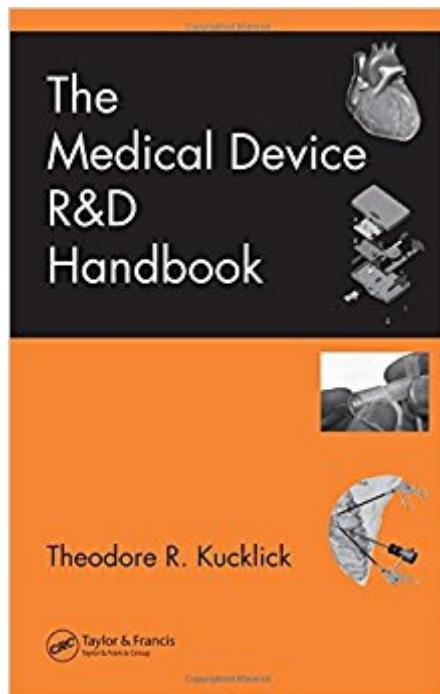


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# The Medical Device R&D Handbook



## Synopsis

The Medical Device R&D Handbook presents a wealth of information for the hands-on design and building of medical devices. Detailed information on such diverse topics as catheter building, prototyping, materials, processes, regulatory issues, and much more are available in this convenient handbook for the first time. The Medical Device R&D Handbook also includes exclusive interviews with pioneers and leaders in the medical device industry, offering an insider's perspective on issues that are critical to the medical device entrepreneur. Highlights include: An Introduction to Medical Plastics; Catheter Forming Equipment and Operations; Basics of Catheter Construction; Basics of Medical Needles; Rapid Prototyping for Medical Devices; Reverse Engineering for Medical Devices; Using Medical Illustration in Product Development; Introduction to Pre-Clinical Studies; Introduction to Regulatory Affairs; Assessing Biocompatibility; Exclusive Interviews with Key Industry Leaders; and More. This practical handbook is a unique, insightful guide that helps you design, test, and successfully introduce new medical devices to the marketplace.

## Book Information

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This is the first in its class of multidisciplinary books for medical device innovators, reaching across several disciplines to capture what innovators need. Michael Gertner, MD, Co-Director, Surgical Innovation Program at Stanford University, and noted physician-entrepreneur. The Keiretsu Forum is America's largest angel investment group. We see hundreds of presentations for innovative start up companies. This is a resource that will help medical device innovators develop better products, and

more focused companies, more quickly-Randy Williams, Founder The Keiretsu ForumFinally, a real manual that for the first time supports efficient medical device development-Peter H. Muller, President, Interform Product Development

-----Reviews----- "This is the first in its class of multidisciplinary books for medical device innovators, reaching across several disciplines to capture what innovators need" -Michael Gertner, MD, Co-Director, Surgical Innovation Program at Stanford University, and noted physician-entrepreneur "The Keiretsu Forum is America's largest angel investment group. We see hundreds of presentations for innovative start up companies. This is a resource that will help medical device innovators develop better products, and more focused companies, more quickly" -Randy Williams, Founder The Keiretsu Forum "Finally, a real manual that for the first time supports efficient medical device development" -Peter H. Muller, President, Interform Product Development

When I bought this book, I expected it to be used as a reference for catheter laminations and catheter material selection. Although, the book does describe one example of a laminated catheter product, its methods are so primitive that I wouldn't be surprised if the technology is outdated by 10 years. There is no mentioning of braid/coil reinforcement or any concerns with catheter kink-resistance, torquability, and flow-rates. I was sort of hoping that they would at least cover the difference between a flat-wire braid and a round-wire braid in terms of kink-resistance and torque. Overall, this book is recommended for those who're just starting in the in the medical device industry. The technologies introduced here are very basic, but you should never expect these methods to be used to create a product that's competitive in today's marketplace. I guess, a lot of the key technologies are kept as trade-secrets as those "in the know."

This book is a fantastic resource for anyone working in R&D at a device start-up, particularly those who are beginning their careers. I wish I had it when my company began prototyping. The text contains a wealth of knowledge that would take years to assimilate on the job and it is well illustrated (although when provided, photos are black and white only) to elucidate concepts that are difficult to explain with words alone. One of the most useful aspects of the book is the practical examples for how to construct prototype and proof of concept devices. The author provides example fabrication and assembly options that consider development stage (proof of concept/demonstrator, prototype, small production run) which are quite helpful for companies exploring areas beyond their traditional niche. You can be assured that this book will pay for itself

many times over.

This book is way more than I had expected. It was required for a class but once I started reading it amazed me. Very strait forward and down to earth

Oh boy!! When this book arrived I couldn't put it down!! The very thought of the awesomeness the next page would most definitely hold kept me turning those pages all day and night!! I suggest buying 2 copies because once your friends and collegues see you reading this they will probably steal it from you and read it themselves!!

Since I work in academic reseach, I purchased this book to have basic understanding of medical device industry R&D. And I am pleased to say that the book is a concise guide to the complexity of research development and quality affairs.

Well written and presented. It is a huge asset to any medical designer, or someone in the medical field.

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