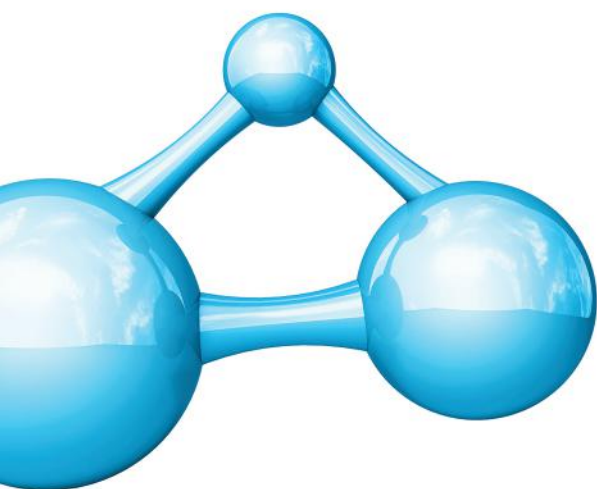




Antimicrobial Skin and Wound Care Products

Highly regarded, FDA-cleared, broad-spectrum, antimicrobials. Anasep® inhibits the growth of multi-drug resistant strains such as *Candida auris*, Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant *Enterococci* (VRE), Carbapenem Resistant *Escherichia coli* (CRE).

Anasep® products are also licensed by Health Canada.





Antimicrobial Skin & Wound Cleanser



Anasept® Antimicrobial Skin & Wound Cleanser is FDA cleared, extremely safe and gentle skin and wound cleanser with 0.057% broad spectrum antimicrobial sodium hypochlorite.

Anasept® Antimicrobial Skin and Wound Cleanser is a clear, isotonic liquid that helps in the mechanical removal of the debris and foreign material from the application site, by the action of the fluid (Wound Cleanser) moving across the wound bed or application site. Anasept Antimicrobial Skin and Wound Cleanser contains a broad-spectrum antimicrobial agent sodium hypochlorite. It inhibits the growth of bacteria such as *Acinetobacter baumannii*, *Clostridium difficile*, *Escherichia coli*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Staphylococcus aureus*, including antibiotic resistant strains, such as Carbapenem Resistant *E. Coli (CRE)*, Methicillin Resistant *Staphylococcus aureus (MRSA)* and Vancomycin resistant *Enterococcus faecalis (VRE)* that are commonly found in wound bed, as well as fungi, such as *Aspergillus niger*, *Candida albicans*, and *Candida auris*.

Anasept is a very pure, completely colorless, isotonic, tissue compatible solution. Anasept is stable for 2 years from date of manufacture, when stored at normal room temperature up to 25°C (77°F) and is free of necrotizing chemicals such as sodium hydroxide. Anasept is stable up to 14 weeks after initial use.

INDICATIONS FOR USE

OTC USE:

Anasept is intended for OTC use for mechanical cleansing and removal of dirt, debris and foreign material from skin abrasions, lacerations, minor irritations, cuts, exit sites and intact skin.

PROFESSIONAL USE:

Anasept is intended for use under the supervision of a healthcare professional for cleansing of foreign materials, including microorganisms from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.

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 (ISO Agarose Overlay method)
- Systemic toxicity (ISO Acute Systemic Toxicity)
- ISO Sensitization Study

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

In the time kill studies below, extremely high concentrations of pathogenic microorganisms were exposed to Anasept over the course of precisely timed intervals in the presence of an interfering substance that simulated the organic load condition of the wound environment and is known to inhibit the action of antimicrobial agents.

