Product Design Specification Report
Brain Model for Neuro-Endoscopic Teaching and Practice

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Problem Statement

Our client, Dr. Bermans Iskandar, of the Department of Neurological Surgery at the UW Hospital, performs pediatric neurosurgeries. Currently, his medical students do not have a surgical simulator to practice endoscopic third ventriculoscopy to remove blockages in the cerebral aqueduct. A model of the ventricular system to teach and practice surgeries is necessary so that patients are not subject to initial trial surgeries by medical students. The model needs to be anatomically correct and allow the surgeon to practice control of their fine motor skills. The model should include insertion of the endoscope into the ventricles and be durable enough to train multiple students on the surgical techniques.

Client requirements

- Practice Endoscopic Third Ventriculoscopy
- Simulate blockages within cerebral aqueduct between 3rd and 4th ventricles
    - Cause of blockage: duct malformation, hemorrhage, tumor, or cysts
- Surgical entrance, if present should be located on coronal suture, 2-3mm away from the midline
- No air bubbles present if fluid is used inside model
    - Would allow practice siphoning and replacing CSF
- Train surgeon's fine motor skills in controlling endoscope
- Model is 1 unit
- Weigh less than 5 kg
- Dimensions less than 25cm x 25cm x 25cm
- Must allow 1-6.2 mm diameter endoscope to be used in procedure
- Material is similar in texture of brain structures
    - elastic
    - Non-abrasive
- Material must not degrade with constant use
    - Lifetime is 2 years
    - Use daily
        - 90 minute procedure
- Material must withstand room storage conditions
    - 25ºC
    - 50% humidity

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The model will be used daily to simulate the 90 minute neuro-endoscopy procedure. The practice model material must not degrade with multiple uses or with storage periods from 1 week to 1 year.

b. *Safety*: This model must not endanger the user. There must not be toxic materials or sharp edges within the model. There should not be any pathological concerns due to fluids or gels used in model. Though dangerous tools may be used during operation of model, the model itself should not pose a safety risk to the user.

c. *Accuracy and Reliability*: This model should accurately replicate a neuro-endoscopic procedure. 730 practice surgeries to be performed on the model without significant degradation of model features.

d. *Life in Service*: The model should not degrade performing practice procedures daily for 2 years. The materials should uphold their anatomical features to allow for multiple repetitions of neuro-endoscopy procedures.

e. *Shelf Life*: The materials of the model should not degrade over time in storage for 5 years. The model will not be in storage for more than a week at a time under normal conditions of use.

f. *Operating Environment*: The model will be used by one surgeon at a time. The practice neuro-endoscopy will be performed at 25°C and 50% humidity.

g. *Ergonomics*: Model should only be used with proper neuro-endoscopic tools such as the endoscope.

h. *Size*: The model should not exceed a size of 25cm x 25 cm x 25 cm. There should be a minimum of 1 m of space surrounding the model to allow proper use by a surgeon.

i. *Weight*: The model should be portable with the use of a cart or other transportation device. The model should not exceed 5 kg.

j. *Materials*: Materials used must be safe for use around humans. Any material used should not pose a health risk or be abrasive when the model is handled. Non-radioactive, non-flammable, and non-corrosive materials should be used. Material must not degrade when introduced to fluid (to be determined) inside the model.

k. *Aesthetics, Appearance, and Finish*: The model should be pleasing to the eye and follow basic anatomical shapes. The colors do not have to be realistic, but realistic colors are preferable. The finish should be smooth and clean looking.

2. Production Characteristics

a. *Quantity*: One model is required at this time. However, if the product is to be produced on a large scale in the future, additional models will have to be manufactured.

b. *Target Product Cost*: The target manufacturing cost for the product is $500, which is significantly cheaper compared to existing products. One of the cheaper models currently on the market costs around $5000 and other models are even more expensive.

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 basic requirements: anatomically accurate and targeted toward training medical students in neuro-endoscopy. The client's requirements will be addressed in producing the model.

c. *Patient-related concerns*: The product will not be in contact with any patients, nor will the patients' data be utilized in any way; therefore patient-related concerns will not be applicable. The model should not endanger surgeon practicing with 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.