Clinical Investigational Plan (CIP) INFORMATION	
Title:	**R**andomized Controlled Study Comparing Colon **E**valuation With The Pure-Vu System To A **S**tandard **C**olonoscopy In Patients Who Are High Risk For Inadeq**u**ate Bowe**l** Preparation ("RESCue")
CIP Number:	**CL00048**
Version Date:	November 12, 2019
Version:	1.0
NCT number	04285008
Sponsor:	Motus GI Medical Technologies LTD. Keren Hayesod 22, Tirat Carmel, ZIP 3902638, Israel Tel: 954-541-8258 Fax: 954-541-8265

Summary of Changes to CIP			
Version	**Section**	**Description of Change**	**Reason for Change**
1	NA	NA	Investigator Initiated Study conversion to Sponsored Study Protocol format

1.0 Signature Page

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

2.0 Table of Contents

3.0 Protocol Synopsis

Study Summary	
Study Purpose	The aim of this study is to assess the efficacy of Pure-Vu in the outpatient colonoscopy setting.
Objective	The objective of this study is to evaluate the bowel cleansing after Pure-Vu use in outpatient subjects at high risk for inadequate colon preparation.
Study procedures	• Eligible subjects will be consented • Subject will be randomized and undergo procedure either in the Control arm (standard of care) or with the Pure-Vu System
Protocol Number	CL00048
Protocol Title	Randomized Controlled Study Comparing Colon Evaluation With the Pure-Vu System To A Standard Colonoscopy In Patients Who Are High Risk For Inadequate Bowel Preparation ("**RESCue**")
Study Sponsor	Motus GI Medical Technologies, Keren Hayesod 22, Tirat Carmel, ZIP 3902638, Israel
Study Type	**Multicenter, prospective, randomized controlled trial**
Study Product	**Pure-Vu System**
Study Phase	Post-market
510 (k) Number	K191220 Class II
Study Location	United States
Study Duration	Study period will last approximately 12 months

Planned Follow-Up	Follow-up call will be conducted 1-3 days after the procedure
Subject Population	Eligible outpatient subjects who are indicated for colonoscopy procedure
Sample Size	88 subjects inclusive of a 10% attrition rate (44 per arm)
Planned # of Sites	Up to 4 clinical sites
Primary Endpoint	Boston Bowel Preparation Score (BBPS) after attempts to cleanse the colon are completed. (Bowel preparation adequacy defined as BBPS $\geq$ 2 in each segment)
Secondary Endpoints	The following secondary endpoints will be determined: 1. Assess the willingness of consented subjects to pay for Pure-Vu prior to colonoscopy 2. Colonoscopy procedural measures for Intervention and Control arms 3. Endoscopists' experience 4. Safety assessment for all subjects on the day of procedure per endoscopist 5. Post-colonoscopy patient experience and safety check with scripted phone call 1-3 days after colonoscopy 6. Assess the willingness of consented subjects to pay for the Pure-Vu System 1-3 days after colonoscopy
Randomization	Randomization to Intervention or Control will use stratification by site, endoscopist, and blocking.

Eligibility Criteria	**Inclusion Criteria** 1. Adults ≥ age 22 2. Elective outpatient colonoscopy by participating gastroenterologist 3. Stool clarity grade 1-3 at presentation for colonoscopy **Exclusion Criteria** 1. Not competent to consent 2. Bleeding disorder – known or suspected 3. Hereditary Gastrointestinal Cancer syndrome 4. Known PT INR > 1.5 5. Known elevated PTT 6. Anti-platelet agent or anticoagulant (other than aspirin or nonsteroidal agent) which has not been stopped for the colonoscopy 7. Known platelet count < 50,000 8. Known absolute neutrophil count < 1,000 9. History of surgical colon resection 10. Pre-colonoscopy intent to enter terminal ileum 11. Prior incomplete colonoscopy due to technical & non- bowel preparation related reasons 12. Regular use of non-topical steroid 13. Pregnant 14. Prisoner or institutionalized for any reason 15. Psychiatric illness greater than mild 16. Colonoscopy without anesthesia administered (MAC) sedation 17. Diverticulitis 18. Active inflammatory bowel disease (Crohn's, Ulcerative Colitis, or Indeterminate) 19. Known or suspected colon stricture
Interim analyses	None

4.0 Acronyms and Definitions

ADE	adverse device effect
ADL	activities of daily living
AE	adverse event
CRF	case report form
CRO	Clinical Research Organization
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
FDA	Food and Drug Administration
GCP	good clinical practice
GI	Gastrointestinal
ICF	informed consent form
IFU	Instruction for use
ICH	International Conference on Harmonisation
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
WS	Workstation
BBPS	Boston Bowel Preparation Scale

5.0 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.

5.1 Background

Colorectal cancer is the fourth most common cancer in men and the third most common cancer in women worldwide. In 2017, there were 1.8 million (95% UI, 1.8-1.9 million) incident cases of colon and rectum cancer, and 896,000 (95% UI, 876,000-916,000) deaths. Between 2007 and 2017, incidence increased by 38% (95% UI, 34%-41%), from 1.3 million to 1.8 million cases. Most of this increase can be explained by an aging and growing population (20% and 13%, respectively); however, even with the same population size and age structure, colorectal cancer cases would have increased by 5% , owing to changing age-specific incidence rates (3). Because colorectal cancer tends to develop slowly, screening and early detection can significantly reduce both the incidence and associated mortality of the disease (2).

