Graduated Bowman Probe

BMEDesign: Product Design Specification

February 5, 2026

Biomedical Engineering 301

Section 304

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Function

Bowman probes are the standard instrument used in interrogation of the nasolacrimal (tear duct) system in Ophthalmology. They are available in various sizes and provide tactile feedback to the surgeon when probing the canalicular/nasolacrimal system, allowing them to assess for strictures, discontinuities, obstruction, or other abnormality within its lumen. Probing is typically performed prior to the passage of implants such as nasolacrimal stents (eg. Crawford, Lacriflow, Nunchucku, Monoka), to confirm patency of the nasolacrimal system. Available probes on the market do not have any markings on them which may allow the surgeon to make measurements to points within the canalicular/nasolacrimal lumen (eg. a stricture at 30 mm distal to the punctum), which can be helpful in correlating with imaging findings, or for accurate clinical documentation and therefore inform management of nasolacrimal pathologies. The development of such a stent with inscribed bands corresponding to millimeter markings will be essential during canalicular or nasolacrimal probing for the simple location of duct obstructions.

Client requirements

- The design must feature accurate line markings that are easily recognizable during procedures
- Device must be smooth and shouldn't have any engravings that result in a rough-textured surface
- The device's material must be compositionally strong after addition of measurement markers
- The design must be able to withstand autoclaving and repeated sterilization
- The design should fit standard probe size guidelines

Design requirements

1. **Physical and Operational Characteristics**

    a. **Performance requirements -** The device should be able to accurately present the depth of nasolacrimal duct probe insertion in millimeters. The device must be similar in comfort to the user's previous probes to avoid discomfort and procedural-change. The device must also be able to undergo multiple rounds of sterilization via autoclaving, and therefore must maintain structural and chemical integrity throughout high temperature exposure. Finally, the device must be able to withstand long-term usage without material degradation and/or mechanical failure.

    b. **Safety -** The selected design must comply with ISO-13485:2016 to uphold necessary safety and regulatory requirements[1]. This standard specifies the need for design risk assessment, product cleanliness, and overall quality assurance for medical devices. Should the design feature laser engraved measurement markings per the client's request, it must be tested and held to ISO-13485:2016 standards to ensure material composition and therefore patient safety is not jeopardized. Furthermore, the design's strength should be tested through MTS compression testing to confirm material integrity after the addition of measurement markers. While the procedure has minimal operating times, with the device being implanted for less than one minute, the design must follow ISO-10993-1 which specifies necessary guidelines for biomaterial interactions with live tissue. A majority of design safety specifications are largely covered in sections 3a: Standards and Specifications and 3c: Patient Related Concerns.

    c. **Accuracy and Reliability -** The design should have accurate markings every 5 millimeters along the probe as requested by the client, and feature inscribed bands corresponding to millimeter markings. The chosen device must also be within a normal range of standard commercial bowman probes in terms of weight, length, and diameter to comply with standard procedural operation. The measured values must be within a 5% range of the correct nasolacrimal duct obstruction millimeter length.

d. **Life in Service -** The design must be reusable, withstanding 5-10 years of clinical use. In order to achieve this, the probe should be designed from a material significantly resistant to wear and corrosion, such as stainless steel. This is particularly important for the design, since wearing down of the markings could harm functionality of the probe or lead to incorrect measurements In addition, the probes must be capable of withstanding hundreds of sterilization cycles, typically performed via autoclaving[2]. Individual uses of probes last from seconds to a minute.

e. **Operating Environmen**t - The design must be able to withstand all qualities of a clinical environment, as well as the environment of the tear duct. Firstly, the probe must be able to withstand temperatures of up to 132-135 °C to withstand the autoclaving process[2]. The probe will not be subjected to significant pressure, and will be exposed to the moderate humidity of operating rooms, ranging from 20-60% RH[3]. Additionally, the probe will be exposed to increased moisture during autoclaving. While being used, the probe will be exposed to the fluids of the tear duct, including tears, blood, and mucous. Particular care must be used to ensure probes are not contaminated between uses.

