# A Novel Device for Improving Visualization in an Inadequately Prepared Colon

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## INTRODUCTION

Poor bowel preparation affects the completeness of the colonoscopy and can result in longer procedural times, missed adenomas, earlier repeat procedures, increased costs, and decreased patient satisfaction.

The MOTUS GI Pure-Vu<sup>™</sup> System (Tirat Carmel, Israel) has been designed to improve visualization in an inadequately prepared colon by facilitating intra-procedural cleaning. The primary aim was to rate adequate colon cleansing level as defined by a Boston Bowel Prep Score (BBPS), at baseline and after the use of Pure-Vu. The secondary endpoints were Pure-Vu usability via questionnaire and safety evaluation.

# METHODS

#### **Pure-Vu System**

The system consists of a disposable single-use over-sleeve and a workstation controller. The disposable over-sleeve fits easily over standard colonoscopes without interfering with the working channel or the navigation or advancement of the colonoscope. The workstation controls the delivery of a novel irrigation mode via 4 jets and a regulated evacuation cycle that effectively removes considerable colon content and prevents potential clogging through an auto-purge function.

Pure-Vu Work Station Controller



Pure-Vu Disposable on Colonoscope



Pure-Vu Disposable Distal End – Irrigation Mode



# **STUDY DESIGN**

The Pure-Vu system was used in 35 procedures in swine (66% female) performed by 4 experienced gastroenterologists. In order to ensure an inadequate bowel preparation, the animals underwent a reduced preparation. Immediately after the procedure, physicians graded the cleanliness of the colon at baseline and after use of Pure-Vu as one segment using the Boston Bowel Prep Score and completed a questionnaire on the Pure-Vu usability. Following their colonoscopy, the animals were observed for 48 hours to ensure their full recovery and document any post-procedural adverse events.

#### **Evaluation of Cleansing Level**

The level of the cleansing was evaluated by using the Boston Bowel **Preparation Scale definitions**\* An adequate colon cleansing level was defined by a BBPS  $\geq$  2.

#### **Evaluation of Pure-Vu Usability**

The usability of the Pure-Vu system was done via a questionnaire after each procedure. Physicians were requested to grade the Pure-Vu usability on a 5 point scale where 1 was considered unacceptable and 5 as excellent.

#### The questionnaire included the following evaluation criteria:

- **General Ease of Use**
- 2. Ease of Insertion into Rectum
- 3. Ease of Angulation (steering capability)
- 4. Torque Response
- 5. Ease of Advancement

#### **Evaluation of Safety**

Adverse events were evaluated during and post-procedure for 48 hours. Any adverse events during the procedure were recorded per physician discretion. Following the procedure, the animals were observed for 48 hours to assess the effect of the procedure on their health.

### RESULTS

#### **Cleansing Performance**

The average BBPS score prior to the use of Pure-Vu was 0.5 with 86% of the animals being inadequately prepped (BBPS score <2) and the majority (60%) having a score of zero. Following the use of Pure-Vu 100% (35/35) of the animals had a BBPS score = 3 (i.e., Excellent).

Figure 1. below shows the distribution of BBPS scoring at baseline and after the use of the Pure-Vu. The level of adequate bowel prep at baseline and after Pure-Vu use is shown in Figure 2.

% of Adequate Cleansing (BBPS ≥ 2) Figure 1 at Baseline & After Pure-Vu Use n=35





- 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.
- Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well.
- ucosa of colon segment seen well with no esidual staining, small fragments of stool and/or

\*Lai E.J. et al," The Boston Bowel Preparation Scale: A valid and reliable instrument for colonoscopy-oriented research", Gastrointestinal Endosc., 2009: 69(3 Pt 2): 620–625

- 6. Device Stiffness
- 7. Device Holding Force (weight, comfort)
- 8. Ease of Use Foot Pedals
- 9. Ease of Use Foot Buttons
- **10. Safety Evaluation**









After Pure-Vu Use 15P0862

#### **Pure-Vu Usability**

The physicians were satisfied with the Pure-Vu's ease of advancement and navigation, stiffness, and torque response. They found Pure-Vu easy to use and intuitive to operate.

The average score across all usability parameters assessed was 4.6 ± 0.5 (Figure 3). With the exception of the general ease of use assessment for one procedure (Animal 15P0889), all parameters were scored a '4' (Good) or '5' (Excellent).

#### Figure 3. Ease of Use



#### Safety

No adverse effects were noted and the study animals recovered and survived to their study time point in good health.

# **SUMMARY & CONCLUSIONS**

The Pure-Vu System was safe with no adverse effects noted and study animals recovering and surviving to their study time point in good health. The Pure-Vu System was effective in cleansing inadequately prepped colons, improving the percentage of adequately prepped colons from 14% at baseline to 100% after use of Pure-Vu (p<0.001). The physicians were satisfied with the Pure-Vu's ease of advancement and navigation, device stiffness, and torque response. They found Pure-Vu easy to use and intuitive to operate. Pure-Vu was found to be simple, safe and effective in cleansing inadequately prepared swine colons.

This technology may provide an opportunity to improve visualization of the mucosa in patients with poorly prepped colons and reduce the need for early repeat examinations, thereby improving patient satisfaction and reducing costs. The technology may also be very useful in patients that have difficulty with compliance to standard colonic preparation regimens.

The images below are representative of colon cleansing levels at baseline and after Pure-Vu use.





After Pure-Vu Use 15P0845



After Pure-Vu Use 15P0877



After Pure-Vu Use 15P0719