

Radially Expanding Uterine Cervical Dilator

Contents of PDS – October 19, 2012

Alex Schmidt, Megan Courtney, Ryan Lane, and Michael Martinez

Function: The current procedure for dilating a cervix requires the doctor to use progressively thicker dilators until the desired diameter is reached. This method is very tedious for the surgeon and may put patients at a higher risk for a uterine perforation. To decrease the risk of a uterine perforation, we are going to make a device that, once inserted through the cervical canal, can be controlled by a surgeon to radially dilate the cervix to a desired diameter as indicated on a dial.

Client requirements:

- Device should increase in diameter once inserted into cervix
- Device should have dial or another way to increase diameter of dilator
- Dial should have markings to let doctors know the size of dilation
- Would prefer device to be curved at the end
- Would like indicator to let doctor know if dilator passed through the entire cervical canal

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The device is expected to be used to dilate a patient's cervix so that a surgeon can then insert other medical devices into the uterus, which is then cleaned out. The device would be used repeatedly, but the actual number depends on the amount of women needing a procedure that requires the cervix to be dilated. The device must be strong enough to withstand the pressure from the cervix.

b. *Safety:* The device must not have any sharp points or edges. The device should only be manufactured using materials that are safe for the human body and that don't pose a large allergy risk.

c. *Accuracy and Reliability:* The device needs to be extremely accurate since the surgeon increases dilation by 1 mm increments. The device should be off by no more than 0.1 mm. The device will also need to be very precise. It should read the same diameter or a value within 0.1 mm of the desired diameter every time it is used.

d. *Life in Service:* The amount of time that the device will be used during each procedure

will vary from patient to patient. The length of time it takes a surgeon to dilate the cervix depends upon the skill of the surgeon, how much strength the surgeon chooses to use when inserting the dilator, and the compliance of the cervix. An estimated time that the device will be used during each procedure is 10 minutes.

e. *Operating Environment*: During operation, the device will be used in either a hospital setting or a doctor's office. The device will be exposed to the cervical canal. A doctor will be operating the device.

f. *Ergonomics*: The force that the device puts on the cervix needs to be applied radially so that it does not tear the cervix. According to *Lamicel: a new technique for cervical dilation before first trimester abortion*, by Nicolaidis et. al, it takes approximately 52.4 N of force to dilate the cervix 1 cm in women who have never given birth. Therefore, our device will need to be able to withstand over 52.4 N of force after taking into account a safety factor.

g. *Size*: Our device needs to start at a size of 3 mm in diameter and increase to a size of 1 cm in diameter. The length of our device should be between 9 in and 12 in.

h. *Weight*: The device should be able to be held in a single hand. Weight is not a huge concern since our device will be so small in size. However, the device should only weigh around 1 oz.

i. *Materials*: Due to allergies, latex and nickel should not be used when manufacturing the device.

j. *Aesthetics, Appearance, and Finish*: The device does not need to be a specific color. The texture should be smooth so that it does not irritate the cervical canal.

2. Production Characteristics

a. *Quantity*: 1

b. *Target Product Cost*: Our client does not have an exact cost that he has set for our device yet. Other cervical dilators on the market cost about \$40, so we would want our manufacturing cost to be less than \$40.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required to use this device.

c. *Patient-related concerns*: The device will need to be sterilized between uses.

d. *Competition*: We have yet to find any devices that use a coil-like method to dilate the cervix. There are several patents for different dilators that use a balloon to dilate the cervix, which is partly why we decided not to follow through with our balloon designs.