More than fifteen million colonoscopies are performed yearly in the United States (3). This is not surprising given that colonoscopy is a powerful tool for detecting and preventing colon cancer, offering high screening sensitivity and the ability for diagnostic and therapeutic intervention (4,5). However, the adequacy of bowel preparation bears significantly on the accuracy and utility of this procedure, particularly as it is already known to be operator dependent even under optimal circumstances. Bowel preparation directly impacts colonoscopy quality, cost, and efficiency.

Bowel preparation affects multiple measures of colonoscopy quality. In a large, prospective, multicenter trial, cecal intubation rates, a proxy for colonoscopy completeness, were significantly higher among patients with better preparation. In addition, this study found that time to cecal intubation and overall difficulty of the procedure were notably higher in the setting of preparations deemed to be of low quality (6).

Adenoma detection rate, the primary quality measure for colonoscopies (7), is highly influenced by bowel preparation. Poorer preparation has been associated with lower detection rates, particularly for small adenomas (8). In addition to improved detection of subcentimeter adenomas, better bowel preparation is associated with higher overall adenoma detection rates as well as higher detection of adenomas with advanced histology (9). Suboptimal bowel preparation has been associated with missing close to 50% of

all adenomas, including advanced adenomas, in a study evaluating subsequent lesion detection in patients requiring repeat colonoscopy due to poor preparation (10).

Adequate preparation, which can be defined as a degree of cleansing that allows providers to adhere to guidelines for colonoscopy follow-up (11), is a prerequisite for accurate screening. As such, there has been great scrutiny applied to the effect of bowel preparation on physician adherence to guidelines for colonoscopy screening and surveillance. The importance placed on guideline adherence is reflected in a recent study examining the frequency of colonoscopist recommendation for a ten-year colonoscopy interval for average risk patients who have undergone a negative screening colonoscopy.(12) The US Multi-Society Task Force guideline suggests that colonoscopies with poor preparation be repeated within one year, with an even shorter interval when advanced neoplasia is identified in the setting of inadequate prep (11,13). Notwithstanding these recommendations, sub-optimal preparation that may not meet the threshold of "inadequate" is also associated with more frequent deviation (shortened interval) from screening and surveillance guidelines (12,13).

Increased colonoscopy frequency resulting from inadequate preparation raises a number of safety and cost considerations. Adverse events related to bowel preparation are common and a large deterrent to undergoing colonoscopy. Up to one third of patients experience minor symptoms related to colonoscopy, such as abdominal pain and bloating (14). There are financial considerations with respect to early repeat colonoscopy for patients, payers, and endoscopists. For patients and those providing them with transportation, there are costs related to missing time from work and co-pays related to the purgative and colonoscopy. Patients and the person transporting them lose, on average, a day from their normal activities for every colonoscopy performed (15). Insurers are beginning to not cover a second colonoscopy when done for prior inadequate preparation or, if covered, the reimbursement is reduced. Finally, many patients who have inadequate cleansing do not return for a subsequent colonoscopy. In total, inadequate bowel preparation resulting in early repeat colonoscopy is estimated to increase direct colonoscopy costs anywhere from twelve to twenty-two percent (15).

Despite the impact, inadequate preparation has been reported in up to twenty-four percent of colonoscopies yearly (10,14) and these same patients have a high chance of inadequate cleansing on subsequent colonoscopy (16,17). Despite this very high proportion of inadequate preparations, there is minimal

evidence-based guidance on bowel preparation for patients who have had, or are at high risk for, inadequate cleansing. As a result, numerous patients present on the day of colonoscopy with an inadequate preparation at which point there are no ideal options for managing this problem. Most often the colonoscopy is cancelled and rescheduled, but aggressive and prolonged flushing and suctioning, supplemental standard or through-the scope enemas, and additional oral purgative for later day or next day colonoscopy have all been tried (11). Limiting these options are issues of scheduling, space, time, and efficacy.

Thus, effective salvage of inadequate colon cleansing at the time of colonoscopy is a great unmet need. Pure-Vu is a new intra-procedure device that enables conversion of an inadequate preparation to one that is adequate. This FDA-cleared device is placed over the colonoscope insertion tube and utilizes a novel irrigation technology. Pure-Vu was developed using animal models (18) and is currently being investigated in the inpatient setting through a multi-center clinical trial in the United States. The device has already been studied at a variety of clinical sites abroad and has shown promise as a safe and efficacious endoscopic tool (19, 20). While inadequate preparation is a problem in the inpatient population, given that over 95% of colonoscopies in the U.S. are outpatient, the magnitude of the problem of inadequate cleansing is far greater for outpatients.

This study is a prospective randomized controlled trial using the Pure-Vu System in patients presenting for elective outpatient colonoscopy with brown or liquid brown stool clarity grade (21) at the time of procedure.

6.0 Study Device

6.1 General Description

The Pure-Vu System enables colon cleansing during colonoscopy using a standard or slim colonoscope with a length of 1630mm – 1710mm and an outer diameter range of 11.7mm – 13.3mm (slim) and 12.8mm – 13.7mm (standard). The Oversleeve, which fits over the colonoscope and is connected to an external Workstation, generates fluid and gas 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 System consists of the following main components:

- Disposable device which includes an Oversleeve and an Umbilical Section. The Oversleeve fits over the colonoscope and the Umbilical section is connected to the external Workstation.

