Flexible Endoscope Processing Updates

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Faculty/Presenter Disclosure

Mary Ann Drosnock is an employee of Healthmark Industries

Healthmark is a manufacturer and distributor of medical products related to device reprocessing.

All opinions are those of the presenters.

This presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings, precautions, and steps for using the device(s).

Learning Objectives

Discuss updated flexible endoscope standards, such as SGNA, ASGE, ANSI/AAMI ST91, AORN, CSA and other new endoscope processing standards

Identify recently published literature and reports on endoscope processing topics

Highlight trends in endoscope processing, including the use of simethicone, while reviewing the latest study data on alternatives

ST91: 2021

- Flexible and semi-rigid endoscope reprocessing in health care facilities

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- Contains best practices for scope reprocessing in ANY setting
- Excludes TEE/ultrasound probes/dilators/manometry and rigid scopes
- Covers ALL steps of processing from precleaning through reuse

https://store.aami.org/s/store#/store/browse/detail/a152E000006Y1ApQAK

ST91 Highlights

Strict unidirectional workflow and preferred 2-room design

- If not 2 rooms, minimum 4 feet of separation between decontam and clean work area with a wall or barrier extending 4 ft above sink rim

New High-risk scope category

- Duodenoscopes, linear ultrasound (EUS) endoscopes, bronchoscopes, endobronchial ultrasound (EBUS) endoscopes, ureteroscopes, cystoscopes, and as determined by the facility

Note the time of precleaning and convey to processing staff

Transport soiled scopes in a biohazard labeled bin or case cart with leakproof sides and bottoms and puncture resistant

ST91 Highlights

Keep scopes moist but not submerged for transport

Follow delayed reprocessing protocol

Leak test for 60 seconds

Test your leak tester each day it’s used for pressure output

Cleaning verification requirements

Visually inspect every scopes after cleaning

- Recommends lighted magnification and borescope

ST91 Highlights

Recommends **AGAINST** manual HLD
- Except in an emergency situation

Move all scopes that can be sterilized to sterilization
- Reaffirms original Spaulding Classification system

All scopes must be completely dry before storage or reuse
- Typically, 10-minute flush with compressed air or drying cabinet

Clean the storage cabinet regularly, at least weekly

Check that your scopes are dry in storage

Use patient ready indicator on scopes in storage

ST91 Highlights

Dry scopes externally using a single-use non-linting cloth

Handle all scopes with gloved hands

Transport back to reuse in a closed container labeled clean

Reprocess transport containers appropriately (MIFU)

Water testing for water feed for sinks and processing equipment

Water testing for final rinse water in AER

TIR 99 – Reprocessing of Ultrasound Probes and Dilators

AAMI
Advancing Safety in Medical Technology

TEE Probes, Vaginal Probes, Rectal Probes, and Dilators

Update on status of document

Expected in early 2023

Multisociety Guidelines 2021

Multisociety guideline on reprocessing flexible GI endoscopes and accessories

https://www.asge.org/docs/default-source/default-document-library/multisociety-guideline-reprocessing-gi-endoscopes.pdf?sfvrsn=e60b2c5d_7

GI Societies Joint Statement on ANSI/AAMI ST91

"Do not support **some** of the finalized revisions to the standards and therefore voted negative on the vote for approval."

- Cleaning verification
- Segregation of buttons/valves – traced to patient
- Borescope

My thoughts:

Impractical ≠ Impossible

Recognition of recommendations vs requirements

https://www.giejournal.org/article/S0016-5107(22)00098-0/fulltext

SGNA 2023

Updated Endoscope Processing Guidelines expected early 2023

No details at this point

Currently guidelines:

- **Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting (2017)**
- **Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes (2018)**
- **Standard of Infection Prevention in the Gastroenterology Setting (2019)**

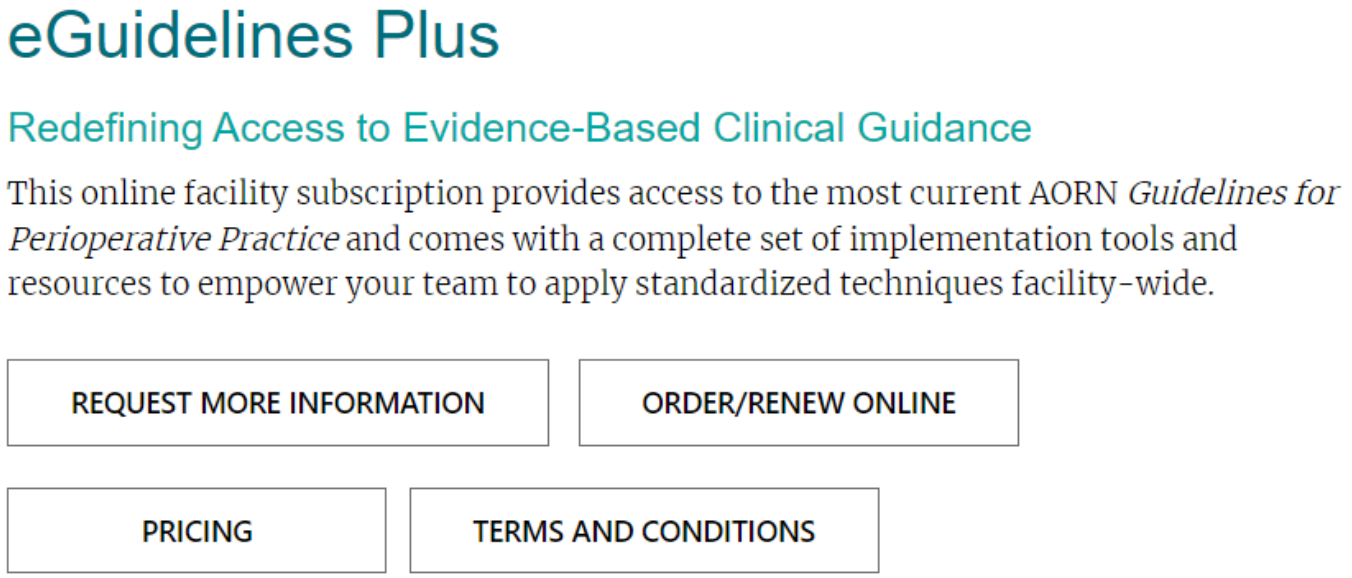
AORN 2022

New Endoscope Processing Guidelines Issued in Sept. 2022

Purchase in the ebook

In print in 2023

Harmonized with AAMI ST91



https://www.aorn.org/eguidelinesplus

CSA Z314 - Updates

Expected Feb. 2023

Expanded title to be all-inclusive to all healthcare settings

Major updates:

