advisor       | Spencer Wendel     | Approval |
| Customer              | CoorsTek Medical   | Acceptance |
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APPENDICES

A. Conceptual Test Report
B. Verification Email
1 PROBLEM DEFINITION

1.1 OVERVIEW

1.1.1 Objective
The objective is to design improved instrumentation for performing a spine discectomy. In particular, the instrument should remove the nucleus pulposus without damaging the annulus in order to prepare the spine disc for the insertion of an artificial spacer. As more nucleus pulposus is removed from the disc, the spine will fuse more quickly and completely after the artificial spacer is inserted. The current process involves removing the nucleus pulposus piece by piece with pituitary rongeurs. This process is slow and often incomplete.

1.1.2 Customer
The customer is CoorsTek Medical, an engineering company that designs medical devices. The customer has designed multiple artificial disc spacers and needs a device to remove the nucleus pulposus entirely before the artificial spacers can be inserted. CoorsTek Medical would like the device to make the removal of the nucleus pulposus more efficient and complete than the current method, possibly with a method of confirming that the entire nucleus pulposus has been removed. The confirmation is needed to aid vertebrae fusion.

1.1.3 Target End User
The target end users are neurosurgeons and orthopedic surgeons. Their preferred methods and requirements vary greatly, although some preferred aspects of the design are universal. These surgeons want a device that will be ergonomic, minimizing the physical strain exerted by the surgeon during a spine discectomy. Additionally, they want a device that will minimize the amount of time needed to perform the surgery.

1.1.4 Interfacing Systems and Users
The interfacing systems are the surgeon, the patient, and the patient's spinal disc. The design should remove the nucleus pulposus of the spine disc without unintentionally damaging other organs in the process. The instrument could also interface with other surgical instruments such as suction devices.

1.1.5 Issues of Primary Concern
The primary concern is removing the nucleus pulposus completely and safely.
1.2 ENGINEERING REQUIREMENTS

1.2.1 The instrument shall ablate the nucleus pulposus.

Source: The primary purpose of the instrument is to ablate and remove the nucleus pulposus, which has a maximum ultimate tensile strength of 0.65 MPa. The material must be ablated to the point it can be removed through the 16 mm diameter hole in the annulus.

Verification Evidence: The instrument was able to successfully ablate and remove Aloe Vera gel through a hole approximately 16 mm in diameter as discussed in Test E in Appendix A. Aloe Vera gel was determined to be a suitable analogue to the nucleus pulposus as discussed in Test A.

1.2.2 The instrument shall not damage the annulus.

Source: The annulus must remain intact in order to insert an implant into the disc. The annulus has a minimum ultimate tensile strength of 2.0 MPa. This is in contrast to the minimum pressure of 0.65 MPa that must be applied to the nucleus pulposus

Verification Evidence: The water jet used in the instrument was applied to the annulus of a cow spine as discussed in Test B found in the Appendix A. The annulus was unaffected.

1.2.3 The instrument shall fit through a hole with a 16 mm diameter, with a height less than 8 mm inside the spine disc

Source: The customer has designed a disc implant spacer device intended for a discectomy that requires a 16 mm diameter hole in the annulus. All instruments that require access to the nucleus pulposus shall fit within this hole to minimize further damage during surgery as well as improve mobility within the cavity. The height of the disc cavity is approximately 8 mm, but can be distracted.

Verification Evidence: The largest diameter of the shaft that enters the patient’s body is designed to be 12 mm. The nozzle of the instrument is 8 mm tall.

1.2.4 The instrument shall remove at least 5 mL of nucleus pulposus

Source: The largest lumbar disc in most humans contains 5 mL or less of nucleus pulposus. This entire volume must exit the spine disc through the 16 mm diameter hole in the annulus.

Verification Evidence: The instrument was able to successfully ablate and remove 5 mL of Aloe Vera gel through a hole approximately 16 mm in diameter as discussed in Test E in Appendix A. Aloe Vera gel was determined to be a suitable analogue to the nucleus pulposus as discussed in Test A.
1.2.5 The instrument shall provide confirmation that the disc is sufficiently cleared of nucleus pulposus

**Source:** This is a concern with the current instruments and would greatly improve the current procedure. All of the material must be out in order for the spine to fuse, which is the ultimate goal of this procedure.

**Verification Evidence:** The instrument is designed to include a 1 mm fiber optic camera. The user will be able to determine that the disc is sufficiently clear of nucleus pulposus by visual inspection.

