



ASPR

Argentum (Silverlon®)

USG-Argentum Collaboration Supports Repurposing of Commercial Burn Dressing for Radiation Injury

BARDA Industry Day

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Product Description



Argentum Medical

Product: Silverlon® dressings

- Sterile, porous, non-adherent, knitted nylon plated with 99% elemental silver and 1% silver oxide)
 - Deliver antimicrobial Ag ions when activated by moisture.
- Marketed since 2000 with (14) different 510(k) premarketing clearances
- US Military: since 2003 for burn and traumatic wounds
- 5-year shelf life and 7-day use indication
- Nearing completion of GLP animal studies for submission to the FDA
 - Sulfur mustard injuries



Why Silverlon®: A Single Commercial product for management of burns

- **2015:** \$20M procurement for the SNS through Project BioShield
- Include thermal, chemical, and radiological burns
- BARDA strategy for repurposing product indications and creating ideal products for use in mass casualty event



Procured for
Burn Blast Kits
(BBKit)



“One danger of radiation exposure that many people do not think about is damage to the skin, which can range from mild to potentially life threatening. As we work to strengthen our nation’s security against radiological weapons, repurposing commercially available products has many advantages to protect the public from radiation injuries.”

-BARDA Director Rick Bright, Ph.D.

BBKit Upgrade in Addressing Initial Care with MCMs to Control Infection

| | Description |
|----|---|
| 1 | Bandage, Dressing burn, USP type VII gauze 18 x 18 |
| 2 | Bandage, abdominal pad, sterile, 8"x 10" |
| 3 | Bandage, Conforming Gauze 4x4 |
| 4 | Bandage, gauze sterile bulk, 4.5"x147" |
| 5 | Fluorescein Dye Strips |
| 6 | Bandage, dressing, gauze, 4x4, sterile sponge (2 per pack) |
| 7 | Alcaine Ophthalmic, 0.5%, 15ml |
| 8 | Dextrose 5 NACL .45Injection 1000ml |
| 9 | Lidocaine 1% with Epinephrine 10ml vial |
| 10 | Midazolam Versed 5mg/5ml vials |
| 11 | Lactated Ringers Injection 1000ml |
| 12 | Morphine Sulfate, 10mg/ml, 1ml, LL(luer-loc) |
| 13 | Sodium Chloride for inj., 0.9 1000ml flexi-bag |
| 14 | Polymixin/bacitracin antibiotic ointment, 0.9gm packet |
| 15 | Silverdene Cream 1% Silver Sulfadiazine |
| 16 | Bacitracin Ointment 30gm |
| 17 | Lidocaine 1 w/o Epi |
| 18 | Oxycodone/Acetaminophen 5mg/325mg #500 tabs |
| 19 | Suture, Dexon/vicryl 4-0 30" p-12 needle |
| 20 | Suture, Monosof 4-0 18" black PC-3/PC-11 needle |
| 21 | Suture, Dexon/vicryl 5-0 18" p-3/p-13 needle |
| 22 | Suture, Monosof 5-0 18" black p-3/p-13 needle |
| 23 | Suture, Dexon/vicryl 6-0 18" p-3/p-13 needle |
| 24 | Suture, Monosof 6-0 18" black p-3/p-13 needle |
| 25 | Stapler, Skin, Disposable |
| 26 | Laceration Repair Kit, Sterile |
| 27 | Bacitracin 500u/polymixin 10,000u, 3.5G ophthalmic ointment |
| 28 | Potassium Chloride 2mEq/ml, 20ml vial |



Silverlon™ by Argentum Medical
Interagency Agreement with Defense Logistics Agency

Previous Approach

- Silverdene Cream
- Painful
- Need to sedate patients
- Need for multiple/daily applications



2015 BARDA Acquisition to the Strategic National Stockpile

Current Approach

- Silverlon - Burn Dressing
- Easy to use
- Applied once for up to 7 days
- Field tested by warfighters
- Multiple threat potential



Project Overview

Objectives and Scope: Advance the development of Silverlon® Wound Contact, Burn Contact Dressings for the treatment of radiation dermatitis (**RD**) and cutaneous radiation injuries (**CRI**)

- **Contract award:** Sept. 6, 2018
- **Total BARDA cost:** \$8.4 M
- **Regulatory Filings and Non-Clinical Studies**
 - Paper 510(k) clearance application submission with radiation dermatitis and CRI
 - Additional 510(k) for more severe radiation induced burns
- **Clinical Studies**
 - Option for clinical study based on FDA result of 510(k)
- **Technology transfer and Non-Clinical Pivotal Study**

USG Partnership: Helping Partners with Pathway to CRI

- **Teamwork**
 - 7-year shelf life in progress
- **Coordination**
 - Argentum
 - BARDA PCT
 - Contracting oversight

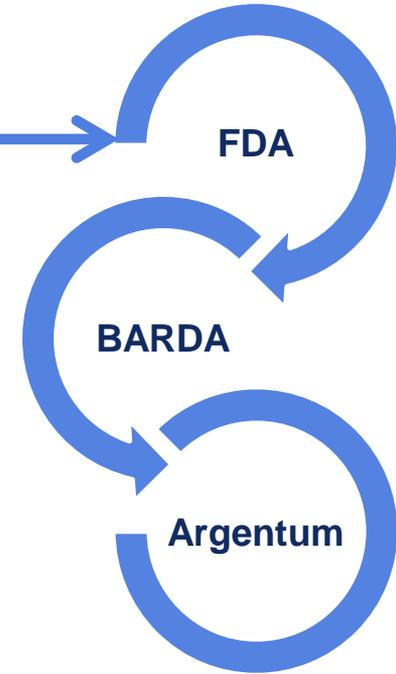
Identified

Challenge: Pathway forward from Regulatory Agency

Solution:

With FDA guidance, a two-pronged approach for CRI:

1. 510(k) pathway for radiation-injury indications symptoms:
 - Erythema
 - Dry Desquamation
2. Animal studies for mitigation of more severe radiation injuries typically not seen in RD cases



Summary

Successful Collaboration

Leads to ONE Commercial Product being developed into 3 different USG Needs

1. Burn/Trauma Dressing
 - Part of the Burn Blast kit
2. Chemical MCM
 - Injuries from sulfur mustard
3. Radiation MCM
 - Cutaneous Radiation Injuries