ABL Medical™

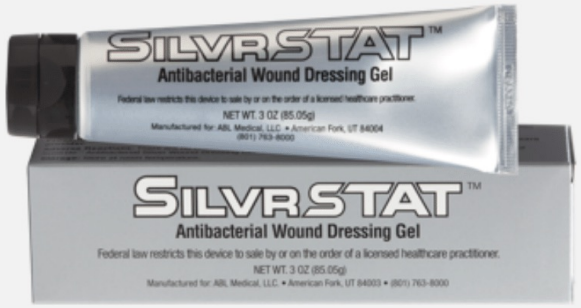
Presentation on:

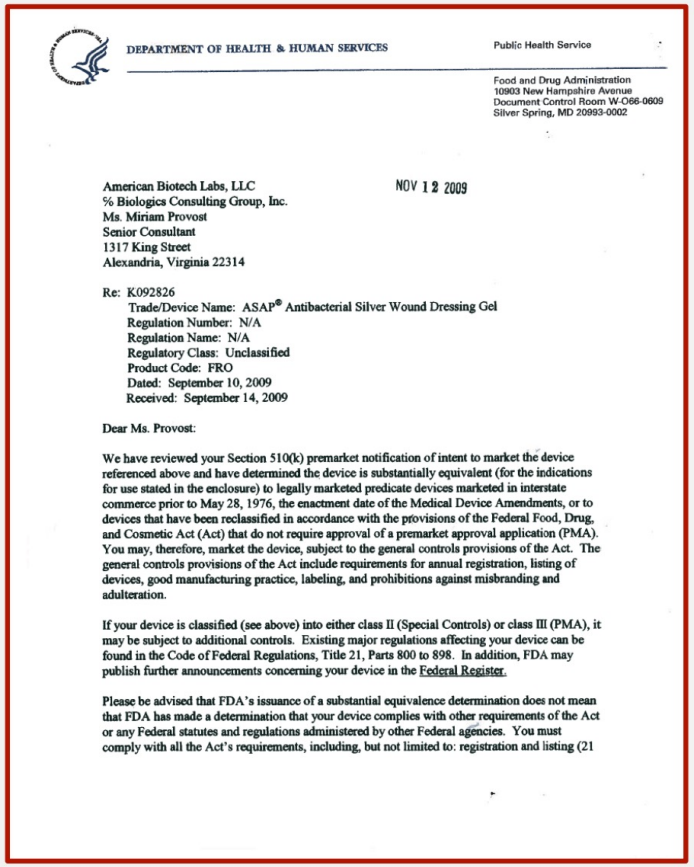
SILVRSTAT
Antibacterial Wound Dressing Gel

Paul Schwitzer
pauls@ablmedical.com
801-709-3320

WOUND CARE **silver gel.**

- Our antibacterial silver wound dressing gel is indicated for the OTC local management of:
  - ✓1st and 2nd Degree Burns
  - ✓Lacerations
  - ✓Abrasions
  - ✓Minor Cuts
  - ✓Skin Irritations
- And by the order of a licensed healthcare practitioner for the management of:
  - ✓Wounds Such as Stasis Ulcers, Pressure Ulcers, and Diabetic Ulcers
  - ✓Device Insertion Site Wounds
  - ✓Surgical Incision Sites
  - ✓Graft Sites
  - ✓Donor Sites
  - ✓Skin Tears





DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 12 2009

American Biotech Labs, LLC
% Biologics Consulting Group, Inc.
Ms. Miriam Provost
Senior Consultant
1317 King Street
Alexandria, Virginia 22314

Re: K092826
Trade/Device Name: ASAP® Antibacterial Silver Wound Dressing Gel
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 10, 2009
Received: September 14, 2009

Dear Ms. Provost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

ABL Medical™

Silver Wound Gel **purpose/ingredients.**

- Our antibacterial silver wound dressing gel contains silver that in laboratory tests has been shown to inhibit the growth of microorganisms such as:

  - ✓Staphylococcus Aureus
  - ✓Pseudomonas Aeruginosa
  - ✓Escherichia Coli
  - ✓Antibiotic Resistant Strains
  - ✓MRSA
  - ✓VRE
  - ✓Fungi Such As Candida Albicans

- Made with Patented Silver Technology

  - ✓No Stinging
  - ✓No Staining
  - ✓No Sticking
  - ✓No Chloride
  - ✓No Scent

- Probiotic friendly

- **Contents:** 32 ppm Proprietary Silver (purified water, nano-silver at .01 micron), Propylene Glycol, Triethanolamine, Carbomer.