- Workstation that is reusable and supplies an irrigation mixture of water or saline and gas, and evacuates fecal material & fluids.
- Loading Fixture that is reusable and aids in assembling the Oversleeve onto the colonoscope.
- Additional components include 60cc luer lock syringe/3-way stopcock assembly, sealing plug, and air line tubing.

Below is a drawing showing the various components of the system

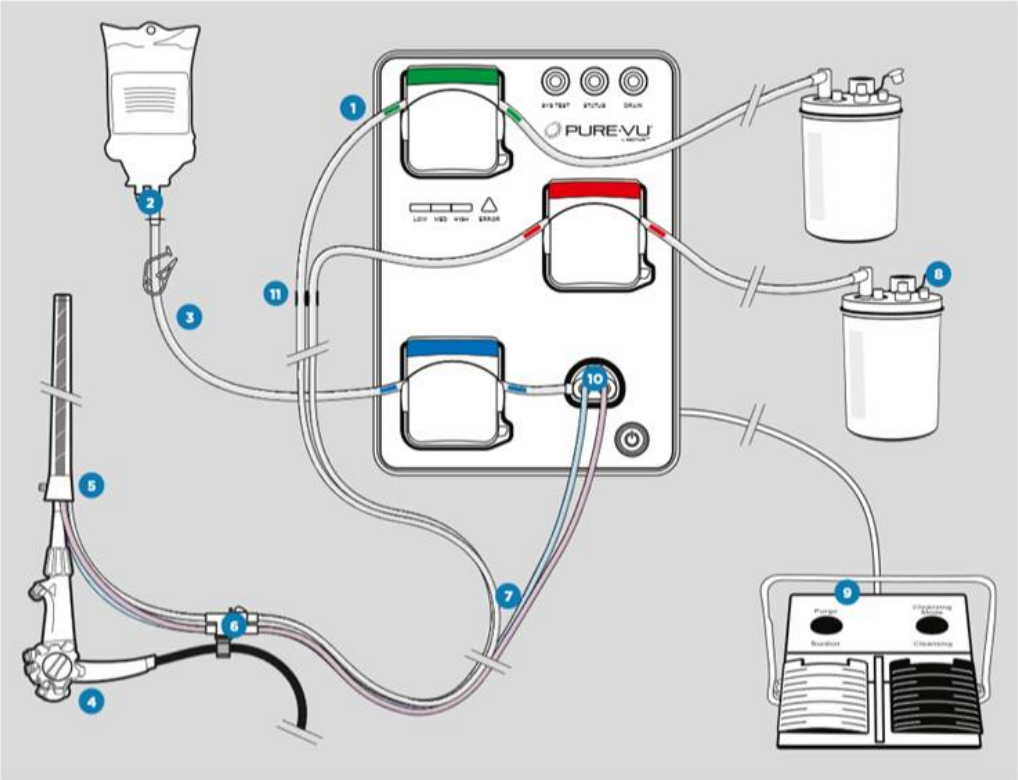


Figure 1: Pure-Vu Workstation – General design & components

1 Workstation
2 Irrigation Bag
3 Irrigation Line Clamp
4 Colonoscope
5 Oversleeve
6 In-Line Connector
7 Umbilical Section
8 Waste Container
9 Foot Pedal
10 Main Connector
11 Suction Tubing Clamp

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

6.1.1 Work Station (WS)

The Workstation is designed to provide water or saline for irrigation and suction to evacuate fecal matter & fluids out of the body during the colonoscopy procedure.

The WS has the following main functions:

- Cleansing: Creates an irrigation stream with simultaneous evacuation. The cleansing has three modes, high, medium and low with medium being the default setting. The high and medium modes are a mixture of liquid (water or saline) and air, and the low mode is a stream of liquid only. The physician can operate the system as per his professional clinical judgment. It is important to note that the evacuation function noted below is active during cleansing so that fluid is inserted and removed from the colon simultaneously.
- Evacuation: Removes fecal matter and fluids out of the colon. The evacuation function is active during the cleansing as previously noted and can also be used independently. During evacuation the system senses the pressure in the evacuation channel of the Oversleeve and if the pressure goes below pre-set limits will automatically reverse the flow to purge a potential blockage and then switch back to continue evacuation. The user also has the ability to manually purge the evacuation channel as well.
- User interface: Consists indicators on the WS itself as well as a foot pedal to activate the main functions of the system so that users' hands are free to manipulate the colonoscope.

6.1.2 Oversleeve

The Oversleeve is mounted on top of a Standard or a Pediatric colonoscope and is connected to the WS via the Umbilical. The Oversleeve includes the following main components:

- Tubing: Four (4) tubes that support the irrigation, evacuation and sensing functions of the system.
- Suction and Irrigation head: The Oversleeve's distal end which contains irrigation ports, suction ports, and channel for sensing blockages.