- Semi-critical device **shall** be sterilized if it can be sterilized according to the MIFUs (minimal level is HLD)
- Annually have a review/audit of MDR process, optimally by an outside entity
- For devices that are difficult to reprocess or cannot be reprocessed effectively or safely, single-use devices or components shall be used (ex., Sharp components, small lumens, tubing, and burrs)
- Drying updates
- Ultrasound Probes updated
- Cleaning Verification updates

WGO Guideline

Table 1 Specific recommendations for reprocessing and storage

Activity	Recommendations
Precleaning	— Precleaning must be carried out *immediately* after use.
Cleaning	— Cleaning (manual or using an AFER with an FDA or nationally approved cleaning cycle) must be carried out *promptly** within 30 minutes after precleaning. — Always follow the most up-to-date specific instructions from the manufacturer for cleaning for each model of endoscope.
Disinfection	— After manual cleaning of the endoscope, machine or manual high-level disinfection must be undertaken promptly. — Endoscopes should be thoroughly rinsed with bacteria-free water after disinfection.
Alcohol flush and forced-air drying	— After disinfection by any means, the endoscope must have a prompt initial alcohol flush and forced-air drying† for 10 minutes and storage in an approved forced-air storage/drying cabinet.‡
Drying cabinet storage	— Endoscopes must remain in approved forced-air drying cabinets until the next use in a patient.
Bacteriological surveillance	— Perform regular bacteriological surveillance of endoscopes and AFERs at intervals appropriate to local conditions and resources.
Maintenance	— Send endoscopes for regular yearly maintenance and consider replacing the instrument channel every 2 years or according to workload (or more frequently, as recommended by the endoscope manufacturer).

Endoscope Disinfection Update

Dr. Alfa is a member of this group that finalized the guidelines

https://www.worldgastroenterology.org/guidelines/endoscope-disinfection/endoscope-disinfection-english

Recent Studies and Reports - 2022

Infections linked to cystoscopes, ureteroscopes, **duodenoscopes, gastroscopes**, and bronchoscopes (Guler et al., 2022; FDA MAUDE database)

Single-use and disposable endcaps falling off into patients (FDA MAUDE database)

Retained stents being pushed into patients (FDA MAUDE database)

Higher risk associated with new duodenoscopes including adverse events, contamination, and injury (Pasricha, 2022)

FDA received more than 5400 MDRs on endoscope and processing equipment (FDA MAUDE database)

- Visibly damaged and dirty scopes being used on patients
- Infections related to reuse of single-use valves and failure to flush all channels

Recent Studies and Reports - 2022

Three studies used borescopes to inspect endoscopes

- 100% of 25 inspected scopes had visible soil or damage at baseline and 2 months later and 80% required repair (Ofstead et al., 2022)
- Bacteria found in 26% of scopes, and most scopes had retained fluid in them and damage (Wallace et al., 2022)
- GI scopes accumulated damage over a 3 yr period and those with >400 uses were 5.6 x more likely to fail leak test or have severe damage (Barakat et al., 2022)

Microbial growth found in 43% of HLD ERCP and EUS scopes (15% were high concern), 27 % failed ATP (Kwakman, et al., 2022)

Forced air greatly reduces contamination levels, flushing with alcohol increases dry time (Nerandzic et al., 2022)

Recent Studies - 2022

Manual cleaning of ultrasound probes and GI scopes resulted in significant splashing of technicians. Droplets went more than 7 ft from sink (Ofstead et al., 2022)

High rates of contamination with potential pathogens on high-touch areas, including endo departments (Cadnum et al., 2022)

Persistent contamination of ERCP scopes with Pseudomonas (85-95% post-HLD) despite reprocessing. Drying cabinets reduced microbial levels (Kwakman, 2022)

Carbapenam-resistant K.pneumoniae resistant to peracetic acidic used for HLD (Brunke, 2022)

Recent Studies - 2022

Pathology study reported GI endoscopists vastly overestimate polyp size (used to determine frequency of colonoscopy) with 82% of patients being told to come back too soon (Helwick, 2022)

FDA recommended transition to single-use duodenoscopes or those with disposable endcaps (https://www.fda.gov/news-events/press-announcements/fda-recommends-health-care-facilities-and-manufacturers-begin-transitioning-duodenoscopes-disposable)

Alfa, Pineau, and Olympus posted results of post-market safety surveillance for ERCP scopes at 16 US facilities

- 65% had microbial growth with 5.3 % High-concern organisms
- (Alfa and Pineau, 2022 in ICHE journal)

Simethicone Usage Updates

Let’s review the latest info and guidance

Simethicone usage – Background

What is simethicone?

- Anti-foaming agent used during endoscopy procedures
- Active ingredient in a variety of anti-gas medications
- Consists silicone-containing polymers
- Inert but difficult to remove due to its hydrophobicity
- Not water soluble
- Has additives such as sugars, flavorings, thickeners
- Studies have demonstrated improved adenoma detection rates with use of simethicone
  - Kutyla et al., 2018

Simethicone usage – Why is it a Problem?

Why is it a problem?

