TITLE: Visualization of the papilla through use of the NuView device in patients with FAP

Protocol Version Date: May 5, 2022

1. PURPOSE

The NuView device is a single-use distal endoscope attachment that is intended to facilitate direct visualization of the papilla with a forward viewing endoscope in order to eliminate the need for passage of the much bulkier, non-intuitive, risk prone side-viewing endoscope to visualize the papilla. In this early feasibility study, the NuView device will be used to atraumatically insert and navigate a conventional forward-viewing upper endoscope (gastroscope) from insertion at the mouth, through the esophagus, the stomach, and into duodenum to visualize the papilla in patients with familial adenomatous polyposis (FAP). FAP is a hereditary condition in which a person develops numerous precancerous polyps, called adenomas, within the small and large intestine. These patients also have a high prevalence of adenomas that develop on the duodenal papilla, which are particularly hard to visualize due to the curvature and geometry of the small intestine[1]. Currently, it is recommended that FAP patients undergo serial endoscopic exams to assess the colon for polyp formation every year and every 2-3 years to look for adenomas in the small intestine—specifically on the duodenal papilla. This requires two different specialized endoscopes to perform the upper endoscopic procedure. The first endoscope that the endoscopist uses is a forward facing gastroscope, with which they are able to visualize the stomach and portions of the duodenum. Due to the anatomic location of the papilla, the forward-viewing endoscope is not adequate for visualization of the papilla, and therefore the endoscopist must switch to a second specialized endoscope (called a duodenoscope) that allows for side viewing but lacks forward visualization. There are several well-known problems with duodenoscopes. First, they are notoriously difficult to sterilize and have been linked to alarmingly high infections rates that have in some cases resulted in patient deaths[2,3]. The FDA has even issued a call-to-action to medical device manufacturers to invent new disposable solutions to mitigate or eliminate this problem[4,5]. Secondly, side-viewing endoscope that are currently used are difficult to navigate because they lack forward viewing capabilities. The NuView device was designed to eliminate the need for a duodenoscope by enabling a forward facing gastroscope to also have some side-viewing capabilities. In this early feasibility study, the NuView device will be used with a forward facing gastroscope to enable FAP patients to undergo their routine screening endoscopic exam. We hypothesize that the minimally invasive endoscopic procedure may offer the following benefits: (1) reduced infection rates due to the elimination of the need for a specialized side-viewing duodenoscope, (2) shorter procedure time including shorter general anesthesia time by eliminating the need to switch endoscopes during the procedure, and (3) yield potentially less trauma to patient tissue due to the atraumatic features of the NuView (only needing to insert and remove one endoscope as compared to using two different endoscopes to complete the examination).

We propose an early feasibility study to determine if visualization of the papilla is possible using a forward facing gastroscope equipped with the NuView. The study will involve only otherwise healthy FAP patients between the age of 18 and 70 (see selection criteria for a full description).

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[1]J. R. Alexander, R. W. Burt, "High prevalence of adenomatous polyps of the duodenal papilla in familial adenomatous polyposis" Dig Dis Sci. 1989;34(2):167-170.

[2]R. M. Humphries and G. McDonnell, "Superbugs on duodenoscopes: The challenge of cleaning and disinfection of reusable devices," Journal of Clinical Microbiology, vol. 53, no. 10, pp. 3118, 2015.

[3]United States Senate Health, Education, Labor and Pensions Committee, "Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients," 2016.

[4]FDA, "FDA recommends health care facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection," 2019.

[5]FDA, "The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing

Instructions: FDA Safety Communication," 2019.

The clinical practice at Vanderbilt University Medical Center is to first perform the routine upper endoscopic exam with a forward-viewing gastroscope to evaluate the patient's esophagus, stomach, and duodenum. After this has been completed, the forward-viewing endoscope will be removed from the patient and outfitted with the EndoTheia NuView. The endoscope with NuView will then be inserted transorally down the esophagus, traverse the stomach, and be passed into the duodenum for visualization of the papilla. After the papilla is visualized, the endoscope with NuView will be removed from the patient. As per standard of care, the conventional side-viewing endoscope will then be inserted transorally down the esophagus, traverse the stomach, and be passed into the duodenum for visualization of the papilla. The side-viewing endoscope will then be removed from the patient.

We plan to enroll 3 FAP patients who are already scheduled to undergo their standard of care endoscopic exam. The primaryendpoint of the study is successful visualization of the papilla with the NuView platform.

2. DESCRIPTION OF DEVICE

The EndoTheia NuView is a distal endoscope attachment type device which is intended "*to be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following:*

- *Keeping the suitable depth of endoscope's view field*
- *Helping the endoscope with being inserted into the gastrointestinal tract"*

The EndoTheia *NuView* can be seen in Figure 1.

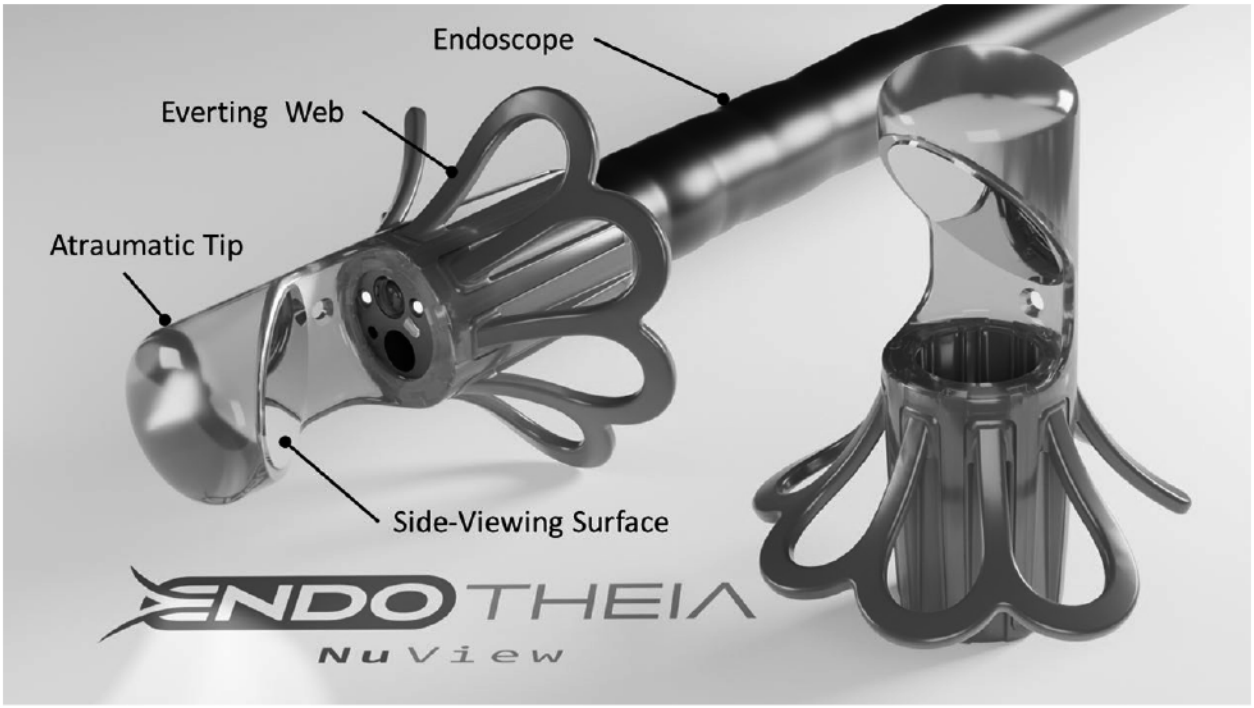

Figure 1. The NuView device is a distal endoscope attachment device which features (1) an atraumatic tip to help with insertion into the body, (2) a side-viewing surface which enables the physician with more lateral viewing capabilities, and (3) an everting web which interacts with patient tissue to help maintain the correct field of view and increase visualization.

Distal endoscope attachment devices are not new. There are many such devices currently on the market and in use within the clinical setting. Some similar distal endoscope attachment devices on the market are the Arc Endocuff (K151801) and the Reveal Distal Attachment Cap (K140315). These devices function similarly to the NuView device by attaching to the endoscope, maintaining the correct field of view, and helping with atraumatic insertion of the endoscope. The NuView device maintains attachment with the endoscope through a press-fitting attachment that is tight enough to maintain attachment but not tight enough to damage the endoscope in any way, similar to other FDA approved distal attachments. Similarly, the NuView device has an atraumatic insertion tip that is rounded and made from a biocompatible material, which is meant to facilitate atraumatic interaction with the patient's tissue and enable safe insertion of the endoscope into the patient. Another aspect of the NuView device is that it contains soft, flexible side projections to smooth out the mucosal folds inside the gastrointestinal (GI) tract (similar to other FDA approved distal endoscope attachment devices such as the EndoCuff Vision® (Olympus America, PA, USA) and the EndoRings™ (ENDO-AID inc., PA, USA), as well as a side-viewing reflective surface that will redirect a portion of the field of view of the endoscope. The soft projections are proximally-biased, allowing them to fold down onto the endoscope body during insertion, and evert upon retraction to expand and flatten mucosal folds, thereby providing an enhanced view of the lumen as viewed through the side-viewing reflective surface. These features are meant to help keep a suitable depth of the endoscope's view field and to give the surgeon an excellent view of the mucosal lining to visualize tissue to the side of the endoscope, in addition to preserving a portion of the normal forward-facing field of view capabilities. The shape of the NuView device, the flexible side projections, and the side viewing reflective surface will aid in keeping the suitable depth of endoscope's field of view and increase the surgeon's ability to visualize desired tissue targets by smoothing mucosal folds and preventing tissue from collapsing around the endoscope.

The devices used in this study are the following:

I. Olympus Gastroscope GIF-H190 which is FDA cleared for endoscopy and endoscopic surgery within the upper digestive tract.

II. NuView consisting of a soft distal endoscope attachment device (investigational device).

III. Olympus Duodenoscope TJF-Q180V which is FDA cleared for endoscopy and endoscopic surgery within the duodenum.

Table 1. Devices used in this study

Product	Model	FDA Information	Availability
Olympus Gastrointestinal Videoscope	GIF-H190	K112680	FDA cleared and commercially available
NuView Device	Not available	Investigational	Not commercially available
Olympus Video Duodenoscope	TJF-Q180V	K143153	FDA cleared and commercially available

3. PROTOCOL

3.1.1 Synopsis

Investigational Device: NuView

Study Title: Visualization of the papilla through use of the NuView device in FAP patients.

Study Design: Early Feasibility Study

Number of Participants: 3

Study Population: Adult FAP patients who are already scheduled for their standard of care upper endoscopic FAP screening examination.

Study Duration: Upper endoscopic examinations for FAP are relatively short duration out-patient procedures lasting 20-30 minutes in duration. As is standard of care at VUMC, a post-procedure follow-up phone call is then conducted 3-5 days post-procedure.

Schedule: (1) Screening of patients for meeting inclusion criteria; (2) Routine upper endoscopic examination with forward-viewing endoscope; (3) Passage of the forward-viewing endoscope with NuView; (4) Passage of the conventional side-viewing endoscope; (5) Follow-up phone call 3-5 days post examination as per VUMC standard practice for patients who have undergone endoscopy.

3.1.2 Study Objective

The objective of this early feasibility study is to determine if visualization of the papilla is possible using a forward-facing endoscope outfitted with the NuView device.

3.1.3 Study Design

3.1.3.1 Overview

This early feasibility study will be a prospective clinical trial in which 3 patients will be enrolled. All patients will undergo their routine yearly upper endoscopic examination using the conventional forward-viewing gastroscope, side-viewing gastroscope, and forward-viewing gastroscope equipped with the NuView platform.

3.1.3.2 Study Endpoints

PRIMARY

The primary study endpoint will be successful visualization of the papilla with a standard gastroscope equipped with the NuView platform.

SECONDARY

i. Time of procedure as recorded by research personnel
ii. Ease of use of the device as recorded by the endoscopist via the completion of a NASA task load index questionnaire post-procedure

3.1.4 Study Devices

The NuView is an investigational distal endoscope attachment type device that consists of soft, flexible, and biocompatible 3D printed material, an embedded optical mirror, and biocompatible adhesive. All materials used in the NuView have both been confirmed to be biocompatible and have been shown to withstand autoclave sterilization well. For all biocompatibility and sterility verification testing information please refer to Appendix B.

3.1.5 Participant Selection

3.1.5.1 Inclusion Criteria

1. Male or female, 18 to 70 years of age.
2. Able to provide written informed consent.
3. Have FAP

3.1.5.2 Exclusion Criteria

1. Females who are pregnant. As part of routine pre-operative care, all females of childbearing potential will undergo either urine or blood pregnancy testing.
2. Cancer positive subjects or any patients currently undergoing any treatment or therapy to treat, cure, or mitigate cancer.
3. Patients who do not meet inclusion criteria
4. Patients who are unable or unwilling to provide informed consent

3.1.6 Study Procedures

3.1.6.1 Screening

Potential subjects will be identified from the list of patients in the Vanderbilt University Medical Center Digestive Disease Center who are scheduled to undergo their endoscopic screening for FAP by members of the VUMC clinical research trained personnel team. Those participants who express interest in taking part in the research study will be asked to sign a written informed consent that has been approved by the Vanderbilt University Medical Center IRB. Participants will have the study explained to them and will be given the opportunity to read and review the consent document and have any questions addressed. Once informed consent is obtained, final eligibility for enrollment into the study will be determined basedon the inclusion/exclusion criteria.

Participants will undergo pre-operative and post-operative procedures as per routine standard of care for their VUMC endoscopic exam. We anticipateenrolling 3 patients to complete the study.

3.1.6.2 Day of Endoscopy

Once the patient has been successfully prepared for the endoscopic procedure and has been administered monitored anesthesia care (MAC) by the VUMC Anesthesia team as per routine care, the following steps will be followed.

Note: only step "b)" below deviates from the current standard clinical practice for upper endoscopic examination of FAP patients. Step "b)" is when the investigational Non-Significant Risk (NSR) device is used and the only step that is not usually performed during FAP endoscopic

examinations.

a) *Endoscopic assessment using a standard gastroscope.* This assessment is the first step in the routine FAP patient endoscopic examination. During this step, the endoscopist introduces a gastroscope into the patient to assess the esophagus, stomach, and duodenum for polyps. This will be performed per standard of care without deviation from standard of care procedure.

b) *Endoscopic visualization of the papilla using a gastroscope equipped with the NuView.* After the gastroscope assessment is complete and the gastroscope is removed from the patient, the NuView device will be attached to the gastroscope, introduced into the patient, and the papilla will be visualized. Steps in sequential order are:

1. The NuView device's sterile packaging will be inspected and confirmed intact
2. The NuView package will be opened
3. The NuView will then be pressed onto the distal end of the gastroscope using the press-fitting attachment feature and confirmed to be securely fastened
4. The gastroscope equipped with the NuView will be inserted into the patient
5. The gastroscope will be navigated to the duodenum and the papilla will be visualized using the NuView
6. The gastroscope equipped with a NuView will be removed from the patient.

c) *Duodenoscope visualization of the papilla as a secondary confirmation using another clinically accepted method.* Following papilla visualization using the NuView, the papilla will be visualized and inspected again using a duodenoscope. This will be performed in the standard method, using the standard protocol for FAP patients during their routine screening upper endoscopic examination. The endoscopist will insert a duodenoscope into the patient and navigate to the duodenum as is normal with routine endoscopic procedures for patients with FAP. Using this accepted clinical method, they will inspect the papilla to confirm what was visualized using the NuView device. This is a protection in line with what is outlined in 21 CFR 812, which states that any diagnostic NSR device should have a confirmation of diagnosis using a second clinically accepted method. Once the papilla has been visualized using the duodenoscope, the duodenoscope will be removed from the patient in the standard clinical method.

d) *Any adverse events occurring during the surgical procedure will be documented.* Any adverse events that occur during the procedure will be documented and reported in accordance with 21 CFR 812 and Vanderbilt's IRB protocols.

3.1.6.3 Post-operative visit/follow up

In line with standard clinical practice for patients who have received MAC at VUMC, the patient is observed for 30 mins during the immediate post-operative period and then released to a chaperone to leave the endoscopy unit. The patient then receives a post-operative phone call 3-5 days post procedure to inquire about status of the patient.

Primary Endpoint: Successful visualization of the papilla with a standard gastroscope equipped with NuView.

Secondary Endpoints:

i. Time of the procedure will be recorded.

ii. Endoscopist survey regarding ease of use and other specifics about the NuView (NASA Task Load Index)

3.1.6.4 Participant Termination/Withdrawal

Patients may be terminated from the study for the following reasons:

- A change in patient's health status that would preclude continuation in the study(e.g. cardiac event during surgical procedure). If this would occur, the patient will continue to be followed as per routine care.
- If the patient changes their mind and requests to be withdrawn from study should this occur, data will continue to be collected unless the patient requests in writing for data collection to cease.

3.1.7 Table of Procedures

Table 2. Study Procedures

	Screening	Endoscopic Examination	Follow up
Obtain Informed Consent	X		
Review Inclusion/Exclusion Criteria	X		
Review Medical History	X		
Routine Pregnancy Testing (urine or blood)		X[a]	
Gastroscope assessment of tissue		X	
Endoscopic Validation of target with the NuView		X[b]	
Endoscopic confirmation of target using a standard Duodenoscope		X	
Review Adverse Events		X	X
Endoscopic Post-Op NASA/Questionnaire			X[b]

(a) Performed pre-operatively for women of childbearing potential

(b) The Investigational Step in this study procedure. All other steps within the protocol will be performed per the standard of care

3.2 Data Analysis

In this early feasibility study, our primary endpoint is successful visualization of the papilla with a standard gastroscope equipped with the NuView. Procedure time will also be captured as a secondary endpoint.

We will stop enrolling patients in this study if:

1. We do not believe that additional patients should undergo the procedure becausethe risks of the procedure outweigh the potential benefits to participants

and/or

2. An unanticipated adverse effect would warrant that the study be stopped forassessment of the effect.

3.3 Quality Assurance

The conduction of this early feasibility study will be overseen by the PI. The PI will meet with the sub-investigators and research staff to assure protocol adherence and accuracy of data collection. Prior to study initiation, all study staff will be trained regarding the approved protocol. All data will be entered into a password protected computer database by qualified research staff. Any inconsistencies in the data will be reconciled and documented appropriately. As there will be only 3 subjects in this trial, all subject records will be reviewed by the PI.

3.4 Regulatory Considerations

3.4.1 Adverse Events/Effects

3.4.1.1 Definitions

Adverse event is defined as any undesirable experience associated with the use of the device under study that appears or worsens during the clinical study from the period commencing with the surgical procedure through the time the participant completes the study, and that may or may not be related to the investigational device or study related procedures.

A ***related adverse event*** is an event in which there is a reasonable possibility that the investigational device or study related procedures caused or contributed to the event.

An ***unanticipated adverse device effect*** is defined as any serious adverse event on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degreeof incidence in the investigational plan or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

A ***serious adverse event*** is defined as an adverse event whereby the patient outcome meets any of the following criteria:

a. Results in death
b. Is life-threatening (defined as an event in which the participant was at substantial risk of death at the time of the adverse event, or use or continued us of the device might have resulted in the death of the patient)
c. Requires inpatient hospitalization
d. Prolongs an existing hospitalization
e. Results in persistent or significant disability (substantial disruption of a person's ability to conduct normal life functions)
f. Results in a congenital anomaly or birth defect
g. Requires medical or surgical intervention to preclude permanent impairment of a body function or prevent permanent damage to a body structure.

h. The event does not fit above criteria (a) through (g), but may jeopardize the patient and may require medical or surgical intervention to prevent any of (a) through (g) above.

3.4.1.2 Adverse Event Collection and Reporting

The investigator and sub-investigators will assess on a routine basis if any adverse events occur during the endoscopic procedure through the time the participant completes the study. All adverse events/complications that occur during this time period whether device relatedor not will be reported and recorded.

Pre-existing conditions that are present at the time of enrollment into the clinical study will be considered concurrent medical conditions and will not be recorded as adverse events unless the subject experiences a worsening or complication of such a concurrent condition,in which case the adverse event will be recorded and evaluated by the investigator.

Patients will be closely monitored in a recovery room setting. All available clinical data, including exam findings, and clinical impressions, will be monitored. The investigator will evaluate any changes in physical status and will determine if the change is clinically important and different from what is anticipated in the course of treatment.

Any events determined by the PI to be unanticipated adverse device effects will be reported to the reviewing IRB and the study team as soon as possible but not more than 10 working days after the investigator first learns of the effect.

Any unanticipated adverse device effect will be immediately evaluated by the Sponsor-investigator. Should it be determined that the unanticipated adverse device effect presents an unreasonable risk to study subjects, the study or the part(s) of the study that presents that risk will be terminated as soon as possible but not later than 5 working days after the Sponsor-investigator first receives notice of the effect.

3.4.2 Protocol Deviations

Protocol deviations are defined as any incidents involving non-adherence to the protocol and may result from actions of the participant, investigator, or staff. Protocol deviations will be recorded and will be reported to the reviewing IRB per IRB policy. Protocol deviations intended to protect the life or physical well-being of a participant in anemergency situation and any incidence of failure to obtain informed consent must be reported to the reviewing IRB as soon as possible but no later than 5 working days after the emergency occurred. Except for such an emergent situation, changes that may affect the scientific soundness of the investigational plan or the rights, safety or welfare of studyparticipants, must be approved by the IRB prior to implementation.

3.4.3 Sponsor Responsibilities

The sponsor will select only qualified investigators to participate in the research study and will provide investigators with a study protocol and the information they need to properly conduct the study. The sponsor will also assure monitoring is conducted according to the monitoring plan. IRB approval of the study must be obtained prior to start of the study and this documentation will be kept on file. The sponsor will promptly notify the IRB of any significant new information about this investigation.

3.4.4 Investigator Responsibilities

Investigators are responsible for conducting the study in accordance with the signed Investigator's Letter of Agreement, the investigational plan, any IRB imposed conditions, and applicable FDA regulations for protecting the rights, safety, and welfare ofsubjects under the investigator's care, and for obtaining informed consent from each research participant prior to any study-related procedures. Investigators are also responsible for maintaining control of the investigational device.

This early feasibility study is being conducted at Vanderbilt University Medical Center, Nashville, TN, USA. Investigators may determine if potential subjects would be interested in taking part in the investigation prior to IRB approval, but written informed consent will not be obtained from study participants and study participation will not be allowed until IRB approval is received.