ABL Medical™

Independent *In Vitro* Report on the Antibacterial Effects of the Active Ingredient in SilvrSTAT®

Disinfectant Efficacy Results @ 5 and 10 Minutes of 60 Different Tests Per Bacteria

ORGANISM	TIME POINT (MIN.)	CARRIER TITER (CFU/CARRIER)	NUMBER OF CARRIERS TESTED	NUMBER SHOWING GROWTH	NUMBER SHOWING NO GROWTH
P. aeruginosa	5	5.5×10^4	60	0	60
	10	5.5×10^4	60	1	59
S. aureus	5	5.5×10^6	60	6	54
	10	5.5×10^6	60	1	59
S. choleraesuis	5	5.5×10^6	60	1	59
	10	5.5×10^6	60	0	60

Data on File

ABL Medical™

Independent *In Vitro* Report on Antimicrobial Effects of the Active Ingredient in SilvrSTAT®

Kill Time Study with 32PPM Gel				
Organism	**Exposure Interval**	**Avg. Control Titer (CFU/ml)**	**Percent Reduction**	**Log Reduction**
MRSA	1 HR	1.9×10^6	>99.99	>4.98
	24 HR	1.9×10^6	>99.99	>4.98
P. Aeruginosa	1 HR	2.1×10^6	>99.99905	>5.02
	24 HR	2.1×10^6	>99.99905	>5.02
VRE	1 HR	1.9×10^6	>99.56	2.35
	24 HR	1.9×10^6	>99.99	>5.38

Bacteria	Not less than 1.0 log reduction from the initial calculated count at 7 days, not less than 3.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days

FDA Required Time Study: Nelson Laboratories (#474527, #474527A, #474527B, #474527C, #474527D, #474527E Data on File

ABL Medical™

INDEPENDENT IN VITRO REPORT

Comparing SilvrSTAT® With Other Products In Same Regulatory Category

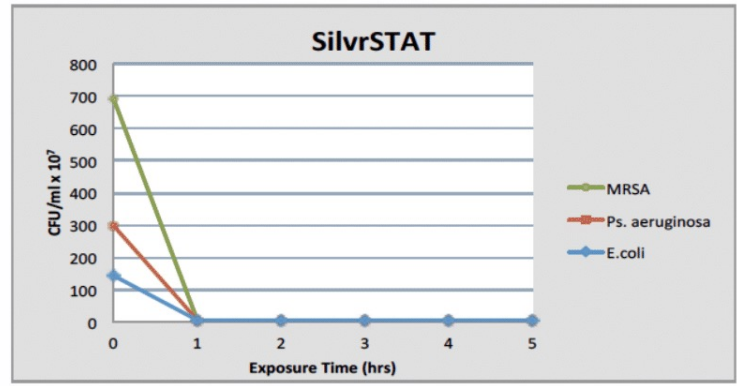
PRODUCT	EXPOSURE INTERVAL	MRSA $3.8X10^5$ CFU/ml	VRE $7.2x10^5$ CFU/ml	P. aeruginosa $5.2x10^5$ CFU/ml	E. Coli $8.1x10^5$ CFU/ml	C. albicans $6.8x10^5$ CFU/ml	S. agalactiae $4.3x10^5$ CFU/ml
SilvrSTAT®	10 min	220000	500000	<10	8000	<10	250000
	1 hr	1200	10000	<10	<10	<10	15000
	4 hr	200	250	<10	<10	<10	<10
	24 hr	<10	<10	<10	<10	<10	<10
Medical Grade Honey	10 min	18000	450000	300	500000	700	8500
	1 hr	10000	180000	100	350000	<10	8000
	4 hr	20000	150000	<10	200000	<10	800
	24 hr	<100	600	<10	1300	<10	100
Mupirocin Ointment	10 min	<10	400000	65000	500000	150000	<10
	1 hr	<10	150000	700	80000	40000	<10
	4 hr	<10	150000	<10	16000	14000	<10
	24 hr	<10	180000	100	<10	12000	<10
Ionic Silver Gel	10 min	150000	350000	180000	450000	250000	280000
	1 hr	80000	35000	<10	75000	40000	3500
	4 hr	200	15000	<10	<10	35000	200
	24 hr	200	18000	<10	<10	800	<10
Silver Sulfadiazine Cream	10 min	120000	350000	1300	65000	7000	4000
	1 hr	2000	7000	100	300	100	100
	4 hr	300	<10	100	100	<10	<10
	24 hr	100	100	<10	<10	100	<10
Botanical Extract Gel	10 min	150000	420000	500	5500	14000	8000
	1 hr	75000	200000	100	200	300	3000
	4 hr	15000	200000	<10	<10	<10	100
	24 hr	<10	40000	<10	<10	100	200

