**Fluid-Filled Cervical Dilator**

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**Introduction**

- The national percentage of induced labors has increased from 9.0% to 19.4%. [1]
- A confidentiality agreement was obtained from the Office of Technology transfer to protect our device, and initial patent paperwork was filed to protect the intellectual property of the device. The device was registered under Case Number VU9615.
- The engineering drawings, from Figure 3 and others, were sent to Interface USA, Inc.
- A quote for the production of a prototype of the device was obtained from Interface.
- A functional and enlarged mock-up prototype was made.

**Methods**

- A ballon catheter can be inserted into the cervical canal and filled with saline at a calculated fill rate, providing a predictable dilation rate and unmatched safety for the mother and fetus (Figure 1).
- Once commercially available, the device can potentially improve the quality of care received on a global level, as it will cost significantly less and offers many more advantages than currently used methods.
- The purpose of this project is to design a balloon catheter system that is filled with saline at a controlled rate in order to dilate a cervix for the induction of labor. The device will replace current, less sophisticated approaches for accomplishing this task by being safer, more reliable, and easier to use.

**Results**

- Drawings of the cervical dilator from ProE are shown in Figure 3.
- A confidentiality agreement was obtained from the Office of Technology transfer to protect our device, and initial patent paperwork was filed to protect the intellectual property of the device. The device was registered under Case Number VU9615.
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**Market Potential**

- Currently, approximately 19.4% of all labors are induced, resulting in 800,000 induced labors annually [6].
- Among these, 400,000 labors each year require a cervical ripening agent.
- The potential market for this device is as high as 800,000 labors/year in the United States alone.

**Conclusion**

- We have successfully designed a fluid-filled cervical dilator that can be used for safe and efficient cervical dilation.
- The final design that was decided to be most optimal was a three-balloon system, with one balloon anchoring the device above the cervical canal and the other two performing the dilating procedure.
- We have disclosed our device to the Vanderbilt University Office of Technology Transfer, and they have filed initial patent paperwork on our behalf to protect the intellectual property of this device.
- We have received confirmation from Interface USA, a firm specializing in the production of balloon catheter devices, that they could produce a prototype of our device.
- The prohibitively high cost of acquiring a prototype has prevented us from contracting this service at this point.

**Recommendations**

- It is recommended that the next step in this project be the purchase of a prototype.
- Once a prototype has been constructed, the device needs to be tested to confirm the safety and reliability of the device.
- Testing will commence on synthetic human models, progressing to animals with similar dimensions to humans, and finally for clinical trials on human patients, perhaps under the supervision of Dr. Beyer.
- A complete device will come with syringes pre-filled to the necessary volume to inflate the balloons to the desired size.

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**References**