The Effective Use of Hydrofera Blue®
Bacteriostatic Dressing in Difficult-to-Heal Wounds: An Evaluation of Six Case Studies

HyddroferaBLUE®

Wound healing is heavily dependent upon the stability of the wound environment.

A host of issues—such as underlying health conditions or a deficiency in components essential for wound healing—can corrupt a wound environment. Another key factor that can delay healing is wound infection.[1-4]

Wound infection results from the opportunistic invasion and multiplication of microorganisms.[1] Wound infections may delay the natural healing process[1] or the surgical closure of wounds,[1-3] causing increased pain or discomfort for patients.[5] Additionally, some infections will require treatment with antibiotics, which may promote resistant strains that make future treatment even more challenging.[2-5] Infections also increase the risk of tissue damage,[4] limb loss,[3-4] and even death. As long as wound healing is delayed, healthcare costs and hospital stays will continue to rise.[2-5]

Wound infection in itself is a challenge. There are a number of bacterial strains that can cause infection, some of which may be resistant to certain treatments.[5] Furthermore, the infection is not always apparent and will be identified only through symptoms and clinical signs.[5] In fact, research has shown that 70% of clinicians will treat a wound without ever culturing it for infection identification.[5]

One way to help manage the wound environment and protect it from bacterial contamination is the incorporation of an antimicrobial dressing.[4,6] Common antimicrobials available include silver-impregnated, iodine-impregnated, and gentian violet/methylene blue-impregnated dressings. While these options are all effective in promoting moisture balance and providing a barrier against wound contamination,[6-8] some also have limitations. Silver-based and iodine-based options have minimal absorptive qualities, and are associated with the potential for cytotoxicity and the inactivation of growth factor therapies, which may impact successful wound healing.[1,3,7-9] Both are also contraindicated for use with enzymatic debridement agents.[7,10-12] Microbial resistance to silver exists, which may affect the potency of the antimicrobial as well as introduce problems similar to those of antibiotic-resistant bacteria.[13,14] Furthermore, iodine-impregnated antimicrobials are contraindicated in patients with an allergy or sensitivity to iodine.[6]

These concerns over silver- and iodine-based antimicrobials call for an alternative that helps prevent infection while allowing greater flexibility in wound management.

One such alternative is the use of a gentian violet/methylene blue-impregnated dressing. Hydrofera Blue® Bacteriostatic Dressing utilizes the agents gentian violet and methylene blue to help manage wound bioburden and protect against infection. It has exhibited a broad spectrum of activity against microorganisms commonly found in wounds, including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *enterococcus* (VRE). In addition, research has shown Hydrofera Blue® to be highly absorptive versus other silver and foam dressings, and to exhibit no inhibition of either enzymatic debriders or growth factor activity.[7,8,9,15]

On the following pages we describe a number of case studies of patients who received Hydrofera Blue® Bacteriostatic Dressing as part of wound management therapy. These wounds occurred in patients with underlying health conditions such as diabetes and acute respiratory distress syndrome (ARDS) or in patients who were otherwise previously healthy. The application of Hydrofera Blue® was associated with wound improvement in these difficult-to-heal cases.

The clinical significance of these data is not established.

Case Study 1: Failed Flap

Patient: 62-year-old male in otherwise good health with no significant past medical history.

Wound characteristics and prior treatment:

Large cyst on the back was excised by a dermatologist, with an advancement flap to cover the defect. Distal end of the flap lost blood supply and necrosed. Twenty-five days after the excision, wound presented with dry eschar and softening edges. Wound underwent post-excisional debridement, then was dressed with silver alginate and covered with foam dressing.

- Three days later, additional non-excisional debridement was performed and NPWT was initiated
- After 2 weeks, wound was slightly smaller and NPWT was discontinued
- The following week, wound presented with a film over the surface and required non-excisional debridement of the lower edge

Treatment:

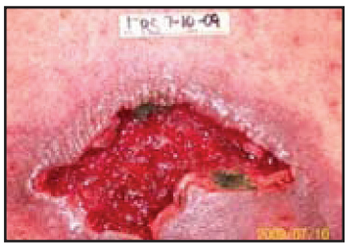
Hydrofera Blue® Dressing with no other dressings was initiated 1 month after initial wound presentation.

