

George E. Yanulis

M. ENG., M.S., D. ENG.

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Experience in Representing and Consulting for Major Multi-National Medical Device Companies

EDUCATION

Doctorate in Engineering <i>Biomedical Engineering</i>	Cleveland State University/Cleveland Clinic	2008
Master of Science <i>Bioengineering</i>	University of Pittsburgh	2002
Master of Engineering <i>Biomedical Engineering</i>	University of Virginia	1981
Bachelor of Arts <i>Premedical Studies/Chemistry</i>	Syracuse University	1977

PROFESSIONAL EXPERIENCE

President / Subject Matter Expert <u>Medical Device Consulting, LLC</u> <i>Clinical Engineering</i>	Pinellas Park, FL June 2014 - Present
Adjunct Professor <u>Temple University</u> <i>Bioengineering Department</i>	Philadelphia, PA January 2016 – January 2018
Expert Consultant <u>B. H. Barkalow & Assoc, LLC</u> <i>Clinical Engineering</i>	Newaygo, MI March 2014 – June 2016
Senior Medical Device Consultant <u>Laughlin Engineering Firm, LLC</u> <i>Forensic Engineering Division</i>	Houston, TX November 2011- May 2016
Adjunct Professor <u>College of Staten Island</u> <i>Engineering/Physics Departments</i>	Staten Island, NY August 2009- December 2013

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Pre-doctoral Fellow
Cleveland Clinic Foundation
Biomedical Engineering Department

Cleveland, OH
November 2005- May 2008

MEDICAL DEVICE RESEARCH & DEVELOPMENT EXPERTISE/EXPERIENCES

- Expertise in all types of medical device R&D including surgical forceps.
- Expertise in the R&D of orthopedic implants
- Expertise in surgical stapling systems
- Expertise in consulting and the R&D of all types of cardiac systems
- Performing ECG signal detection & cardiac pressure/volume analysis (over 250 sessions)
- Cardiac echo imaging
- Designing pre-clinical device trial formulations for all types of medical devices
- 3 Peer Review Publications in atrial fibrillation and heart failure related to doctoral research; submitting 2 Abstracts, JACC March 11, 2008; and awarded 2 Awarded Innovation Awards (Cleveland Clinic).

Ablation Therapy Systems Expertise

- The NAVISTAR® THERMOCOOL® and EZ Steer THERMOCOOL® Nav Irrigated Deflectable Diagnostic/Ablation Catheter for Treatment of Paroxysmal Atrial Fibrillation (Biosense Webster, Inc.)
- The Arctic Front® Cardiac Cryoablation Catheter for Treatment of Paroxysmal Atrial Fibrillation (Medtronic Cryocath, LP)
- The Therapy Cool Path Duo™ Ablation Catheter, Safire BLU Duo™ Ablation Catheter, and IBI1500T9-CP V1.6 Cardiac Ablation Generator for Treatment of atrial Flutter (Irvine Biomedical, Inc.)
- The R&D of conventional AF ablation used in pulmonary vein isolation (PVI), and those systems used in clinical practice, e.g. units which create circular RF lesions in a point-by-point fashion around the pulmonary valve.

Expertise in the Mapping Systems used in cardiac mapping systems:

- The NxT steerable introducer, EnSite Precision™ cardiac mapping system
- Performing ECG signal detection & cardiac pressure/volume analysis (over 250 sessions)
- Cardiac echo imaging
- Designing pre-clinical device trial formulations for medical devices.
- 3 Peer Review Publications in atrial fibrillation and heart failure related to doctoral research; gave two Abstracts, JACC March 11, 2008; and awarded 2 Awarded Innovation

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Awards (Cleveland Clinic).

- Review of Urgent Field Safety Notice on orthopedic and cardiac device systems
- ISO 14937:2009 - Sterilization of health care products
- MEDDEV 2.7.1 rev 4 and Clinical Evaluation Reports (CER) for Medical Devices
- ISO/TR 80002-2:2017 - Medical device software -- Part 2: Validation of software for medical device quality systems

PEER REVIEWED PUBLICATIONS

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 dyssynchrony, *Europace*. 2010 Mar;12(3):430-6. doi: 10.1093/europace/eup440

Grimm , Patrick J. Tchou , Nicolas Lellouche , Don W. Wallick, DOI: 10.1093/europace/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,

http://rave.ohiolink.edu/etdc/view?acc_num=csu1216064065

Cingoz F, **Yanulis G**, 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. doi: 10.1016/j.athoracsur.2006.10.102. PMID: 17462414.