anasept®

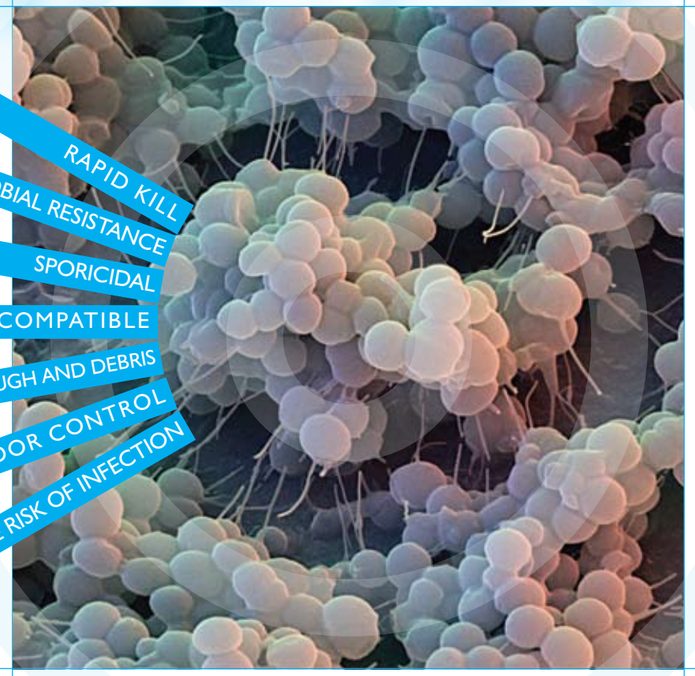
ANTIMICROBIAL SKIN & WOUND CLEANSER

Ordering Information
Anasept® Antimicrobial Skin & Wound Cleanser

CATALOG NO.		NDC NUMBER	SIZE	CASE QUANTITY
4004C	(Dispensing Cap	67180-400-04	4 oz	24
4008C	(Dispensing Cap)	67180-400-88	8 oz	12
4008SC	(Sprayer)	67180-400-88	8 oz	12
4008TC	(Trigger Sprayer)	67180-408-88	8 oz	12
4012SC	(Trigger Sprayer)	67180-400-12	12 oz	12
4016C	(Dispensing Cap)	67180-400-16	15 oz	12
Anasept® Antimicrobial Skin and Wound Gel				
5003G	(Tube)	67180-500-03	3 oz	12

Anasept® is a registered trademark of Anacapa Technologies. Anasept products are manufactured in the USA.

- RAPID KILL
- NO KNOWN MICROBIAL RESISTANCE
- SPORICIDAL
- SAFE AND TISSUE COMPATIBLE
- AIDS IN THE DEBRIDEMENT OF SLOUGH AND DEBRIS
- OUTSTANDING ODOR CONTROL
- HELPS REDUCE THE RISK OF INFECTION



Scanning Electron Micrograph: Staphylococcus epidermidis enlarged 27,000x

ANACAPA™
TECHNOLOGIES

301 E. Arrow Hwy, Ste. 106
San Dimas CA 91773

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Website: www.anacapa-tech.net

1009

Anasept® is also available as Anasept Antimicrobial Skin and Wound Gel, a clear, thick, isotonic hydrogel with long-lasting, broad-spectrum antimicrobial properties.

Anasept® Gel's Medicare reibursement code is HCPCS:A6248

ANASEPT®
The clear, safe and
MOST EFFECTIVE CHOICE FOR
skin and wound antisepsis®

PRODUCT DESCRIPTION AND USES:

Anasept® is an extremely safe and gentle skin and wound cleanser with exceptionally rapid broad-spectrum bactericidal, fungicidal and virucidal properties through the action of antimicrobial sodium hypochlorite. Anasept helps in the mechanical removal of the debris and foreign material from the wound or application site. Anasept is a very pure, completely colorless, isotonic, tissue compatible solution.
Anasept is stable for two-years and is free of necrotizing chemicals such as sodium hydroxide.

