HALYARD*

Silver Gelling Fiber Dressing

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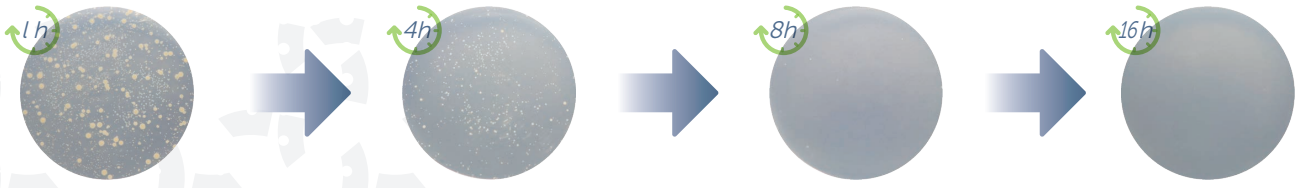
Silver Gelling fiber dressing with high wet strength and effective anti-bacterial properties.

HALYARD* Silver Gelling Fiber Dressing is a soft, conformable, non-woven pad or ribbon dressing composed of carboxymethyl cellulose fibers, enhanced fibers and ionic silver. Based on in vitro testing, the silver in the dressing inhibits bacterial growth in the dressing and provides a barrier against bacterial penetration through the dressing for up to seven days. This conformable and highly absorbent dressing absorbs wound drainage transforming into a soft gel, which provides an ideal moist wound healing environment.

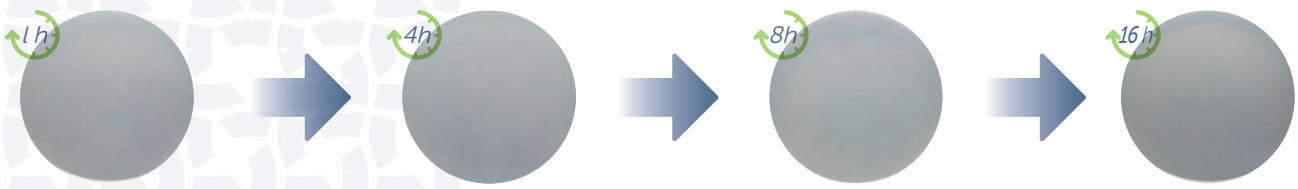
- Safe and effective for wound bioburden management.
- Inhibits a broad-spectrum of infection up to 99.99% for 7 days.
- Provides moist environment to help promote wound healing.
- Highly biocompatible.
- No evidence of bacterial resistance.
- Extended Wear Time

Broad-spectrum Anti-bacterial & Rapid Effectiveness

Methicillin-resistant Staphylococcus aureus (MRSA)



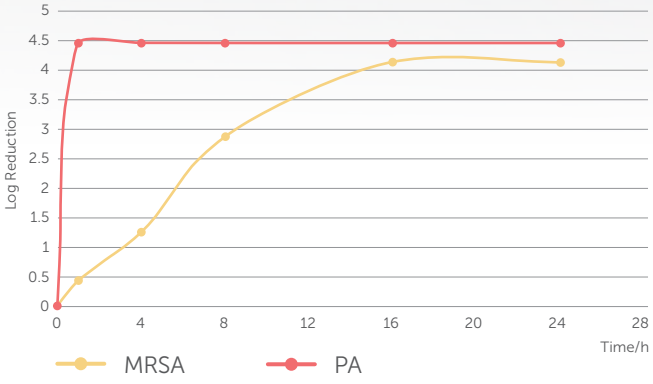
Pseudomonas aeruginosa (PA)



How does Silver Gelling Fiber Dressing work?

- Safe and effective for wound bioburden management.
- Inhibits a broad-spectrum of infection up to 99.99% for 7 days.
- Perfect balance between absorbency and wet-strength.
- Shrink resistant to help maintain dressing shape.

Fig 1 The Anti-bacterial Effectiveness Test of HALYARD* Silver Gelling Fiber Dressing



- Fig 1 shows that HALYARD* Silver Gelling Fiber Dressing has anti-bacterial effect on both Gram-negative and Gram-positive bacteria. The anti-bacterial effect on Gram-negative bacteria can reach to 99.99% in one hour. It is also effective against drug-resistant bacteria, MRSA for example. And the anti-bacterial rate can reach to 99.99% in 16 hours.