- Inner sleeve: This sleeve attaches the Oversleeve to the colonoscope along its length. This sleeve is inflated to allow the colonoscope to be inserted through and will hold the colonoscope when deflated.
- Outer sleeve: This sleeve covers the entire insertion tube of the colonoscope, keeping the tubes in position and providing a smooth surface to interface with the interior of the colon. The Oversleeve is hydrophilically coated to provide a lubricious surface to aid in navigation through the colon.
- Inflation hub: Provides the port to pressurize the inner sleeve during the loading of the colonoscope and provides the entry location for the colonoscope to be inserted into the Oversleeve.

6.1.3 Umbilical Section

The Umbilical section allows the integration of the Oversleeve to the workstation. It is connected by the inline connector and includes a clip which that can connect to the colonoscope umbilical section.

6.1.4 Loading Fixture

The loading fixture consists of a pressure source and a distal sealing plug to facilitate inflation of the inner sleeve of the device as well as a base to keep the Oversleeve in a stable position to allow insertion of the colonoscope.

6.2 Pre-Clinical Data

The Pure-Vu system was used by four experienced gastroenterologists in 35 Yorkshire cross swine (66% female) that 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 was then employed to cleanse the colon and the prep was then assessed post-Pure-Vu use.

No adverse effects and no failed or prematurely terminated cases were noted. 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.

6.3 Clinical Data to Date

The Pure-Vu System has been evaluated in multiple clinical studies.

An outpatient feasibility study including 47 outpatients enrolled at 3 clinical sites has previously 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), and high rates of physician satisfaction regarding system usability (20). An additional outpatient study of 50 outpatients who received minimal pre-procedure preparation showed that 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) (19). For both studies, similar protocol was used for screening, diagnostic or surveillance indication. 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 before and after use of the Pure-Vu System with the Boston Bowel Preparation Score (BBPS) (1).

The Pure-Vu significantly increased the number of subjects with an adequate cleansing level (BBPS >= 2 for all 3 colon segments) from 25%; CI 95% [17%, 35%] at baseline to 99%; CI 95% [94%, 100%] after Pure-Vu. Cecum intubation rate was 98%; CI 95% [94%, 100%]). Mean post-treatment BBPS score was 8.7 ± 1.0 vs. 3.9 ± 2.2 prior to Pure-Vu use. Physicians were satisfied with the device's use. No major difficulties were experienced when performing polypectomy and no serious adverse events were reported.

For the inpatient population, a study was performed which 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 body mass index (BMI) was 28.02 ± 6.62. 53 patients 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.

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). Adequate preparation, defined as pre Pure-Vu BBPS scores of 2 or higher, was reported in 60%, 62%, and 47% of the left-side, transverse, and right segments, respectively. After cleansing with Pure-Vu, adequate preparation was reported in 100%, 99%, and 97% of the left-side, transverse, and right segments, respectively. Patient assessment of poor clarity of last bowel movement (21) was associated with lower BBPS score prior to cleansing with Pure-Vu. Pure-vu cleansing improved BBPS score regardless of pre-procedure clarity score as shown in figure 2.

Pre Pure-Vu BBPS scores were similar in patients that consumed 2, 3, 4, or more than 4 Liters of bowel preparation prior to colonoscopy, however patients that consumed less than 2 Liters of bowel preparation treatment had a lower Pre Pure-Vu BBPS score. Pure-Vu 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 serious adverse event 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.

7.0 Risk/Benefit Analysis

7.1 Anticipated Risks Associated with the Study Device conjunction with a colonoscope

The Pure-Vu is used in conjunction with a colonoscope during a colonoscopy procedure. Hence, the complications associated with using the Pure-Vu are anticipated to be similar to those associated with the colonoscopy procedure. As with any colonoscopy procedure, when using the Pure-Vu there are some risks

of a missed lesion, bowel perforation, pain, or bleeding. Although the risks of the procedure with the Pure-Vu System are expected to be comparable to conventional colonoscope (0.35%), the device is an add-on to a colonoscope.

The Pure-Vu system was tested in an animal study including 35 pigs and in preliminary clinical studies including 97 subjects. No major complication or serious adverse events occurred within the course of those studies.

In addition, clinical studies demonstrated an excellent cleansing effectiveness; the Pure-Vu System improved the cleansing level from 25% at baseline to 99% after the cleansing was operated and in 98% of the subjects the cecum were reached and the procedures completed successfully.

Considering the residual risks and the potential and the risk against benefit assessment, it can be concluded that the system may offer potential benefit to the subjects along with no significant risk increase.

7.2 Residual Risks Associated with the Study Device

The Pure-Vu System is an FDA 510(k) cleared device which is indicated to cleanse poorly prepped colons during colonoscopy.

Residual risk is defined as the risk remaining after controls have been implemented. Risks associated with the use of the Pure-Vu System were mitigated in accordance to the EN ISO 14971:2012 risk management process. For more details please request the risk analysis report.

7.3 Potential Benefits to the Subject

The potential benefits of the Pure-Vu System are the cleaning technology that may improve visualization, reduced reliance on subject pre-procedure colon preparation and reduced need for repeated colonoscopies required due to insufficient colon preparation, these consequently may reduce pain, discomfort, risks, costs and lost productivity.

Considering the residual risks and the risk against benefit assessment, it can be concluded that the system may offer potential benefit to the subjects along with no significant risk increase compared to the standard of care procedure.

