WHITE PAPER

Eliminating the need for Extended Endoscope Soak Times by the use of INTERCEPT™ Detergent and INTERCEPT™ Foam

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Introduction

It is well established that it is not possible to effectively disinfect flexible endoscopes which are not clean. Timely steps in processing ensure that this cleaning meets the required standards for the endoscope to be successfully high-level disinfected.

The current accepted time frame between the bedside or pre-cleaning and the manual cleaning process is one (1) hour. While most reprocessing centers can meet this time requirement there are many circumstances that can affect the ability to achieve manual cleaning within this time frame.

Failure to complete manual cleaning promptly can allow the formation of biofilm and increase the likelihood of patient soil drying on and in the endoscope channel system which can cause significant challenges during the manual cleaning process.

The intent of this experiment was to establish a method of verifying that the application of INTERCEPT™ Detergent (liquid) and INTERCEPT™ Foam during the bedside or pre-cleaning process could extend the time to manual cleaning by up to 72 hours. This would help in situations such as emergency and out-of-hours procedures or when the manual clean process cannot be started within (1) hour due to logistical challenges.

Note: INTERCEPT Detergent and INTERCEPT Foam comply with all specific criteria provided by endoscope manufacturers for types of detergents to be used with their endoscopes.

- **Olympus** states “Olympus’ general recommendation is for a low-foaming (as a solution), neutral pH detergent that has been formulated for use with medical instruments. The detergents may also contain enzymes and should be bacteriostatic.”[1]
- **Pentax** states “The solutions must be enzymatic detergents or other cleaning agents specially formulated to clean flexible endoscopes.”[2]
- **Fujifilm** states only “Neutral detergent:”[3]

Experimental Methods and Materials

Experiment designed to show endoscope “conditioned” with INTERCEPT Detergent and INTERCEPT Foam and stored in a sealed container for 72 hours is “as good as, or better than a ‘one hour non-conditioned’ endoscope”

The object of the experiment was to demonstrate that ‘conditioned’ endoscopes would not dry out after 72 hours to the extent that the manual cleaning process was more challenging than a ‘non-conditioned’ endoscope would be after one hour of drying. Testing was also performed to confirm that the ‘conditioned’ scope did not promote the growth of biofilm.

1. Choice of Test Soils

The first consideration was to determine a soil that would give good differentiation between the various drying times that would be tested.

Various candidates of soils were tested including; Edinburgh soil, ATS, Austrian ISO soil, German ISO soil, UK ISO soil (2 types) and French ISO soil. After many tests, ~~Brownes~~ soil was chosen for its ability to show a differentiation in drying time.

Testing was conducted on the most common of endoscope materials: stainless steel, insertion tube sections, bending rubber samples and sections of internal channel material.

2. Cleaning study results on Test Material Samples

Three (3) replicates of eight (8) different time periods were tested as controls. The stainless steel coupons were inoculated with a measured amount (by weight) of the ~~Brownes~~ soil. The coupons were allowed to dry for the appropriate amount of time as per the protocol.

Each coupon was then affixed to a rinsing fixture where the angle, pressure, flow and time of the rinse water exposure was carefully controlled for a prescribed time. Visual results are shown in **Figures 1, 2, 3, 4 and 5**.

Note: The control samples represent a ‘non-conditioned’ state. For the ‘conditioned state’ to be equivalent or better than a one-hour ‘non-conditioned’ state, the amount of soil on the ‘conditioned’ samples should be equal to, or less than the soil on the control sample at 60 minutes.

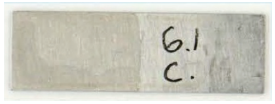
DRY TIMES	CONTROL	INTERCEPT™ FOAM		
		24 HOURS	48 HOURS	72 HOURS
30 seconds				
2.5 minutes				
5 minutes				
15 minutes				
30 minutes				
60 minutes		Foam results must be as good as, or better than 60-minute control		

Figure 1. Stainless Steel (sample size 1 of 3)

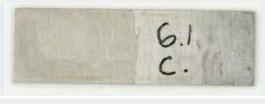
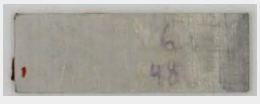
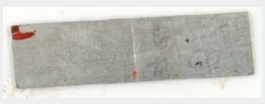
DRY TIMES	CONTROL	INTERCEPT™ FOAM		
		24 HOURS	48 HOURS	72 HOURS
30 seconds				
2.5 minutes				
5 minutes				
15 minutes				
30 minutes				
60 minutes				

