

COMPLICATIONS ASSOCIATED WITH IMPLANTED MEDICAL DEVICES

Nearly half of all medical devices implanted in the human body are plagued with one or more complications – including healthcare associated infections, blood clots, improper healing, and cell overgrowth.

Healthcare Associated Infection (HAI)

- The majority of HAIs stem from the colonization of implantable medical devices, which provide a source of contamination and a surface for bacterial growth. Once these infections take hold on the device surface, they form complex “biofilms,” which are often untreatable by conventional antibiotics.
- If infection reaches the bloodstream, it lengthens average hospital stays by approximately two weeks, costs up to \$50,000 to treat, and increases mortality by up to 25%, resulting in nearly \$30 billion per year in direct medical expenses^{1,2}.
- The continuous growth of antibiotic resistance to certain bacteria and the lagging development of novel antibiotics are making the treating of healthcare associated infection increasingly difficult.
- There is mounting pressure in the healthcare industry to quickly address these growing problems, fueled by reduced Medicare reimbursement for hospital errors, mandatory infection rate reporting, and the skyrocketing prevalence of drug-resistant bacteria.
- The U.S. Department of Health and Human Services has determined that the scientific basis for acquisition of numerous healthcare associated pathogens is poorly understood. In its Action Plan to Prevent HAIs, HHS has recommended the development of strategies to prevent and/or eliminate biofilms associated with medical devices.

Blood Clots

- **Device thrombosis, or blood clotting, can clog catheters in up to 25% of cases³.** “Openness” to blood flow is a critical concern for catheters, vascular grafts, and stents. Thrombus formation on the surface of these technologies can constrict or block flow entirely, often requiring costly device replacement and increasing the risk of severe complications and death.

Improper Healing

- **Improper healing can necessitate device removal.** Despite advances made in orthopedic joint implants, for example, there is still a high failure rate for devices implanted into osteoporotic bone which does not fully integrate into the implant surface.

Cell Overgrowth

- **Hyperplasia, or cell overgrowth, often leads to device failure.** The use of pharmaceuticals known as “restenosis inhibitors” in the drug-eluting stent market has made marked advances to reduce hyperplasia. However, a range of other devices, such as vascular grafts, are in need of improved protection from cell overgrowth in long-term use.