Fig 2 The Comparison of MRSA

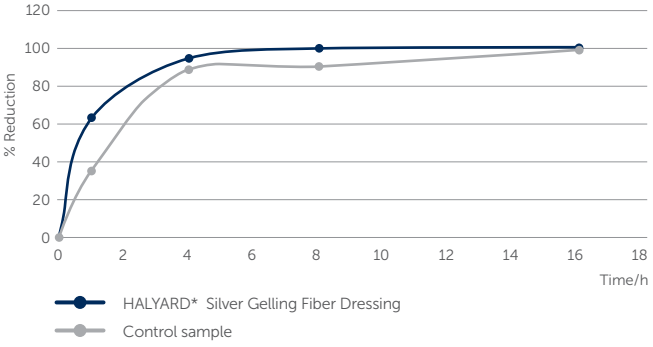
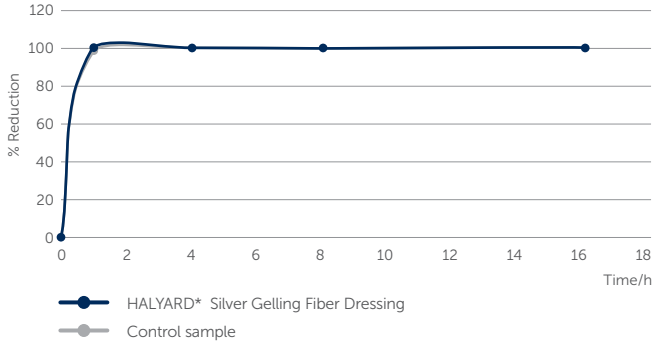


Fig 3 The Comparison of PA



- Fig 2 and Fig 3 show that HALYARD* Silver Gelling Fiber Dressing and the control sample both have anti-bacterial effects on Gram-negative and Gram-positive bacteria. For Gram-negative bacteria, the anti-bacterial effect of HALYARD* Silver Gelling Fiber Dressing is equivalent to that of the control sample. For Gram-positive bacteria, the anti-bacterial effect of HALYARD* Silver Gelling Fiber Dressing is better than that of the control sample.

