Clinical Investigational Plan (CIP) INFORMATION	
Title:	Outpatient Colonoscopy: Demonstrating Effective Salvage of Inadequate Colonoscopies Utilizing the Pure-Vu EVS System
CIP Number:	**CL00052**
Version Date:	October 31, 2022
Amendment	2.0
Sponsor:	Motus GI Medical Technologies LTD. 1301 E. Broward Blvd. 301 Fort Lauderdale, FL 33301

Summary of Changes to CIP			
Version	**Section**	**Description of Change**	**Reason for Change**
Original	NA	NA- Original document	NA
Amendment 1	Throughout protocol	Updated statistical strategy for sample size; additional exclusion criteria added. Safety endpoint changed to a comparison to reported standards. Formatting and grammar updates.	Updated Statistical Calculations, Clarification for all sections
Amendment 2	Statistical	Updated sample size and clarified statistical definitions. Added bulleted expected risks to align with consent language. Updated exclusion criteria and aligned post procedure follow up visit up to 14 days.	Updated sample size; Updates based on feedback received during the investigator meeting

Investigator Signature Page

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I, the undersigned, have read and understood the protocol specified above and agree on its content. I agree to perform and conduct the study as described in the protocol and in accordance with the relevant laws/regulations and standards.

_____ _____ _____

Name Signature Date

Table of Contents

1) Protocol Synopsis

Study Summary	
Study Purpose	The aim of this study is to demonstrate that the use of the Pure-Vu EVS System can salvage inadequately prepared optical colonoscopies (OCs) to adequate OCs. Inadequate OCs defined as such if any of the following are met: ▪ Boston Bowel Preparation Score (BBPS) < 6 (Adequacy is defined as BBPS of 2 or greater in each segment) ▪ Inability to identify > 5mm polyps
Primary Objective	The primary objective of this study is to demonstrate the reduction of inadequate colonoscopies when Pure-Vu EVS System is used to salvage inadequately prepped colons as defined by the multi-society guidelines (USMSTF).
Secondary Objective	The secondary objective of this study is to assess the impact of the Pure-Vu System on patient outcomes.
Study Procedures	
Protocol Number	CL00052
Protocol Title	Outpatient Colonoscopy: Demonstrating Effective Salvage of Inadequate Colonoscopies Utilizing the Pure-Vu EVS System
Study Sponsor	Motus GI Medical Technologies LTD. 1301 E. Broward Blvd. 301

	Fort Lauderdale, FL 33316
Study Type	Multicenter, Prospective, Consecutive Series, Pragmatic Clinical Trial
Study Device	Pure-Vu EVS System
Study Phase	Post-market
510 (k) Number	K220007 Class II
Study Location	United States
Study Duration	Study period will last approximately 12 months
Planned Follow-Up	Follow-up call will be conducted within 14 business days after the procedure
Subject Population	Patients who are eligible and are scheduled for an outpatient colonoscopy procedure
Sample Size	Subjects will be enrolled until 115 inadequate bowel prep cases via SOC are accrued and subsequently treated with Pure-Vu. 115 IBP cases provides 90% power and with an expected 12% inadequate bowel prep rate and accounting for 10% attrition, approximately 1,067 subjects will need to be enrolled to achieve 115 inadequate preps required Pure-Vu. A minimum of 50% of enrollees with inadequate bowel prep must utilize Medicare or Medicaid as their insurance provider. The following assumptions were considered for sample size calculation: • Performance goal for 30% reduction • ≥90% Power and two-sided α= 0.05 • True reduction in IBP vs. SOC = 50% • ~10% attrition rate
Planned # of Sites	Up to 15 clinical sites

Primary Endpoints	Rate of incomplete colonoscopies due to inadequate preparation salvaged to adequate colonoscopies with the use of the Pure-Vu EVS System. Inadequate OCs defined as such if any of the following are met: ▪ BBPS < 6 (Adequacy is defined as BBPS of 2 or greater in each segment) ▪ Inability to identify > 5mm polyps The estimated rate of salvaged preparations will be calculated and presented with exact two-sided 95% confidence interval: Number of preps inadequate with SOC and adequate after Pure-VU EVS System / Number of preps inadequate with SOC. The lower bound will be compared to a 30% performance goal.
Secondary Endpoints	The following secondary endpoints will be assessed: 1. Number of polyps and adenomas: type, location, size, pathology, and morphology, as well as: ● Polyp Detection Rate (PDR) ● Polyp Miss Rate (PMR) ● Adenoma Detection Rate (ADR) ● Adenoma Miss Rate (AMR) ● Adenoma Per Colonoscopy (APC) ● Adenomas Per Positive Patient (APP) ● Sessile Serrated Adenoma Detection Rate 2. BBPS before and after Pure-Vu EVS use 3. Other Procedural Outcomes (including but not limited to): ● Sedation type ● Procedure time: time to cecum and withdrawal time ● Intraprocedural tools 4. Cecum Intubation Rate

	5. Compliance to published interval guidelines for surveillance or repeat screening (Proscribed intervals per USMSTF)
Tertiary Endpoints	1. Clinician Satisfaction 2. Economic Impact
Primary Safety Endpoint	Comparison of SAE rates between Pure-Vu subjects and the published serious complication rate of standard colonoscopy procedures (2.8%)[12]
Secondary Safety Endpoint	All adverse events that are definitely and/or potentially attributed to Pure-Vu will be summarized using descriptive statistics.
Eligibility Criteria	**Inclusion Criteria** 1. Eligible adults aged between 40-80 2. Elective outpatient colonoscopy by participating gastroenterologist **Exclusion Criteria** 1. Not competent to consent 2. Known or suspected bleeding disorders such as, but not limited to hemophilia and von Willebrand disease 3. History of colonic resection 4. Prior incomplete colonoscopy due to patient anatomy 5. Diverticulitis 6. Active Inflammatory bowel disease (Crohn's, Ulcerative Colitis, or Indeterminate) 7. Known or suspected colon stricture/fistula 8. Hereditary Colorectal Cancer Syndrome 9. Subject is pregnant or suspected pregnant
Interim analyses	There are no interim analyses planned.

2) Acronyms and Definitions

ADE	Adverse Device Effect
AE	Adverse Event
BBPS	Boston Bowel Preparation Scale
CIP	Clinical Investigation Plan
CMP	Clinical Monitoring Plan
CRC	Colorectal Cancer
CRF	Case Report Form
CRO	Clinical Research Organization
DMP	Data Management Plan
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GI	Gastrointestinal
IBP	Inadequate Bowel Preparation
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IFU	Instruction For Use
IRB	Institutional Review Board
ISO	International Organization for Standardization
OC	Optical Colonoscopy

MAC	Monitored Anesthesia Care
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
USADE	Unanticipated Serious Adverse Device Effect
USMSTF	United States Multi-Society Task Force
WS	Workstation

3) Introduction

This document is a protocol for human research study. This study will be conducted in accordance with local government regulations, and applicable international standard of Good Clinical Practice, and institutional research policies and procedures.

4) Background

As of 2019, it is estimated that more than sixteen million colonoscopies were performed annually in the United States (1). This is not surprising given that colonoscopy is the gold standard in visualizing the lower gastrointestinal (GI) tract. Patients receive a colonoscopy for a variety of reasons including lower GI bleeds, chronic diarrhea and abdominal pain, iron deficiency anemia, hematochezia, and most importantly, for colorectal cancer (CRC) screening and surveillance, which currently accounts for 60-70% of colonoscopy indications (2). While it is true that other minimally or noninvasive technologies exist, such as blood-immunological test, CT colonography and capsule endoscopy, colonoscopy remains the current gold standard as it allows a clinician to view the entire lower GI tract, detect and diagnose the cause of symptoms, screen for precursor colorectal neoplasia, and in some instances, provide interventions in real time.