1.2.6 The instrument shall articulate at least 30°

**Source:** The instrument must articulate in order to access the entire disc space for every possible entry method.

**Verification Evidence:** The tip of the instrument articulates a maximum of 45° as measured with a protractor.

1.2.7 The instrument shall include an intuitive user interface similar to current instruments

**Source:** The surgeon must be able to intuitively use the instrument without prior training. Surgeons already use many instruments with similar functions, therefore the instrument should be used similarly to these.

**Verification Evidence:** CoorsTek Medical has confirmed that the user interface is intuitive and similar to current instruments as shown in Appendix B.

1.2.8 The instrument shall reach at least 30 cm from the user interface to the tip

**Source:** The instrument will be extended through an incision in the body. The surgeon must be able to access the disc space without putting his or her hands inside of the incision.

**Verification Evidence:** The shaft of the instrument is designed to be 30 cm from where it attaches to the housing to the tip.
1.3 GOALS

1.3.1 The instrument should remove a layer of cartilage at least 1 mm thick

Source: In order for fusion to occur, the cartilaginous endplate must be removed enough to provide bleeding at the bone. The cartilaginous endplate is at most 1 mm thick. This removal is currently done with a separate instrument. Although this is not required for our instrument, it would greatly simplify the process.

Discussion: The current instrument does not incorporate a method for removing cartilage. The method of manufacturing the prototype did not allow for the structural support necessary to supply such loads. It was also determined that the current method of cartilage removal, using a rasp, is effective and the time necessary to remove our instrument and insert a rasp is sufficiently short.

1.3.2 The instrument should remove the nucleus pulposus in less than 20 min.

Source: The portion of a spine discectomy that the instrument will perform typically takes 10-30 minutes. Although thoroughness is the primary object of the instrument, speed will allow surgeons to perform more surgeries in less time.

Discussion: For Test E in Appendix A using a banana and Aloe Vera gel, the Aloe Vera gel was removed in less than 2 min. An actual spine disc would add complexities that would require more time. A human cadaver was not available for testing during this phase of the project. Therefore, further testing is necessary to determine how well the instrument fulfills this goal.

1.4 FUNDAMENTAL ASSUMPTIONS

The assumption is being made that the user is trained to perform medical procedures. The assumption is also made that the current procedures will not drastically change. Although there are multiple entry methods to the spine disc (e.g. Posterior Lumbar Interbody Fusion (PLIF), Transverse Lumbar Interbody Fusion (TLIF), Anterior Lumbar Interbody Fusion (ALIF)), the general procedure has stayed constant. There are no known indications that this procedure will change in the near future. The assumption is made that CoorsTek will ensure that the final product conforms to the Food and Drug Administration (FDA) standards for medical materials. The assumption is also made that the operating room will have standard medical devices such as a surgical suction pump and a rotary power source.

Modeling assumptions, particular to the individual analyses contained in Appendix A, are documented and described in the context of the calculations contained in said appendices.

1.5 GOVERNING STANDARDS

The instrument must follow standards for medical procedures as outlined by the FDA including consisting of Medical Grade materials.
1.6 DELIVERABLES

- System Requirements Report, 1/28/17
- Conceptual Design Report, 4/28/17
- Preliminary Design Report, 5/5/17
- Critical Design Report, 9/29/17
- Critical Design Review, 10/3/17
- Final Design Report, 11/24/17
- Final Design Review, 11/27/17
- Engineering Prototype, 12/1/17

2 CONCEPTUAL ANALYSIS

2.1 DESIGN SPACE

The main function of the instrument is to remove the nucleus pulposus without damaging the surrounding annulus. Some removal methods include suction, evaporation through superheating, and manual removal (the current method). The capability of the final product must surpass the existing removal method in terms of speed and efficacy. Because patient safety is also a priority, the instrument shall consist of biocompatible materials and shall not produce excessive heat. The suction removal method was assumed to have the most potential for removal speed and efficacy, while being safe enough for this procedure. This assumption and the aforementioned limitations shift the focus of the design to methods that assist suction removal.

While not a direct requirement, the simplicity of the design affects the timeliness of this project. The project must reach a primary prototyping phase within eight months of work. If the design is too complex, the time needed to progress through the project will be too great. These ideas influence the design by putting the focus on a simple, safe, and suction-oriented device.
2.2 CLINICAL IMMERSION
The unfamiliar nature of the disc material was the largest obstacle to overcome in the conceptual design phase. To become familiar with this foreign substance, 5 full (non-consecutive) weeks were spent in clinical immersion. During this period, surgical videos and papers were researched, common surgical instruments were used, and dissections were performed on a lamb, pig, cow, and human spine. These pursuits were difficult to arrange and time consuming to perform, but the results were well worth the time and man power.