The investigational device will only be used on research subjects with the investigator's supervision and will not be used on any person who is not authorized under 21CFR812 to receive it.

Investigators will disclose accurate financial information to allow complete and accurate certification or disclosure statements that may be required. This information will be collected via FDA Forms 3454 and 3455, as appropriate, and will be updated promptly if any relevant changes occur during the course of the clinical study and for one year after the completion of this study.

3.4.5 Selection of Investigators

All clinical investigators taking part in this study are accomplished gastrointestinal endoscopists who commonly perform endoscopic procedures as part of their practice. All understand and will comply with their responsibilities regarding adherence to the approved protocol and the signed Investigator's Letter of Agreement. The research protocol will take place at Vanderbilt University Medical Centerwith the principal investigator (PI) being Dr. Keith L. Obstein. His *curriculum vitae*is included in Appendix C.

3.4.6 Informed Consent

Once a potential study subject has been identified, a member of the research team will present the research study to the subject in person, via phone, or via secure electronic transfer (e.g. secure email or My Health at Vanderbilt electronic portal). The potential participant will be provided with a copy of the consent form to read and will be provided with an opportunity to ask questions. Once the study participant's questions have been answered and prior to performing any study-related procedure, an IRB-approved consent form will be signed and dated by the study participant and by the person obtaining informed consent. A copy of the signed consent form will be provided to the subject and the informed consent process will be documented in the study participant's medical record.

3.5 References

Please see the footnotes throughout application.

4. RISK ANALYSIS

4.1 Description, Analysis, and Mitigation of Risks

There are inherent risks common to all endoscopic procedures. **These risks are not unique to this research** and are listed in the table below.

Table 3. Risk Analysis and Mitigation

Risks which are NOT UNIQUE to this research		
Potential Hazard	**Resultant Harm**	**Risk Analysis Discussion andMitigation Strategy**
Endoscopic procedure	*Risks include but are not limited to bleeding, infection, and/or need for additional surgery.*	*Standard of care for patients with FAP is to undergo a routine endoscopic examination of the mucosal lining to assess polyp formation every 1 year for colonoscopy and every 2-3 years for upper endoscopy. The surgical risks described are no greater for patients receiving the investigational procedure than for standard of care procedures for this population. Patients will be counseled about these risks.*
Monitored Anesthesia Care (MAC)	*Risks of anesthesia include butare not limited to stroke and death.*	*The risks described are no greater for patients receiving the investigational procedure than traditional examination. Patients will be counseled about these risks.*

There also risks which are unique to this research. These risks, along with designed and implemented risk controls are listed in the table below. An in-depth discussion of each of these unique risks and the implemented risk controls to mitigate these risks follows the table.

Table 4. Risk Analysis and Mitigations (unique to this research).

Risks which are UNIQUE to this research		
Potential Hazard	**Resultant Harm**	**Risk Analysis Discussion andMitigation Strategy**
Device Detachment from the endoscope while deployed in the patient	*Slight delay in patient care due to device retrieval*	*Distal endoscope attachment devices do have a small chance of device detachment from the endoscope. Our review of the MAUDE database for other distal endoscope attachment devices shows that even when the device does detach from the endoscope it does not cause harm to the patient (see MAUDE data in Appendix A). If the device does detach during use, the device is retrieved using endoscopic tools such as a Roth net or an alligator forceps as is standard practice for retrieval of foreign bodies in the gastrointestinal tract. Patients will be counseled about these risks. For more information regarding this risk please see a detailed discussion here.*
Non-biocompatible material used	*Allergic reaction*	*All materials and adhesives used in the device constructions are biocompatible. Please refer to Appendix B for biocompatibility information/testing certificates. We have*

in the device		*determined that because all materials used in the device are biocompatible and have been tested to the appropriate ISO 10993 standard that the risks associated with biocompatibility are acceptable and do not pose serious risk to the health, or welfare of the subject. Patients will be counseled about these risks. For more information regarding this risk please see a detailed discussion here.*
Non-sterile NuView device used	*Patient infection*	*Materials have been selected with the proposed sterilization process in mind. All materials used in the construction of the device hold up well to autoclave sterilization. The safety and verification data performed on the device as part of this application was performed post sterilization to give confidence that the device can be sterilized appropriately. Further, endoscopy within the GI is considered a clean-contaminated type procedure, meaning that while the device is packaged sterile, the environment itself is not sterile. Sterility will be maintained per the standard of care. Patients will be counseled about these risks. For more information regarding this risk please see a detailed discussion here.*
Device projections breakage	*Slight delay in patient care due to retrieval*	*We have examined the MAUDE database for device breakages for a similar type device and one of the most commonly seen device failures for this type of device is that of projection breakages (See MAUDE data in Appendix A). We have taken this into account during the design of the device and have created redundancy through the addition of a safety loop so that each projections needs at least two independent breakages for any one projection to break off from the device. Similarly, we have designed out the thin pin-joint failure zone which we believe contributes to the majority of the breakages for the Arc Endocuff device that our NuView device is designed after. Together, these activities have led us to determined that this risk has been mitigated to an acceptable level through the implemented risk controls and as such does not pose serious risk to the health, or welfare of the subject. Patients will be counseled about these risks. For more information regarding this risk please see a detailed discussion here.*
Irrigation and/or illumination blockages	*Slight delay in patient care*	*We have mitigated this risk through inherent design, having made the press fitting attachment feature such that it will only come into contact with the side profile of the endoscope and will stay securely in place without covering the front face of the endoscope where the suction and irrigation channels are located. Further we have incorporated a drainage hole located in the backbone of the device to aid in irrigation. We have also run verification tests to ensure that irrigation and/or illumination have been maintained. For more information regarding this risk please see a detailed discussion here.*
Traumatic features,	*Tissue trauma*	*We have designed the NuView using a soft, flexible, biocompatible material that should reduce tissue trauma. We*

sharp edges, Maximum insertion width		*have included an atraumatic insertion tip with an atraumatic profile featuring a smooth rounded dome. We have also rounded all exposed edges on the device in accordance with human factors HE-75 guidance to facilitate more atraumatic insertion and we have designed the device in accordance for maximum insertion width in accordance with the international endoscope standard ISO-8600. We have determined that while tissue trauma is an inherent risk to all distal endoscope attachment type devices such as the NuView, this risk has been mitigated to an acceptable level through the implemented risk controls and as such does not pose serious risk to the health, or welfare of the subject. Patients will be counseled about these risks. For more information regarding this risk please see a detailed discussion here.*

Device detachment risk mitigations:

Unintentional device detachment from the endoscope is currently the most probable risk for the NuView device. If an unintentional detachment happens before the device is inserted into the patient there is no risk to the patient or user. The user would simply need to open and attach a new NuView device and then insert the endoscope with attached NuView device normally. If the unintentional detachment happens after the endoscope has been inserted into the patient, the device will need to be retrieved before the procedure can continue. Based on our review of the MAUDE database for similar distal endoscope attachment type devices, unintentional device detachment within the patient is the most common adverse event reported for this type of device. While the most common, it does not appear to be a significant risk to the patient. Within our review of the MAUDE database, unintentional detachment within the patient was reported 24 times. None of these detachment events resulted in harm to the patient. Instead, they reported a slight delay to the procedures due to the devices needing to be retrieved by a minimally invasive method such as through the use of a Roth net (Figure 2) in line with ASGE foreign body removal guidelines here. For more details on the MAUDE database reports relating to device detachment for similar type devices to the NuView device (and how we used this information to drive appropriate risk controls during the design and development process) please refer to Appendix A.

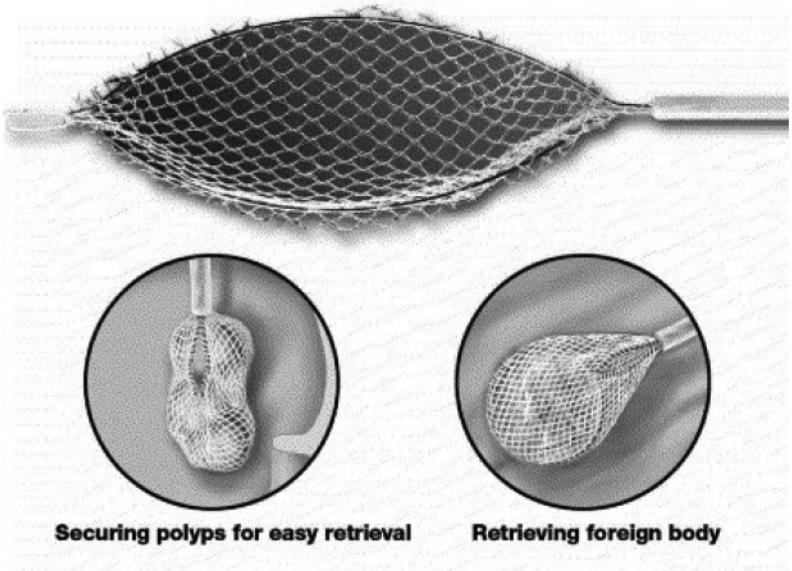

Figure 2. Roth net used for foreign body retrieval within the GI tract.

We have mitigated this risk of unintentional detachment in part by design changes to the NuView device's press fitting feature. We have undersized this press fitting to increase the force with which

it attaches to the endoscope. Currently the endoscope is 9.9 mm in diameter while the NuView press fitting an undersized 9.25 mm. The NuView can still fit on the endoscope easily even though it is undersized due to the biocompatible elastic material that it is constructed from. This material is ideal for the press fitting due to its high resilience, excellent stretch and compression properties, and tensile strength. For a full characterization of this material please refer Appendix B. These material properties allow the press fitting to tightly and securely fit onto the endoscope, while still being soft and flexible so as not to damage the endoscope itself. The material is also biocompatible and easily sterilized having been tested to the international ISO-10993 biocompatibility standard and shown to maintain material properties robustness after common sterilization methods such as autoclave sterilization, gamma sterilization, e-beam sterilization, and Ethylene Oxide (EtO) Sterilization (refer to Appendix B for biocompatibility and sterilization data/reports).

The NuView has also undergone bench and usability testing to aimed at assessing and ensuring that the NuView maintains attachment to the endoscope. The following is a brief summary of the internal bench and user testing completed to verify that the NuView will maintain attachment to the endoscope.

a. *Strength of attachment assessment:*
We have characterized the force required to remove the NuView from the endoscope. The detachment force was measured by properly affixing the NuView device to the endoscope tip and mounting the endoscope to the 3D printed detachment force jig. The test setup for this experiment can be seen in the figure below.

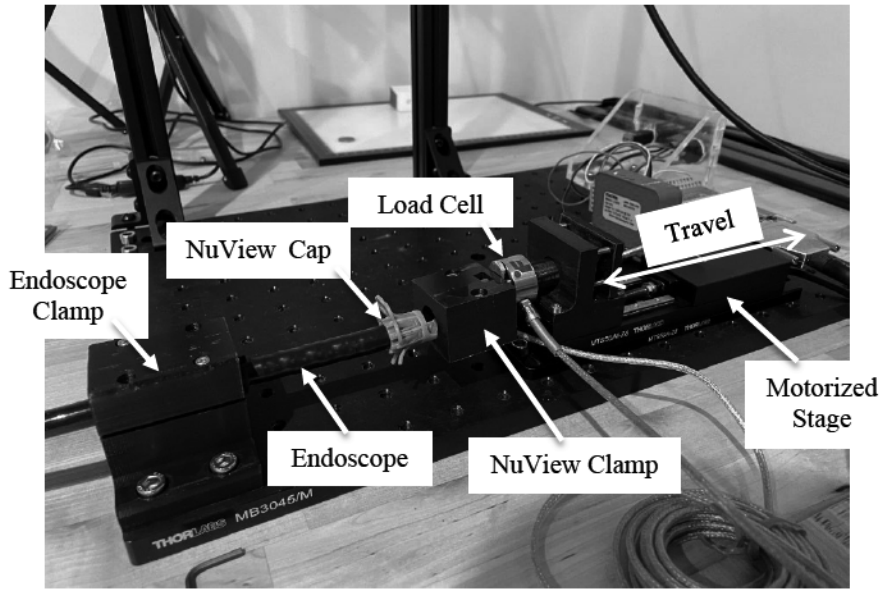

Figure 3. Experimental setup for accessing forces required to detach the NuView device from the endoscope.

The NuView was mounted into a clamp and a load cell was attached to the clamp on one side and a motor on the other side. The motor was programmed to retract until the NuView became fully detached from the endoscope and the detachment force was recorded. To ensure endoscope attachment robustness eight different NuView devices were attached/detached from the endoscope tip at least 15 times each. Through these tests, it was found that an average detachment force of 9.64 N across all experiments and minimum detachment force of 7.92 N was required to fully detach the NuView from the gastroscope.

This removal force greatly exceeds the expected forces on the NuView when deployed in the patient giving confidence that the device will not unintentionally detach during the procedure. No systemic device failures or breakages were observed in these experiments. The only nonperformance observed in these experiments was that one of the press-fit collars for a single device started to show adhesive failure on the 15th time of being reattached and unattached from the endoscope. We believe this was in part due to the experimental setup, where higher and repeated stress was placed on this seam than would be seen in clinical use where the physician would attach the device once and then remove the device once at the end of the procedure. In total, of the 120 attachment/detachments performed only one single device showed a single adhesive issue on the last of the 15 attachment/detachment runs. Of all the other devices tested, no failure was detected; this enforces the assumption that this failure was a one-off test setup or manufacturing failure. During an actual procedure, we expect the NuView to be attached once at the beginning of the procedure and then detached from the endoscope once upon completion of the procedure. This data gives confidence that the endoscope attachment press fitting is more than sufficiently robust.

Table 5. Summary of the forces required to detach the NuView from the endoscope

Device	Average Force [N]	Min Force [N]	Max Force [N]
1	*9.46*	*8.72*	*10.23*
2	*9.50*	*9.00*	*10.40*
3	*8.22*	*7.92*	*8.65*
4	*10.19*	*9.30*	*11.91*
5	*10.10*	*9.56*	*11.65*
6	*9.96*	*8.95*	*10.64*
7	*9.54*	*8.69*	*10.20*
8	*10.09*	*9.58*	*10.79*
Overall average:	***9.64***	***8.97***	***10.56***

b. *Comparing detachment forces to an FDA approved distal endoscope attachment device:* We have compared the force required to remove the NuView from the Endoscope to an FDA approved distal endoscope attachment device similar to the NuView, called the Arc Endocuff. This is to ensure that the NuView device is at least as safe from detachment events as the Arc Endocuff. The detachment force was measured by attaching the Arc Endocuff to an endoscope and pulling it off the endoscope using a calibrated force gauge similar to how the NuView detachment forces were characterized. Through these tests, it was found that an average detachment force of **8.9 N** and minimum force of **6.4 N** is required to fully detach the Arc Endocuff from the endoscope. A summary of the forces required to remove the Arc Endocuff from the endoscope can be seen in the table below.

Table 6. Summary of the force required to detach the Arc Endocuff (FDA approved device)

Device	Average Force [N]	Min Force [N]	Max Force [N]
1	*11.36*	*9.60*	*14.60*
2	*7.14*	*6.40*	*8.40*
3	*8.88*	*7.80*	*11.20*
4	*8.16*	*7.00*	*9.00*

Overall average:	***8.9***	***7.7***	***10.8***

This experiment demonstrates that the minimum NuView detachment force exceeds the minimum average force of the Endocuff, indicating that the NuView is less likely to detach from the endoscope when compared to a very similar FDA approved device.

c. *Assessing clinically relevant forces placed on the NuView in a porcine colon model:* The final test to ensure that the NuView's attachment to the endoscope is sufficiently robust was performed using a porcine colon simulated use experiment. This experiment measured the clinically relevant forces the device would experience during insertion and removal from the colon. We attached the NuView to an endoscope and then continuously measured the forces that the device faced during insertion and removal from the porcine colon by using a load cell connected to the gastroscope during insertion and removal into the porcine colon. This experiment was repeated 10 times. Through this experiment, we measured a retraction force 2.5 N +/- 1 N. This retraction force during use is substantially less than the minimum NuView detachment force (7.92 N) measured in Test 1, meaning the NuView is not likely to detach from the endoscope through the course of a normal procedure.

Risk summary: We have determined that while detachment is an inherent risk to all distal endoscope attachment type devices such as the NuView, this risk has been mitigated to an acceptable level through the implemented risk controls and as such does not pose serious risk to the health, or welfare of the subject.

Non-biocompatibility risk mitigations:
All materials used in the NuView are biocompatible. The risks surrounding biocompatibility for medical devices are well understood and the FDA has excellent biocompatibility guidance documents. Similarly, there are recognized international standards surrounding biocompatibility such as ISO 10993-1.

We have taken the risk of biocompatibility into account in the development of the NuView device. The device is made from 100% biocompatible materials for piece of the device. Below is a list of all materials used in the device, including any adhesives, 3D resins, or other materials

Carbon Inc.'s Sil 30 printable resin: The press-fit collar will be made from Carbon Inc.'s SIL 30 material which is a soft, biocompatible, silicone urethane elastomer that has undergone ISO-10993 testing for skin and mucosal membrane contact. The press-fit collar will be made from this soft, elastic, silicone urethane elastomer in order to safely interact with tissue during FAP. This soft silicone urethane elastomer (SIL 30) has undergone rigorous biocompatibility/sterility testing which makes it ideal for short term mucosal membrane contact (up to 24h in duration). See Appendix B for additional details relating to biocompatibility and sterility.

Formlabs's Medical Grade Tough 1500 Resin: Tough 1500 material has been tested to ISO-10993 biocompatibility standard (see Appendix B). This material currently makes up the NuView's body and backbone. It is an excellent material for the this because of it's stiff, yet pliable nature being able to bend and spring back quickly to its original shape. Similarly, this material is compatible with a wide range of common sterilization processes for medical devices. For more information on this material, including biocompatibility and sterility information please refer to Appendix B.

Mirror: The mirror is made from 1 mm-thick mirrored glass. This component will be custom-

manufactured by Knight Optical using a scribing process. Upon delivery to EndoTheia, the mirror will be cleaned using 99% isopropyl alcohol prior to assembly.

Adhesive info: Loctite 435 humidity-cured ethyl-based adhesive from Henkel has been tested to ISO-10993 biocompability standard (see Appendix B). This adhesive is used to fasten the press-fitting feature with projections and the mirror to the structural body of the NuView. Similarly, this adhesive is compatible with a wide range of common sterilization processes for medical devices, such as cold sterilants, ethylene oxide, and gamma radiation. For more information on this material, including biocompatibility and sterility information please refer to Appendix B.

Risk summary: We have determined that because all materials used in the construction and all adhesives used during device assembly are biocompatible and have been tested to the appropriate ISO 10993 standard that the risks associated with biocompatibility are acceptable and do not pose serious risk to the health, or welfare of the subject.

Sterility risk mitigations:
Sterilization risks are inherent to all medical devices. Both the risks associated with infection when devices are not sterilized and the risks associated with material property degradation if an inappropriate sterilization method is chosen for a given material. We have taken both of these potential risk categories into account during the development of the NuView device.

We have included information in Appendix B with regards to sterility showing how an independent sterility testing house (STERIS) has verified that autoclave is an appropriate method of sterilization of both of the Formlabs's resins we've used in the construction of the device. Similarly, the medical grade adhesive we've used during the assembly process has shown to be resilient up to temperatures much higher than those seen in the autoclaving process appropriate for the NuView (Appendix B for data on adhesive). We have also verified that this adhesive maintains its properties and functional strength sufficient post sterilization. All materials used in the construction and assembly are appropriate materials for our selected sterilization process of autoclaving and all of the materials show resilience to the autoclaving sterilization process. Please refer to Appendix B to see the resilience of selected material and the appropriateness of the autoclaving sterilization process.

Risk summary: We have determined that the risks associated with sterility and the sterilization process are currently acceptable and do not pose serious risk to the health, or welfare of the subject.

Device breakage & failure risk mitigations:
Another risk inherent to medical devices is the risk of device breakages or failures. Indeed, a large part of the development process is aimed at identifying and mitigating potential device breakages and failure points. Large efforts are made to identify these possible breakages through a systematic process such as Failure Modes & Effects Analysis (FMEA) and Fault Tree Analysis (FTA). As part of our development process, we employ both of these methods for identifying potential device failures and breakages. Another way device developers try to identify potential failure modes or likely breakages is to research what the failures and breakages are reported in the FDA's MAUDE database for other similar type devices. We have reviewed this MAUDE database data for device

breakages and failures for devices similar to the NuView (refer to Appendix A) and then taken this information into account during design to create risk controls to prevent similar type of failures/breakages from happening during use of the NuView device.

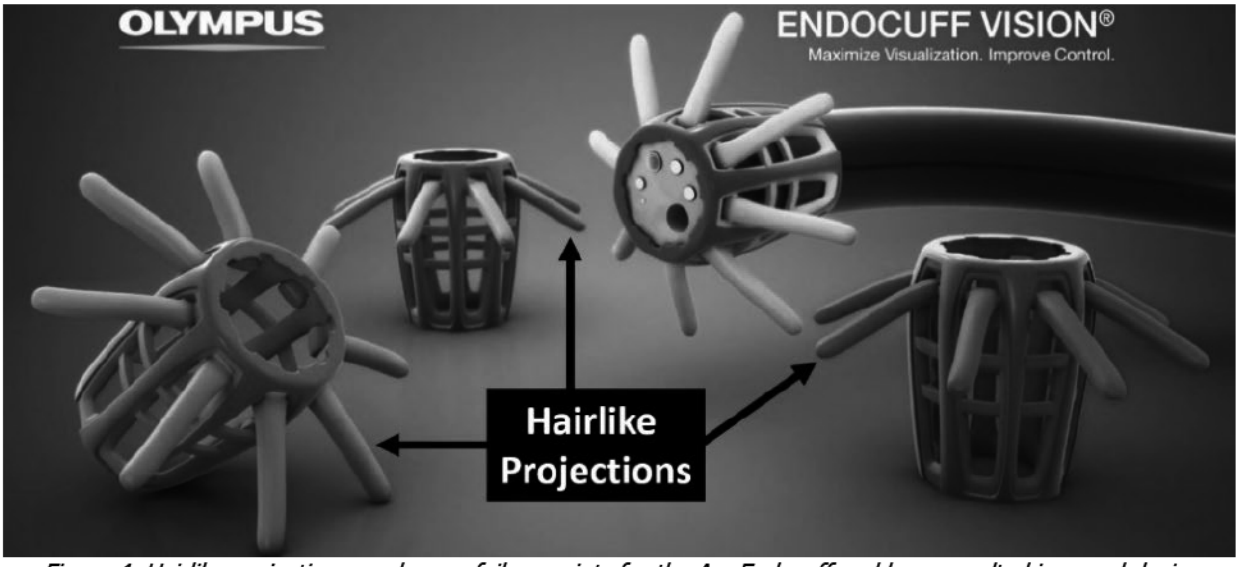

Figure 4. Hairlike projections are known failure points for the Arc Endocuff and have resulted in sevral device breakages during use in human patients.

