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Interfering Substances in Endoscopic Exams and Their Impact on Microbiologic Surveillance of Flexible, Reusable Endoscopes

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Conflict of Interest

I am a full-time employee of Olympus Corporation

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Agenda

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Background: Reprocessing validation

01

Validation of Endoscope Reprocessing Efficacy

- Reprocessing efficacy validation uses artificial test soils to **mimic worst-case clinical use situations**
- **Organic and inorganic** challenges are added during cleaning validation[2]
- **Limited attention is given to use of additional interfering substances** due to the increasing therapeutic nature of current endoscopic exams

- ISO 15883-4:2018[3]

4.4.2.4.2 The efficacy of the disinfectant and the interaction between the disinfectant and **residues** (e.g. **soil, detergents**) shall be tested under conditions in which residues are at or above the maximum level that might occur in use and the disinfectant is at or below the minimum specified in-use concentration.

- ST98:2022[4]

6.2.3. Test soils shall include substances representative of tissue/fluids and associated processing or procedural chemicals that are **contaminants** and are intended to be removed during cleaning. If these contaminants (e.g. **cement, lubricants, simethicone, radiopaque dyes**) are not included as part of the simulated use or test soil, a scientific justification shall be documented.
[…]
7.3 Process steps that could cause **test method interference** (e.g. […] lubricants) and result in inaccurate results **shall be** identified and **eliminated** if possible. Either inclusion or elimination of the interference should be adequately justified within in the cleaning validation.

Interfering substances in endoscopic exams

02

Range of substances used during endoscopic exams

Substances	Purpose	Examples
Defoaming agents	decreasing the surface tension of gas bubbles in the GI tract, decrease foam inside the gastrointestinal tract to enhance visibility	Simethicone/silicone-compounds, polyethylene glycol
Hemostasis products	bleeding management, enhance visibility	oxidized regenerated cellulose (ORC), porcine gelatin, bovine collagen, thrombin, polysaccharide spheres (aerosoled bentonite), adrenalin →Powder, gel, or spray applications
Chromo-Endoscopy / dyes	marking injuries / lesions and abnormalities in the GI tract	indigo-carmine, methylene blue, Lugol's solution, acetic acid, crystal-violet
X-Ray contrast media	visualization of vasculature in an organ of interest, to better delineate benign from malignant pathology	Barium-sulfate (oral administration), iodine-based and gadolinium contrast materials (commonly injected in the arteries)
Lubricants	local or regional anesthesia to facilitate endoscopic access / prevent choking	Lidocain, Xylocaine

→ **Literature research** confirmed the increasing therapeutic characteristic of endoscopic GI procedures. And even more, complex therapeutic therapies often require a **multitude of substances.**

Test I: Investigate characteristics of substances used in endoscopic procedures

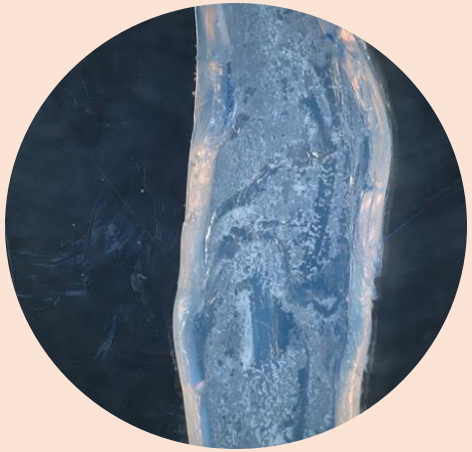
Assess bacteriostatic and bactericidal effect of 4 representative examples, using EN 13727 methods[5]

Test II: Assess their impact on microbiological sampling and culturing results

Compare the **extraction efficiency** of microbiologic sampling:

- 1st run: **interfering substance** + microorganisms
- 2nd run: microorganisms + **interfering substance**

Test III: Understand build-up of interfering substances in endoscope channels over time



Evaluate if interfering substances will **build up residues** over time, despite reprocessing

Simulating use in

- Brushable channels (4mm Ø)
- Non-brushable channels (2mm Ø)

Result I:
Interfering substances have no bacteriostatic/ bactericidal effect

- **Test** for **bacteriostatic or bactericidal effect**
- Test bacteria:
  - *S. aureus*
  - *E. coli*
  - *P. aeruginosa*
- Substances and test concentrations
  - Xylocain Gel 2 %: 2.0 + 1.0 + 0.5 %
  - Sab simplex: 0.5 + 0.25 + 0.125 %
  - Proveblue: 0.5 + 0.25 + 0.125 %
  - Peritrast: 50 + 25 + 12.5 %
- Test methods employed EN 13727 test requirements

