Dual Antimicrobial Silicone Adhesive Securement Dressings.

What's the difference, and why it matters.

Val DiTizio, Ph.D, Chief Scientific Officer | John Hands, Executive Vice President

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Executive Summary

Central line associated blood stream infections (CLABSIs) represent the most costly of all hospital acquired infections (HAIs)[1]. Healthcare innovations, including antimicrobial vascular access dressings have contributed to the fight against these costly events. Skin can, however, be vulnerable to components of these dressings, including, but not limited to the amount of antimicrobial used, and the nature of the adhesive. Now, a new dual antimicrobial silicone adhesive film dressing - IV Clear™ (Covalon Technologies Ltd.) is available. This innovative technology protects over 7 days, achieving 99.99% bactericidal activity without the potential down-sides of higher levels of antimicrobial or acrylic adhesives on the skin.

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On a per-case basis, central line–associated bloodstream infections were found to be the **MOST COSTLY HAIs** *at $45,814*[1]

Healthcare-associated infections (HAIs) in hospitals impose significant economic consequences on the healthcare system.

HAIs are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care[2]. Risk factors for HAIs, and Catheter Related Blood Stream Infections (CRBSI) in particular include patient-, catheter-, and operator-related factors. Patient-related factors that increase risk of bloodstream infection include increasing severity of illness, granulocytopenia, compromised integrity of the skin, and presence of distant infection[3]. HAIs are usually serious infections typically causing a prolongation of hospital stay and increased cost and risk of mortality.

Although antiseptic agents are used to disinfect the skin prior to catheter insertion, bacteria remain on the skin and bacterial re-growth will occur over time[4]. Hence, healthcare facilities are facing increasing pressure to minimize the total cost of infection and are highly committed to finding solutions, and while quality improvement initiatives have decreased HAI incidence and costs, much more remains to be done[1].

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A new tool in the box:

Transparent Dual Antimicrobial Silicone Adhesive Dressings

One recent innovative solution has been to incorporate antimicrobial agents within a vascular access dressings' own adhesive. IV Clear™, developed by Covalon Technologies Ltd., has utilized an advanced technology to integrate two antimicrobial agents (chlorhexidine and silver) into a soft and hypoallergenic silicone adhesive, which is then coated on a breathable, waterproof, and transparent polyurethane film. The patented technology protects the incorporated silver from discoloration, maintaining the transparency of the dressing for up to seven days. This allows for continuous visual assessment of the insertion site, and prevents unnecessary dressing removal.

The absence of site visibility can be serious, as was realized by a young patient whose mother (who also happens to be an RN) wrote to the authors saying,

> *"He had an acrylic film dressing <brand name removed by author> and a chlorhexidine impregnated disc <brand name removed by author> on.... I wanted to take advantage of having the IV Clear and get the acrylic film off ASAP; it had only been 4 days. Thank God I did because other than the standard redness from the acrylic film, … I found such a nasty reaction under the chlorhexidine impregnated disc. I had no idea he was blistering like this."*

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Furthermore, IV Clear™ can be used to secure devices to skin and is waterproof, so patients are able shower without saturating the dressing.

Another patient's mother wrote to the authors recalling the importance of what these features mean to her son's quality of life, underscoring that innovations of infection prevention products aren't always judged solely on their ability to kill bacteria:

> *"Thanks to IV Clear, instead of worrying about his line, he is able to spend more of his time doing things typical kids do; playing games with his family and friends, riding mules, creating YouTube videos, dancing, and focusing on schoolwork"*

This innovative transparent dual antimicrobial silicone adhesive technology represents the nexus between patient protection and patient comfort.

Not Created Equal

IV Clear™ has the unique advantage of two antimicrobial agents, chlorhexidine and silver. Chlorhexidine has broad-spectrum activity against a wide range of both Gram-positive and Gram-negative organisms as well as yeast and fungi with a low mammalian toxicity profile[5,6].

Although chlorhexidine has been found to be effective against a wide range of bacteria, some hospital-acquired Gram-negative bacteria, including Pseudomonas and Klebsiella, are resistant to chlorhexidine[7,8]. Therefore, silver was added in combination with chlorhexidine to enhance the antimicrobial performance of IV Clear™. Silver has been used for many years in clinical settings. It is an antimicrobial agent with broad-spectrum antimicrobial activity and low toxicity to the human body. It is reported to have activities against Gram-negative and Gram-positive bacteria and there is also a minimal development of bacterial resistance. Of the commonly used forms of topical silver application, silver dressings are used extensively for wound management[9].

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Furthermore, it has been shown that there is actually a 'synergistic' effect of having both chlorhexidine and silver within the silicone medium. "The combination of chlorhexidine diacetate and silver sulfate has synergistic, enhanced antibacterial activity against several strains of P. aeruginosa and MRSA. These results suggest improved skin antisepsis when these antimicrobial agents are used in combination in a cover dressing" Bloom et al (2014)[10].