TIME KILL STUDIES for Anasept Antimicrobial Skin and Wound Cleanser

Table of Microbial Activity

Test Organisms:	Initial Microorganism Count/ML	Exposure time / % Kill		
		30 seconds	1 minute	5 minutes
Pathogenic Bacteria				
<i>Acinetobacter baumannii</i>	10 ⁷	-	99.089%	99.98%
Carbapenem Resistant <i>E. coli</i> (CRE)	10 ⁶	99.999%	99.999%	99.999%
<i>Clostridium difficile</i>	10 ⁵	100%	100%	100%
<i>Escherichia coli</i>	10 ⁷	100%	100%	100%
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	10 ⁷	100%	100%	100%
<i>Proteus mirabilis</i>	10 ⁸	99.998%	100%	100%
<i>Pseudomonas aeruginosa</i>	10 ⁷	100%	100%	100%
<i>Serratia marcescens</i>	10 ⁷	100%	100%	100%
<i>Staphylococcus aureus</i>	10 ⁷	100%	100%	100%
Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	10 ⁷	100%	100%	100%
Pathogenic Fungi				
<i>Aspergillus niger</i>	10 ⁷	99.99%	99.9999%	100%
<i>Candida albicans</i>	10 ⁷	99.1%	99.9%	100%
<i>Candida auris</i>	10 ⁵	99.1%	>99.9%	>99.9%

Table of Sporicidal Activity

Test Spore	Initial Spore Count/ML	Exposure Time	Percent Reduction	Log Reduction
<i>Clostridium difficile</i> - spore	10 ⁶	15 minutes	99.999%	>5.7

Table of Virucidal Activity

Test Virus	Initial Virus Count/ML	Exposure Time	Percent Reduction	Log Reduction
HIV-Type 1 (Human Immuno Deficiency Virus)	10 ⁶	5 minutes	99.997%	≥4.5
SARS Related Coronavirus 2	10 ^{5.25}	5 minutes	≥99.98%	≥3.75
Human Coronavirus Strain 229E	10 ^{5.5}	5 minutes	≥99.99%	≥4.0

*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.

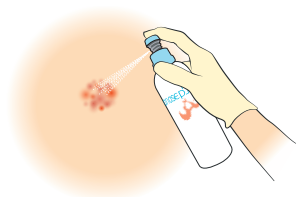


Antimicrobial Skin & Wound Cleanser

GENERAL DIRECTIONS FOR USE

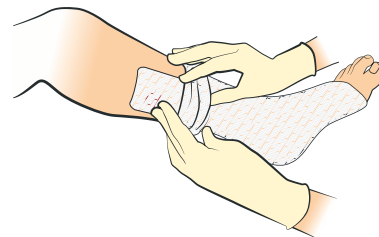
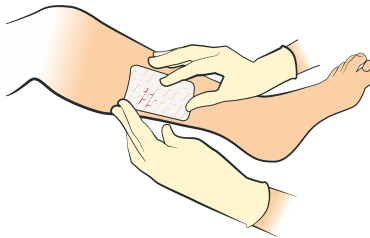
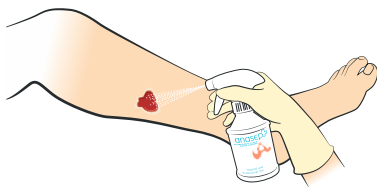
SKIN CLEANSING:

- 1) Spray intended area or saturate sterile gauze and apply to site.
- 2) Air dry for 2 minutes or maintain 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) Tape in place along dressing border.
Alternate: for less tape caused skin trauma, secure in place with Staytex™ Elastic Tubular Dressing or similar dressing.
- 5) Repeat procedure once a day. Ensure that wound bed remains moist between dressing changes.



* NOTE: The trigger sprayer is designed to exhibit nozzle pressure between 8 to 12 psi, which meets AHCPR and NPUAP guidelines for mechanical debridement, wound irrigation and cleansing.



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.
Not for Ophthalmic use.
Discontinue use if redness or irritation occurs.
DO NOT FREEZE.
Store at room temperature up to 25°C (77°F).

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.

- SAFE AND TISSUE COMPATIBLE
- AIDS IN THE DEBRIDEMENT OF NECROTIC SLOUGH AND DEBRIS
- OUTSTANDING ODOR CONTROL
- LATEX FREE
- STABLE FOR UP TO 14 WEEKS AFTER INITIAL USE

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)	67180-400-08	8 oz	12
4004SC	(Sprayer)	67180-400-44	4 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

Health Canada License #97043

In the time kill studies below, extremely high concentrations of pathogenic microorganisms were exposed to Anasept over the course of precisely timed intervals in the presence of an interfering substance that simulated the organic load condition of the wound environment and is known to inhibit the action of antimicrobial agents.