Before the clinical immersion, little was known within the team about the disc material. Since the clinical immersion, the consistency of the disc material is better categorized, and the material's behavior is known for a number of circumstances. These findings helped specify general requirements and more clearly define the design space. Specific results from the most significant of these clinical immersion pursuits can be found in the conceptual test report located in Appendix A.

2.3 CONCEPTS CONSIDERED
The concepts considered were generated by observation of competitor's products, existing products that perform similar functions, and current surgical methods. The most viable competing products that were found are a design that utilizes an auger rotating about two axes and a design that rapidly spins a wire around a needle point. All the concepts considered could easily incorporate an endoscopic camera for confirmation and incorporate suction to minimize steps in the removal process.

Some concerns with a suction system include clogging of the instrument due to the viscosity of the nucleus pulposus, maneuverability, and damage to the annulus. The suction pressure needs to be adequate to remove a highly viscous fluid, but do minimum damage to the annulus. With a suction system, the instrument must completely remove all the nucleus pulposus by being able to reach the entire disc interior.

2.3.1 Weed Whacker
The weed whacker design consists of a rotating head with blades attached to it. These blades could be in the form of a wire, blunt-tipped knife, or spoon. The rotating blades will rip apart the nucleus pulposus and feed the material into a suction tube. A concern with this design is the potential for the blades to damage the annulus. The main benefit of this design is how fast the nucleus pulposus is removed.

2.3.2 Grinder
To best ablate the nucleus pulposus, a grinding system will be implemented in the form of either motorized wheels or another mechanism meant to "chew up" the nucleus while "feeding" it into the suction line. While this method shares some ideas with the weed whacker, it differs in that this process serves to regulate the speed and quantity of nucleus being sent through the suction line. In addition, this concept can be used to satisfy goal 1.3.2 by providing an abrasive (potentially rotating) surface to remove cartilage on the upper and lower faces of the disc cavity.
2.3.3 Water Jet
The water jet design involves abrating the nucleus pulposus with a high velocity jet of water and removal of ablated material via suction. The device is composed of a long steel primary tube with an internal, fully enclosed channel that connects to an extruding tube of much smaller diameter. The extrusion curves about 145 degrees towards the mouth of the primary tube. The primary tube is connected to a suction hose in order to remove ablated nucleus pulposus. The back end of the channel is connected to a pressurized water source, effectively sending water through the channel and producing a jet of water from the curved extruding tube. This jet of water will both ablate the nucleus pulposus and direct the fragments towards the entrance of the primary tube for removal by suction.

2.3.4 Pincer Straw
The pincer straw design is entirely enclosed within the suction tube. Two retractable pincers are set on opposite sides of the tube and set in so that the only material they can touch is material that has been pushed inside of the tube. The pincers bend inward when pushed forward, causing material between them to be cut. That material is sucked further into the tube, while the pincers retract, allowing more material to be pushed between them, and the process is repeated. This design would ensure that the cutting portion of the instrument would never come in contact with the annulus.

2.3.5 Sheathed Grater
The sheathed grater design consists of two concentric tubes with port holes cut out of both. The inner tube would provide suction, while the outer tube would rotate, causing the nucleus pulposus material to be sheared off between the edges of the two port holes. The main benefit of this design is that the end of the instrument could be blunted, protecting the annulus. The maneuverability of the instrument may be limited, as bending the tubes may make rotation more difficult.
2.4 OPTIONS ANALYSIS

The decision matrix shown in Table 1 was used to determine which concept should be further developed. The requirements and goals used to determine the most promising concept were weighted according to their importance to the design. For each requirement (shown on the left), 100 points were divided between the five proposed concepts. These points were multiplied by the weight factors and totaled for each concept.