Fig 4 Releasing Silver Curve

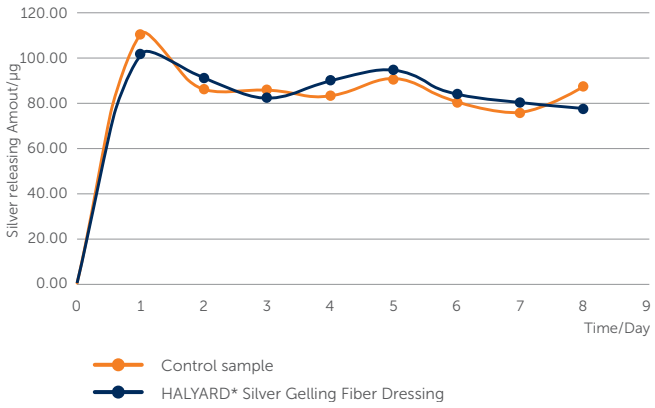


Fig 5 Cumulative Silver Releasing Amount

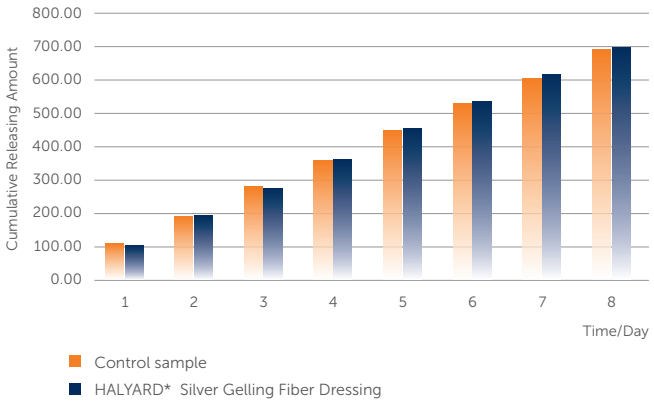


Fig 6 Cumulative Silver Release Rate

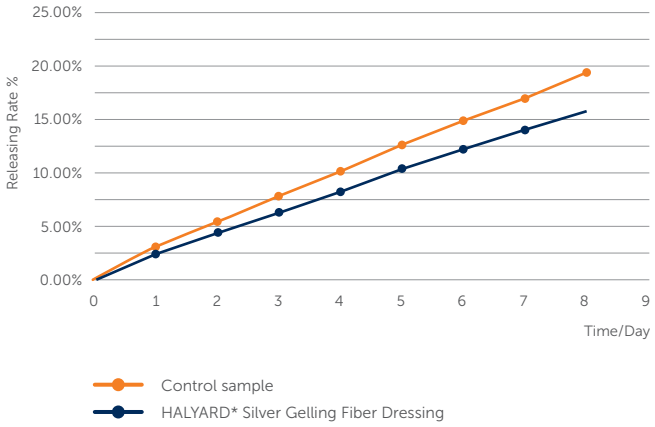


Fig 4, 5 and 6 show that HALYARD* Silver Gelling Fiber Dressing releases silver ions stably every day for 8 consecutive days like the control sample. The releasing rate was roughly the same as that of the control product. The statistics show that the cumulative silver releasing amount of HALYARD* Silver Gelling Fiber Dressing is far below 3800mg which is the toxic dose of silver for human in a number of clinical and academic studies. For single use or multiple use, the releasing of silver ion is much lower than the toxic dose of silver. Therefore, HALYARD* Silver Gelling Fiber Dressing is a safe and effective anti-bacterial dressing, and achieves better anti-
bacterial effect with a relatively small dose of silver.

Rx Indications

Under the supervision of a healthcare professional: HALYARD* Silver Gelling Fiber Dressing may be used for the management of moderate to heavily exuding chronic and acute wounds as an effective barrier to prevent bacterial penetration through the dressing, including:

- Partial thickness burns (second degree);
- Diabetic foot ulcers;
- Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology);
- Pressure ulcers (partial and full thickness);
- Donor sites;
- Surgical wounds;
- Traumatic wounds.

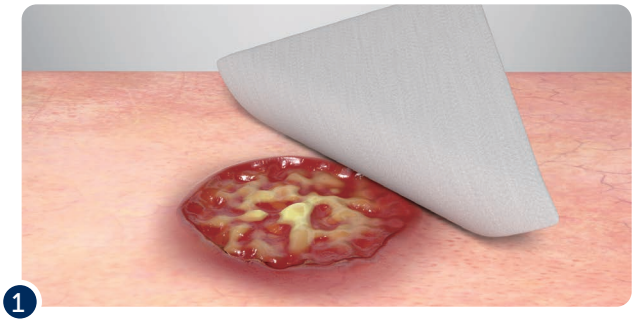
OTC Indications

HALYARD* Silver Antibacterial Gelling Fiber Dressing may be used for:

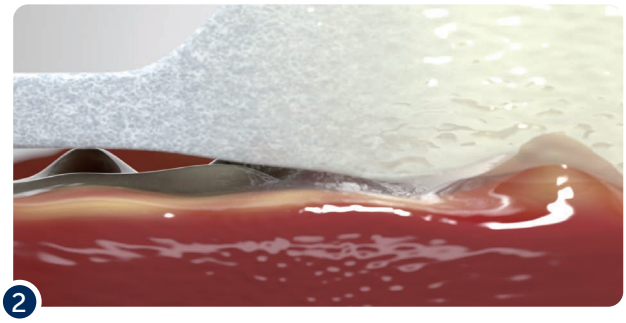
- Minor abrasions;
- Minor lacerations;
- Minor cuts;
- Minor scalds and burns.

How does Silver work?

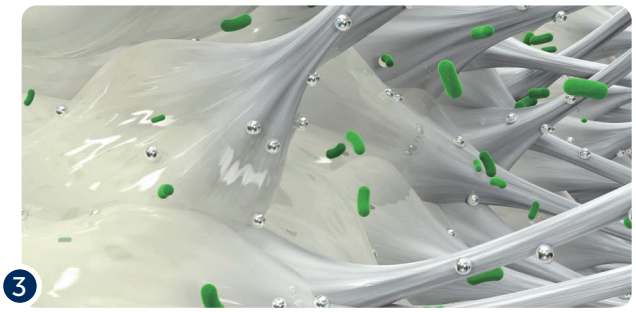
The topical anti-microbial agent silver has been used for hundreds of years in wound care. Silver ions are highly reactive and affect multiple sites within bacterial cells, ultimately causing bacterial cell death. They bind to bacterial cell membranes, causing disruption of the bacterial cell wall and cell leakage. Silver ions transported into the cell disrupt cell function by binding to proteins and interfering with energy production, enzyme function and cell replication. Silver ions are active against a broad range of bacteria, fungi and viruses, including many anti-bioticresistant bacteria, such as Methicillin-resistant Staphylococcus aureus (MRSA) and Vancomycin-resistant Enterococcus (VRE).†