8.0 Study Objectives

8.1 Primary Objective

To evaluate the frequency of bowel cleansing adequacy after Pure-Vu as compared to standard colonoscopy ("Control") in subjects who are high risk for inadequate colon preparation

8.2 Secondary objectives

1. Assess the willingness of consented subjects to pay for Pure-Vu prior to colonoscopy
2. Colonoscopy procedural measures for Intervention and Control arms
3. Endoscopists' experience
4. Safety assessment for all subjects on the day of procedure per endoscopist
5. Post-colonoscopy patient experience and safety check with scripted phone call 1-3 days after colonoscopy
6. Assess the willingness of consented subjects to pay for the Pure-Vu System 1-3 days after colonoscopy

9.0 Study Endpoints

9.1 Primary Endpoint

A comparison between the two study arms (i.e., Pure-Vu vs. standard colonoscopy) of the rate of overall cleansing as well as cleansing per segment will be evaluated by the BBPS scoring index (Bowel preparation adequacy defined as BBPS $\geq$2 in each segment)

9.2 Secondary Endpoints

1. Assess the willingness of consented subjects to pay for Pure-Vu prior to colonoscopy
    a. Would want Pure-Vu bowel cleansing device to be used on day of colonoscopy if preparation were inadequate ("Yes" or "no")
2. Colonoscopy procedural measures for Intervention and Control arms
    a. Duration: Insertion and withdrawal time without intervention other than cleansing

b. Colonoscopy completion: "Yes" or "no;" if "no" then record most proximal extent of exam and reason exam was incomplete (it is acceptable to switch to a different scope if needed due to anatomical reasons)

c. Polyp detection - For each polyp: Location, size, morphology (pedunculated, sessile, flat), removal technique (cold biopsy, hot biopsy, cold snare, hot snare, EMR), histology

d. Non-polyp colonoscopy findings: Finding, location

e. Assessment of need for early repeat colonoscopy (defined as endoscopist recommendation for early repeat colonoscopy due to preparation): "Yes" or "no"

3. Endoscopist experience

a. Intervention arm

i. Ease of use of Pure-Vu (visual analogue scale 0-10)

ii. Efficacy of Pure-Vu (visual analogue scale 0-10)

b. Intervention *and* Control arms

i. Technical difficulty performing colonoscopy (visual analogue scale 0-10)

4. Safety assessment for all subjects on the day of colonoscopy by endoscopist

a. Type, incidence, severity, Relation to procedure and clinical consequence(s) of adverse event.

5. Post-colonoscopy patient experience with scripted phone call 1-3 days after colonoscopy

a. Patient satisfaction

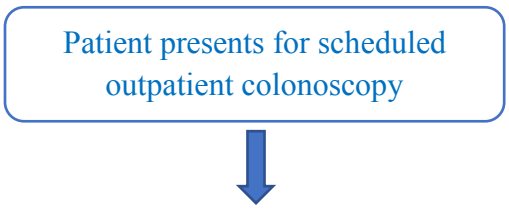
i. Colonoscopy experience overall (analogue scale 0-10)

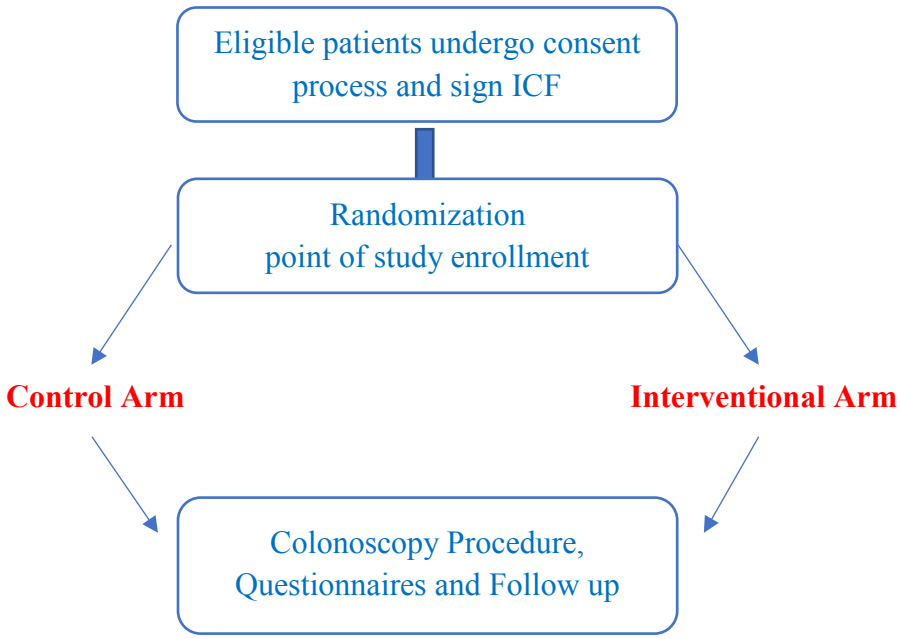
6. Assess the willingness of consented subjects to pay for Pure-Vu 1-3 days after colonoscopy

a. Would want Pure-Vu bowel cleansing device to be used in the future for colonoscopy if preparation were inadequate ("Yes" or "no")

10.0 Study Design

Study Flowchart





11.0 Selection and Enrollment

After providing informed consent, the subject will sign the sites' designated IRB approved informed consent form (ICF). Enrollment of up to 88 subjects is planned.

