TECHNICAL SPECIFICATION SHEET





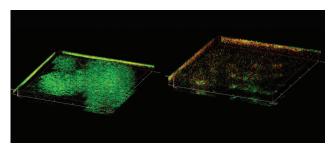


Indications

JumpStart® antimicrobial wound dressing is intended for the management of wounds to provide a moist wound environment and is indicated for surgical incisions, partialand full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, first- and second-degree burns, donor and recipient graft sites, etc.

PRODUCT DESCRIPTION

JumpStart antimicrobial wound dressings are the only wound dressings powered by V.Dox[™] Technology in the orthopedic and sports medicine markets. JumpStart wound dressing's proprietary islands of elemental silver and elemental zinc form a matrix of moistureactivated microcell batteries. When in direct contact with a conductive medium (such as sterile saline, water, or an amorphous hydrogel), JumpStart generates electricity at the dressing surface.² V.Dox Technology is designed to mimic the skin's own physiologic electrical energy, harnessing the power of the electricity to support the skin's natural healing process.^{2,3} With demonstrated antimicrobial impact, JumpStart's V.Dox Technology kills a broad spectrum of pathogens, including multidrug-resistant⁴ and biofilm-forming bacteria, 5,6 thus providing a non-antibiotic solution to infection control.



ANTIMICROBIAL IMPACT ON BIOFILM-FORMING BACTERIA: Live/dead fluorescence staining demonstrated bacterial killing of a biofilm-forming P aeruginosa bacteria within JumpStart bioelectric dressing, compared to silver and placebo control dressings at 24 hours. Red=dead, Green=alive.6

Precautions

- Caution: United States federal law restricts this device to sale by or on the order of a physician.
- Single use only.
- Electron beam irradiation sterilized. Opening the dressing pouch compromises the sterile barrier. Do not use if the pouch is open or damaged prior to use.
- Remove JumpStart dressing prior to a MRI or HBOT procedure and apply a new dressing after the procedure.
- For external use only.
- Do not apply JumpStart dressing in conjunction with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams or ointments, silver- or zinccontaining creams, oxidizing agents, or petroleum-based products.
- Secondary dressings should be used as stated in their instructions for use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- JumpStart dressing is not intended to be used on wounds with uncontrolled bleeding.
- Remove JumpStart dressing during energy-based procedures (such as radio frequency, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid direct dressing contact with electrodes or conductive gels during electronic measurements (eg, EEG or ECG).
- JumpStart dressing may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily JumpStart dressing use for longer than 28 days has not been studied.



Contraindications

Do not use JumpStart wound dressings on individuals with sensitivity or allergy to silver, zinc, or other dressing components.



Warnings

Frequent or prolonged use of this product may result in temporary discoloration of the skin in rare instances.



JumpStart® Antimicrobial Wound Dressing

JumpStart Contact Layer Dressing							
Product #	Dressing Size (inches)	Dressing Size (cm)	Qty/Box				
ABS-4001	1 × 1 Fenestrated	2.5 × 2.5 Fenestrated	10				
ABS-4005	1.5 × 8	3.5 × 20	10				
ABS-4006	1.5 × 10	3.5 × 25	10				
ABS-4002	2 × 2	5 × 5	10				
ABS-4025	2 × 5	5 × 12.5	10				
ABS-4003	3 × 3	7.5 × 7.5	10				
ABS-4004	4 × 4	10 × 10	10				
ABS-4008	8 × 8	20 × 20	1				
ABS-4012	12 × 12	30.5 × 30.5	1				

JumpStart wound dressing is available as a contact layer and a composite (island) dressing. JumpStart contact layer dressing should be used under a secondary dressing or bandage (not provided) to keep it in place and help maintain a moist wound environment. JumpStart composite (island) dressing is a 3-layer dressing, comprising a broad-spectrum antimicrobial contact layer, an absorbent layer, and a semi-occlusive outer adhesive layer to keep the dressing in place and help maintain a moist wound environment.

JumpStart Composite Dressing								
Product #	Adhesive Size (in)	Dressing Size (in)	Adhesive Size (cm)	Dressing Size (cm)	Qty/Box			
ABS-4054	2.5 Diameter	1.0 Diameter	6.0 Diameter	2.5 Diameter	10			
ABS-4056	4.0 Diameter	2.0 Diameter	10 Diameter	5.0 Diameter	10			
ABS-4053	4 × 4	2 × 2	10 × 10	5 × 5	5			
ABS-4051	5 × 6	1.5 × 5	12.5 × 15	3.5 × 12.5	5			
ABS-4052	4.5 × 10	1.5 × 7	11 × 25	3.5 × 17.5	5			
ABS-4050	6 × 11.5	2 × 9	15 × 29	5 × 22.5	5			
ABS-4057	4.4 × 9.6	1.5 × 6.5	11.2 × 24.4	3.8 × 16.5	5			
ABS-4058	4.2 × 7.5	1.4 × 4.5	10.7 × 19.1	3.6 × 11.4	5			

JumpStart Contact Layer Dressing	JumpStart Composite Dressing 2.5 and 4 inches in diameter	JumpStart Composite Dressing 4 × 4 inches	JumpStart Composite Dressing 5 × 6 inches	JumpStart Composite Dressing 4.5 × 10 inches	JumpStart Knee Dressing 6 × 11.5 inches	JumpStart Shoulder Dressing 4.4 × 9.6 inches	JumpStart Elbow Dressing 4.2 × 7.5 inches

References

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- 3. Nuccitelli R. A role for endogenous electric fields in wound healing. Curr Top Dev Biol. 2003;58:1-26.
- 4. Kim H, Makin I, Skiba J, Ho A, Housler G, Stojadinovic A, Izadjoo M. Antibacterial efficacy testing of a bioelectric wound dressing against clinical wound pathogens. Open Microbiol J. 2014;8:15-21. doi:10.2174/1874285801408010015.
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- 6. Banerjee J, Das Ghatak P, Roy S, et al. Silver-zinc redox-coupled electroceutical wound dressing disrupts bacterial biofilm. *PLoS One*. 2015;10(3):e0119531. doi:10.1371/journal.pone.0119531.