RAPID ACTION:

Anasept demonstrates exceptionally rapid microbiocidal action. Most pathogenic organisms are killed within 2 minutes or less following application. There is no known microbial resistance to Anasept.

CLINICALLY TESTED:

Anasept is clinically proven to reduce wound bioburden levels and improve the rate of healing.*

SAFETY:

Anasept has been subjected to rigorous safety testing at an independent laboratory and shown to meet the criteria for safe use.

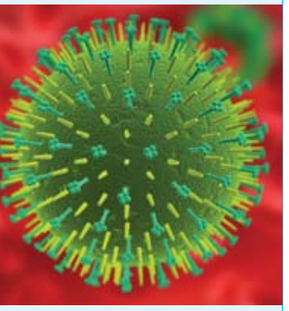
- *Modified Primary Skin Irritation* (FHSA method – 7 day exposure with repeated insult to intact and abraded skin)
- *Cytotoxicity* (1S0 Agarose Overlay method)
- *Systemic toxicity* (ISO Acute Systemic Toxicity)
- *ISO Sensitization Study*

ENVIRONMENTALLY FRIENDLY:

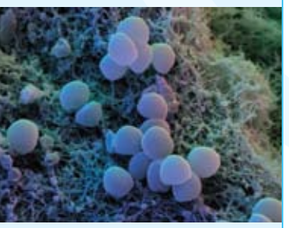
Anasept does not leave any toxic residues or by-products. Anasept chemically breaks down into salt and water and is completely safe for disposal in the public sewer system.

WARNINGS:

For **External Use Only**. Discontinue use if redness or irritation develops. **DO NOT USE** in the eyes.



Virus (artist's rendion of Electron Micrograph enlarged 120,000x)



Scanning Electron Micrograph: Methicillin-Resistant Staphylococcus aureus (MRSA)

Scanning ElectronMicrograph: E. coli enlarged 21,000x

GENERAL DIRECTIONS FOR USE

Skin Cleansing:

1) Spray intended area or saturate sterile gauze with Anasept and clean skin area with a circular motion beginning at the center of the site and move outward until the selected dermal area has been thoroughly cleansed.
2) Air dry for 2 minutes. If preferred, allow Anasept saturated sterile gauze to remain in place as a wet dressing.

Wound Cleansing:

1) Debride wound, if necessary.
2) Spray Anasept onto entire wound bed, including the wound margin. Avoid pooling.
Alternate: Saturate sterile gauze pad with Anasept and apply to wound site.
3) Cover wound site with a sterile gauze or other appropriate wound dressing.
4) Repeat procedure once a day. Ensure that wound bed remains moist between dressing changes.

*J. Lindfors, *A Comparison of an Antimicrobial Wound Cleanser to Normal Saline in Reduction of Biobuden and Its Effect on Wound Healing*. Ostomy/Wound Management. 2004; 50 (8): 28-41.

TIME KILL STUDIES

Test Organisms: Table of Anti-microbial Activity

Pathogenic Bacteria	Initial Microorganism Count/ML	Exposure time / % Kill 30 seconds	1 minute	5 minutes
Escherichia coli	10^8	100%	100%	100%
Staphylococcus aureus	10^8	100%	100%	100%
Methicillin Resistant Staphylococcus aureus (MRSA)	10^8	100%	100%	100%
Vancomycin Resistant Enterococcus faecalis (VRE)	10^8	100%	100%	100%
Pseudomonas aeruginosa	10^8	100%	100%	100%
Proteus mirabilis	10^8	99.998%	100%	100%
Serratia marcescens	10^8	100%	100%	100%
Acinetobacter baumannii	10^7	–	99.96%	99.98%
Clostridium difficile	10^5	100%	100%	100%
Pathogenic Fungi				
Candida albicans	10^8	99.1%	99.9%	100%
Aspergillus niger	10^8	99.99%	99.9999%	100%

Extremely high concentrations of pathogenic micro-organisms were exposed to Anasept over the course of precisely timed intervals in the presence of an interfering substance that simulates the organic load condition of the wound environment and is known to inhibit the action of antimicrobial agents.

