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Product Design Specifications

Project: Endotracheal Tube Cuff Valve

Team: Michael Alexander (Leader)
Jack Ho (Communications)
Claire Edlebeck (BWIG)
Samantha Bergh (BSAC)

Purpose: Develop a valve for an endotracheal tube cuff that will not allow inflation pressures to exceed 25 cm H_2O pressure. Overinflation of the cuff that provides a tight seal between the endotracheal tube and the patient's trachea is a common problem. The excess pressure can cause many complications, especially in children. Our task is to create a cuff that fails predictably at 25 cm H_2O so the cuff can be safely utilized in pediatrics.

Client Requirements:

- Cuff cannot fail before reaching 25 cm H_2O pressure.
- Cuff must fail after 25 cm H_2O pressure**.**
- Cuff failure can be bypassed to accommodate unforeseen situations.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance requirements*: Must perform at level consistent of existing endotracheal tubes (i.e. intibation for surgery, through recovery).
    b. *Safety*: Must be FDA approved for humans. No need to be autoclavable.
    c. *Accuracy and Reliability*: Must fail at 25 cm H_2O +/- .25 cm H_2O
    d. *Life in Service*: Must last for duration of patient intibation, whether short term or long. Will be disposed of when no longer in use.
    e. *Shelf Life*: Should be able to be stored in optimal conditions for 1 year.
    f. *Operating Environment*: During use, the cuff valve will be used in both E.R. and O.R. settings. During storage, it will be held on a shelf with little outside exposure.
    g. *Size*:
    h. *Weight*:
    i. *Materials*: Should not increase MRI visibility of endotracheal tube.
    j. *Aesthetics, Appearance, and Finish*: Should be clean, with white finish for high visibility.
2. **Production Characteristics**
    a. *Quantity*: Working prototype
    b. *Target Product Cost*: < $10

3. **Miscellaneous**
    a. *Standards and Specifications*: FDA approval for use in human pediatrics.
    b. *Customer*: Customer already has means to inflate cuff. Must have means to bypass valve.
    c. *Competition*: Lanz® brand endotracheal tubes (30 cm H_2O)