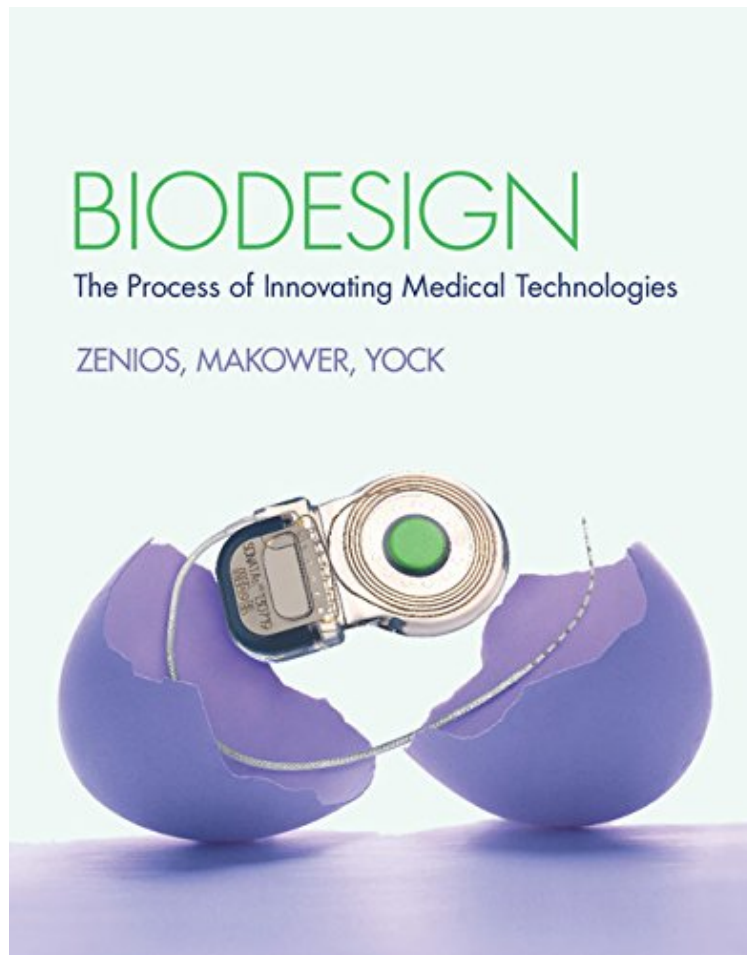


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## Biodesign: The Process of Innovating Medical Technologies

*Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel*

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**Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel : Biodesign: The Process of Innovating Medical Technologies** before purchasing it in order to gauge whether or not it would be worth my time, and all praised Biodesign: The Process of Innovating Medical Technologies:

1 of 1 people found the following review helpful. Comprehensive and real-life experience-based By Cmdr Bill It's very comprehensive and detailed in a well-structured presentation of the process of introducing a biomedical product or process into the market place. It's solidly based on the real-life experience of one of the authors, Josh Makower, a Successful serial entrepreneur. It also includes examples from the classroom at Stanford, where this book is used as the textbook for the senior design class. Important concepts are often illustrated with real cases from the field. Plenty of references help the readers dig deeper. It's not suitable for casual reading or for someone who just wants to get a quicky on selling an invention, but is excellent for entrepreneurs who are considering getting into the field and senior

students who are training for an entrepreneurial career. 1 of 1 people found the following review helpful. the best available textbook on how to go from need identification ...By Nick D. A little too formulaic for many of the processes, and then it will completely brush over some complex processes that probably need more information. All together, the best available textbook on how to go from need identification all the way to business concept and beyond. I'd highly recommend pairing this with The Startup Owners Manual and Business Model Generation. Both books are the go-to textbooks for startup generation at the moment. 2 of 2 people found the following review helpful. Primer for Medical Device Design, Experimentation Commercialization By ZMed This is the best printed resource for helping physicians and entrepreneurs invent, prove commercialize new medical technologies. Creating medical innovations which make it all the way through clinical proof and as successful products are the greatest contributions we can have beyond our own hands. However, the process is complex and products are often commercial failures even when they are effective. This book helps to explain why. I run Innovation Grand Rounds, a forum for medical innovation among MIT, Harvard Medical School, MGH and other teaching hospitals, hosted by the Center for Integration of Medicine Innovative Technologies (CIMIT). My AccelMed blog also provides information and case studies on medical device invention commercialization [...] Kudos to the authors for compiling practical advice across the entire lifecycle, from validating the clinical need, to early prototyping, to navigating clinical regulatory roadmaps. It will be a standard text for medical school and biomedical engineering programs focused on innovation.

