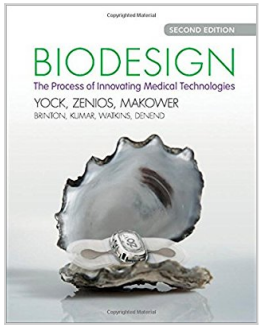

Biodesign: The Process of Innovating Medical Technologies

By Paul G. Yock, Stefanos Zenios, Josh Makower, Todd J. Brinton, Uday N. Kumar, F. T. Jay Watkins, Lyn Denend, Thomas M. Krummel, Christine Q. Kurihara

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This step-by-step guide to medical technology innovation, now in full color, has been rewritten to reflect recent trends of industry globalization and value-conscious healthcare. Written by a team of medical, engineering, and business experts, the authors provide a comprehensive resource that leads students, researchers, and entrepreneurs through a proven process for the identification, invention, and implementation of new solutions. Case studies on innovative products from around the world, successes and failures, practical advice, and end-of-chapter 'Getting Started' sections encourage readers to learn from real projects and apply important lessons to their own work. A wealth of additional material supports the book, including a collection of nearly 100 videos created for the second edition, active links to external websites, supplementary appendices, and timely updates on the companion website at ebiodesign.org. Readers can access this material quickly, easily, and at the most relevant point in the text from within the ebook.

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Editorial Review

Review
"Biodesign is on the forward edge of one of the most exciting new frontiers of health care. This impressive and engaging work provides a thorough look at the innovation process. But this is certainly not just for the scientific innovators: it is a must-read for anyone in any aspect of health care today."
Alex Gorsky, Chairman and CEO, Johnson & Johnson

"I can't think of a more important place to turn creativity loose than in designing the future of healthcare. But it's a complicated scene - and it's easy to get lost in the maze of stakeholders, regulation, and financing. Biodesign lays out a clear and logical map to find and pursue opportunities for real innovation. One of the core messages in this new edition is that by placing the need for affordability up front in design process, innovators can more explicitly create technologies that bring value to the healthcare system. This is design thinking at its best!"
David Kelley, Founder, Hasso Plattner Institute of Design, Stanford University, and Founder, IDEO

"A [must-read] textbook for anyone in academia or industry, in any country, who wants to innovate and deliver value to patients and health systems around [the] world."
Koji Nakao, Chairman, Terumo, and Japanese Federation of Medical Device Associations

"If you want to know how to come up with a both innovative and transformative technology in medicine, there isn't a better resource than this book by Paul Yock and his colleagues at Biodesign. Over thirteen years ago, the program at Stanford brought together transdisciplinary innovators - engineers, physicians and business experts - to not only design their formidable program, but to teach all the rest of us how to do it."
Eric J. Topol, Director, Scripps Translational Science Institute

"... this book on biodesign will be invaluable for any inventor or entrepreneur. It contains very useful information on such critical areas as design principles, regulatory issues, clinical trial strategies, intellectual property, reimbursement strategies, and funding - and it backs them up with interesting real-life experiences and case studies."
Robert Langer, David H. Koch Institute Professor, Massachusetts Institute of Technology

"This practical but comprehensive resource is keeping up with the rapid developments affecting medical device innovation. The authors draw on their own extensive experiences and insights, as well as diverse case studies, to present the full range of strategic and operational considerations to bring valuable new therapies to patients in the US and around the world."
Mark McClellan, Director, Health Care Innovation and Value Initiative, Brookings Institution

"Since its first release, Biodesign has established itself as a unique foundation of expertise for medical device entrepreneurship. No other manual has been so popular and so influential, reflecting admirably the entrepreneurial values sustaining the Biodesign endeavor. [The] second edition, by the outstanding founding editorial team, preserves the highly praised detail, clarity and refreshing essence of [the] previous edition ... an indispensable manual and reliable companion for all students and professionals, from business, medical or engineering arenas ..."
Professor Jacques Marescaux, President, IRCAD Institute, and Founder and CEO, Strasbourg Institute of

About the Author

Paul Yock is the Weiland Professor and Founding Co-Chair of the Stanford Department of Bioengineering, with a joint appointment in Cardiovascular Medicine and courtesy appointments in Mechanical Engineering and Operations, Information, and Technology in the Graduate School of Business. He founded and directs the Program in Biodesign, a unit of Stanford's Bio-X initiative that focuses on invention and technology transfer related to biomedical engineering. He is internationally known for his work in inventing, developing, and testing new devices, including the Rapid Exchange(TM) angioplasty/stent system, which is now the primary system in use worldwide, and the Doppler-guided access system known as the Smart Needle(TM) and PD-Access(TM). Dr Yock has cofounded several medical technology companies, including Cardiovascular Imaging Systems, acquired by Boston Scientific.