TIME KILL STUDIES for Anasept Antimicrobial Skin and Wound Gel

Table of Microbial Activity					
Test Organisms:	Initial Organism Count	Exposure Time/% Kill			
Pathogenic Bacteria:		1 min.	3 min.	5 min.	10 min.
<i>Acinetobacter baumannii</i>	10 ⁷	98.56%	99.99%	99.998%	99.9999%
Carbapenem Resistant <i>E. coli</i> (CRE)	10 ⁶	99.999%	99.999%	99.999%	99.999%
<i>Clostridium difficile</i>	10 ⁵	100%	100%	100%	100%
<i>Escherichia coli</i>	10 ⁷	99.25%	99.986%	99.9995%	100%
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	10 ⁷	100%	100%	100%	100%
<i>Proteus mirabilis</i>	10 ⁷	99.888%	99.998%	99.9998%	100%
<i>Pseudomonas aeruginosa</i>	10 ⁷	99.996%	100%	100%	100%
<i>Serratia marcescens</i>	10 ⁷	100%	100%	100%	100%
<i>Staphylococcus aureus</i>	10 ⁷	100%	100%	100%	100%
Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	10 ⁷	100%	100%	100%	100%
Pathogenic Fungi:					
<i>Aspergillus niger</i>	10 ⁶	100%	100%	100%	100%
<i>Candida albicans</i>	10 ⁶	100%	100%	100%	100%
<i>Candida auris</i>	10 ⁵	>99.9%	>99.9%	>99.9%	N/A
Table of Sporicidal Activity					
Test Spore	Initial Microorganism Count/ML	Exposure Time	Percent Reduction	Log Reduction	
<i>Clostridium difficile</i> - spore	10 ⁶	15 minutes	99.99%	>4.0	
Table of Virucidal Activity					
Test Virus	Initial Microorganism Count/ML	Exposure Time	Percent Reduction	Log Reduction	
HIV-Type 1 (Human Immuno Deficiency Virus)	10 ⁶	5 minutes	99.97%	≥3.5	
SARS Related Coronavirus 2	10 ^{5.25}	5 minutes	≥99.98%	≥3.75	
Human Coronavirus Strain 229E	10 ^{5.5}	5 minutes	≥99.9%	≥3.0	

TIME KILL STUDIES-24 HOUR CHALLENGE Table of Antimicrobial Activity

Table of Microbial Activity				
Test Organisms:	Initial Organism Ct. / Re-challenge Organism Ct	Exposure time after re-challenge at 24 hours / % Kill		
Pathogenic Bacteria:		5 min.	10 min.	15 min.
<i>Acinetobacter baumannii</i>	10 ⁷ / 10 ⁷	13.64%	85.27%	99.25%
<i>Escherichia coli</i>	10 ⁷ / 10 ⁷	71.25%	96.63%	99.49%
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	10 ⁷ / 10 ⁷	95.69%	99.38%	99.78%
<i>Proteus mirabilis</i>	10 ⁷ / 10 ⁷	67.14%	97.71%	99.74%
<i>Pseudomonas aeruginosa</i>	10 ⁷ / 10 ⁷	84.35%	98%	99.88%
<i>Serratia marcescens</i>	10 ⁷ / 10 ⁷	96%	99.36%	99.94%
<i>Staphylococcus aureus</i>	10 ⁷ / 10 ⁷	95.91%	96.45%	99.16%
Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	10 ⁷ / 10 ⁷	92.8%	96.9%	99.61%
Pathogenic Fungi:				
<i>Candida albicans</i>	10 ⁶ / 10 ⁶	98.89%	99.99%	99.9996%
Mix of all above including <i>Candida albicans</i>	10 ⁷ / 10 ⁷	88.75%	97.31%	99.8%

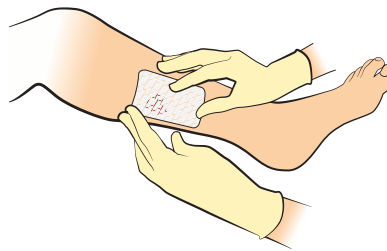


Antimicrobial Skin & Wound Gel

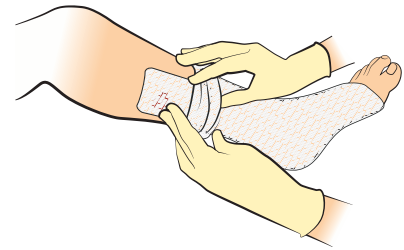
DIRECTIONS FOR USE:

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) Tape in place along dressing border.
Alternate: for less tape caused skin trauma, secure in place with Staytex™ Elastic Tubular Dressing or similar dressing.
- 6) Change dressing once a day. Maintain a moist wound environment between dressing changes.



