Technical Data Monograph

Decontamination of Reusable Medical Devices

Innovative FAST Cycles using Prolystica® Ultra Concentrate System in Reliance® Synergy® Washer/Disinfectors

STERIS®

Introduction - More With Less is Now Faster

STERIS Corporation is taking the ergonomic benefit demonstrated with the Prolystica® Ultra Concentrate System one step further. Not only can more be done with less chemistry, but now it can be done faster than traditional STERIS cleaning chemistries. This family of innovative chemistries has demonstrated exceptional cleaning performance, an enhanced level of instrument protection, the ability to handle a variety of water qualities, at a fraction of the concentration of other chemistries. All of this can lead to enhanced productivity of the medical device cleaning process.

FAST INSTRUMENTS and FAST UTENSILS cycles in the Reliance® Synergy® Washer/Disinfector are validated cleaning cycles using the Prolystica Ultra Concentrate Cleaning System. These validated cycles offer enhanced productivity using optimized cycles for both instruments and utensils, shortening the turn-around time of processed devices.

FAST Cycles as an option on the Reliance Synergy Washer/Disinfector provides shorter time cycles while offering intermediate-level disinfection to ensure the safety of healthcare workers handling potentially contaminated processed medical devices.

Prolystica Ultra Concentrate System

Prolystica Ultra Concentrate formulas clean and protect instruments, while providing optimal safety and ease-of-use for staff. Prolystica Ultra Concentrates provide superior performance against blood, mucous and even the most challenging fatty soils, while working effectively in all types of water qualities. The system consists of two chemistries; an enzymatic cleaner and a neutral detergent (optional lubricant available). These FAST Cycles combine the benefits of both Prolystica Ultra Concentrate chemistries into one productive solution.

Prolystica® Ultra Concentrate Enzymatic Cleaner
Prolystica Ultra Concentrate Enzymatic Cleaner achieves exceptional cleaning performance against blood, mucous, and the most challenging fatty soils. This dual enzyme system works exceptionally well within a wide range of water qualities and types. Prolystica Ultra Concentrate Enzymatic Cleaner utilizes biodegradable ingredients to help protect the environment.

Prolystica® Ultra Concentrate Neutral Detergent
Prolystica Ultra Concentrate Neutral Detergent cleans blood, mucous, and a wide range of challenging fatty soils. Built-in corrosion inhibitors protect instruments and prolong washer life, while chelating and sequestering agents enhance cleaning performance regardless of water quality. Prolystica Ultra Concentrate Neutral Detergent utilizes biodegradable ingredients to help protect the environment.

Fast cycles with Prolystica Ultra Concentrates

Optimized FAST Cycles when used in conjunction with Prolystica Ultra Concentrate Enzymatic Cleaner and Neutral Detergent are intended for use in the cleaning, rinsing, intermediate-level disinfection and drying of rigid surgical instruments, trays, bedpans, basins, bowls, and other miscellaneous reusable items used in the care of patients.

The ability to enhance productivity with shorter cycle times without sacrificing cleaning performance is the result of a dual product cleaning cycle using Prolystica Ultra Concentrate Enzymatic Cleaner and Neutral Detergent. These chemistries were designed to maximize the efficiency of the cleaning process by maintaining good pressure and washer arm movement within the Reliance Synergy Washer/Disinfector. The Prolystica Ultra Concentrate chemistries are injected at specified intervals and temperatures, allowing them to act under their individual optimal conditions together within the wash cycle for the appropriate and most beneficial cycle times. Further, every preprogrammed cycle includes a thermal disinfection phase which is intended to render the items safe to handle by hospital staff for the preparation and packaging prior to sterilization.

Test Program

STERIS designed a test program to separately asses the cleaning, and intermediate-level disinfection efficacy of the Reliance Synergy FAST Cycles using Prolystica Ultra Concentrate Enzymatic Cleaner and Neutral Detergent. The cleaning performance has been evaluated visually, according to Association for the Advancement of Medical Instrumentation (AAMI) Recommended Guidelines for Cleaning and Disinfection. The intermediate-level disinfection efficacy has been evaluated by calculating the reduction in known concentrations of microorganisms in ampoules located in the critical areas of the load chamber and items, as previously established by thermal profiling. Test results have demonstrated efficacy for both processes evaluated.