Multiple studies have demonstrated that simethicone remains in endoscope channels despite repeated cleaning and disinfection procedures, including the water jet.

- Interferes with flushing during cleaning, increases risk of bacterial contamination and biofilm development
- Ofstead et al, 2016; Barakat, 2019; Ofstead, 2019, Van Stiphout, 2016;

No direct link to patient infections

- Yet?

Simethicone usage - Risks

Sugars and thickeners in formulation can promote microbial growth

Difficult to detect in endoscope channels

Study demonstrated increased water droplet retention when using simethicone

- Barakat, 2019

Dutch Article: All 16 scopes had crystallized simethicone

- https://www.thieme-connect.com/products/ejournals/pdf/10.1055/s-0042-120261.pdf

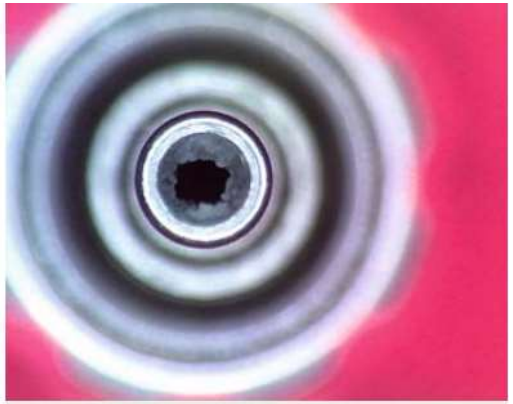


Fig. 3 Crystal deposits within the connector.

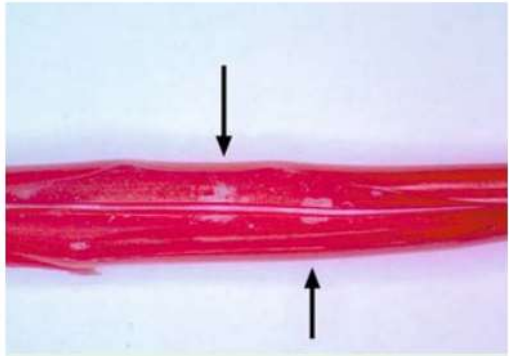


Fig. 4 Crystal deposits within the waterjet channel (tube cut open) (arrows).

Simethicone usage - Recommendations

AAMI ST91 – Annex G

Does not recommend the use of simethicone

Citing:

- Endoscope manufacturers do not recommend
  - Lowest effective volume if needed
    - Barakat, 2019 demonstrates retention even at low levels
  - Biopsy channel only
- FDA does not approve of this application of simethicone
  - OTC anti-gas drug, not for use as a bowel prep
- Multiple instances of contaminated simethicone
  - Major pharma, 2019; Sutton, 2012, Drucker, 2008

Simethicone usage

ASGE:

- Limit Simethicone Volume and Concentration During Endoscopy
  - https://dev.asge.org/home/resources/publications/journal-scan/issue/limit-simethicone-volume-and-concentration-during-endoscopy
- Recommends against using it in water jets. Instead, use as a bowel prep. Study indicates does should at least 320 mg or more
  - https://www.asge.org/home/resources/publications/journal-scan/issue/impact-of-simethicone-during-bowel-preparation-on-colonoscopy-quality-systematic-review-and-meta-analysis-of-38-randomized-controlled-trials
- Multi-society guideline:
  - Follow MIFU for use of simethicone, lowest concentration, through biopsy port
  - https://www.asge.org/docs/default-source/default-document-library/multisociety-guideline-reprocessing-gi-endoscopes.pdf?sfvrsn=e60b2c5d_7

Simethicone usage

SGNA

- Recommends careful use of oil-based and silicone lubricants is warranted and should follow manufacturers' IFU on the recommended agent and proper use. If simethicone must be used, the lowest possible concentration must be used (FDA, 2015; Ofstead, Wetzler et al., 2017).
- Residue from these products promote an environment that protects microorganisms and promotes biofilm formation. This has an effect on HLD and sterilization, including EO.
- https://www.sgna.org/Portals/0/SGNA%20Standards%20of%20infection%20prevention%20in%20reprocessing_FINAL.pdf?ver=2018-11-16-084835-387

Simethicone usage

Endoscope Manufacturers:

- Olympus statement:
- https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Customer-Letter-Use-of-simethicone-and-lubricants.pdf
- Pentax recommends not to use
  - https://www.pentaxmedical.com/pentax/en/94/1/Customer-Notices
- Fuji
  - Does not recommend
  - Reference: Fujinon Films USA ED [reprocessing summary and guide for Fujinon/Fujifilm flexible GI endoscopes]

Simethicone Alternative

Have we found the white whale?

Poster at SGNA 2022

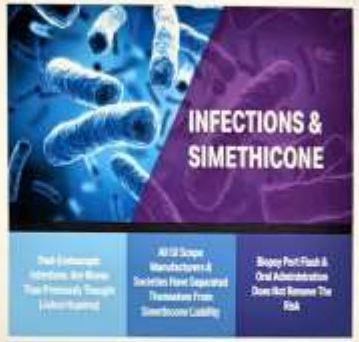
A Water-Soluble Alternative to Simethicone
Have We Found Our White Whale?

Providence SWEDISH

Teri Mallard BSN, RN | Sandra Roswell BSN, RN | Amarnath Ramakrishnan MBBS, MD |
Providence Health & Services | Swedish Medical Center, Issaquah |

Background

Multiple independent studies have shown that simethicone, even when used in low concentration, injected down the working channel, is associated with retention of fluid (silicone, cellulose or sugars and water) droplets within the endoscope working channel despite brushing, manual cleaning, reprocessing and drying. Simethicone is insoluble in water and alcohol, and it contains sugars and thickeners that are retained in the scope channel. Although simethicone effectively eliminates gas bubbles, its presence as residual fluid droplets within endoscope channels is undesirable because it may promote bacterial proliferation, increase infection risks, and cause potential damage to scopes from over brushing. Due to these risks, currently all endoscope manufacturers have recommended against simethicone use. Thus, there is a true medical need for a new, safe and practical alternative to Simethicone. GI Ease is an anti-gas product that is water-soluble and devoid of sugars, thickeners, or binding agents. The primary objective was to demonstrate the effectiveness of GI ease for elimination of bubbles.