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.

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 peristomal area.
- 2) Allow to dry.
- 3) Apply Ostomy appliance.

SKIN CARE:

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

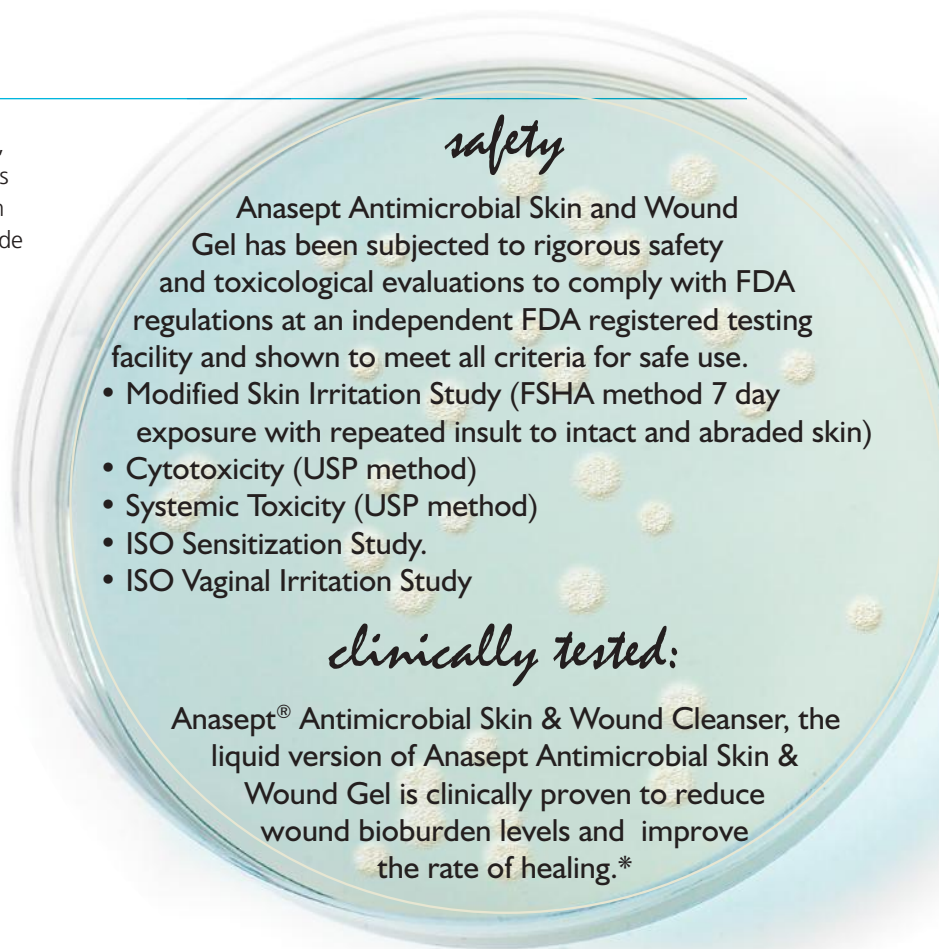
WARNINGS: For External Use Only.
Not for Ophthalmic use.
Discontinue use if redness or irritation occurs.
Store at room temperature up to 25°C (77°F).

latex*FREE*

Ordering Information

Anasept® Antimicrobial Skin and Wound Gel				
CATALOG NO.		NDC NUMBER	SIZE	CASE QUANTITY
5015G	(Tube)	67180-500-15	1.5 oz	12
5003G	(Tube)	67180-500-03	3 oz	12

Medicare Reimbursement HCPCS code # A6248
Health Canada License #97167



*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.