Result:

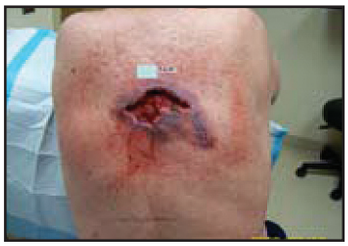
- After 11 days with Hydrofera Blue® Dressing, wound was reduced by 85.5%

Individual results may vary.

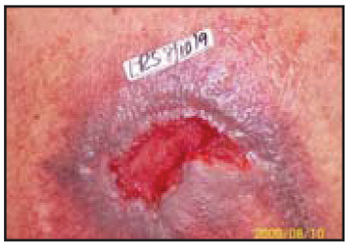
July 10, 2009
(Wound prior to treatment)



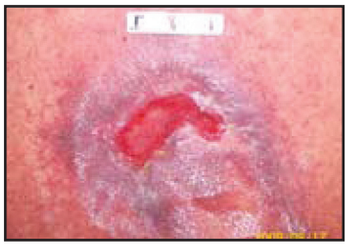
July 10, 2009
(Wound dressed with silver alginate and covered with foam dressing. NPWT initiated)



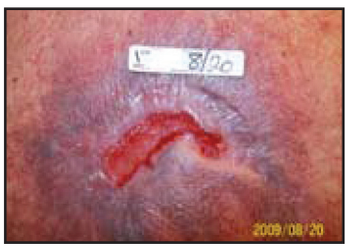
August 10, 2009
(1 week after NPWT discontinued. Hydrofera Blue® initiated)



August 17, 2009
(1 week after application of Hydrofera Blue®)



August 20, 2009
(85.5% reduction 11 days after Hydrofera Blue® application)



Case Study 2: Large Hand Hematoma in ARDS Patient

Patient: 76-year-old male with acute respiratory distress syndrome (ARDS); on multiple medications, including Solu-Medrol® (methylprednisolone sodium succinate) and Lovenox® (enoxaparin sodium injection).

Wound characteristics and prior treatment:

Large hematoma caused by restless banging of hand into bed rail. Hematoma was debrided, with the addition of Ag gel to maintain moisture. Within a few days, additional problems developed, including necrosis/coagulum over the surface and macerated edges.

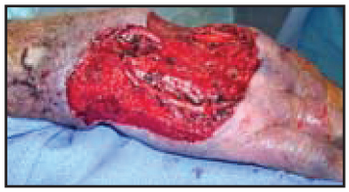
Treatment:

Hydrofera Blue® Dressing applied 5 days after initial debridement.

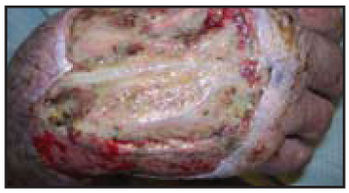
Result:

- Within 9 days following Hydrofera Blue® Dressing application, wound cleaned up and began to granulate
- After 13 days, split thickness skin graft (STSG) was performed with minimal debridement; bolstered with negative pressure wound therapy (NPWT)
- NPWT removed on Day 19
- After 27 days, wound near closure, presenting with a few small areas of graft separation at proximal and distal edges

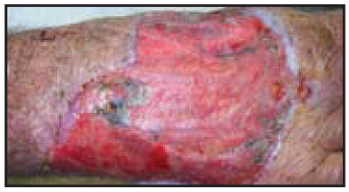
May 8, 2009
(Wound prior to treatment)



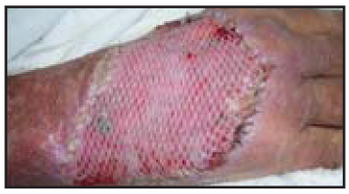
May 13, 2009
(Hydrofera Blue® initiated)



May 22, 2009
(10 days into treatment)

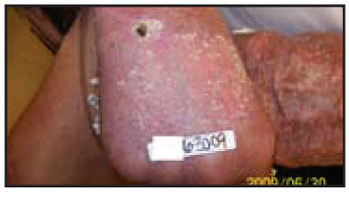


May 26, 2009
(STSG performed and bolstered with NPWT)



June 9, 2009
(27 days into treatment)

June 30, 2009
(Final visit)



Individual results may vary.

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Case Study 3: Acute Necrotizing MRSA-Infected Wound in Long-term Acute Care Setting

Patient: 56-year-old morbidly obese, psychiatrically disabled patient in a long-term acute care setting.

