Project Design Specifications

Expandable Nasogastric Tube

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Problem Statement

Nasogastric tubes (NG tubes) are commonly used for aspiration of gastric contents and gastric decompression in patients with small bowel obstruction. Placement of a NG tube causes discomfort and pain during insertion due in part to the large diameter of the tube. This project requires a nasogastric tube which is small enough to reduce discomfort, while still being functional. Secondary design specifications include pH sensitivity to allow visual confirmation of when the tube reaches the stomach, incorporation of a lubricant/anesthetic, and recyclability.

Client Requirements

The developed nasogastric tube must:

- minimize patient discomfort upon insertion by reducing tube diameter and/or incorporating an anesthetic or lubricating agent
- increase ease of insertion for the physician
- enable aspiration of stomach/small bowel contents without collapsing or harming patient
- be visible on x-rays used to confirm proper tube positioning
- incorporate a color indicator that confirms when tube is in the low pH environment of the stomach
- contain materials that are recyclable or made from recycled materials

Design Requirements

1. Physical and Operational Characteristics

a. *Performance requirements:* The developed NG tube must be able to remove gastric contents as well or better than current models. This means the diameter of the tube must be large enough to prevent excessive blockages and the tube material must be stiff enough to withstand suction pressures up to 120 mmHg. Additionally, the NG tube should be approximately 3 mm in diameter during insertion and expand to approximately 6 mm in diameter once in place. Furthermore, the tube must be able to withstand acidities as low as a pH of 2, as it will be exposed to the conditions within the stomach. In addition, the tube must be flexible enough to be manipulated through the nose, down the esophagus, and into the stomach but stiff enough to prevent coiling or kinking during insertion. The tube must also include a radio-opaque strip to confirm tube placement on X-rays and would also ideally include a pH sensor to further confirm placement in the stomach. Other ideal requirements include incorporation of a lubricant or anesthetic to enhance insertion comfort and the use to materials that enable the tube to be recycled. Currently, tubes are used once and thrown away.

b. *Safety:* The tube must be non-allergenic (no latex). It also must not have any sharp ends/edges to prevent laceration of any body tissues upon insertion. The design should also not require suction greater than 120 mmHg to prevent injury to the stomach lining of the patient.

c. *Accuracy and Reliability:* The tube should have markings every inch so that physicians can consistently measure how far the tube has been inserted into the patient. Furthermore, the tube must have a method to confirm proper placement in the stomach such as a radio-opaque strip and pH or CO2 sensor.

d. *Life in Service:* The tube must last up to one week in the environment of the stomach through the nasal passageway.

e. *Shelf Life:* The tube must last at least 3 months on the shelf.

f. O*perating Environment:* The nasogastric tube is currently used in hospitals and medical clinics. It will be stored at room temperature with little exposure to humidity and pressure. This device will be inside the body, touching visceral organs, so while it is in use, it will have to withstand core body temperatures, ~100º F, and the acidity of the stomach, ~2 pH. The device can be in the body for up to one week so it will have to be completely resistant to corrosion at these temperature and acidity conditions.

g. *Ergonomics*: There are many ergonomic restrictions since the device will be used inside the human body. The nasogastric tube will be guided through the nasopharynx into the esophagus, so the torque required to bend the tube must be limited to prevent tissue damage. Furthermore, the diameter of the tube has to be small enough to fit inside of the nose. Additionally, the tube must have enough stiffness so the physician can use minimal force during insertion and removal without worrying about kinking or coiling.

h. *Size:* The device will be 48 inches long. Ideally, the developed tube will expand from an initial diameter of approximately 10 Fr (~3 mm) which is the size of current NG feeding tubes to a diameter of about 18 Fr (~6 mm) , the current diameter of NG decompression tubes.

i. *Weight:* The device should weigh less than 2 kg.

j. *Materials:* All materials must be non-allergenic, non-irritable, and biocompatible. The selected materials must also be able withstand initial sterilization likely by ethylene oxide. Tube materials will most likely be made of polyurethane or polyvinylchloride, like current NG tubes.

k. *Aesthetics, Appearance, and Finish:* The device should look professional, the finish and appearance is not a factor, since function is 100% of the focus.

2. Production Characteristics

a. *Quantity*: One prototype is needed at this time. There is the possibility of mass production in the future.

b. Target Product Cost: Target cost for device is kept to a minimum. The budget for prototyping the design is $1000. This tube mass produced and on the market should cost less than $20.

3. Miscellaneous

a. Standards and Specifications: FDA approval is required for the device before mass production.

b. Customer: The developed NG tube will be used by physicians and nurses who perform procedures involving removal of gastric contents and/or small bowel obstructions.

c. Patient-related concerns: The tube must have a small diameter to improve patient comfort and smooth end/edges to prevent injury. Furthermore, the tube must be non-allergenic. The device will initially be sterile and only used once so there is no potential for disease transfer. There is no patient data storage so no such safeguards are necessary.

d. Competition: There are a wide variety of NG decompression tube models created by several different companies on the market. Most of these tubes are constructed of PVC or PU and have large diameters, causing discomfort to the patient. These tubes vary in gauges and lengths. The average cost per device is between $12 and $20. There are also pH and CO2 sensors that can be attached to these tubes to confirm placement within stomach. However, there are no tubes on the market that expand once inserted.