The first colonoscopy procedures were conducted in 1969 and by the late 1970's it was cemented as a standard procedure for most gastroenterologists (3). Between 1969 and today, several advancements have been made in the colonoscopy space including improved endoscopes, the move to video endoscopes, streamlined bowel preparation regimens, updates to intraprocedural tools, and by 2020, the first artificial intelligence aided screening colonoscopies were occurring in Europe. While advancements in the GI space have been made continually since the first procedures, it wasn't until

2006, 35+ years after the first colonoscopy, that standardized quality metrics were adopted and tracked in clinical practice. Even with these innovations and guideline creations, certain aspects of colonoscopy still present significant hurdles to both the patients and treating clinicians. One such barrier is that of bowel preparation.

Each patient presenting to colonoscopy is required to prepare their bowel to ensure that the bowel is empty of any contaminants and that the mucosa of the large intestine is properly exposed. For an outpatient colonoscopy (and the standard of care for this trial), a typical preparation regimen includes 24-hour clear liquid diet in combination with a prescribed or over-the-counter purgative. Bowel purgative can include anything from over-the-counter laxatives to a 2L-4L liquid pharmacologic agent. Even though there has been some innovation around bowel preparation, such as split dose regimens and low volume prep agents, bowel preparation remains one of the largest impediments to getting patients to a screening or surveillance colonoscopy. Contributing factors are in part due to the volume of fluid ingested, the intended effects of preparation, the need to take off work for multiple days, the out-of-pocket cost and the side effects related to the preparation process. In instances where a patient is fully compliant with the bowel preparation regimen, they may still present for their procedure inadequately prepped. Several risk factors associated with inadequate bowel preparation (IBP) include older age, medications such as opioids and antidepressants, comorbidities like diabetes and obesity, socio-economic status, and while these factors have been identified, there is no validated algorithm that can predict whether a patient will present with IBP (4). It should be noted that once a patient presents with an inadequately prepped colon at the initial procedure, 24-36% of those patients will have a recurrence of IBP at subsequent procedures (5).

The United States Multi-Society Task Force (USMSTF) defines adequate bowel preparation by the clinician's ability to see polyps larger than 5mm which is a key metric in obtaining a high-quality colonoscopy (6). In fact, guidelines suggests that colonoscopies with inadequate preparation be repeated within one year, however in real world practice, sub-optimal bowel preparation that doesn't quite meet the threshold of "inadequate" is associated with more frequent deviations (shortened interval) from colorectal cancer (CRC) screening and surveillance guidelines.

Increased colonoscopy frequency resulting from inadequate preparation raises a number of safety and cost considerations for both patients as well as the overall healthcare system. Even in situations where a patient presents with adequate bowel preparation for a repeat colonoscopy, there are significant financial considerations for patients, payers, and endoscopists. When factoring in the unpleasant preparation experience, potential side effects and financial burdens for patients, roughly 54% of

patients do not return for the recommended repeat colonoscopy (5). For the healthcare system, after an incomplete examination, the reimbursement paradigm does not always guarantee that a repeat colonoscopy is 100% reimbursed. Due to this, average interval times for inadequately prepped colons often exceed the recommended guidelines.

Per an article published by Calderwood et al in 2022, 25% of procedures are inadequately prepped, but even with this significant number, there has been limited evidence-based guidance on bowel preparation for patients who have had, or are at high risk for, inadequate preparation (7). As a result, numerous patients present on the day of colonoscopy with inadequate preparation and their treating clinicians are left with limited options to salvage poor preparation. In these instances, clinicians can prescribe additional oral purgative for later in the day colonoscopy or reschedule for a next day colonoscopy (thus prolonging the patient experience), attempt additional cleaning through the endoscope at time of procedure, or attempt a through-the scope enema. Regardless of salvage approach, there's an inherent trickledown effect impacting scheduling, space, time, site of care resourcing, procedural time, and efficacy. Effective salvage of inadequate colon cleansing at the time of colonoscopy is a substantial unmet need and Motus GI has developed an intraprocedural cleansing tool to aid clinicians in obtaining optimal visualization. The Pure-Vu EVS System is an FDA cleared, intra-procedure device that enables salvage of an inadequate preparation to one that is adequate, thus allowing the colonoscopy to continue as scheduled. This FDA-cleared device is placed over the colonoscope and utilizes a novel irrigation and suction technology.

The goal of this consecutive series, pragmatic trial is to demonstrate that when the Pure-Vu EVS System is utilized to salvage poorly prepped colons, an overall reduction in the number of inadequate colonoscopies results, thus proving that the Pure-Vu EVS System is a viable solution in addressing the unmet need of inadequate preparations.

5) Study Device

6) General Description

The Pure-Vu EVS System is an FDA 510(k) cleared cleansing device that enables colon cleansing during colonoscopy. The system attaches to a standard or slim colonoscope. The Oversleeve, which fits over the colonoscope and is connected to an external Workstation (WS), generates fluid and air to break up feces. The fecal matter & fluids are removed through the suction channels of the Oversleeve into an external waste container.

The Pure-Vu EVS System consists of the following main components:

- Disposable device which includes an Oversleeve section with an integrated loading element and an Umbilical Section. The Oversleeve fits over the colonoscope. The Umbilical Section connects the Oversleeve to the external Workstation.
- Workstation that is reusable and supplies an irrigation mixture of water or saline and gas and evacuates debris & fluids.

Below is a drawing showing the various components of the system and where they connect to each other.

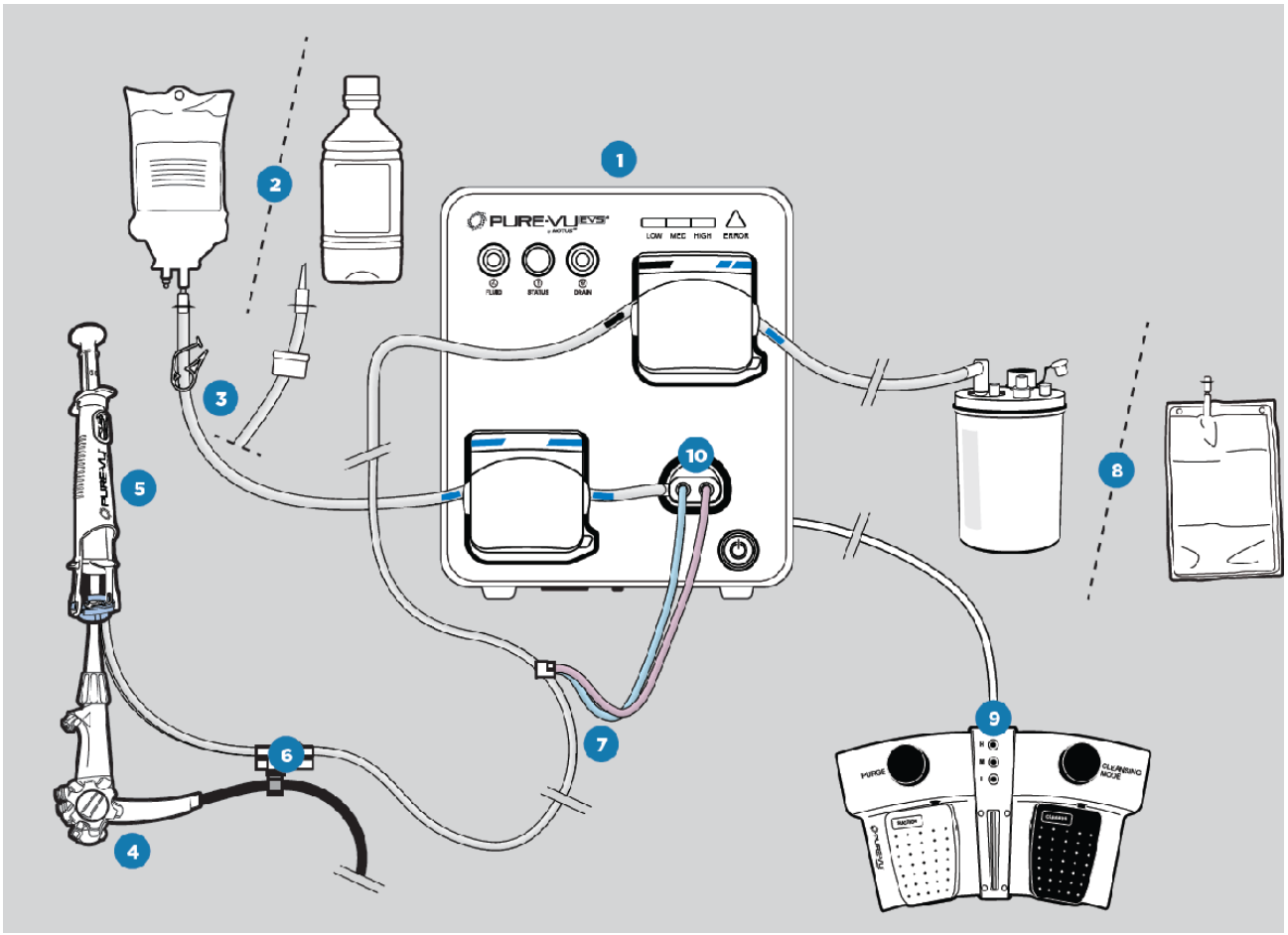
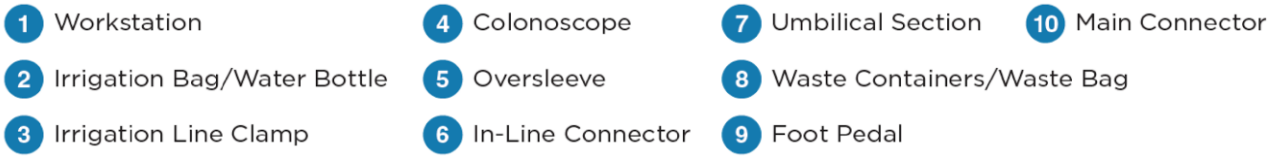