One of the most commonly seen device breakages reported in the MAUDE database for distal endoscope attachment type devices is that of projection breakages. These endcaps have hairlike projections that are meant to smooth out the mucosal folds and increase endoscope visualization. These hairlike projections can be seen in the figure below. These projections are intended to fold back during endoscope insertion and then to fan outwards and interact with the mucosal tissue as you gently pull the endoscope backwards. During this interaction with the mucosal lining, they both smooth the folded tissue and also keep the tissue slightly away from the endoscope's tip so that the tissue is at the proper viewing distance from the endoscope optic or viewing lens. These hairlike projections are also prone to breaking off from the device due to their slim profile and pinpoint connections to the body of the device. For example, there were several different reports of this type of device breakage reported in the MAUDE database for the arc Endocuff device (K151801). The below table lists a few examples reports for hairlike projection breakages for the Arc Endocuff and there are links within the table to the full reports.

Table VII. MAUDE Data (from the FDA database)

MAUDE DATA: Example reports for hairlike projection breakages				
Device	**Date**	**Problem**	**Description**	**Harm**
K151801	**12/09/2015**	Detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	**7/23/2015**	Break; detachment of device component	Device detaches from the endoscope	**No harm to the patient**

Figure 5. Risk control features implemented in the NuView device based on known failures of similar type devices as reported in the FDA's MAUDE database.

We have taken this MUADE breakage data into account during the design and development of the NuView device by creating a risk control that ensures redundancy through the design of the projections themselves. This risk control is an added safety loop (seen in the picture below) connecting each hairlike projection so that each individual hair is no longer able to detach through a single breakage. Instead, now there needs to be at least two breakages for any one project to break off from the device and in some cases two breakages will still not be sufficient to dislodge a projection. Similarly, another risk control was to design out the thin pin-joint failure zone which we believe contributed to several of the breakages of the Arc Endocuff device and instead us a more robust and larger joint of molded flexible material.

We have also conducted verification tests related to the forces required to break these arm-like projections to gain confidence in the device's robustness. The following give examples of how strong these arm-like projections are and then we compare this strength to another FDA approved device to gain confidence that the NuView device is sufficient at resisting this type of device breakage.

a. ***Strength of Visual Enhancement web attachment:***

We have characterized the force required to detach the NuView arm-like projections (called the Visual Enhancement web). The detachment force was measured by properly affixing the NuView device to a small clamp mounted to the bottom of a force gauge and grabbing individual web projections using another clamp attached to the lever arm of the calibrated force gauge. The test setup for this experiment can be seen in the figure below.

The safety loop on the NuView device were cut to allow for the measurement of the individual web detachment forces. The top clamp was opened and the first projection was inserted and the clamp was shut. The lever was lowered and the NuView device itself was attached to the mounted clamp on the bottom of the force gauge. The force on the force gauge was set to peak tension and zeroed. The clamp was slowly pulled upwards until the

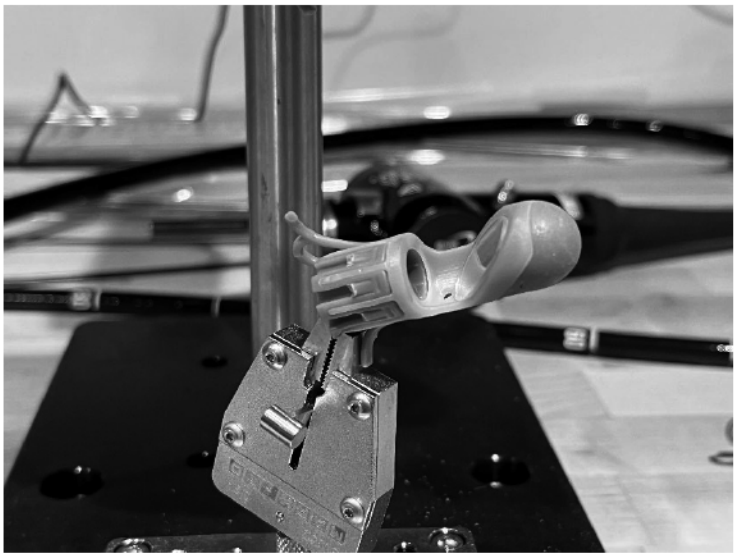

Figure 6: Experimental setup for the removal of the NuView Visual Enhancement web

projection became fully detached. That detachment force was recorded and the entire test setup was repeated for all eight NuView projections. Through these tests it was found that an average detachment force of **8.3 N** and minimum detachment force of **6.6 N** was required to fully detach the visual enhancement webs.

This detachment force greatly exceeds the expected forces on the NuView when deployed in the patient, giving confidence that the device will not unintentionally lose any web projections during the procedure. Additionally, 5 of the projections are equipped with a safety loop, increasing the force needed to fully detach those sections during a procedure. No device failures or breakages were observed in these experiments. During an actual procedure, we do not expect the webbed portions of the visual enhancement web to become detached from each other. This data gives confidence that the endoscope attachment press fitting is more than sufficiently robust.

Table 8. Summary of the forces required to detach the NuView Visual Enhancement web

Device	Average Force [N]	Min Force [N]	Max Force [N]
1	*8.6*	*6.6*	*11.0*
2	*8.0*	*7.6*	*8.4*
3	*8.8*	*8.4*	*9.0*
4	*7.8*	*7.4*	*8.0*
Overall average:	***8.3***	***6.6***	***8.0***

b. ***Comparing Visual Enhancement web detachment forces to an FDA approved device:***
We have compared the force required to detach the Visual Enhancement Web from the NuView to an FDA approved distal endoscope attachment device similar to the NuView, called the Arc Endocuff. This is to ensure that the Visual Enhancement web is at least as safe from detachment events as the ones present on the Arc Endocuff. The detachment force was measured by attaching the Arc Endocuff to a clamp and pulling the projections off individually using a calibrated force gauge similar to how the NuView detachment forces were characterized. Through these tests, it was found that an average detachment

force of 8.5 N and minimum force of 6.20 N is required to fully detach the Arc Endocuff from the endoscope. A summary of the forces required to remove the Arc Endocuff from the endoscope can be seen in Table IX.

Table 9. Summary of the forces required to detach the Arc Endocuff Visual Enhancement web

Device	Average Force [N]	Min Force [N]	Max Force [N]
1	*7.8*	*6.2*	*9.0*
2	*8.9*	*7.4*	*11.0*
3	*8.4*	*7.2*	*11.0*
4	*8.9*	*7.8*	*11.4*
5	*8.7*	*7.4*	*11.0*
Overall average:	***8.5***	***6.2***	***11.0***

Each of the arm like projections that make up the NuView's enhancement web appear to be as robust as each of the arm-like projections of the FDA approved comparison device. The NuView has also included a safety loop that adds redundance into these arm-like projections which means that no single failure can cause the projection to tear off. The FDA comparison device does not have this redundancy and yet is still considered safe.

Risk Summary: Based on our review of the MAUDE database for device breakages and failures of similar type device to the NuView and our proposed risk controls to mitigate these known breakages, as well as our verification testing to ensure the NuView's robustness, we have determined that the risks associated with device failures and breakages are currently acceptable and do not pose serious risk to the health, or welfare of the subject.

Blocking irrigation/illumination risk mitigations:

With any distal endoscope attachment type device there is a risk of blocking functionality of the endoscope if the device is poorly designed. For instance, it would be easy to cover the front face of the endoscope and block the irrigation or suction channel if the device was designed in such a way that its mechanical press fitting covered the front surface of the endoscope or had some other feature which blocked the suction or irrigation channel. We have taken this risk into account during the design of the NuView and the following are risk controls which will prevent our device from blocking functionality of the endoscope:

1. The press fitting attachment feature was design such that it will only come into contact with the side profile of the endoscope and will stay securely in place without covering the front face of the endoscope where the suction, insufflation and irrigation channels are located. We have confirmed that suction, insufflation and irrigation work normally while the NuView is attached to the endoscope.
2. The endcap design offsets the mirror from the front face of the endoscope by >5mm, leaving sufficient space for suction, insufflation, and irrigation to enter the surgical field. Further, a minimal lip is designed into the endcap that extends no more than 1mm into the front face of the endoscope, leaving the objective lens, illumination, working channels, auxiliary water port, and lens cleaning port unobstructed. We have confirmed that suction, insufflation and irrigation work normally while the NuView is attached to the endoscope.
3. We have incorporated a 1.75 mm drainage hole into the device design located on the structural backbone of the NuView to enable fluid draining. In addition, the space opposite

the NuView mirror is left fully open as shown in Figure 1 promoting further drainage.

Risk Summary: We have determined that the risks associated with irrigation/suction have been mitigated to an acceptable level through the implemented risk controls and as such does not pose serious risk to the health, or welfare of the subject.

Tissue trauma risk mitigations:

Tissue trauma is inherent to all endoscopic procedures. Specific to the NuView device, the most likely risks of tissue trauma are during insertion and removal of the endoscope. We have taken this risk into account when designing the NuView device and have added risk control features to minimize the likelihood of this risk. The following are risk control measures were added to reduce the risk of trauma to tissue to an acceptable level:

a. We have designed the NuView using a rounded biocompatible material that is equal to or lower durometer than the front face of the most endoscopes and this should reduce the potential for trauma to the patient tissue
b. We have included an atraumatic insertion tip that is designed for easy insertion and is made from a smooth, non-abrasive material to reduce forces placed on tissue during insertion and navigation.
c. We have rounded all exposed edges during in accordance with HE75 human factors standard to facilitate less trauma and give confidence that the device is atraumatic on insertion and navigation.
d. We have also tested the NuView in a porcine colon model, where we intentionally inserted and removed 2 of the devices 5x times each and then performed a visual inspection and a submersion test to inspect the colon for any sustained trauma or perforation. There was no observable tissue damage in any of these experiments.
e. We have accounted for maximum insertion width in accordance with the international endoscope standard ISO 8600 for maximal allowable insertion width. Similarly, the maximum rigid width of the endoscope and the NuView as measured while the NuView is attached is 16 mm, which is less than other approved endoscopes currently on the market which are considered safe to insert into the patient.

Risk Summary: We have determined that while tissue trauma is an inherent risk to all distal endoscope attachment type devices such as the NuView, this risk has been mitigated to an acceptable level through the implemented risk controls and as such does not pose serious risk to the health, or welfare of the subject.

4.2 Justification for Investigation

The goal of this early feasibility study is to demonstrate that the papilla can be visualized using a forward facing gastroscope equipped with the NuView, enabling FAP patients to undergo their yearly routine endoscopic exam without the use of a duodenoscope. We hypothesize that the minimally invasive endoscopic procedure may offer the following benefits: (1) reduced infection rates due to the elimination of the need for a duodenoscope, (2) shorter procedure time including shorter general anesthesia time due to not needing to switch scopes mid procedure and reducing the total number of scopes used in the procedure, and (3) potentially less trauma to patient tissue due to the atraumatic features of the NuView and due to only needing to insert and remove one endoscope compared to two different insertions with two different scopes. This early feasibility

study will focus on the advantages of the new technology to the patient. Advantages to the healthcare system will be examined during future studies.

4.3 Description of Patient Population

The patient population for this study are familial adenomatous polyposis (FAP) patients. FAP is caused by pathogenic germline variants in the APC tumor-suppressor gene and is considered a hereditary cancer syndrome. Individuals with FAP develop hundreds to thousands of colorectal adenomas, which usually arise during adolescence or early adulthood. Once the diagnosis of FAP is made, most of the attention tends to focus on management of polyps within the colon and upper GI tract. Data from historical FAP cohorts estimated the lifetime risk of intestinal cancer to be 90% to 100% for affected individuals and advances in early detection and prophylactic surgery are currently the definitive therapy for preventing cancer formation in FAP patients.

Duodenal and ampullary cancers are a leading cause of cancer death for individuals with FAP[6]. The cumulative risk of upper GI cancers is correlated with the number, size, and histology of duodenal polyps (assessed by Spigelman et al[7] stages 0–IV). Management guidelines for FAP issued by gastroenterology and surgical professional societies stress the importance of lifelong careful surveillance of the stomach, duodenum, and papilla[8, 9, 10, 11]

In this early feasibility study 3 adult subjects, 18 to 70 years of age, will be studied. Subjects will be recruited from the Gastroenterology clinic at Vanderbilt University Medical Center and must qualify endoscopic examination of the papilla. Men and women of any ethnicity, race or socioeconomic status with FAP who meet inclusion criteria will be offered enrollment into the study. Subjects will be screened to ensure that they do not haveany underlying comorbidities or other considerations that would preclude the use of the investigational device.

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[6] *Vasen, H. F., ... & Wijnen, J. (2008). Guidelines for the clinical management of familial adenomatous polyposis (FAP). Gut, 57(5), 704-713.*

[7] *Groves, C. J., ... & Phillips, R. K. S. (2002). Duodenal cancer in patients with familial adenomatous polyposis (FAP): results of a 10 year prospective study. Gut, 50(5), 636-641.*

[8] *Yang, J., ... & Samadder, N. J. (2020). American Society for Gastrointestinal Endoscopy guideline on the role of endoscopy in familial adenomatous polyposis syndromes. Gastrointestinal endoscopy, 91(5), 963-982.*

[9] *Syngal, S., ... & Burt, R. W. (2015). ACG clinical guideline: genetic testing and management of hereditary gastrointestinal cancer syndromes. The American journal of gastroenterology, 110(2), 223.*

[10] *Monahan, K. J., ... & Hill, J. (2020). Guidelines for the management of hereditary colorectal cancer from the British Society of Gastroenterology (BSG)/Association of Coloproctology of Great Britain and Ireland (ACPGBI)/United Kingdom Cancer genetics group (UKCGG). Gut, 69(3), 411-444.*

[11] *van Leerdam, M. E., ... & Ricciardiello, L. (2019). Endoscopic management of polyposis syndromes: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy, 51(09), 877-89*

5. DESCRIPTION OF THE PROCEDURE

An overview of the procedure can be seen in below.

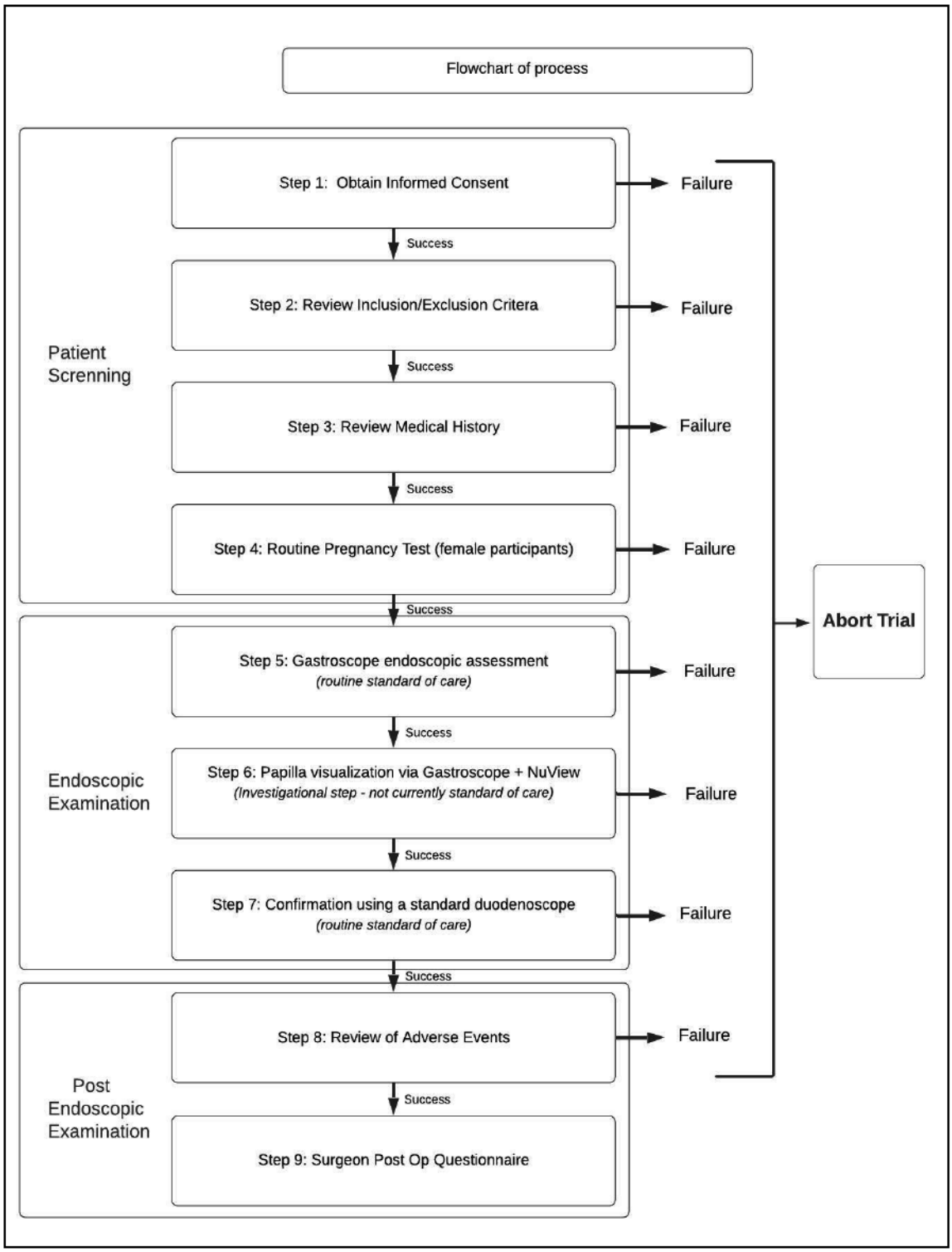

Figure 7. Study overview showing the proposed flow of the experiment. Note that step 6 is the only investigational step within this study. All other steps (with the exclusion of the post-op surgeon NASA index / questionnaire) are currently the standard of care for FAP patients undergoing routine endoscopic

As detailed below and in Figure 6, the components in Table I are used perform the yearly routine endoscopic examination of FAP patients. The only investigational step is when the NuView device is attached on the endoscope and used to visualize the papilla. There is no therapy delivered during this procedure and the only primary endpoint in this feasibility study is to successfully visualize the papilla using the NuView.

5.1 STEP 1: Obtain Patient Consent. The potential participant will be provided with a copy of the consent form to read and will be provided with an opportunity to ask questions. Once the study participant's questions have been answered and prior to performing any study-related procedure, an IRB-approved consent form will be signed and dated by the study participant and by the person obtaining informed consent. A copy of the signed consent form will be provided to the subject and the informed consent process will be documented in the study participant's medical record.

5.2 STEP 2: Review Inclusion/Exclusion Criteria. Prior to the study, when a potential candidate is identified, a review of the inclusion/exclusion criteria will be performed. Namely, the patient must be: (1) between the ages of 18 to 70 years old, and (2) must be able to provide written informed consent. Similarly, the candidate must not be: (1) currently pregnant, and (2) cannot be currently diagnosed or being treated for cancer.

5.3 STEP 3: Review Medical History. In line with standard clinical practice, the patient's medical history will be reviewed before the procedure to ensure the candidate does not have any items that would preclude them from being a good candidate for the procedure.

5.4 STEP 4: Routine Pregnancy Test (female participants). Any identified candidate that is female will have a routine pregnancy test prior to the procedure as part of the inclusion/exclusion criteria. Those participants who are confirmed to be pregnant will be excluded from the study.

5.5 STEP 5: Gastroscope endoscopic assessment. Using a standard gastroscope, the Olympus GIF-H190, the surgeon will introduce the scope into the patient to assess the esophagus, stomach, and duodenum for polyps. This will be performed per the standard of care without deviation from the current clinical practice during the yearly routine endoscopic examinations for FAP patients.

5.6 STEP 6: Endoscopic visualization of the papilla using the NuView *(investigational step).* Once the surgeon has completed the initial assessment using a gastroscope the NuView device will be attached to the gastroscope and introduced into the patient. The device will be navigated to the duodenum and the papilla will be visualized. Exact sequential protocol for this step is as follows:

a. The NuView's sterile packaging will be inspected and confirmed intact.

b. The NuView's packaging will be opened.

c. The NuView will be attached to the gastroscope and the fitting and attachment will be confirmed to be secure.

d. The gastroscope equipped with the NuView will be inserted into the patient in the standard endoscopic fashion.

e. The gastroscope will be navigated to the duodenum and the papilla will be visualized using the NuView.

f. The gastroscope and device will be removed from the patient.

This is the investigational step of the protocol. All subsequent steps will be performed per the standard of care as they are usually performed for routine endoscopic FAP examinations.

5.7 STEP 7: Confirmation using a standard duodenoscope. The surgeon will then confirm papilla visualization using a secondary method which is clinically accepted. This will be achieved by inserting a standard duodenoscope, the Olympus TJF-Q180V, to visualize the papilla. This will ensure that anything not visualized with the NuView will be seen using a standard clinically accepted method. Further anything that was visualized by the NuView will again be visualized using a second clinically-accepted standard method. The insertion and assessment with the Duodenoscope will be performed per the standard of care, using the standard protocol for FAP patients during routine yearly endoscopic examinations. The surgeon will insert a duodenoscope into the patient and navigate to the duodenum. The papilla will be inspected to confirm what was visualized using the NuView device. This is a protection in line with what is outlined in 21 CFR 812, which states that any diagnostic NSR device must have a confirmation of diagnosis using a second clinically accepted method. Once the papilla has been visualized using the duodenoscope, the scope will be removed from the patient in the standard clinical method.