Recognize market opportunities, master the design process, and develop business acumen with this 'how-to' guide to medical technology innovation. A three-step, proven approach to the biodesign innovation process - identify, invent, implement - provides a practical formula for innovation. The experiences of hundreds of innovators and companies, in the form of case studies, quotes and practical advice, offer a realistic, action-orientated roadmap for successful biodesign innovation. Real-world examples, end-of-chapter projects, and Getting Started sections guide the reader through each of the key stages of the process and provide a template to create their own new medical devices. Addressing common medical, engineering, and business challenges to develop well-rounded expertise, this book is the complete package for any biodesign entrepreneur. The text is supported by valuable resources, including up-to-date industry changes: found at [ebiodesign.org](http://ebiodesign.org).

"Everything you ever wanted to know about medical device entrepreneurship and more. Paul, Josh and Stefanos have led an A class team of experienced device company builders to produce a reference document to guide an aspiring device entrepreneur through all the challenges of getting an idea to market. These are tough times. Whether you're a physician with an idea, an engineer or a businessman, this is a unique and powerful resource." John Abele, Founder Chairman, Boston Scientific "This is a must read for device entrepreneurs. I only wish I had such a roadmap when I was starting out in my career. Biodesign: The Process of Innovating New Medical Technologies is a wonderful guide with lucid case studies that illustrate the critical steps necessary for the translation of ideas into commercial solutions. It is the Gray's Anatomy of device innovation." William Hawkins, Chairman and CEO of Medtronic "Biodesign: The Process of Innovating New Medical Technologies is direct, clear and simultaneously sophisticated yet practical as it unravels the many issues related to successfully navigating the entire biodesign path from concept to final product launch. I highly recommend that anyone seriously interested in developing an entrepreneurial venture in the medical products field read this book. It is likely to spare budding entrepreneurs a lot of trial-and-error and painful on-the-job training." Dean Kamen, Inventor and Founder/President of DEKA Research and Development "The Chapters are thoughtfully organized. With an excellent blending of scientific information, clinical problems, and examples of solutions, including case studies, the book has succeeded in accomplishing its goal of being very practical. The ending of each chapter with a 'getting started' section can greatly facilitate the reader to get started with the information on valuable resources. The mirroring of materials on a website with active links is another wonderful feature. This allows the readers to gain rapid access to the FDA website, etc. This book of Biodesign will be the standard in this very important field. It will be of great value in the education of undergraduate and graduate students in biomedical engineering and related fields, as well as for industrial scientists and university faculties who educate/train young bioengineers or want to pursue the process of innovating new medical technologies themselves." Shu Chien, M.D., Ph.D. UCSD "Biodesign is a handbook for medical device entrepreneurs based upon the key premise that innovation is a process and skill that can be learned. Furthermore, the key to medical device innovation is getting the clinical need in correct focus. This book will walk the student through the innovation process from how to properly define the clinical need all the way through getting the company funded and developing a quality product. Important topics like the FDA regulatory process, patents, ethics, quality and manufacturing are addressed. I don't know of any other text that has the wealth of practical and usable information on the entrepreneurial process as Biodesign. This is a much needed 'how-to' book written by people who actually have done it many times themselves. No thirty-thousand foot views necessary or appropriate here. Each chapter has a 'getting started' section that will help guide the budding entrepreneur through the necessary steps. This book should be required reading for anyone wanting to develop a new medical device or to start a new company in the medical field." William Brody, Former President, Johns Hopkins University "Whether you're a

physician with an idea, an engineer, or a businessman, this is a unique and powerful resource."CHI Bulletin

About the Author  
Stefanos Zenios is the Charles A. Holloway Professor at the Graduate School of Business, Stanford University. His pioneering work on maximizing the benefits of medical technology to patients when resources are limited has influenced policies in the US and Europe. He has quantified the ethical implications of technology allocation choices on patients and society as featured in the Financial Times and Times.com. At Stanford University, he was the first to introduce courses on the interface between medicine, engineering, and management in the MBA curriculum. Dr Zenios advises medical device and biopharmaceutical companies on health economics and outcomes studies for marketing and reimbursement strategies. He is also a co-founder of Culmini Inc., a company funded by the National Institutes of Health to develop web-tools that help patients and families with difficult choices.