

# Product Design Specifications

Hip Aspirate Model to Teach Physicians

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## Function:

Septic arthritis is a relatively rare, but dangerous condition that needs quick diagnosis and action. Due to the rarity, residents may receive little clinical experience with the aspiration procedure that is used as treatment and diagnosis of the condition, thus delaying treatment. The hip aspirate model will allow residents to perform the procedure in a practice environment. This will ultimately lead to a higher number of experienced surgeons and better patient outcomes.

## Client Requirements:

- Base infant model, aspiration insert, anatomic insert
- X-Ray and ultrasound compatible
- Anterior surgical method option
- Repricable
- Reusable

## Design Requirements:

### 1. Physical and Operational Characteristics:

- Performance requirements:* The model must accurately mimic a pediatric patient with septic arthritis. This includes the anatomical structures as well as the mechanical properties at the puncture site. Residents must be able to perform several needle aspirations on the model at any given time. The model should be x-ray and ultrasound compatible to perform the procedure properly. The model should be able to withstand multiple attempts (punctures by the needle) before any parts must be replaced.
- Safety:* The device should be safe for physicians to hold, carry, and practice the hip aspiration procedure on. The result of a failed technique must not harm the residents. Any sharp components must be covered for safe handling.

- c. *Accuracy and Reliability*: The model should match the shape and size of a 2 year-old hip joint. The joint should have fluid uniformly surrounding the femoral head with similar viscosity to synovial fluid. The model must be completely x-ray and ultrasound compatible to guide the physicians as in a real aspiration procedure. The section of the model that will be punctured must mimic the mechanical properties of human skin (dermis and epidermis), fatty tissue, muscle, and the fibrous tissue of the joint capsule.
- d. *Life in Service*: Each aspiration procedure takes 1-2 minutes. The model must last for at least three months with four practice sessions per month before any replacements are needed. The model should be able to accommodate 15 needle sticks per practice session.
- e. *Shelf Life*: The model should be able to withstand multiple needle punctures during in each training session. Ideally, no parts will need to be replaced in between trials. The model should last for a few months of training sessions before any parts need to be replaced. The replaceable parts should be inexpensive and simple to replace. The model as a whole should last multiple years at a training facility or clinic when stored in dry, room temperature conditions.
- f. *Operating Environment*: The model will mostly be used in a controlled, indoor environment. Under normal circumstances the device should not have to withstand extreme temperatures. The model will have to hold fluid to be functional so the materials will have to be capable of this.
- g. *Ergonomics*: The model should be able to handle all interaction and stresses of a hip aspiration while accurately representing a real child. This includes withstanding multiple insertions of a needle while maintaining the mechanical qualities of the artificial tissues.
- h. *Size*: The model should be the size of a pediatric hip, age 2. This includes a femur that is 18-20 cm in length. The entire model should be 24x13x55 cm in size.
- i. *Weight*: The model should be light enough to transport and store with relative ease while having enough weight to accurately represent an infant for surgery. The target weight is 6.1 pounds.
- j. *Materials*: The materials used for skin, soft tissue, joint capsule, and bone should produce accurate images using ultrasound imaging and x-ray imaging. The mechanical properties of the skin, soft tissue, and joint capsule should also be comparable to those of an infant. The skin and soft tissue should be able to withstand many injections so that the model can be reusable. The joint capsule material must also resist puncturing more than the other materials.
- k. *Aesthetics, Appearance, and Finish*: The model should resemble the appearance of a human infant hip as much as possible. It would be desirable, for aesthetic reasons, to have a full body infant model but it is not necessary. There should be no extensions beyond the body of the model

## 2. **Production Characteristics:**

- a. *Quantity*: 1 infant hip model

b. *Target Product Cost*: This semester's budget is \$500.

**3. Miscellaneous:**

- a. *Standards and Specifications*: No regulatory requirements exist for this project. However, notes from previous teams stated that the client wished the model to be based upon the anatomical measurements of an 18 month infant.
- b. *Competition*: There is no record of a competing model produced by another body that would fulfill the purpose of this model. Ultrasound phantoms exist for the aspiration of intraperitoneal fluid from the body cavity, such as the one developed by Blue Phantom. Kyoto Kagaku developed a pediatric phantom to train technicians in ultrasound of infants.