Figure 2. Stainless Steel (sample size 1 of 3)

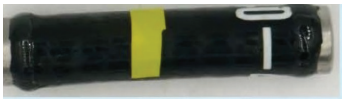
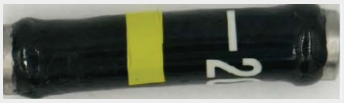
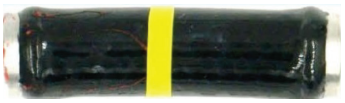
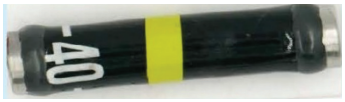
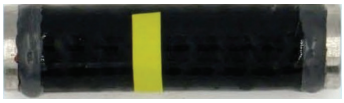
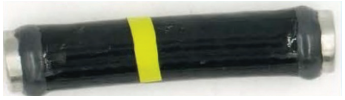
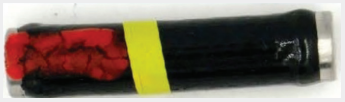
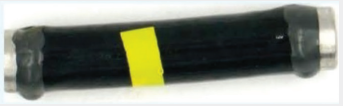
DRY TIMES	CONTROL	INTERCEPT™ FOAM	
		24 HOURS	72 HOURS
30 seconds			
2.5 minutes			
5 minutes			
15 minutes			
30 minutes			
60 minutes			

Figure 3. Insertion Tube (sample size 1 of 3)

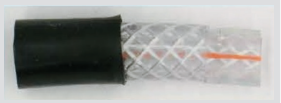
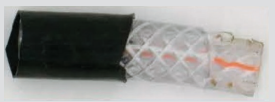
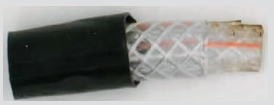
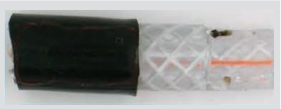
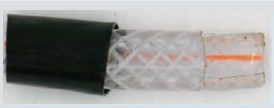
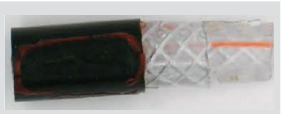
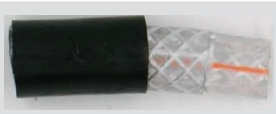
DRY TIMES	CONTROL	INTERCEPT™ FOAM		
		24 HOURS	48 HOURS	72 HOURS
30 seconds				
2.5 minutes				
5 minutes				
15 minutes				
30 minutes				
60 minutes				

Figure 4. Bending Rubber (sample size 1 of 3)

BENDING RUBBER TEST

60 minute samples

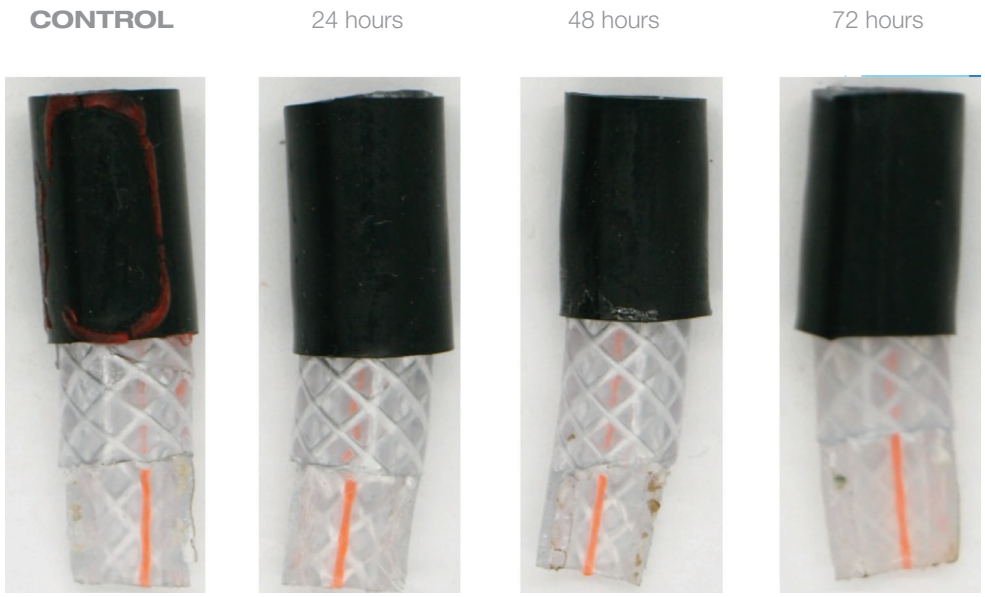


Figure 5. Bending Rubber (60 minute samples)

