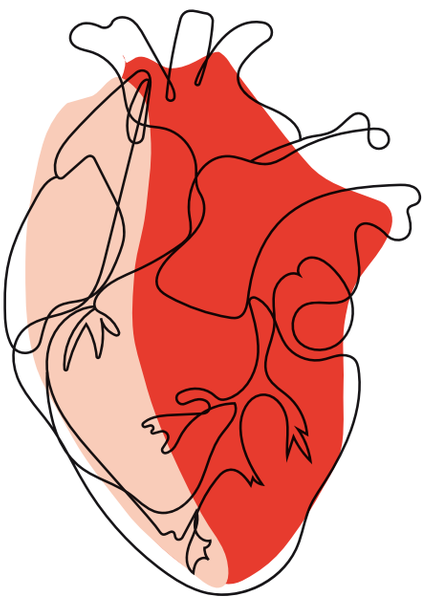
REDUCING IMPLANTABLE DEVICE INFECTIONS



EVEN AS JEFFERSON RESEARCHERS HELP ADVANCE MEDICAL care by developing wholly new treatments, methods and tools, they are also working hard to reduce complications associated with procedures performed by tertiary care centers across the country. Post-procedure infections, in particular, can be a pernicious and costly problem. Clinician-scientists throughout the Jefferson system are pursuing clinical trials that aim to address the problem.

For example, **Arnold J. Greenspon, MD**, professor of medicine and director of the **Jefferson Cardiac Electrophysiology Laboratory**, is working to address the problem of infections associated with cardiac implantable electronic devices (CIEDs), such as pacemakers, implantable cardioverter-defibrillators and cardiac resynchronization therapy devices. While any medical device or product implanted in the human body can become infected, hospitals across the country have seen the rate of CIED infection grow faster than that of other types of device implantations. These patients must return to the hospital to have the device removed and to undergo antibiotic treatment. Subsequently, they must have a replacement implanted.

Surgical site infections can be devastating to patients; consequences can include sepsis, limb loss and even death. In addition, these infections can be costly to our nation's healthcare system, adding an average of 4.3 days to hospital stays and $10,497 per patient to the overall cost.

"Although overall infection rates are very low—currently, only about one percent of recipients develop a CIED-related infection—they are bad experiences for patients, potentially even fatal," says Dr. Greenspon.

Moreover, a study he co-authored last year found that CIED infections are quite costly—with expenditures for Medicare fee-for-service beneficiaries ranging from $22,000 to $77,000 per case.

Studies to Prevent CIED Infections

For those reasons, Dr. Greenspon has been collaborating in a series of research studies seeking to define the factors that cause these infections to develop. He has also partnered in an array of multi-center trial approaches for reducing the rate of CIED infection. A report on the most recent of those trials, centering on an absorbable, antibiotic-eluting mesh "envelope" for the CIED, was published recently in New England Journal of Medicine. It showed that use of the antibacterial envelope resulted in a significantly lower incidence of major CIED infections than standard-of-care infection-prevention strategies alone, without notable added complications.

Now, Dr. Greenspon is collaborating with researchers at Vanderbilt University on a trial with

patients at high-risk for CIED infection. It will seek to determine if use of the antibacterial envelope with an additional, post-procedure application of systemic antibiotics will further reduce incidence of infection.

Reducing Infections in Vascular Procedures

Paul DiMuzio, MD, MBA, William M. Measey Professor of Surgery and director of **Jefferson's Division of Vascular and Endovascular Surgery**, has led two studies on the use of a "negative pressure therapy" to reduce infections at the incision site in vascular surgical procedures. Both studies compare standard surgical dressings with the PREVENA™ Dressing Kit, a negative pressure dressing that continuously drains exudates from surgical incisions, which is applied immediately in the operating room.

The first study, published last year in the *Journal of Vascular Surgery*, focused on vascular groin incisions, where complications rates are as high as 44 percent, nationally. The randomized controlled trial focused on 119 femoral artery incisions considered high-risk for complications. Compared to patients receiving standard dressing, the negative pressure therapy resulted in significantly fewer wound infections (9 percent), reduced patient reoperation and readmission and an average savings of $6,045 per patient.

The second study, now in progress, is testing negative pressure therapy for surgical wounds following lower-leg amputation. Wound complications in this setting have been reported as high as 34 percent nationwide. This multi-center trial aims to enroll 440 patients who will undergo above- or below-knee amputations at one of six participating medical centers in the United States and Europe. Results from the study are expected to be available in late 2021.

"We are particularly excited about the potential for reducing wound infections for this patient population, many of whom are suffering from peripheral vascular disease, diabetes or heart failure and are particularly vulnerable to post-surgical infections," says Dr. DiMuzio. ■