Clinical Case Study - Venous Stasis Dermatitis And Weeping Ulcers

by: **Martin Winkler, MD, FACS**

Creighton University Department of Surgery
(Contributed Service), Omaha, NE

University of Nebraska Department of Surgery (Contributed Service),
Omaha, NE

Laura Wesnieski, RN, CWS

Bergan Mercy Wound Care Clinic, Omaha, Nebraska

Sara M. Winkler

Dept. of Biomedical Engineering,
Stanford University, Palo Alto, CA

THE PROBLEM:

- Painful venous stasis dermatitis
- Multiple weeping venous leg ulcers
- Comorbid CHF, COPD, PVD
- Sleeps sitting up

Navy veteran, sleeps sitting up, uses prednisone for COPD, and has mild peripheral vascular disease (PVD). Stasis dermatitis, present for months, now has multiple ulcers weeping serum. Weeping serum dries to form adherent crusts and plaques that crack and create new skin ulcers. Mechanical debridement of dry plaques injures friable skin and caused bleeding and pain.

TREATMENT:

- Hypochlorite gel* for debridement and biofilm control
- Layered compression dressings

Na Hypochlorite gel has the advantage that reactive oxygen species are released from hydro gel slowly for up to 3 days. In addition to killing biofilm bacteria, reactive oxygen species break bonds between proteins. Anecdotal experience suggested that the reactive oxygen species in hypochlorite gel was clinically effective to debride wound eschar.

Hypochlorite gel is liberally applied to wound before Robert Jones dressing is applied at weekly clinic visits. This science poster is, to our knowledge, a

first human use report to use hypochlorite, in a concentrated slow release gel form, to break down protein and debride wound eschar. It has been long understood that reactive oxygen breaks chemical bonds between proteins. This study suggests that this sodium hypochlorite protein break down effect, which is similar to how HCl digests protein in the stomach, is effective for debridement.



14 days of hypochlorite gel and elastic compression treatment has softened dry skin and plaques of dried serum enabling debridement, without injury to the thin underlying at-risk skin.



After two weeks of hypochlorite gel and Robert Jones dressing elastic compression, photos show eschar separation

without injury to at-risk skin. Skin remains exquisitely painful due to dermatitis.

OUTCOMES:

- Sodium Hypochlorite gel debrides VLUs
- Wounds heal in 8 weeks
- Fuzzy Wale Elastic Compression controls stasis dermatitis



At week six, stasis dermatitis is still evident, but wounds are nearly healed.



Observe resolution of stasis dermatitis after 6 weeks of Robert Jones Dressings and hypochlorite gel.

Clinical Case Study - Lymphorrhea

by: **Martin Winkler, MD, FACS**

Creighton University Department of Surgery

(Contributed Service), Omaha, NE

University of Nebraska Department of Surgery (Contributed Service),
Omaha, NE

Laura Wesnieski, RN, CWS

Bergan Mercy Wound Care Clinic, Omaha, Nebraska

Sara M. Winkler

Dept. of Biomedical Engineering,

Stanford University, Palo Alto, CA

THE PROBLEM:

- Recurrent painful refractory VLU, treatment week #22
- Lymphedema of morbid obesity
- Comorbid AODM, depression
- CHF, sleeps in chair
- Refused mechanical debridement

Recurrent refractory VLU, wound clinic treatment week #22. Lymphedema of morbid obesity is difficult to treat with elastic compression because of cone shaped obese legs. Zinc oxide protects skin from maceration under the Robert Jones dressing.



After months of therapy with honey, porcine collagen, seaweed alginate, home nurses, prayer chains and low dose tricyclic antidepressants for pain, wound clinic staff is nihilistic about these wounds.



TREATMENT:

- Sodium Hypochlorite Gel* to "debride" exuberant granulation
- Layered Jones compression dressing

Observe thick exudative funky granulation tissue. Pain, patient is depressed, prevented adequate curette debridement. Honey to



debride the exuberant granulation tissue macerated the surrounding skin after one week. Clinic staff was bummed out, aka "therapeutic nihilism" that wounds were not healing.

Hypochlorite gel was selected to control the exuberant granulation tissue. Gel was liberally applied to wound under a cotton batting Robert Jones dressing at weekly clinic visits.