ABL Medical™

ABL Medical Date on File - Analytical Resource Laboratory; Orem, UT 03/14

SILVRSTAT®

Antibacterial Wound Dressing Gel



- SilvrSTAT Antibacterial Wound Dressing Gel is indicated for the management of 1st and 2nd degree burns, wounds such as stasis ulcers, pressure ulcers, diabetic ulcers, lacerations, abrasions, skin tears, surgical incision sites, device insertion site wounds, graft sites and donor sites.[2]
- It is ***not*** an ionic silver.[1]
- SilvrSTAT should be applied directly to the affected area and covered with an appropriate dressing.[2]
- For burns, SilvrSTAT should be applied to the affected area and allowed to dry.
- There are no known adverse events associated with the use of SilvrSTAT for external wound management.[2]

SilvrSTAT offers:

- Superior wound management
- Inhibition of broad spectrum bacteria including MRSA and VRE
- Visualization of the wound through a transparent gel
- No Sulfa or Alginate components
- No Alcohol
- Non-flammable

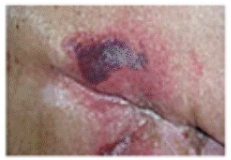
References

1. R. Roy et al, Materials Research Innovations 2007 Vol 11 No 1
2. SilvrSTAT Antibacterial Wound Dressing Gel United States Package Insert
ABL Medical Data On File

ABLMedical™
801.763.8000 American Fork, UT 84003
www.silvrstat.com
www.ablmedical.com

Skin and Wound Care Quick Reference/Guideline
Protocols Provided By MEDEON

SILVRSTAT



Suspected Deep Tissue Injury (sDTI)

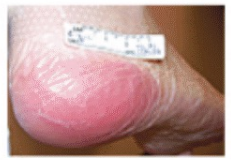
Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear.

Further description: The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with treatment.

Prevention Guidelines
- Pressure redistribution support surface as appropriate
- Turn and reposition q 2h in bed and q 1h in chair
- Offloading device to keep heels elevated off bed
- Monitor skin at least q 8hrs

Cleanse
- Cleansing Shampoo, Foam, or Body Wash

Apply
- Skin Repair Cream to moisturize skin
- Skin prep for at risk skin
- Zinc prep for compromised skin
- SilvrSTAT for yeast/fungus



Stage I Pressure Ulcer

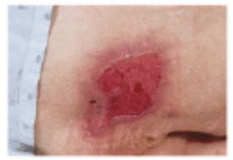
Intact skin with non-blanchable erythema of a localized area usually over a bony prominence. Discoloration of the skin, warmth, edema, hardness or pain may also be present. Darkly pigmented skin may not have visible blanching.

Further description: The area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue. Category/Stage I may be difficult to detect in individuals with dark skin tones. May indicate "at risk" persons.

Intact Skin

Cleanse
- Cleansing shampoo or foam

Apply
- Protective Barrier or Hydrocolloid



Stage II Pressure Ulcer Partial Thickness Skin Loss or Blister

Partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough. May also present as an intact or open/ruptured serum filled or serosanginous filled blister.

Further description: Presents as a shiny or dry shallow ulcer without slough or bruising. This category/stage should not be used to describe skin tears, tape burns, incontinence associated dermatitis, maceration or excoriation.

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

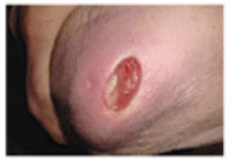
Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT hydrogel to base
- Alginate filler

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound



Stage III Pressure Ulcer or Stage IV Pressure Ulcer or Full Thickness Wound

Stage III: Full Thickness tissue loss (fat visible) Full thickness tissue loss. Subcutaneous fat may be visible but bone, tendon or muscle is not exposed. Some slough may be present. May include undermining and tunneling.