1 2 3 4

→ **None** of the substances showed **any growth inhibiting effect**[7]

Assessing extraction efficiency ratios between interfering substances

Interfering substance + microorganisms

Reprocessed endoscope channels (150 cm):

- Aspiration of 50 ml of interfering substance
- Incubation for **5** minutes (RT)
- Artificial contamination with a microbial suspension (*E. coli*, *S. aureus* and *P. aeruginosa*) prepared in 0,9% NaCl solution (7,5 ml)
- **30** minutes of incubation (RT)
- Sampling using the French (flush) method.
- Determination of microorganisms present in each sample and calculation of efficiency per EN 11737-1:2018

Microorganisms + interfering substance

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- Aspiration of 50 ml of interfering substance
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Impact of interfering substances

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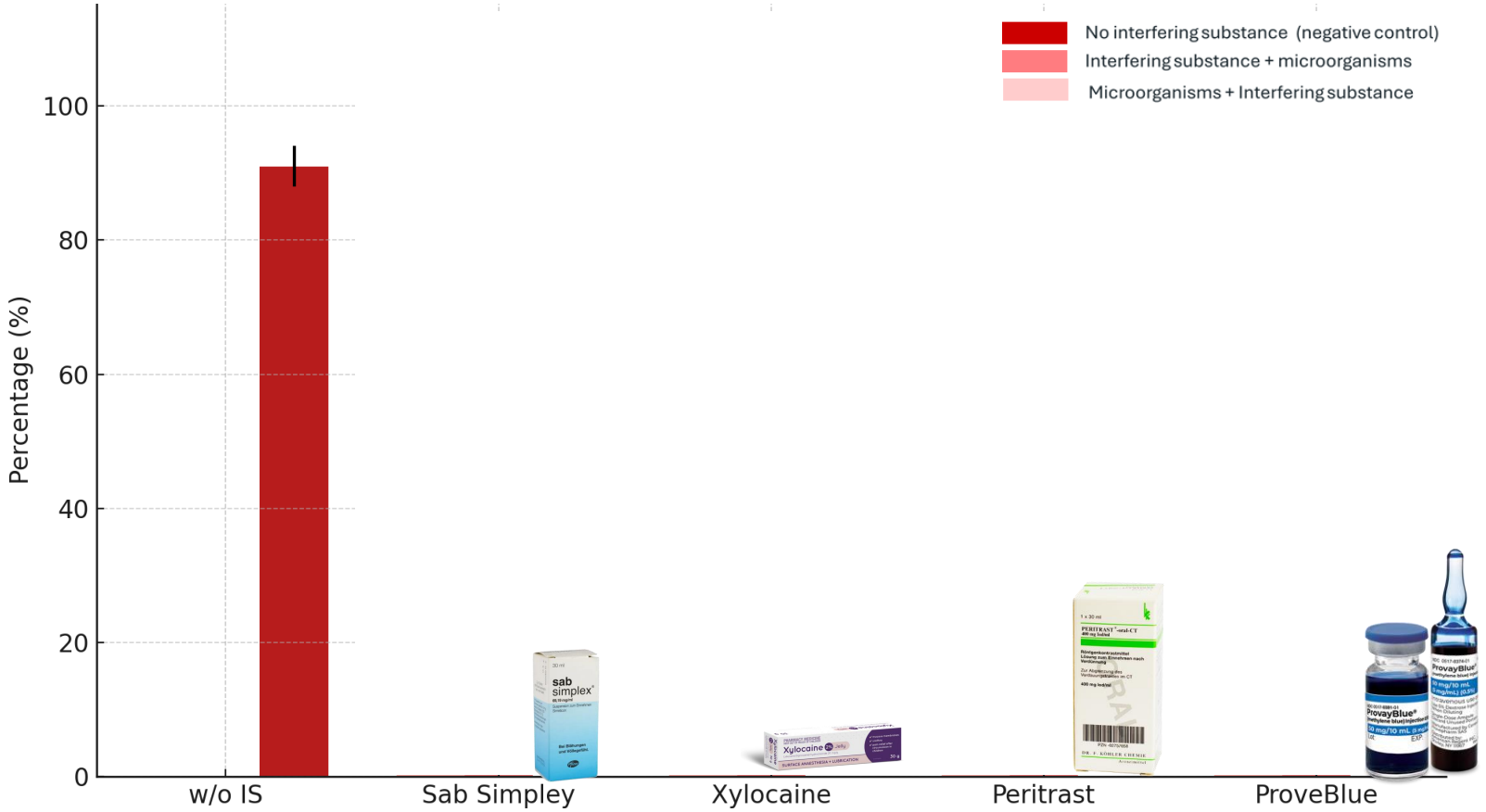
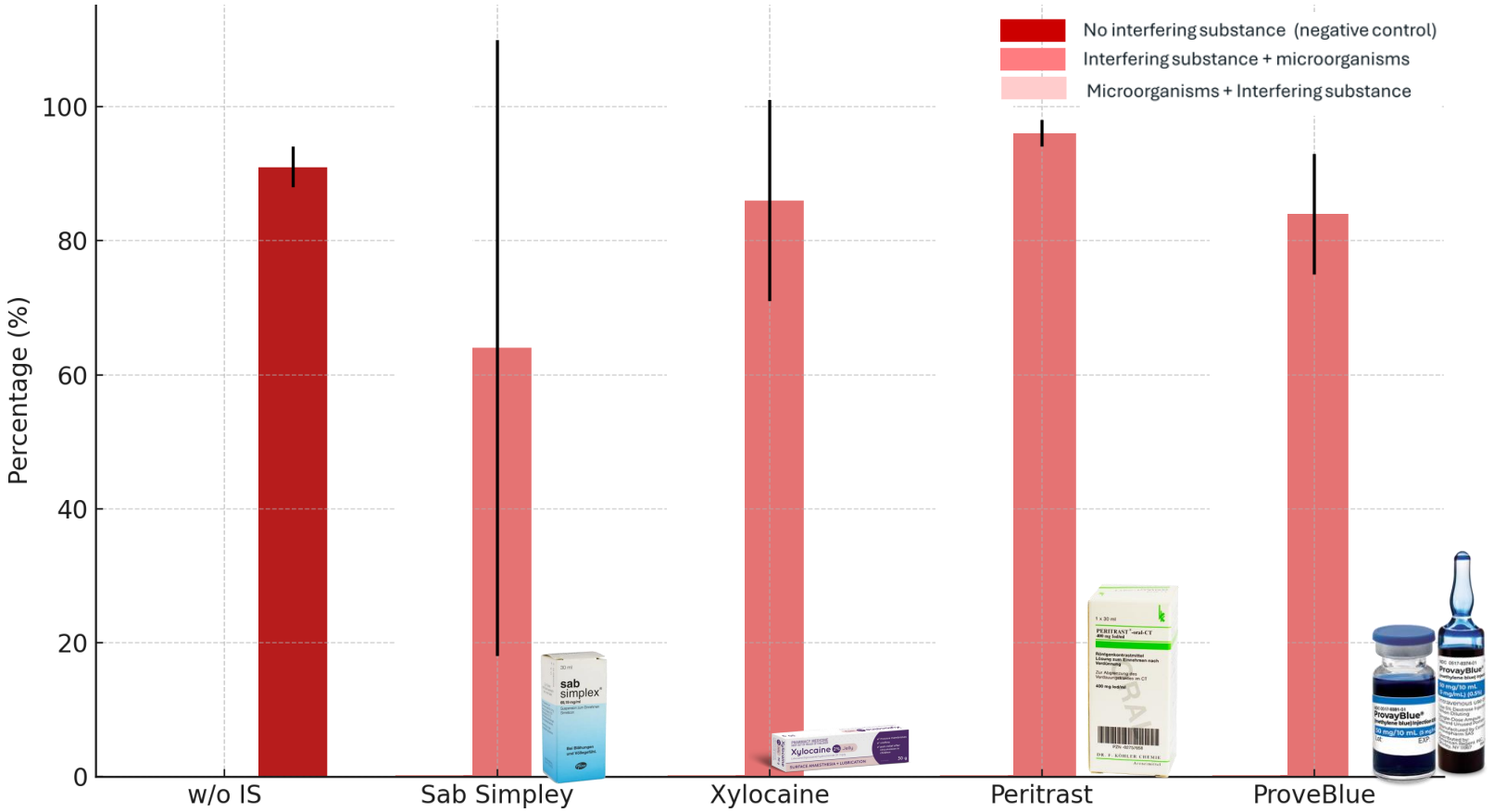
Result II:
Effect of interfering substances on extraction efficiency



Negative control / no interfering substance

- Extraction efficiency around 90%

Result II:
Effect of interfering substances on extraction efficiency



Negative control / no interfering substance

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Interfering substance + microorganisms:

- values obtained are close to those attained for negative control
- However, considerable reduction for Sab Simplex / defoaming agent

