TECHNICAL SPOTLIGHT

Abstract: Evaluation of the Lubricant used in DEFENDO™ Sterile Single-use Valves on Bacterial Growth

MEDIVATORS
A Cantel Medical Company

Introduction

Lubrication is routinely used in the manufacture of a variety of medical devices to reduce friction. Lubrication is particularly useful in instruments that require repeated action or movement. Reducing friction makes the devices more efficient and easier to use.

DEFENDO™ Sterile Single-Use Valves use a minimal amount of silicone-based lubricant to reduce friction between the valve and the endoscope port.

These tests were conducted to evaluate the use of the silicone-based lubricant in our DEFENDO Valves and the potential for that lubricant to foster bacterial growth.

Two tests were performed:
1. Bacterial Growth Testing
2. High Level Disinfection (HLD) Effectiveness Testing

In each scenario, the results of the tests using the silicone-based lubricant were compared to the results of the same tests using no lubricant.

The analysis of the test results show that the silicone-based lubricant used in DEFENDO Valves does not promote bacterial growth and does not interfere with HLD effectiveness.

Test 1: Bacterial Growth

Purpose

Evaluate whether the silicone-based lubricant used in DEFENDO Valves prohibits, promotes or has no effect on bacterial growth.

Experimental Method

- *Pseudomonas aeruginosa* was chosen as the organism for this test because it is one of the leading causes of gastrointestinal infections in hospitals.[1]
- 10 samples of the silicone-based lubricant were mixed with an inoculum containing *P. aeruginosa* bacteria. The mixture sat at room temperature for four hours and was then applied to growth plates and incubated for 72 hours.
- The test samples were then compared to a positive control of inoculum *P. aeruginosa*, which was not mixed with the silicone-based lubricant. As with the test samples, the control sat at room temperature for four hours, was applied to the growth plate and incubated for 72 hours.

Results

- The silicone-based lubricant used in DEFENDO Valves produced 87.5% bacterial recovery, indicating that the lubricant neither prohibited nor promoted the growth of *P. aeruginosa* in this test.
- The industry best practice range for bacterial recovery, as defined by the Microbiological Examination of Non-Sterile Products, is between 50-200%.[2]
- Recovery below 50% indicates that the test subject harms or kills bacteria. Recovery above 200% means that the test subject promotes bacterial growth.

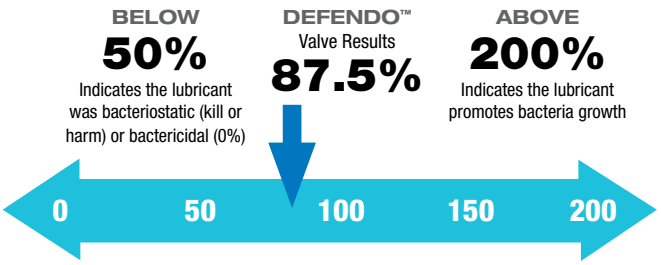

TABLE 1: TEST 1 BACTERIAL GROWTH TEST RESULTS

Sample	CFU per 100 µl	CFU per 100 ml	Percent Recovered
1	102	1020	100
2	74	740	72.5
3	75	750	73.5
4	96	960	94.1
5	78	780	76.5
6	71	710	69.6
7	78	780	76.5
8	76	760	74.5
9	94	940	92.2
10 (25 µl sample X4)	148	1480	145.1
Average	89.2	892	87.5

Test 2: High Level Disinfection Effectiveness

Purpose

Evaluate whether a silicone-based lubricant interferes with high-level disinfection.

Experimental Method

- *Mycobacterium terrae,* a non-pathogenic organism, was selected for this test because it is recommended as a test organism in the United States and Europe for high-level disinfection.[3,4]
- *M. Terrae* was introduced into the air and water channels of an endoscope fitted with DEFENDO™ Valves. The air and water valves were actuated multiple times, simulating use conditions.
- The endoscope was left to dry for approximately 1 hour and 15 minutes at room temperature.
- The endoscopes then went through a 5-minute high-level disinfection cycle in the ADVANTAGE PLUS™ Automatic Endoscope Reprocessor (AER).
- The endoscope was then immediately assessed for surviving organisms.
- The test was run 3 times.
- A fourth run was completed with valves that did not have the silicone-based lubricant applied.

Results

- After each disinfection run, the endoscope was aseptically placed in a sterile bin and evaluated for any surviving organisms.
- No surviving bacteria were found on the endoscope in any of the test runs.
- Note: A typical disinfection cycle is 23 minutes. This test used a 5-minute cycle.

TABLE 2: TEST 2 HLD RESULTS FOR SIMULATED-USE OF DEFENDO™ VALVES

Test Run (Runs 1-3 used the silicone-based lubricant; Run 4 did not)	**Inoculum** (*M. terrae* CFU/mL)	**Bacterial Survivors** Post-HLD(CFU)
1	1.6 x 107	0
2	1.6 x 107	0
3	6.0 x 106	0
4	6.0 x 106	0

Conclusion

Medivators actively tests and validates the performance of our products. In this study, we conducted two tests to evaluate whether or not the use of a silicone-based lubricant in our DEFENDO Valves fostered bacterial growth or interfered with high-level disinfection. The results of those tests were conclusive:

- The silicone-based lubricant used in DEFENDO Valves does not promote bacterial growth
- The silicone-based lubricant used in DEFENDO Valves does not interfere with high-level disinfection

1. Mena KD, Gerba CP. Risk assessment of Pseudomonas aeruginosa in water. Rev Envrion Contam Toxicol. 2009; 201:71-115.
2. United States Pharmacopeia (USP 38). Vol 1. Rockville, MD: United States Pharmacopeia Convention; 2009: 71-75.
3. Guideline of the Robert Koch Institute on Validation of the Efficacy of Disinfectants for Chemical Disinfection of Instruments in the Case of Tuberculosis. 1995. Hygiene and Medizin. 20(2): 80-84.
4. Content and Format of Premarket Notification {510(k)} Submissions for Liquid Chemical Sterilants/High Level Disinfectants. January 3, 2000.

* This is an abstract. The full technical write-up is available upon request.

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