Purpose

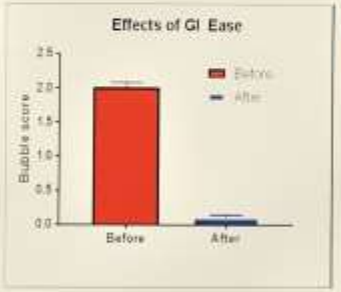
To evaluate an effective water-based alternative to simethicone, that aligns with the scope manufacturer recommendations, and eliminates GI bubbles to improve endoscopic mucosal visualization.

Methods

This is a single center, non-randomized, prospective, open-labeled pilot study design with 100 subjects. Upper endoscopies and colonoscopies were performed by 7 different providers. Sixty-four mL of GI Ease was diluted in 1000 mL of sterile water. During the endoscopic procedures, GI Ease flushes were delivered as 60 ml injections via the working channel of the endoscopes. The grading scheme was determined by a bubble scale scoring system, ranging from grade 3 (bubbles filling the entire lumen) to 0 (no or minimal bubbles). The number of GI ease flushes delivered to achieve the desired mucosal visibility (grade 0-1) were recorded by a registered nurse.

Results

In 99/100 participants, the bubble scale score improved to a grade 0-1, facilitating improved GI visualization. Our pre-post paired t-test of bubble scores showed significant bubble decline ($t=27$, $p<.00001$). Multiple regression analyses, using bubble score change as the dependent outcome, showed number of flushes to be a significant predictor (adjusted $R2=.155$, $p<.001$) with no age or sex differences.

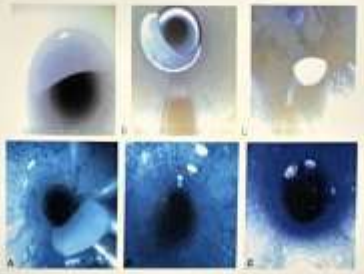


Conclusions

We found that GI Ease, a water-soluble solution, was effective in reducing gas bubbles and improved visualization. Future studies are needed to further define the potential for residual droplets and its long-term effects on scopes. We concluded that the inherent characteristics of GI ease being water-soluble, presents distinct advantages over Simethicone and makes this an attractive option for endoscopists, scope manufacturers, endoscopy labs, and patients.

We Can Have Bubble Elimination

Without Simethicone Retention



References

- Johns Hopkins 2018 Wang P, et al. Gut 2018;67:1626–1636. doi:10.1136/gutjnl-2017-315308
- University of Minnesota, Ofstead, et al. American Journal of Infection Control 44 (2016) 1237-40
- Stanford, Barakat, et al 2019, Volume 89, No. 1 : 2019 GASTROINTESTINAL ENDOSCOPY
- University of Minnesota, Ofstead, et al. American Journal of Infection Control 47 (2019) 666–670
- American Society of Health-System Pharmacists 2015; Drug Information 2015. Bethesda, MD: 2015

Manufacturer Statements

- https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Customer-Letter-Use-of-simethicone-and-lubricants.pdf
- https://www.pentaxmedical.com/pentax/en/94/1/Customer-Notices
- Fujifilm USA, 2013, Use of Simethicone Anti-Gas Products