1 Bacteria are absorbed into HALYARD* Silver Gelling Fiber Dressing along with the wound exudate.

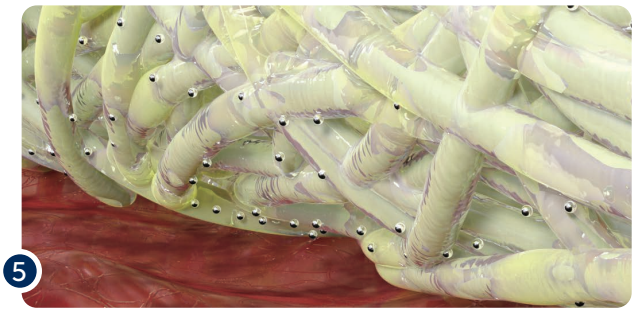


2 The silver ions in the dressing show affinity to various types of bacteria.

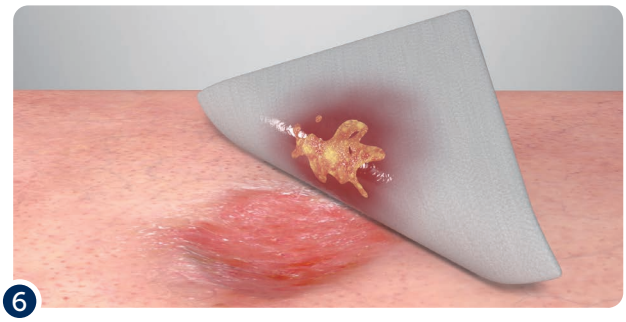


3 Silver ions bind to bacterial cell membranes, affect multiple sites within bacterial cells.

4 Bacterial cell walls are disrupted and cellular components leak out, affecting cell function and leading to bacterial death.



5 Bacteria will be removed along with the dressing during dressing change.

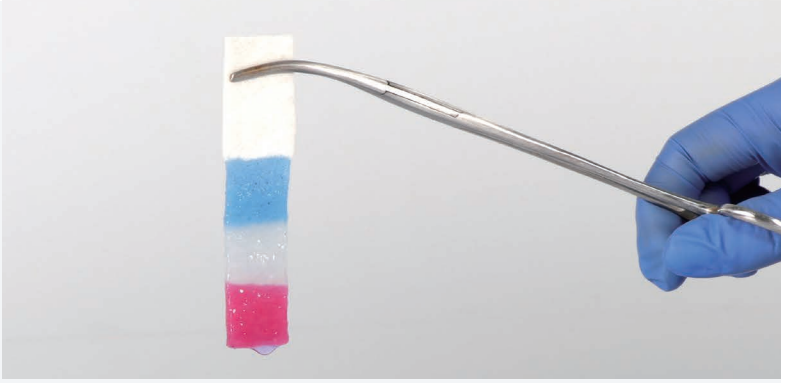


6 By effectively managing the bioburden, the condition of the wound will be improved.

Reference: International consensus. Appropriate use of silver dressings in wounds. An expert working group consensus. London:Wounds International, 2012.Available to download from:www.woundsinternational.com.

Case

Successful Treatment of Complex Wounds Using a New Silver Gelling Fiber Dressing



Chronic wounds are unable to support re-epithelialization, failing to progress through an orderly and timely sequence of repair. These full thickness wounds often present secondarily to diabetes, surgical procedures, inadequate lower extremity vascularization, venous insuciency, or trauma. The use of silver ions has been demonstrated to be effective against a broad range of bacteria to aid in healing complex wounds and burns. The purpose of this case series is to illustrate the use of silver gelling fiber dressing† containing silver ions in full thickness wounds allowing for development of granulation tissue and neoepithelialization of the wound to closure.

Methods

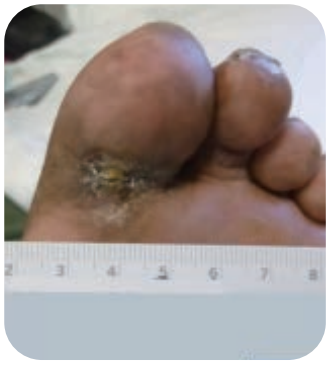
Four patients with full thickness wounds were treated with silver gelling dressings† impregnated with broad spectrum anti-microbial silver ions. The gelling fiber dressing was placed onto the wound bed where devitalized tissue was removed using sharp and/or ultrasonic debridement. A secondary dressing was applied to secure the primary silver dressing, facilitating a moist healing environment. Adequate offloading and compression therapy was utilized as indicated. The silver gelling fiber was changed every 2-3 days.

