

**Pure-Vu®**

Colonic Irrigation for Colonoscopy



# Speaker

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# Device Overview



The Pure-Vu System consists of a Workstation and Oversleeve that connects to currently marketed colonoscopes to reduce the dependency on preprocedural preparation by providing high intensity intra-procedural cleansing of the colon during a colonoscopy.

This is achieved by the device creating:

- High Intensity Pulsed Irrigation Jet to break-up fecal matter, blood clots and other debris and scrub the walls of the colon
- While simultaneously removing the debris using a synchronized pumping system
- Allows use of the colonoscope working channel while cleansing



# The Pure-Vu® System Technology Details



## PULSED VORTEX IRRIGATION

- ✓ Four irrigation jets deliver a patented mixture of water and air to effectively break up fecal matter and clear the field of view.



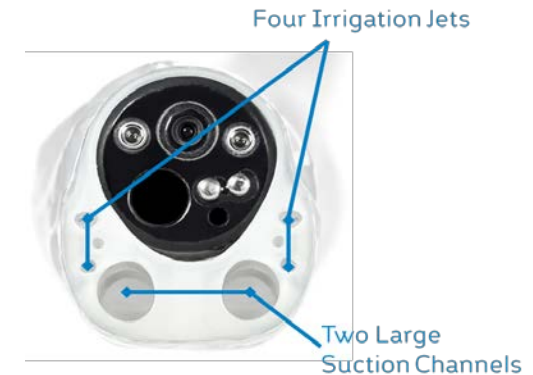
## SMART SENSE SUCTION

- ✓ System senses the formation of clogs and automatically clears the channel and prevents mucosal wall suctioning.
- ✓ Two large suction channels facilitate effective removal of fecal material and debris with twice the suction area as a standard scope.



## SMOOTH GLIDE NAVIGATION

- ✓ Provides minimal friction for smooth advancement through all segments of the colon.



The Pure-Vu System is indicated to help facilitate the cleaning of a poorly prepared colon during the colonoscopy procedure.



# Patient Population

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- Targeted for patients that need to undergo an urgent diagnostic or therapeutic colonoscopy or are unable or incapable to achieve an adequate preparation for their colonoscopy due to comorbidities, motility issues, mental status or have contraindications for traditional bowel prep.
- Relevant Indications for Colonoscopy
  - Acute Lower GI Bleeding
  - Unknown abdominal pain
  - Colonic obstruction
  - Incessant diarrhea
  - Foreign body removal
  - Other emergent colonic pathologies
  - Outpatient – CRC screening, IBD and other disease management
- Indicators of inadequate preparation:
  - Advanced age, diabetes, chronic constipation (opioid use), compromised mental status, immobility (wheelchair bound or bed ridden), additional motility issues and other comorbidities.
  - Contraindicated to preparation due to allergies to purgatives, renal compromise, foreign body removal or other forms of colonic obstruction where preparation is contraindicated.