Subjects' participation in the study will last approximately 2 days, including the procedure day, and one follow up call during the follow up period (1-3 days after the procedure). Subjects will be considered for the study if they meet the specific inclusion and none of the exclusion criteria.

11.1 Inclusion/Exclusion Criteria

Inclusion Criteria

1. Adults > age 22
2. Elective outpatient colonoscopy by participating gastroenterologist
3. Stool clarity grade 1-3 at presentation for colonoscopy

Exclusion Criteria

1. Not competent to consent
2. Bleeding disorder – known or suspected
3. Hereditary Gastrointestinal Cancer syndrome
4. Known PT INR > 1.5
5. Know elevated PTT
6. Anti-platelet agent or anticoagulant (other than aspirin or nonsteroidal agent) which has not been stopped for the colonoscopy
7. Known platelet count < 50,000
8. Known absolute neutrophil count < 1,000
9. History of surgical colon resection
10. Pre-colonoscopy intent to enter terminal ileum
11. Prior incomplete colonoscopy due to technical & non-bowel preparation related reasons
12. Regular use of non-topical steroid
13. Pregnant
14. Prisoner or institutionalized for any reason
15. Psychiatric illness greater than mild
16. Colonoscopy without anesthesia administered (MAC) sedation
17. Diverticulitis
18. Active inflammatory bowel disease (Crohn's, Ulcerative Colitis, or Indeterminate)
19. Known or suspected colon stricture

11.2 Withdrawal Criteria

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:

1. Severe side effects clearly related to the study device.
2. Presence or appearance of exclusion criteria.
3. Appearance of accompanying diseases rendering further participation in the study impossible.
4. A significant protocol violation, as determined either by the sponsor or the investigator
5. 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, the following will be recorded:

Age, gender identity, indication for colonoscopy, stool clarity grade, reason for screen failure (if screen failure).

11.3 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, case report form (CRF) completion, and Good Clinical Practice (GCP), as well as the device and system (including procedural use, device characteristics, shelf life and storage requirements, warnings, and precautions), if applicable.

12.0 Study Procedures

12.1 Screening and Informed Consent

At the screening visit, subjects 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.

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.

On the day of elective outpatient colonoscopy, patients will be identified at the time of admission to endoscopy. At the time of admission patients will be asked about the color/clarity of their last bowel movement, which is standard of care. Patients presenting for colonoscopy and reporting brown stool will

be shown a laminated card with color photos of the clarity scale and will select the photo most representative of their most recent stool and this will be recorded. Those who select the brown fecal clarity Grade 1, 2, or 3 will then be offered entry into the study and, if interested, will be screened for eligibility. If eligible, informed consent will be obtained. Consented patients will be randomized to the Intervention or Control arm and the Colon preparation details will be recorded.

12.2 Randomization

Randomization to Intervention or Control arm will use stratification by site, endoscopist and blocking. Sites are expected to contribute approximately equal numbers of procedures, and no site will be allowed to contribute more than 50% of the target sample size. The randomization sequences will be provided in advance by the study's statistician using an online system to obtain the randomization assignment and the corresponding colonoscope will be prepared. Randomization assignment will be recorded for each subject.

12.3 Screen Failures

A subject is considered enrolled in the study when the randomization has occurred. Only subjects who undergo the colonoscopy procedure, regardless of treatment arm, will be followed. Subjects who provide study consent, but then are determined to be ineligible will be considered screening failures and will not require additional study follow-up.

For screen failures, the following will be recorded: Age, gender identity, indication for colonoscopy, pre-procedure stool clarity grade, reason for screen failure.

12.4 Pre- Procedure

As standard operating procedure in the outpatient population setting, bowel preparation is prescribed for individuals undergoing a colonoscopy procedure. Although bowel preparations are prescribed, it is not a requirement that the subject completes the bowel preparation prior to the colonoscopy procedure for the study.

Prior to the procedure the patient will be asked to complete pre-colonoscopy questionnaire regarding willingness to pay for Pure-Vu recorded.

Demographics, medical and surgical history will be recorded: Colonoscope (adult/pediatric), age, BMI, gender identity, racial identity, indication for colonoscopy, preparation details (purgative, dose, administration schedule, and diet), pre-procedure stool clarity grade, medications, medical history, and abdominal and pelvic surgery.

12.5 Colonoscopy Procedure

The insertion during the colonoscopy procedure will be performed by the clinical study investigator(s), experienced in GI endoscopy according to local standard of care. In cases where upper endoscopy is planned, it will be conducted per the physician's discretion. Monitored Anesthesia Care (MAC) sedation will be utilized and documented.

The Colonoscope will be prepared as per normal routine and the research assistant will cover the colonoscope before the patient enters the endoscopy room to keep him/her blinded to the study arm. This is uncovered once the patient is sedated. During the colonoscopy, standard flushing and suctioning (Control arm) or the Pure-Vu System (Intervention arm) will be used at the endoscopist's discretion.

Pure-Vu data: After each Pure-Vu colonoscopy, information regarding the use of the Pure-Vu System (number of times the pump is used and the total duration of use in seconds) will be documented.