Table 1. Decision Matrix

<table>
<thead>
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<td></td>
<td></td>
<td></td>
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<td>Procedure Time Goal 1.3.3</td>
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<tr>
<td>Total</td>
<td></td>
<td>117.25</td>
<td>136</td>
<td>185</td>
<td>118.5</td>
<td>98.25</td>
</tr>
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</table>

The removal of the nucleus pulposus was weighted the most, as this is the primary objective of the design. Clogging the suction tube with large chunks will cause the design to fail. Range of motion is the second highest weighting because this is what will set the design apart from the current method. The curved geometry of the disc makes it difficult to access the material to either side of the entry hole. Side wall removal, or the ability to scrape off the nucleus pulposus closest to the inner wall of the annulus, was rated similarly to range of motion because this also determines the amount of nucleus pulposus the device is able to remove. Protecting the annulus was weighted lower because the annulus can be scratched or damaged slightly, as long as the structural integrity remains intact. Removing cartilage and speed were weighted much lower because these features would add value to the instrument but are not crucial.
2.4.1 Range of Motion
The water jet was rated as the best range of motion because this design could easily swivel without affecting the spraying mechanism. The nozzle could also be adjusted to cover a wider area. The weed whacker and grinder could both cover a wide circular area once inside the disc. The grater and pincer straw could not swivel and still maintain the effectiveness of the cutting mechanism.

2.4.2 Side Wall Removal
The water jet was rated best for side wall removal because the water could be sprayed directly at the wall. The grinder and weed whacker were rated well because they can ablate material as far as they can reach. On the other hand, the pincer straw and grater incorporate guards that would keep them from getting as close to the annulus as the other designs.

2.4.3 Protecting Annulus
The pincer straw is clearly the best for protecting annulus because of its guard; the pincer portion would never even be able to come in contact with the annulus. The water jet would do well in this category because the pressure can easily be kept beneath the allowable stress for the annulus. The only portion of the grinder that comes in contact with the annulus is the wheels, which would do very little damage. The grater could still pinch the annulus on either side, and the weed whacker applies equal force to the annulus as it does to the nucleus pulposus.

2.4.4 Removing Nucleus
Because the nucleus pulposus is water soluble, the water jet could easily dilute the nucleus pulposus, making it much easier to suction. The grinder could ablate the nucleus pulposus very finely, allowing only very small pieces to enter the suction tube. The weed whacker, pincer straw, and sheathed grater would not be able to ensure that these pieces would be as small.

2.4.5 Removing Cartilage
The wheels of the grinder could easily incorporate an abrasive surface that would only grind above the instrument, where the cartilage is located. The weed whacker could incorporate a similar surface, although the range of motion for the surface would be limited.

2.4.6 Speed
The weed whacker would cover a large area in a short amount of time. The grinder and water jet would require some amount of maneuvering but would ablate the majority of the nucleus pulposus quickly. The pincer straw and grater would all have to be maneuvered around inside the disc, ablating a small area at a time.
2.5 PROPOSED CONCEPT
From the options analysis, it was determined that the water jet concept is the best option. The water jet concept was projected to be equal to or better than the other concepts for each of the above criteria excluding removing cartilage, which is not weighted very heavily. The pressure of this design could easily be adjusted to remove the material on the side walls without damaging the annulus. The addition of water will allow the nucleus pulposus to be suctioned more easily. This design could easily be altered to provide maximum mobility within the spine disc.

2.6 ENVIRONMENTAL AND SOCIETAL IMPACT
This water jet solution requires fabrication by machining medical grade metals and molding of polymers. As such, it is important to note that these materials produce small amounts of pollution in their mining and refinement, respectively. Additionally, the solution will require electricity to power its electrical processes and a water supply. While it is good to acknowledge these sacrifices, it is important to note that these environmental risks are very small.

This product should be able to be of operative use for at least five years and as further development progresses, this life expectancy will increase. When this product terminates its usefulness, it will be safe to throw away and will also be mostly eligible for recycling. Maintenance should be simple and parts that easily wear are under consideration for disposable treatment.

The societal effects of this product are many. By making an effective and easier method of removing the nucleus pulposus from the spinal disc, surgeons will be able to perform better discectomies and provide a faster, safer service. By doing so, patients will have few medical complications later, and surgeons will be able to earn more money by performing more surgeries.

