

**Heart Failure Therapy/LVAD Research and Development Expertise for Dr. George Yanulis,
D.ENG. (Biomedical Engineering)**

- Involved and continue to be involved left ventricular assist device research and development (R&D)
- Expertise on the R&D Bridge to transplantation devices for patients in heart failure
- Research & Expert case-related experiences
- Extensive cardiac device implant and ablation device product design and design and execution of animal studies, including over 200 implants and 500 physiological monitoring studies (canine model).
- Performed over 500 ECG signal detection & cardiac pressure/volume analysis (canine model)
- Provided all biomedical engineering analysis and fabrication and participating in the cardiac device implants in the preclinical device animal surgical suite (Cleveland Clinic – 2005-2008)
- Provided my Expertise for a Heart Bypass System
- Reviewed Perfusion Systems Diagrams fir a Heart Bypass System case as an Expert Witness
- Reviewed Quality Assurance Testing and Results for both atrial fibrillation (AF) therapy and other heart failure (HF) devices
- Expert on cardiac pacemaker and ICD devices for Medtronic; St Jude Medical/Abbott; and BSCI and 2 health systems (over 15 to date)
- Evaluated cardiac pacing and ICD lead/system failures
- Reviewed cardiac pacing and ICD monitoring sessions as an Expert Witness for over 10 cardiac pacemaker and ICD cases
- Expertise in the use radio frequency ablation systems for cardiac ablation therapy systems as a Consultant (for a health care system) and has part of my doctoral research at the Cleveland Clinic:
- Participated in Ablation Therapy Devices being tested on the canine model as a doctoral student (Cleveland Clinic)

- Evaluated and provided my expertise for successful approval with the FDA for two start-up firms involved in AF system development
- Expertise in technical file review including the following for atrial ablation therapy system; several cardiac pacemaker device cases; ICDs; heart bypass systems
- Evaluated Design verification and validation protocols and reports as an Expert Witness
- Have reviewed over 1000 MAUDE as an Expert Witness/Medical Device Consultant
- Have Reviewed several MDR(s), Complaint Investigations, CAPA(s), Non-conformance(S) and Change Control(s) for all types of cardiac device and cardiac imaging systems
- Expertise in developing Final Evaluation Report(s) related to their current validation and verification tasks and provided recommendations as part of their submission to the FDA subsequent to an FDA site visit which had been approved by & Development and Quality Review Divisions at BSCI, Therakos, Inc, St. Jude/Abbott, and Medtronic.

Additional Heart Failure (HF) therapy device patient expertise

- Co-Investigated the implementation of coupled pacing (CP) (a novel pacing paradigm) for controlling the ventricular rate of mechanical contraction (VRMC)
- Performed Preclinical Device Trials on cardiac pacing algorithms (Cleveland Clinic, 2005-2008)-
- Expertise in inducing rapid pacing in six dogs, we applied the following pacing modalities: rapid right ventricular (RV) pacing, rapid CRT, CRT with an additional RV paced beat (CP) at a specific delay (CRT + CP), and CRT with vagal stimulation (CRT-VS) in order to better understand the physiological changes associated with Heart Failure (refer to peer review publications listed below):

-Lim P, Yanulis GE, Verhaert D, Greenberg NL, Grimm RA, Tchou PJ, Lellouche N, Wallick DW. Coupled pacing improves left ventricular function during simulated

atrial fibrillation without mechanical desynchrony. Euro pace. 2010 Mar;12(3):430-6. doi: 10.1093/euro pace/eup440

-Yanulis GE, Lim P, Ahmad A, Popović ZB, Wallick DW. Coupled pacing reverses the effects of persistent atrial fibrillation on the left ventricle. Ann Thorac Surg. 2008 Sep;86(3):984-7. doi: 10.1016/j.athoracsur.2008.03.085

-Yanulis GE. A novel cardiac pacing paradigm for atrial fibrillation and heart failure patients [dissertation]. [Cleveland (OH)]: Cleveland State University; 2008 May. 106 p.

-Cingoz F, Yanulis GE, Ching E, Fukamachi K, Wallick DW. Use of conventional dual chamber pacemakers with custom lead adapters to induce atrial fibrillation or heart failure in dogs. Ann Thorac Surg. 2007 May;83(5):1858-62.

- **Reviewed a Heart Bypass Template Risk Analysis and Risk Management Materials**
- **Reviewed System's Perfusion Bypass Records**