Improved Endoscope Cleaning Performance

with Biofilm-removing Detergents

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INTRODUCTION

It is well established that it is not possible to effectively disinfect flexible endoscopes which are not clean. Effective cleaning requires an effective kill of bacteria AND removal of residual bacterial trapping structures known as biofilms. Recent studies of clinical flexible endoscope channels have shown significant biofilm residuals which are not removed by most detergents [1-5]. This paper presents data on a new detergent, Intercept®, which has a highly effective kill rate against resident bacteria and removes residual biofilms without the use of enzymes. Intercept was designed to penetrate, detach and disrupt protective biofilm colonies. A summary of safety data for Intercept and other detergents is included.

Intercept complies with all specific criteria provided by endoscope manufacturers for detergents to be used with their endoscopes.

- **Olympus** states "Olympus' general recommendation is for a low-foaming, neutral pH detergent that has been formulated for use with medical instruments. The detergents may also contain enzymes and should be bacteriostatic."[11]
- **Pentax** states "The solutions must be enzymatic detergents or other cleaning agents specially formulated to clean flexible endoscopes."[12]
- **Fujinon** states only "Neutral detergent:"[13]

EXPERIMENTAL METHODS AND MATERIALS

a) Experimental conditions for Bacterial Biofilm Removal Studies

Bacterial biofilm removal studies were conducted according to the guidelines described in the prEN/ISO 15883-1. *Pseudomonas aeruginosa* biofilms were grown in 2 mm diameter Teflon tubing sets for 96 hours at 30˚C for testing with each detergent. A portion of each tube set was set aside and used as a control. A biofilm bearing segment of the tubing set was then subjected to a detergent wash for five (5) minutes at the temperature recommended by the specific detergent manufacturer. After treatment, the biofilm bio-mass remaining in the tube was quantified using a crystal violet dye staining procedure[1]. Dye bound to the residual biofilm bio-mass was quantified by $OD_{540\ nm}$ measurements. The CFU Log reduction in viable bacterial biofilm numbers was then calculated and the results are summarized in Table 1.

b) Experimental conditions for Cleaning Studies on Medical Instruments

Cleaning studies with immersible endoscopes involved using an established artificial test soil (Alfa et al., 2005) to soil the interior endoscope channels and surface. The loading of the endoscopes was >200 mg/cm^2 (exceeding worst case soiling levels, Alfa et al.1999), and the endoscopes were dried for 1 hour (after loading the soil) before the cleaning was performed. The soil was evaluated before and after cleaning by analyzing for total protein and total carbohydrate content.

Cleaning studies with forceps involved soiling forty (40) surgical forceps using the German blood soil described in the prEN/ISO 15883-1 guidelines. The soil was mixed with a trace of radioactive Technetium to determine the amount of soil residue after the cleaning procedure. Detectable radioactivity above background and after cleaning was an indication that a soil residue was present on a forcep. The effectiveness of a detergent was determined by the largest number of forceps with radioactive counts below background.

c) Experimental conditions for Olympus Endoscope Compatibility

An endoscope compatibility study was conducted using Intercept and an Olympus endoscope in the Medivators Advantage Plus automated endoscope reprocessor. The endoscope was exposed to 500 cycles of cleaning with Intercept and high level disinfectant, and the endoscope was monitored for materials and performance changes.

It should be noted that per Olympus "Olympus no longer tests detergents for endoscope compatibility, nor issues detergent compatibility statements."[11] The detergent manufacturer is responsible for ensuring the detergent meets Olympus's general recommendations. Medivators Intercept is a low-foaming, neutral pH, bacteriostatic detergent formulated for use with medical instruments, which meets Olympus's detergent criteria.

RESULTS OF EXPERIMENTS

a) Results of Bacterial Biofilm Removal Studies

Table 1 shows the viable cell counts regarding bacterial biofilm kill. Intercept resulted in greater than 7.21 log reduction in viable bacterial biofilm numbers, whereas enzymatic detergents demonstrated little or no reduction in the number of CFU/cm^2.

Table 1 - Bacterial kill in model biofilms

Detergent	Type	Concentration	Bacterial CFU Log reduction/cm^2
Intercept – Medivators	Non-enzymatic	1:25	7.21
Intercept – Medivators	Non-enzymatic	1:100	7.21
Endozime – Ruhof	Enzymatic	6 ml/L	0.8
Cidezyme – J&J	Enzymatic	16 ml/L	0.25
Medizyme – Whiteley	Enzymatic	6 ml/L	0

b) Results of Cleaning Studies on Medical Instruments

1. Cleaning study results on immersible endoscopes

The efficacy of Intercept on washing immersible endoscopes was evaluated using manual and semi-automated cleaning methods and a conventional blood-containing test

soils (Alfa, 2002). The cleaning was observed by monitoring the total protein and total carbohydrate removal from the test articles, and all endoscopes were cleaned to AAMI TIR-30 standards. The study data concluded that cleaning with 0.25% +/-.05% Intercept for a minimum contact time of 60 seconds adequately removed all of the soil from the endoscopes. The cleaning results are summarized in Table 2.

Table 2 - Cleaning efficacy of Intercept using different cleaning methods.

Cleaning Method	Concentration	Time (sec)	Protein Removal	Carbohydrate Removal
Scope Buddy (semi-automated)	0.25%	30	90%	98.3%
Scope Buddy (semi-automated)	0.25%	60	100%	99.5%
Manual Cleaning	0.25%	60	100%	99.8%

A comparison of protein and carbohydrate soil removal by Intercept and an enzymatic cleaner was evaluated using manual cleaning and a conventional blood-containing soil. Intercept proved to be extremely effective at a lower use-concentration and in a significantly shorter contact time when compared to enzymatic detergents. The cleaning results are summarized in Table 3.

