The Product Design Specification (PDS)

Title: Reversible Contraception

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Function:

Current technologies for female contraception often require the intake of pharmaceutical agents or invasive surgeries. These chemicals can cause side-effects such as: headache, uterine bleeding, nausea, breast tenderness, abdominal pain, mood changes, and increased risk of vascular problems, liver disease, or high blood pressure (Bayer HealthCare Pharmaceuticals, 2001). Mechanical surgeries can lead to scarring and usually involve ligation, which causes permanent infertility. Ultimately, a female should be able to choose when to be fertile or infertile without the use of hormones.

The device should provide non-permanent, or reversible contraception to allow a woman to control her fertility. Our initial design involves a valve consisting of biomaterials that can be integrated into the reproductive system. Although not a high priority, another goal is to be able to suggest suitable materials for this device. The primary goal of our project is to design a valve that can be controlled from outside the body. One possible design is to construct the valve using an electromagnetic material that would utilize two coils to induce current, creating a magnetic field that can be harnessed to open and close the valve.

Client requirements:

- Utilize a valve to implant in the fallopian tubes
- Valve should open to enable fertility and close to prevent conception
- Valve should be controlled remotely from outside the body
- Withstand contractions during childbirth
- Prevent sperm from passing through the valve

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*

Due to the nature of the placement of this device in the female reproductive system, there are many physiological and functional constraints that we must take into consideration. The first item that we must factor in is the sensitivity of the reproductive system. Because we are looking to incorporate a mechanical system into the biological system of the body we must make sure not to damage the fallopian tubes. This calls for a material that can withstand the rigors of being in the human body, as well as work with the body without causing destruction or unnecessary stress. It must be able to withstand uterine contractions during childbirth in addition to daily biological activity.

This device must be able to open and close an indefinite number of times to control the female's fertility, providing a high level of contraceptive efficacy when elected to do so.

b. *Safety*

Because the device will be implanted in the human body, many safety precautions must be considered to ensure proper functionality without imposing unnecessary stress on the reproductive system. There are three key concerns involving the device: implantation in the fallopian tube, the lasting effects of having the device in the body, and the moving mechanical parts within the device.

The first major hurdle comes with physically implanting the device. Currently many of our designs involve first cutting the fallopian tube, and implanting the device between the two ends of the cut fallopian tube, effectively connecting it again. The challenge of this is twofold. First the surgery itself must be performed so that permanent infertility is not caused. Second the device must be able to be implanted onto the fallopian tube snugly so that it does not move out of place.

Once in the body, the device cannot cause any long term harm to the reproductive system. Primarily, a material that is compatible with the biology of the reproductive system must be used so that the fallopian tube can grow around the device. Secondly, the device cannot involve any materials toxic to the body that could lead to sickness or permanently inhibit fertility.

The last concern is the fact that a mechanism involving a ferrous material would prevent use of an MRI because of the powerful magnetic fields in an MRI room and distortion of the MRI image.

c. *Accuracy and Reliability*

Once installed, the effectiveness of this device should near 100%. In other words, the women will not be able to get pregnant while the valve is closed. Also, the device will not interfere with her fertility when the valve is open.

d. *Life in Service*

The device should not require replacement once implanted. Therefore, the mechanism must last as long as the female is capable of reproduction. The device may be in service for up to 40 years.

e. *Shelf Life*

Conditions for storage prior to implantation depend on the materials the device utilizes. The shelf life of our device should be 5 years. Based on comparable devices, It's likely that hospitals will use the device within 6 months. Our device will not be composed of oxidizing metals, therefore rust will not have an impact on the duration of the shelf life.

f. *Operating Environment*

Our device will be operating in the fallopian tubes of a woman, both of which have a very small, irregular diameter. Each fallopian tube is roughly 10 cm in length and 1 cm in diameter. The device will have to operate under body temperatures, around 37 °C. Within the fallopian tube are 3 different sections which serve different functions but overall work to unite sperm with egg for fertilization. The second segment, the ampulla, becomes more dilated in diameter due to it being the key spot for fertilization (Schnatz, R. H. 2012). This dilation in diameter requires our device to be able to expand with the fallopian tube so it does not get dislodged. During menstruation, uterine contractions are low in pressure, around 30 mmHg. The device must be able to withstand pressures up to 200 mmHg during labor contractions.

g. *Ergonomics*

Due to our device being located in the fallopian tubes, it will not be involved in outside interactions. The only interaction of the device with humans will be during surgical insertion of the device into a woman's fallopian tubes. The device should be composed of materials that will be durable and not be at risk of damage during limited interaction with humans.

h. *Size*

The device must not greatly exceed the size of the woman's fallopian tube. Not all fallopian tubes are the same size and thus testing would need to be done in order to see the limitations of size for the device for the particular patient. The average size of the device will be roughly 4 cm in length and 1.5 cm in diameter. The only way the device may be accessed for maintenance will likely be through surgical procedures.

i. *Weight*

Each valve should have minimal weight, less than 30 g, due to the sensitive environment it would be placed in, inside of the Fallopian tube of female human body. Excessive weight may result in the sagging of the fallopian tube and dysfunctions of the device itself as well as other unwanted effects.

The device would achieve optimal weight when the subject doesn't feel or detect the presence of it inside the body, as well as not affecting (or altering) any regular function of the female reproductive system, especially the fallopian tubes.

j. *Materials*

The materials exposed to tissue, such as the case and lumen, must be biocompatible, pharmaceutically inert, nontoxic, sterile and most importantly, must be able to function in the environmental condition of Fallopian tubes. The device must be composed of non-ferrous metal materials in order to be compatible for both MRI machine and CT scan. The use of copper exposed to tissue should be avoided due to its non-reversible contraceptive properties (Trussell, 2007; WHO, 2007).

k. *Aesthetics*, *Appearance, and Finish*

These factors will be determined upon the fabrication of the device. The device should have a smooth finish with rounded corners and no sharp edges that might damage tissue.

2. Production Characteristics

a. *Quantity*

Two units are needed per individual. Quantity demanded for production will be defined later in the process.

b. *Target Product Cost*

The cost of production should be targeted around $50 per unit, with two units required per individual.

3. Miscellaneous

a. *Standards and Specifications*

FDA approval of the device is required.

b. *Patient-related concerns*

Materials must be non-toxic and biocompatible. Any metals used must be hypoallergenic.

c. *Competition*

There are several contraception methods available. Many strategies such as oral contraception, contraceptive vaginal ring, and transdermal patch rely on hormones to prevent conception (Sitruk-Ware, 2013). There are fewer nonhormonal contraception options available. ParaGard is an intrauterine device that is thought to prevent sperm from reaching the egg. It diffuses copper as an additional contraception source. Finally, Essure is a non-surgical, nonhormonal, permanent contraception method that is implanted in the fallopian tubes.

References

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