Result II:
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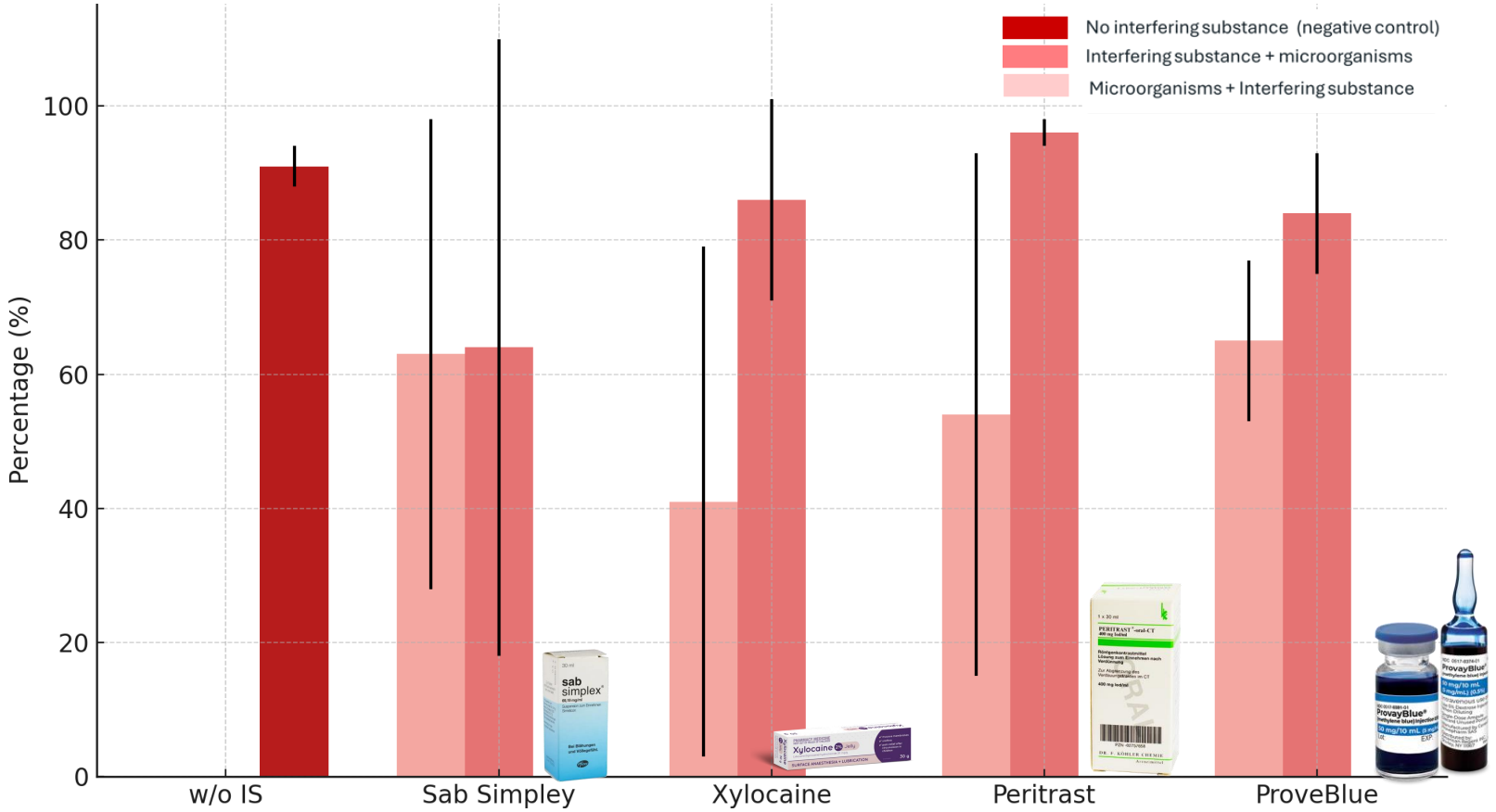

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- Extraction efficiency around 90%

Interfering substance + microorganisms:

- values obtained are close to those attained for negative control
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Microorgansims + **Interfering substance** :

- important reduction of extraction efficiency for **all** additives
- considerable standard deviation

Impact of interfering substances

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Simulation treatment and reprocessing on pure PTFE channels