Wound characteristics and prior treatment:

Acute necrotizing back wound infected with Methicillin-resistant *Staphylococcus aureus* (MRSA). Wound presented with extensive cellulitis on the back, extending to the flank, down the hip and lateral thigh. Multiple abscesses, tracking to muscle, expressing copious purulent drainage.

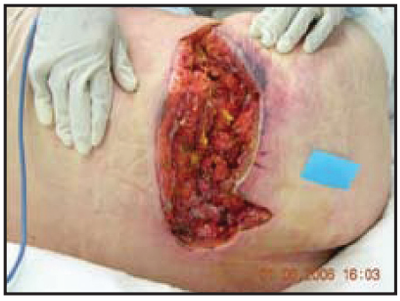
Treatment:

Aggressive surgical intervention followed by application of Hydrofera Blue® Dressing.

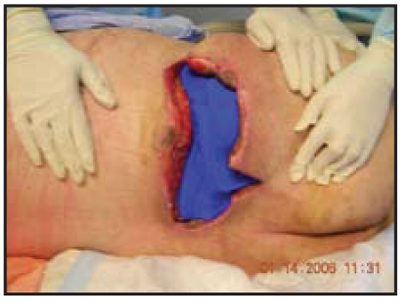
Result:

- Patient progressed to healing and discharge without infection or need for further surgical intervention

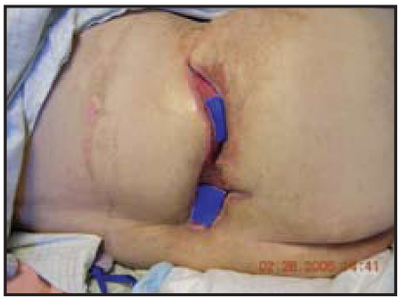
January 6, 2006
(Wound prior to treatment)



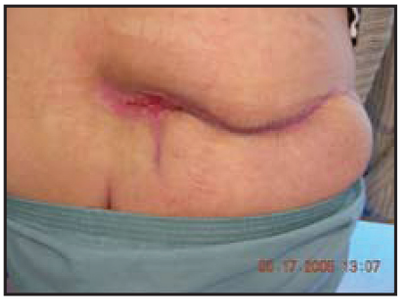
January 14, 2006
(8 days into treatment showing placement of Hydrofera Blue®)



February 28, 2006
(53 days into treatment showing placement of Hydrofera Blue®)



May 17, 2006
(After 4 months of treatment)



Individual results may vary.

Case Study 4: Traumatic Wound in Diabetic Patient

Patient: 75-year-old male with Type 2 diabetes suffered fall on left knee.

Wound characteristics and prior treatment:

Traumatic wound on left knee due to a fall. Wound surgically evacuated and treated with negative pressure wound therapy (NPWT), a silver hydrofiber dressing (Aquacel® Ag Hydrofiber® Dressing), and a natural extracellular matrix (Apligraf®). After 52 days, wound still unhealed with hypergranulation tissue present.

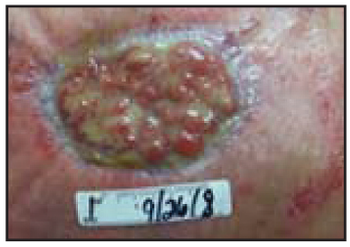
Treatment:

After 52 days, wound management changed to Hydrofera Blue® Dressing.

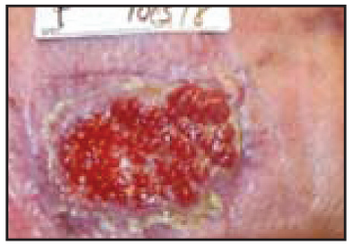
Result:

- After 7 days with Hydrofera Blue® Dressing, wound was cleaner with less hypergranulation
- After 14 days, wound was smaller. OASIS® Wound Matrix added to Hydrofera Blue® Dressing
- After 21 days, switched from Hydrofera Blue® Dressing to a plain foam dressing
- Wound near complete closure at Day 27

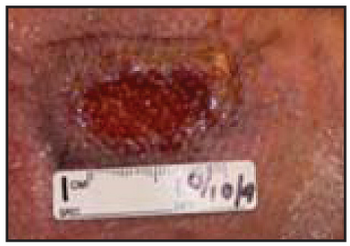
September 26, 2008
(Begin Hydrofera Blue®)



