



Graduated Bowman Probe

BMEDesign: Product Design Specification

September 17, 2026

Biomedical Engineering 400

Section 407

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Function

Bowman probes are standard ophthalmological medical instruments used in the interrogation of the lacrimal (tear duct) apparatus. They are commercially available in several millimeter-sized diameters, providing tactile feedback to surgeons when probing the lacrimal system. These instruments allow ophthalmologists to assess for strictures, discontinuities, obstructions, or other abnormalities within the lacrimal lumen. Probing is typically performed prior to the passage of implants, i.e., nasolacrimal stents (e.g., Crawford, Lacriflow, Nunchucku, and Monoka), to confirm patency of the lacrimal system. A graduated Bowman probe would provide a surgeon the ability to make more quantitatively accurate assessments of lacrimal impairments within the tear duct (e.g., a stricture at 30 mm distal to the punctum), which can be used for accurate clinical documentation and therefore informed management of lacrimal pathologies. The development of such a probe with inscribed bands corresponding to millimeter markings along the shaft of the probe is essential for accurate appraisal of canalicular and nasolacrimal probing procedures.

Client requirements

- The design must feature accurate 1 & 5 mm graduated line markings that are easily recognizable during procedural use
- The device must be smooth and shouldn't have any tactile engravings that result in a rough-textured surface
- The device's material must remain 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
- The design should include a nasal lacrimal phantom/mimic for probe testing and future procedural training
- The Nasolacrimal phantom/mimic should imitate physiological conditions of the lacrimal canal

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 1 millimeter along the probe as requested by the client and feature larger, darker bands corresponding to 5 millimeter markings. The

device must also reside within standard range commercial Bowman probes in terms of weight, length, and diameter to comply with standard procedural operation. The measured values must be within a 5% error band of the true impairment depth.

- 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 Environment** - 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 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 0.7mm, 0.8mm and 1mm diameters, respectively. Additionally, market probes are available in lengths ranging from 130-150mm with the client having no preference for this metric. Finally, the probes come either curved or straight, however our client only uses straight probes.
- h. **Weight** - These probes are typically light, approximately 45 grams, to allow the ophthalmologist fine control of the probe while performing procedures. If the laser marking process were to reduce the probe's weight via intense engraving i.e. graduation deeper than 50µm, the probe's weight and structural integrity could be more likely to fail during the procedure and further complicate the procedure [5].
- i. **Materials** - The materials used to make the probes must be organic metals which can be used in the body and minimize the risk of adverse immunogenic response. The majority of the probes are made from stainless steel as the material combines biocompatibility, strong structural integrity, and 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 patient injury.
- j. **Aesthetics, Appearance, and Finish** - The probes will be thin, smooth, and sleek. There should be no difference to the probes already used in practice by ophthalmologists other than the addition of graduated 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.
- b. **Target Product Cost** - The target product cost is \$100 but can be manipulated 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.
- vi. ISO 14971:2019 specifies a systematic risk management process for medical devices throughout their entire lifecycle. The standard outlines procedures for identifying potential hazards associated with a device, evaluating the corresponding risks, and implementing relevant risk control measures. This is relevant to this project since modifications to the conventional probe design may introduce risks such as tissue damage and probe deformation. Following this standard provides a framework for identifying these potential failure modes and guides the development of the probe design and potential testing using a phantom to evaluate device safety before being tested on living patients as our client intends [13].

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.
- ii. The probe will first be implemented into regular use at the UW Hospital following IRB approval and can eventually further be placed on the market if the team decides to follow the WARF patent procedure
- iii. The phantom component of the project will serve as an educational tool for UW-Madison medical students and ophthalmology residents to practice lacrimal procedures.

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 [14]. 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 [15]. The probe must undergo a surface restoration process in order to prevent this response from occurring, such as electropolishing, or undergo adequate testing utilizing a lacrimal phantom to prove the device's safety [16]. 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 [17].

- 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 [17]. Since lacrimal epithelium is thin and delicate, there is potential for abrasion and damage to the surrounding tissue [18]. Damage to the lacrimal tissue within the duct can lead to small scale hemorrhage and the development of scar tissue within the lining, further closing the duct [19]. Similar to alloy deposition, smooth and safe surface texture determined through quantitative testing procedures 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 [20]. They are known for reliability and quality and offer probe customization with various sizes and material options including stainless steel and silver [21].
- 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 [21]. They are not graduated and therefore though medically acceptable, are not as quantitatively precise as desired by the client.
- iv. A single Sklar probe costs approximately 120 USD which stands at a higher end market price and quality.

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 [22].
- 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.

- iv. These probes are not commercially available and therefore cannot be monetarily purchased.

Pristine Medical Anatomy Lab Nasolacrimal Duct Obstruction Trainer

- i. Pristine Medical sells an Anatomy Lab nasolacrimal training phantom designed for practicing irrigation of the lacrimal passages. The model includes bilateral lacrimal drainage pathways and adjustable duct angles [23].
- ii. Correct irrigation allows fluid to discharge through the nasal and oral cavities. The model also supports simulated discharge within the lacrimal passages and can be disassembled and washed for repeated use [23].
- iii. This trainer is mainly marketed as a procedural training device. Its published specifications do not provide tissue mechanical properties or insertion-depth measurement accuracy. [23].

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

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