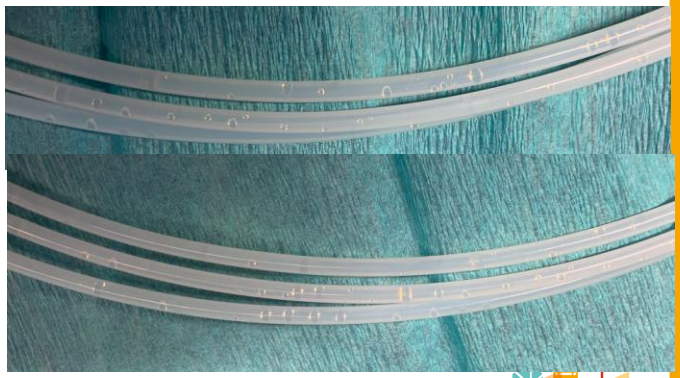
Test procedure including flushing with simethicone, pre- cleaning, manual cleaning and disinfection procedure

Step 1	Flush Simethicone
Interfering substance	Simethicone / Sab Simplex
Concentration:	1,5% -dilution in 0.9% NaCl solution
Volume:	20 ml for d=4 mm channel / 10 ml for d = 2 mm channel
Execution:	Flush 20 ml (10 ml) (dyed) Simethicone/ saline mixture through the channel using syringe Flush 50 ml (30 ml) water of standardized hardness through the channel using syringe 2 x Air purge of 10 ml using syringe 30 min contact time Follow **step two** and **step three**

Devices under test	contact
d = 2 mm; l = 60 cm, 3x	1x
d = 2 mm; l = 60 cm, 3x	5x
d = 2 mm; l = 60 cm, 3x	10x
d = 2 mm; l = 60 cm, 3x	20x
d = 4 mm; l = 60 cm, 3x	1x
d = 4 mm; l = 60 cm, 3x	5x
d = 4 mm; l = 60 cm, 3x	10x
d = 4 mm; l = 60 cm, 3x	20x

Step 2	Manual Cleaning
	Prepare EndoPreZyme Cleaning solution (acc. to IfU) Water bath: 5 litres + 0,5% EndoPreZyme (save time and money) Immerse surrogate completely in detergent solution 2 mm: no brushing 4 mm: brush once using (BW412T) while immersed - brush the channel once (back and forth) Flushing with detergent solution using syringe 2 mm - flushing with 30 ml detergent solution 4 mm - flushing with 50 ml detergent solution Keep immersed for contact time t = 7 min Flushing with ordinary tap water solution using syringe 2 mm - flushing with 30 ml water 4 mm - flushing with 50 ml water 2 x Air Purge with 10 ml air Wipe external surface of the surrogate after cleaning procedure

Step 3	Manual Desinfektion
	Prepare disinfectant solution: Water Bath 5 l + Sekusept Aktiv 2% (PAA) Immerse surrogate completely in disinfectant solution Flushing with disinfectant solution using syringe 2 mm - flushing with 30 ml disinfectant solution 4 mm - flushing with 50 ml disinfectant solution Keep immersed for contact time t = 15 min Prepare water bath with 5 l ordinary tap water Immerse surrogate completely in water bath 2 mm - flushing with 30 ml water 4 mm - flushing with 50 ml water 2 x Air Purge with 10 ml air Wipe external surface of the surrogate after rinsing procedure



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Result III: Droplet formation inside PTFE channels after 1 or 10 simulated use cycles

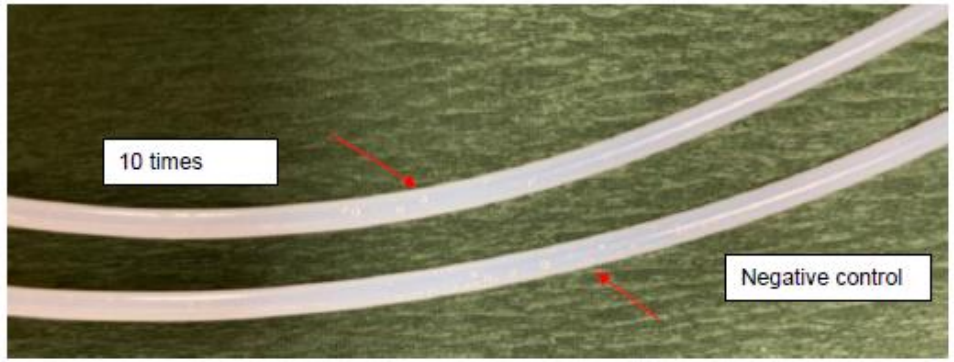


figure 19 Tubes of 4 mm after 10 times of reprocessing within 120 hours compared to negative control (one time reprocessing)

