



June 29, 2018

**RE: Use of simethicone and other non-water soluble additives with Olympus flexible endoscopes**

Dear Health Care Provider,

This letter is intended to inform Olympus customers regarding the use of simethicone and other non-water soluble additives with Olympus flexible endoscopy equipment.

Olympus does not recommend the use of non-water soluble additives with our flexible endoscopes or ancillary equipment. These products may be difficult to remove during manual cleaning and may reduce the efficacy of the reprocessing procedure. Simethicone and petroleum/oil/silicone-based lubricants are non-water soluble and thus not recommended for use by Olympus.

**Simethicone**

Simethicone is a form of silicone found in several over-the-counter anti-gas products. Some gastrointestinal (GI) endoscopy practices use simethicone in an effort to improve visualization during endoscopy. In this case, simethicone is typically diluted in a water container and injected into the patient via the endoscope's water channel or auxiliary water channel, or injected directly through the endoscope's instrument port with a syringe.

Customer reports indicate that the use of high concentrations of simethicone may be difficult to remove from Olympus endoscopy equipment (e.g., endoscopes and water containers) despite strict adherence to the Olympus reprocessing instructions. Failure to remove simethicone during manual cleaning from Olympus endoscopy equipment may reduce the efficacy of the reprocessing procedure.

Simethicone is insoluble in both water and alcohol.<sup>1</sup> In addition, solutions containing simethicone (i.e. infant gas drops) typically contain sugars, thickeners, and binding agents. These ingredients could potentially support microbial and biofilm growth and may be difficult to remove during reprocessing.<sup>2</sup>

Due to these concerns, Olympus does not recommend the use of simethicone with Olympus endoscopes or ancillary endoscopy equipment.

**Lubricants for Olympus flexible endoscope insertion tubes**

Olympus recommends medical grade, water-soluble lubricants (e.g., K/Y jelly, lidocaine jelly) for the insertion tube of their flexible endoscopes. In addition, Olympus cautions customers against the use of petroleum-based (e.g. ointments, Vaseline), oil-based, and silicone-based lubricants. Oil or petroleum based lubricants may damage Olympus endoscopes and may be very difficult to remove during reprocessing.

**Removal of residue from Olympus flexible endoscopes**

As stated above, Olympus does not recommend the use of non-water soluble products with flexible endoscopes or ancillary equipment.



However, if your facility has determined that the benefit of using a non-water soluble product outweighs the risk of potential reprocessing difficulties, please follow the below suggestions.

Consider administering simethicone either orally or via the biopsy port of the endoscope as the biopsy channel is manually brushed during reprocessing. Avoid administering simethicone via addition to the water bottle or flushing pump. Use these products sparingly by diluting the product as much as possible in order to achieve the desired clinical result.

Reprocess your flexible endoscope(s) according to the Olympus endoscope Reprocessing Manual, detergent instructions for use (IFU), disinfectant IFU, automated endoscope reprocessor (AER)/endoscope washer disinfectant (EWD) IFU, and any other instructions pertaining to the products you use to perform reprocessing.

Healthcare facilities may consider using a neutral-pH, low-foaming, medical grade detergent designed to remove lipids when manually cleaning endoscopes that have been exposed to simethicone or other non-water soluble additives.

If residue or debris are observed on the endoscope after complete reprocessing, Olympus recommends their removal followed by repeated cleaning and high level disinfection prior to patient use. Residues can be removed by repeating manual cleaning until the residue is no longer visible, or by wiping the residue with 70% ethyl or isopropyl alcohol on a low-linting or lint-free cloth or gauze until visibly removed. Alcohol prep pads saturated with 70% isopropyl alcohol are appropriate for this task.

If residue or debris is found on the endoscope despite repeat reprocessing, Olympus recommends that the facility and staff involved in endoscope reprocessing fully review the current reprocessing methods. All individuals engaged in reprocessing should be monitored to ensure adherence to all instructions outlined in the endoscope's Reprocessing Manuals as well as IFUs for all ancillary equipment (detergents, AER/EWD, etc.).

Customers who employ simethicone and other non-water soluble additives have reported periodic and minor residue findings after comprehensive review of their reprocessing procedures. Testing of this residual material indicates the presence of petroleum-based lubricants, silicone-based lubricants, and simethicone. Olympus recommends that healthcare facilities work closely with their infection control department and all related equipment and service providers.

### **Current Position Statements and Guidelines**

The following are excerpts from position statements and guidelines published by reputable professional societies worldwide on the subject of simethicone use in gastroenterology procedures:

“Simethicone, often used during endoscopy procedures, may foster microbial growth and biofilm development despite proper reprocessing because it contains sugars and thickeners. Minimize use of simethicone pending further studies.”

*Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting.* The Society of Gastroenterology Nurses and Associates, Inc.<sup>3</sup>



“...it is advised that Simethicone is administered either orally or via the biopsy port of endoscopes and NOT via either the water bottle or flushing pump devices. This will ensure that manual brushing of relevant channels can take place post procedure. The strength of the diluent should also be kept to a minimum to achieve the desired effect.”<sup>4</sup>

*Simethicone Residue in Endoscopes.* British Society of Gastroenterology.<sup>4</sup>

“...we recommend following the instruction-for-use of endoscopes released by the manufacturers, to adhere to strict high level reprocessing protocols, and to consider performing regular microbiological surveillance. We also suggest that endoscopy units reconsider the routine addition of simethicone to the water pump used during procedures. Finally, if health practitioners are to use simethicone, the lowest effective volume should be used.”

*Position Statement: The Impact of Simethicone on Endoscope Reprocessing.* Canadian Association of Gastroenterology.<sup>5</sup>

If you have any additional questions regarding the use of simethicone and other non-water soluble additives, please contact your local Olympus representative.

#### References

1. O'Neil, M.J. (ed.). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. Cambridge, UK: Royal Society of Chemistry, 2013, p. 585
2. Ofstead, C.L., et al., Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing. Am J Infect Control, 2016. 44(11): p. 1237-1240.
3. Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting. Society of Gastroenterology Nurses and Associates, Inc., 2017.
4. Griffiths H. Simethicone residue in endoscopes. British Society of Gastroenterology. eNewsletter, May 5 2017.
5. Benmassaoud A, Parent J. CAG Position Statement: The Impact of Simethicone on Endoscope Reprocessing. Canadian Society of Gastroenterology. July 10 2017.