



Product Design Specification

Dislodgement Resistant Endoscopic Dissecting Cap

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September 22, 2023

Function: Dr. Amber Shada's lab performs endoscopies which are procedures where an endoscope is inserted into the esophagus in order to view the human gastrointestinal tract. Currently the client uses caps for the end of the endoscope which are attached via water resistant tape. The caps however frequently fall off due to the unsecure method of attachment and can become dislodged.

Our team plans to improve this by working with the client to create an endoscopic cap that will be secured to the end of the endoscope. The cap will be dislodgement resistant meaning that it will remain at all times attached to the endoscope while in the intestinal tract. This cap will also be detachable for when the endoscope is not being used in the body.

Client requirements:

- Cap must fit onto the 9.9 mm diameter distal end of the endoscope
- Cap must be dislodgement resistant
- Cap must be detachable at the client's discretion
- Cap must be made from material that will not cause harm to the patient
- Cap must be transparent and colorless
- Cap should have a beveled end
- Cap should have some flexibility but overall remain rigid
- Cap should be sterilizable through use of ethylene oxide

Design requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The endoscopic dissecting cap should be able to be easily attached and detached from the endoscope. The cap should also not become dislodged and remain secure during the endoscopy as that could cause damage to the patient undergoing the procedure and increase the length of the surgery. The cap should also be shaped in a way to allow for the endoscope to easily maneuver the walls of the tissue allowing for a better viewing area. Finally, the cap should have some flexibility to allow for easier navigation through the gastrointestinal tract however the cap must overall remain rigid throughout the procedure.

b. Safety: The endoscopic dissecting cap must be made of a safe material that

will not harm the patient undergoing an endoscopic discectomy operation. The procedure must be conducted by a professional who has been properly trained [1].

c. Accuracy and Reliability: The cap should be able to navigate various directions throughout the entirety of the procedure without detaching from the endoscope. Accuracy and reliability will be measured by performing a test similar to an endoscopy to mimic the movements of the endoscope along the walls of the gastrointestinal tract. The dislodgement and displacement of the cap during the test will then be measured.

d. Life in Service: Endoscopic cap should be sterilizable through use of ethylene oxide. The device should not dislodge throughout the whole procedure, which can last from 45 minutes to two and a half hours.

e. Shelf Life: The endoscopic cap will be designed to be sterilized through ethylene oxide sterilization and could potentially be indefinitely reused until signs of damage.

f. Operating Environment: The operating environment of the endoscopic cap will be the human gastrointestinal tract. The cap will need to withstand a pH of 3.5-6, a temperature of 37 degrees Celsius and be fluid resistant to comply with the physiological conditions of the intestines [2].

g. Ergonomics: Endoscopic dissecting cap must be made out of a material that can be used safely inside an organism with no reaction and can be gas sterilized. A potential material could be silicone as it is used for internal medical devices such as catheters and can be sterilized with ethylene oxide. The cap must have the ability to attach and to detach from a EVIS EXERA III GIF-HQ190 gastroscope without making permanent alterations to the device. The cap should have the ability to maneuver through the human gastrointestinal tract without dislodgement. In order to perform endoscopic surgery or tissue samples, the cap must create a tight seal with the endoscope. Otherwise, bodily liquids may interfere with the viewing field.

h. Size: Must have minimum inner diameter of 9.9 mm to attach to distal end of endoscope [3]. Similar products have dimensions of 11.35 mm in outer diameter and 4 mm length from distal end of endoscope [4].

i. Weight: No additional restrictions on weight. Size and material constraints restrict the possible weight of the cap to within the weight range of similar products.

j. Materials: Must be colorless, transparent, non-ferrous, biocompatible, and sterile [5]. Current products are made from Spunbond Polyethylene and are typically soft, smooth, single use [6]. Client prefers a more rigid material.

k. Aesthetics, Appearance, and Finish: Must have smooth, thin and semi-flexible walls, must have ports in walls to release fluid. Must be transparent and colorless [6]. Must be cylindrical and is preferred to have a beveled end in addition to the 4mm length from distal end of endoscope [7].

2. Production Characteristics:

a. Quantity: Only one final model of the endoscopic cap will be produced, but it must be kept in mind that the final product should have the ability to be mass produced in the future.

b. Target Product Cost: The total cost of production, including all prototyped models, has a target cost of \$500. Production of solely one final product should ideally be less than \$500.

3. Miscellaneous

a. Standards and Specifications: FDA approval of all medical devices in the United States is required. This is therefore applied to endoscopes and endoscopic dissecting caps [8]. Endoscopes are classified as a Class II Medical Device and must comply with all FDA guidelines and regulations under Title 21 [9]. Must adhere to ISO 10993 biocompatibility guidelines [10] as well as ISO 8600-4 endoscopic insertion width requirement [11].

b. Customer: The customer is asking for an endoscopic cap which can fit securely onto the distal end of an endoscope. To prevent additional costs to the customer, the final product is to be reusable and made from a material that can be gas sterilized. The customer prefers a beveled end to the endoscopic cap to allow for easier maneuverability through the gastrointestinal tract.

c. Subject-related concerns: The materials and shape of the cap must ensure that the patient is unharmed during use of the endoscope. Furthermore, the

cap must comply with all medical standards and procedures to prevent cross-contamination of bacteria.

d. Competition: Ovesco Endoscopy has a patent filed for a medical gripping device, which is attached onto the front end of the endoscope. The cap has two flexible control mechanisms for the medical gripping device, which allows the operator to use grip onto internal tissues for sampling. [12]

Additionally, Cilag GmbH International has a patent filed for an endoscopic apparatus with an electrode probe placed inside. The apparatus is securely fit onto the endoscope, through locking numerous pieces together. The electrode probe is used to non-thermally ablate tissue within the body. [13]

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