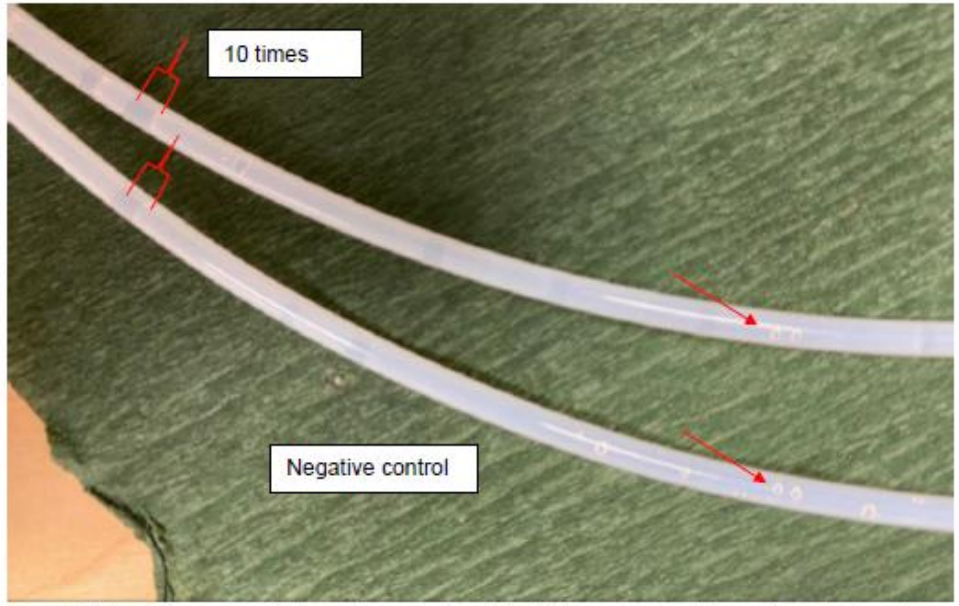


figure 20 Tubes of 2 mm after 10 times of reprocessing within 120 hours compared to negative control (one time reprocessing)

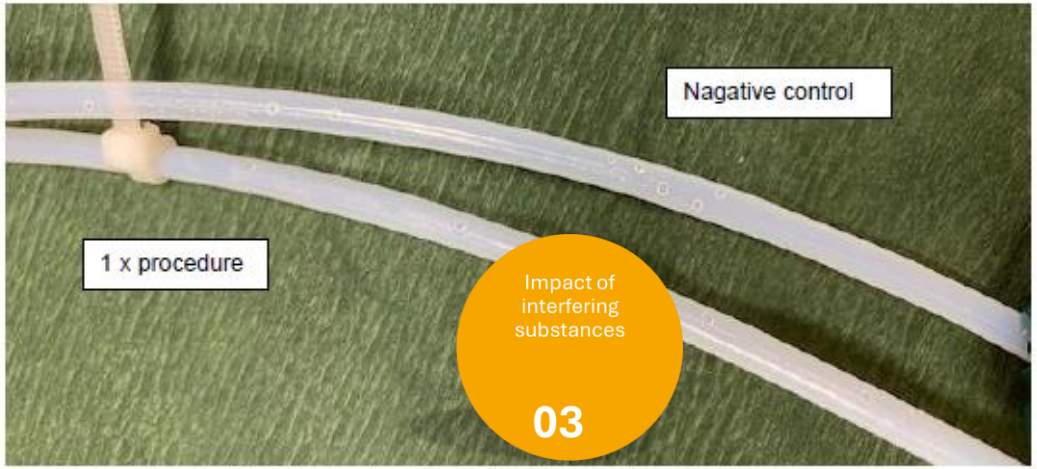


figure 12 4 mm tube after 1 time the procedure in comparison to the negative control