TIME KILL STUDIES

Test Organisms: Table of Sporicidal Activity

Test Substance	Initial Microorganism Count/ML	Exposure Time	Percent Reduction	Log Reduction
Clostridium difficile - spore	10^6	15 minutes	99.999%	>5.7

CATEGORIES FOR USE:

Dialysis*:
Preparation of site for Graft-Fistula Cannulation
Exit Site Dressing change for Peritoneal Dialysis
Central Line Site Preparation.

* Detailed site preparation procedures are available upon request. *Compatible with catheters used in dialysis procedures. Catheter compatibility reports available upon request.*

Topical and Wound Care:
Application to skin or wound to establish antisepsis at the site.

- **RAPID KILL**
- **NO KNOWN MICROBIAL RESISTANCE**
- **SPORICIDAL**
- **SAFE AND TISSUE COMPATIBLE**
- **AIDS IN THE DEBRIDEMENT OF NECROTIC SLOUGH AND DEBRIS**
- **OUTSTANDING ODOR CONTROL**
- **HELPS REDUCE THE RISK OF INFECTION**
- **LATEX FREE**

safety

Anasept® Antimicrobial Skin and Wound Gel has been subjected to rigorous safety and toxicological evaluations to comply with FDA regulations at an independent FDA registered testing facility and shown to meet all criteria for safe use.

- Modified Skin Irritation Study(FSHA method 7 day exposure with repeated insult to intact and abraded skin)
- Cytotoxicity (USP method)
- Systemic Toxicity (USP method)
- ISO Sensitization Study.

Test reports available upon written request.

clinically tested:

Anasept® Antimicrobial Skin & Wound Cleanser, the liquid version of Anasept Antimicrobial Skin & Wound Gel is clinically proven to reduce wound bioburden levels and improve the rate of healing.*

Anasept® is also available as Anasept Antimicrobial Skin & Wound Cleanser in a wide-variety of dispensers specifically designed for skin & wound cleansing applications. Anasept Antimicrobial Skin & Wound Cleanser has all the same powerful broad spectrum antimicrobial and safety features inherent in Anasept Antimicrobial Skin & Wound Gel.

Anasept products are manufactured in the USA.

EXTERNAL USE ONLY.
NOT FOR OPTHALMIC USE.

latex FREE

ANACAPA TECHNOLOGIES

DIRECTIONS FOR USE:

Wound Care:

1) Debride wound, if necessary or cleanse wound with a wound cleanser such as Anasept® Antimicrobial Skin and Wound Cleanser.
2) Apply a generous amount (1/4 " to 1/2 "thick) of Anasept Antimicrobial Skin and Wound Gel to entire wound bed, including areas of undermining.
3) Apply a thin coating to peri-wound skin area and allow to dry.
4) Cover with appropriate wound dressing or covering (avoid silver and other wound dressings containing heavy metals).
5) Change dressing once a day. Maintain a moist wound environment between dressing changes.

NOTE: Anasept products contain sodium chloride which is not compatible with wound care products that contain silver. Silver in the presence of sodium chloride will be converted to insoluble silver chloride and become inactive.

Indwelling Vascular Catheters:

1) Apply sufficient quantity of Anasept Antimicrobial Skin & Wound Gel to completely cover skin area around the indwelling vascular catheter.
2) Cover with appropriate site dressing.

Ostomy:

1) Apply a thin coating of Anasept Antimicrobial Skin & Wound Gel to peri-stomal area.
2) Allow to dry.
3) Apply Ostomy appliance.

Skin Care:

1) Cleanse affected area with appropriate skin cleanser.
2) Allow to dry.
3) Apply a thin coating of Anasept Antimicrobial Skin & Wound Gel.
4) Reapply as necessary.

