Enhanced Safety and Visualization for Endoscopic Sinus Surgery.
Project Design Specification (PDS)

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Client: Dr. Ashley Anderson

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Function: Currently endoscopic sinus surgery telescopes present a fire danger in the operating room, as they can ignite paper drapes. In addition, inserting and extracting the scope from the nose frequently results in blood on the lens. This project will attempt to address both those problems with a scope caddy containing defogging solution, and an alar (nose) opening retractor which will reduce contamination of the scope during insertion. In addition, other ergonomic and practical improvements to this procedure will be considered, including the possibility of incorporating an irrigation system into the retractor.

Client Requirements:
The client requires the design to:
• Enhance safety of endoscopic equipment
• Lens defogging and cleaning

1. Physical and Operational Characteristics
a. *Performance requirements*: Disposable after single use. Design must be able to practically incorporate into hospital settings and current procedures.
b. *Safety*: Biocompatible with nasal environment if needed. Minimize heat and fire hazards. Chemical resistance to cleaning and defogging solutions.
c. *Accuracy and Reliability*: To the extent that is needed to maintain the safety and sterility of the operating environment.
d. *Life in Service*: One time use.
e. *Shelf Life*: Dependant upon the incorporation of cleaning and defogging solutions and their estimated shelf life. Overall, approximately one year prior to use.
f. *Operating Environment*: Operating room in a sterile field. Any endoscopic accessory devices may be exposed to biological and chemical fluids as well as heat from the scope. Most components will not be in direct contact with the patient
g. *Ergonomics:* Should incorporate into OR environment with accessibility and ease of use, including versatility to suit various endoscopic devices.
h. *Size*: Minimal size and footprint. The device should not detract, clutter, or interfere with the operating environment and procedures.
i. *Weight:* Minimal, comparable to size constraints.

j. *Materials:* Plastic materials are desired for ease of processing, size and weight constraints, and cost effectiveness.
k. *Aesthetics*, *Appearance, and Finish*: Secondary to safety and functionality. Simplicity is key, the design should be unassuming to the surrounding environment.

2. Production Characteristics

a. *Quantity*: Design should have to ability to be mass produced if desired by the client.
b*. Target Product Cost*: To be determined, but must be compatible with the disposable nature of the product.

3. Miscellaneous

a. *Standards and Specifications:* Must be FDA approved for OR use.
b. *Customer*: Product must not be time consuming or interfere in anyway with patient treatment to insure use of product by medical personnel specifically ENT surgeons.
c. *Patient-related concerns*: Materials, chemicals, or necessary electronics must not endanger patient.
d. C*ompetition*: Informed that no similar product is currently marketed. Previous patents existing for similar ideas include but may not be limited to the EndoSheath®.