Figure 1: Pure-Vu Workstation – General design & components



A detailed description of the system components, its principles of operation, dimensions and packaging is elaborated in the device's Instruction for use (IFU).

7) Pure-Vu Workstation

The Workstation is designed to provide water or saline and gas for irrigation and suction to evacuate debris & fluids out of the body during the colonoscopy procedure. Care should be taken when removing the Workstation from the package so as not to damage any components.

The WS has the following main functions:

- Monitoring & Control Unit control the delivery of irrigation fluids and gas into the colon, and suction of fluids and debris from the colon.
- Irrigation Bag/Bottle (saline or water) which is connected to the irrigation line.
- Waste Containers/Bag for collecting the colon content & fluids that are suctioned from the colon through the suction lines.
- Foot Pedal that activates the cleansing, suction and purging functions, and enables switching between cleansing modes used by the physician.

8) Pure-Vu Disposable Kit

The Pure-Vu® Disposable Kit is comprised of the Oversleeve, and the Umbilical Section. The Pure-Vu Oversleeve is a single use device, which fits over a standard or slim colonoscope with a length of 1630mm – 1710mm and an outer diameter range of 11.7mm – 13.7mm. Once mounted over the colonoscope the effective outer diameter is less than 22mm.

The Pure-Vu Oversleeve consists of a single irrigation channel and a single suction channel which is also used for in-line pressure sensing. The Oversleeve allows for proper connection to the colonoscope. Proximal to the scope grip is the in-line connector that enables attachment to the Umbilical Section. The Umbilical Section connects the Pure-Vu Oversleeve to the Workstation via the main connector.

9) Pure-Vu Prior Investigations

Device/ Type of investigation/ Number of subjects	Methodology	Outcome and Conclusion
Pure-Vu System during Product Development **Preclinical study:** **35 Yorkshire cross swine (66% female) (8)**	Study subjects received a reduced bowel preparation to ensure an inadequate bowel preparation at baseline. Prior to the colonoscopy the Pure-Vu System was attached to the colonoscope and the baseline prep was assessed during insertion. The Pure-Vu System cleansed the colon and the prep was then assessed post-Pure-Vu use.	There were no adverse events, failed or prematurely terminated cases. Fourteen percent of the swine colons were adequately prepped at baseline (mean BBPS score 0.5 ± 0.7) and improved to 100% after use of the Pure-Vu system ($p < 0.001$) (mean BBPS score 3.0 ± 0.0). The Pure-Vu System effectively cleaned inadequately prepped swine colons and found to be easy to use.
Pure-Vu System: Generation 1 **Clinical Study: Outpatient feasibility study including 47 outpatients enrolled at 3 clinical sites in Germany and the Netherlands (9)**	Study subjects indicated for screening, diagnostic or surveillance indication were enrolled and received minimal pre-procedure bowel preparation To ensure an inadequately prepped colon, subjects underwent a reduced preparation consisting of dietary restrictions (no dried fruit, seeds or nuts) starting 2 days prior to the colonoscopy, and 18 to 24 hour clear liquid diet with a split dose of 20mg Bisacodyl. The cleansing quality	Study reported high rates of cecal intubation (97.9%), significant improvements in BBPS scores (Median score of 3.0 pre Pure-Vu to 9.0 post Pure-Vu cleansing), proportion of subjects with adequate bowel cleansing (from 19.1% to 97.9%; $P<0.001$), and physicians were satisfied with the ease of use of the device and it was well tolerated by the subjects. No SAEs occurred during the study.

	was evaluated using BBPS before and after use of the Pure-Vu System.	
Pure-Vu System: Generation 1 **Clinical Study: Outpatient study including 50 outpatients in 2 sites in Israel and Spain (10)**	Study subjects indicated for screening, diagnostic or surveillance indication were enrolled and received minimal pre-procedure bowel preparation To ensure an inadequately prepped colon, subjects underwent a reduced preparation consisting of dietary restrictions (no dried fruit, seeds or nuts) starting 2 days prior to the colonoscopy, and 18 to 24 hour clear liquid diet with a split dose of 20mg Bisacodyl. The cleansing quality was evaluated using BBPS before and after use of the Pure-Vu System.	Study reported a cecum intubation rate of 98%. Pure-Vu increased BBPS scores and increased the proportion of patients with an adequate cleansing level (31% of patients at baseline vs. 98% post Pure-Vu cleansing) and mean BBPS improvement of 5 to 9.
Pure-Vu System: Generation 1 **Clinical Study: Inpatient Study including 95 hospitalized subjects from 6 clinical sites in the US and Germany (11)**	This inpatient study included 95 hospitalized patients. One patient was excluded due to the discovery of ulcerative colitis during the procedure which was a study exclusion. A total of 94 subjects (60% male) were enrolled from 6 clinical study sites. The mean age of the subjects was 62.44 ± 13.47 (range 28-88y) and the mean	The proportion of patients with an adequate cleansing level (BBPS≥2 in each of the evaluated colon segments), increased significantly from 38% (32/84) at baseline to 96% (81/84) after use of Pure-Vu ($P<0.001$). Increase of adequate preparation, defined as pre Pure-Vu BBPS scores of 2 or higher, was reported in 60%, 62%, and 47% to 100%, 99%, and 97% of the left-side,

	body mass index (BMI) was 28.02 ± 6.62. 53 subjects had colonoscopy performed with a Standard Oversleeve and 41 procedures used a Slim Oversleeve. The clarity of the last bowel movement was available in 93 patients. Clear to moderately clear (grade 4-5) bowel movements were reported in 49% (46/93) of patients and dirty (grade 1-3) bowel movements were reported in 51% (47/93) of patients.	transverse, and right segments, respectively after cleansing with Pure-Vu. While subject assessment of poor clarity of last bowel movement was associated with lower BBPS score prior to cleansing with Pure-Vu, it was able to increase BBPS regardless of pre-procedure clarity score. Pure-Vu System cleansing improved BBPS scores regardless of pre-procedure volume of bowel preparation consumed. Successful colonoscopy, defined as completed colonoscopy for the intended indication in the first attempt, was achieved in 98% (92/94) of subjects. In this study, 12% (11/94) of procedures achieved a diagnosis for the intended indication prior to cecum intubation. Of the remaining 83 procedures, 96% (81/83) of the colonoscopies reached and visualized the cecum during the study procedure and 86% (71/83) of these cases achieved cecum intubation using Pure-Vu. In the 71 patients where the cecum was reached and successfully visualized with the Pure-Vu device, the total mean procedure time was 27.43 minutes.