Ordering Information

Anasept® Antimicrobial Skin and Wound Gel

Catalog No.	NDC Number	Size	Case Quantity
5003G	67180-500-03	3oz	12

Medicare Reimbursement Code: HCPCS #A6248

301 E. Arrow Hwy, Ste. 106
San Dimas, California 91773
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Tel: 909-394-7795
Fax: 909-394-9895
e-mail: anacapa@anacapa-tech.net
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ANASEPT® ANTIMICROBIAL SKIN AND WOUND GEL

The clear, safe and most effective choice for skin and wound antisepsis™

Kills all bacteria, fungi, viruses and spores without harming healthy tissue

anasept® GEL

KILLS MRSA & VRE IN 60 SECONDS

product description:

Anasept® Antimicrobial Skin and Wound Gel is an extremely safe topical hydrogel with exceptionally rapid broad spectrum bactericidal, including the antibiotic resistant strains MRSA & VRE, fungicidal, virucidal and sporicidal properties through the action of sodium hypochlorite. There is no known microbial resistance to Anasept Antimicrobial Skin & Wound Gel.

Anasept® Antimicrobial Skin and Wound Gel is pure, completely colorless, isotonic, non-cytotoxic, tissue compatible viscous hydrogel. Anasept Antimicrobial Skin & Wound Gel has a 3 year shelf-life when stored at normal room temperature up to 25° C (77° F).

time kill studies:

Extremely high concentrations of pathogenic micro-organisms were exposed to Anasept Antimicrobial Skin and Wound Gel over the course of precisely timed intervals in the presence of an interfering substance that simulates the organic load conditions of the wound environment and is know to inhibit the action of antimicrobial agents. Anasept Antimicrobial Skin and Wound Gel proved 100% effective against all pathogenic micro-organisms tested within the first ten minutes of application except for Acinetobacter baumannii where it was shown to be 99.998% effctive in the same test period (see tables).

TIME KILL STUDIES

Test Organisms: Table of Antimicrobial Activity

Pathogenic Bacteria:	Initial Organism	Exposure Time/% Kill			
	Count	1 min.	3 min.	5 min.	10 min.
Escherichia coli	10^7	99.25%	99.986%	99.9995%	100%
Staphylococcus aureus	10^7	100%	100%	100%	100%
Methicillin Resistant Staphylococcus aureus (MRSA)	10^7	100%	100%	100%	100%
Vancomycin Resistant Enterococcus faecalis (VRE)	10^7	100%	100%	100%	100%
Pseudomonas aeruginosa	10^7	99.996%	100%	100%	100%
Proteus mirabilis	10^7	99.888%	99.998%	99.9998%	100%
Serratia marcescens	10^7	100%	100%	100%	100%
Acinetobacter baumannii	10^7	99.722%	99.977%	99.996%	99.998%
Clostridium difficile	10^5	100%	100%	100%	100%
Pathogenic Fungi:					
Candida albicans	10^6	100%	100%	100%	100%
Aspergillus niger	10^6	100%	100%	100%	100%

TIME KILL STUDIES

Test Organism: Table of Sporicidal Activity

Test Substance	Initial Microrganism Count/ML	Exposure Time	Percent Reduction	Log Reduction
Clostridium difficile - spore	10^6	15 minutes	99.986%	>4.0

indications for use:

Anasept® Gel is intended for OTC use for management of skin abrasions, minor irritations, lacerations, cuts, exit sites and intact skin.

Professional Use:
Anasept® Gel is intended to be used under the supervision of a healthcare professional in the management of wounds such as stage I-IV pressure ulcers, partial & full thickness wounds, diabetic foot & leg ulcers, post surgical wounds, first & second degree burns, grafted & donor sites.

24 hour challenge test:

Anasept Antimicrobial Skin and Wound Gel was subjected to a high concentration of pathogenic micro-organisms (amount known to cause infection) in the presence of an interfering substance that simulates the organic load of the wound and is known to inactivate the antimicrobial agents. The duration of antimicrobial effectiveness of Anasept Antimicrobial Skin and Wound Gel was determined in a re-challenge of the original test sample with a high concentration of freshly prepared micro-organisms after 24 hours of initial exposure to pathogenic micro-organisms.

