

What are biofilms?

Microbial biofilms are emerging as a topic of increasing concern in many areas of clinical medicine. Biofilms – organized populations of microbes adherent to a surface (“sessile”), rather than free-floating in solution (“planktonic”) – are formed when adherent microbes (most commonly bacteria) secrete and surround themselves with a complex matrix of macromolecules, producing a physical barrier that provides protection from host immune cells and reduces diffusion of antimicrobial drugs. In addition, the bacteria within the biofilms have altered responses to antimicrobial agents. As a result, microbes within biofilms are significantly more resistant to standard antibiotic therapy, requiring (according to some reports) up to 1000 times the antibiotic dose to achieve efficacy.

Why are biofilms important clinically?

It is estimated that the majority of clinical infections exist as a biofilm rather than as planktonic cells. Biofilms commonly form on all types of implantable devices, including temporary implants (such as urinary and vascular catheters) and permanent implants (such as pacemakers and defibrillator devices). If left untreated, biofilm device infections can lead to significant morbidity and mortality, and may impair device function. Removal and/or replacement of devices is often the only treatment option, which can be very costly and also risky to the patient.

In addition, biofilms are estimated to be present on the surface of 60% or more of chronic wounds, and likely contribute to the inability of such wounds to heal in response to standard therapies. Because the biofilms are recalcitrant to standard antibiotic treatment, wound care now includes debridement, or physical scraping, of the wounds to physically remove the biofilm, which is a time-consuming and painful process. While debridement may allow for efficacious treatment of the infection and re-epithelialization of the wound, new therapeutic approaches are needed to better address this clinical problem.

Although administration of intravascular antibiotics is considered a standard regimen to prevent surgical site and other infections, the formation of a biofilm means that standard intravenous antibiotic therapy will often be ineffective at eradicating the bacteria. In addition, the continuing emergence of bacterial strains resistant to antibiotics has led to a more judicious approach to systemic antibiotic use in order to limit further development of resistant strains. Taken together, these trends – emergence of biofilms in clinical infections, and the rise in resistant strains – present greater challenges in treating and preventing infections in the clinical setting.

What does this mean for medical device and biologics manufacturers?

Since standard antibiotic therapies are proving to be relatively ineffective at reducing or eradicating biofilm infections, new approaches and technologies must be developed and tested to provide the next generation of infection-control products and therapies. Products aimed at reducing existing biofilms are needed for wound treatment and other applications, while products aimed at preventing device infections from becoming established (for example at the site of surgical implants to prevent surgical site infections) may also provide clinical benefit by eradicating bacteria before they have the opportunity to form a biofilm. To meet the demand of biofilm-targeted product development, new methods of testing products for their effects on biofilm are being generated. Both in vitro and in vivo models of biofilm formation and/or infection are being utilized to provide safety and efficacy testing for these important products.

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