Contact

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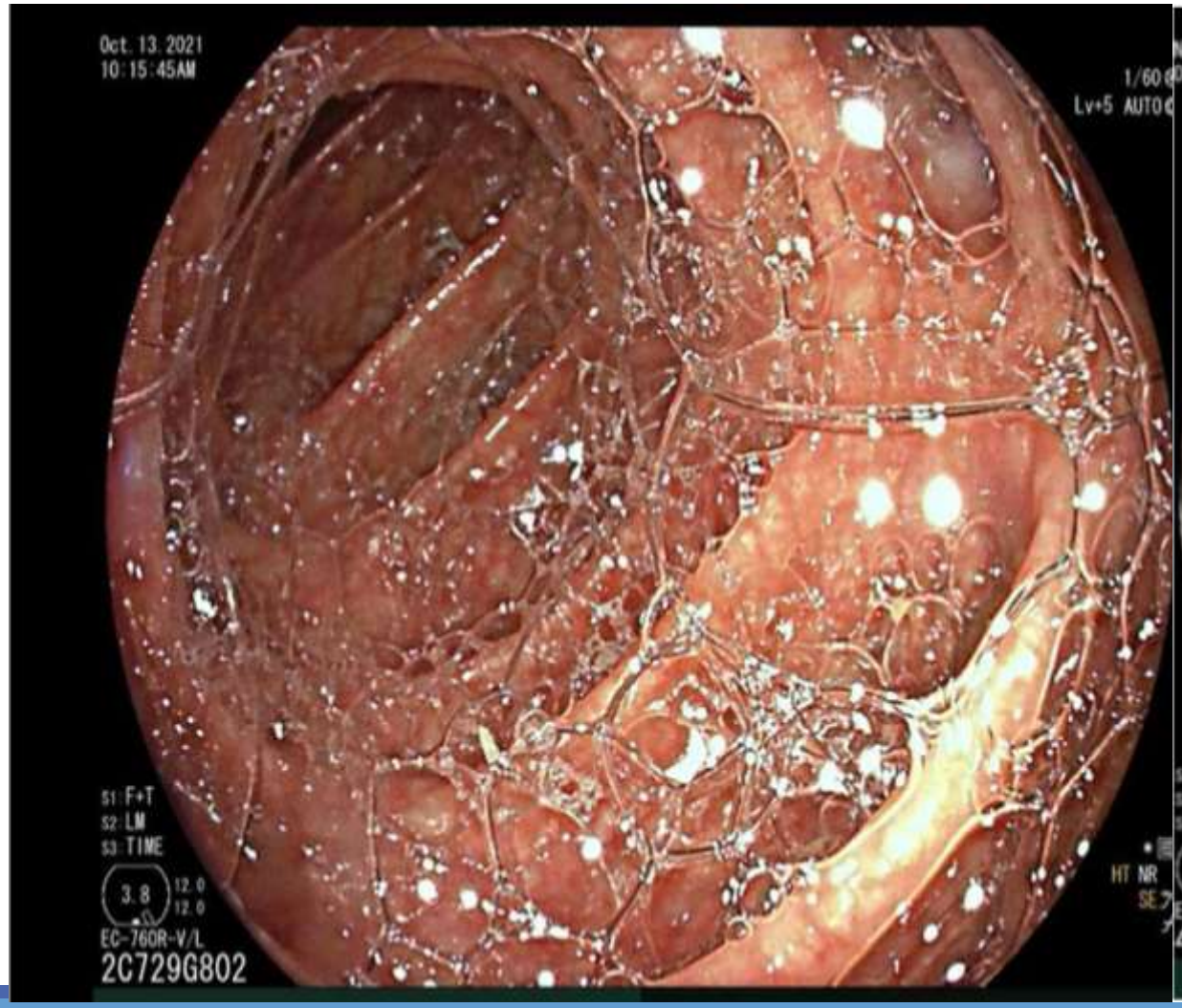
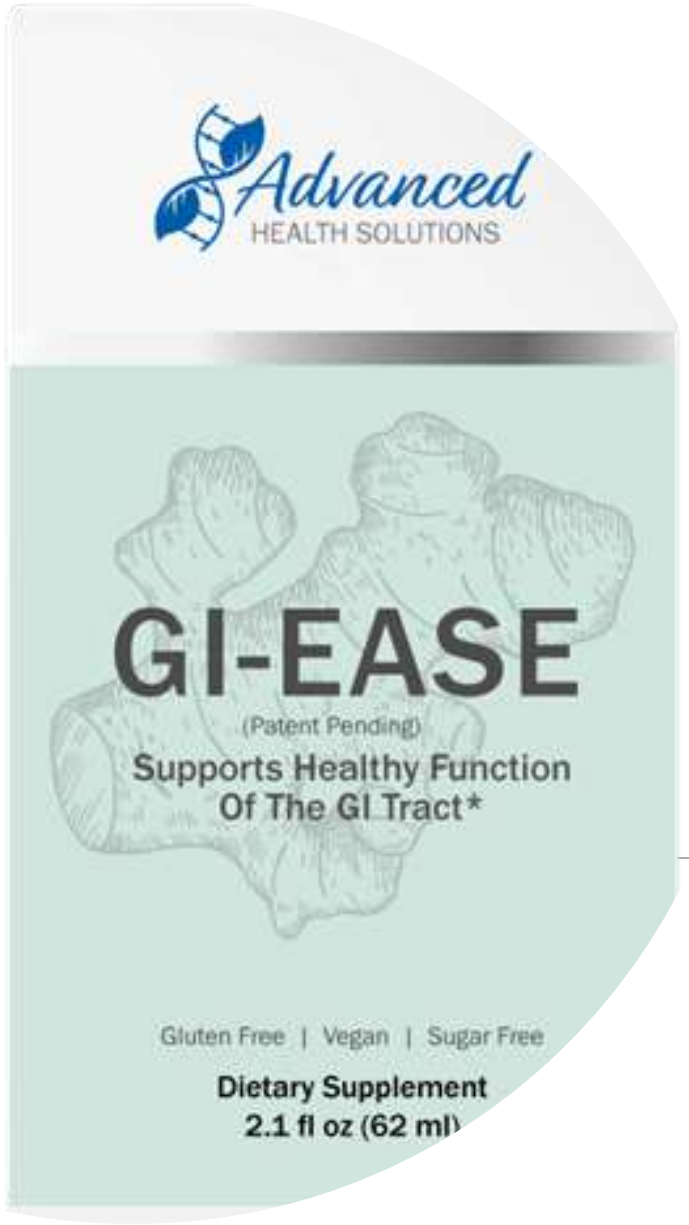
Let’s Talk Bubbles…



