

Inflatable Vertebral Distractor

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Date: September 20, 2015

Problem Statement:

In some cases of spine surgery the intervertebral disc is removed and the vertebral bodies are distracted to help with alignment of the spine and to create more operating space. The goal of this project is to develop an inflatable vertebral body distractor that can be easily used and will not cause spinal fractures. It must be less invasive than current distracting techniques and create a separation of 4-8mm. Currently, spatula-like distractors are used but are susceptible of chipping of pieces of the vertebra or causing fractures.

Client Requirements:

- Insertable using a needle with an inner diameter of 2-3mm, preferably jam sheedy needles
- Medical grade silicone recommended
- The inflatable portion will have one use
- Needs to work on lumbar region
- Consider use of pressure sensors, but not required

1. Physical and Operational Characteristics

a. Performance requirements:

* This product must successfully distract vertebra 4-8 mm to allow disc removal and disc replacement. It is to be less invasive than current techniques, ideally to be inserted in the space created by the needle used in the operation. It will be inserted on the opposite side of the vertebrae of which the the procedure will take place. The product must maintain separation of the vertebra for the duration of the operation which can be up to 8 hours. Inflatable distractor inside of cannula must be reversibly distractible.

b. Safety:

- * It should not cause further harm to the patient or user while in use
- * Should have a surface area enough to prevent cracking and chipping of the bone of the vertebra.
- * Must be easily removable without damaging vertebrae

c. Accuracy and Reliability:

* The device should create enough force in a uniaxial direction to separate vertebrae a distance of 4-8 mm for the client to operate on the disc. It must last the duration of an operation (3-8

hours) and occupy only half of the space in between the vertebrae (approximately 13-15mm²). This device should never fail under any circumstances.

d. Life in Service:

* The device needs to last the whole procedure, approximately a few hours up to 8 hours.

e. Shelf Life:

* The main component of the product which will be used outside of the human body must last up to 6 years. The inflatable component of the product used within the body to separate the vertebrae will only be used on time.

f. Operating Environment:

* There are two different operating environments. One part of the product will be used inside the human body, specifically in the spinal region in between the lumbar vertebrae. Therefore the material must be biocompatible and withstand body temperature of 37 degrees Celsius. The other part of the product will be used in the sterile operating room and does not need to be biocompatible.

g. Ergonomics:

* inflatable with one hand, implantable by a single person

* Must fit in the desired operating space in between two lumbar vertebrae (minimum 1.75mm high, 7.4mm wide) while being less invasive than current distracting techniques.

h. Size:

* The product must be easy to transport by hand by the users and compact enough as to not disrupts the surgical operations performed by the client. The client would prefer if it could be inserted through the space created by the needle already used by the client.

i. Weight:

* No more than 500 g

j. Materials:

* A portion of the product will be used within the human body, meaning it must be composed of a biocompatible material. The client wants it to be inflatable while being able to withstand enough force to create separation between the vertebrae. The portion outside the body must be durable and lightweight as it will be used multiple times, however it does not need to be biocompatible.

k. Aesthetics, Appearance, and Finish:

* Rust preventative and smooth outer surface surrounding the inflatable distractor .

2. Product Characteristics

a. Quantity:

* We must fabricate one working product and if time fabricate multiple attachments for use inside the body.

b. Target Product Cost:

* Less than \$500.00

3. Miscellaneous

a. Standards and Specifications:

* Abide to FDA medical device regulations

b. Customer:

* Prototype refinement

- * Requires testing in bone analog

 - c. Patient-related Concerns:

 - * Must not generate debris

 - * Must not damage bone or influence patient physiology after use

 - d. Competition:

 - * Synthes Vertebral Distractor: Uses metal rods and a pneumatic pump in order to create separation between vertebrae. However, does not incorporate a balloon or inflatable segment.