Stefanos Zenios is the Charles A. Holloway Professor at the Graduate School of Business, Stanford University and the director of its Center for Entrepreneurial Studies. An innovative educator, he was the first to introduce courses on the interface between medicine, engineering, and management in the MBA curriculum, and he is the lead architect of Startup Garage, a popular experiential elective on forming new startups. His pioneering research on maximizing the benefits of medical technology to patients when resources are limited has influenced policies in the US and Europe. Dr Zenios is the co-founder of Konnectology.com, a website funded by the National Institutes of Health to help kidney patients find transplant centers.

Josh Makower has dedicated his life to the creation of medical technologies that improve the quality of life for patients. He is the CEO and Founder of ExploraMed Development, LLC, a medical technology incubator, through which he has founded several healthcare companies, including Acclarent, acquired by J&J, TransVascular, acquired by Medtronic, EndoMatrix, and GI Reflux, acquired by C. R. Bard. He is also a Venture Partner with New Enterprise Associates, where he supports investing activity in the medical device arena. Dr Makower holds over 200 patents for medical devices in the fields of orthopedics, ENT, cardiology, general surgery, drug delivery, and urology. He serves as a Consulting Professor of Medicine at Stanford University Medical School and co-founded Stanford's Biodesign Innovation Program.

Todd J. Brinton is a Clinical Associate Professor of Medicine (Cardiovascular) and Consulting Associate Professor of Bioengineering at Stanford University. He is also an interventional cardiologist at the Stanford University Medical Center and the Palo Alto VA Hospital. His clinical practice focuses on general cardiovascular disease and complex coronary interventions. Dr Brinton is also a clinical investigator for new interventional-based therapies for coronary disease and heart failure. He has served as the Fellowship Director for the Biodesign Program since 2006, through which he has mentored numerous innovators in the biodesign innovation process. He also serves as the co-director of the graduate courses in Biodesign Innovation and the Biodesign Executive Education Program at Stanford. He is co-founder of BioParadox and Shockwave Medical, both venture-backed medical device companies, where he is a member of the board of directors and directs clinical development and strategy.

Uday N. Kumar is the Founder, President and CEO of Element Science, Inc., a company focused on the treatment of sudden cardiac death, that he started during his time as an Entrepreneur-in-Residence at Third Rock Ventures, LLC. He also is a co-founder and board member of Qurious.io, Inc., a healthcare information technology company, a co-founder and board member of Sympara Medical, Inc., a company developing a novel therapy for hypertension, and the founder of iRhythm Technologies, Inc., a company focused on developing cost-effective new devices and systems for cardiac rhythm monitoring. He served as a board member and Chief Medical Officer of iRhythm from founding through broad commercialization of its Zio®

Patch cardiac monitoring device. Dr Kumar currently serves as a Consulting Associate Professor of Bioengineering at Stanford University and is the Fellowship Director of Stanford's Global Biodesign Programs.

Jay Watkins has extensive experience founding and funding healthcare companies. He is a Managing Director with De Novo Ventures and an active individual investor and advisor to emerging medtech companies. He serves as a Lecturer in Management at the Graduate School of Business, Stanford University. Previously, Mr Watkins was on the Guidant management committee and served as president of several divisions, including the Minimally Invasive Surgery Group, and Heart Rhythm Technologies. While President of the Cardiac and Vascular Surgery Group, he initiated the development of a minimally invasive vein harvesting technology, which has been used to treat almost two million patients worldwide. He also has served as an executive with multiple start-up companies, a consultant with McKinsey and Company, and co-founder and founding CEO of Origin Medsystems, a venture funded medical technology start-up acquired by Eli Lilly and Company.

Lyn Denend is the Associate Director for Curriculum of the Biodesign Program at Stanford University, responsible for the development of written and multimedia curricular materials to support Biodesign courses and initiatives. Previously, Ms Denend worked at the Stanford Graduate School of Business (GSB) as the staff director for the school's Program in Healthcare Innovation, where she specialized in research related to the challenges of global health innovation. She also authored a variety of papers and teaching materials as part of the GSB case writing office. Prior to joining the Stanford community, Ms Denend was a management consultant with Cap Gemini Ernst and Young.

Thomas M. Krummel is Professor/Chair, Department of Surgery at Stanford University. He has served in leadership positions in all of the important surgical societies, has mentored over 200 students, residents, and postdocs, and is the recipient of more than $3 million in research grants. He is Co-Director of the Stanford Biodesign Program. Dr Krummel has been a pioneer and innovator throughout his career. He has received two Smithsonian Information Technology Innovation Awards for work in the application of information technology to simulation-based surgical training and robotics. He remains an active start-up consultant with three successful exits and nine in the pipeline.

Christine Q. Kurihara is Senior Associate Director of Global and Communication for the Biodesign Program at Stanford University, responsible for overseeing the Biodesign Global Fellowship Programs, global relationships, and providing support to Stanford students, fellows, and faculty working on device projects based on global needs. She also manages all IT, web projects, marketing, and communications for the program. Ms Kurihara joined Biodesign after an 11-year career with Stanford in the area of media services. In her previous role, she spearheaded media development efforts for an on-campus service unit, where her team produced websites, online courseware, video and broadcast products. Prior to running Media Solutions, she coordinated the first Stanford University website.

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