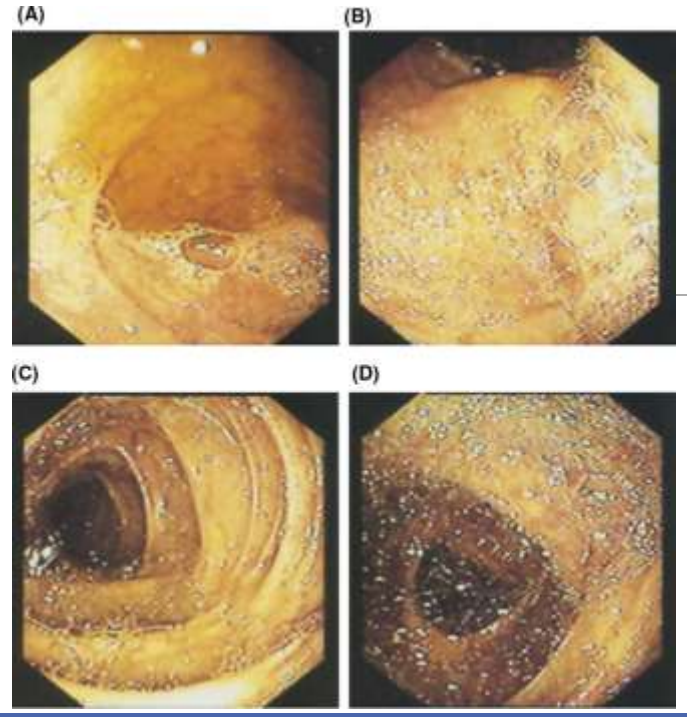


Found Something Promising

Method Approval

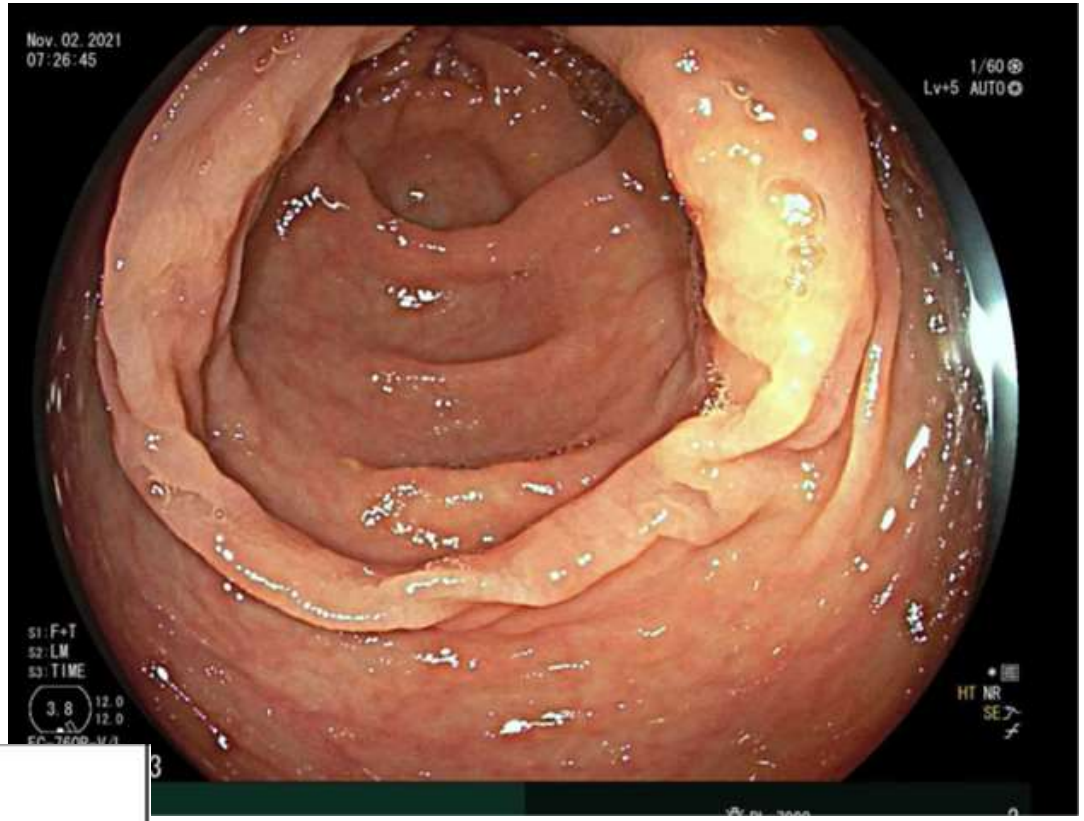
SINGLE CENTER, NON-RANDOMIZED, PROSPECTIVE, OPEN-LABELED PILOT STUDY DESIGN WITH 100 SUBJECTS

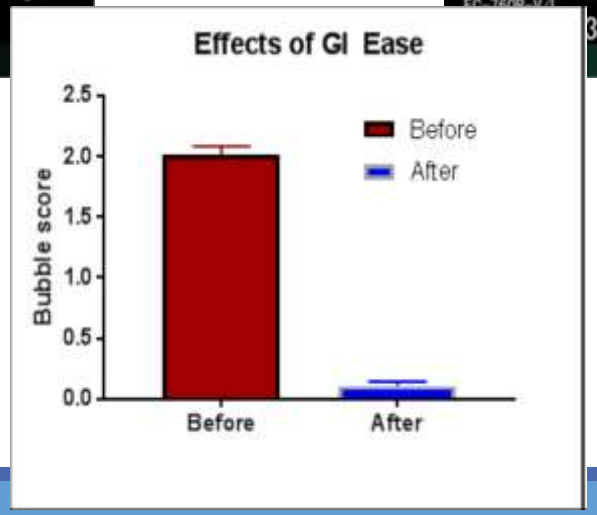
Bubble Scale Score (0-3)