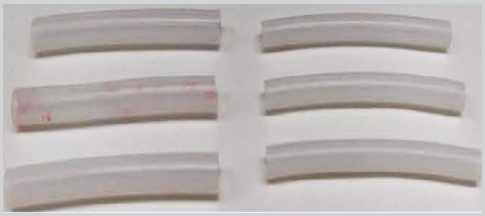
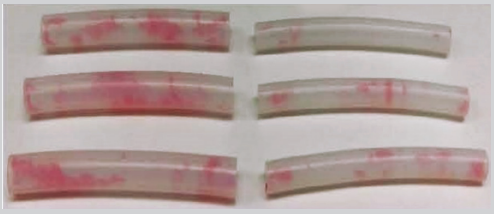
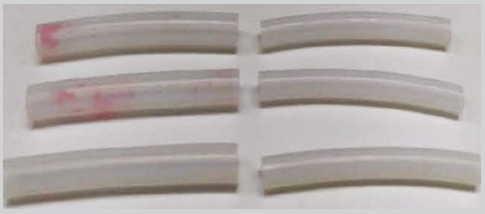
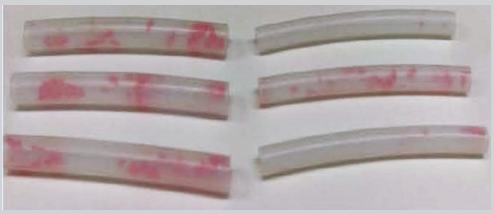
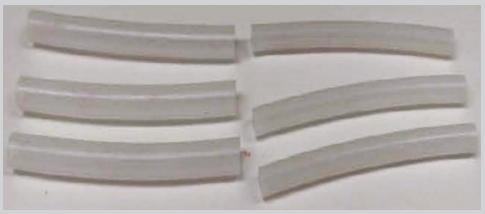
DRY TIMES	CONTROL	FOAM/SOAK TIMES	SUGGESTED PROCESS SAMPLES
2.5 minutes		24 hours	
15 minutes		48 hours	
60 minutes		72 hours	

Figure 6. Channel Sections

3. Results of Drying Test

All testing was completed with 3 replicates at each condition. Controls were run at up to 8 different time periods with 4 different materials. Conditioned samples were run after foam or detergent for up to three days (72 hours). In all there were 120 control samples and 180 conditioned samples tested. In all cases, the conditioned samples had less soil on them than control samples at 60 minutes which show the soil on the conditioned samples was not as dry as soil that had remained on the non-conditioned samples for one hour.

4. Microbial Benefits of Foam Application

Additional testing was performed to show that a conditioned scope was at a minimum, in a bacterial static condition. Test methodologies included suspension testing and inoculation of endoscopes.

The suspension testing was performed in test tubes. A solution of *Pseudomonas aeruginosa*, a known biofilm forming bacteria, at a starting concentration above 10^6 CFU/ml was split into two samples. The first sample was left as the positive control. INTERCEPT™ Detergent was added to the second sample at the minimum recommended concentration. Both samples were tested at times out to 72 hours. The results are shown in **Figure 7**.

