

Product Description:

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

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

Biocompatibility and Safety:

Silver-Sept 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 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

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.

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 %	
Staphylococcus aureus	10 ⁷	99.77%	100 %	100 %	
Methicillin Resistant Staphylococcus aureus (MRSA)	10 ⁷	98.32%	100 %	100 %	
Vancomycin Resistant Enterococcus faecalis (VRE)	10 ⁷	98.27%	100 %	100 %	
Pseudomonas aeruginosa	10 ⁷	99.9996%	100 %	100 %	
Proteus mirabilis	10 ⁷	99.9998 %	100 %	100 %	
Serratia marcescens	10 ⁷	99.9538%	100 %	100 %	
Fungi:					
Candida albicans	10 ⁶	99.1 %	99.9 %	100 %	
Aspergillus niger	10 ⁶	99.99 %	99.9999 %	100 %	

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.

Test Organisms:		Table 2 – Repeated Exposure Time Kill Study						
Bacteria:		EXPOSURE TIME / % KILL						
		2nd day			4 days after 3rd			
		1 day after	2nd	1 day after	3rd	3rd day, 1 day	inoculation, and	
		initial test	inoculation	2nd	inoculation	after 3rd	1 week after initial	
		inoculum	inoculation after day 1	inoculation	after day 2	inoculation	inoculation	
Escherichia coli	10 ⁷	100 %	10 ⁷	100 %	10 ⁷	100 %	100 %	
Staphylococcus aureus	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%	
Fungi:								
Candida albicans	10 ⁶	100 %	10 ⁶	100 %	10 ⁶	100 %	100%	
Aspergillus niger	10 ⁶	98.667 %	10 ⁶	98.333%	10 ⁶	99.5%	100%	

Indications:

Silver-Sept® 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

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 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.
- Repeat as necessary.

EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE
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US & International Patents Pending

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



Silver-Sept® is manufactured in the USA by:
Anacapa Technologies, Inc.
San Dimas, CA
Tel: (800) 489-2591
Fax: (909) 394-9895
e-mail: anacapa@anacapa-tech.net
Website: www.anacapa-tech.net

