

Product Design Specifications

Transcervical Model

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Function:

During transcervical chorionic villus sampling, doctors must navigate through the cervical canal of a pregnant woman, and retrieve a sample of placental tissue from the wall of the uterus. Due to the risk and difficulty associated with this procedure, doctors require a great deal of practice in order to perfect their technique. Our client has requested a model to accurately mimic the anatomical structures of a pregnant woman (i.e. vagina, cervix, uterus, amniotic sac). The entire process of chorionic villus sampling is monitored via ultrasound, so the model must appear on an ultrasound image as would an actual patient's abdomen. Repeated use of this model as a training device should prepare doctors to safely complete a transcervical chorionic villus sampling procedure.

Client Requirements:

- Rigid and restrictive cervical canal with accurate dimensions and feel
- General vaginal opening with adjustable vagina-cervix angle
- Accessible uterine cavity to place placental sample
- Liquid-filled sack to simulate amniotic sac
- Cervix and uterus must be penetrable to ultrasound waves

Physical and Operational Guidelines:

Performance Requirements- Accurately depict the anatomy of a pregnant woman in her first trimester. The model will be used daily by doctors, and should be able to accommodate all medical instrumentation associated with transcervical chorionic villus sampling. This instrumentation includes but is not limited to ultrasound equipment and a 1mm diameter catheter. The model must be reloaded with placental tissue prior to each use.

Safety Requirements- The use of this model will be limited to doctors and residents in training, and will not directly interact with any patients, so there are minimal safety requirements to be considered. Sharp edges should be avoided to prevent lacerations.

Accuracy and Reliability- Since the anatomical dimensions can vary from patient to patient, the size of the model should be in the range associated with the average pregnant woman in her first trimester. However, all relative locations of anatomical structures should be closely followed.

Life in Service- Service should be conducted as deemed necessary by the doctors using the model. The model should be able to withstand daily use, for up to 2 years before requiring service.

Shelf Life- Long periods of storage time should not affect the performance of the model.

Operating Environment- The model will be subject to ultrasound waves and ultrasound gel during use. The model must also exhibit durability during frequent handling in between uses. Usage in a hospital will pose a clean environment, with normal pressure and temperature ranges.

Ergonomics- The model should interface with a doctor as would the pelvic region of an actual patient.

Size- The cervical canal should be 2mm in diameter and 50-60mm in length. The size of the uterus is much more flexible, but should be no larger than 150mm.

Weight- Transportation will be conducted by hand, so the design should minimize bulk and weight. Our client has specified that weight is of minimal concern.

Materials- All materials must be permeable to ultrasound waves in order that their image appears on an ultrasound image. Therefore, the model cannot be made of thick materials and air cannot be involved in the system. All materials should also accurately correspond to the texture and level of rigidity of the tissue they represent.

Aesthetics- The appearance is of minimal concern to our client.

Production Characteristics:

Quantity- Only one unit will be constructed at this time.

Target Cost- A maximum amount of \$500 should be spent in designing this product.