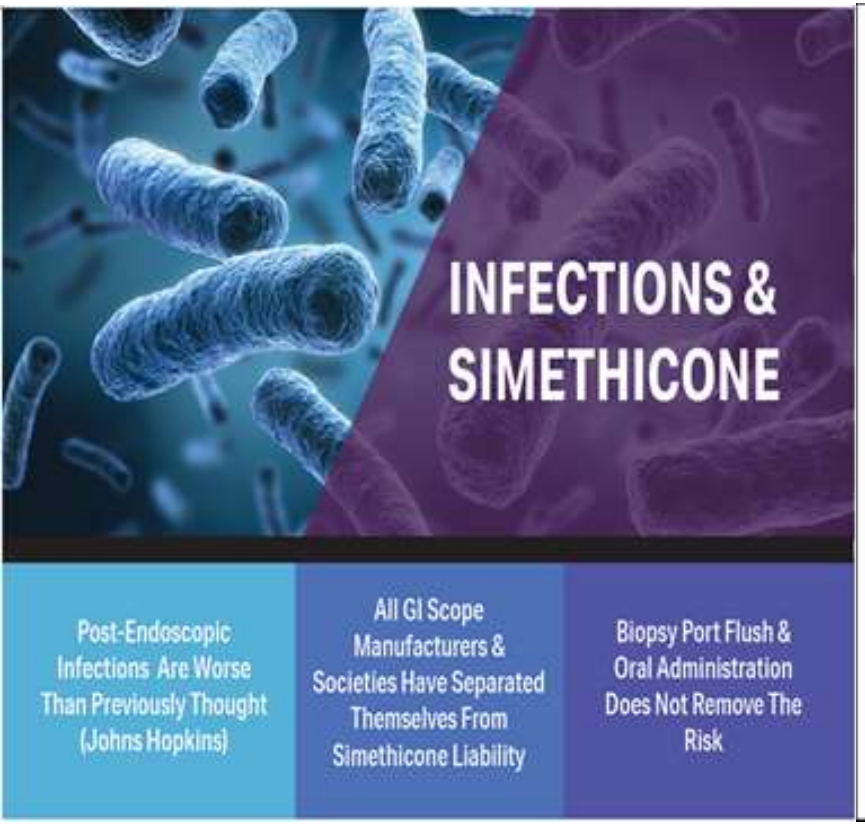
Mixing Method

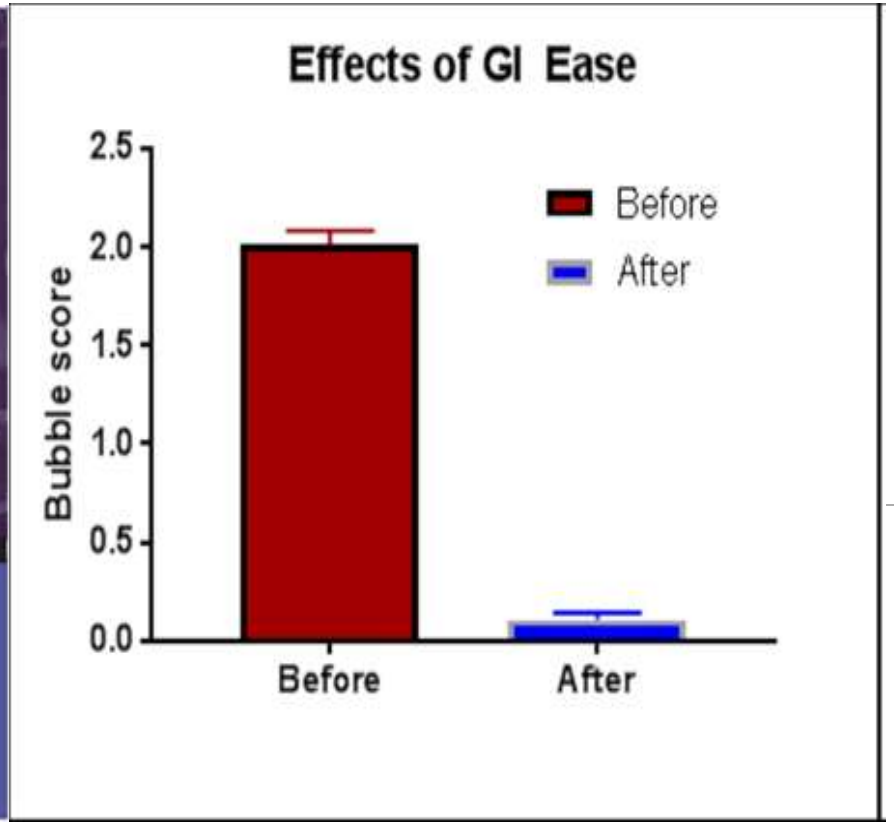

Nov. 02. 2021
07:26:30
1/60
Lv+5 AUTO
HT NR
4C729G003


Nov. 02. 2021
07:26:45
1/60
Lv+5 AUTO
HT NR


Effects of GI Ease
Bubble score
2.5
2.0
1.5
1.0
0.5
0.0
Before
After
Before
After

Results/Conclusion





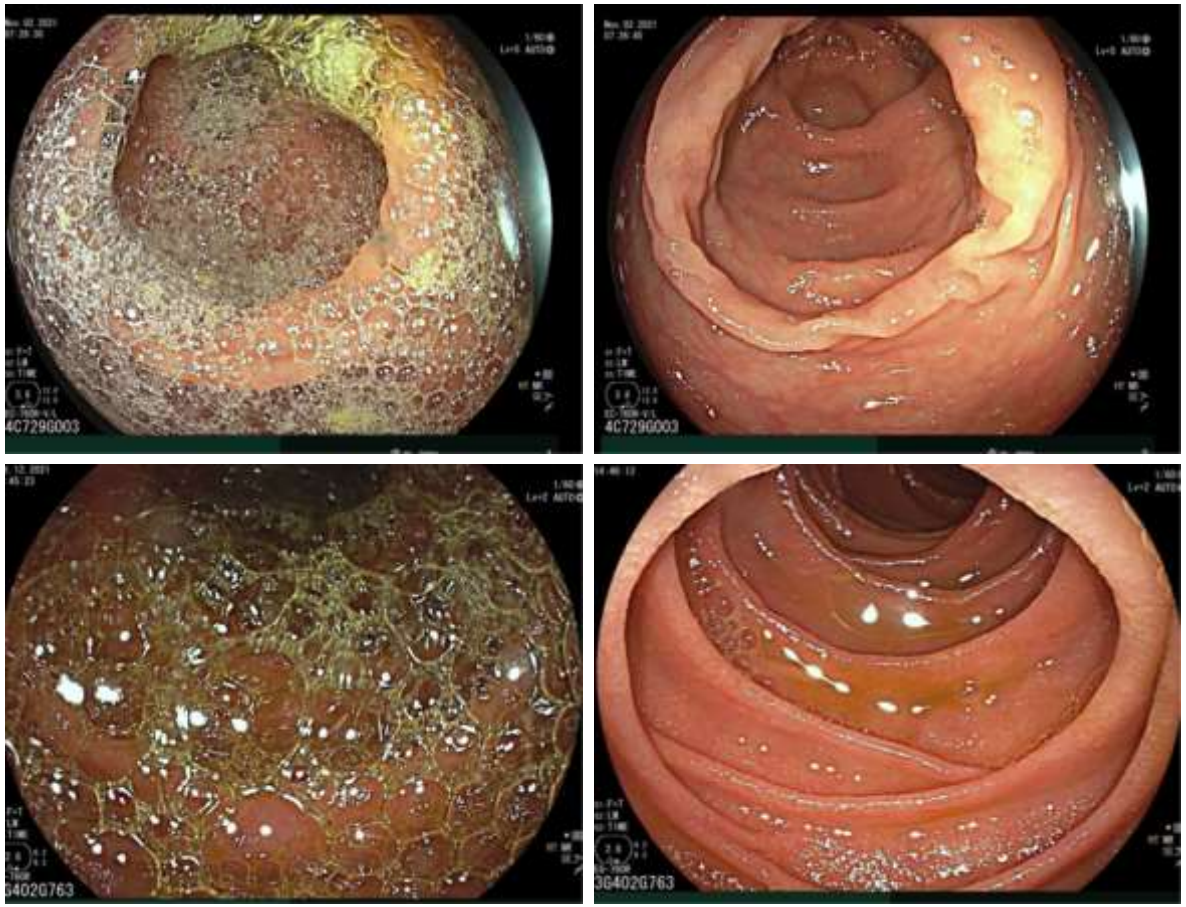
Water-Soluble Alternative Solution Effectively Eliminated Gas bubbles.

