Research Study

In Vitro Evaluation of Microbicidal Efficacy Of BIASURGE® Advanced Surgical Solution

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INTRODUCTION

Surgical Site Infections (SSIs) represent the most prevalent type of Hospital-Acquired Infections (HAIs), affecting 160,000 to 300,000 individuals annually and are linked to a 2- to 11-fold increase in mortality risk, with 75% of SSI-related deaths directly attributed to the infection.[1-3] Approximately 3% of surgery patients develop SSIs, leading to extended hospital stays and raising hospitalization costs by over $20,000 per admission. Consequently, SSIs impact US healthcare with an estimated staggering cost of around $3.3 billion annually.[2,4] The need for effective microbicidal solutions in healthcare settings is paramount to prevent infections and ensure patient safety.

BIASURGE® Advanced Surgical Solution (Sanara MedTech) is a no-rinse irrigation solution based on the synergistic mechanism of action of a combination of EDTAs, PHMB, and vicinal diols.[5]

This white paper presents the results of a series of studies conducted to evaluate the microbicidal efficacy of BIASURGE Advanced Surgical Solution against a panel of 18 microorganisms over a 24-hour period, as well as USP <51> preservative challenge over the course of 28 days. The research methodology, results, and implications are discussed in detail.

The results demonstrate rapid and broad-spectrum microbicidal effect within BIASURGE Advanced Surgical Solution against various Gram-positive bacteria, Gram-negative bacteria, and yeasts in both short and extended time frames.

METHODOLOGY

Kill-rate testing: Kill-rate testing was performed against a panel of 18 microorganisms, including Gram-positive bacteria, Gram-negative bacteria, and yeasts **(Figure 1)**. Briefly, aliquots of the BIASURGE solution were placed in sterile containers followed by the addition of the microbial inoculum (approximately 10^7 CFU/mL) and thorough mixing. The inoculated test samples of BIASURGE were then placed into an incubator set at 37°C for the specified testing periods: 30 seconds, one minute, five minutes, and 24 hours. At designated time points, an aliquot of the BIASURGE solution was neutralized and surviving microorganisms enumerated through serial dilution and agar plating.

USP <51> testing: This testing followed the procedures outlined in the standard and utilized five common pathogens **(Table 1)**. Briefly, aliquots of the BIASURGE solution were inoculated with approximately 10^5 CFU/mL of the test microorganism. At designated time points (14 and 28 days), an aliquot of BIASURGE solution was removed and enumerated as described above.

Pre-clinical study results may not directly correlate to human clinical outcomes.

RESULTS

The results of the kill-rate testing are summarized in **Table 1** and demonstrate the remarkable efficacy of BIASURGE Advanced Surgical Solution against all tested microorganisms. Within 30 seconds of contact, BIASURGE Advanced Surgical Solution reduced the microbial load of all 18 tested microorganisms by more than five logs (>99.999%).

By five minutes, no survivors were detected for any of the tested microorganisms. Even after 24 hours of contact, no survivors were found, indicating the long-lasting microbicidal activity of BIASURGE Advanced Surgical Solution.

Log Survival		Time Points				
MICROORGANISM	**STRAIN DESIGNATION**	**CONTROL** (T=0)	**30 SEC**	**1 MIN**	**5 MIN**	**24 HR**
S. aureus	ATCC 6538	7.50	0.00	0.00	0.00	0.00
S. aureus (MRSA)	ATCC BAA-1717	7.36	1.34	0.90	0.00	0.00
S. epidermidis	ATCC 12228	7.30	0.00	0.00	0.00	0.00
S. epidermidis (MRSA)	NR-45861	7.34	0.00	0.00	0.00	0.00
C. acnes	HM-514	7.40	0.00	0.00	0.00	0.00
E. faecalis (VRE)	ATCC 51299	7.34	1.89	1.06	0.00	0.00
C. difficile	NR-32882	7.40	0.00	0.00	0.00	0.00
P. aeruginosa	ATCC 9027	7.60	0.00	0.00	0.00	0.00
E. coli	ATCC 8739	7.20	0.00	0.00	0.00	0.00
A. baumannii	ATCC 19606	7.52	1.37	0.00	0.00	0.00
E. cloacae	ATCC 13047	7.49	0.00	0.00	0.00	0.00
K. pneumoniae	ATCC 2524	7.51	0.00	0.00	0.00	0.00
P. mirabilis	HM-752	7.36	0.00	0.00	0.00	0.00
S. enterica	ATCC BAA-710	7.54	0.00	0.00	0.00	0.00
C. albicans	ATCC 10231	7.32	0.48	0.00	0.00	0.00
C. auris	NR-52715	7.36	0.00	0.00	0.00	0.00
M. circinelloides	NR-49108	6.78	0.00	0.00	0.00	0.00
T. rubrum	ATCC 28188	7.36	0.00	0.00	0.00	0.00

Table 1: *Microorganism Kill-rate for BIASURGE Advanced Surgical Solution*

Pre-clinical study results may not directly correlate to human clinical outcomes.

The USP <51> testing shown in **Table 2** demonstrates that BIASURGE Advanced Surgical Solution, if contaminated post opening, preserves microbicidal efficacy over the course of at least 28 days.

MICROORGANISM STRAIN	DAY 14 CFU/mL	DAY 28 CFU/mL
S. aureus (ATCC 6538)	<10	<10
E. coli (ATCC 8739)	<10	<10
P. aeruginosa (ATCC 9027)	<10	<10
C. albicans (ATCC 10231)	<10	<10
A. brasiliensis (ATCC 16404)	<10	<10

Table 2: *Results of the USP <51> testing showing extended microbicidal effect within BIASURGE Advanced Surgical Solution*

CONCLUSION

The study findings highlight rapid and sustained microbicidal effect within the solution of BIASURGE Advanced Surgical Solution. The ability to eliminate a wide spectrum of microorganisms, including antibiotic-resistant strains, positions BIASURGE Advanced Surgical Solution as a promising solution in infection prevention strategies. Its rapid action, coupled with its enduring microbicidal activity, makes it a valuable asset in the fight against healthcare-associated infections.

RESEARCH REFERENCES

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The unapproved use(s) of the medical product has not been reviewed by FDA and the safety and effectiveness of the medical device for the unapproved use(s) has not been established.