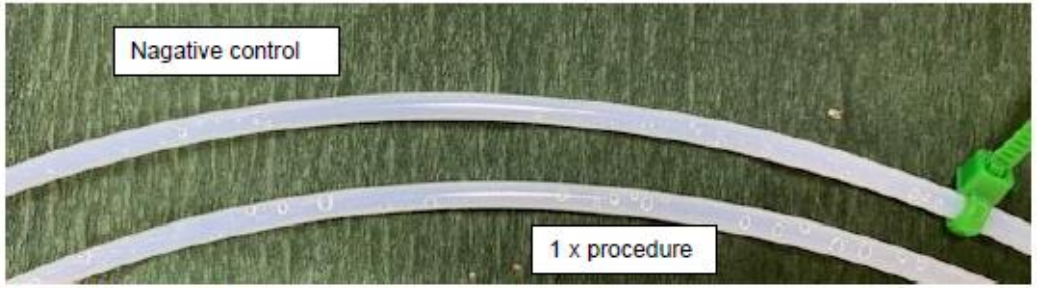
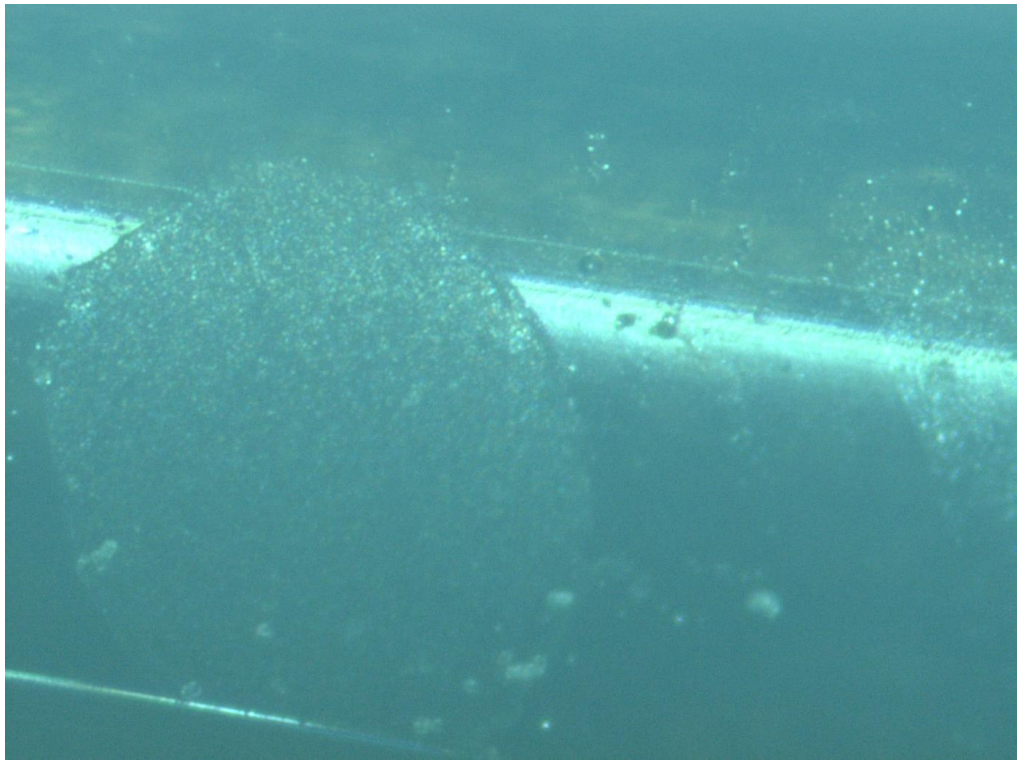
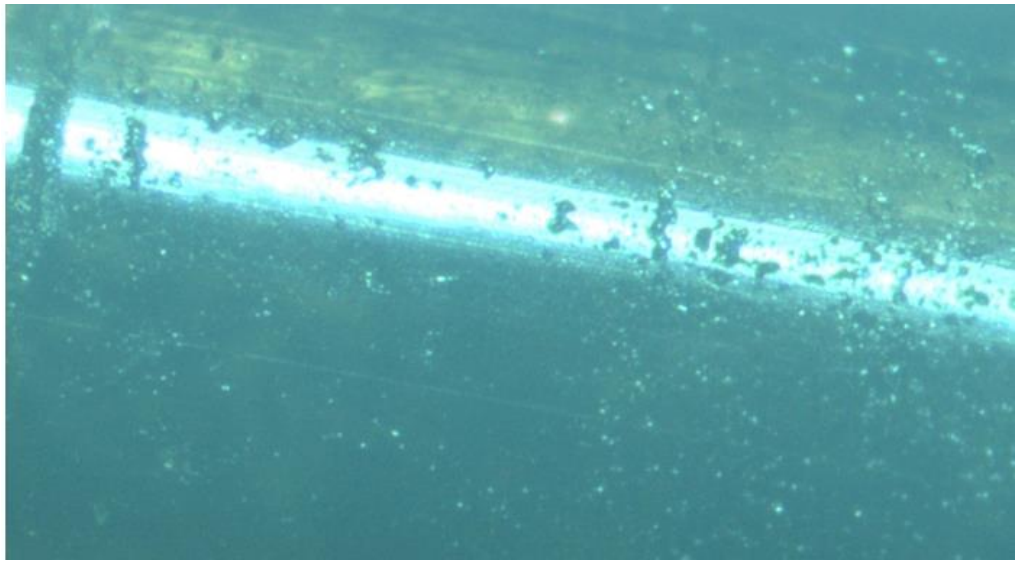
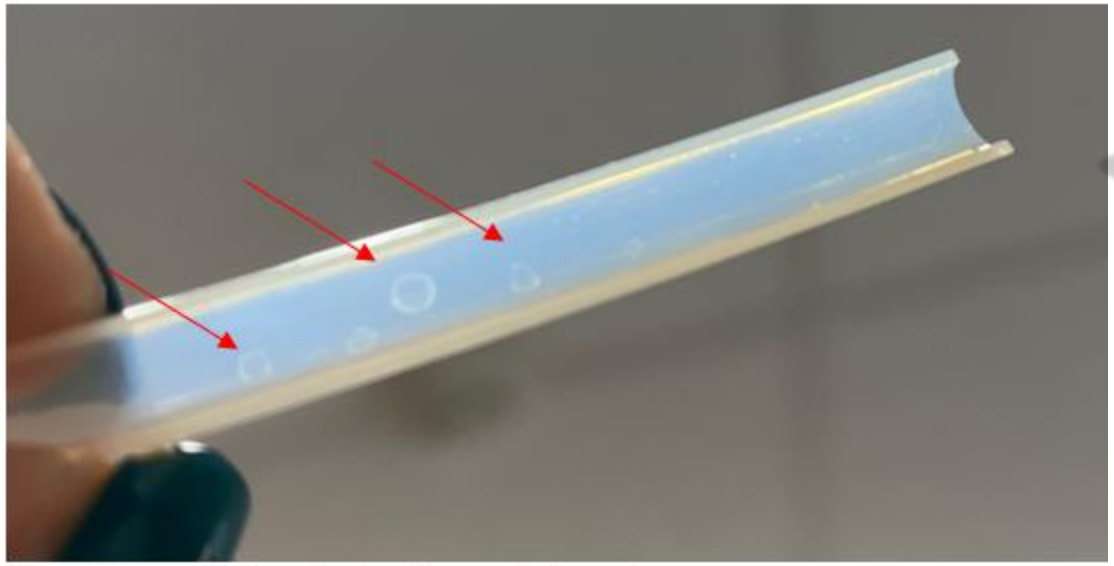