5.8 STEP 8: Review of adverse events. In line with standard clinical practice, patients will be closely monitored during the procedure and in a recovery-room setting following the procedure. All available clinical data, including exam findings, and clinical impressions, will be monitored. The investigator will evaluate any changes in physical status and will determine if the change is clinically important and different from what is anticipated in the course of treatment. Similarly, the investigator and sub-investigators will assess on a routine basis if any adverse events occur during the study at any point. All adverse events/complications that occur during the study whether device related or not will be reported and recorded.

5.9 STEP 9: Post-endoscopy surgeon NASA index / questionnaire. Following the procedure, a short NASA task load index / questionnaire will be given to the surgeon to explore various items of interest related to the useability of the device such as mental demand, physical demand, effort, frustration, etc. (Appendix D)

6. MONITORING PROCEDURES

As the Principal Investigator (PI) of this early feasibility study, Dr. Keith Obstein will be responsible for overseeing the safety of this trial on a daily basis. Clinical data will be reviewed daily for adverse events. In addition, Dr. Obstein is available to the sub-investigators, research staff, and bedside nurses, who will be monitoring participants for adverse events. All unanticipated adverse device effects will be promptly evaluated and reported as per protocol in Section 3.6.1.2. Dr. Obstein may pause the trial to investigate possible safety related issues and/or submit changes to the study design to address any safety-related concerns and may discontinue the trial should risks to participants beconsidered unacceptable.

Should it be discovered that a sub-investigator is not in compliance with the signed agreement, the approved investigational plan, or any IRB requirements for the conduction of this study, Dr. Obstein will promptly secure compliance or the sub-investigator will be removed from the study.

6.1 Written Monitoring Procedures

Dr. Obstein will perform reviews and/or according to the following sequential schedule:

- After the first patient undergoes the research protocol.
- At any point in which an adverse event is encountered and/or at any timewhere the risk/benefit of the research changes.
- At any point at which a complaint of a research participant is received that cannot be resolved by the principal investigator (PI) and/or research coordinator (RC).

Each review will result in a written report summarizing the monitors findings.

7. LABELING

Vanderbilt University Medical Center
Digestive Diseases Center
1301 Medical Center, Dr suite 1660
Nashville, TN 37232
Phone: (TBD) XXX-XXXX

Contents: One NuView device

CAUTION: Investigational Device. Limited by Federal (or United States) law to investigational use.

Cautionary Statement: Device only to be used under the direction of the investigators of Vanderbilt IRB approval number TBD#.

8. CONSENT MATERIALS

Informed consent will be obtained prior to the study. Please see Appendix E for informed regarding informed consent documentation.

9. IRB INFORMATION

The study will be submitted in standard fashion via the VUMC Human Research Protections Program online platform and assigned to the IRB Health Sciences Committee Chair for assignment and review.

Vanderbilt Human Research Protection Program
Health Sciences Committee
1313 21st Ave. S.
504 Oxford House
Nashville, TN 37232-4315

10. OTHER INSTITUTIONS

Vanderbilt University Medical Center is the only institution participating in this earlyfeasibility study.

11. ADDITIONAL RECORDS AND REPORTS

Complete and accurate records will be kept during the investigation and for a period of 2 years after either the date on which the investigation is terminated or completed or the datethat records are no longer required in support of an FDA market application. Records will include all correspondence relevant to the investigation, IRB approved study documents, device accountability records, source and case report form documentation, to include signed consent documentation and any adverse event reports for any participant.

12. MANUFACTURING

The NuView consists of three components that are manufactured independently using biocompatible materials: the structural support, mirror, and press-fit collar. These components are shown in Figure 7, below. This section details the manufacturing plan for each component, as well as the assembly and sterilization processes for the completed NuView device.

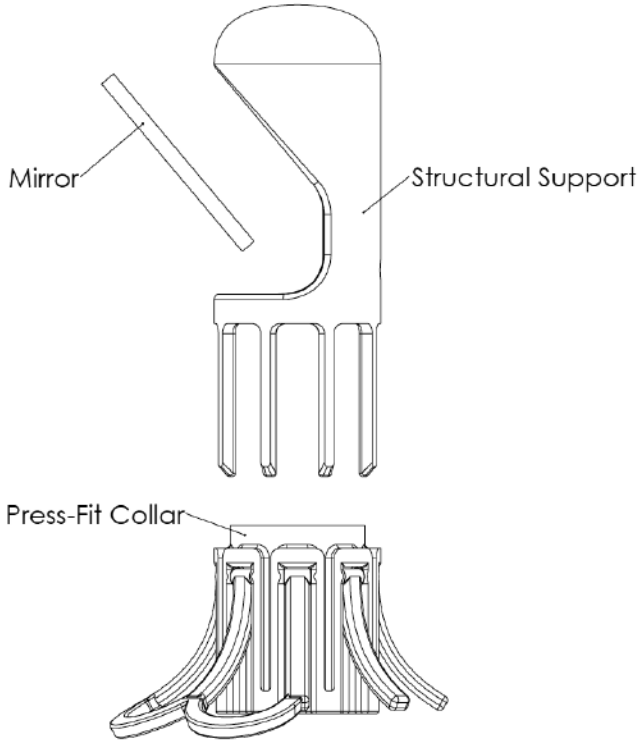

Figure 8: Three components of NuView device. Each component will be manufactured independently, fastened with medical-grade adhesive, packaged, and sterilized.

Structural Support: the structural support component will be manufactured using a Formlabs Form 3 3D printer (Somerville, MA). The Form 3 is a stereolithography (SLA) 3D printer, which uses a UV laser to cure liquid material resins layer-by-layer on a dedicated build tray. More information on the Form 3 can be found at https://formlabs.com/3d-printers/form-3/. This component is 3D printed using Formlabs Tough 1500 Resin, a resilient material designed for stiff and pliable parts with similar strength and stiffness to polypropylene. Tough 1500 Resin is a medical-grade, biocompatible material that is certified for permanent skin contact.[1] After printing, the structural support component will be cleaned in 99% isopropyl alcohol using the recommended Form Wash settings and then cured to full strength using the recommended Form Cure temperature profile. Following the curing process, excess material from the 3D printing process (i.e., support material) will be removed with side-cutting pliers and the support locations will be finished with sandpaper for a smooth, uniform surface finish.

Mirror: The mirror is made from 1 mm-thick mirrored glass (a borosilicate substrate with a thin

[1] Addition information on Formlabs Tough 1500 resin and its ISO 10993 biocompatibility certification can be found at https://formlabs-media.formlabs.com/datasheets/Tough_1500_TDS_EN.pdf and

enhanced aluminum mirror coating). This component will be custom-manufactured by Knight Optical using a scribing process. Upon delivery to EndoTheia, the mirror will be cleaned using 99% isopropyl alcohol prior to assembly.

Press-Fit Collar: the press-fit collar is designed to be soft and elastic in order to safely interact with tissue during FAP, as well as to fit tightly on the tip of the endoscope. It will be made from a soft, biocompatible, and tear-resistance silicone urethane elastomer that is ideal for skin-contact and mucosal membrane applications. This soft silicone urethane elastomer is known as SIL-30 and will be supplied to us from Carbon, Inc. It has undergone rigorous biocompatibility/sterility testing which makes it ideal for short-term mucosal membrane contact (up to 24h in duration). See Appendix B for additional details relating to biocompatibility and sterility.

Assembly: All components will be secured together using medical-grade, biocompatible Loctite #435 cyanoacrylate (Henkel Corporation, Rocky Hill, CT).[2] The Loctite cyanoacrylate will be allowed to cure for a full 24 hours before proceeding to sterilization.

Sterilization: Following assembly, the completed NuView device will be sterilized according to protocols validated by STERIS (Mentor, Ohio) and included in Appendix B, STERIS Steam Sterilization Validation Report, which specifies the following parameters:

Sterilizer Type:	Prevacuum
Minimum Temperature:	132 C
Sterilization Cycle Time:	4 minutes
Dry phase:	30 mins
Test Article Configuration:	Single wrapped

[2] Loctite #435 is ISO 10993 certified. More information can be found at http://tds.henkel.com/tds5/Studio/ShowPDF/?pid=435&format=MTR&subformat=REAC&language=EN&plant=WERCS, https://web-emea.henkel.com/adhesives/henkel/productapprovals.nsf/24e98e11f0a9f0c7802572f300484965/0908d38905a2728ec125830700299db5/$FILE/Loctite%20435,%20Biocompatibility,%20ISO%2010993,%202009,%20US%20manufactured%20only.pdf, and https://dm.henkel-dam.com/is/content/henkel/medical-product-selector-guide-adhesives-for-medical-device-assembly

Appendix A: MAUDE data review for devices similar to the NuView

This section provides a review of the MAUDE data related to the Arc Endocuff device. The data presented is based on all available reports between January 1, 2000 to July 31, 2021. To date, there have been a total of 11 MAUDE reports for the Arc Endocuff as shown in Table 10.

Table 10: MAUDE data for the Arc Endocuff

MAUDE DATA: ARC ENDOCUFF (all available data)				
Device	**Date**	**Problem**	**Description**	**Harm**
K151801	12/09/2015	Detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	10/24/2015	Detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	10/24/2015	Detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	7/23/2015	Break; detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	5/13/2015	Detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	4/29/2015	Detachment of device component; Difficult to remove	Device detaches from the endoscope	**No harm to the patient**
K151801	4/17/2015	Detachment of device component	Device detaches from the endoscope	**No harm to the patient**
K151801	2/19/2014	Adverse Event Without Identified Device or Use Problem	An adverse event that was not attributed to the device	**No harm attributed to device**
K151801	10/18/2013	Adverse Event Without Identified Device or Use Problem	An adverse event that was not attributed to the device	**No harm attributed to device**

Review of the available MAUDE data for the predicate device, the Arc Endocuff, shows that the most commonly reported device problem is that of detachment from the endoscope. These detachments do not appear to result in any harm to the patient, as in all 8 unintended detachment events, no patient was reported to have been harmed and no follow up treatment was recommended in any case. Further, none of these detachment events has been contributed to misuse of the device in any of the MAUDE database reports.

The output of this MAUDE data has been incorporated into the product development process of the EndoTheia NuView. Further, a review of the MAUDE database indicates that surgeons can use the Arc Endocuff predicate device safely, as not a single harm of serious nature was attributed to the device in any of the MAUDE reports. It therefore stands to reason that, due to the similarities between the Arc Endocuff and the EndoTheia NuView, surgeons should also be able to use the NuView safely. We will confirm this through our Use Related Risk Assessment process, as well as through our development Verification & Validation testing.

MAUDE Data for devices similar to the EndoTheia NuView

As part of our risk assessment, and in an effort to take a broad approach at understanding the potential use related errors that users might experience while using the NuView device, we have also reviewed the MAUDE database reports for other similar devices to the EndoTheia NuView.

EndoAid's EndoRings distal endoscope attachment device:

EndoAid's EndoRings is a distal endoscope attachment and is very similar to the NuView in both technology and in intended use. The EndoRings device has the following intended use, "*The EndoRings is intended to be attached to the distal end of the endoscope to facilitate endoscopic therapy, to be used for the following: Keeping the suitable depth of endoscope's view field."* Because of the similarities between the two devices, we believe that the MAUDE database reports for the EndoRings are highly relevant to the NuView device and should be considered in our design process. All available reports for the EndoRings are presented in Table 11.

Table 11: MAUDE data for Endorings

MAUDE DATA: ENDORINGS (all available data)				
Device	**Report**	**Problem**	**Description**	**Harm**
K133359	12/01/2017	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	02/08/2017	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	02/08/2017	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	01/27/2017	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	12/13/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	07/13/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	03/18/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	03/03/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	08/27/2015	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K133359	08/13/2015	Adverse Event Without Identified Device or Use Problem	An adverse event that was not attributed to the device	**No harm to the patient**

It is clear that the most common problem with the EndoRings is unintended device detachment as all 10 reports are in regard to this observed problem. While there was no patient harm in any of these reports, it is important information regarding likely adverse events that we could potentially see in regards to the NuView device. We have taken this information into account within our design and development process and plan to include risk mitigations relating to detachment such as the inclusion of clasping features as well as specific tolerance specs relating the NuView/endoscope fitting. Exact risk controls around possible detachment events are still under development. Another thing that stands out in regards to the MAUDE data for the EndoRings is that the device appears to be relatively safe to use as none of these detachment events led to any patient/user harm.

United States Endoscopy Group's The US Endoscopy Distal Attachment Cap device:

Another device which is similar to the NuView device in terms of technological characteristics is that of United States Endoscopy Group's "*The US Endoscopy Distal Attachment Cap"* device.

This device's intended use is somewhat similar to the NuView device except that it also includes an indication for "gastrointestinal mucosal resection" which the NuView device is not intended for. Still, MAUDE reports for the US Endoscopy Distal Attachment Cap are relevant to the NuView in that they are both distal endoscope attachment type devices. All publicly available MAUDE data for The US Endoscopy Distal Attachment Cap is presented in Table 12.

Table 12: MAUDE data for Reveal Distal Attachment Cap

MAUDE DATA: REVEAL DISTAL ATTACHMENT CAP (all available data)				
Device	**Report**	**Problem**	**Description**	**Harm**
K140315	01/29/2021	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	07/29/2019	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	02/13/2019	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	09/26/2018	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	04/08/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	04/08/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	03/03/2016	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**
K140315	09/17/2015	Detachment Of Device Component	Device detaches from the endoscope	**No harm to the patient**

The MAUDE data for The US Distal Attachment Cap device points to unintended detachment as the most common problem for this device. Since this device's introduction into the marketplace there have been a total of 9 reports, all of which relate to the unintended detachment of the device. No patient/user harm was seen in any of these 9 reports, again suggesting that this device (like the EndoRings device) appears to be relatively safe for use.

Overall, our review of the MAUDE database for devices similar to the NuView device suggest that unintentional device detachment will be the most probable problem that we are likely encounter. Fortunately, this problem does not appear to lead to a serious level harm, as none of the reports suggest patient harm related to this detachment issue. Nevertheless, we are taking this into under advisement during the development of our device and plan to implement risk controls for this known issue in other similar devices.

Appendix B: Device Biocompatibility & Sterility Information

SIL 30

SIL 30 is a soft, biocompatible, and tear-resistant silicone urethane elastomer that is ideal for skin-contact applications.

Tensile Properties ASTM D412, Die C, 500 mm/min	**Metric**	**US**
Tensile Modulus	3 MPa	440 psi
Elongation at Break	350%	350%
Stress at 50% Elongation	0.4 MPa	60 psi
Stress at 100% Elongation	0.7 MPa	100 psi
Stress at 200% Elongation	1.5 MPa	220 psi
Ultimate Tensile Strength	3.5 MPa	500 psi

Other Mechanical Properties	**Metric**	**US**
Tear Strength, Die C (die cut), ASTM D624	10 kN/m	57 lbf/in
Compression Set, 23 °C, 72 h, ASTM D395-B	10%	10%
Bayshore Rebound Resilience, ASTM D2632	20%	20%

Thermal Properties	**Metric**	**US**
T_g (DMA, tan(d)), ASTM D4065	10 °C	50 °F

Dielectric/Electric Properties	
Dielectric Constant, ASTM D150	7.6
Dissipation Factor, ASTM D150	0.15

General Properties	
Hardness, ASTM D2240	35 (Instant), 31 (5 sec), Shore A
Density, ASTM D792	1.07 g/cm^3
Density (liquid)	1.05 g/cm^3

The information in this document includes values derived from printing various parts, reflects an approximation of the mean value of a range of values, and is intended for reference and comparison purposes only. This information should not be used for testing, design specification or quality control purposes. End-use material performance can be impacted by, but not limited to, design, processing, color treatment, operating and end-use conditions, test conditions, etc. Actual values will vary with build conditions. In addition, product specifications are subject to change without notice.

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Parts were processed using an M series printer and a Smart Part Washer with VF 1 as the solvent.

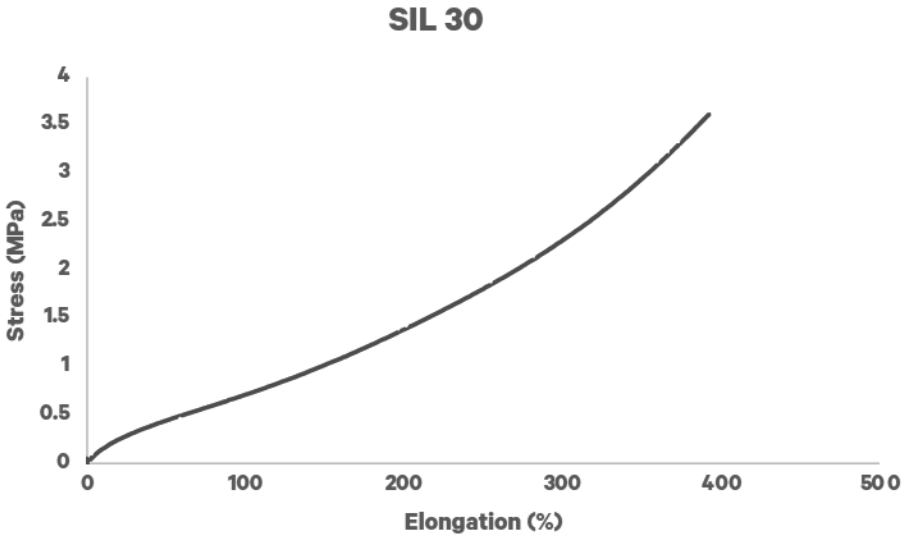
SIL 30

Extended TDS

SIL 30 Mechanical Properties

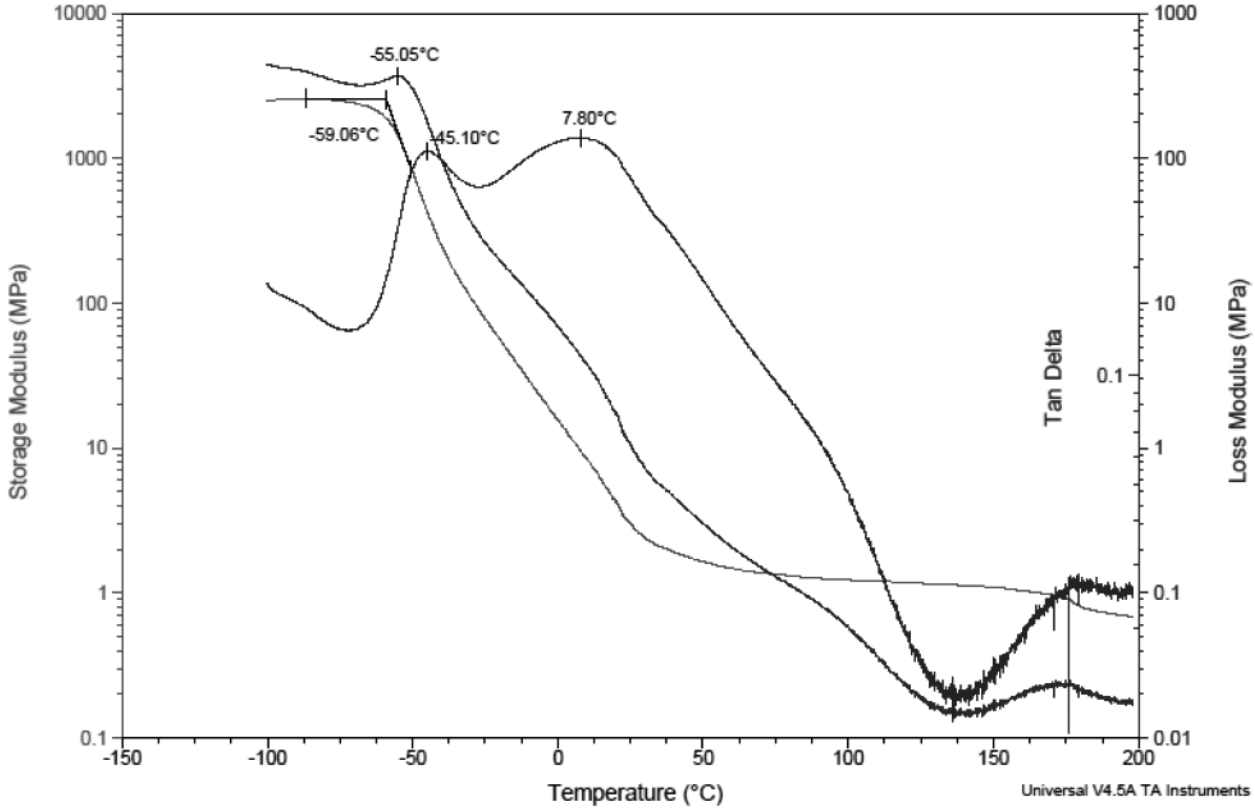
Representative Tensile Curve

ASTM D412, Die C, 500 mm/min



SIL 30 Dynamic Mechanical Analysis (DMA)

Dynamic mechanical analysis provides insight into a material's viscoelastic properties across a range of temperatures. The figure below shows a temperature ramp of SIL 30. The peak in the tan(d) curve indicates that the glass transition temperature for this material is approximately 10 °C. A rubbery plateau is observed in the storage modulus from 20 – 150 °C reflecting the elastic nature of this material within this temperature window.



Standard: ASTM D4065
Instrument: TA DMA Q800
DMA Mode: Tension
Sample Dimensions: L=20 mm, W=10 mm, t=1 mm (rectangular block)
Strain Amplitude: 0.1% (linear regime of viscoelasticity)
Oscillation frequency: 1 Hz
Temperature Range: -100 ºC to 200 ºC
Ramp Rate: 1.5 ºC/min
Print Conditions: All DMA samples were printed using software v1.9. Samples were hand-wiped and not washed with solvent. The thermal cure for all materials complies with the Carbon user manual.