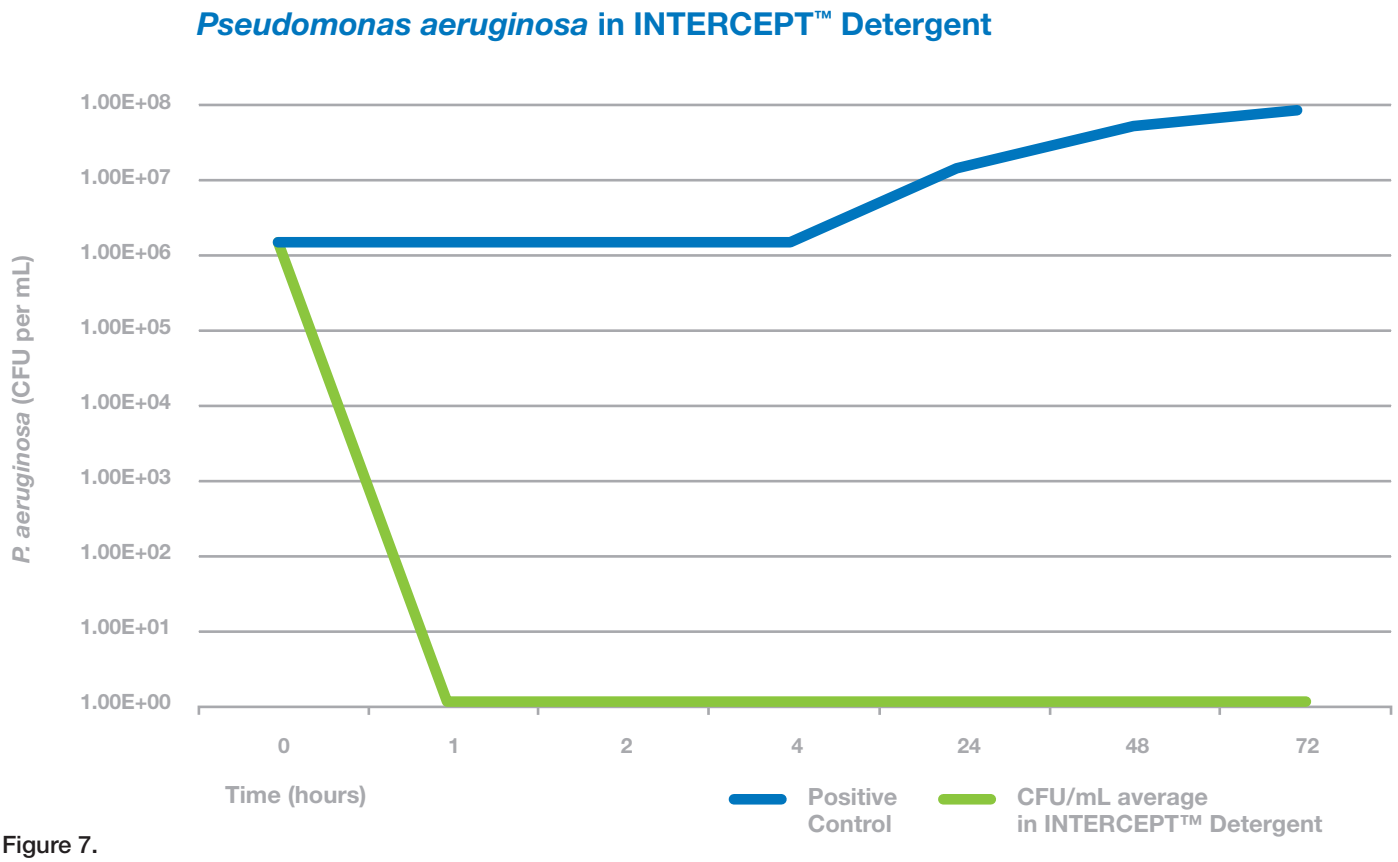


Figure 7.

In addition to the suspension test, a sample of endoscopes had the suction/biopsy channels inoculated with *Pseudomonas aeruginosa*.

INTERCEPT™ Detergent was suctioned through the suction/biopsy channel as per normal bedside cleaning practice.

The endoscope was then left for a period of a weekend before recovery was performed. Recovery took place on the Monday and demonstrated a 6 log reduction in *Pseudomonas aeruginosa*.

5. Conclusions

The results of the testing has shown that suctioning INTERCEPT Detergent through the suction/biopsy channel during the precleaning process and then placing the endoscope in a sealable container and covering the external surfaces with INTERCEPT™ Foam, will provide an endoscope that can be left in this condition for up to 72 hours without the need for any additional manual cleaning steps (i.e. an extended soak). See Medivators Instructions for Use (document 50098-1534) on our website (http://www.medivators.com) for a detailed description of this process.

*INTERCEPT Foam is intended only for use to preclean or decontaminate medical devices including semi-critical devices such as endoscopes prior to further reprocessing and high-level disinfection or sterilization. It is not intended for use as a general purpose hard-surface disinfectant or intended for decontamination or disinfection of environmental surfaces.

INTERCEPT Foam is not an EPA registered general purpose disinfectant and it is not labeled or claimed to have general purpose bactericidal properties.

REFERENCES

1. OLYMPUS AMERICA INC., Detergents Compatible with Olympus Flexible Endoscopes, September 17, 2003.
2. PENTAX CORPORATION, PENTAX Reprocessing/Maintenance Manual, Video GI Scopes, 70K Series, 80K Series, 2003. 07. K100.
3. FUJINON CORPORATION, FUJINON Operation Manual (Cleaning, Disinfection and Storage) Video-Bronchoscope EB-450/470 Series, 202B9451180, 0409-6.0-DT-E.

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