		One SAE was reported. A patient had a procedure-related, 1 cm rectal perforation which required surgical repair. The patient was discharged 48 hours post operatively and fully recovered with no additional clinical sequela. 3 mild adverse events were also reported including fever, abdominal pain, and a drop-in hemoglobin from 7.6 grams/dL pre-procedure to 6.6 grams/dL. All minor adverse events resolved, and the investigators recorded that the events were unlikely related to the Pure-Vu device.

10) Risk to Benefit Ratio

11) Anticipated Risks Associated with the Study Device

The potential risks of having a colonoscopy may include death, colon perforation, infection, bleeding, swelling of the colon tissue, hemorrhoids and anal tearing, mucosal trauma, rectal/anal bleeding, abdominal pain, nausea, vomiting and bloating feeling; in rare instances, there might be changes in a subject's heartbeat, low blood pressure or lack of oxygen as a result from the anesthesia. The risks associated with the specific use of Pure-Vu are expected to be similar to colonoscopies. There may be other risks that are unknown and cannot be foreseen. As with any colonoscopy procedure there are risks associated missed lesions, bowel perforation, pain, or bleeding. The risks associated with the specific use of Pure-Vu are expected to be comparable to standard colonoscopies. Also, risks have been mitigated to the furthest extent as required by regulatory bodies. Based on low adverse event rates in past studies as well as risk mitigations per the applicable standards, the Pure-Vu System does not introduce significant additional risk to patients.

12) Potential Benefits to the Subject

The potential benefits of the Pure-Vu System include improved visualization of the bowel mucosa that is obscured due to inadequate preparation or residual fecal matter. Additionally, there is a potential reduced need for repeated colonoscopies due to insufficient colon preparation, these consequently may reduce pain, discomfort, risks, costs and lost productivity.

13) Study Purpose

The aim of this study is to demonstrate that the use of the Pure-Vu EVS System can salvage inadequately prepared optical colonoscopies (OCs) to adequate OCs.

Inadequate OCs defined as such if any of the following are met:

- Boston Bowel Preparation Score (BBPS) < 6
  (Adequacy is defined as BBPS of 2 or greater in each segment)
- Inability to identify >5mm polyps

14) Primary Objective

The primary objective of this study is to demonstrate the reduction of inadequate colonoscopies when Pure-Vu EVS System is used to salvage inadequately prepped colons.

15) Secondary Objectives

The secondary objective of this study is to assess the impact of the Pure-Vu EVS System on patient outcomes.

16) Primary Endpoint

Rate of incomplete colonoscopies due to inadequate preparation salvaged to adequate colonoscopies with the use of the Pure-Vu EVS System.

Inadequate OCs defined as such if any of the following are met:

- BBPS < 6 (Adequacy is defined as BBPS of 2 or greater in each segment)
- Inability to identify > 5mm polyps

17) Secondary Endpoints

The following secondary endpoints will be assessed:

1. Number of polyps and adenomas: type, location, size, pathology, and morphology, as well as:
    - Polyp Detection Rate (PDR)
    - Polyp Miss Rate (PMR)
    - Adenoma Detection Rate (ADR)
    - Adenoma Miss Rate (AMR)
    - Adenoma Per Colonoscopy (APC)
    - Adenomas Per Positive Patient (APP)
    - Sessile Serrated Adenoma Detection Rate
2. Boston Bowel Preparation Score (BBPS) before and after Pure-Vu EVS use
3. Other Procedural Outcomes (including but not limited to):
    - Sedation type
    - Procedure time: time to cecum and withdrawal time including additional time necessary to perform Pure-Vu EVS, in cases where Pure-Vu is utilized.
    - Intraprocedural tools
4. Cecum Intubation Rate
5. Compliance to published interval guidelines for surveillance or repeat screening (Prescribed intervals per USMSTF)

18) Tertiary Endpoints

- Clinician Satisfaction: Each clinician will complete a questionnaire for each completed Pure-Vu EVS procedure.
- Economic Impact: An assessment of the economic impact will be performed as part of the overall study analysis. Impact will be calculated by utilizing both data generated as part of the study (such as polyp demographics, insurance type, and colonoscopy indication/type) and data published on the costs associated with outpatient colonoscopies and subsequent findings.

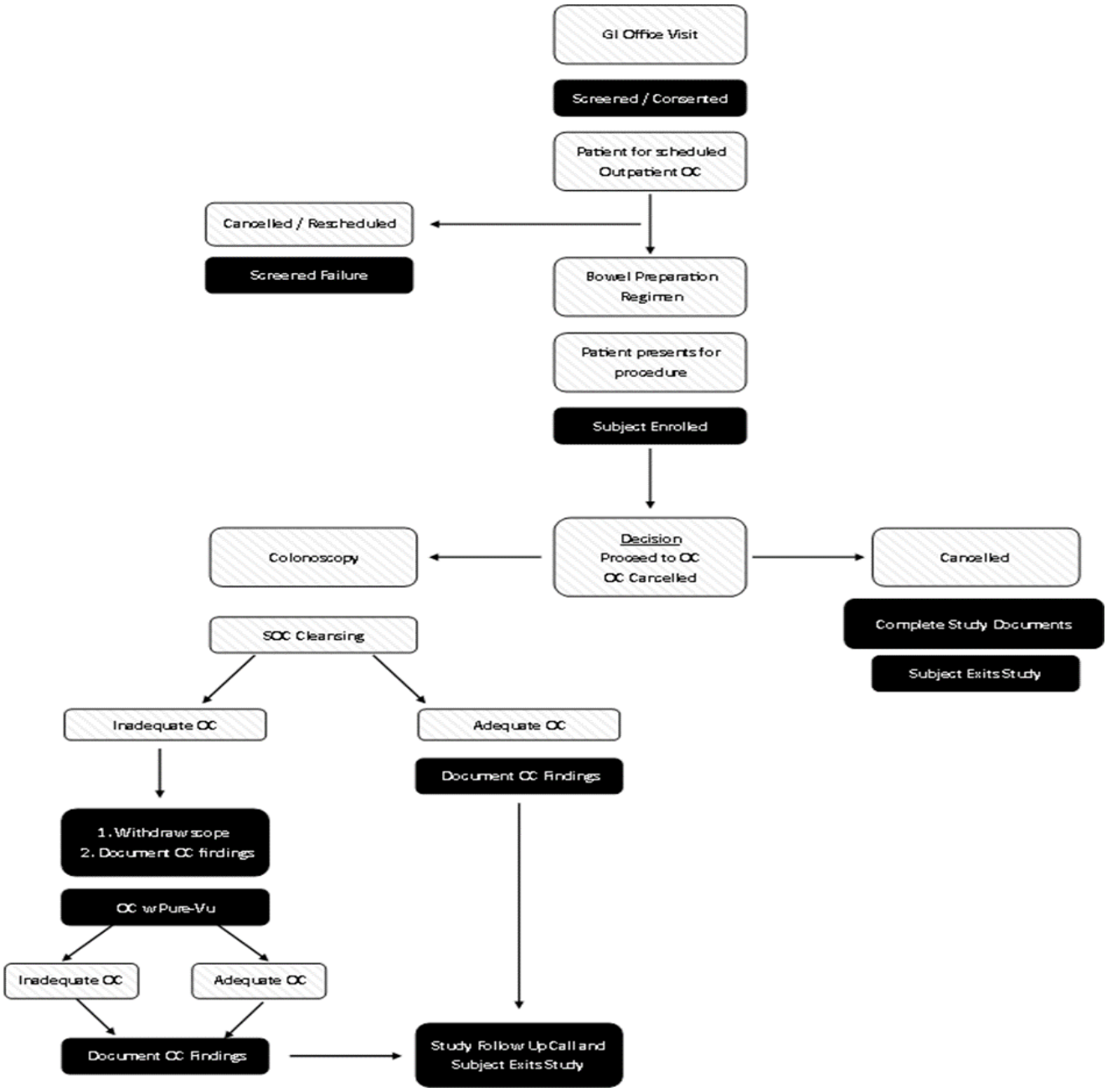
19) Primary Safety Endpoint

A comparison of SAE rates between Pure-Vu subjects and the published serious complication rate of standard colonoscopy procedures (2.8%)[12].