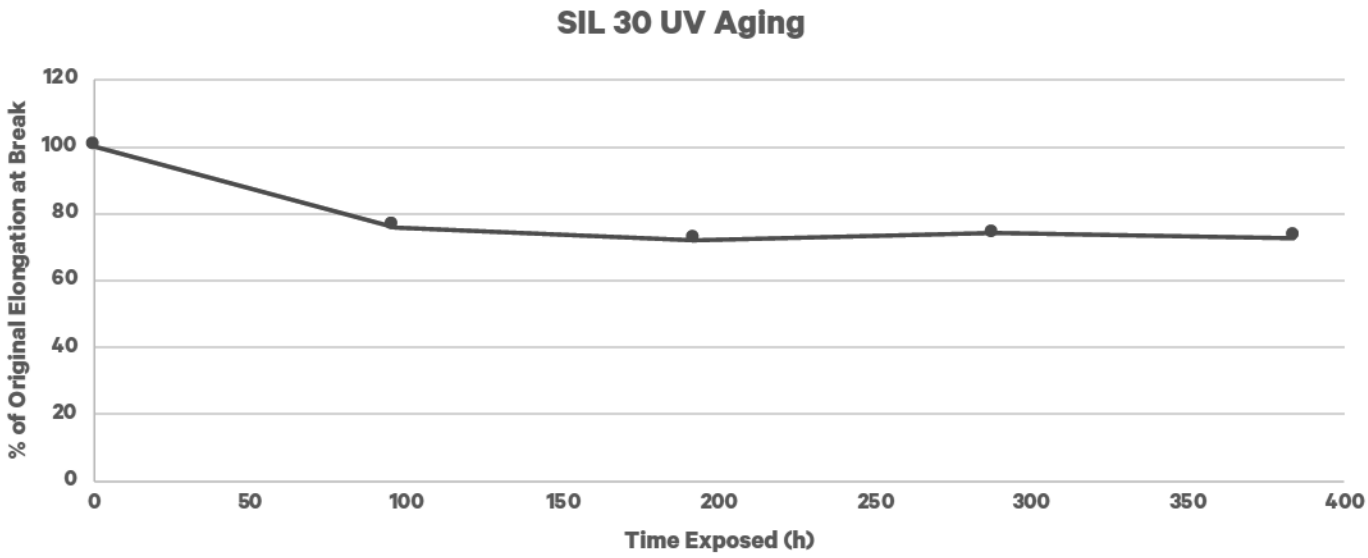
SIL 30 Chemical Compatibility

	Mass Gain* (%)
Household Chemicals	
Bleach (NaClO, 5%)	< 5%
Sanitizer (NH_4Cl, 10%)	5 – 15%
Distilled Water	5 – 15%
Sunscreen (Banana Boat, SPF 50)	5 – 15%
Detergent (Tide, Original)	5 – 15%
Windex Powerized Formula	5 – 15%
Hydrogen Peroxide (30%)	15 – 30%
Ethanol (95%)	> 30%
Industrial Fluids	
Engine Oil (Havoline SAE 5W-30)	< 5%
Brake Fluid (Castrol DOT-4)	> 30%
Airplane Deicing Fluid (Type I Ethylene Glycol)	< 5%
Airplane Deicing Fluid (Type I Propylene Glycol)	5 – 15%
Airplane Deicing Fluid (Type IV Ethylene Glycol)	< 5%
Airplane Deicing Fluid (Type IV Propylene Glycol)	5 – 15%
Transmission Fluid (Havoline Synthetic ATF)	< 5%
Engine Coolant (Havoline XLC, 50%/50% premixed)	< 5%
Diesel (Chevron #2)	15 – 30%
Gasoline (Chevron #91)	> 30%
Skydrol 500B-4	> 30%
Strong Acid/Base	
Sulfuric Acid (30%)	> 30%
Sodium Hydroxide (10%)	< 5%

Percent weight gained after 1 week submersion following ASTM D543. Values do not represent changes in dimension or mechanical properties.

SIL 30 UV Aging

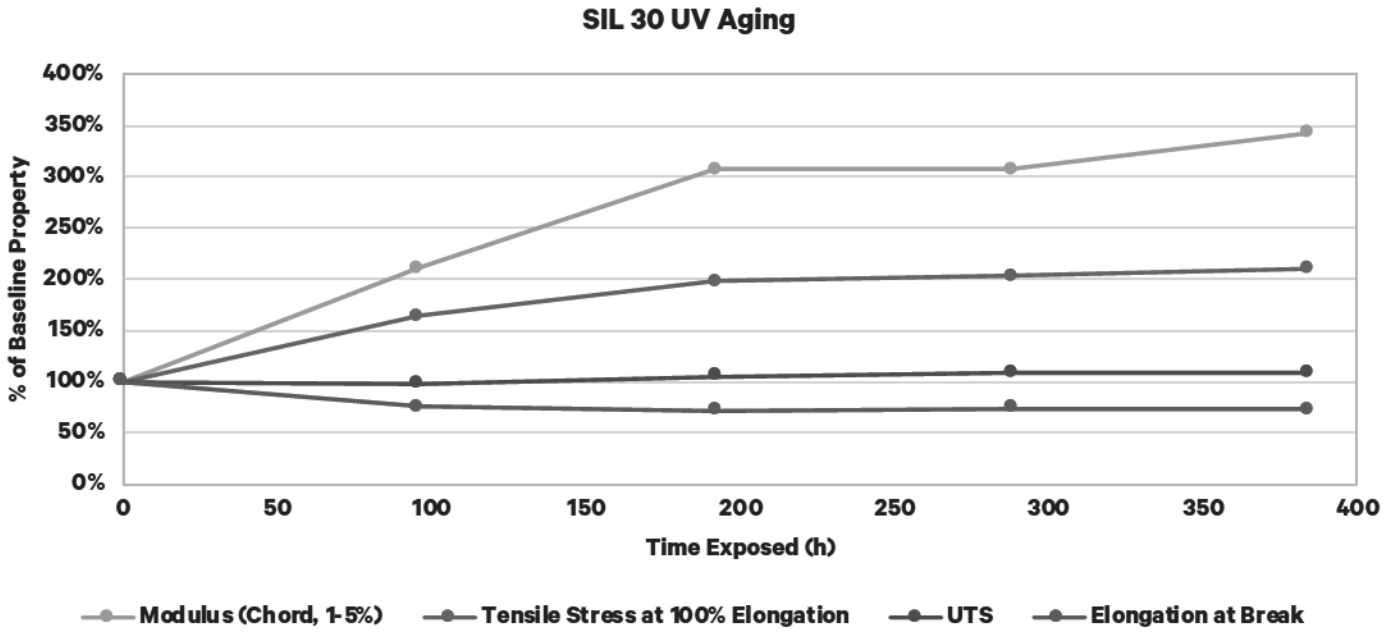
Natural polymer aging can occur in the presence of light, sun, and heat. Carbon evaluated the UV aging performance of SIL 30 using ASTM D4459, which is intended to simulate indoor exposure of solar radiation through glass.



ASTM D4459: Q-Sun XE-1, 0.8 W/m^2 at 420 nm, 55 °C
ASTM D412: Die C, 500 mm/min, average values represented

SIL 30 UV Aging

Natural polymer aging can occur in the presence of light, sun, and heat. Carbon evaluated the UV aging performance of SIL 30 using ASTM D4459, which is intended to simulate indoor exposure of solar radiation through glass.



ASTM D4459: Q-Sun XE-1, 0.8 W/m^2 at 420 nm, 55 °C
ASTM D412: Die C, 500 mm/min, average values represented

SIL 30 Biocompatibility

Biocompatibility Testing

Printed parts were provided to NAMSA for evaluation in accordance with ISO 10993-5, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-10, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (GPMT).* Parts were processed using an M series printer and a Smart Part Washer with VF 1 as the solvent. The results for all tests indicated that SIL 30 passed the requirements for biocompatibility according to the above tests. **Carbon makes no representation and is not responsible for the results of any biocompatibility tests other than those specified above.**

Disclaimer

Biocompatibility results may vary based on printing and/or post-processing procedures.

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Carbon, Inc. | www.carbon3d.com
1089 Mills Way Redwood City, CA 94063
1 (650) 285-6307

Biocompatibility Requirements

SIL 30 Resin: Printing & Processing Protocols for Carbon M Series Printers

The protocols described in this document were tested by Carbon for printing parts from SIL 30 Resin material so that they are suitable for prolonged skin contact (more than 30 days) and short-term mucosal-membrane contact (up to 24 hours).

Follow the instructions in this document when using SIL 30 resin on Carbon M1 and M2 printers to ensure biocompatibility of the resulting part.

Resin Dispensing

SIL 30 resin is a two-component material supplied in a dual-chamber, light-resistant cartridge. At print time, the A and B components are mixed in a 1:1 ratio using a static mixer tip attached to the end of the cartridge which installed into a Albion motorized dispensing unit. It is suggested that the initial volume (~5 mL) of resin is burned into a waste container to prevent off-stoichiometry. An appropriate volume of the mixed resin (as specified by the print planner software) is then dispensed into the printer cassette and the cassette is placed on the optical deck.

Note: When switching between materials, the cassette should be cleaned with isopropanol (IPA) to ensure that residual resin from the previous print is not mixed with the SIL 30 resin. For additional information see the "Cleaning the cassette" section of the User Guide.

Printing

A cleaned build platform is installed onto the Z-stage and the print process initiated by uploading a suitable STL, entering run parameters (resin type, print orientation, support construction, etc.) and requesting print initiation. Print speed and light intensity are controlled by Carbon's proprietary software to ensure part accuracy and degree of UV network cure.

Part Removal from Build Platform

Once the "green" state part (only the UV network is cured) is built, the build platform is removed from the printer, the part gently removed from the build platform using a variety of scrapers, tweezers and blades.

Washing

Remove excess resin using sponge swabs and wipes and with compressed air (in a cabinet).

Wash the parts with mild agitation in **Vertrel XM™**, an azeotropic mixture of 1,1,1,2,2,3,4,5,5,5-Decafluoropentane and methanol (91-93 to 9-7, w/w, Chemours™) for 3 to 5 minutes. Agitation can be achieved by placing the parts in a stainless steel small-parts basket and rotating the basket at 5-20 rpm in sufficient Vertrel XM™ to cover or using the Carbon Smart Part Washer. In the latter case, the washer will provide the proper wash cycle.

For additional information, see the "Washing parts" section of the User's Guide.

Support Removal

Supports can be removed prior to washing or after the wash and cure cycles. To remove support material from the printed part, use clean tweezers or clean protective gloves.

For additional information, see the "Removing supports" section of the User's Guide.

Thermal Cure

Place the parts on a non-stick tray. Then place the tray in a clean, dedicated convection oven at 120°C for 8 hours.

Biocompatibility Testing

Parts printed and processed as outlined in this document were provided to NAMSA for evaluation in accordance with ISO 10993-5, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-10, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (GPMT)*. The results for all tests indicated that SIL 30 resin passed the requirements for biocompatibility according to the above tests. Carbon makes no representation and is not responsible for the results of any biocompatibility tests other than those specified above.

Disclaimer
Biocompatibility results may vary if protocols are used other than those outlined in this document.

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Tough 1500 Sterilization Results

The purpose of this paper is to evaluate the compatibility of Formlabs Tough 1500 Resin with various biological sterilization methods: autoclave, gamma, e-beam, and ethylene oxide sterilization (EtO). Changes in mechanical properties will be presented pre- and post- sterilization. The results presented are intended to help inform potential uses, but should not be used as a substitute for application-specific testing.

Sample Preparation

Printing

All samples were printed on Form 3B SLA printers equipped with clean Build Platforms, Form 3 Resin Tanks and Tough 1500 Resin V4 cartridges. Part orientations and placement were kept constant for all samples.

Post Processing

After printing, testing samples attached to a build platform were washed twice in a Form Wash. The first wash was 10 minutes in <=95% IPA to remove the majority of uncured resin. The second wash was 10 minutes in >99% IPA to ensure removal of any residual uncured resin. Compressed air was used to dry the parts thoroughly. Parts were removed from supports and cured for 60 min at 70° C in a Form Cure.

Formlabs Form Wash, Form Cure, and finishing tools were used according to the recommended Instruction for Use to ensure optimal performance and biocompatibility compliance.

Results

Biocompatibility Testing

Printed and post-processed parts were provided to NAMSA for ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity study using the ISO elution method. The results show no evidence of causing cell lysis or cytotoxicity; with 0% lysis detected.

Results and conclusions of the cytotoxicity testing are based on a standard geometry and sample set per ISO 10993-5. Biocompatibility and sterilization compatibility results may vary if there are any deviations from the recommended Instructions for use. Formlabs is not responsible for any biocompatibility results except the one specified in this report. Users are responsible for confirming biocompatibility for their specific application.

Mechanical Property Testing

Tensile Testing: Tensile bars (ASTM D638 Type I) were prepared as described in the “Sample Presentation” section. The samples were conditioned and tested according to ASTM D638.

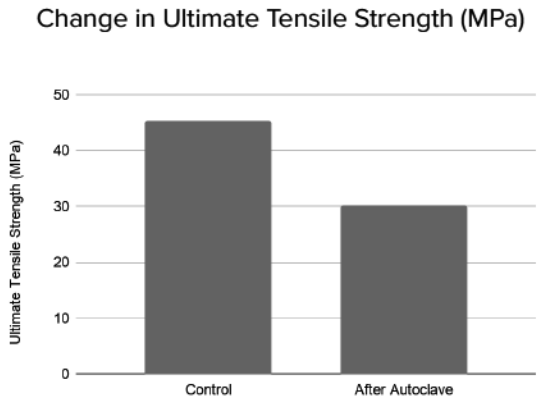
Flexural Testing: Flexural bars were prepared as described in the “Sample Preparation” section. The samples were conditioned and tested according to ASTM D790 - Method B.

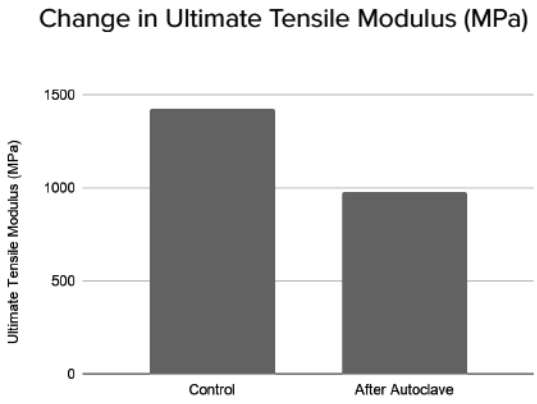
Parts printed and tested under different conditions, such as printer, storage conditions, etc. may produce different results.

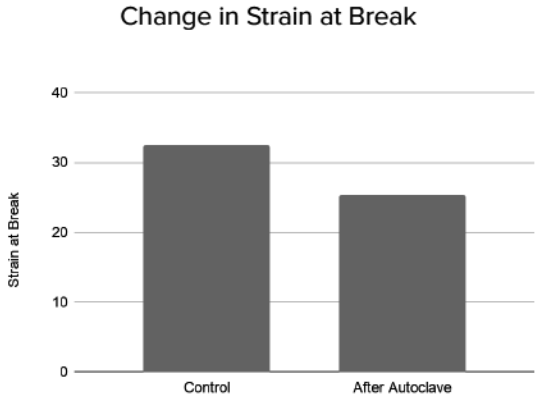
Autoclave (Steam) Sterilization

Tensile and flexural bar samples were provided to STERIS for autoclave processing. The parts underwent 5 cycles of pre-vacuum steam sterilization at 132° C with a 4-minute sterilization phase and 30 minutes dry phase. Parts were allowed to cool 30 minutes between cycles.

The mechanical property testing below shows the compatibility of Tough 1500 Resin printed parts with autoclave sterilization. No appreciable losses in material properties, deformations, cracking or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.





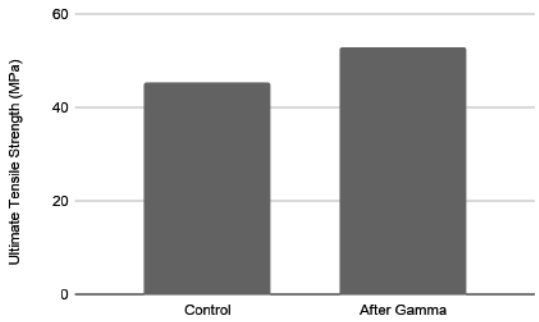


Gamma Sterilization

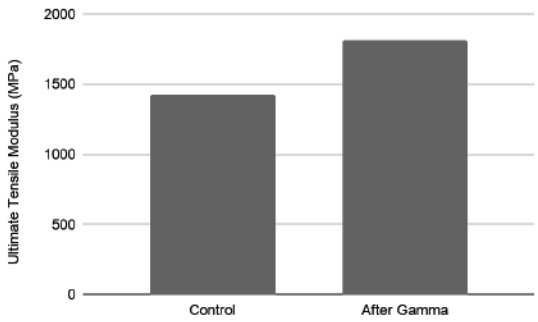
Tensile and flexural bar samples were prepared and provided to Sterigenics - Rockaway, NJ for Gamma processing. The samples were exposed to 29.4-31.2 kGy of gamma radiation.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Tough 1500 Resin printed parts with gamma sterilization. No appreciable losses in material properties, deformations, cracking or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.

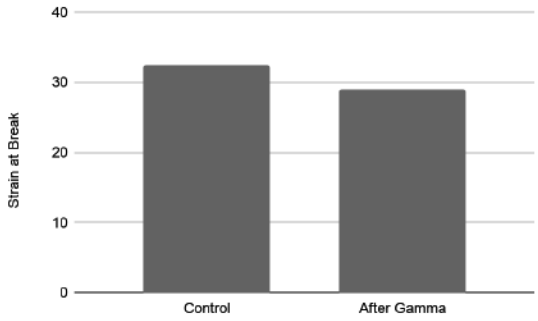
Change in Ultimate Tensile Strength (MPa)



Change in Ultimate Tensile Modulus (MPa)



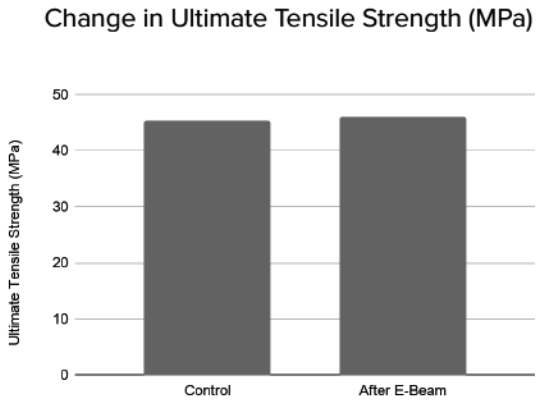
Change in Strain at Break

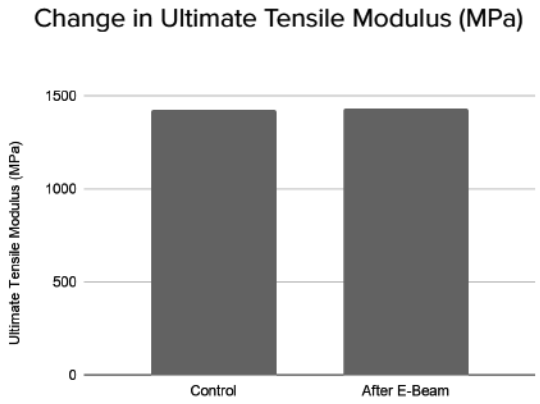


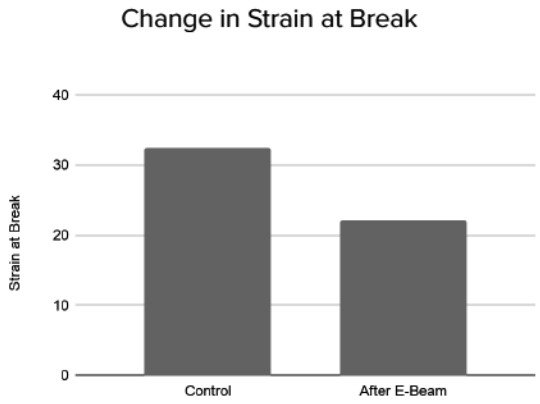
E-beam Sterilization

Tensile and flexural bar samples were prepared and provided to Sterigenics - San Diego, CA, for e-beam processing. The samples were exposed to a surface dose of 35 kGy of e-beam radiation.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Tough 1500 Resin printed parts with e-beam sterilization. No appreciable losses in material properties, deformations, cracking or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.



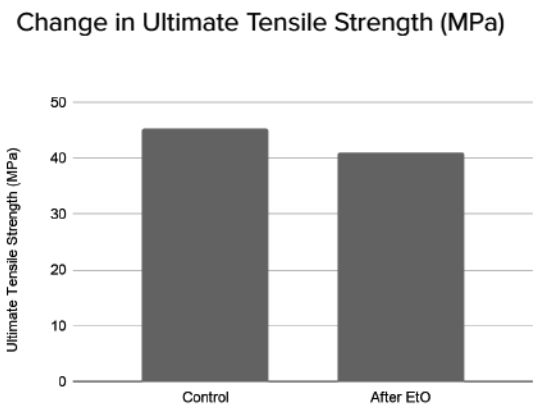


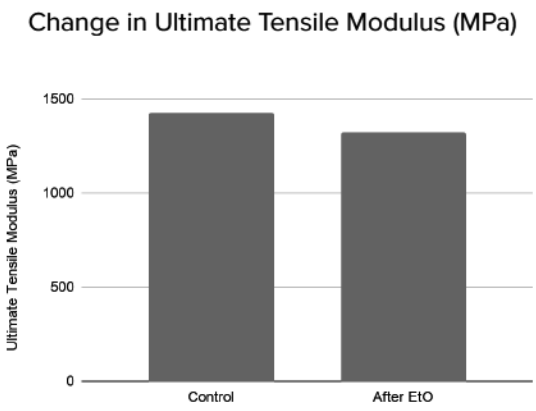


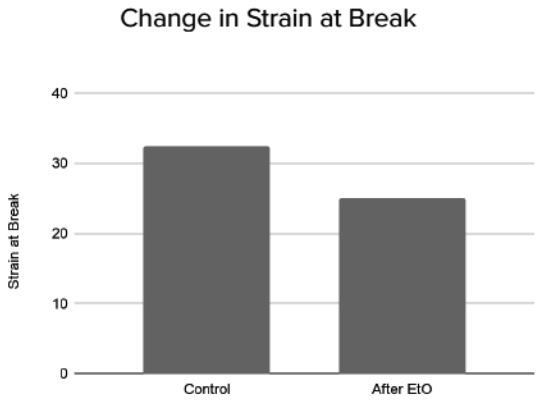
Ethylene Oxide (EtO) Sterilization

Tensile and flexural bar samples were prepared and provided to Blue Line Sterilization Services for EtO processing. The samples were conditioned at 55°C, 50% relative humidity, and 50 mbar for 78 minutes. The samples were then exposed to a single cycle of 100% EtO at 55°C for 180 minutes.

Parts were provided back to Formlabs for mechanical property testing using ASTM D638 and ASTM D790 compliant methods. The mechanical property testing below shows the compatibility of Tough 1500 Resin printed parts with EtO sterilization. No appreciable losses in material properties, deformations, cracking or significant changes in color were observed after processing. Flexural properties were tested and followed similar trends as tensile testing.