Specific situations occurring during colonoscopy

If the attempt to reach the cecum is fails, the investigator shall have the option to perform the procedure with a pediatric or any other colonoscope he/she may choose without Pure-Vu. The subject will complete the study as planned. If a medical condition requiring treatment is detected during colonoscopy, the subject will be treated as per the standard care.

Post-Examination Follow-up

Subjects will be transferred to 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 will be conducted 1-3 business days after the procedure to verify that there has been no change in their clinical status and record their willingness to use the Pure-Vu System in the future. Before a subject is considered "lost to follow-up", there must be at least two documented attempts to contact the subject.

13.0 Statistical Analysis

13.1 Sample Size Determination

Assuming 60% preparation adequacy in the Control arm, and 90% preparation adequacy in the Intervention arm, a total sample size of 80 participants (40 per arm) has 85% power (using 2-sided alpha 0.05). To account for an expected dropout rate of 10% per arm, 44 participants per arm will be enrolled, for a total of 88 patients.

13.2 Description of Statistical Methods

Basic demographic and other baseline characteristics will be collected and analyzed for all subjects. Summary statistics (mean, standard deviation, median, minimum and maximum for quantitative variables) will be presented for the total study population. Frequency tables for qualitative data will be provided.

All main analyses will follow the intent-to-treat principle.

Any deviation from specified statistical plan will be in addition to "per protocol" analysis and will be reported as such.

13.3 Primary Endpoint Analysis

The primary statistical hypothesis is that the cleansing level post cleansing with the Pure-Vu (Intervention arm) will be significantly improved as compared to the cleansing level post standard colonoscopy procedure (Control arm). The Intervention (Pure-Vu) and Control (standard colonoscopy) arms will be compared with respect to preparation adequacy (BBPS ≥2 in every segment). In case of incomplete procedure, the segments that are not evaluated due to dirtiness are assigned a score of 0. In case of non-evaluated segment due to anatomical challenges (stricture, mass, etc.) segments will be excluded from analysis.

The risk ratio was estimated along with a 95% confidence interval, and use the Mantel-Haenszel test with stratification by site to test whether preparation adequacy differs between the two arms (with a 2-sided alpha 0.05). All main analyses will follow the intent-to-treat principle. In case of substantial deviations from the protocol, secondary per-protocol analyses will also be carried out.

13.4 Secondary Endpoints Analysis

Secondary dichotomous outcomes (intubation, adverse events) will be analyzed similarly using the Mantel-Haenszel test, with site as stratification variable (with a 2-sided alpha 0.05). Secondary continuous outcomes (timing, number of polyps, patient and endoscopist satisfaction) will be analyzed using linear regression, with site as a covariate.

13.5 Interim Analysis

No Interim Analysis will be performed for this study.

14.0 Adverse Events and Classifications

AE and AE subcategories are defined per ISO14155:2011, as described below.

14.1 Adverse Event (AE)

An AE is any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, whether or not related to the investigational medical device.

This definition includes events related to the investigational medical device or the comparator and the procedures involved.

AEs will be collected starting from the time subject is enrolled until the follow-up period is completed.

14.2 Serious Adverse Event (SAE)

A Serious AE (SAE) is an AE that has

a) Led to death,

b) Led to serious deterioration in the health of the subject, that either resulted in

1) A life-threatening illness or injury, or

2) A permanent impairment of a body structure or a body function, or

3) In-patient or prolonged hospitalization, or

4) Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

c) Led to fetal distress, fetal death or a congenital abnormality or birth defect

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the clinical investigational plan, without serious deterioration in health, is not considered an SAE.

Some important medical events, although they 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.

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.

Disability means a substantial disruption of a person's ability to conduct normal life's functions.

14.3 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.

14.4 Serious Adverse Device Effect (SADE)

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

14.5 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.

14.6 Classification of Event Severity, Relationship and Outcomes

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:** Incapacitating, with an inability to perform ADL

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

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.

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.

14.7 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.

14.8 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 CRF 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 AEs observed during this study, regardless of severity or relationship to the investigational device will be recorded on the appropriate CRF.

14.9 Reporting Responsibilities

An investigator shall submit to the sponsor and to the reviewing IRB a report of any SAEs, ADEs, SADEs, 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.

A sponsor who conducts an evaluation of an unanticipated adverse device effect under 21 CFR Part 812.46(b) shall report the results of such evaluation to FDA and to all reviewing IRB's and participating investigators within 10 working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as FDA requests (21 CFR Part 812.150).

15.0 Ethics and Compliance

15.1 Statement of Compliance

This clinical investigation will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, ISO 14155:2011 (Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice), 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.

15.2 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, but in no event later than 5 working days after the emergency has occurred. 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.

15.3 Institutional Review Board (IRB)

Documented approval from the appropriate Institutional Review Board (IRB) 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.

15.4 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) and must adhere to GCP and to the ethical principles originating in the Declaration of Helsinki. Written 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.

15.5 Insurance

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

15.6 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. Only the subject number and initials will be recorded in the CRF, and if the subject name appears on any other document, it must be obliterated. In cases were the local law does not allow using the subject initials serial number will be appointed (e.g. AAA, BBB). 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/EC 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.

15.7 Use of Data and Publications

Information regarding the study and study data will be made available via publication on clintrials.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 time line 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.