The antimicrobial effectiveness of IV Clear™ has been demonstrated in both *in vitro* and *in vivo* studies with greater than 4-log reductions or 99.99% of initial inoculum achieved for eight microbial pathogens commonly associated with catheter-related blood stream infections†.

IV Clear™s antimicrobial activity is achieved while using minimal amounts of chlorhexidine when compared to competitors on a per dressing basis*:

"Do No Harm"

Chlorhexidine skin reactions are rare, but can happen as evidenced in a recent JAMA Dermatology paper documenting the susceptibility of pediatric skin to high local concentrations of chlorhexidine[11]. As stated in Weitz et al. (2013),

> *"Because the patients most likely to be exposed to chlorhexidine gluconate-containing dressings are severely ill and often immune-compromised, they are most vulnerable not only to the irritant sequelae of this exposure but also to infectious processes that could mimic ICD (irritant contact dermatitis)"*

This erosive effect can then ironically lead to the exact opposite of the desired objective by creating a larger portal of entry for infection.

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The appearance of erosive contact dermatitis in sensitive patients upon exposure to chlorhexidine-impregnated dressings such as Tegaderm™ CHG is consistent with both the relatively high chlorhexidine concentration in the dressing and the rapid rate of release of the chlorhexidine when exposed to moisture (2327 3 837 Qg/g after 7-days elution†).

IV Clear's antimicrobial activity is achieved while using minimal amounts of chlorhexidine when compared to competitors on a per dressing basis*

Brands	Total Chlorhexidine per Dressing	
	Smallest	**Largest**
Biopatch	52.5mg	92mg
Tegaderm CHG (Gel Pad)	15mg	78mg
IV Clear	7.2mg	54mg

Table 1

In contrast, the chlorhexidine diacetate present in IV Clear™ is less easily removed from the dressing because of its lower water solubility relative to chlorhexidine digluconate. In addition, the majority of the chlorhexidine diacetate is embedded within a hydrophobic silicone matrix, which helps to moderate the release of chlorhexidine (466 3 126 Qg/g after 7-days elution†) and reduces the likelihood of developing erosive contact dermatitis when using IV Clear™ on sensitive individuals.

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Nobody Likes "MARSI"

In addition to the skin damage that may be caused by the presence of chlorhexidine in some IV dressings, the adhesive itself is often linked to adverse events in sensitive patients. It is well known that the acrylic adhesives used in many film dressings can lead to epidermal stripping and pain, and may result in more severe consequences such as wounds. Medical Adhesive Related Skin Injuries (MARSI) is an under-recognized complication that occurs across all care settings and among all age groups, however some patient groups may be at higher risk (ie. pediatrics, geriatrics, oncology).[12]

IV Clear™ overcomes the disadvantages of acrylic adhesives through the use of silicone polymers as the adhesive component.

The aggressive nature of acrylic adhesives can be explained in part by the chemical nature of the bond between the acrylic polymer and skin components. The latter bonding reaction occurs not only immediately upon contact between dressing and skin, but continues to develop in strength as long as the dressing is in place. Beyond the mechanical damage caused by acrylic adhesives, the pain or anxiety related to dressing changes causes patients stress, which can contribute to poorer outcomes.

Based on this reduced risk of injury, clinicians are choosing IV Clear™ for patients that are at risk (i.e. infusion patients) while recognizing the greater potential of the "highly desirable" characteristics of the dressing as a whole.[13]

IV Clear™ overcomes the disadvantages of acrylic adhesives through the use of silicone polymers as the adhesive component. Silicone materials are highly inert with high tolerances to both heat and cold and they do not easily form chemical bonds to other materials, including skin. The adhesive nature of certain silicone polymers is derived from purely physical interactions between the polymers and the contact surface.

Consequently, silicone adhesives have a lower surface tension, resulting in lower peel force and less propensity for epidermal cell stripping and discomfort[11]. The skin-friendly properties of IV Clear™ were clearly demonstrated in a comparative study in human volunteers which showed significant reductions in pain scores relative to an acrylic adhesive-based competitor upon dressing removal†. Preventing MARSI has the potential to reduce complications, increase patient satisfaction, and improve clinical outcomes.[14]

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Now, the choice is **Clear.**

The use of antimicrobial dressings has increased substantially over recent years, with numerous dressings now available on the market. The scientific literature contains a wide variety of publications supporting the use of these dressings to suppress the re-growth of the skin's natural flora, which is known to contribute to the majority of CRBSIs.[15]

IV Clear™ dual antimicrobial silicone adhesive dressings now give the clinician a new option that won't force a decision between:

- Gram-positive and Gram-negative antimicrobial efficacy
- Transparency and comfort
- Adhesion and patient skin safety
- Infection protection and cost

If you are a clinician and are interested in evaluating IV Clear™ at your facility, please contact Covalon at ivclear@covalon.com or call 1-877-711-6055.

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† Covalon Technologies Ltd. Data on file.

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