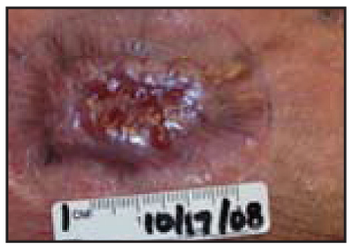
October 3, 2008
(Hydrofera Blue® continued)



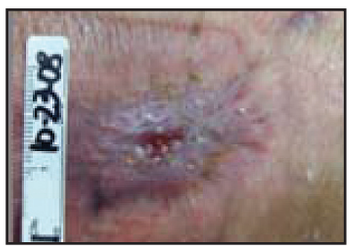
October 10, 2008
(OASIS® Wound Matrix applied; covered with Hydrofera Blue®)



October 17, 2008
(Covered with foam dressing)



October 23, 2008
(Wound nearly closed)



Individual results may vary.

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Case Study 5: Traumatic Wound With Venous Insufficiency

Patient: 60-year-old male with evidence of venous insufficiency. Peripheral pulses present; no other significant medical history.

Wound characteristics and prior treatment:

Wound due to injury 2 months before initial visit. Wound was debrided, dressed with silver hydrofiber, and covered with multilayer wrap. Hypergranulation tissue was present after 8 days of silver hydrofiber dressing and compression.

Treatment:

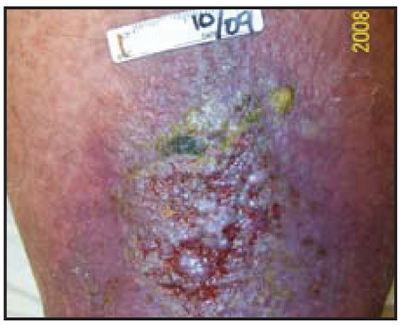
Hydrofera Blue® Dressing added after 8 days.

Result:

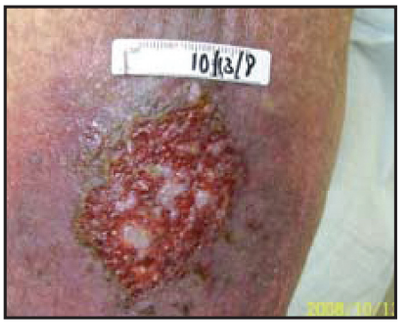
- After 7 days of Hydrofera Blue® Dressing, wound 100% resurfaced with some dermatitis

Individual results may vary.

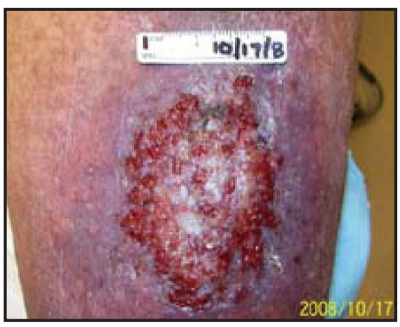
October 9, 2008
(Before treatment)



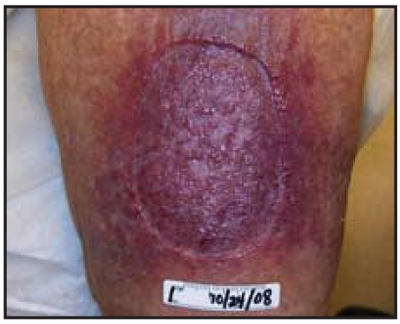
October 13, 2008
(4-day evaluation)



October 17, 2008
(Hydrofera Blue® added)



October 24, 2008
(Wound 100% resurfaced)



Case Study 6: Chronic Venous Ulcers

Patient: 49-year-old female; venous insufficiency; history of sickle cell anemia and previous ulcers.

Wound characteristics and prior treatment:

Two venous ulcers; 2 months' duration; painful to the touch. Initial excisional debridement was performed, followed by cadexomer iodine, dry dressing, and a multilayer compression wrap. Wounds worsened at Week 2, becoming larger with thickened edges, requiring maintenance debridement.

