



BioInteractions

Advancing Healthcare
Through Innovation™

Biointerfaces

Microbiology assays

BioInteractions have developed and adapted several assays to test the antimicrobial properties of non-leaching coatings, directly on medical device surfaces. BioInteractions can provide microbiological evaluation of your coated device.

The Challenge

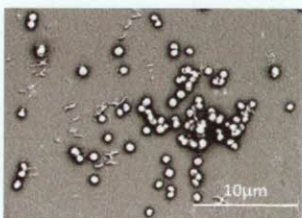
Most assays, designed to test the antimicrobial properties of coatings, are optimized for leaching coatings. Leaching coatings release antimicrobial compounds to the surroundings and have short lifetimes, while non-leaching coatings maintain their properties over time because they are based on anti-adhesive and contact kill technologies. Most microbiology tests are only able to assess bacterial kill in the environment surrounding the devices for short periods and are not able to evaluate the antimicrobial properties of the coating directly on the coated device; or, were designed to test representative materials only.

BioInteractions have designed a range of microbial assays designed to investigate each individual step, leading to bacterial colonisation of medical devices

1) Device Contamination

Bacteria come into contact with medical devices in many ways. Non-leaching antimicrobial coatings inactivate microorganisms through a contact-kill mechanism and this property can be tested using **BioInteractions' Dynamic Contact Assay**. The assay is designed to facilitate optimal contact between bacteria in suspension and the device, thus allowing efficient evaluation of the contact kill properties of the coatings. The performance of the non-leaching coating is indicated by a reduction of live bacteria in the suspension.

2) Bacterial Adhesion



Bacterial infection starts when bacteria adhere to the device, forming clusters of cells. The **Ahearn Adhesion Test** quantitatively measures live bacteria attached to the device surface. For that, the device is challenged with bacteria under optimized conditions, which

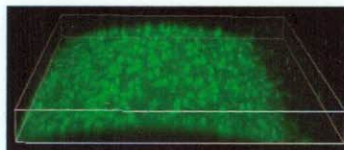
promote high bacterial attachment to the device surface. Comparison of the number of bacteria recovered from coated and uncoated surfaces indicates the coating efficiency.

3) Bacterial Colonization and Biofilm Formation

After adhesion, bacteria start to multiply on the surface, forming 3D structures (biofilms) that have increased resistance to antibiotic treatment. BioInteractions have developed a novel method to quantitatively evaluate biofilm formation on a device surface. In the **Static Biofilm Assay**, devices are challenged in optimal conditions for biofilm growth. The biofilm formed on the device surface is recovered and quantified. The coating efficiency is evaluated by comparing biofilm formation on coated devices against uncoated controls. For certain devices, such as catheters, this assay allows simultaneous evaluation of biofilm formation in the lumen(s) and on the catheters exterior surface.

4) Mature Biofilms

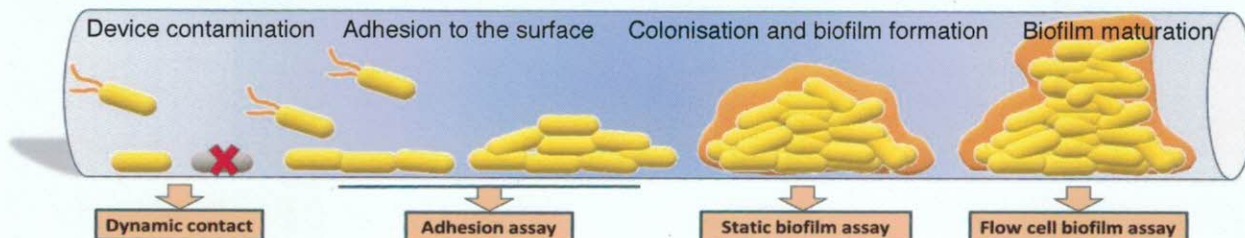
Prolonged colonization results in maturation of the biofilm. In the body, mature biofilms can lead to septicemia (blood infection). The flow cell system was further developed to challenge devices under constant flow of fresh nutrients that allow bacteria to develop mature biofilms. In **BioInteractions' Flow Cell Assay** the devices (coated and uncoated) are challenged inside an uncoated flow chamber. Biofilm formed on the wall of the uncoated chamber ensures constant challenge of the devices, which creates an extreme environment where the coating can be tested for resilience. The biofilm can then be visualised using Microscopy or quantified using various established methods.



Confocal 3D image of biofilm on the surface of an uncoated catheter, after challenge in the flow cell assay. The biofilm covers the entire surface, revealing the catheter's shape.

Collaboration

BioInteractions offers a range of services to support our clients and can provide performance data for technical files, marketing material and data for regulatory submissions / approval.



BioInteractions Ltd.
Science and Technology Centre
Earley Gate, Whiteknights Road
Reading, Berkshire, RG6 6BZ
United Kingdom

T +44 (0)118 935 7000
F +44 (0)118 935 7917
E general@biointeractions.com

www.biointeractions.com



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