20) Study Design

This study is a multi-center prospective, consecutive series, pragmatic clinical trial, which reflects real world practices in the outpatient setting. Patients are to be enrolled in a consecutive series manner, be indicated for outpatient colonoscopy and must have attempted or completed bowel preparation regimen. Academic institutions, private practice, outpatient centers and ambulatory surgical centers will be approached for participation in this study.

Below is the diagram of the study design and patient flow.



21) Selection and Enrollment

A patient may be introduced to the study at the GI office when an outpatient colonoscopy is indicated. Once it's determined that the patient is interested in participation and eligible for participation, he or

she will be consented for the study. After conducting the consent process, obtaining informed consent, and answering questions, the subject will sign the sites' designated IRB approved informed consent form (ICF). This study also allows for an electronic consenting process. Enrollment of approximately 1,067 subjects is planned to achieve 115 patients with inadequate bowel prep.

Subjects' enrollment in the study will begin on the day of procedure and will last approximately 15 days, including the procedure day, and one follow up call during the follow up period (within 14 days after the procedure). Safety assessments will begin at the time of enrollment.

22) Inclusion and Exclusion Criteria

Inclusion Criteria

1. Eligible adults aged between 40-80
2. Elective outpatient colonoscopy by participating gastroenterologist

Exclusion Criteria

1. Not competent to consent
2. Known or suspected bleeding disorders such as, but not limited to hemophilia and von Willebrand disease
3. History of colonic resection
4. Prior incomplete colonoscopy due to patient anatomy
5. Diverticulitis
6. Active inflammatory bowel disease (Crohn's, Ulcerative Colitis, or Indeterminate)
7. Known or suspected colon stricture/fistula
8. Hereditary Colorectal Cancer Syndrome
9. Subject is pregnant or suspected pregnant

23) Withdrawal and Screen Failures

Subjects may withdraw from the study at their own request or at the request of their legally acceptable representative. The investigator may withdraw a subject from the study at any time for the following reasons:

- Severe side effects clearly related to the study device.

- Presence or appearance of exclusion criteria.
- Appearance of accompanying diseases rendering further participation in the study impossible.
- A significant protocol violation, as determined either by the sponsor or the investigator
- Subject noncompliant with study procedures

The sponsor must be informed in each withdrawal case. For screen failures, and those satisfying inclusion/exclusion criteria but choosing not to participate in this study, Subject details will be documented in the screen failure log. Subjects who have screen failed will be allowed to re-screen within 120 days of the initial screened date.

24) Selection of Investigators and Training

Board-certified gastroenterologists in accordance with US and hospital guidelines will be considered for participation as investigators in this study. Physicians in training (residents, fellows) and physician assistants may assist the Study Investigator in any aspect of the procedure as per standard practices at his/her institution but will not participate in performing the colonoscopy.

Each Investigator participating in the clinical trial and the associated clinical study staff will receive training on the clinical protocol. This includes training on AE reporting, electronic case report form (eCRF) completion, and Good Clinical Practice (GCP), as well as the study device and system (including procedural use, device characteristics, shelf life and storage requirements, warnings, and precautions), if applicable.

25) Study Procedures

26) Screening and Informed Consent

Once the patient is indicated for an outpatient colonoscopy, he or she will be approached to review the study and obtain consent on the informed consent form (ICF) prior to any study procedures. The purpose of the study and the benefits and risks of the procedures will be explained to the subject and the consent process will be documented accordingly in the medical records. Subjects who agree to study participation must sign an IRB-approved ICF. Subjects will be informed that their participation in this study is voluntary and they may refuse to participate or discontinue from

the study at any time. Subjects will be given the opportunity to ask the investigator questions so that they are informed about the research. A copy of the signed informed consent must be provided to the subject and the informed consent process will be documented in source documents. This study also allows for an electronic consenting process.

If new information becomes available that may affect a subject's decision to continue to take part in the study, this information will be discussed with the subject by the investigator.

Screened subjects will be documented in the screening log until the subject presents for the day of procedure in which at that time the subject will receive a subject number.

27) Day of Procedure (D0)

On the day of elective outpatient colonoscopy, the subject's eligibility to participate will be assessed again and if still eligible for the study, the subject will be assigned a study subject number in the format of 2-digit Site Number and 3-digit Subject Number (i.e. 01-001, 02-002).

28) Pre-Procedure

If the subject is eligible to continue within the study, the following information will be collected:

- Demographics (age, gender and race)
- BMI
- Relevant medical and surgical history
- Colonoscope type
- Indication for colonoscopy
- Bowel preparation prescription details (type, dose, administration schedule, and diet)
- Bowel preparation consumption details
- Pre-procedure stool clarity grade
- Relevant medications

29) Colonoscopy Procedure

The insertion during the colonoscopy procedure will be performed by the clinical study investigator(s), experienced in GI endoscopy according to the local standard of care. The type of

sedation will not be dictated by the study but will be documented. The colonoscope will be prepared and the procedure will proceed per the standard of care.

During the procedure, the study endoscopist will be requested to document BBPS for each colon segment. Once the endoscopist notices an inadequate segment, the endoscopist should attempt to cleanse per his/her standard of care practices with the goal to achieve a BBPS of 2 or higher for that segment. This should be repeated for each colonic segment. If the study definition of inadequate is met in any segment, even after SOC cleansing, the endoscopist is required to take pictures of all accessed segment(s) including the inadequate segment(s). The endoscopist will withdraw the colonoscope and all procedural outcomes and findings should be documented. Then the Pure-Vu Oversleeve will be placed onto the colonoscope, and the procedure will be performed utilizing the Pure-Vu System for cleansing. Photo-documentation of each segment will be required to show BBPS after Pure-Vu use. Once the procedure has been completed with Pure-Vu, procedural outcomes (inclusive of final adequacy determination after Pure-Vu use and findings will be documented again.

If during the standard of care colonoscopy, the patient cannot proceed onto Pure-Vu and/or will be deemed an incomplete colonoscopy due to any reason other than inadequate prep, that subject will be withdrawn from the study. Such an instance might occur when a mass or stricture is found, or when an active inflammatory condition is detected but is it ultimately up to the Principal or Sub-Investigator to make the determination during the procedure.

30) Post Procedure Follow Up

As part of the routine post-examination follow up, subjects will be transferred to the recovery room for observation per clinical site's colonoscopy protocol and will continue his/her medical flow as per the standard of care. Follow-up call will be conducted within 14 business days after the procedure to verify that there has been no change in their clinical status. If a clinical status change has occurred (ie. New onset of an AE or worsening condition after day of procedure), then the adverse event should be documented and followed until event resolution or until site is closed by the Sponsor. If no change has occurred, the subject can then be exited from the study.