Treatment:

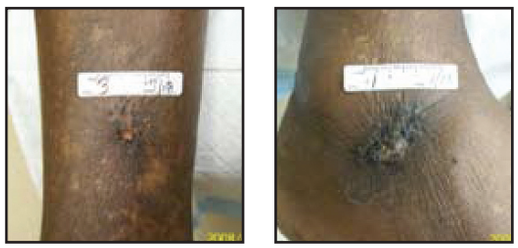
After 2 weeks maintenance debridement was performed, and therapy was switched to Collagenase SANTYL® Ointment* under Hydrofera Blue® Dressing and a multilayer compression wrap.

Result:

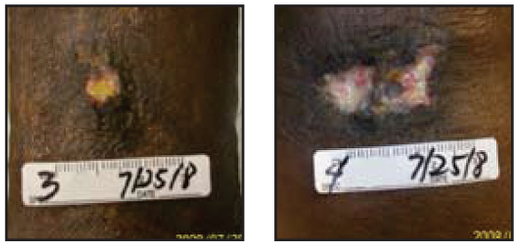
- Medial wound re-epithelialized 1 week later (Week 3); lateral wounds smaller with flatter edges
- At Week 4, medial wound closed and lateral wounds epithelializing
- Lateral wounds healed at Week 6

Medial ▼ Lateral ▼

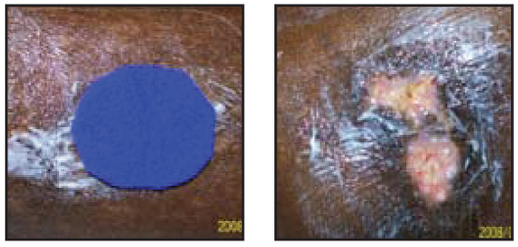
Before treatment
(0.07cm^2; 1.76cm^2)



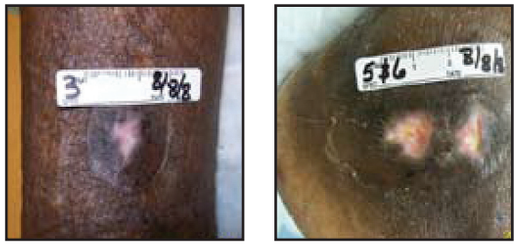
Week 1
(on iodine)



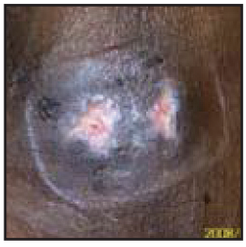
Week 2
(showing SANTYL® Ointment and Hydrofera Blue®)



Week 3



Week 4



Collagenase SANTYL® Ointment is a registered trademark of Healthpoint, Ltd.

Individual results may vary.

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Discussion

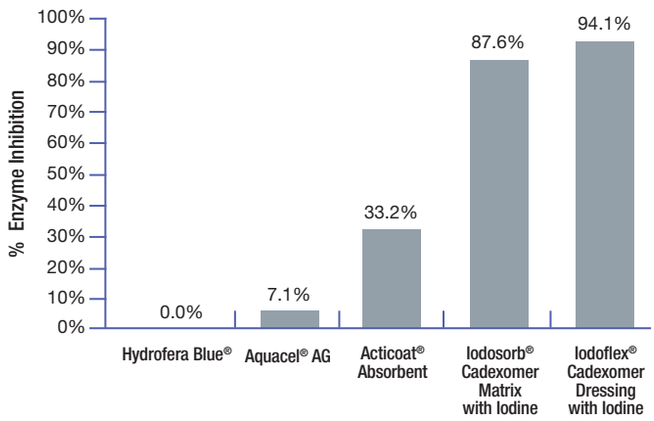
These case studies demonstrated the effectiveness of Hydrofera Blue® to help in the management and prevention of infection in a variety of wound types, including knee, back, and hand wounds and chronic venous leg ulcers. With the exception of one case, these wounds had been unsuccessfully managed with other therapies prior to the application of Hydrofera Blue®. There was no evidence of wound infection present in any case after the initiation of Hydrofera Blue®. Improvement was noted within 1 to 2 weeks following initial application. Two wounds were at complete closure within 4 to 6 weeks after application; 2 additional wounds were near closure within 4 weeks.

Patients were within the ages of 49–76. Most were suffering from other underlying health conditions that may have contributed to the wound's slow progression toward healing including diabetes, obesity, venous insufficiency, sickle cell anemia, and acute respiratory distress syndrome (ARDS). One case featured an acute necrotizing wound infected with Methicillin-resistant *Staphylococcus aureus* (MRSA). This wound progressed toward healing without infection after the application of Hydrofera Blue®.