Further description: The depth of a Category/Stage III pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and Category/Stage III ulcers can be shallow. In contrast, areas of significant adiposity can develop extremely deep Category/Stage III pressure ulcers. Bone/tendon is not visible or directly palpable.

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT hydrogel to base
- Alginate filler

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound

Stage IV: Full Thickness tissue loss (muscle/bone visible). Full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present. Often include undermining and tunneling.

Further description: The depth of a Category/Stage IV pressure ulcer varies by anatomical location. The bridge of the nose, ear, occiput and malleolus do not have (adipose) subcutaneous tissue and these ulcers can be shallow. Category/Stage IV ulcers can extend into muscle and/or supporting structures (e.g. fascia, tendon or joint capsule) making osteomyelitis or osteitis likely to occur. Exposed bone/muscle is visible or directly palpable.

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT hydrogel to base
- Alginate filler

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

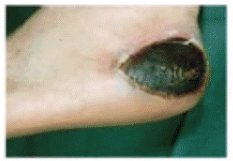
Change
- Daily or as indicated by type and condition of the wound

ABL Medical™

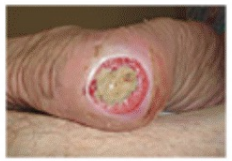
Rev 10/14

Skin and Wound Care Quick Reference/Guideline
Protocols Provided By MEDEON

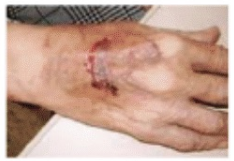
SILVRSTAT



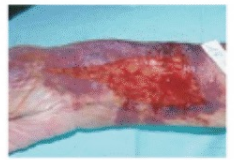
Unstageable Pressure Ulcers



Necrotic Wounds



Skin Tear Category I or II



Skin Tear Category III

Colonized or Infected Wounds

Unstageable: Full thickness tissue loss in which actual depth of the ulcer is completely obscured by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

Further description: Until enough slough and/or eschar are removed to expose the base of the wound, the true depth cannot be determined; but it will be either a Category/Stage III or IV. Stable (dry, adherent, intact without erythema or fluctuance) eschar on the heels serves as "the body's natural (biological) cover" and should not be removed.

Category I: Skin tear without tissue loss. Characteristics are based on whether the damage is a linear tear or a skin-flap type tear. Both tears can be fully approximated.

Category II: Skin tear with partial tissue loss. Tears will have a partial thickness epidermal tissue loss. The tears are further classified as scant versus moderate to large tissue loss.

Category III: Skin tear with complete tissue loss where the epidermal flap is absent. These are wounds with complete tissue loss.

Colonized: Bacterial load is high enough that the host is losing control over wound environment may not show critical signs of infection.

Infected: Represents the invasion of bacteria into healthy tissue where they continue to proliferate and elicit a reaction from the host will typically show signs of clinical infection.

Solid Dry Eschar on Heels

Cover
- No Dressing
- Keep Dry

Float heels to relieve pressure

Other Necrotic Wounds with Eschar, Yellow or Black Slough

Cleanse
- Wound Cleanser

Apply
- Skin prep to periwound skin
- Sharp debridement if possible, if not then use an enzymatic debrider for 4 -5 days.
- Following debridement use SilvrSTAT Hydrogel

Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel to wound

Cover
- Gauze/Rolled Gauze

Change
- Daily or as indicated by type and condition of the wound

Approximate edges when possible with moistened swab

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel to wound bed

Cover
- Silicone adhesive foam gentle/Super absorbent dressing

Change
- Daily or as indicated by type and condition of the wound

Dry to Scant Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel

Cover
- Waterproof bordered gauze

Change
- Daily or as indicated by type and condition of the wound

Moderate to Heavy Exudate

Cleanse
- Normal Saline

Apply
- Skin prep to periwound skin
- SilvrSTAT Hydrogel

Cover
- Calcium Alginate cover dressing

Change
- Daily or as indicated by type and condition of the wound

ABL Medical™

Poster Presented at Spring SAW-C 2014

A Novel New Nanoparticle Silver Hydrogel* on Surgical Sites - A Case Series

Eric J. Lullove, DPM CWS FACCWS, Boca Raton, FL
West Boca Center for Wound Healing

The investigator retained full independence in the conduct of this research.

