



**CANADIAN ASSOCIATION OF GASTROENTEROLOGY  
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## **CAG Position Statement:**

### **The Impact of Simethicone on Endoscope Reprocessing**

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A recent study by Ofstead et al. published in the American Journal of Infection Control described the presence of residual simethicone and non-pathogenic bacterial colonization in endoscopes despite adherence to reprocessing procedures[1]. These findings received significant media attention, in part because they were released following a warning issued by the Food and Drug Administration and the Centre for Disease Control regarding the potential transmission of multi-drug resistant bacteria associated with the use of duodenoscopes [2, 3]. In light of the findings described by Ofstead et al., the Canadian Association of Gastroenterology (CAG) would like to update its members on what is currently known.

#### **Simethicone and its current state of use**

Simethicone is a fully methylated silicone-based polymer which is commonly used to decrease the surface tension of gas or air bubbles. Its anti-foaming properties have been exploited during endoscopic procedures since 1978[4]. Although not used routinely in clinical practice as an adjunct before upper or lower endoscopic procedures, simethicone is frequently mixed in the water pump to disperse the remaining bubbles during the examination. This makes it a ubiquitous product in an endoscopy unit.

McDonald et al. were the first to demonstrate that swallowing a simethicone solution before peroral endoscopy is a simple way to eliminate foam and bubbles that could otherwise obscure the visual field[4]. Since then, multiple randomized clinical trials and a meta-analysis have evaluated its benefits when used as an adjunct to upper and lower endoscopic procedures. The meta-analysis published in 2011 by Wu et al. showed that the addition of simethicone to bowel cleansing preparations before colonoscopies did not change the overall efficacy of colon preparation (OR 2.06, 95% CI 0.56-7.53, p=0.27), but decreased the quantity of bubbles (OR 39.32, 95% CI 11.38-135.86, p=0.00)[5]. Subsequent randomized clinical trials have shown that simethicone decreases flushing time and lowers endoscopist fatigue during colonoscopies[6, 7].



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With the available body of evidence, the consensus statements and guidelines from the American and European Societies for Gastrointestinal Endoscopy (ASGE and ESGE) offer differing perspectives on the use of simethicone[8, 9]. While the ASGE makes no recommendation regarding its use, the ESGE recommends it as an adjunct to bowel cleansing preparations before colonoscopies for improved results.

With regard to gastroscopies, the addition of simethicone before the procedure has been shown in randomized clinical trials to improve the total mucosal visibility score (TMVS), decrease the number of bubbles and possibly lead to a shorter procedure time[10-12]. Unlike for colonoscopies, no recommendations exist for the use of simethicone during gastroscopies.

### **Current controversies**

The study from Ofstead et al. is the first of its kind to investigate the presence of simethicone in endoscopes after reprocessing[1]. This prospective study was based at an ambulatory endoscopy unit where 20 Olympus endoscopes were used. The procedure followed for reprocessing included immediate bedside pre-cleaning, leak testing, manual cleaning, high level disinfection in an automated endoscope reprocessor (AER), flushing with alcohol, air purge in the AER, wiping with a lint-free towel, and storing in a ventilated cabinet. After ensuring adherence to the reprocessing procedure with unannounced audits, the authors identified multiple fluid droplets inside ports and channels of 19 of 20 endoscopes. Of these, 8 endoscopes had a white cloudy fluid droplet which seemed consistent with simethicone. Fluid was within reach in 3 endoscopes and the presence of simethicone was confirmed using infrared spectroscopy in 2. Furthermore, although colony counts were low, microbial cultures were positive for non-pathogenic bacteria in all 3 endoscopes. Following this study, Van Stiphout et al. also identified crystal deposits consistent with dimethicone in the water jet channel of a Fujinon colonoscope[13]. After further assessment, crystal deposits were found in all of their 16 colonoscopes.

Although not confirmed at this stage, these findings are significant as simethicone residues can potentially contribute to the formation of biofilms and lead to microbial growth[14]. The formation of biofilms is an important factor in microbial colonization and it has been implicated in the outbreak of post-ERCP bacteremia[14]. It is important to note that simethicone itself has not been associated with nosocomial infections.

While these findings were only recently published in the medical literature, Olympus released a statement to health practitioners in 2009 acknowledging that simethicone products might be difficult to remove from endoscopes if used in high concentration despite strict adherence to reprocessing instructions. Olympus recommended that if simethicone was necessary, it should be used at the lowest concentration possible to achieve the desired effect[15]. Pentax Medical also warns against the addition of silicone-based products to the water supply and/or the automated reprocessing system of their endoscopes as these can be very difficult to remove[16]. Pentax states



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that silicone-based products can reduce the effectiveness of the disinfection or sterilization process and result in equipment malfunction.

In agreement with the ASGE position, the CAG is currently unable to make clear recommendations regarding the use of simethicone during endoscopic procedures as the clinical significance of the recent findings remain unclear and merit further research[17]. In the meantime, 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.

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