2.7 SAFETY
Safety is an important consideration when designing a surgical instrument. An instrument of this kind could potentially damage nearby organs and nerves, cause unnecessary pain, or even leave foreign bodies unintentionally in the patient. These safety hazards can make problems for patients and the medical professionals in the form of lawsuits, infection or even death. Therefore, it is essential to lessen the chances for these disasters. The development team addressed these concerns by opting for more permanent means of assembly (such as trading screws for mechanical joining), allowing for guard mechanisms and researching the strengths of the body parts in the design space. Unlike some of the other design concepts considered, the water jet does not include moving parts within the spine disc, minimizing the chance of excessive damage. The most important part of safely designing a surgical instrument is clinical immersion. Clinical immersion provides spatial reasoning, full understanding of the problem statement, and the concerns that medical professionals would have. Through clinical immersion, the team gained knowledge of safety concerns, particularly regarding spatial and strength constraints.
2.8 BILL OF MATERIAL (BOM) OVERVIEW AND BUDGET

The budget for this project is variable to the completeness of the project. A budget of $200, see table 2, is the initial allotment, but we wish to have a margin of $50, see section 2.8.1. Our primary prototypes will be 3D printed using one of CoorsTek’s 3D printers at no expense. Depending on the effectiveness of the primary prototypes, we are allowed to request further funds for higher quality prototype construction. These “secondary” or final prototypes will have the most significant effect on the project’s budget. This cost is highly subject to the final prototype designs. CoorsTek has many manufacturing and prototyping resources at their disposal (including a machining shop). These resources will not have an effect on our budget, meaning the costs associated with the final prototypes could be non-existent if completely handled by CoorsTek. However, if the design of these final prototypes involves a manufacturing process that isn’t readily available from CoorsTek, the cost could surpass thousands of dollars. This variability in expense is the reasoning behind our adaptable budget.

Table 2. Bill of materials and budget table

<table>
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<th>Design Phase</th>
<th>Item</th>
<th>Description</th>
<th>Price</th>
<th>Source</th>
<th>Remaining Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conceptual</td>
<td>Waterpik</td>
<td>Water jet oral care device for testing feasibility of water jet concept, as well as intuitive risk assessment</td>
<td>$56.99</td>
<td>Walmart.com</td>
<td>$143.01</td>
</tr>
<tr>
<td>Preliminary</td>
<td>Water Jet Prototype</td>
<td>Rough 3D printed water jet apparatus for intuitive analysis (free)</td>
<td>CoorsTek Medical</td>
<td>$143.01</td>
<td></td>
</tr>
</tbody>
</table>

2.8.1 Margin Management

Seeing as we are unaware of any needed expenses, outside of those listed in table 2, our current margin is $143.01 out of the total $200 budget. We do not expect any further purchases to be necessary at this time. During the critical design phase, this assumption will likely change.
3 SYSTEM OVERVIEW

3.1 PHYSICAL DESCRIPTION
The discectomy instrument consists of a long, thin, rigid shaft extending from a pistol-grip type handle as shown in Fig. 1. The tip of the instrument inserts through an incision and into the disc to suction and remove the nucleus pulposus. Water is carried from a pump, through tubing in the instrument, and sprayed into the disc out of a nozzle at the tip of the instrument. The suctioned material follows a system of tubing up the barrel, through the handle, and out the back of the handle of the instrument. The tubing extending from the back of the handle then connects to a waste container and a vacuum pump, which creates the suction in the tubing.

A fiber optic camera with built-in light runs through the instrument to the tip to provide visual confirmation. The tip of the instrument articulates when the user pulls a lever attached to the handle. The lever actuates a pushrod, which in turn extends a Nitinol ribbon that will bend the nozzle where the tubes are fixed.

3.2 FUNCTIONAL DESCRIPTION
As previously mentioned, the function of this instrument is to remove, by suction, the inner disc material (nucleus pulposus) of a herniated disc. After the surgeon makes an incision on the disc, the surgeon activates the air pump, creating a constant suction through the barrel, and inserts the instrument through the incision to interact with the material inside the disc. A jet of water is sprayed out the tip of
the barrel and into the disc. Introducing water inside the disc breaks down and washes the nucleus pulposus from the wall of the annulus. The water also dilutes the disc material to prevent clogging in the tubing system and enable the material to pool for easier suction access. A camera and light mounted on the tip of the instrument provide visual confirmation of nucleus pulposus removal.
4 REFERENCES


Appendix A

Test Report
Test A: Pig Dissection

Description: On 3/2/17 in the CoorsTek Medical surgery room, the team performed a dissection on a pig and lamb spine. The client (CoorsTek Medical), obtained these spines from a butcher and offered their own facilities for the procedure. This procedure involved cutting a spinal disc from a pig and observing its cross-section, and properties.

