Magnetic Repulsion Based Lumbar Disc Replacement to Treat Spinal Degenerative Diseases

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INTRODUCTION

The Mag-L Disc is a lumbar disc replacement implant, designed to withstand spinal loads using magnetic repulsion. It consists of two endplates fixated to the inferior L4 vertebra and the superior L5 vertebra. The surface of the two endplates will feature keels to assist with fixation, with a triangular trabecular surface to aid osteointegration. The most notable attribute of the Mag-L Disc is the use of magnets as its central component allowing for a decrease of fretting compared to traditional disc prostheses.

- Diagnosed Spinal Degenerative Disease:
  - 30% at the age of 40
  - 90% by the age of 60
- About 352,000 Interbody Fusions Performed Annually in US
- Global Lumbar Disc Replacement Market Worth $740.3 Million USD in 2020
- Three Predicate Implants Have Received FDA Clearance

The BackPack intends to achieve pain relief by designing a spinal implantation device for the lumbar region aimed at treating mechanical issues caused by spinal degenerative diseases. Our goal is to allow for an adult still in the workforce to go back to work with back mobility.

CUSTOMER STATEMENT

Though the Mag-L will relieve symptoms of degenerative disc diseases for patients, our main customer is the surgeon. The main requirements for our customer with our device is:

- Easy to implant
- Decompression
- Biocompatible
- Longevity
- Maintain Range of Motion

FUNCTIONAL SPECIFICATIONS

- 300 N (passive)
- 10° flexion, 6° extension, 8° lateral
- Total disc height: 12-14 mm
- 10+ years
- Diameter ranges: (13-18) mm in 1mm increments
- Thickness ranges: (2-5) mm in 0.1mm increments
- Length ranges: (17-24) mm in 2mm increments

FINAL PRODUCT: The Mag-L Disc

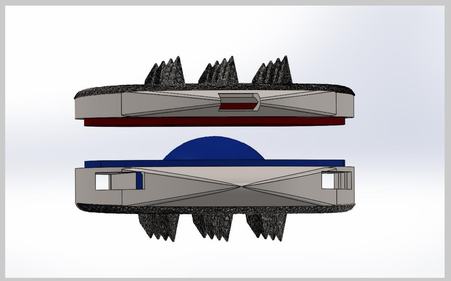


Figure 1: Anterior View of Mag-L Disc

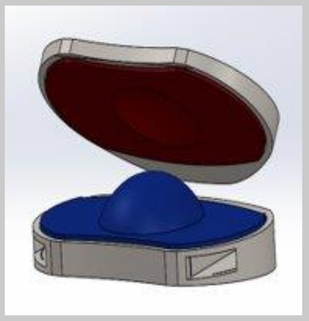


Figure 2: Posterior View to Show Superior (red) and Inferior (blue) Magnets

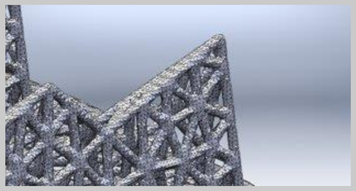


Figure 3: Porous Keel Close-Up

SURGICAL APPROACH

Figure 4: Kraken Surgical Instrument

Surgical Technique: Our device uses an anterior lumbar total disc arthroplasty approach. An incision between 3-5 inches will be made slightly to the left of the naval. The muscle and soft tissue will then be retracted to the side. All anatomy will then be identified and marked by the surgeon using x-ray. Once marked, the anterior longitudinal ligament covering the L4/L5 disc will be cut to allow for the removal of the diseased disc. Imaging will once again be taken to determine if any bone remodeling is necessary. Next, a device measuring template will be placed in the disc cavity to determine the appropriate endplate footprint size. Once the device size is confirmed, the Kraken will be used to help persuade the Mag-L into proper depth in the disc cavity while keeping correct alignment. Finally, when implanted the Kraken is removed and imaging is used to confirm proper placement.

Instrumentation: The Kraken functions by having two clamps that hold the Mag-L in place while having a wedge in-between them to keep a predetermined spacing. Once the device is secured, the head of the device is placed in the disc cavity. Stoppers towards the tip will allow for the maintaining of the proper depth. Finally, the handle functions as a screwdriver causing the head to splay open. As the head splays open the device will be implanted and decompression of the spine will occur.

TESTING RESULTS

Figure 5: Anterior X-Ray Image

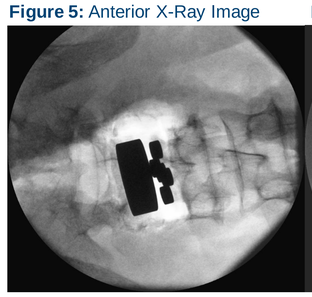
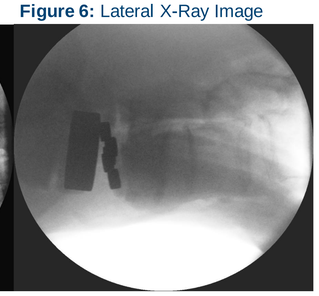


Figure 6: Lateral X-Ray Image



TR 1.1- Orientation: The objective of this test was to determine the optimal repulsion of the magnets. Specifically, the orientation will be determined to continue testing of the device for compression. **Result:** The geometry of the magnets drastically affects not only the repulsion of the magnets but also how strong the "sliding" effect is as well. For this reason, we chose a spherical magnet for our design.

TR 2.1- Compression: The objective of the testing is to determine compression limits of the magnets. Specifically, the maximum compression load will be determined. **Result:** The surface area of the top magnet heavily impacted the total decompression force applied by the bottom magnet. Meaning that for our design having a large surface area for the magnets was important.

TR 3.1- Cadaver Lab: The objective of the testing is to determine the range of motion and easy implantation of the Mag-L. Specifically, the degrees of flexion and extension will be determined. **Result:**

Flexion:	10°	☑ Criteria Met
Extension:	3°	✖ Criteria Not Met
Lateral:	8°	☑ Criteria Met
Avg. Decompression:	287.7 N – 65 lbs	☑ Criteria Nearly Met

PERSONNEL AND REPORTING

Personnel	Cost
Senior Engineers	$5,125
Engineers	$36,900
Reporting	$2,990

Total Personnel Cost: $45,015

MANUFACTURING COSTS

Expenses	Cost
Manufacturing	$280
Materials	$122.50
Sterilization & Packaging	$50

Total Prototype Cost: $452.50 per Device

CLAIMS

The Mag-L Disc Will:

- Not Have Adverse Effects to the Body
- Decompress the Spine
- Last 15+ Years in the Body
- Enable Motion of the Lumbar Spine
- Require Minimal Training for Surgeons

CONCLUSIONS

- Endplates Do Not Pose a Risk to the Body
- Magnets Will Be Coated with FDA Approved Parylene-C to Prevent Adverse Effects
- Magnets Must Be Altered to Achieve Necessary Decompression
- Fatigue Testing Must Be Done to Confirm Longevity of Device
- Majority of Motion Is Preserved
- Surgical Procedure Is Similar to ALIF Procedure
- Surgical Instrumentation Will Greatly Aid Implantation

TEAM MEMBERS & MENTORS

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