Photo demonstrate our "soft debridement" technique. Wounds are soaked with hypochlorite solution** and derided, via abrasion, with dry terry cloth.



Photo shows soft debridement results, note exudate on terry cloth, for three passes with dry terry cloth abrasion



OUTCOME

Near complete healing with five weeks of hypochlorite gel debridement

* Anasept® Antimicrobial Skin and Wound Gel

** Anasept® Antimicrobial Skin and Wound Cleanser



Clinical Case Study - Leg Wound

by: Jean O. Galloway, PT-Superior Rehab Center
Newport Beach, CA.

Clinical Challenge:

To heal wound on Left Leg

THE PATIENT:

Mr. C. is a 75 year old male who sustained an injury to his left leg while getting out of a boat. Mr. C. Is active and alert with no other major medical issues.

START OF CLAIM:

First Saw patient on 2/18/2014 (See photo below). Wound measured 2.2 x 1.5. Tissue color was red/black. Patient had incurred the injury approximately 3 weeks prior to being referred here as he thought he could care for it himself. He was using Neosporin and Band-aids. Top skin of wound was still in a small pile in center of wound and had never been removed. I debrided wound and applied Anasept Gel. Wound was covered with Telfa and Island Barrier Dressing. Anasept cleanser was used before and after debriding and that protocol continues.

CONTINUING TREATMENT:

Patient seen twice weekly with Anasept Gel continually being used under Telfa and Island Barrier Dressing.

New photo taken on 3/6/2014 (see photo below) showing progress. Wound now measured 2.0 x 1.5. Patient pleased with results to date.

New photo taken once again on 3/28/2014 (see photo below). Wound now measuring 1.5 x 2.0. Progressively getting smaller with good red granulation. Patient pain level had decreased considerably and encouraged by the results to date.

CLINICAL/RESULTS STATEMENT:

I am very pleased with the results I am receiving from using Anasept Gel and will continue until wound closure.



2/18/2014. First patient visit. Wound measured 2.2 x 1.5.



3/6/2014 Wound shows progress. Measured 2.0 x 1.5



3/28/2014. Wound measuring 1.5 x 2.0

Clinical Case Study - Leg Wound

by: Jean O. Galloway, PT-Superior Rehab Center
Newport Beach, CA.

Clinical Challenge:

To heal wound on Right leg.

THE PATIENT:

Mrs. N. is an 89 year old female who struck her right anterior lateral leg on the corner of her car door. It did not break the skin on impact. Incident occurred on 2/6/2014.

START OF CLAIM:

I first saw the patient on 3/6/2014. Wound measured 1.8 x 1.7 (see photo below). Tissue was dark red and grey. Patient said that there had been a bruised area for several days. It then developed into a hematoma. Patient saw her physician for 3 or 4 times and was told to use Neosporin, however, it continued to draining so she was referred to SRC. I debrided and decided to use the Anasept Gel. The Anasept spray is used prior and after debriding. I covered with a Primapore and asked to see patient twice weekly.

CONTINUED TREATMENT:

Patient continued to be seen twice weekly with debriding and Anasept Gel the protocol. Wound looked cleaner and smaller with each visit. On 3/20/2014 wound now measured 0.8x 0.3. I was extremely pleased with the quick results the patient was achieving.

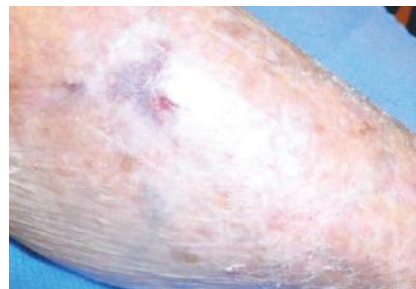
New photo was taken on 3/28/2014 and wound was closed and healed (see photo on the right). Patient was discharged and delighted.

CLINICAL/RESULTS STATEMENT:

Dramatic results evident as the patient was seen only 7 times and wound was closed and healed. I attribute the use of the Anasept Gel as the reason for this. I am quite pleased and will continue the use of this product.



3/6/2014 wound measured 1.8 x 1.7



3/28/2014 wound was closed and healed.