figure 13 2 mm after one time of procedure in comparison to the negative control







4mm tube after drying showing the remaining spots

Impact of interfering substances

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Dried Simethicone drop (left side) against a chalk drop (right side)

Under the microscope it can be clearly seen that the structure remains viscous and does not dry out completely.

Impact of interfering substances

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Test Result III: Simethicone residues in endoscope channels

Simethicone Residues in channels

- Complete processing of 2 mm and 4 mm (including brushing) after Simethicone flush over time
- Quantification analysis of Simethicone residues demonstrates accumulation over time
- Based on current cleaning and disinfection techniques, Simethicone cannot be removed completely from endoscope channels

#	Description	Si Value	Unit
1	Sample Control	2.1	%
2	Negative Control	5	µg
3	Positive Control	8000	µg
4	Flushing 5x	20	µg
5	Cleaning & Disinfection Process - 2mm tube, 1x	11	µg
7	Cleaning & Disinfection Process, - 2mm tube 5x	28	µg
8	Cleaning & Disinfection Process, - 2mm tube 10x	76	µg
9	Cleaning & Disinfection Process, - 2mm tube 20x	90	µg
11	Cleaning & Disinfection Process - 4mm tube, 1x	17	µg
12	Cleaning & Disinfection Process, - 4mm tube 5x	50	µg
13	Cleaning & Disinfection Process, - 4mm tube 10x	130	µg
14	Cleaning & Disinfection Process, - 4mm tube 20x	110	µg

The determination was carried out after dissolving the samples in 40 mL IPA xylene (1:1) using atomic emission spectrometry (ICP-OES).

Outlook on further reserach

04

Take away and Outlook

Observed Impacts & Take Aways

- **Interfering substances** are **widely used** in endoscopic procedures, but their impact on reprocessing efficiency remains unclear
- **Incomplete removal** of these substances may **lead to residual deposits** in endoscope channels, i.e. as they may not dry out
- Data suggests that interfering substances **can hinder bacterial removal** and impact extraction efficiency, i.e. if interfering substance is applied on a contaminated surface
- **Defoaming agents** build up in endoscope channels over time; **standard reprocessing does not remove** them

Outlook on future research

- Gain understanding if residues of interfering substances also **preserve contamination**
- Evaluate strategies for **effective handling** (use / removal) of **interfering substances**

Sources

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8. International Organization for Standardization (ISO). ISO 11737-1:2018 - Sterilization of Medical Devices—Microbiological Methods—Part 1: Determination of a Population of Microorganisms on Products. ISO; 2018.

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Thank you

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