Two of these cases demonstrated the successful use of Hydrofera Blue® with other wound management agents. This finding is consistent with other studies documenting the compatibility of Hydrofera Blue® with enzymatic debridement agents.[7,15]

Hydrofera Blue® Dressings are Compatible With Enzymatic Debriders

In vitro 24-hour Digestion of Collagen in Artificial Eschar Model by Collagenase[7]



As shown in these case studies, Hydrofera Blue® helps protect against infection by inhibiting the growth or reproduction of bacteria commonly associated with wound infection, including MRSA and vancomycin-resistant *enterococcus* (VRE). To further protect wounds from harmful microorganisms, Hydrofera Blue® absorbs bacteria-laden exudates away from the wound bed and physically binds endotoxins to the dressing.[7]

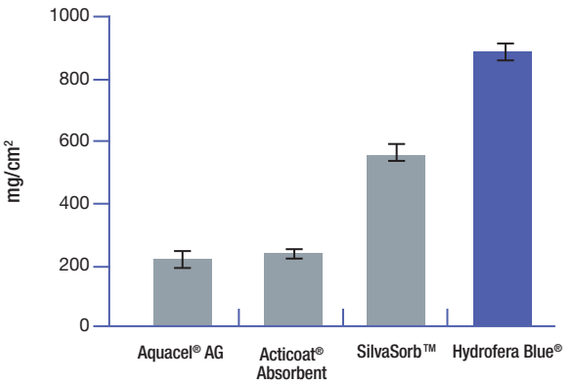
Collagenase SANTYL® Ointment is a registered trademark of Healthpoint, Ltd.

Hydrofera Blue® is a highly absorptive dressing, with absorption capacity superior to many silver-impregnated dressings, and equal to that of high-absorbency foams.[9]

Furthermore, Hydrofera Blue® has been shown to not inhibit the activity of enzymatic debriders,[7,15] fibroblast growth factors (FGF), or platelet-derived growth factors (PDGF).[7,8]

Absorbency Compared to Silver Dressings[9]

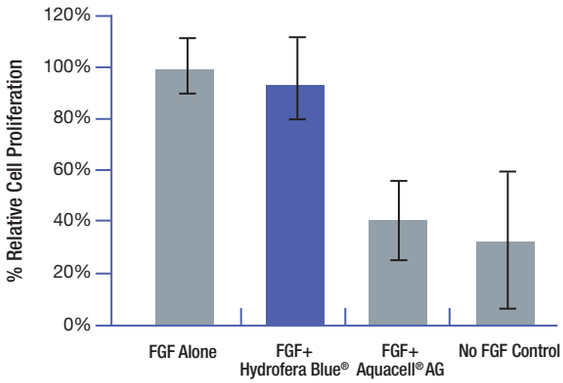
Absorbency Comparison by Surface Area *(in vitro study)*



Greater absorption capacity than leading silver-impregnated dressings.

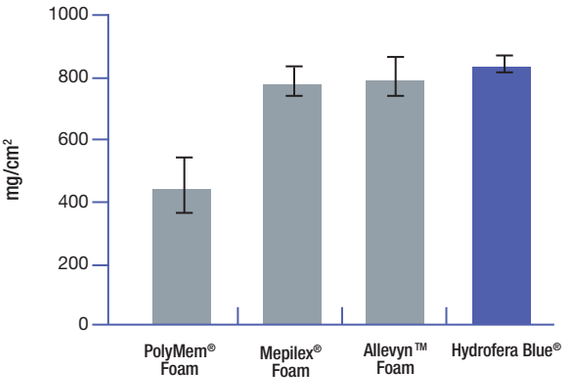
Hydrofera Blue® Dressings Do Not Inhibit Growth Factor Activity[8]

Hydrofera Blue® Dressing Does Not Inhibit Fibroblast Growth Factor (FGF) in *in vitro study*



Absorbency Compared to Foam Dressings[9]

Absorbency Comparison by Surface Area *(in vitro study)*



Similar or superior absorbency than other highly absorptive dressings.

In conclusion, these studies substantiate the advantages of Hydrofera Blue® Bacteriostatic Dressing to help manage wound bioburden and help prevent infection in a variety of wound etiologies.

The clinical significance of these data is not established.

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