Table 3 - Comparison of Intercept with an enzyme detergent.

Detergent	Concentration	Contact Time (sec)	Protein Removal	Carbohydrate Removal
Intercept	0.25%	60	100%	99.6%
Intercept	0.25%	60	100%	99.8%
Endozime AW	0.78%*	120	99.6%	99%
Endozime AW	0.78%*	120	99.2%	98.6%
Microzyme	0.78%*	120	100%	98.8%
Microzyme	0.78%*	120	98.1%	98.0%

* 1 ounce per gallon, per label

2. Cleaning study results on surgical forceps

The efficacy of different detergents was evaluated against conventional blood soils using a radionuclide method on forty (40) surgical forceps in an automated process. The effectiveness of each detergent was determined by the largest number of forceps with radioactive counts below 5 counts/sec. Excellent cleaning results were achieved by Intercept and two other detergents as summarized in Table 4; however, we must also consider that bacterial reduction and soil removal are equally important in detergent selection.

Table 4 - Soil removal using radionuclides in an automated washer.

Detergent	Type	Concentration	Total Passing Forceps (Highest possible score 40)
Intercept – Medivators	Non-enzymatic	0.25%	35
Soluscope C+ Soluscope	Non-enzymatic	0.25 %	33
DS-2 Clean	Non-enzymatic	0.7 %	37
Metrizyme – Metrex	Enzymatic	0.5 %	30
Endozime AW – Ruhof	Enzymatic	1 %	38

c) Results of Olympus Endoscope Compatibility Study

An Olympus endoscope was exposed to 500 cycles of cleaning with Intercept and high level disinfection using a Medivators Advantage Plus automated endoscope reprocessor. No changes in the endoscope materials or performance were observed during the inspection of the endoscope after 500 cycles.

Olympus states "Though Olympus recommends use of only those products that have passed our testing, use of an untested product in no way prejudges its compatibility with Olympus endoscopes nor does it automatically void the Olympus standard warranty."[11]

The compatibility testing results confirm Intercept detergent is compatible and safe for use on Olympus endoscopes.

SAFETY OF DETERGENTS

The ideal detergent would be formulated at a neutral pH of 7.0 for optimal compatibility with medical devices and contain no agents which have the potential for human sensitization. The detergent labels and safety data summary in Table 5[6] shows four products; Klenzyme, Enzol, Endozime and Metrizyme which all contain enzyme active agents and are listed as either respiratory or skin sensitizers, or both. While the exact language used in the material safety data sheets vary from "may result in respiratory sensitization" to "may cause skin sensitization" the message is clear. Use of enzymatic detergents does carry a certain risk for the user, and optimal personal protection measures are to be used with this class of products.

The second class of detergents, Tergal 800 and Cavicide, do not contain enzymatic detergents and the associated sensitization risk, but they are formulated at very high pH ranges. At a range of pH 10 – 12, the products are extremely caustic and certainly have the potential to damage devices and act as a strong irritant for the user. In the case of Cavicide, the product is also flammable with an ignition temperature of just 83°F and contains 19% isopropyl alcohol.

In the third category there is only one product - Intercept. Intercept contains no enzymes and is the only product formulated at a neutral pH for optimal device compatibility and user-safety. Intercept has no sensitizing affects when mixed with cool to warm water (as specified on the manufacturer's direction for use) and properly diluted to a 0.25% or 0.5% use concentration.

Table 5 – Material Safety Data Sheet and Label Detergent Comparisons

Detergent	Active Agent	pH	Sensitizer – Respiratory or skin
Intercept – Minntech	Neutral detergent	7.0	No
Klenzyme – STERIS Corp.	Proteolytic enzymes	7.5 - 8.0	Yes – respiratory
Enzol – ASP* **	Proteolytic enzymes	7.8 – 8.8	Yes – skin
Endozime – Ruhof	Enzymes	6.0 - 7.5	Yes – inhalation
Metrizyme – Metrex	Proteinase enzymes	6.5 – 8.0	Yes – inhalation
Tergal 800 – Custom Ultrasonics	Alkyl alcohol ether	10 - 12	No
Cavicide – Metrex	Alkyl alcohol ether	11 – 12.5	No but flammable risk

DISCUSSION OF RESULTS

When considering the choice of a detergent, the user should choose products with demonstrated reduction of viable bacteria in a biofilm challenge. Many enzymatic detergents fail to reduce the bacteria levels as seen in the cited studies. Secondly, consider products with data to support significant removal of biofilm surface layers. While we are only beginning to understand how model studies will relate to on-site clinical reprocessing, there is a growing body of evidence that biofilms can increase the potential for nosocomial infections. In the face of this growing body of evidence, reprocessing centers would act prudently to develop an aggressive cleaning protocol employing detergents with proven performance against the most resistant challenges.

Reprocessing managers should also consider the risks detergents might pose to their reprocessing staff. Most enzymatic material safety data sheets inform the user that enzymatic detergents may cause sensitization by skin contact and affect the eyes, skin, lungs and respiratory system.

The studies cited support Intercept performance in removal of biofilms from endoscope channel materials, complete removal of biochemical components of soil, and complete kill of 10^7 CFU/cm^2 of viable bacteria. Along with superior cleaning efficacy, Intercept has also been formulated to be low foaming. This combination of features make it the ideal choice for cleaning of endoscopes. A complete bacterial kill increases the effectiveness of the subsequent disinfection step of the reprocessing protocol and reduces the potential for biofilm regrowth. Intercept is safe based on its material safety data and more than five years of clinical use.

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