In the event a subject does not answer the initial follow-up call, there must be at least two additional, documented attempts to contact the subject within the 14 business day follow up timeframe. If after the additional calls a subject does not answer, they will then be considered lost to follow up.

31) Statistical Analysis

32) Sample Size Determination

The study is planned to enroll at fifteen sites and will enroll until 115 subjects are identified with inadequate bowel prep.

Assuming a 12% inadequate prep rate 1067 patients would be enrolled to achieve 115 patients inadequate bowel preparation. The final sample size, however, will be determined by the number needed to undergo colonoscopy to achieve 115 and therefore may be greater than or less than 1067.

The sample size of 115 was determined to provide at least 90% power for the primary endpoint of demonstrating conversation rate of inadequate colonoscopies after the use of the Pure-Vu EVS System is greater than a 30% performance goal.

Assuming a true conversion rate of 50%, then 115 inadequately prepped patients undergoing Pure-Vu with the opportunity to convert to adequate prep will provide $\geq$ 99% power and at least 115 patients for safety. To be conservative, 115 inadequately prepped patients will provide $\geq$ 90% power to produce an exact 95% CI > 30% even if the true conversion rate is 45%.

33) Description of Statistical Methods

Basic demographic and other baseline characteristics will be collected and analyzed for all subjects. Unless specified otherwise, descriptive statistics will be presented for the total study population, by colonoscopy prep adequacy group, and overall. Subgroup analyses may occur, including but not limited to age group (40 to <65 vs 65 to 80), insurance type, site care location, and colonoscopy indication, all of which will be further described in the Statistical Analysis Plan (SAP). For

quantitative summaries, mean, standard deviation (SD), median, minimum, and maximum will be presented. For qualitative summaries, counts and percentages will be presented.

34) Safety Population

The safety population is defined as any subject presented for procedure and enrolled into the study. This population will be used for all safety analyses.

35) Intent-to-Treat (ITT) Population

The ITT population is defined as any subject who was able to proceed with an optical colonoscopy and have a complete procedure or an incomplete procedure solely due to inadequate bowel prep. This population will be used for all efficacy analyses. A completed procedure is defined as one with the ability to reach the cecum with OC either before or after Pure-Vu.

36) Per Protocol (PP) Population

The PP population is defined as any subject in the ITT who do not have any major protocol deviations and in whom the Pure-Vu system was utilized as planned. This population will also be used for all efficacy analyses.

37) Inadequate Bowel Preparation (IBP) Population

The IBP population is defined as any subject that were identified to have inadequate prep after initial OC and were indicated for cleansing with the Pure-Vu System and did not have any major protocol deviations.

38) Primary Endpoint Analysis

The primary endpoint is conversion rate of inadequate colonoscopies to adequate colonoscopies after the use of the Pure-Vu EVS System, where inadequate OCs defined as such if any of the following are met:

- BBPS < 6 (Adequacy is defined as BBPS of 2 or greater in each segment)
- Inability to identify >5mm polyps

The conversion rate, θ, is defined as number of preps inadequate with SOC and adequate after Pure-VU EVS System divided by the number of preps inadequate with SOC.

$$H_0: \theta \leq 0.30$$

$$H_1: \theta > 0.30$$

The conversion rate and its two-sided 95% exact binomial interval will be presented and compared to the 30% performance goal. The proportion of preps inadequate after SOC and inadequate after SOC + Pure-Vu will also be reported.

39) Secondary Endpoint Analysis

All secondary endpoints will be summarized using descriptive statistics and full details on additional planned analyses with be provided in the prospective Statistical Analysis Plan.

40) Tertiary Endpoint Analysis

All tertiary endpoints will be summarized using descriptive statistics and full details on additional planned analyses with be provided in the prospective Statistical Analysis Plan.

41) Safety Endpoint Analysis

All adverse events (AE) and serious adverse events (SAE) that are definitely and/or potentially attributed to Pure-Vu will be summarized using descriptive statistics.

42) Adverse Events and Classifications

AE and AE subcategories are defined per GCP and CFR.

43) Adverse Event (AE)

An AE is any untoward medical occurrence in a subject, which does not necessarily have a causal relationship with the treatment. An AE can be any unfavorable and unintended sign (such as an abnormal laboratory finding), symptom, or disease temporarily associated with the use of the study device, whether it is considered to be study device related. This includes any newly occurring event or previous condition that has increased in severity or frequency since enrollment in the study.

44) Serious Adverse Event (SAE)

An adverse event will be considered serious if it meets at least one of the following criteria, regardless of causality or relationship to the study device:

- Death- results in fatality
- Life-threatening – subject was at an immediate risk of death from the reaction as it occurred.
    - Life threatening means that the subject was, in the view of the investigator, at immediate risk of death from the reaction as it occurred. This does not include an AE that, if more severe, might have caused death.
- Hospitalization (Initial or Prolonged) - Requires inpatient hospitalization or prolongs a hospital stay during the period of the therapy and/or within 24 hours after completion of study exit.
- Disability or Permanent damage - A substantial disruption of a person's ability to conduct normal life's functions.
- Congenital anomaly/birth defect - If exposure to the device prior to conception or during pregnancy may have resulted in an adverse outcome in a child.
- Requires intervention to prevent permanent damage - an intervention is required to prevent permanent damage.
- Important Medical Event - Events that may not result in death, be life-threatening, or require hospitalization may still be considered SAEs when, based upon appropriate medical judgment, they are felt to jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

45) Adverse Device Effect (ADE)

An Adverse Device Effect (ADE) is an AE related to the use of an investigational medical device.
This definition includes AEs resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.
This definition includes any event resulting from use error or from intentional misuse of the investigational medical device.

46) Serious Adverse Device Effect (SADE)

A Serious Adverse Device Effect is an anticipated adverse device effect that has resulted in any of the consequences characteristic of an SAE.

47) Unanticipated Adverse Device Effect (UADE)

An Unanticipated Adverse Device Effect is an adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report.

48) Unanticipated Serious Adverse Device Effect (USADE)

An Unanticipated Serious Adverse Device Effect is a serious adverse device effect which by its nature, incidence, severity, or outcome has not been identified in the current version of the risk analysis report.

49) Classification of Event Severity, Relationship and Outcomes

50) Adverse Event Severity Classification

Severity will be defined according to the following criteria:

- Mild: Awareness of event, but easily tolerated
- Moderate: Discomfort enough to cause some interference with activities of daily living (ADL)
- Severe: Considerable interference with ADL, may be incapacitating and may require hospitalization

An AE can be classified as severe and not deemed a SAE. Similarly, a SAE is not automatically severe in nature.

51) Adverse Event Relationship Classification

Relationship to study device administration will be determined as follows:

- *No Relationship*: No relationship between the AE and the administration of study device and a known relationship to other etiologies such as concomitant medications, procedure, or subject's clinical state.
- *Possible Relationship:* An AE that follows a reasonable temporal sequence from administration of the study device and follows a known response pattern to the study device but could have been produced by the participant's clinical state or by other therapies.
- *Probable Relationship:* An AE that follows a reasonable temporal sequence from administration of the study device; follows a known response pattern to the study

device; and cannot be reasonably explained by the known characteristics of the participant's clinical state or by other therapies.

- *Definite Relationship:* An AE that follows a plausible temporal sequence from administration of the study device and follows a known response pattern to the study device. The reaction cannot be reasonably explained by the known characteristics of the subject's clinical state or other therapies administered to the subject.
- *Unknown/Impossible to Determine:* Given the information available, sequence and timing of events, it is unknown or impossible to determine the relationship of the AE with the study device.

52) Adverse Event Outcome Classification

Outcome of the event will be defined according to the following:

- *Resolved:* The event has fully resolved at the end of the study.
- *Resolved with sequelae*: The event has resolved but retained pathological conditions resulting from the prior disease or injury.
- *Ongoing:* The event is ongoing at the end of the study.
- *Death:* This event is determined to be the cause of death.