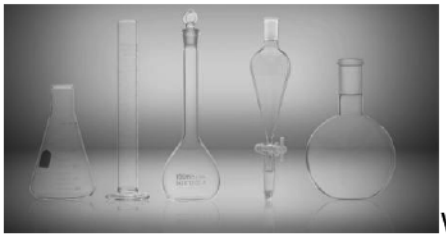






DISCLAIMER: The data presented in this report applies only to the articles tested by Formlabs. Formlabs takes no responsibility for testing completed on customer's products. Biocompatibility, sterilization, and mechanical compatibility results may vary depending on the test conditions and protocol used.

Cleaning Lab
Glass



WPI sells a new line of quality borosilicate glassware for laboratories. This article includes information on caring for your glassware.

Soda lime glass is a softer glass and should not be used for laboratory purposes, because it cannot endure the temperature or pressure changes of borosilicate glass, and it should not be autoclaved at the high temperatures. Most bottles are made of soda lime glass.This article deals with borosilicate glass. Do not mix soda lime glass with borosilicate glass in racks when you are cleaning or autoclaving.

New Glassware

New glassware is usually a little alkaline. After inspecting it for clips and cracks, wash the glass in warm, soapy water and then soak it in a solution of 1% HCl or HNO_3 for a short period of time. Wash the glassware again and rinse it thoroughly with distilled water.

Why Glass Fails

When laboratory glass breaks under normal use, it is usually the result of a chip, abrasion or scratch, or because it was exposed to quick temperature or pressure changes.

- Inspect your laboratory glassware upon receipt and before use. Hold the glass up to natural sunlight and look for chips, cracks and fractures. Even tiny fractures can cause the glass to break under pressure or in elevated temperatures.
- Avoid bumping glassware against anything (other glassware, the side of the sink, desktop...). This can cause tiny fractures or cracks.
- To avoid damage to the glass, do not soak it for long periods in strong alkaline solutions.

Proper Cleaning Tips

At a minimum, laboratory glass should be free of chemical residue and grease. Depending on your experiment, it may also need to be sterilized. Some tips for cleaning include:

- Use a soft bristle brush for cleaning to avoid unnecessary scratches.
- Never use hydrofluoric acid (HF) to clean glass. Among other uses, HF is used as a descaler, a rust remover, a metal cleaner, a glass-etcher and a metal plating compound.It is highly caustic.
- Never use strong alkali soaps or acids to clean glass.
- Standard borosilicate glass is autoclaveable. If you autoclave the glass, vent the autoclave and let it cool slowly. Autoclave at 230-240°C. For short periods of time (after an extreme use) it can be autoclaved at 400°C.
- Ashing glass in mechanical ovens over 500ºC for long periods of time will shorten the life of your

glassware.

- To test that a glass container is fully wettable (especially important when making precise liquid measurements), verify that distilled water will wet all surfaces equally.
- Wash all glassware immediately after use to remove all residues. If immediate cleaning is impossible, soak the glassware.
- Never use wire brushes or brushes with a wire core to clean glassware.
- **Alconox** is the best cleaner for glass. However, a non-abrasive dish soap also works well.
- Always rinse clean glassware well and follow with a distilled water rinse.
- **Cidex** is good biocide.
- Remove grease by boiling the glass in a weak sodium carbonate solution. Or, use acetone. Rinse well with water.
- Ultrasonic cleaning is an excellent choice for glassware, especially when it is combined with a heated solution of mild detergent.

Stain Removal

Stain	Removal Solution
Permanganate	Mix equal parts of 3% sulfuric acid with 3% hydrogen peroxide
Iron	Mix one part hydrochloric acid with one part water
Bacteriological contaminant	Soak is disinfectant solution like **Cidex**, steam autoclave, wash and rinse

When in doubt, refer to MSDS sheets for cleaning solutions to determine if they will react with chemicals on the glassware.

Drying Glassware

Oven drying at 100°C is best, but rack drying is fine.

Steam Autoclaving

Autoclave borosilicate glassware for 15-20 minutes at 100-120ºC. Remove all closures, clamps, clasps, etc. when autoclaving. If it is not possible to remove them, at least loosen or unscrew them to avoid pressure buildup.

You can find WPI's complete line of glassware products on **wpichemisty.com**. If you have questions, please contact Heidi at 866.606.1974 or **heidih@wpiinc.com**.

Soda-Lime Glass

Glass Fabrication

Coating Deposition

CNC Machining

Strengthening - Chemical & Heat

Screen Printing of Graphics

Abrisa Technologies, a member of HEF Photonics, is a globally recognized technology glass fabrication and optical thin film coating company with expertise in high volume manufacturing and engineering capabilities, delivering Total Solutions that provide excellent performance, fitness-for-use and economies of scale.

Our US based, state-of-the-art ISO 9001:2015 and ITAR registered facilities include Abrisa Industrial Glass in Santa Paula, CA and ZC&R Coatings for Optics in Torrance CA. These two divisions produce solutions from cut-to-order coated glass components to custom complex and ready-to-install fabricated, strengthened, optically coated, electronically enabled and branded sub-assemblies.

Our Total Solutions serve a variety of markets including Micro-Electronics, Defense and Avionics, Display, Industrial Automation, Optical Sensors, Imaging, Photonics, Medical & Dental, Life Science and more.

ABRISA TECHNOLOGIES
HEF® PHOTONICS

CERTIFIED ISO 9001:2015 COMPANY · International Traffic in Arms Regulations Compliant ITAR · REACH COMPLIANT · COMPLIANT · COMPLIANT ROHS

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Santa Paula, CA 93060

ZC&R Coatings for Optics
1401 Abalone Avenue
Torrance, CA 90501

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www.abrisatechnologies.com
info@abrisatechnologies.com

SLG 10/21

ABRISA TECHNOLOGIES
HEF® PHOTONICS

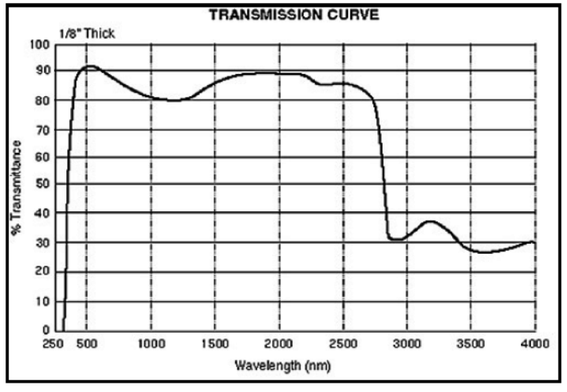
Your Total Solution Partner

Soda-Lime Glass

Clear & Tinted Soda-Lime Glass provides high light transmission, can be AR coated for super high transmission, can be chemically strengthened, and has good flatness.

Soda-lime glass is the most prevalent type of glass and is prepared by melting he raw materials, such as soda, lime, silica, alumina, and small quantities of fining agents in a glass furnace at temperatures up to 1675°C.

Soda-Lime sheet glass is made by floating molten glass on a bed of molten tin. This method gives the sheet uniform thickness and very flat surfaces. Soda-lime glass is the base material for most clear, colored and patterned glass types.



Soda-Lime Glass is:

- Less Expensive than other glass with specialized properties such as borosilicates and aluminosilicates.
- Soda-Lime glass is chemically stable, preventing corrosion and therefore chemically compatible.
- Soda-Lime is a hard glass, so it has some abrasion resistance, and more so if chemically strengthened.
- If heat tempered, soda-lime glass can be less vulnerable to thermal shock.
- Soda-Lime glass is a good insulator as it does not transmit electricity well due to its high specific resistivity and low dielectric constant.
- Soda-Lime glass is highly transmissible making it an excellent choice where light transmission is required.

Dimensions:

- Thicknesses: 0.02” – 1” (0.55mm – 25.4mm)
- Sizes: Up to 96” x 72” (2440mm x 1830mm)
- Other sizes may be available upon request

Soda-Lime Glass

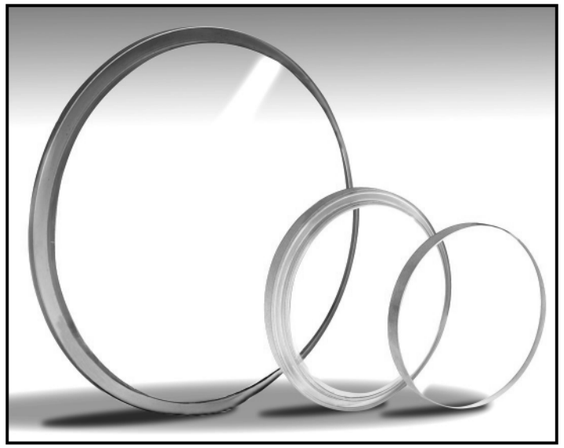
Thermal Properties	Measurement	Explanation
Thermal Coefficient of Expansion	**(0/300°C): 8.6 x 10^{-6}/°C**	How much a material's volume changes as it heats or cools
Annealing Point	**1015°F/546°C**	The temperature where residual stress in a material is reduced within several minutes
Softening Point	**340°F/726°C**	The temperature at which a material slumps under its own weight
Strain Point	**957°F/514°C**	The temperature where residual stress in a material is reduced within several hours
Mechanical Properties	**Measurement**	**Explanation**
Density	**2.44 g/cm^3 @ 20°C/68°F**	Mass per unit of volume
Knoop Hardness	**585 Kg/mm^2 + 20**	Measures hardness and resistance to indentation
Hardness Mohs Scale	**6-7**	Measures scratch resistance
Modulus of Elasticity (Young's)	**7.2 x 10^{10} Pa**	How stiff a material is
Modulus of Rigidity	**3.0 x 10^{10} Pa**	How much shear a material can handle
Bulk Modulus	**4.3 x 10^{10} Pa**	How compression-resistant a material is
Poisson's Ratio	**.22**	How much a material stretches in one direction and narrows in another when it's pulled in two different directions
Optical Properties	**Measurement**	**Explanation**
Refractive Index • **1µm, 2µm**	**1.523 (435nm), 1.513 (645nm)**	The measurement of how much light passes through a material instead of being reflected
Chemical Properties	**Measurement**	**Explanation**
Hydrolytic Resistance	**Class 3**	How likely a material is to contaminate chemicals in contact with it (its chemical durability)
Acid Resistance	**N/A**	
Alkali Resistance	**N/A**	

Soda-Lime Glass

Electrical Properties	Measurement
Dielectric Constant How much a material is affected by a magnetic field	**7.75 @ 20°C E**
Specific Resistivity How well a material resists conducting electricity	**7.94 x 10^{17} to 7.94 x 10^{18} µohm·cm**

Features:

- Can be chemically strengthened to increase mechanical strength*
- Can be heat strengthened or heat tempered to increase thermal shock resistance and mechanical strength
- Can be machined, optically coated, chemically etched, sandblasted, colored, or laminated
- Good flatness and surface quality due to float process
- The lowest cost solution for sheet fabricating glass components



Options

Coatings:

- Custom V-Coat, Multi-band, Broadband AR
- AR Coatings to MIL-C-14806 A
- ITO/IMITO for EMI Shielding, Heater, LC Devices
- Custom SWP, LWP, Bandpass, UV & NIR Blocker
- Broad/Narrowband Scanning Mirror Coatings
- Deposition onto Filters, Silicon & Other Materials
- Autoclavable, Bio or Chemically Compatible

Substrates:

- **Fabrication to Shape & Size**
  - Cut & Seam or Circle Ground to Size & Shape
  - Precision CNC - Holes, Bevels, Steps, Notches
- **Damage Resistant Substrates**
  - HIE™ Aluminosilicates
    - AGC Dragontrail™
    - Corning® Gorilla®
    - SCHOTT AS 87
  - Chemically Strengthened Soda Lime Float
- **Low Expansion Chemically Resistant Substrates**
  - SCHOTT Borofloat® 33
- **Ultra Thin and Wafer Substrates**
  - AGC EN-A1
  - Corning® Eagle XG®
  - SCHOTT AF32, D263® & AS 87
- **Other**
  - Applied Films & Tints
  - Gasket Application
  - Edge Treatment/Blackening
  - Laser Marking (QR & Barcodes, S/N)

Easy-to-Clean & Anti-Fog Solutions:

- Oleo/Hydrophobic Options
- ITO Heater, HTAF Anti-Fog Solutions

Graphics & Bus Bars:

- Color Matched Epoxy Ink
- Non-Conductive Ink
- High Temperature Frit Ink
- Deadfront Ink - Partially Transmissive
- Infrared IR Transmitting Ink
- Silver Epoxy, Silver Frit, CrNiAu Bus Bars

**Mechanical strength is the general ability of a material to withtand stress and strain. The mechanical strength of tempered or chemically strengthened glass can be 4 times as much as ordinary glass.*

FOR US PRODUCED CA 435 ONLY

TOXIKON
Leaders in Life Science and Technology

Sponsor:
Henkel Corporation
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: July 15, 2009
Project Numbers: 09–1572
Page: 1 of 3

ATTN: Colette Kingsbury–Rich

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: LOCTITE® 435
Bulk Number: IDH# 1250431
Lot/Batch #: L39F007699

INTRACUTANEOUS INJECTION (ISO) – Toxikon Project 09–1572–G1: The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400, and alcohol in saline did not produce a significantly greater biological reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 32, National Formulary 27, 2009; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered a negligible irritant.
Reference: Biological Evaluation of Medical Devices – Part 10: Irritation and Delayed–Type Hypersensitivity, ISO 10993–10, 2002, as amended 2006.

ACUTE SYSTEMIC INJECTION (ISO) – Toxikon Project 09–1572–G2: The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400, and alcohol in saline did not produce a significantly greater biological reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 32, National Formulary 27, 2009; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material.
Reference: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity, ISO 10993–11:2006.

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

CYTOTOXICITY (ISO) – Toxikon Project 09–1572–G3: The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non–cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993–5.
Reference: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity, ISO 10993–5:1999.

HEMOLYSIS (ISO) – Toxikon Project 09–1572–G4: This assay is designed to evaluate the hemolytic potential of the test article. Hemolytic activity of the test article with rabbit blood indicated that the test article was non–hemolytic (< 5%).
Reference: Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, ISO 10993–4, 2002, as amended 2006.

***IN VITRO* HEMOCOMPATIBILITY (ISO) – Toxikon Project 09–1572–G5**: This assay is designed to ensure that the test article extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested included complete blood count, including platelets, hematocrit, erythrocyte indices, and platelet count. The test article extract did not have any adverse effects on any of the hematological parameters tested.
Reference: Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, ISO 10993–4:2002, as amended 2006.

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

PHYSICOCHEMICAL TEST (USP) – Toxikon Project 09–1572–G6: This test determines the physical and chemical properties of extracts of the test article. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 31, National Formulary 26, 2008.

IMPLANTATION TEST (ISO) – Toxikon Project 09–1572–G7: The test article was implanted in the paravertebral muscle tissue of New Zealand White rabbits for a period of two weeks. The results indicate that the test article does not demonstrate any remarkable difference as compared to the control implant sites in local tissue responses and the potential to induce local toxic effects.
Reference: Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation, ISO 10993–6: 2007.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

Director of Biocompatibility

Quality Assurance

Date of Certificate: July 21, 2009

Technical Data Sheet

LOCTITE® 435™

December 2020

PRODUCT DESCRIPTION

LOCTITE® 435™ provides the following product characteristics:

Technology	Cyanoacrylate
Chemical Type	Ethyl cyanoacrylate
Appearance (uncured)	Colorless to straw colored, slightly cloudy liquid[LMS]
Components	One part - requires no mixing
Viscosity	Low
Cure	Humidity
Application	Bonding
Key Substrates	Metals , Plastics and Rubbers

LOCTITE® 435™ is a rubber toughened adhesive with increased flexibility and peel strength along with enhanced resistance to shock. The product provides rapid bonding on a wide range of materials, including metals, plastics and elastomers, as well as porous and absorbent materials like wood, paper, leather and fabric.

ISO-10993

LOCTITE® 435™ has been tested to Henkel's test protocols based on ISO 10993 biocompatibility standards, as a means to assist in the selection of products for use in the medical device industry.

TYPICAL PROPERTIES OF UNCURED MATERIAL

Specific Gravity @ 25 °C 1.1

Flash Point - See SDS

Viscosity, Cone & Plate, mPa·s (cP):
Temperature: 25 °C, Shear Rate: 1,000 s^{-1} 100 to 250[LMS]

TYPICAL CURING PERFORMANCE

Under normal conditions, the atmospheric moisture initiates the curing process. Although full functional strength is developed in a relatively short time, curing continues for at least 24 hours before full chemical/solvent resistance is developed.

Cure Speed vs. Substrate

The rate of cure will depend on the substrate used. The table below shows the fixture time achieved on different materials at 22 °C / 50 % relative humidity. This is defined as the time to develop a shear strength of 0.1 N/mm² .

Fixture Time, seconds:	
Steel (degreased)	30 to 45
Aluminum (Isopropanol wiped)	≤60[LMS]
Zinc dichromate	90 to 105
Neoprene	30 to 45
Rubber, nitrile	<5
SBR	90 to 105
ABS	10 to 20
PVC	60 to 75
Polycarbonate	45 to 60
Phenolic	10 to 20
G-10 Epoxy	45 to 60
Wood (oak)	75 to 90
Wood (balsa)	<5

Cure Speed vs. Bond Gap

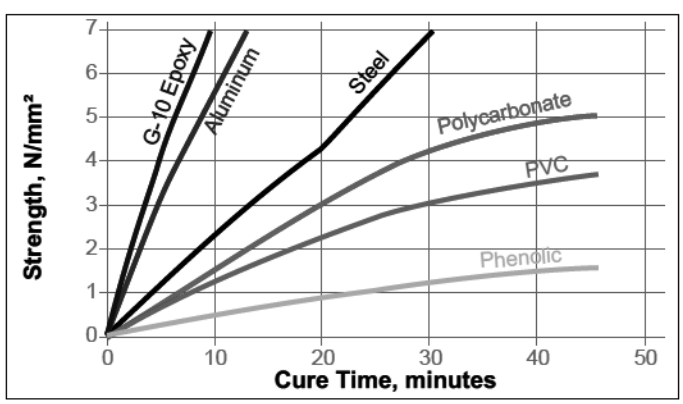
The rate of cure will depend on the bondline gap. Thin bond lines result in high cure speeds, increasing the bond gap will decrease the rate of cure.

Cure Speed vs. Activator

Where cure speed is unacceptably long due to large gaps, applying activator to the surface will improve cure speed. However, this can reduce ultimate strength of the bond and therefore testing is recommended to confirm effect.

Cure Speed vs. Time

The graph below shows the shear strength developed over time at 22 °C / 50 % RH on various substrates and tested according to ISO 4587.



TYPICAL PROPERTIES OF CURED MATERIAL

Cured for 24 hours @ 22°C

Physical Properties:

Coefficient of Thermal Expansion, ISO 11359-2, K^{-1}	80×10^{-6}
Coefficient of Thermal Conductivity ISO 8302, W/(m·K)	0.1
Glass Transition Temperature ISO 11359-2, °C	130

Electrical Properties:

Surface Resistivity, IEC 60093, Ω	10×10^{15}
Volume Resistivity, IEC 60093, Ω·cm	10×10^{15}
Dielectric Breakdown Strength, IEC 60243-1, kV/mm	25
Dielectric Constant / Dissipation Factor, IEC 60250:	
0.1 kHz	2.65 / <0.02
1 kHz	2.75 / <0.02
10 kHz	2.75 / <0.02

TYPICAL PERFORMANCE OF CURED MATERIAL

Adhesive Properties

Cured for 24 hours @ 22°C

Lap Shear Strength :

Steel (grit blasted)	N/mm²	19
	(psi)	(2,700)
Aluminum	N/mm²	15
	(psi)	(2,200)
Nitrile	N/mm²	0.4
	(psi)	(60)
EPDM	N/mm²	0.5
	(psi)	(80)

Block Shear Strength, ISO 13445:

ABS	N/mm²	14
	(psi)	(2,000)
PVC	N/mm²	9
	(psi)	(1,300)
Polycarbonate	N/mm²	6
	(psi)	(840)
Phenolic	N/mm²	13
	(psi)	(1,800)
G-10 Epoxy	N/mm²	20
	(psi)	(2,900)

Tensile Strength, ISO 6922:

Steel (grit blasted)	N/mm²	30
	(psi)	(4,400)
Buna-N	N/mm²	3
	(psi)	(400)

Side Impact Resistance, , J:

Aluminum	≥4[LMS]

Cured for 48 hours @ 22°C

Lap Shear Strength :

Steel (grit blasted)	N/mm²	≥15[LMS]
	(psi)	(≥2,175)

180° Peel Strength, ISO 8510-2:

Steel (grit blasted)	N/mm	4
	(lb/in)	(20)

TYPICAL ENVIRONMENTAL RESISTANCE

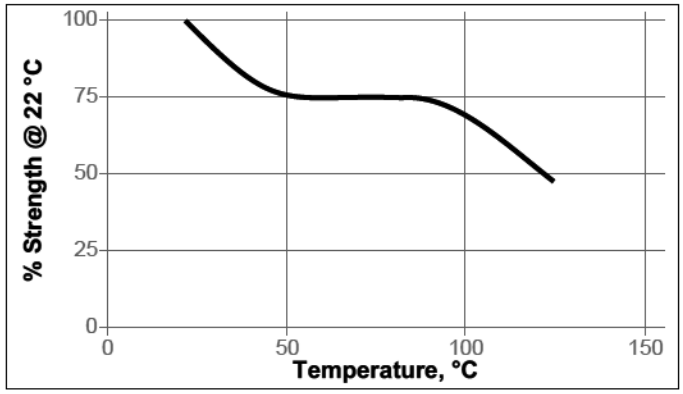
Cured for 72 hours @ 22°C

Lap Shear Strength ISO 4587:

Steel (grit blasted)

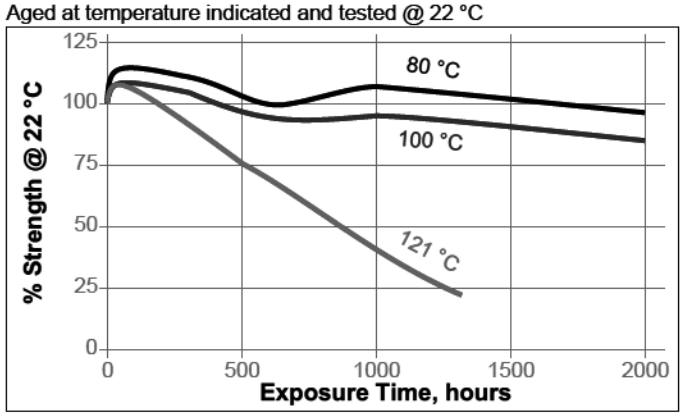
Hot Strength

Tested at temperature



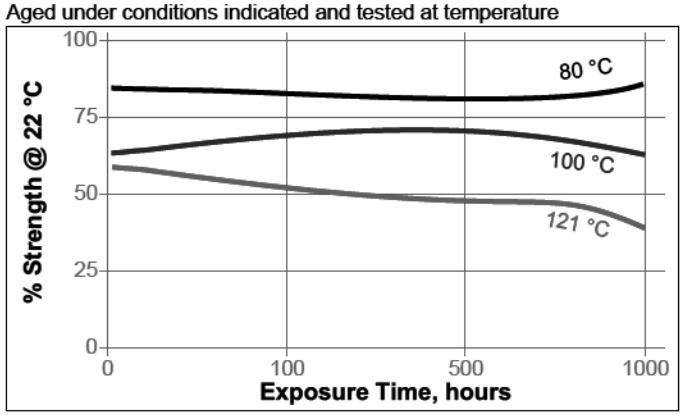
Heat Aging

Aged at temperature indicated and tested @ 22 °C



Heat Aging/Hot Strength

Aged under conditions indicated and tested at temperature



Chemical/Solvent Resistance

Aged under conditions indicated and tested @ 22 °C

		% of initial strength		
Environment	**°C**	**100 h**	**500 h**	**1000 h**
Motor oil	40	100	100	100
Gasoline	22	100	100	90
Ethanol	22	100	100	100
Isopropanol	22	100	100	100
Heat/humidity 95% RH	40	100	100	100

Cured for 72 hours @ 22°C

Block Shear Strength, ISO 13445:

Polycarbonate

Chemical/Solvent Resistance

Aged under conditions indicated and tested @ 22 °C.