Diabetic Foot Ulcer (Left Great Toe)

CASE 01

This is a 39 year-old female with history of Diabetes, HTN, HLP, PVD with revascularization, and obesity with recurrent DFUs to the left great toe. The patient was lost to follow up after back surgery returning for evaluation with a DFU, worsening after walking several miles daily for exercise to facilitate weight loss. She reported compliance with bariatric diet, recent weight loss, and glycemic control. She was offloaded with walking boot, as she was unable to tolerate casting due to left lower extremity weakness. MRI revealed osteomyelitis which she received treatment for guided by ID. Dressings were changed 3 times weekly and prn with silver gelling fiber dressing.† Duration of treatment - 14 weeks to wound resolution.

Initial Presentation



14 weeks of treatment - Closed

Chronic Ulcer (Both Ankle Joints)

CASE 02

69 year-old male with history of severe PAD, mixed disease, history of tobacco abuse and CAD presented for evaluation and treatment of chronic ulcers to bilateral ankles. Patient reported his shoes rubbed against his ankles resulting in wounds. Patient initially had limitations with compression due to PAD prior to peripheral bypass grafting as well as successful atherectomy and stenting of the LLE. Wounds resolved in 13 weeks of treatment with aggressive Wound Medicine and silver gelling fiber dressings† changed three times weekly.




Initial Presentation

13 weeks of treatment - Closed

Diabetic Foot Ulcer (Right Foot)

CASE 03

Patient is a 59 year-old AAM a PMHx of DM-2, PVD, HTN, HLD, and asthma presented for evaluation of a right plantar DFU. The patient was s/p right foot surgical debridement after developing a callus, which later became infected. Infection was addressed with antibiotic therapy, and the wound offloaded with football wrap and Darco offloading shoe. The patient was educated on glycemic control for optimal wound healing. Dressings were changed three times weekly with silver gelling fiber dressing† to reduce bioburden. The wounds resolved after 13 weeks of treatment.




Initial Presentation

13 weeks of treatment - Closed

Diabetic Foot Ulcer (Left Heel)

CASE 04

70-year-old female with DM, CAD, HTN, and ESRD referred for treatment of a left heel DFU. The patient was known to our service after developing a sacral pressure ulcer postoperatively following CABG. The sacral pressure ulcer resolved, although the patient later developed the DFU secondary to pressure following a fall. The wound was debrided weekly, culture obtained, and silver gelling fiber dressings† utilized to reduce bioburden and allow granulation and epithelialization. The patient's heels were offloaded with offloading boots and nutritional support provided to optimize wound healing. The wound resolved in under 13 weeks with dressing changes three times weekly with silver gelling fiber dressings.†

Initial Presentation

13 weeks of treatment - Closed

Results

Overall wound improvement and closure was appreciated in full thickness wounds. The silver ions assisted in providing an environment where granulation tissue was able to develop allowing for improved epithelialization. The wounds included were an arterial ulcer, a diabetic foot ulcer, and surgical wounds. Patient comorbidities included diabetes and inadequate lower extremity vascularization. Average initial wound size ranged from 3 – 15 cm². The number of silver gelling fiber applications ranged from 1-13 and time to complete wound epithelialization ranged from 45 – 90 days. .

Conclusion

This case series exhibits successful treatment of complex chronic wounds using adequate wound bed preparation and a gelling fiber containing anti-microbial silver ions.† Similar outcomes have been achieved with alginate dressings impregnated with silver ions. Further study is required to determine if silver gelling fiber dressings improve healing effcacy over other alginate dressings impregnated with silver ions.

ITEM NUMBERS	DESCRIPTION	BOX UOM	HCPCS CODE
56344	HALYARD* Gelling Fiber AG, 2"x 2"	10	A6196
56345	HALYARD* Gelling Fiber AG, 4"x 5"	10	A6197
56346	HALYARD* Gelling Fiber AG, 4"x 8"	10	A6197
56347	HALYARD* Gelling Fiber AG, 6"x 6"	10	A6197
56348	HALYARD* Gelling Fiber AG, 1" x 12", Reinforced	10	A6199

References:

1. Dissemond J, Böttrich JG, Braunwarth H, et al. Evidence for silver in wound care - meta-analysis of clinical studies from 2000-2015. J Dtsch Dermatol Ges. 2017;15:524–535. [PubMed] [Google Scholar]
2. Silver S. Bacterial silver resistance: molecular biology and uses and misuses of silver compounds. FEMS Microbiol Rev. 2003;27:341–353. [PubMed] [Google Scholar]
3. Warriner R, Burrell R. Infection and the chronic wound: a focus on silver. Adv Skin Wound Care. 2005;18(suppl 1):2–12. [PubMed] [Google Scholar]
† HALYARD* Data on file