Product being water-soluble, presents distinct advantages and is an attractive option to eliminate gas bubbles.

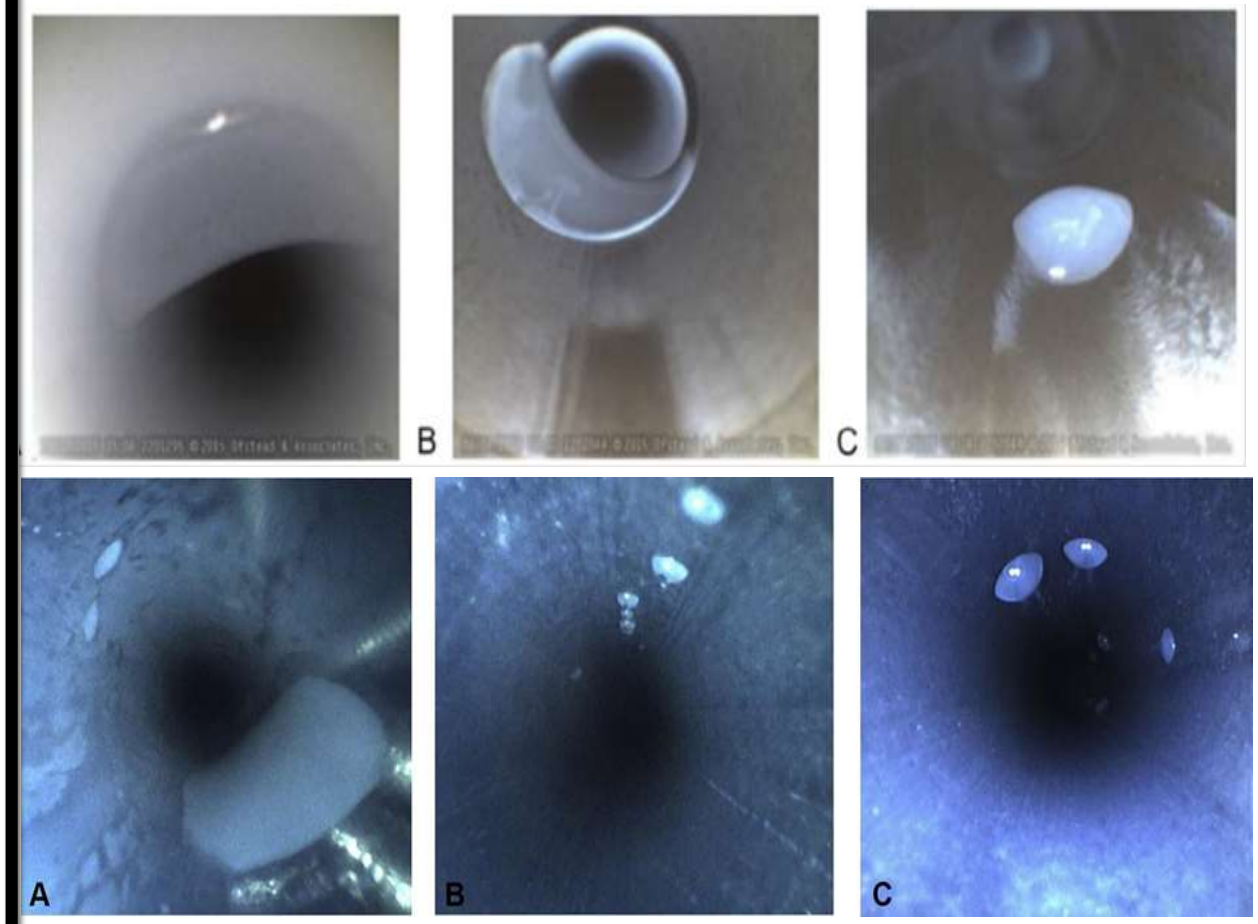
WE CAN HAVE BUBBLE ELIMINATION

Before

After



WITHOUT RISK OF INFECTION



Alternative to simethicone

Currently working on a multi-center study to replicate original study findings

- Large teaching institutions in the US

Manufacturer is working on FDA clearance for use during a procedure through a scope

- For now, has the same FDA approval as simethicone. Dietary supplement
- Has GRAS (**G**enerally **R**egarded **A**s **S**afe) rating

References

AAMI ST91: 2015, 202

AAMI TIR99

FDA MAUDE database: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

And as noted on slides

Thank you! Time for Q & A

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