		% of initial strength

Environment	°C	100 h	500 h	1000 h
Heat/humidity 95% RH	40	100	100	100

GENERAL INFORMATION

This product is not recommended for use in pure oxygen and/or oxygen rich systems and should not be selected as a sealant for chlorine or other strong oxidizing materials.

For safe handling information on this product, consult the Safety Data Sheet (SDS).

Directions for use

1. For best performance bond surfaces should be clean and free from grease.
2. This product performs best in thin bond gaps (0.05 mm).
3. Excess adhesive can be dissolved with Loctite cleanup solvents, nitromethane or acetone.

Loctite Material Specification[LMS]

LMS dated November 01, 2005. Test reports for each batch are available for the indicated properties. LMS test reports include selected QC test parameters considered appropriate to specifications for customer use. Additionally, comprehensive controls are in place to assure product quality and consistency. Special customer specification requirements may be coordinated through Henkel Quality.

Storage

Store product in the unopened container in a dry location. Storage information may be indicated on the product container labeling.
Optimal Storage: 2 °C to 8 °C. Storage below 2 °C or greater than 8 °C can adversely affect product properties. Material removed from containers may be contaminated during use. Do not return product to the original container. Henkel Corporation cannot assume responsibility for product which has been contaminated or stored under conditions other than those previously indicated. If additional information is required, please contact your local Henkel representative.

Conversions

(°C x 1.8) + 32 = °F
kV/mm x 25.4 = V/mil
mm / 25.4 = inches
µm / 25.4 = mil
N x 0.225 = lb
N/mm x 5.71 = lb/in
N/mm² x 145 = psi
MPa x 145 = psi
N·m x 8.851 = lb·in
N·m x 0.738 = lb·ft
N·mm x 0.142 = oz·in
mPa·s = cP

Disclaimer

The information provided in this Technical Data Sheet (TDS) including the recommendations for use and application of the product are based on our knowledge and experience of the product as at the date of this TDS. The product can have a variety of different applications as well as differing application and working conditions in your environment that are beyond our control. Henkel is, therefore, not liable for the suitability of our product for the production processes and conditions in respect of which you use them, as well as the intended applications and results. We strongly recommend that you carry out your own prior trials to confirm such suitability of our product. Any liability in respect of the information in the Technical Data Sheet or any other written or oral recommendation(s) regarding the concerned product is excluded, except if otherwise explicitly agreed and except in relation to death or personal injury caused by our negligence and any liability under any applicable mandatory product liability law.

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Reference 1.4

Appendix C: PI *curriculum vitae*

Curriculum Vitae

KEITH L. OBSTEIN, MD, MPH, FASGE, FACG, AGAF

Office Address: 1301 Medical Center Drive; 1660 TVC
Nashville, TN 37232

Office Phone Number: 615-322-0128

Mobile Phone: 215-901-9661

Education:

The Johns Hopkins University, Baltimore, MD, B.S. Biomedical Engineering (Materials Science and Engineering concentration), 1996 – 2000

Northwestern University Feinberg School of Medicine, Chicago, IL, M.D., 2000 – 2004

Hospital of The University of Pennsylvania, Philadelphia, PA, The University of Pennsylvania School of Medicine**,** Internship in Internal Medicine (2004-2005). Residency in Internal Medicine (2005-2007)

Brigham and Women's Hospital, Boston, MA, Harvard Medical School, Fellowship in Gastroenterology, 2007 – 2010

Harvard University School of Public Health, Boston, MA, M.P.H. (2009-2010); Program in Clinical Effectiveness (2008)

Licensure and Certification:

Medical Training License, Commonwealth of Pennsylvania, Number MT-183793; Inactive; Original date 06/2004; Expiration date 06/2007

Medical Training License, Commonwealth of Massachusetts, Number 231927; Inactive; Original date 07/01/2007; Expiration date 06/30/2010

Board Certified Internal Medicine, American Board of Internal Medicine, Number 283578; Original date 08/24/2007; Expiration date 12/31/2017

Medical License, State of Tennessee**,** Number 46246; Active; Original date 05/19/2010; Expiration date 10/31/2022

Board Certified Gastroenterology, American Board of Internal Medicine, Number 283578; Active; Original date 11/14/2011; Expiration date 12/31/2022

Academic Appointments:

Vanderbilt University Medical Center, Nashville, TN, Professor of Medicine, Vanderbilt University School of Medicine, Division of Gastroenterology, Hepatology and Nutrition, 01/2022 - Present

Vanderbilt University, Nashville, TN, Associate Professor of Mechanical Engineering, Vanderbilt University School of Engineering, Department of Mechanical Engineering, 07/2015 - Present

Vanderbilt University Medical Center, Nashville, TN, Associate Professor of Medicine, Vanderbilt University School of Medicine, Division of Gastroenterology, Hepatology and Nutrition, 07/2015 - 12/2021

Vanderbilt University, Nashville, TN, Assistant Professor of Mechanical Engineering, Vanderbilt University School of Engineering, Department of Mechanical Engineering, 2012 - 2015

Vanderbilt University Medical Center, Nashville, TN, Assistant Professor of Medicine, Vanderbilt University School of Medicine, Division of Gastroenterology, Hepatology and Nutrition, 07/2010 - 06/2015

Professional Organizations:

American Society for Bioethics and Humanities (2004)

American Gastroenterological Association (2007)

American Society for Gastrointestinal Endoscopy (2010)

Vanderbilt Institute in Surgery and Engineering (2011)

American College of Gastroenterology (2011)

Professional Activities:

Johns Hopkins University Office of Undergraduate Admissions
Alumni Admissions Representative, 2000 – Present

Northwestern University Feinberg School of Medicine–Office of Admissions
Medical School Admissions Committee Member (2003-2004).
Tour Guide and Panel Discussion Participant (2000-2003).
Role included reviewing applicants to identify suitable candidates and to recommend admission of those candidates into the medical school, 2000 - 2004

Hospital of the University of Pennsylvania Ethics Committee
Ethics Committee Member, Housestaff Representative.
Member of the Ethics Committee participating in consults, meetings, education, and policy formation, 2004 - 2006

The Journal of Clinical Ethics
Invited Peer-Reviewer, 2005 – 2010

Brigham and Women's Hospital, Division of Gastroenterology, Education Committee
Fellow Representative, 2008 – 2010

American Society for Gastrointestinal Endoscopy (ASGE)
Member, Training Committee, 2012-2015
Develop residency and fellowship program guidelines for training in endoscopy and related procedures. Develop policy and recommendations for the Society's role on behalf of gastrointestinal endoscopy in its relations with Directors of residency training programs and certifying organizations. Coordination of the First-Year Fellows Endoscopy Training Course. Development of training modules on ASGE website. Plan and evaluate the annual Training Directors Workshop and develop training requirements in all aspects of new and advanced endoscopic skills. Develop templates for educational programs in endoscopy for Training Program Directors. Track trends and statistics in Gastroenterology training programs.

American College of Gastroenterology (ACG)
Member, Public Relations Committee, 2012 – 2018
Increase the visibility of the ACG to the general public through key communications channels: radio, television, print, video, Internet and patient education materials. Serve the public and general press as the authority on clinical GI and liver issues. Strive to earn recognition for ACG's advocacy for patient health care benefits, e.g., colorectal cancer screening. Conduct media outreach surrounding the Annual Scientific Meeting to promote new research findings and advances in clinical gastroenterology.

American College of Gastroenterology (ACG) Educational Affairs Annual Meeting Abstract Review Subcommittee
Member, Stomach Section 2014
Chair, Stomach Section 2015
Member, Clinical Vignettes Section 2017
Member, Clinical Vignettes Section 2020

Endoscopy (Journal)
Invited Peer-Reviewer, 2014 – Present

Gastroenterology (Journal)
Invited Peer-Reviewer, 2014 – Present
Special Section Editor: Continuing Medical Education (CME), 2016 - Present

American Society for Gastrointestinal Endoscopy (ASGE)
Member, Endoscopist-in-Residence (EIR) Task Force, 2014 – 2017
Member, Member Engagement and Diversity Committee, 2016 – 2019
Member, ASGE Recognized Industry Associate (ARIA) Program Task Force, 2015 – 2019
Member, E-Learning Committee, 2019 – 2021

Member, ASGE Recognized Industry Associate (ARIA) Program Committee, 2020 – Present
Member, GI and Advanced Endoscopy Fellows (GIAEF) Training Work Group, 2021 – Present
Member, Education Curriculum and Competencies Council (ECCC), 2021 – Present

Vanderbilt University Medical Center
Program Director, Gastroenterology Fellowship Training Program, 2015 – Present
Director, Continuing Medical Education (CME) Gastroenterology Division, 2015 – Present
Gastroenterology – Emergency Department Liaison, 2017 – Present
Department of Medicine Wellness Task Force, GI Section Chair, 2020 – Present
Participant, Mid-Career Leadership Development Program, 2017
Associate Program Director, Gastroenterology Fellowship Training Program, 2013 – 2015

Alliance for Academic Internal Medicine (AAIM)
Association of Specialty Professors (ASP) Council Member, 2017 – Present
ASP Liaison to the AAIM Research Committee, 2018 – 2020
The AAIM is a national organization that fosters the advancement of learning, discovery, and caring by enhancing the professional growth of academic internal medicine faculty, administrators, and physicians-in-training. I serve as a council member in the leadership structure of the organization and represent the Gastroenterology societies. I am also the liaison for ASP to the AAIM research committee.

Virgo
Member, Medical Advisory Board, 2017 – Present
Medical and surgical solutions company that specializes in automated medical video capture.

American Society for Gastrointestinal Endoscopy (ASGE)/TouchSurgery
Dellert E and Obstein KL; Polypectomy: jumbo cold biopsy forceps, cold snare, and snare cautery for TouchSurgery mobile application
TouchSurgery is the most downloaded app-based surgical simulation platform globally, delivering simulation content to 2.5 million surgeons and healthcare providers around the world. The simulation library for polypectomy is built through active collaboration with the ASGE to provide interactive App-based simulation to learn, simulate, rehearse, and test surgical skills/techniques.

National Image-Guided Therapy (IGT) Workshop 2018
Session 4: Robotic Surgery, Surgical Training, Therapy Delivery Co-Chair, October 2018 (Boston, MA)
The National IGT Workshop is sponsored by the National Institutes of Health (NIH) to foster discourse in translational research in image-guided therapy in the NIH funded community and to communicate the availability of the National Center for Image Guided Therapy as a national resource for tools and technologies in the field. Attendees include NIH funded academic scientists, clinicians, and leaders from industry and federal agencies interested in image-guided interventions.

Accreditation Council for Graduate Medical Education (ACGME)

Milestones 2.0: Gastroenterology Milestones, Committee Member, 2019-Present
The ACGME is the body responsible for accrediting the majority of graduate medical training programs for physicians in the United States. It is a non-profit private council that evaluates and accredits medical residency and internship programs. I serve as a member of the Gastroenterology Milestones work-group/committee.

American Gastroenterological Association (AGA)
Member, Gastroenterology Training Examination (GTE) Committee, 2019-Present
The AGA GTE Committee is responsible for the creation, revision, analysis, and administration of the annual examination that is taken by Gastroenterology trainees across the world. I serve as a member of the committee with special focus on the sections of general gastroenterology and small bowel.

Vanderbilt University Medical Center, Department of Internal Medicine, Wellness Committee
Member, 2020 – Present.
The Department of Internal Medicine at VUMC, under the direction of the Chair of Medicine, has established a Wellness Committee to facilitate community building, engagement with the institution and department, and foster a community of kindness, encouragement, and support for faculty, trainees, and staff at VUMC.

Neptune Medical
Consultant, 2021.
Medical and surgical solutions company that specializes surgical/endoscopic devices.

Vanderbilt University: Destination Vanderbilt—Computer Science
Computer Science Faculty Search Committee Member, 2021 – Present.
Vanderbilt University has established the goal of doubling the faculty of the Department of Computer Science. Under the direction of the Chair of Computer Science, I serve as a member of this committee to create a pool and hire talented candidates.

Vanderbilt Institute for Surgery and Engineering (VISE) Steering Committee
Member, 2021 – Present
The VISE is an interdisciplinary Institute that spans Vanderbilt University and Vanderbilt University Medical Center to facilitate advancement of technologies through effective, efficient, and novel collaboration between Engineers, Computer Scientists, and Medical Professionals. Central to the mission of the institute is the translation of methods, techniques, and devices from the laboratory to the patient, first internally then externally through commercialization of the intellectual property center members have generated.

Vanderbilt University School of Medicine
2022 Faculty Award Review Committee Member, 2022 – Present.
Member of the award review committee.

Academy for Excellence in Education – Vanderbilt University School of Medicine
Member, 2022 – Present.

The Academy for Excellence in Education is an organization to promote, facilitate, and champion excellence in the School of Medicine educational endeavors across the Vanderbilt enterprise. Membership into the Academy is a highly selective process based on demonstration of educational skill, curriculum development, mentorship, multi-format teaching, and scholarship.

Honors and Awards:
Eagle Scout–Boy Scouts of America, 1994

Tau Beta Pi, The National Engineering Honor Society, 1998

Alpha Eta Mu Beta, National Biomedical Engineering Honor Society, 1999

Omicron Delta Kappa, National Leadership Honor Society, 1999

Student Excellence Award for Leadership and Service**,** Johns Hopkins University, 2000

Sonix Corporation Award in Immersion Ultrasonics, 2000

Northwestern University Medical School M1 International Health Fellowship Program, Grant Recipient for Independent Research conducted in Amsterdam, The Netherlands, 2001

Northwestern University Medical School M4 International Health Fellowship Program, Grant Recipient for Independent Work conducted in Chelmsford, England, 2004

Fellow, American Society for Gastrointestinal Endoscopy (FASGE), 2016

Hamlyn Symposium of Medical Robotics Surgical Robot Challenge Overall Winner and Best Application Prize 2016, London, UK, 2016

Fellow, American College of Gastroenterology (FACG), 2017

International Symposium on Medical Robotics, Winner: Best Student Paper Prize 2018, Atlanta, GA, USA, 2018

Fellow, American Gastroenterological Association (AGAF), 2019

Hamlyn Symposium of Medical Robotics Surgical Robot Challenge Best Video Award 2019, London, UK, 2019

Medica 2019 KUKA Innovation Award, Team RoboFORCE, Düsseldorf, Germany, 2019

Digestive Disease Week 2020 Poster of Distinction, Chicago, IL, USA, 2020

Best-of-the-Best Video Award, ASGE Video Competition, Online due to COVID-19, 2020

Teaching Activities:

Patient, Physician and Society II: The Profession of Medicine Class
Guest Lecturer
Northwestern University Medical School. Guest Lecturer on the topic of Physician Assisted Suicide/Euthanasia, with emphasis on the Dutch experience, 2001 - 2004

Education for Physicians on End-of-Life Care (The EPEC Project)
EPEC Trainer–Instructor
A Robert Wood Johnson Foundation supported program that trains healthcare providers to become teachers of the core competencies of palliative care. Currently there are approximately 1400 certified EPEC trainers, 2003 – 2007

The University of Pennsylvania School of Medicine, Department of Medicine, Housestaff Steering Committee
Intern Class Representative (2004-05)
Resident Class Representative (2005-2007)
Elected representative of the Department of Medicine Housestaff to the Residency Program

Hospital of the University of Pennsylvania Ethics Committee
Ethics Committee Member, Housestaff Representative.
Member of the Ethics Committee participating in consults, meetings, education, and policy formation, 2006 - 2007

Patient Doctor II Course: The Abdominal Exam
Faculty, Harvard Medical School.
Teaching second-year medical students examination of the abdomen, 2008- 2010

Introduction to Clinical Medicine
Faculty, Harvard Medical School
Teaching MD/PhD students history taking and physical examination skills. Preceptor for patient encounters in the hospital. Reviewer of students' written H&P's, 2010

Internal Medicine Residency Didactic Curriculum Committee
Gastroenterology Faculty Representative, Vanderbilt University Medical School
Assist with the selection and prioritization of appropriate curriculum topics for interns and residents. Facilitate faculty presenters for each topic. Identify faculty for non-lecture format sessions. Organize and facilitate the educational curriculum, 2010 – 2015

Preceptorship in Clinical Medicine
Preceptor, Vanderbilt University School of Medicine
Preceptor for patient encounters in the outpatient setting for two first-year medical students, 2011 - Present

Patient, Profession, and Society II (PPS II)
Faculty, Vanderbilt University Medical School

Teaching second-year medical students basic epidemiology, biostatistics, and literature review techniques around critical clinical, social, cultural, and interpersonal issues associated with the practice of medicine, 2012 – 2015

Endoscopy Core Curriculum
Co-Director (2012-2020), Director (2020-Present), Vanderbilt University Medical Center, Division of Gastroenterology, Hepatology and Nutrition.
Endoscopy education course for all Gastroenterology Fellows at Vanderbilt University. Features a series of didactic and hands-on experiences, 2012 – Present

Internal Medicine Residency Journal Club
Invited Clinical Expert, Gastroenterology, Vanderbilt University Medical Center
Provide clinical background and expertise for manuscripts that are reviewed/discussed within the field of Gastroenterology, 2012 – Present

American College of Gastroenterology (ACG) Southeast Regional Course
Faculty, Hands-On Session, 2013
Faculty, Hands-On Session, 2015
Faculty, Hands-On Session, 2016
Faculty, Hands-On Session, 2017

Vanderbilt University Gastroenterology Fellowship Program
Program Director, 2015 - Present
Associate Program Director, 2013 - 2015

American Society for Gastrointestinal Endoscopy (ASGE)
Co-Director, First Year Fellows Course, 2013, 2014, 2015
Faculty, First Year Fellows Course, 2017
Annual endoscopy course for first year Gastroenterology fellows that includes both diadatic presentations and hands-on experience. The course takes place at the ASGE's Institute for Training and Technology (IT&T) in Downers Grove, IL.

American Society for Gastrointestinal Endoscopy (ASGE)
Faculty, Senior Fellows Course, 2015
Annual endoscopy course for second- and third-year Gastroenterology fellows that includes both didactic presentations and hands-on experience. The course takes place at Digestive Disease Week the annual Gastroenterology meeting of the AGA, ASGE, AASLD, and SSAT.

Vanderbilt University Division of Gastroenterology, Hepatology and Nutrition
CME Activity Director, 2015 – Present

American Society for Gastrointestinal Endoscopy (ASGE)
Faculty, Lower-EMR Skills Training Assessment Reinforcement (STAR) Certificate Program, 2017, 2019, 2020
The ASGE STAR Certificate Program is an assessment-based curriculum that prepares endoscopists to overcome challenges, gain confidence and demonstrate their "readiness" to perform advanced techniques to medical colleagues. This course focused on Lower-EMR.

American Society for Gastrointestinal Endoscopy (ASGE)
Co-Director, ASGE Recognized Industry Associate (ARIA) Course, 11/09/2015
Director, ASGE Recognized Industry Associate (ARIA) Course, 04/10/2017
Faculty, ASGE Recognized Industry Associate (ARIA) Course, 04/09/2018
Director, ASGE Recognized Industry Associate (ARIA) Exact Science Course, 09/09/2019
Director, ASGE Recognized Industry Associate (ARIA) Course, 11/03/2019
Director, ASGE Recognized Industry Associate (ARIA) Regeneron Course, 06/28-06/29/2022
Director, ASGE Recognized Industry Associate (ARIA) Ironwood Course, Date TBD (COVID)
The ARIA course is a Gastroenterology topic-based educational program for industry representatives to keep them up-to-date on relevant gastroenterology and endoscopic topics. The course takes place at the ASGE's Institute for Training and Technology (IT&T) in Downers Grove, IL and includes didactics, question and answer series, and a hands-on session.

American Gastroenterological Association (AGA)
Faculty, Training Directors' Workshop, 2017
The biennial workshop for all Gastroenterology fellowship program directors, associate/assistant program directors, and program coordinators/administrators that is co-sponsored by the AGA Institute, American College of Gastroenterology, American Association for the Study of Liver Diseases and the American Society for Gastrointestinal Endoscopy.

American Society for Gastrointestinal Endoscopy (ASGE)
Faculty, EMR Skills Training Session, 2017
Hands-on training session held at Digestive Disease Week 2017 in Chicago, IL for those participating in the ASGE post-graduate course.

