

Product Design Specification

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Problem Statement:

Present methods of positioning a patient's head while performing a fluoroscopic examination of a fractured neck are inefficient and unsafe. A technician must physically move the patient's head in various positions with their hands while the examination is taking place. This procedure is potentially dangerous for the patient and time consuming for the radiologist. The device to be designed will flex and extend the head about the neck in a fluoroscopy room. The device is designed to prevent obstruction of x-ray imaging. It provides rotation about the spine isocentric to the normal rotation point for flexion and extension.

Client Requirements:

- *Improve current design*
- *Increase ease of operation*
- *Accurately mimic natural neck movement*
- *Must not obstruct x-ray imaging*
- *Cost efficient*

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirement: The device must be capable of rotating the neck 45 degrees backward (extension) and 25 degrees forward (flexion). This rotation must also mimic the natural rotation of the neck.

b. Safety: The device must comply with all medical safety regulations. It must be comfortable for use with a variety of sized patients. The device must move slowly and smoothly to prevent injury. Sharp edges should be covered with padding. The head must be held securely during operation. The device must not get tangled with patients' hair.

c. Accuracy and Reliability: The device must operate successfully over repeated uses. The rotation must be smoothly adjustable with one degree of sensitivity.

d. Life in Service: The device must be capable of being used daily, but will likely be used once or twice a month. It should have a lifespan of ten years minimum.

e. Operating Environment: The device must be capable of withstanding the conditions encountered in a fluoroscopy room. Its operation must not be impaired by x-rays.

f. Ergonomics: The device must be comfortable for the patient. It should also be easy to use and require only one person to operate.

g. Size and Shape: The device must fit easily within a standard c-arm fluoroscope. The shape should allow for transport by one person. The head support must be able to accommodate a head width of up to seven inches.

h. Weight: The device must be less than twenty pounds to be easily transported by one person.

i. Materials: The device must be strong enough to avoid deformation over repeated uses. Material must have a low mass attenuation coefficient to minimize x-ray shielding.

j. Aesthetics, Appearance, and Finish: The appearance should be appropriate for a hospital setting.

2. Product Characteristics:

a. Quantity: One device is required.

b. Target Product Cost: The prototype should cost less than \$500 to build.

3. Miscellaneous:

a. Standards and Specifications: The device should comply with all regulations established by the FDA for medical instruments. More information can be found on the FDA website.

b. Customer: The customer will typically use the device in a fluoroscopy room, so all design choices must take the conditions of such an environment into account. The preferred focus is on extension, with optional side-to-side rotation functionality.

c. Patient-related concerns: The patient must feel comfortable, and the device must not cause claustrophobia.

d. Competition: No similar device currently exists.