

## Product Design Specification

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. Currently, residents may receive little clinical experience with the aspiration procedure due to the limited number of cases. This in turn delays the critical treatment. The hip aspirate model will be used to thoroughly train more residents to perform the procedure through repeated trials and documentation. 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:** This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project)

#### 1. Physical and Operational Characteristics:

- Performance requirements:* The model must accurately mimic an infant septic arthritis patient. This includes the anatomical structure as well as the mechanical properties of the puncture location. 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 so physicians can ensure the procedure is being performed properly. The model should be able to withstand multiple attempts before any parts need to be replaced.
- Safety:* The device must be safe for physicians to hold, carry, and practice the aspiration procedure on. The result of a failed technique must not harm the residents. The model

will contain fluid which must be isolated from any electrical components that may be included. 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 evenly surrounding the femoral head that has viscosity similar to that of synovial fluid. The model must be completely x-ray and ultrasound compatible to guide the physicians as they would be in a real aspiration. 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 be able to accommodate any number of procedures that are attempted a given time. Lengths and frequencies of training periods may vary.
- 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 same size as an infant or young child.
- i. *Weight*: The model should be light enough to transport and store with relative ease while having enough weight to accurately represent and infant for surgery.
- 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.

## 2. **Production Characteristics:**

- a. *Quantity*: 1 infant hip model
- b. *Target Product Cost*: Last semester they had a budget of \$500 so our budget this semester should probably be around that mark.

**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.