ABSTRACT

Over the years there have been many opportunities to address surgical site contamination and post-operative infections in the outpatient setting. Most notably, since the advent of Methicillin-resistant infections and an increasing diabetic patient population (this also includes pre-diabetic patients), the risks for surgery have increased in the ability of a patient to properly heal, even with primary intention closure.

For centuries, human beings have utilized silver-based dressings and silver itself as a method of battling contaminant bacteria and viruses. In today's modern age of medicine, the use of nanometric silver products has become mainstream.

A newer, more agile molecular silver hydrogel has shown effective use in the treatment of nosocomial infections and bacteria. This novel new silver hydrogel is a 32 ppm nanoparticle which has multivalent and catalytic antimicrobial properties. The molecular silver hydrogel is multivalent, resulting in multiple electrons being physically pulled from the bacteria cell wall, allowing for rapid antimicrobial effect. Additionally, this multivalent silver hydrogel is catalytic, causing a reaction where the molecular silver remains unbound allowing for use at low concentration and reducing potential side effects.

This new nanoparticle silver hydrogel is clinically indicated for pressure ulcers, diabetic foot ulcers, surgical incision sites, autograft and allograft sites, first and second degree burns, venous stasis ulcers, lacerations and abrasions, device insertion site wounds and donor sites.

This case study series will demonstrate this new nanoparticle molecular silver hydrogel and its use in preventing surgical site infections and contamination on high-risk diabetic and peripheral arterial disease patients. The use of this nanoparticle molecular silver hydrogel not only showed high effectiveness in preventing infection or contamination, but as a result, also prevented dehiscence of the surgical sites.

METHODS

The purpose of this case study series is to show the use of a new nanoparticle silver hydrogel effect on surgical wound sites both post-operative and during the follow-up phases of surgery, which shows that the use of the hydrogel effectively continues to maintain an antimicrobial layer between the sutures and the incision site.

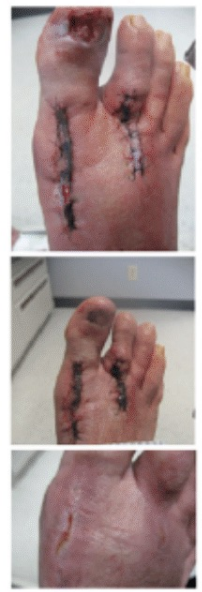
The use of the nanoparticle silver hydrogel is to maintain a moist healing environment, but also maintain an antimicrobial environment, capable of destroying and killing bacteria that cause nosocomial post-operative infections.

Applications of nanoparticle silver hydrogel immediately post-operative and at each post-surgical visit until suture removal. All patients were cleared post-surgically of any residual contamination or infection by day 14. There was no evidence of any dehiscence or breakdown of the incision after 14 days.

In short, the use of Nanoparticle silver hydrogel can be beneficial in areas of surgical management of high to low-risk surgical patients in the inpatient and outpatient settings where the need for more antibiosis is required in patients post-operatively.

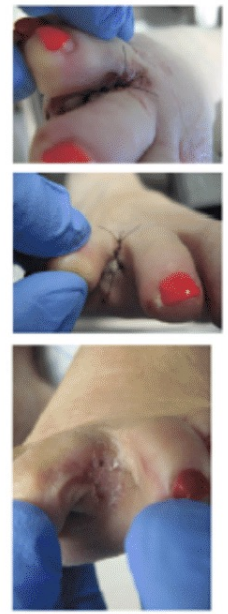
Case 1

52 y/o diabetic male patient underwent elective corrective repair for hallux valgus and predislocated 2nd MPJ right foot. Patient was given nanoparticle silver hydrogel immediately post-operative and throughout the duration of post-operative suture care every 3rd day. Patient sutures removed at day 18 without any signs of infection, dehiscence or pull-out from the nanoparticle silver hydrogel.



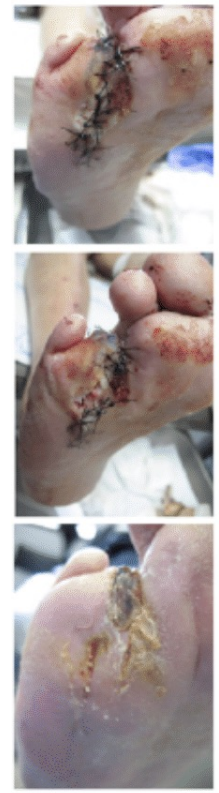
Case 2

56 y/o female patient underwent elective plantar digital neuroplasty to her 3rd intespace right foot. Nanoparticle silver hydrogel was used post-operatively and changed every 3rd day. Sutures removed at day 15 without pull-out, dehiscence or infection.