f. **Ergonomics -** The probe will be designed for use by trained clinical personnel and Ophthalmologists, who are familiar with bowman probes and how to handle clinical instruments. The probe must be designed to be comfortably and precisely controlled by gloved fingertips, typically achieved using a flat center. The probe must withstand minimal insertion force, up to 1 N[4], and the minimal torsion force caused by twisting. Fatigue is not a concern for this design, as they are intended to be used for a short duration. To ensure the safety of the patient, the probe should feature a rounded, atraumatic tip to prevent cutting. Finally, the design material should have a smooth, polished surface to prevent tissue trauma and improve tactile feedback. This extends to the graduated markings or engravings of the design.

g. **Size -** Bowman probes are available in sizes ranging from 0000-8. For the purposes of this project, the client is most concerned with sizes, 00, 0, and ½, representing 0.7 mm, 0.8mm and 1mm diameters, respectively. Additionally, probes are available in lengths ranging from 130-150mm. Finally, the probes come either curved or straight, however our client only uses straight probes.

h. **Weight** - These probes are typically very tiny and light to allow the ophthalmologist to be as precise as possible while performing the procedure to minimize error. Bowman probes weigh roughly 45 grams. If this weight were to be increased by using different material, the probe would be more likely to cause error by puncturing the walls of the nasolacrimal cavities. If it were to be lighter, the probe's structural integrity could be more likely to fail during the procedure and further complicate the procedure.

i. **Materials -** Materials used to make probes must be organic metals that can be used in the body and minimize the risk of the patient creating some toxicity or allergy to it. The majority of the probes are made from stainless steel since the material combines strong structural integrity with flexibility [5]. The bowman probe must also be able to withstand sterilization techniques, the most prominent of which being the autoclave (temperatures range from 121 to 134 degrees C). Finally, the material must be smooth and blunt to, again, minimize injury. A semi-sphere will be attached to the end of the probe to remove any sharp edges that could cause damage to the patient.

j. **Aesthetics, Appearance, and Finish** - Probe will be thin, smooth, and be very forward looking about its usage. There should be no changes to probes already used in practice by ophthalmologists other than the changes to read measurements.

2. **Production Characteristics**

a. **Quantity** - As a preliminary approximation, 10 probes should be made for testing, allowing for multiple trials testing the integrity of the measurement tactics used. Allowing for multiple probes will provide a good baseline for techniques that work and those that don't. Although 10 is an approximation, it is likely that more will be used during testing especially because of the teams lack of training when applying these probes. Multiple errors could be made during fabrication assuming that a specific technique would be used and the probes are built accordingly, but in reality, medical professionals use another resulting in these probes to break.

b. **Target Product Cost -** The target product cost is $100 but can be changed depending on the progress made with the project. Depending on the materials used, the final product can be more expensive but the team will make it a priority to make the product as cost effective as possible. Most of the expense will most likely come from buying the actual probes to prototype on and test. When the device is fully functional, optimizations to the device will be made to further lower the cost to make it more widely available for anyone.

3. **Miscellaneous**
   a. **Standards and Specifications**

      i. ISO 10993-1 provides guidelines for toxicity testing of biomaterials in order to prepare for their interaction with living tissue. The evaluation is based on the specific materials used, how it contacts the body, and the duration of that contact. It provides an in-depth biological risk analysis, evaluation, and control procedure to allow for biocompatible confirmation of a material or device and is an internationally recognized biocompatibility assessment that is required for numerous regulatory applications [6]. The Bowman Probe comes in direct contact with the lacrimal epithelium of the human body during operation and therefore falls under this guideline [7].

      ii. ISO 13402:2025 describes specific test methods to evaluate the resistance of stainless steel surgical instruments from autoclaving, corrosion, and thermal exposure. It outlines procedures specific to typical alloy compositions with each individual test evaluating the materials effective resistance against each of the three aforementioned qualities. [8] The Bowman Probes used at the UW Hospital are sterilized via autoclave and must be corrosion-resistant to ensure long-term durability and to prevent alloy degradation and therefore should abide by this standard.

      iii. ISO 17664 specifies the appropriate procedure for cleaning, disinfecting, and sterilizing medical devices. It describes the characteristics an appropriate medical device must have which includes being easy to clean and sterilize as well as an associating proof of sterilization through formalized testing and data collection. It breaks down medical devices into three categories, critical, semi-critical, and non-critical, with surgical tools being deemed critical and therefore requiring the most attention as they pose the highest risk of infection [9]. Bowman probes are categorized as a surgical tool due to their vital role in ophthalmological procedure and therefore require high sterilization efforts.