Sustained duration of action:

Anasept Antimicrobial Skin and Wound Gel was shown to maintain microbiocidal activity even after 24 hours and repeated exposure to pathogenic micro-organisms in the simulated wound environment. The gel reduced all pathogenic test organisms by more than 99% within the first fifteen minutes of repeated exposure.

TIME KILL STUDIES - 24 HOUR CHALLENGE:

Test Organisms: Table of Antimicrobial Activity

Pathogenic Bacteria:	Initial Organism Ct. / Re-challenge Organism Ct	Exposure time after re-challenge at 24 hours / % Kill		
		5 min.	10 min.	15 min.
Escherichia coli	10^7 / 10^7	71.25%	96.63%	99.49%
Staphylococcus aureus	10^7 / 10^7	95.91%	96.45%	99.16%
Methicillin Resistant Staphylococcus aureus (MRSA)	10^7 / 10^7	95.69%	99.38%	99.78%
Vancomycin Resistant Enterococcus faecalis (VRE)	10^7 / 10^7	92.8%	96.9%	99.61%
Pseudomonas aeruginosa	10^7 / 10^7	84.35%	98%	99.88%
Proteus mirabilis	10^7 / 10^7	67.14%	97.71%	99.74%
Serratia marcescens	10^7 / 10^7	96%	99.36%	99.94%
Acinetobacter baumannii	10^7 / 10^7	13.64%	85.25%	99.25%
Pathogenic Fungi:				
Candida albicans	10^6 / 10^6	98.89%	99.99%	99.9996%
Mix of all above including Candida albicans	10^7 / 10^7	88.75%	97.31%	99.8%

*J. Lindfors. A Comparison of an Antimicrobial Wound Cleanser to Normal Saline in Reduction of Bioburden and its Effect on Wound Healing. Ostomy / Wound Management 2004; 50 (8): 28-41.

Website: www.anacapa-tech.net

GET IN THE FRESH ZONE

SANI-ZONE™

The most effective way to get rid of those nasty odors in the air or in the ostomy pouch

Safe - certified non-toxic by the Consumer Product Testing Company, Inc.

ANACAPA TECHNOLOGIES

800-489-2591
301 East Arrow Highway
Suite 106
San Dimas, CA 91773

Lasts for hours! Extraordinary odor eliminating capability. Leaves a squeaky clean background smell. The Best product you have ever used!

Sani-Zone™ Maximum Strength Odor Eliminator Spray

1008A 1002A

One or two sprays in an average size room eliminates odors and leaves a sqeaky clean fragrance

Outstanding odor control! Unmatched in effectiveness!

Sani-Zone™ Ostomy Appliance Deodorant

1008-OD 1002-OD

Just five drops in an ostomy pouch stops odors for hours.

Powerful and fast-acting, it stands up against the most embarrassing odors.

Medicare Reimbursement HCPCS Code for Sani-Zone Ostomy Appliance Deodorant: A4394

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Just five drops in an ostomy pouch stops odors for hours.

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Medicare Reimbursement HCPCS Code for Sani-Zone Ostomy Appliance Deodorant: A4394

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 resistant 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.

Table 1 – Antimicrobial Activity

Test Organisms:	INITIAL ORGANISM COUNT	EXPOSURE TIME / % KILL		
		1 hour	2 hours	1 day
Bacteria:				
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.

Table 2 – Repeated Exposure Time Kill Study

Test Organisms:	EXPOSURE TIME / % KILL						
Bacteria:	initial test inoculum	1 day after initial inoculation	2nd inoculation after day 1	2nd day 1 day after 2nd inoculation	3rd inoculation after day 2	3rd day, 1 day after 3rd inoculation	4 days after 3rd inoculation, and 1 week after initial 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 OPTHALMIC USE

latex *FREE*

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

ANACAPA™
TECHNOLOGIES

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