Product Design Specification Report

Brain Model

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Problem statement:

Our client, Dr. Bermans Iskandar, Director of Pediatric Neurosurgery in the Department of Neurological Surgery at the University of Wisconsin Medical School, trains medical students to perform pediatric neurosurgeries. Presently, there is no viable model to train the students to perform Endoscopic Third Ventriculostomy to relieve pressure in the ventricles due to build-up of Cerebrospinal Fluid (CSF). An anatomically accurate and realistic model is required to sufficiently train the medical students in technique so that patients are not subject to inexperienced surgeons performing their first surgery. The model should be disposable and similar to a hydrocephalic brain. It has to include the insertion of the endoscope and allow maneuverability in the ventricular system.

Client requirements

- Allow practice of Endoscopic Third Ventriculostomy
- Anatomically accurate and similar to brain texture
    - Allow maneuver of rigid endoscope
- Similar to a hydrocephalic brain
- Disposable and mass-producible
- Include surgical entrance through lateral ventricles
- Include structures in the lateral ventricles and 3rd ventricle
    - Fornix
    - Foramen
    - Ventricle floor (3rd ventricle)
    - Mammillary bodies
    - Optic chiasm
    - Basilar artery
- Allow endoscopes of diameter 4mm-6mm in procedure
    - Tract and foramen at least 7mm in diameter
- Puncturable 3rd ventricle floor
- Allow CSF in model
- Storable under normal conditions
    - 25°C
    - 50% humidity
- Dimensions smaller than 50cm x 50cm x 50cm
- Weight below 10kg
- Under $500 budget

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The model should be able to handle the simulation of a 90-minute neuro-endoscopy procedure, including the addition and removal of mineral oil and the movement of the rigid endoscope within the model.

b. *Safety*: The model should not pose any safety risk to the user or contain any toxic materials or sharp edges. There should be no fluids or materials in the model that can pose pathological concerns. Though dangerous instruments may be used during the usage of the model, the model itself should pose no danger to the user.

c. *Accuracy and Reliability*: The model should accurately reflect the described neuro-endoscopic procedure and include all the necessary structures for teaching this procedure. Specifically, it should be 292mm x 172mm x 195mm, which are the dimensions based on MRI scans. The material should be flexible and resemble brain tissue as closely as possible, with a durometer of 10 Shore A. It should be easily re-producible for multiple procedures.

d. *Life in Service*: The model should not degrade during the 90-minute procedure. It may be destroyed or modified during the procedure, but it should not otherwise change. The model should be identical to all other models produced to ensure anatomical accuracy.

e. *Shelf Life*: The model and all its components should not degrade in storage under normal storage conditions for at least 1 week. It should withstand storage for 1 week under usage conditions without any changes to its structural or material qualities.

f. *Operating Environment*: The neuro-endoscopy procedure will be performed at approximately 25^{o}C and 50% humidity.

g. *Ergonomics*: The model will be used by one surgeon at a time but other surgeons may be present to observe the procedure. The model should only be used with proper neuro-endoscopic tools such as the endoscope, specifically a high quality rigid endoscope. The surgeon will insert the endoscope in the ventricular system through the lateral ventricles, navigate through the ventricular system using the rigid endoscope, arrive at the third ventricle, make an incision on the third ventricle floor and finally stretch the incision to a maximum of 7mm in diameter.

h. *Size*: The model should not exceed 50cm x 50cm x 50cm and should allow a minimum of 1m space around the model to allow the surgeon to access the model easily.

i. *Weight*: The model can be portable or stationary, depending on its sophistication. No limitation on weight since it can depend on the quality of the model.

j. *Materials*: All materials used must not pose health risks or be abrasive to humans under normal use. Materials should be non-radioactive, non-flammable, and non-corrosive. Material should be able to with hold fluid (particularly mineral oil) inside the model.

k. *Aesthetics*, *Appearance, and Finish*: The model should be visually appealing and represent the anatomy of the brain. The color should preferably be gray or another color similar to brain tissue. The overall model should have a smooth, polished appearance.

2. Production Characteristics

a. *Quantity*: One model is required at present. However, the model should be easily replicated and multiple models should be easily manufactured in the future.

b. *Target Product Cost*: The target manufacturing cost for the product is $500, which is approximately one tenth the price of the cheapest comparable products on the market.

3. Miscellaneous

a. *Standards and Specifications*: This model will not require any approval by the FDA because this product is not a medical device used in or with human subjects.

b. *Customer*: The product should adhere strictly to the customer's requirements of being anatomically accurate and effective in the training of medical students in Endoscopic Third Ventriculostomy.

c. *Patient-related concerns*: The product will not be in contact with any patients. However, patient information may be required to produce the hydrocephalic brain model and therefore patient privacy has to be protected. The model should not endanger the surgeons using the model.

d. *Competition*: There are 3 virtual programs and 1 physical model currently on the market that are similar to our client's requirements. The software programs are manufactured by Vivendi Software, Simulated Surgical Systems, and Immersive Touch. The physical model is made by Simulab Corporation. These products are very expensive, limited in practice procedures, or both.