Test Methods

General
All tests were conducted in accordance with the Good Laboratory Practice[3]. Cleaning studies were conducted at STERIS Canada Corporation, Québec, Canada. To ensure statistical significance, all tests were conducted in triplicate with results averaged.

Testing was performed using the following accessories and load configurations:

Accessory	Test Item	Type	Quantity	Cycle Processed	Detergents
5 Level Manifold Instrument Rack	Surgical Instruments	Hemostat Forceps	10 Trays of 50 hemostats	FAST INSTRUMENTS	Prolystica® Ultra Concentrate Enzymatic and Neutral
Multi-Purpose Basin Rack	Utensils: Hollowware	Stainless Steel Round Bowls (various sizes) Stainless Steel Haricots (various sizes) Plastic Bowls Stainless Steel Rectangular Pans (various sizes)	4 11 9 2	FAST UTENSILS	Prolystica® Ultra Concentrate Enzymatic and Neutral

A- Cleaning

Methods
Cleaning efficacy was evaluated by visual inspection of soil removal. The surgical instruments and the bedpans were soiled with a blood-based soil. The items were processed through the cleaning phase of the appropriate cycles and were subsequently evaluated for visual soil remaining on the items.

In addition, a Ninhydrin Protein Detection test kit from Albert Browne subsidiary of STERIS Corporation (Leicester, UK) was used to asses residual proteins on the processed items.

Preparation (Soiling Procedure)
The blood-based soil was composed of whole sheep blood, bovine calf serum, physiological saline, and was reactivated immediately before use to initiate coagulation. The blood soil was sprayed on hemostats suspended in open position to ensure uniform coverage. Hemostats were allowed to air dry for 30 to 45 minutes. Hollowware items were soiled in their entirety, using a paintbrush; soiled hollowware items were allowed to air dry at room temperature for 30 to 35 minutes.

Isolated Phase
The cleaning efficacy was evaluated for the cleaning process only, which includes pre-wash, wash and rinse phases. The items were evaluated immediately after the cleaning process, without being exposed to the thermal rinsing and drying phases of their respective cycle.

B- Intermediate-Level Disinfection

Markers / Methods
Intermediate-level disinfection efficacy was evaluated by measuring microbial reduction. A thermal profile test was performed to determine worst case accessories and chamber cold spots. *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*, and *Mycobacterium tuberculosis var. bovis* were used to evaluate intermediate-level disinfection efficacy. High-density cultures of each strain were sealed in glass ampoules, and placed randomly throughout the load in known cold spots. Cultures were processed through the isolated disinfection phase and were recovered by plate count and membrane filtration methods to enumerate any surviving organisms.

Preparation
Vegetative bacteria, i.e. *Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa*, were each grown in an enrichment broth until stationary phase of growth. *Mycobacterium tuberculosis var. bovis* frozen cultures were thawed, diluted and ground in a tissue grinder. Aliquots of each test organism were transferred to series of glass ampoules and sealed.

Control
A positive control was performed by standard plate counts to determine the initial titers of the test organisms in the ampoules.

Calculations
The percent and logarithmic reduction figures were calculated from the difference between recovered bacterial counts on control (unprocessed) and test (processed) items.

Results

A- Cleaning
This study demonstrates that the FAST UTENSILS and the FAST INSTRUMENTS cycles when used with Prolystica Ultra Concentrate Enzymatic Cleaner and Neutral Detergent, achieve cleaning performance that successfully meets the Ninhydrin Test for the detection of residual proteins.

Standard practice[4,5] is to visually inspect items after processing in the washer/disinfector and to process again any items not completely clean, thus ensuring that no soiled item goes to the sterilization stage.

