



RELIABLE
INFECTION
PROTECTION
FOR CENTURIES

SILVER·SEPT[®]

Silver Antimicrobial Skin and Wound Gel

PRODUCT DESCRIPTION:

Silver-Sept® Silver Antimicrobial Skin & Wound Gel, containing 200µg/gram total silver, is a clear, amorphous hydrogel wound dressing that helps to maintain a moist wound environment that is conducive to healing. Silver-Sept Gel will absorb a mild amount of wound exudate. Silver-Sept Gel will not stain or discolor tissue.

Silver-Sept Gel functions as a long-lasting, antimicrobial barrier by inhibiting the growth of bacteria including the antibiotic resistant strains: MRSA & VRE, as well as, fungi such as: Candida albicans and Aspergillus niger.

BIOCOMPATIBILITY AND SAFETY:

Silver-Sept Gel has been subjected to rigorous biocompatibility and safety testing at independent testing laboratories and shown to be non-irritating, non-sensitizing and non-cytotoxic and meets the highest standards for safe use. Testing included:

- Cytotoxicity Studies
- ISO Skin Irritation Studies
- ISO Sensitization Studies
- USP and ISO Modified Systemic Toxicity Studies

SUSTAINED DURATION OF ACTION:

Silver-Sept Gel has been shown in antimicrobial effectiveness studies (see table 2) to maintain its high level of antimicrobial barrier properties for up to 3 days.

ANTIMICROBIAL ACTIVITY

[TABLE 1] TIME KILL STUDIES: The time kill studies for Silver-Sept Silver Antimicrobial Skin and Wound Gel, were conducted in the presence of an interfering substance that simulates the organic load conditions of the wound environment and is known to inhibit the action of antimicrobial agents.

[TABLE 2] REPEATED EXPOSURE TIME KILL STUDIES: The time kill studies for Silver-Sept Silver Antimicrobial Skin and Wound Gel, were conducted by inoculating high level of test organisms, repeatedly for three consecutive days.

INDICATIONS:

Silver-Sept Gel is intended for OTC use for Abrasions and Lacerations and under the supervision of a healthcare professional in the management of:

- Stage I- IV Pressure Ulcers
- Partial and Full Thickness wounds
- Diabetic Foot and Leg Ulcers
- 1st & 2nd degree burns
- Grafted and Donor Sites



Test Organisms:

Table 1 – Antimicrobial Activity

BACTERIA	INITIAL			
	ORGANISM COUNT	EXPOSURE TIME / % KILL		
		1 hour	2 hours	1 day
Escherichia coli	10 ⁷	99.99985%	100 %	100 %
Methicillin Resistant Staphylococcus aureus (MRSA)	10 ⁷	98.32%	100 %	100 %
Proteus mirabilis	10 ⁷	99.9998 %	100 %	100 %
Pseudomonas aeruginosa	10 ⁷	99.9996%	100 %	100 %
Serratia marcescens	10 ⁷	99.9538%	100 %	100 %
Staphylococcus aureus	10 ⁷	99.77%	100 %	100 %
Vancomycin Resistant Enterococcus faecalis (VRE)	10 ⁷	98.27%	100 %	100 %
FUNGI				
Aspergillus niger	10 ⁶	99.99 %	99.9999 %	100 %
Candida albicans	10 ⁶	99.1 %	99.9 %	100 %

Test Organisms:

Table 2 – Repeated Exposure Time Kill Study

BACTERIA	EXPOSURE TIME / % KILL						
	initial test inoculum	1 day after		2nd day		4 days after 3rd	
		initial inoculation	inoculation after day 1	1 day after 2nd inoculation	3rd inoculation after day 2	3rd day, 1 day after 3rd inoculation	inoculation, and 1 week after initial inoculation
Escherichia coli	10 ⁷	100 %	10 ⁷	100 %	10 ⁷	100 %	100 %
Methicillin Resistant Staphylococcus aureus (MRSA)	10 ⁷	100 %	10 ⁷	100 %	10 ⁷	100 %	100 %
Pseudomonas aeruginosa	10 ⁷	100 %	10 ⁷	100 %	10 ⁷	100 %	100 %
Serratia marcescens	10 ⁷	100 %	10 ⁷	100 %	10 ⁷	100 %	100%
Staphylococcus aureus	10 ⁷	100 %	10 ⁷	100 %	10 ⁷	100 %	100 %
FUNGI							
Aspergillus niger	10 ⁶	98.667 %	10 ⁶	98.333%	10 ⁶	99.5%	100%
Candida albicans	10 ⁶	100 %	10 ⁶	100 %	10 ⁶	100 %	100%



DIRECTIONS FOR USE:

Wound Care:

- Cleanse or debride wound as necessary.
- Apply a generous amount of Silver-Sept Gel directly into wound bed (1/8" to 3/16").
- Cover with a sterile gauze or other appropriate secondary dressing and secure in place.
- Maintain a moist wound environment between dressing changes.

Note: Silver-Sept Silver Antimicrobial Skin & Wound Gel may remain in the wound bed for up to 3 days. More frequent dressing changes may be required dependent upon the amount of wound exudate present and the condition of the secondary dressing.

Ostomy:

- Apply a thin coating of Silver-Sept Gel to peristomal area.
- Allow to dry.
- Apply Ostomy appliance.

Skin Care:

- Cleanse affected area with appropriate skin cleanser.
- Allow to dry.
- Apply a thin coating of Silver-Sept Gel.
- Repeat as necessary.

EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE

Silver-Sept® Silver Antimicrobial Skin & Wound Gel is a registered trademark of Anacapa Technologies, Inc.

US & International Patents Pending

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Ordering Information

Silver-Sept® Silver Antimicrobial Skin & Wound Gel ordering information:

Catalog no.	Description	Packaging
3015 S	1.5 oz tube	12/cs
3003 S	3 oz. tube	12/cs

Medicare Reimbursement Code: HCPCS A6248

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