53) Device Deficiencies

A device deficiency is an inadequacy of a medical device related to its identity, quality, durability, reliability, safety, or performance, such as malfunction, misuse or use error and inadequate labeling.

All device deficiencies will be documented, and the device should be returned to Motus GI for analysis, if possible. Instructions for returning the investigational device will be provided. Device deficiencies should also be documented in the subject's medical record.

Device deficiencies are NOT AEs. However, if there is an AE that results from a device deficiency, that specific event would be recorded on the appropriate CRF.

54) Adverse Event Recording and Reporting

Assessment of the occurrence of an AE will be based on changes in the subject's signs and symptoms. AEs will be monitored until a subject completes the study unless the Investigator

determines the event is related to the investigational device, in which case they will be monitored until resolution if possible. Medical care will be provided, as defined in the informed consent, for any AE related to study participation. AEs will be collected on an AE eCRF and applicable source documentation.

The following should not be considered an AE:

- A condition requiring a preplanned procedure unless the condition worsened since screening
- A preexisting condition found as a result of screening, unless the condition has worsened since enrollment.

All relevant AEs observed during this study, regardless of severity or relationship to the study device will be recorded on the appropriate eCRF. All relevant AEs are associated complications expected during colonoscopies, use of the Pure-Vu System, bowel preparation or anesthesia. It will be the responsibility of the reporting PI to determine if the AE is relevant.

55) Reporting Responsibilities

An investigator shall submit to the sponsor and to the reviewing IRB a report of any SAEs, ADEs, SADEs, UADEs, USADEs, and device deficiencies that could have led to a serious adverse device effect occurring during an investigation within 24 hours of learning of the event, but in no event later than 10 working days after the investigator first learns of the effect. The sponsor will evaluate all AEs and device malfunctions and evaluate whether those are complaints and meet FDA's requirements for MDR reporting. These events will be reportable per the complaint procedure and FDA's MDR regulation (21 CFR Part 803).

56) Ethics and Compliance

57) Statement of Compliance

This clinical investigation will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, ICH-GCP, and any regional or national regulations, as appropriate.

This may include an inspection by Motus GI representatives and/or Regulatory Authority representatives at any time. The investigator must agree to the inspection of study-related records by the Regulatory Authority/ Motus GI representatives and must allow direct access to source documents to the Regulatory Authority/ Motus GI representatives. Regulatory Authority approvals/authorizations/notifications, where required, will also be in place and fully documented prior to study start.

58) Protocol Compliance

No changes to the study protocol will be permitted without the written approval from Motus GI and the IRB. The investigator must notify Motus GI and the reviewing IRB of any deviation from the study protocol when specific to the protection of the life or physical well-being of a subject in an emergency. Such notice must be given as soon as possible. Except in such an emergency, prior written approval by Motus GI is required for changes in or deviations from the protocol. If these changes or deviations affect the scientific soundness of the Plan or the rights, safety, or welfare of human subjects the IRB will also be notified. All other deviations will be reported per the site's IRB deviation policy. Should any deviations from the study protocol occur, these will be reviewed by Motus GI for their clinical significance. If the event is performed without written approval from all parties, the investigator may be terminated from the study.

59) Institutional Review Board (IRB)

Documented approval from the appropriate Institutional Review Board (IRB) per 21 CFR Part 56 will be obtained for all participating centers prior to study start, according to ICH GCP, local laws, regulations, and organization. When necessary, an extension, amendment, or renewal of the IRB approval must be obtained. The IRB must supply to the sponsor a list of the IRB membership and a statement to confirm that the IRB is organized and operates according to GCP and applicable laws and regulations.

60) Subject Informed Consent

Prior to the beginning of the trial, the investigator must have the IRB written approval of the ICF and any other written information to be provided to subjects. The written approval of the IRB together with the approved ICFs must be filed in the study files.
The process of obtaining informed consent must be in accordance with applicable regulatory requirement(s) (e.g. 21 CFR Part 50) and must adhere to GCP and to the ethical principles

originating in the Declaration of Helsinki. Written/electronic informed consent must be obtained before any study specific procedure takes place. Participation in the trial and date of informed consent given by the subject should be documented appropriately in the subject files.

61) Insurance

All subjects participating in the trial will have insurance coverage by the Sponsor, in accordance to applicable local laws.

62) Confidentiality

All records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available.
Subject names will be kept confidential. Study findings stored on a computer will be stored in accordance with local data protection laws. The subjects will be informed in writing that representatives of the sponsor, IRB or Regulatory Authorities may inspect their medical records to verify the information collected, and that all personal information made available for inspection will be handled in strictest confidence and in accordance with local data protection laws. Subjects will also be informed that information regarding the study that does not include subject identifiers will be posted on clinicaltrials.gov.

If the results of the trial are published, the subject's identity will remain confidential.
The investigator will maintain a list to enable subjects' records to be identified.

63) Use of Data and Publications

Information regarding the study and study data will be made available via publication on clinicaltrials.gov.

All data and results and all intellectual property rights in the data and results derived from the study will be the property of Motus GI, who may utilize the data in various ways, such as for submission to government regulatory authorities or disclosure to other investigators, educational, further product development and marketing uses.

The investigators, while free to utilize data derived from the study for scientific purposes, must discuss any publication with the sponsor prior to release and obtain written consent of the sponsor on the intended publication. The sponsor recognizes the right of the investigator to publish the results upon completion of the study. However, the investigator must send a draft manuscript of the publication or abstract to the sponsor 45 days in advance of submission in order to obtain approval prior to submission of the final version for publication. This will be reviewed promptly, and approval will not be withheld unreasonably. In case of a difference of opinion between the sponsor and the investigator(s), the contents of the publication will be discussed in order to find a solution which satisfies both parties. This timeline can be shortened at the mutual agreement of sponsor and investigators.

Disclosure of involvement in a publication (e.g., sponsor of the study; collection, analysis, and interpretation of data; professional writing assistance) must be as specified by journal-specific policies, submission requirements, and prevailing editorial standards, in addition to those specified by International Committee of Medical Journal Editors. Authors must ensure that an acknowledgement/disclosure statement is included in the body of the manuscript for Motus GI to review for accuracy. All authors must also disclose financial or personal affiliations that could be considered conflicts of interest as per journal requirements.

64) Study Monitoring

Site monitoring visits will be conducted by an authorized Motus GI representative or designee to inspect study data, subjects' medical records, and eCRFs in accordance with the Clinical Monitoring Plan (CMP), current ICH GCPs, Declaration of Helsinki and the applicable local and national regulations. To ensure the rights, safety, and welfare of study subjects are being maintained, the monitor will review training records to ensure all study staff are trained on the study protocol and use of the study device.

The Study Investigator and the investigating site will permit authorized clinical research personnel and clinical monitors from Motus GI and/or designee(s) employed by Motus GI to review completed eCRFs, IRB decisions, clinical site records, and facilities relevant to this study at regular intervals throughout the study per the CMP. In instances where data protection regulations prohibit the direct examination of hospital records by the study Sponsor or designee(s), the Investigator will provide another

mechanism of access to allow source data verification by the Sponsor or designee. Monitoring may be performed with in person visits or remotely, when applicable.

The monitor will verify that each subject has consented in writing (or electronic) to directly access to the original source data/hospital records by the use of written patient information and signed informed consent. During monitoring, the data recorded in the eCRFs by the investigator or designee will be compared for consistency with the source data/hospital records by the monitor to ensure protocol adherence and source data verification.

If the monitor discovers that an investigator is not complying with the signed Investigator Agreement, the investigational plan, applicable laws, or any conditions of approval imposed by the reviewing IRB, the monitor will report to the Sponsor and take such steps necessary to promptly secure compliance.