American Society for Gastrointestinal Endoscopy (ASGE)
Faculty, Colonoscopy: Diagnostic to Therapeutic Course, 2018
Colonoscopy course for physicians. The course takes place at the ASGE's Institute for Training and Technology (IT&T) in Downers Grove, IL and includes didactics, question and answer series, and a hands-on session.

American Society for Gastrointestinal Endoscopy (ASGE)
Faculty, GI Organizational Leadership Development (GOLD) Program, 2019
GOLD is a 12-month program offering gastroenterologists an opportunity to develop and enhance leadership and career development skills through education, coaching, and building professional networks. The purpose of the GOLD program is to provide the knowledge and skills needed to enhance the path to leadership within academic or private practice medicine and within ASGE.

EXCellence In Clinical TEaching (EXCITE) Program
Coach, Vanderbilt University Medical Center (VUMC), Division of Internal Medicine, 2019 – Present
The EXCITE Program is a longitudinal curriculum and experiential learning opportunity for Internal Medicine Residents at VUMC to gain foundational knowledge and skills related to teaching as a complement to their professional development.

Research Supervision:

Elan Ahronovich, MS (School of Engineering Doctoral Student)
Role: Research co-advisor, 2021 - Present

Claudio Tombazzi, MD (Internal Medical Resident)
Role: Research mentor, 2020 - Present

Claire Landewee (Undergraduate Student)
Role: Primary research mentor, 2019 - Present

Gabriel Sandoval, MD (Internal Medical Resident)
Role: Primary research mentor, 2019 - Present

Catherine Howe, MD (Gastroenterology Fellow)
Role: Primary research mentor, 2019 - 2021

Sai Rajagopalan, PhD (Vanderbilt University School of Medicine Medical Student)
Role: Primary research mentor, 2018 - 2021

Alex P. Mamunes, MD (Internal Medical Resident; Gastroenterology Fellow)
Role: Primary research mentor, 2018 - 2020

Jordan Orr, MD (Gastroenterology Fellow)
Role: Research committee member, 2018 - 2020

Federico Campisano, PhD (School of Engineering Doctoral Student)
Role: Research mentor and dissertation co-chair, 2015 - 2020

Sean C. Rice, MD (Gastroenterology Fellow)
Role: Primary research mentor, 2015 - 2020

Piotr Slawinski, PhD (School of Engineering Doctoral Student)
Role: Research mentor and dissertation committee co-chair, 2014 - 2019

Nicoló Garbin, PhD (School of Engineering Doctoral Student)
Role: Research mentor and dissertation committee co-chair, 2016 - 2019

Addisu Taddese, PhD (School of Engineering Doctoral Student)
Role: Research mentor and dissertation committee member, 2012 - 2018

Michelle Izmaylov, BS (Medical Student)
Role: Primary research mentor, 2015 - 2016

Cregan Laborde, MD (Gastroenterology Fellow)
Role: Primary research mentor, 2014 - 2016

Marco Beccani, PhD (School of Engineering Doctoral Student)
Role: Research mentor and dissertation committee member, 2011 - 2015

Christian DiNatali, PhD (School of Engineering Doctoral Student)
Role: Research mentor and dissertation committee member, 2011 - 2015

William F. Ergen, MD (Internal Medical Resident)
Role: Primary research mentor, 2013 - 2015

Amy S. Schindler, MD (Gastroenterology Fellow)
Role: Primary research mentor, 2011 - 2013

Eric P. Trawick, MD (Gastroenterology Fellow)
Role: Research committee member, 2011 - 2013

Virginia Pensabene, PhD (School of Engineering Postdoctoral scholar)
Role: Research committee member, 2011 - 2013

Research Program:

State University of New York at Buffalo Advisor: Israel Ziv, MD. Student researcher in the Orthopaedic Research Laboratory conducting biomechanics and orthopaedic research, 1997 – 1999

Johns Hopkins University Mentor: Boro Djordjevic, PhD, Student researcher and design project coordinator for the Department of Materials Science and Engineering Center for Nondestructive Evaluation, 1999 - 2000

Northwestern University Feinberg School of Medicine and Vrije Universiteit
Mentors: Gerrit K. Kimsma, MD, MPh and Tod Chambers, PhD. Independent research study coordinated between Northwestern University Feinberg School of Medicine Department of Medical Humanities and Bioethics (USA) and the Vrije Universiteit Department of Metamedica (Amsterdam, The Netherlands), conducted in The Netherlands on the Dutch experience with euthanasia, 2001 – 2006

University of Pennsylvania School of Medicine, Division of Gastroenterology and the Center for Clinical Epidemiology & Biostatistics
Advisor: Yu-Xiao Yang, MD, MSCE
Research project on colon cancer screening in the demented elderly population and several studies examining the relationships associated with the development of spontaneous bacterial peritonitis, 2005 – 2007

Center for Integration of Medicine and Innovative Technology (CIMIT), Image Guidance Laboratory (IGL)
Mentor: Kirby G. Vosburgh, PhD
Research projects on kinematics for performance measures in endoscopy, endoscopic skills assessment and training, image registered gastroscopic ultrasound (IRGUS), image registered endoscopic retrograde cholangiopancreatography and image guidance technology in endoscopy, 2008 - 2010

Brigham and Women's Hospital, Harvard Medical School
Division of Gastroenterology, Section of Developmental Endoscopy
Mentor: Christopher C. Thompson, MD, MSc, FACG, FASGE
Research projects on endoscopic device development, endoscopic bariatric procedures/outcomes, endoscopy training/education and Natural Orifice Transluminal Endoscopic Surgery (NOTES), 2008 – 2010

Vanderbilt University Medical Center
Division of Gastroenterology
Center for Technology-Guided Therapy
Surgical Navigation Apparatus Research Laboratory (SNARL)
Mentor: Robert L. Galloway, Jr., PhD
Kinematic data for technical performance measures in endoscopy, endoscopic skills assessment and training, image registered colonoscopy, and image guidance technology in endoscopy. Quality improvement in endoscopy, 2010 - Present

Vanderbilt University
Department of Mechanical Engineering
Science and Technology of Robotics in Medicine
The STORM Lab (USA, UK)
United States Lab Director: Keith L. Obstein, MD, MPH, FASGE, FACG, AGAF
United Kingdom Lab Director: Pietro Valdastri, PhD
Collaborator and USA lab director on the development and implementation of a magnetic driven wireless capsule robot for utilization in gastrointestinal endoscopy and surgery, 2011 - Present

Vanderbilt University Medical Center Division of Gastroenterology; Center for Human Nutrition
A prospective, multi-center registry for patients with short bowel syndrome.TED-R13-002
Principal Investigator: Keith L. Obstein, MD, MPH, 2014 - 2016

Tillotts Pharma; Cancer Prevention Pharmaceuticals
A double-blind, randomized, phase III trial of the safety and efficacy of CPP-1X/Sulindac compared with CPP-1X, Sulindac as single agents in patients with familial adenomatous polyposis (FAP). CPP FAP-310; CPP-1X = DFMO = Eflornithine
Site Principal Investigator: Timothy Geiger, MD, 2014 - 2020

Freenome; PREEMPT CRC: PREvention Employing a Multiomics Plasma-based Test for ColoRectal Cancer
A large registrational, multi-site, Pre-Market Approval study of a blood based test for colorectal cancer screening in 14,000 patients undergoing age appropriate average risk colonoscopy. Blood sample collected prior to bowel preparation and colonoscopy. FRNM004: Site 051.
Site Principal Investigator: Keith L. Obstein, MD, MPH, 2020 - Present

Research Funding:
Center for Integration of Medicine and Innovative Technology (CIMIT) Grant

Colonoscopy: Kinematics-based metrics to improve performance and training
CIMIT, Department of Defense USAMRAA
W81XWH-07-2-011
($97,545)
To improve the quality of colonoscopy and efficiency of training by establishing benchmark performance metrics and standards that characterize levels of expertise in colonoscopy, 2011-2012

Vanderbilt Institute for Surgery and Engineering (ViSE) Grant
A novel robotic platform for colorectal cancer screening
Vanderbilt University, ViSE/VICTR
Co-I ($30,000)
To develop a novel technique for colorectal cancer screening by harnessing meso-scale magnetic robots, 2012-2013

Vanderbilt Discovery Grant
Defeating colorectal cancer by a novel robotic approach for screening
Vanderbilt University, University Central
Co-I ($99,988)
To integrate autofluorescence and optical spectroscopy with magnetic manipulation of a capsule robot to improve diagnosis of colorectal cancer, 2012-2014

Given Imaging, Ltd.
Measurement of Friction in the Intestine
Co-I ($10,000)
To measure the friction that a magnetic capsule must overcome to move in the small intestine, 02/2013 – 11/2013

The Broad Foundation
Development and pre-clinical validation of a soft-tethered endoscopic robot to replace colonoscopy
Co-I ($110,000)
This seed grant supports the optimization of a robotic platform for magnetic colonoscopy, focusing on magnetic coupling robustness, real-time tracking of camera pose, and the preliminary development of an intuitive controller. The outcomes of this short project will provide additional preliminary results for the work proposed in the present application, 2013-2014

National Science Foundation (NSF)
CO_2 Insufflator for Minimally Invasive Procedures
Co-I ($50,000)
The goal of this project is to develop and assess a disposable and low-cost CO_2 insufflator based on an effervescent reaction to be used during standard colonoscopy, 2013-2014

National Institutes of Health (NIH) R01 (2014-2020)
A magnetic capsule endoscope for colonoscopy in patients with IBD ($1,504,394.64)
5R01EB018992-03
Principal Investigator (PI) 2016-2020

1R01EB018992-01
Co-I 2014-2016
Preparing a novel robotic magnetic colon capsule endoscopy platform for FDA approval.

Vanderbilt Institute for Surgery and Engineering (ViSE) Grant
Ultra-low-cost endoscopy for gastric cancer screening in Central America.
Vanderbilt University, ViSE/VICTR
PI ($40,000)
Optimization of a novel platform for gastric cancer screening in low- and middle-income countries, 2016

Engineering and Physical Sciences Research Council (EPSRC) Grant
Ultra-low-cost endoscopy for gastric cancer screening in rural China.
EP/P027938/1
Visiting Researcher (£1,584,528.90)
Optimization of a novel platform for gastric cancer screening in rural China.

Higher Education Funding Council for England (HEFCE) Grant
Ultra-low-cost diagnosis of *Helicobacter Pylori* in rural India.
PI of Subcontract Award (£40,000.00)
Optimization of a novel platform for diagnosis of H. Pylori in rural India, 2018-2019

American Gastroenterological Association (AGA)-Boston Scientific Technology and Innovation Pilot Research Award 2018
Whipcord Automated Necrosectomy Debridement (WAND) device: prototype development and *ex vivo* testing.
Collaborator ($30,000)
Design and build a WAND device compatible for use with a flexible endoscope and capable of selective tissue fragmentation.

Cancer Research United Kingdom (CRUK) Grant
A robotic magnetic flexible endoscope for painless colorectal cancer screening, surveillance and intervention.
A27744
Collaborator (£1,129,367.07)
Optimize and conduct a first in-human feasibility study of our magnetic flexible endoscope (MFE) robotic platform.

National Institute for Health Research (NIHR) Grant
An innovation in same-day bowel cleaning and blockage removal.
Collaborator (£10,000)
Award for clinically driven theme: The future of surgery. Design and evaluation of a novel platform for bowel cleansing prior to colonoscopy in patients with Cystic Fibrosis (CF).

National Institutes of Health (NIH) R41 (2019-2021)
Enabling dexterous surgery at the tip of a flexible endoscope: A low-cost, disposable, steerable sheath.
R41EB028229
Co-I ($151,565)
To build a robotic system that will enable proof of concept for a new bimanual endoscopic device which will assist with the removal of colon polyps.

National Institutes of Health (NIH) R44 (2020-present)
Squashing the scope superbug: A disposable system for ERCP that saves patients from bacterial cross-contamination.
R44DK126606
Collaborator ($983,749)
This supports the mechanical design, manufacturing, and experimental validation of a novel disposable system that places the functionality of an ERCP endoscope into a standard forward viewing endoscope.

National Institutes of Health (NIH) R01 (2021-present)
A magnetic capsule endoscope for colonoscopy in patients with IBD ($1,264,552)
2R01EB018992-05
Principal Investigator (PI)
Preparing a novel robotic magnetic flexible endoscopy platform for first-in-human trials and development of a novel colon visualization index.

Vanderbilt Institute for Surgery and Engineering (VISE) Grant (2021-present)
Assist-as-needed intelligent haptics for training and semi-automation of colonoscopy.
Vanderbilt University, VISE/VICTR
Co-PI ($20,000)
Development of an assist-as-needed platform for facilitation of endoscopic training and procedural technical efficiency.

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Thompson CC, Westervelt R, Nemiroski A, **Obstein KL**. System and method for wireless biosensor monitoring. US Patent Application 20130018235; filed November 2010.

Gerding J, Smith BF, **Obstein KL**, Valdastri P. Tetherless Insufflation to Enable Wireless Capsule Endoscopy. US Patent Application 4/029,687; priority date September 17, 2012.

Beccani M, Di Natali C, **Obstein KL**, Valdastri P. Real-time pose and magnetic force detection for a wireless magnetic capsule. US Provisional Application 61/753,755; filed Jan 17, 2013; converted to PCT/US2014/012086 on January 17, 2014.

Smith BF, **Obstein KL**, Valdastri P. Insufflation and CO2 Delivery for Minimally Invasive Procedures. US Patent Provisional Application 61/864,819; filed Aug 12, 2013; converted to PCT/US2014/457,676 on August 12, 2014.

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Obstein KL, Martins FP, Fernández-Esparrach G, Thompson CC. Endoscopic Ultrasound (EUS)-guided Celiac Plexus Neurolysis (CPN) using a Reverse Phase Polymer: An Initial Evaluation in a Porcine Model. World Journal of Gastroenterology. 2010;16(6):728-31.

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Tierney W (host); Presenters/Panelists: Abraham B, Farraye F, **Obstein KL**. ASGE Webinar: The impact of COVID-19 on GI practices. January 27, 2021.

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Obstein KL (moderator). ASGE DDW Fellow Developed Best Case Reports for Advanced Luminal GI. May 21, 2022.

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Appendix D: NASA-TLX Questionnaire

NASA-TLX Questionnaire
EndoTheia NuView Device

Mental Demand
How much mental and perceptual activity was required (thinking, deciding, planning, calculating, searching) when using the NuView device and the forward-viewing endoscope? Was the task easy or demanding, simple or complex, exacting or forgiving?

☐	☐	☐	☐	☐
Very Low	Low	Moderate	High	Very High

Physical Demand
How much physical activity was required (i.e. pushing, pulling, turning, controlling, activating) when using the NuView device and the forward-viewing endoscope? Was the task physically easy or demanding, slow or brisk, restful or laborious?

☐	☐	☐	☐	☐
Very Low	Low	Moderate	High	Very High

Temporal Demand
How much time pressure did you feel while using the NuView? Was the pace slow and leisurely or rapid and frantic?

☐	☐	☐	☐	☐
Very Low	Low	Moderate	High	Very High

Frustration Level
How discouraged, stressed, irritated, and annoyed versus gratified, content, and relaxed did you feel while using the NuView device?

☐	☐	☐	☐	☐
Very Low	Low	Moderate	High	Very High

Overall Performance
How successful do you think you were in accomplishing the goals of the task when using the NuView device? How satisfied were you with your performance in accomplishing these goals?

☐	☐	☐	☐	☐
Very Poor	Poor	Moderate	Good	Very Good

Effort
How hard did you have to work (mentally and physically) to accomplish your level of performance when using the NuView device?

☐	☐	☐	☐	☐
Very Low	Low	Moderate	High	Very High

Visualization Quality

How would you rate the quality of the papilla visualization when using the NuView device? Were you able to clearly and comprehensively visualize the papilla? Was the visualization quality negatively impacted by debris or occlusion?

☐	☐	☐	☐	☐
Very Poor	Poor	Moderate	Good	Very Good

Illumination Quality

How would you rate the quality of the illumination when using the NuView device? Did you have adequate lighting to carry out your clinical objective?

☐	☐	☐	☐	☐
Very Poor	Poor	Moderate	Good	Very Good

Adapted from:

Hart, S. and Staveland, L., 'Development of NASA-TLX (Task Load Index): Results of Empirical and Theoretical Research.' *Human Mental Workload,* 1988. pp. 139-183.

Appendix E: Informed Consent

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Visualization of the papilla through use of the NuView device in patients with FAP
Version Date:	04/25/2022
PI:	Dr. Keith L. Obstein

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to take part in this research study because you are undergoing screening related to Familial Adenomatous Polyposis (FAP) and your medical team has recommended you as an excellent candidate for endoscopic visualization of the papilla (the location where your bile duct enters into your small intestine that is susceptible to polyps and cancer). The purpose of this study is for us to evaluate a new device that attaches to the endoscope to allow your physician to visualize your papilla using a single forward facing gastroscope instead of having to use two different endoscopes. This research has the potential to reduce procedure time for future patients, reduce the chance of infection, and to offer a lower cost option for FAP screening.

This study is a low-risk study that involves all of the usually performed steps in the standard of care for patients undergoing a routine gastroscopic examination of the mucosal lining for FAP. The study includes a single investigational step in which the physician will attempt to visualize your papilla by using the investigational NuView end cap. This step will include attaching the NuView to the endoscope and then inserting the endoscope in the standard clinical method to confirm visualization of your papilla. Following this step, the investigational device will be removed from the gastroscope and remainder of your endoscopy will be performed as usual per the standard of care.

There will be no additional visits beyond the usual standard of care required for this research and the overall amount of time required for the investigational step is negligible in the course of treatment. Similarly, no additional restrictions or limitations on daily activities due to the investigational step are expected.

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You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Side effects and risks that you can expect if you take part in this study:

There are risks associated with any endoscopic procedure and with Anesthesia (Monitored Anesthesia Care: MAC). These risks are rare (less than 1%) and include but are not limited to bleeding, infection, tissue trauma, stroke, and/or the need for additional surgery. These surgical risks associated with endoscopy and anesthesia are rare and no greater for patients receiving the investigational procedure than for the standard of care procedures.

Additional risks associated with this study are as follows:

Detachments events: *as with any distal endoscope attachment, the device may become detached from the endoscope. This event is expected to be rare (less than 1%) and the only harm expected is a slight delay (45-120 seconds) to in the procedure time as the device is retrieved.*

Sterility: as with any endoscopic procedure, sterility is an important consideration in order to prevent infection. The investigational device has been sterilized prior to use.

Biocompatibility: as with any medical device biocompatibility is important to prevent allergic reactions. The investigational device is made from 100% biocompatible materials that have been tested to ISO 10993-1 standards.

Tissue trauma and device breakages/failures: as with any endoscopic medical device, tissue trauma is a potential safety consideration. The investigational device has been designed to be atraumatic and has undergone verification testing to verify its safety.

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Device failures and breakages: as with any medical device there is a potential for device breakages and failures during the procedure. With regard to the investigational device, even if the device does break or fails, the only expected harm would be a slight increase *(45-120 seconds) in procedure time as the device is retrieved and discarded.*

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Other Risks:
N/A

Good effects that might result from this study:

The benefits to science and humankind that might result from this study:

Subsequent physicians may benefit from the proposed research by having access in the future to the best potential patient care options, reducing infections, and by having a more cost-effective treatment option available.

Subsequent patients may benefit from the proposed research by having a decreased overall procedure time during FAP examination and by a reduction of potential for tissue damage by decreasing the number of endoscope insertions during the procedure (the investigational device has the potential to eliminate one of the two endoscopes from being used in the standard of care for patients with FAP). Further, wide scale adoption of the investigational device has the potential to reduce costs associated with the procedure

Procedures to be followed:

The below table outlines the planned study procedures. The procedure will include 1) Informed consent, 2) review of the inclusion/exclusion criteria, 3) review of medical history, 4) a routine pregnancy test for women of childbearing age, 5) gastroscope assessment of tissue, 6) endoscopic validation of the target with the investigational device, 7) endoscopic confirmation of the target using a standard duodenoscope, 8) review of adverse events, and 9) endoscopic post-op NASA/questionnaire completed by the physician.

Study Procedures

	Screening	Endoscopic Examination	Follow up
Obtain Informed Consent	X		
Review Inclusion/Exclusion Criteria	X		
Review Medical History	X		
Routine Pregnancy Testing (urine or blood)		X[a]	
Gastroscope assessment of tissue		X	
Endoscopic Validation of target with the NuView		X[b]	
Endoscopic confirmation of target using a standard Duodenoscope		X	
Review Adverse Events		X	X
Endoscopic Post-Op NASA/Questionnaire			X[b]

(a) Performed pre-operatively for women of childbearing potential
(b) The Investigational Step in this study procedure. All other steps within the protocol will be performed per the standard of care

Payments for your time spent taking part in this study or expenses:

You will not be compensated for taking part of this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:

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If it is determined by Vanderbilt and the Investigator (with input from EndoTheia, Inc.) that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with the treatment of that injury.

There are no plans for Vanderbilt or EndoTheia, Inc. to pay for the costs of any additional care. There are no plans for Vanderbilt or EndoTheia, inc. to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact **Casey Koza, RN** at **(615) 875-6642** or **Dr. Keith Obstein** at **(615) 875-5856**. If you cannot reach the research staff, please page the study doctor at 615-831-6292.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
Participants will be removed from this study if they ask to be removed. Subjects may decline participation at any time by informing Keith Obstein (615-875-5856).

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Confidentiality:

Participants will receive a 3-digit identification number from 001-003 in the order of their enrollment. Patient identification numbers will be linked to their name on a password secured Vanderbilt University Computer only accessible by approved research study staff. The field notes and interview notes taken by any observers will not contain any identifiable information. Any endoscopic video/audio recording will not contain any identifiable information. At the conclusion of the research study, the PI will maintain all the information on a secure, encrypted, Vanderbilt University computer.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Obstein (the PI), and his staff will comply with any and all

laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:
Information the procedure may be made available to others to use for research. To protect your privacy, we will not release your name.

Study Results:
Results will be shared (upon request) with participants for their respective procedure.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Study Title: Visualization of the papilla through use of the NuView device in patients with FAP
Version Date: 04/25/2022
PI: Dr. Keith L. Obstein

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer
Time	

Consent obtained by:

Date	Signature
Time	Printed Name and Title