Observations: This procedure revealed some fundamental differences between assumptions and reality. It was found (Figure A2) that the nucleus pulposus is less viscous (runnier/slimier) than was thought and that the substance contains some pulp-like fleshy bits. The problems with this experiment revealed itself quickly after beginning. Firstly, it became immediately clear that the pig and lamb spines were too small to be very useful. Fortunately, the pig spine vertebrae (Figure A1) were just big enough to make the discussed observations. Additionally, one of the clients mentioned that it is likely that the spines were boiled before the team examined them. A boiled spine could potentially change the properties of the nucleus pulposus. While this cannot be proven for sure, it is important to note and indicates a need for further testing with a cow spine. During the observation period, it was mentioned by one of the clients that the fluid was similar to the human fluid, but perhaps a little too thin. This could be due to factors such as the boiling of the spines, or the quantity of fluid available in the spinal disc. After observation, it was noticed that the fluid was similar to Aloe Vera. This observation allows for a faux substance to test concepts in the future.

Fig. A1. Cross-section of a pig spine, shows the shape and properties of the inside of the disc
Fig. A2. Shows that the consistency of the nucleus pulposus is viscous
Test B: Cow Dissection

Description: On 3/30/17 the team performed a dissection on a cow spine obtained from a local slaughterhouse. The purpose of this dissection was to confirm the observations from the pig dissection on a spine that was larger and fresher. When we obtained the spine, we found that it was cut in half lengthwise, leaving very little nucleus pulposus. We were still able to make use of this dissection by testing the water jet on the material that was left.

Observations: The water jet did not damage the annulus at full power.

Test C: Suction Test

Description: After the decision to model the nucleus pulposus with Aloe Vera, it was important to test the available source of suction for problems that the design could run into later. On 4/6/17, an experiment was performed at CoorsTek Medical. This experiment was to place a sample of Aloe Vera on a surface and use the available vacuum apparatus to observe its effectiveness at removing the sample. Following this experiment, the same process was performed with a sample of water.

Observations: This quick equipment test showed that with a larger diameter suction tube, the suction force is fairly low. Additionally, the suction was able to take in the Aloe Vera pretty easily, but due to the size of the tube, the gel mostly smeared along the walls of the tube. The results produced the hypothesis that with the smaller tube requirements for the device, the suction force would increase and produce more constant force. This assumption resulted from the observation that the gel naturally will naturally coat the inner tube wall and cover the cross-section of the tube. By doing so, the pressure can increase and likely apply consistent force on the gel.

Test D: Cadaver Dissection

Description: On 4/18/17, a dissection of a human cadaver was scheduled in the USU Cadaver Lab. This lab was meant to confirm the properties of the nucleus pulposus, as well as, those of the spinal disc. The details that needed to be determined were confirming that the nucleus pulposus is indeed a gel like substance and that the annulus is distinct from the pulposus. Additionally, this test was to determine the mobility requirements for a device inside the disc. The process performed was to cut a section of the spine from a cadaver and further cut up as to observe multiple cross-sections.

Observations: It was determined that the pulposus and annulus are distinct in a human. Unfortunately, due to the age of the cadaver and the chemicals used in the preserving process, the fluid became hardened. A hardened nucleus made the experiment not very effective for confirming the property assumptions of the pulposus. However, this experiment also provided insight into the range of
motion requirements for a device inside a spinal disc. It was estimated that the required range of motion at anytime is about 20-30 degrees in any direction. An additional detail that was confirmed was that the thickness of the disc varies across the disc. The thickness ranges from 7 mm (Posterior) to 10 mm (Anterior).

**Test E: Instrument Application**

Description: On 11/28/17, the instrument prototype was tested on a mock-up of a spine disc. A banana was hollowed out, leaving a hole approximately 16 mm in diameter. This hollowed out space was filled with Aloe Vera gel, which was determined to be a suitable analogue to nucleus pulposus (see Test A). This space served as a model of the spine disc in approximate size and material properties. The Aloe Vera gel was then removed from the banana peel using the instrument prototype.

Observations: The instrument prototype was successful in removing the nucleus pulposus from the disc cavity as modeled by the Aloe Vera gel and banana peel respectively. By visual inspection, it was determined that the gel was removed entirely. The water jet had to be modulated between the highest power and lowest in order to provide the necessary pressure without filling the cavity with excess water.
Appendix B

Verification Email
Email from CoorsTek verifying fulfillment of requirement 1.2.7:

Hey Logan,

I confirm that your instrument had interfaces that were similar to current instruments in the medical device field.

Thanks,

ZACHARY CHRISTENSEN
Associate Engineer
CoorsTek Medical

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