Accessory	Test Item	Type	Quantity	Detergent	Cycle Processed	Detergents
5 Level Manifold Instrument Rack FDV24-500	Surgical Instruments	Hemostat Forceps	10 Trays of 50 Hemostats	Prolystica® Ultra Concentrate Enzymatic and Neutral	INSTRUMENTS	Clean/Pass
Multi-Purpose Basin Rack FD02-000	Hollowware	Stainless Steel Round Bowls Stainless Steel Kidney dish Plastic Bowls Stainless Steel Rectangular Pans	4 11 9 2	Prolystica® Ultra Concentrate Enzymatic and Neutral	UTENSILS	Clean/Pass

B- Intermediate-Level Disinfection
All test results amply support the intermediate-level disinfection claim.[1] A low-level disinfection process is required[2] to ensure the protection of hospital staff handling the items during the re-assembly, preparation and packaging of instruments for sterilization. The intermediate-level disinfection achievement of the FAST Cycles with Reliance Synergy Washer/Disinfector achieves additional kills (minimum 7 log reduction) of mycobacteria, and a wider amount of viruses and fungi[6], thus offering a high safety assurance level for the hospital personnel.

Test Conditions		Test Results			
Accessory	Test Organism	Positive Controls (cfu/mL)	Recovered Counts (cfu/mL)	Log Reduction	Percent Reduction
5 Level Manifold Instrument Rack FD24-500	*Staphylococcus aureus*	9.5×10^{8}	$<1 \times 10^{0}$	>9.0	>99.99
	Escherichia coli	6.0×10^{8}	1×10^{0}	8.8	>99.99
	Klebsiella pneumoniae	5.8×10^{8}	1×10^{0}	8.7	>99.99
	Pseudomonas aeruginosa	4.9×10^{9}	$<1 \times 10^{0}$	>9.6	>99.99
	Mycobacterium tuberculosis var. bovis	3.1×10^{7}	1×10^{0}	7.1	>99.99
Bedpan Rack FD04-000	*Staphylococcus aureus*	3.5×10^{9}	$<1 \times 10^{0}$	>9.4	>99.99
	Escherichia coli	8.4×10^{8}	1×10^{0}	8.9	>99.99
	Klebsiella pneumoniae	1.6×10^{9}	$<1 \times 10^{0}$	>9.1	>99.99
	Pseudomonas aeruginosa	6.9×10^{9}	$<1 \times 10^{0}$	>9.5	>99.99
	Mycobacterium tuberculosis var. bovis	2.6×10^{8}	1×10^{0}	7.4	>99.99
Multi-Purpose Basin Rack FD02-000	*Staphylococcus aureus*	5.5×10^{9}	1×10^{0}	9.7	>99.99
	Escherichia coli	7.8×10^{8}	$<1 \times 10^{0}$	>8.9	>99.99
	Klebsiella pneumoniae	3.0×10^{9}	2×10^{0}	9.2	>99.99
	Pseudomonas aeruginosa	5.9×10^{9}	$<1 \times 10^{0}$	>9.5	>99.99
	Mycobacterium tuberculosis var. bovis	1.8×10^{8}	$<1 \times 10^{0}$	>7.5	>99.99

Glossary of Terms

Decontamination:
The removal of microorganisms with no quantitative implication. The term is relative, and the end can be achieved by sterilization or disinfection.[7]

Disinfection:
A process that destroys pathogens and other microorganisms by physical or chemical means. Disinfection processes do not ensure the same margin of safety associated with sterilization processes. The lethality of the disinfection process may vary, depending on the nature of the disinfectant, which leads to the following subcategories:[4]

High-Level Disinfection:
A process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

Intermediate-Level Disinfection:
A lethal process utilizing an agent that kills viruses, mycobacteria, fungi and vegetative bacteria, but no bacterial spores.

Low-Level Disinfection:
A lethal process utilizing an agent that kills vegetative forms of bacteria, some fungi and lipid viruses.

Sterilization:
A process which completely eliminates or destroys all forms of life, particularly microorganisms.[4]

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