65) Data Collection and Processing

This study will utilize an electronic database. Data management and data quality control will be performed by the Clinical Research Organization (CRO). Data will be entered into an 21 CFR Part 11 compliant Electronic Data Capture (EDC) system by the clinical sites. Any data queries will be issued to the sites as required for resolution and entered into the database. Only delegated personnel and PIs trained to use the EDC will have access for data entry. Only trained clinical team members and Data Managers from the Sponsor or CRO will have access to the EDC for monitoring and Data Management purposes in accordance with the Data Management Plan (DMP).

The investigators shall ensure the accuracy, completeness and timelines of the data reported in the electronic Case Report Forms (eCRFs) and in all required documentation. Data reported on the eCRF shall be supported by the source documents with any discrepancies being explained. All digital or paper hospital records regarding the treatment of the subject are considered source data. If an item is unavailable or is not applicable, this fact should be indicated; no space is to be left blank. The eCRFs are to be completed in a timely manner after the subject's visit. Once monitoring is complete and all queries are resolved, the investigator who has signed the study protocol signature page or his/her authorized designee is to personally sign the eCRFs to validate that the observations and findings are recorded on the eCRFs correctly and completely.

66) Study Supplies and Device Accountability

67) Packaging

The Pure-Vu EVS System disposables are composed of biocompatible materials and are supplied clean in a sealed package. The shelf life of the device was tested within the device verification and validation process to support shelf-life period of 12 months.

68) Labeling

All the disposable packages are labeled as single use with a lot number and expiration date.

69) Inventory Control

The sponsor will initiate shipment of the product from the sponsor to the site upon receiving all required documents (e.g., approval/favorable opinion from IRB). The sponsor will maintain tracking for all shipment documentation. Prior to any shipment, the site will be informed by the sponsor of the upcoming shipment, expected arrival date, and content of the shipment. The site should confirm receipt of the shipment. The site will file the Sponsor's Shipping Receipt in the Sponsor's Study File.

An Investigator's Device Accountability form will be completed and filed in the Regulatory Binder at each site. In case of technical failure, the site will inform the designated sponsor contact.

For each dispensed Pure-Vu Oversleeve, the following relevant information should be documented: subject study number, Date Oversleeve used, Oversleeve lot number and expiration date.

At the termination of the study, all unused study material must be returned with the corresponding documentation as directed by Motus GI.

70) General Information

71) Study Contact Information

Clinical Affairs
Caitlyn Seidl VP of Clinical Affairs 1301 E. Broward Blvd. #310 Fort Lauderdale, FL 33301 Phone: 954-541-8000 Mobile: 352-514-4260 Email: cseidl@motusgi.com

72) Retention of Records

All source documents and eCRFs will be kept for a period of two years from the study termination or completion or for the period required by applicable laws.

73) Study Completion and Termination of Study

Motus GI reserves the right to discontinue the study at any stage, with suitable written notice to all investigators and reviewing IRBs, following unforeseen events or other factors that do not permit continuation of the study. Similarly, investigators may withdraw from the study at any time, subject to providing written notification to Motus GI 30 days prior to the date they intend to withdraw. However, Motus GI and investigators will be bound by their obligation to complete the follow-up of subjects already participating in the study. The subjects must be followed according to the clinical protocol, and information obtained during subject follow-up shall be reported to Motus GI in the database.

The appropriate IRB will be notified of discontinuation of the trial for any reason not later than 5 working days after the sponsor makes this determination and not later than 15 days after the sponsor receives a notice from the IRB and/or regulatory authority.

74) References

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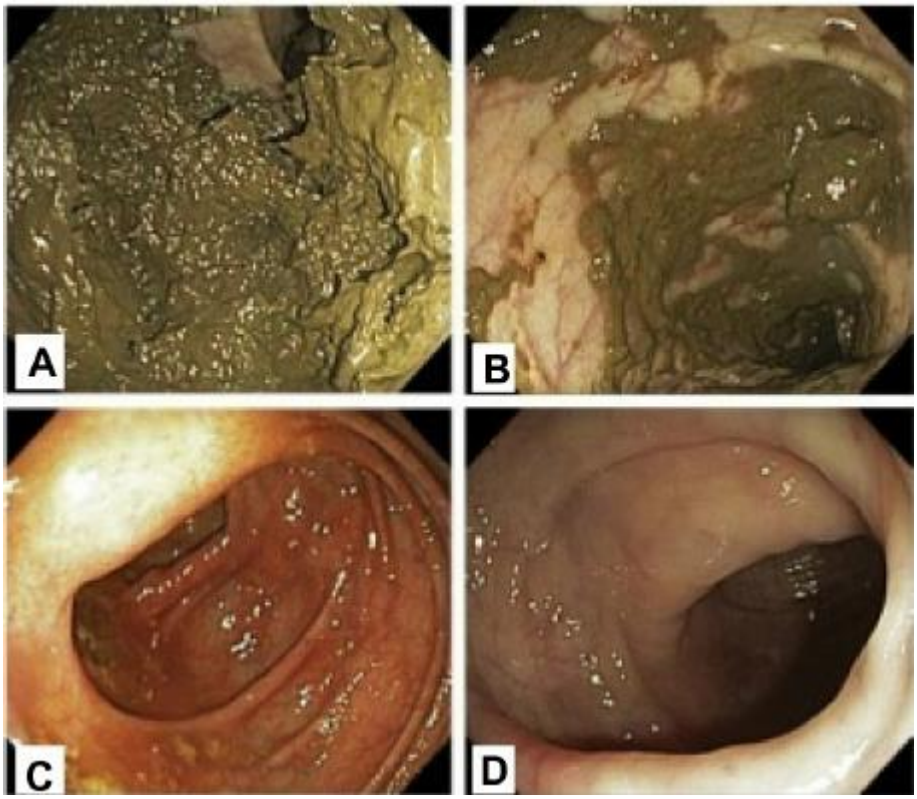
75) Appendices

Appendix A: Study Design and Schedule of Assessment

Assessment	Screening /Pre-Procedure (Up to-120 days)	Day of Procedure[a] (Day 0)	Follow Up (1-14 days post procedure)
Informed Consent and Demographic details	X	X	
Inclusion/Exclusion Criteria	X	X	
Concomitant Medications	X	X	
Medical & Surgical History	X	X	
Body Mass Index		X	
Bowel Preparation Regimen[b] And Clarity Assessment		X	
Colonoscopy Procedure		X	
Adverse Events Reporting		X	X[c]
Clinician Satisfaction (only for study device procedures)		X	

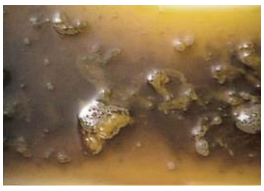
[a]*In the event that patients are screened and enrolled on the same day, all activities must be completed prior to subject entry into the endoscopy suite*
[b]*Bowel Preparation Regimen information will be collected. Subject must have attempted and or completed bowel preparation to be eligible for study continuation*
[c]*Post procedure follow up call will be conducted to ensure reporting of any potential adverse events from the day of procedure*

Appendix B: Boston Bowel Preparation Scale

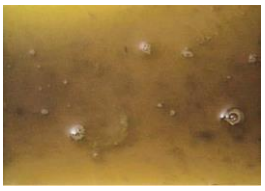


- **A: Score 0-** Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared.
- **B: Score 1** - A portion of the mucosa of the colon segment is seen, but other areas of the colon segment are not seen well due to staining, residual stool, and/or opaque liquid.
- **C: Score 2-** A minor amount of residual staining, small fragments of stool, and/or opaque liquid are visible, but the mucosa of the colon segment are seen well.
- **D: Score 3-** The entire mucosa of the colon segment is seen well with no residual staining, small fragments of stool, or opaque liquid.

Appendix C: Clarity Card

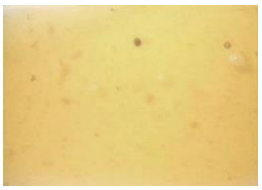


Grade 1



Grade 2

Grade 3



Grade 4

Grade 5