16.0 Monitoring Procedures

Site visits will be conducted by an authorized Motus GI representative to inspect study data, subjects' medical records, and CRFs in accordance with current ICH GCPs and the respective local and national government regulations and guidelines (if applicable).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 CRFs, IRB decisions, and Investigator, clinical site records, and facilities relevant to this study at regular intervals throughout the study per the monitoring plan. Additionally, subject charts and clinical records will be requested and reviewed so that protocol adherence and source documentation can be verified. The accuracy and quality of the data obtained from the investigator and maintained by Motus GI will be confirmed through a structured program of clinical field auditing and internal review detailed in the monitoring plan. 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. Monitoring may be performed with in person visits or remotely, when applicable.

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 devices. 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. If compliance cannot be secured, device shipments to the investigator may be discontinued and the investigator's participation in the investigation terminated. The monitor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

16.1 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 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. The EDC is 21 CRF Part 11 compliant. Only Research Coordinators or PIs trained to the use of 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.

The investigators shall ensure the accuracy, completeness, legibility 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. If an item is not available or is not applicable, this fact should be indicated; no space is to be left blank. The CRFs are to be completed in a timely manner after the participant'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 CRFs correctly and completely.

17.0 Study Supplies and Device Accountability

17.1 Packaging

The Pure Vu disposables are composed of biocompatible plastic parts 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.

17.2 Labeling

All the disposable packages are labeled as single use with a lot number and expiration date. Examples of the main system and packaging label as well as operation instructions, precautions and warnings are defined in the Instructions For Use.

17.3 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 information should be recorded:

- The subject study number
- Date Oversleeve used
- Oversleeve lot number
- Expiration date

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

17.4 Retention of Records

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

17.5 Study Completion/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 on the appropriate CRF.

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.

18.0 Study Contact Information

Clinical Affairs
Annie Choi Director of Clinical Operations Motus GI Technologies LTD. Phone: 954-541-8258 Mobile: 617-935-7366 Email: anniec@motusgi.com

19.0 References

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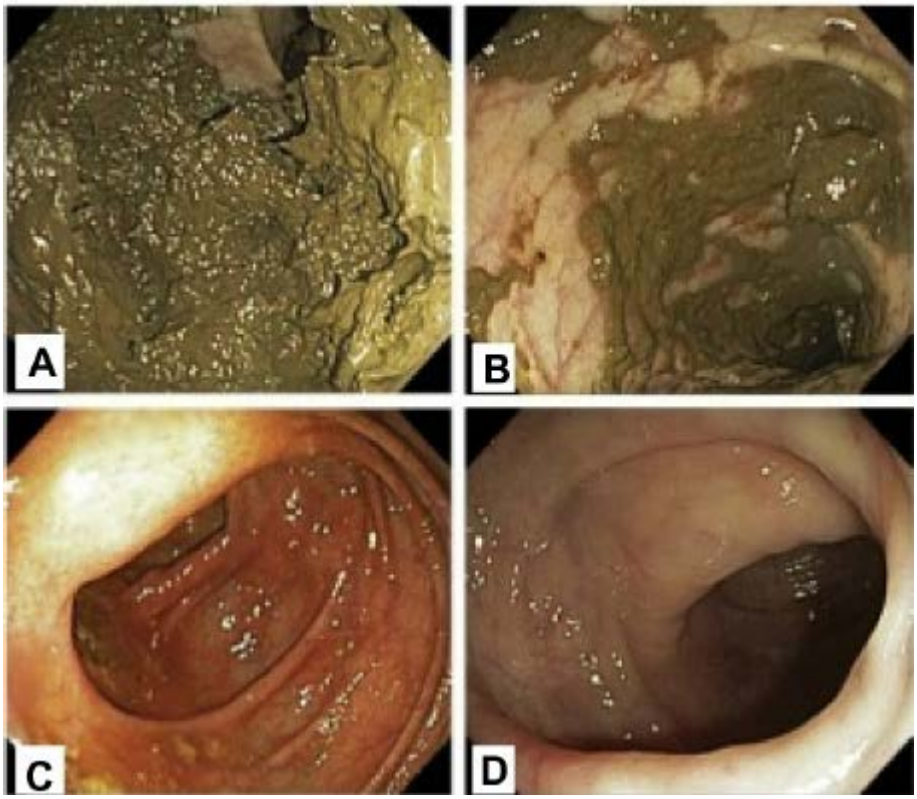
20.0 Appendices

Appendix A: Study Design and Schedule of Assessment

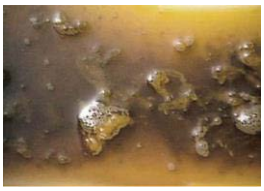
Assessment	Visit 1 (day 0)	Follow Up (1-3 days post procedure)
Informed Consent	X	
Eligibility assessment (medical records, BMI, etc.)	X	
Medical History and Demographic details	X	
Randomization	X	
Colonoscopy Procedure	X	
Follow Up	X	X
Adverse Events Reporting	X	X

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.

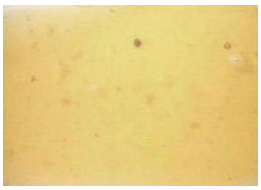
Appendix C: Clarity Card



Grade 1

Grade 2

Grade 3



Grade 4

Grade 5