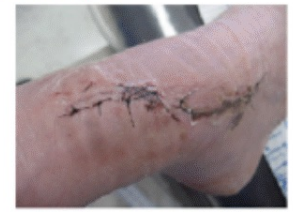
Case 3

72 y/o male diabetic patient underwent non-elective surgical resection of his 4th metatarsal head secondary to acute osteomyelitis. Wound was closed on day 3 post-operatively with use of nanoparticle silver hydrogel. Wound coapted and healed with every 3rd day dressing changes at day 21.



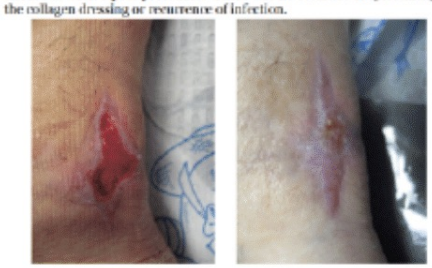
Case 4

34 y/o female underwent emergency I&D of abscess to her right foot secondary to IV Dilaudid injection abuse. Wound closed post I&D at day 4, with application of nanoparticle silver hydrogel. Dressing changed weekly x 2-3 weeks until coaption of tissues. Sutures removed at day 21 without signs of infection, dehiscence or pullout.



Case 5

38 y/o female was seen for emergency as result of brown-recluse spider bite to right medial lower leg. Wound was treated and irrigated, with nanoparticle silver hydrogel applied post-procedure. Nanoparticle silver hydrogel was used in conjunction with ovine forestomach dermal template to obtain wound closure at week 6 post-procedure. There was no evidence of cytotoxicity with the collagen dressing or recurrence of infection.



CONCLUSIONS/LIMITATIONS

The above case series demonstrates that the use of a nanoparticle silver hydrogel with a multivalent structure can be used both post-surgically as a primary dressing and post-surgically with an open wound with concomitant use of collagen wound dressings without loss of tissue due to cytotoxicity. The ability of the silver hydrogel to not only catalytically destroy bacteria, but maintain a moist wound healing environment is novel in the marketplace and further controlled studies and/or post-market RCT should be developed to further introduce this product's wound healing principles. Although this is a small sample case series, the author believes that there is enough clinical evidence to show the functional ability of this product in not only elective post-surgical, but in high-risk, highly infected individuals where the need for a more versatile silver hydrogel product can be used.

REFERENCES

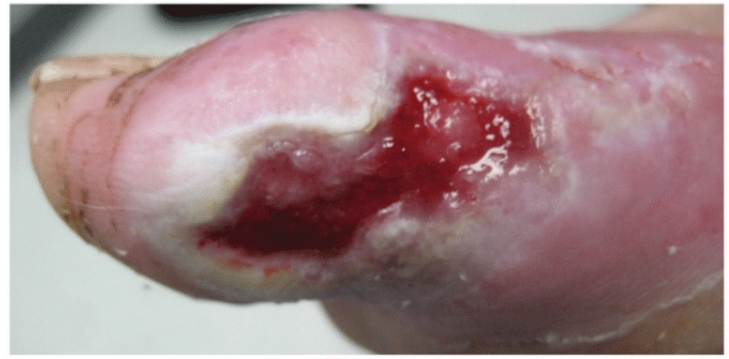
- Munger Mark A., Radwanski Przemyslaw, Hadlock Greg C., Stoddard Greg, Shaaban Akram, Falconer Jonathan, Grainger David W., Deering-Rice Cassandra E., In Vivo Human Time-Exposure Study of Orally Dosed Commercial Silver Nanoparticles, Nanomedicine: Nanotechnology, Biology and Medicine (2013), doi:10.1016/j.nano.2013.06.010.
- Nelson Laboratories: Time Kill Study. June 2009 pg 1-8.
- Analytical Resource Laboratory: SilviSTAT Time Kill data vs. 5 other commonly used antibacterials.
- Castellano JJ, Shafi SM, Ko F, Donate G, et al. Comparative evaluation of the silver-containing antimicrobial dressings and drugs. International Wound Journal. June 2007, Vol. 4 Issue 2. pp. 114-122.
- Smock KJ, Schmidt RL, Hadlock G, Stoddard G, Grainger DW and Munger MA. Assessment of orally dosed commercial silver nanoparticles on human ex vivo platelet aggregation. Nanotoxicology 2013. Online 1-6.