      iv. ASTM B912 specifies the passivation of stainless steel alloys through electropolishing. It gives a detailed outline for the pre-treatment, electropolishing, and post-electropolishing processes for various grades of stainless steel [10]. The Bowman Probes will be manufactured out of stainless steel and will require a surface restoration process following any modifications made to the probe in order to prevent alloy deposition and an associating inflammatory response [11].

v. 21 CFR Part 820 is a quality system regulation standard for medical devices which provides necessary details on the designing, manufacturing, storage, and application of medical devices specific for human use. The criteria for this standard lie in tandem with the FDA and therefore provide a good basis for qualification of an appropriate medical device [12]. This standard could become extremely important for the graduated Bowman Probe depending on the extent of development that is done within the project sphere.

b. **Customer**

i. The users of the device will be Dr. James Law and Dr. Sarah van Landingham as well as other clinical practitioners in the ophthalmology department at the UW Hospital. They desire the implementation of the device to be a seamless process that swaps the current Bowman Probes for the modified devices, where no alteration to the methodology or step-wise process of the operation is required.

c. **Patient-related concerns**

i. For medical patients whose operation will be completed with the modified device, all relevant concerns with the procedure both relating to and not relating to the modified Bowman Probe will have been approved and cleared by numerous medical professionals prior to the operation [13]. This includes all anesthetic, pain-related and biological safety concerns for the procedure. The device will be sterilized with an autoclave prior to and after each use and therefore must be tested for continued autoclave sterilization with no signs of damage or degradation.

ii. Potential exposure of alloy particulates to the epithelial-lined conduit of the nasolacrimal duct from laser engraving could cause an unintended inflammatory response within the eye and long term development of scar tissue [14]. The probe must undergo a surface restoration process in order to prevent this response from occurring, such as electropolishing. [15]. The graduated probes will be implemented into the congenital nasolacrimal duct obstruction procedure. This process involves perforating a thin epithelial membrane and is a relatively brief and concise operation, approximately 1 minute in total invasive time for adult patients . This brevity decreases the opportunity of particle deposition from these engravings and prevents intense chemical breakdown from the moist, protein rich environment of lacrimal mucosa [16].

iii. Because of the generation of microscopic burrs and sharp edges during the engraving process, there is an increased chance of prominent friction between the probe edge and the epithelial lining it contacts [16]. Since lacrimal epithelium is thin and delicate, there is potential for abrasion and damage to the surrounding tissue [17]. Thus, damage to the lacrimal tissue within the duct leading to small scale hemorrhage and the development of scar tissue within the lining, further closing the duct, poses a potential concern [18]. Similar to alloy deposition, surface restoration processes such as electropolishing are necessary to diminish the probability of this occurring.

d. **Competition**

Sklar Surgical Instruments

i. Sklar Bowman Probes are the most monetarily prolific brand in the market, bought in bulk by hospitals and other medical facilities [19]. They are known for reliability and quality and offer

probe customization with various sizes and material options including stainless steel and silver [20].

ii. The probes are thin malleable rods with a rounded end used for clearing of the nasolacrimal duct, as well as other general procedures involving the lacrimal system. The device is double ended with distinct probe sizes on each end of a singular instrument.

iii. All probes offered by Sklar are bought non-sterile, reusable, and absent of any latex material helping prevent common anaphylaxis [20]. They are not graduated and therefore though medically acceptable, are not as quantitatively precise as desired by the client.

Calibrated Bowman's lacrimal probe from Indian journal of ophthalmology.

i. These Bowman Probes were individually manufactured with numbered engraving to improve the diagnostic and therapeutic utility of the Bowman Probe in relevant ophthalmological procedures. The numbers have been engraved on the millimeter scale on either side of the probe using laser engraving [21].

ii. The graduated probes are made of stainless steel and feature the exact same size range as standard probes. They are double sided, contain a central metal plate for grip, and are reusable and sterilizable.

iii. The engravings provide nominal size references rather than specific discrete measurement points. The markings provide general guides for the distance of probe insertion into the lacrimal duct but no high level specificity.

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any quantitative information without references came directly from the client, Dr. Law

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