# Unmet Clinical Need

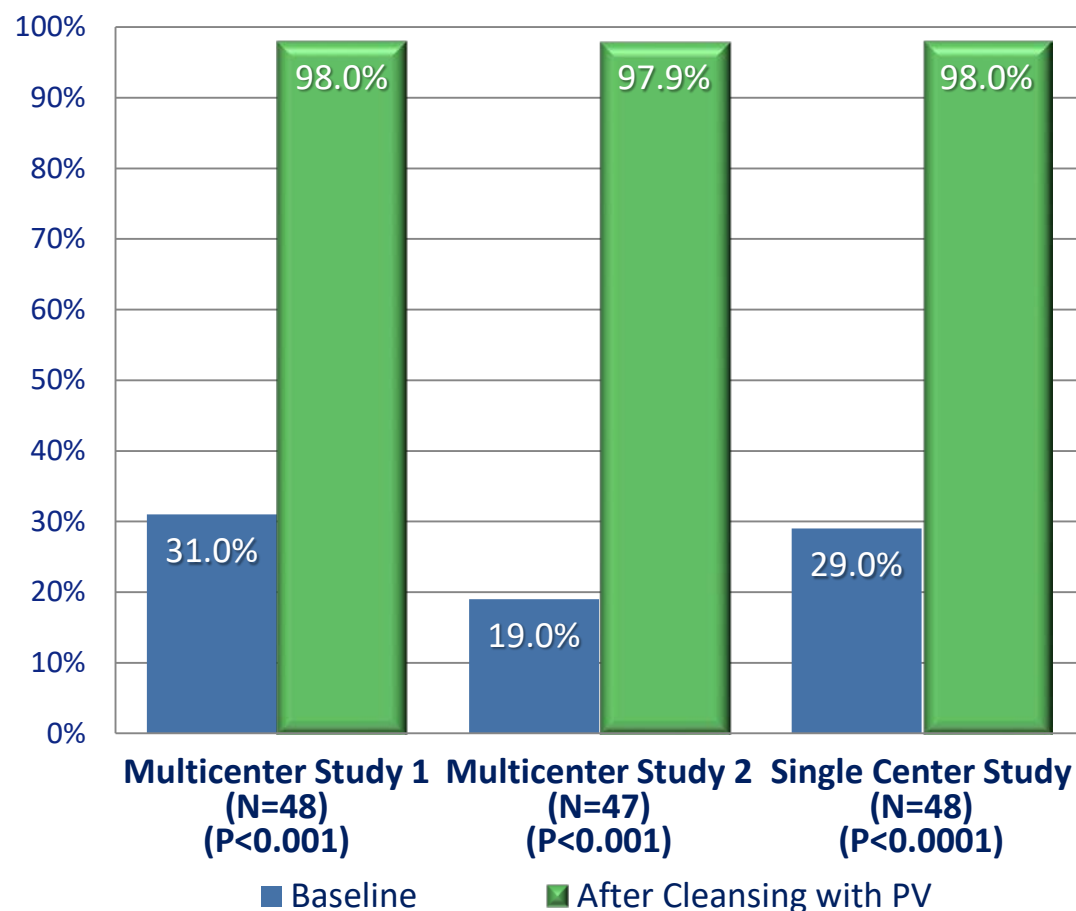
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- Ability to rapidly exam the colon in an urgent situation (i.e., critical GI Bleed)
  - Patients that require an urgent colonoscopy like significant GI bleed where achieving hemostasis as quickly as possible can be critical to the patient, minimize the need for blood products and reduce ICU and overall hospital length of stay.
  - Inadequate preparation negatively impacts the quality of the exam and the diagnostic yield (i.e., ability to find the source of GI bleed).
  - Inadequate preparation is also associated with higher complication rates due to poor visualization.
- In the inpatient setting the ability to adequately prepare the colon is severely compromised as compared to the outpatient setting and leads to extended days of clear liquid diet and high-volume purgative solutions for many patients.
  - Can cause concerns with electrolyte imbalance, renal function and other adverse events in compromised patients

*Currently the only way to clean the colon intra-procedurally is through the colonoscope working channel which is not effective in breaking up significant fecal matter or dislodging adherent debris and effectively removing it from the colon.*

# Clinical Data Overview Minimal Preparation Studies

% of Subjects Adequately Prepped by Boston Bowel Prep Scale (BBPS)



**Study Design:** Patients were prescribed a minimal preprocedural preparation and then underwent a colonoscopy using Pure Vu on the colonoscope. The cleanliness of each segment of the colon was assessed using the BBPS upon entry (baseline) and after cleansing with Pure Vu. All 3 segments of the colon needed to be clean (BBPS  $\geq 2$ ) for the patient to be considered adequately prepped.

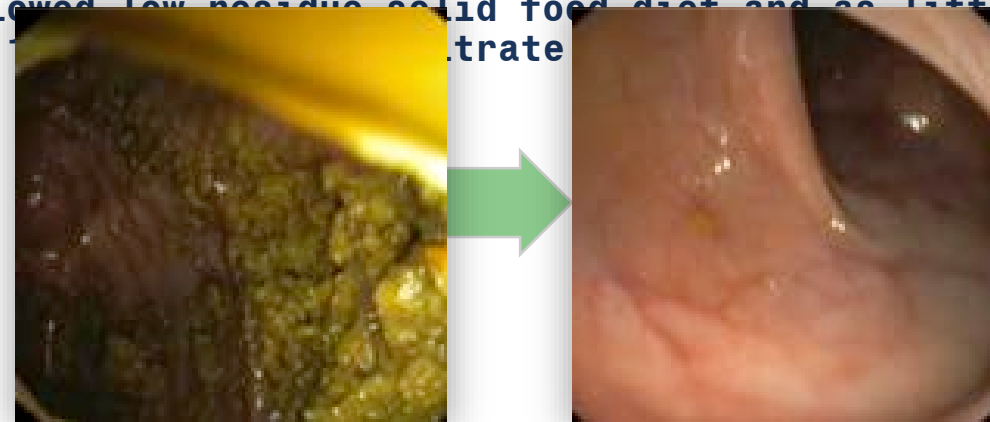
The preparation regime for each study is noted below:

Multicenter 1 and 2 Study Prep:

- 18 - 24 hours full liquid diet and 20 mg Dulcolax®

Single Center Prep:

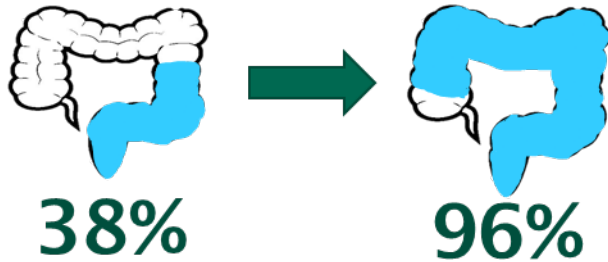
- Allowed low residue solid food diet and as little as 100 mL of laxative



# REDUCE Study Multicenter Inpatient study

## Study Design:

- Patients were prescribed standard preparation overnight and brought down for colonoscopy the next day regardless of the amount of purgative they drank or how dirty their last bowel movement was (No Delays)
- Single arm study of 94 patients with each patient acting as their own control
  - Visualization was assessed in each of the segments of the colon using the Boston Bowel Prep Scale (BBPS) at baseline and after cleansing with Pure Vu



Adequate bowel preparation rate improved significantly following use of Pure-Vu<sup>®</sup> System

98% clinical success rate\*

## Indications:

- GI bleeding (68%)
  - Iron deficiency (28%)
  - Suspected neoplasia or other lesion (21%)
  - Pain/Diarrhea (8%)
  - Pre-transplant evaluation (7%)
- (44.6% of patients were 65 or older)

## Statistically significant improvement

### Boston Bowel Prep Scores:

- Left colon: 1.74 vs 2.89
  - Transverse: 1.74 vs 2.91
  - Right colon 1.50 vs 2.86
- ( $p < 0.0001$  for all 3 segments)

Scale goes from 0 to 3. Score of 2 or better in all 3 segments is considered adequate

\*Patients had a successful inpatient colonoscopy, for the indication that did not need to be rescheduled due to bowel preparation quality.



# Operative Records Documentation

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➤ The following terms may be used by the treating physician in the operative notes:

➤ Device Names

- Pure-Vu System
- Pure-Vu Oversleeve (may note *Slim* or *Standard* size)
- Motus System
- Colonoscope Oversleeve
- Pure Vu (may note *Slim* or *Standard* size)
- Oversleeve
- Cleansing system
- Cleansing Sleeve or Oversleeve
- Slim Sleeve or Oversleeve
- Standard Sleeve or Oversleeve

The device does have Unique Device Identifier (UDI) code registered to the Global Unique Device Identification Database (GUDID).

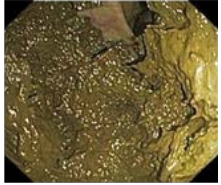
# Summary

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- The technology has demonstrated the ability to cleanse inadequately prepped / unprepared colons during a colonoscopy and achieve a high degree of visualization in several clinical trials with clinical success rates averaging over 96% in patients with minimal prep or at high risk.
  - Inadequate preparation is associated with reduced diagnostic quality leading to missed pathology and delayed, aborted and early follow up procedures.
  - Preparation can be difficult to tolerate for elderly population and those with comorbidities.
  - Time for preparation can delay diagnosis and treatment in emergent patient populations.
- Pure Vu removes the dependency on a successful preprocedural preparation to perform a successful colonoscopy.
- There is no other Oversleeve based intra-procedural colonic cleansing device on the market

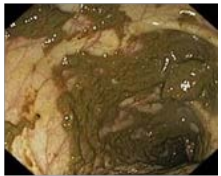
# Boston Bowel Prep Scale ⇓ Definition

## Boston Bowel Preparation Scale (BBPS)



0

Unprepared colon segment with mucosa not seen because of solid stool that cannot be cleared.



1

Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen because of staining, residual stool, and/or opaque liquid.



2

Minor amounts of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well.



3

Entire mucosa of colon segment seen well with no residual staining, small fragments of stool and/or opaque liquid.

Each colon segment given a score between 0 – 3 with the total equaling the BBPS.