

TYRX, Inc. Clinical Study Announcement

TYRX would like to invite CIED-implanting electrophysiologists to participate in the *CENTURION* and *CITADEL* clinical studies of the FDA-cleared AIGISRx® Anti-bacterial Envelope and FS (Flat Sheet Mesh) products.

Background:

CIED infections are increasing in frequency faster than CIED implantations. They are associated with significant morbidity, mortality, and cost.¹ The AIGISRx Anti-bacterial Envelope and FS are FDA-cleared devices that are designed to stabilize the CIED implantation site and help reduce CIED infections by releasing the antibiotics minocycline and rifampin.²



Study Design:

The *CITADEL* Study is a multicenter, prospective cohort study designed to define the clinical performance of the AIGISRx Anti-bacterial Envelope and FS in patients undergoing CIED replacement with an implantable cardioverter-defibrillator (ICD) device. www.ClinicalTrials.gov: *CITADEL* (NCT01043861)

Purpose:

Define the clinical performance of the AIGISRx Anti-bacterial Envelope and FS in patients undergoing CIED replacement with an ICD Device.

Primary Endpoints:

CIED mechanical complications and CIED infection

Patient population:

Patients > 18 years old who receive CIED implantation with an ICD who meet all inclusion/exclusion criteria

Length of Patient Follow-up:

Up to 12 months

Patient Enrollment:

CITADEL is designed to enroll 2300 prospective patients in 50 sites

Data Collection:

Electronic case-report forms

Additional Information:

TYRX Booth # 2010 OR Steve Sisk (609 894 2289 – ssisk@tyrx.com)

- 1 Baddour et al. Update on cardiovascular implantable electronic device infections and their management. A scientific statement from the American Heart Association. *Circulation* 2010; 121: 458-477
- 2 Based upon preclinical *in vitro* and *in vivo* data. Data on file at TYRX and published in *PACE* 2009;32(7) 898-907.

CAUTION: Federal law limits the device to sale by, or on the order of, a licensed practitioner. For full prescribing information, including Indications, Warnings, Cautions and Contraindications, See Instructions for Use.