**SilverSTAT® Antibacterial Wound Dressing Gel*
ABL Medical, LLC, American Fork, UT

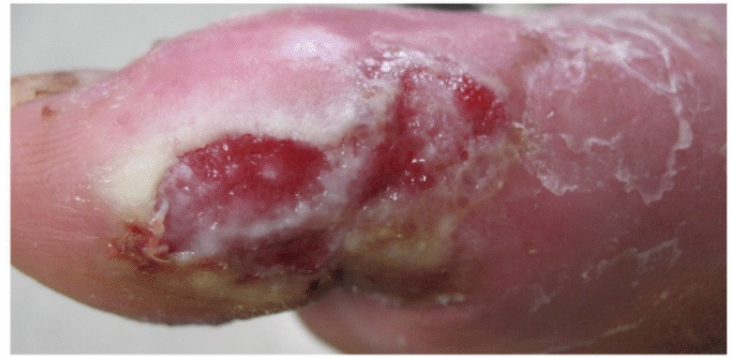
ABL Medical™

SILVRSTAT®
Antibacterial Wound Dressing Gel

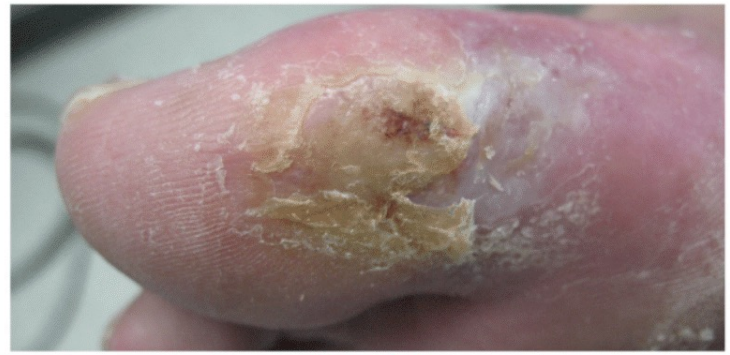
THE NEXT GENERATION IN WOUND DRESSINGS



Day 8
3.5 x 2.5 x 0.15 cm



Day 18
1.5 x 2.0 x 0.15 cm

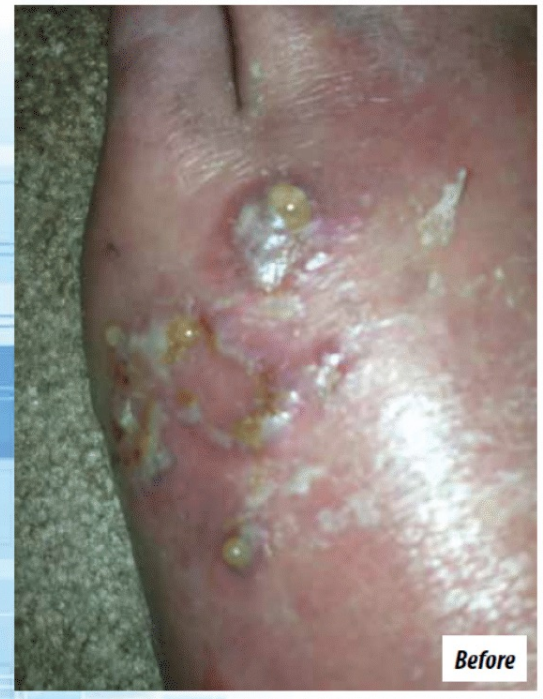


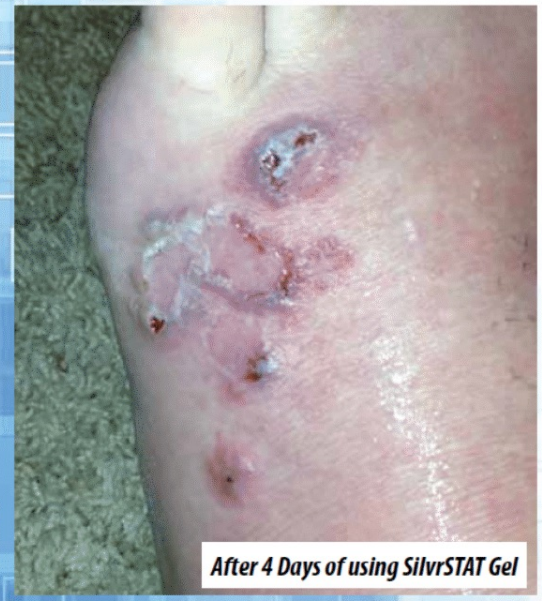
Day 25

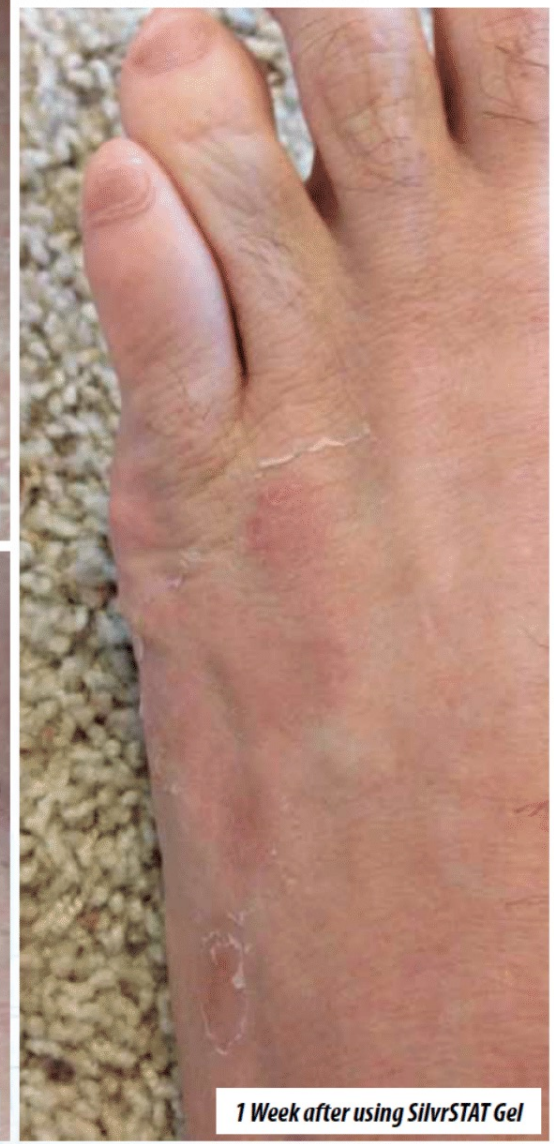
EL-6

ABLMedical™

MRSA Wound : Foot
54 year old Male
Case Study







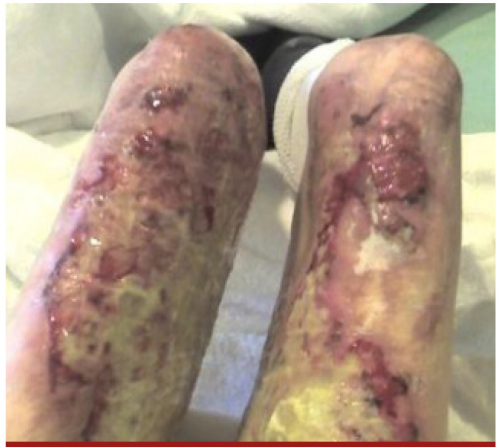
Data on File

SILVRSTAT®

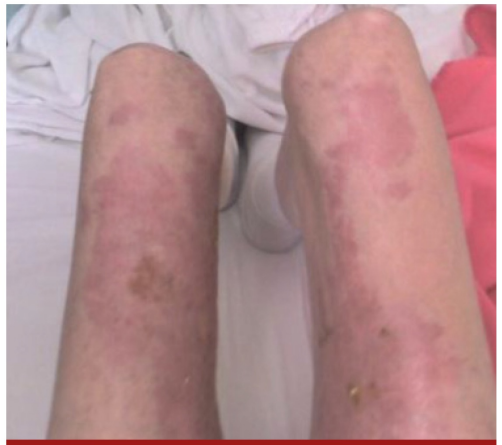
Antibacterial Wound Dressing Gel

THE NEXT GENERATION IN WOUND THERAPY

88 year old woman with severe wound on her legs



Before



65 Days Later

Patient was unable to receive skin grafts due to her age and compromised immune system.

Data on file

ABL Medical®

www.SilvrSTAT.com

877-272-6924