Biomaterials in the Design and Reliability of Medical Devices

Michael N. Helmus
(Kluwer Academic/Plenum Publishers, 2003)
226 pages; $198.00
ISBN 0-306-47690-8

Michael N. Helmus, over the years, has drawn on his extensive background in medical consulting and corporate research and development to provide valuable information to the medical device community on biomaterials compositions, properties, and uses. In this book, which he edits and contributes to as a major author, his expertise in biomaterials for medical devices is showcased.

Chapter 1 (authored by Helmus) provides a comprehensive biomaterials compilation as the foundation for a volume, with multiple themes unified by the goal of optimizing the performance of medical devices through the proper selection, structural design, and testing of biomaterials. A large table, focusing on devices, concisely lists in a useful way materials of construction, predicate devices, design-related issues, and test standards. Another large table lists biomaterials and their properties. A third table usefully provides a flowchart for device design and testing from concept through clinical validation.

Chapters 2–4, authored by the eminent consultants Sharon Northup (Chapters 2 and 4) and Barry Sall (Chapter 3), address the specific testing required to qualify medical devices and their materials of construction. Chapter 2, focusing on biocompatibility, first provides an exhaustive listing of diagnostic and therapeutic medical devices by regulatory classification, followed by test procedures and guidelines. While this information is also available in the U.S. *Code of Federal Regulations* (CFR), it is accompanied here by practical examples of biocompatibility studies and advice on test selection. Chapter 3 focuses on regulatory requirements for gaining approval of medical devices in the United States and abroad, employing flow diagrams and examples to illustrate specific approaches. Chapter 4, under the heading of “Nonclinical Testing,” describes in detail the purposes and execution of the various biocompatibility tests required for device qualification. Taken together, there is considerable repetition in Chapters 2–4, but reading them can be a useful drill in gaining an in-depth understanding of biocompatibility and regulatory issues.

In Chapter 5, Helmus, in describing failure analysis, argues for the value of implanted device recovery and provides guidelines for explant analysis. He also provides insights for predicting device durability during the preclinical design and testing stages.

Using case histories, Roger Snyder describes the special issues encountered by small device companies in Chapter 6. Strategic decisions and operational approaches made early in the product development process can assure or doom the company’s survival. Topics addressed include documentation, testing, prototyping, materials selection, vendor relationships, production, sterilization, and shelf life. Practical insights, clearly based on hard experience, are provided for anyone working in the device field.

Kelvin Brockbank, in Chapter 7, addresses the emerging field of tissue engineering, which applies the principles of engineering and the life sciences to the development of biological substitutes that restore, maintain, or improve tissue function. High-value market opportunities and the technological and regulatory issues relevant to the distinct classifications of biomaterials and “combination” products (e.g., cell/device composites) encountered in this field are described. Two case studies that address issues relevant to the commercialization potential of devices associated with tissue engineering are provided.

In the final chapter, Katherine Tweden gives a comprehensive description of the development of medical textiles modified with bioactive molecules for use in cardiovascular devices. This case study describes in detail the *in vitro* and *in vivo* test protocols and gives results of the tests—a fitting conclusion to the earlier background provided in test selection and execution.

In summary, this book is not a conventional offering. It is both a database and an operating manual. Its value can best be exploited by the reader by first surveying its contents, then bearing down on specific topics. It is a rich source of valuable information that should be accessed from the reference shelf of the biomaterials practitioner.

Reviewer: *Arthur J. Coury is vice president of Biomaterials Research at Genzyme Corp. in Cambridge, Massachusetts.*

Enabling Technologies for MEMS and Nanodevices

Henry Baltes, Oliver Brand, Gary K. Fedder, Christofer Hierold, Jan G. Korvink, and Osamu Tabata
(John Wiley & Sons, 2004)
439 pages; $245.00
ISBN 3-527-30746-X

This book provides a refreshing update to some of the latest trends in the field of microelectromechanical systems (MEMS). While the book is not an exhaustive reference, it covers in detail some topics that are not addressed well in other texts and books on MEMS. While the title suggests a discussion of MEMS and nanodevices, the book is clearly written from the perspective of MEMS research and does not treat nanotechnology and nanosystems with great detail.

The book includes background information on the driving forces for the development of the MEMS field, including markets, investors, and industries that led to the successful commercialization of devices. This brief “history lesson” provides a good picture for the developmental path of MEMS and its current state. Beyond this chapter, the book provides an excellent review of capacitive sensors and resonators, with separate chapters devoted to each. The book provides detailed discussions on fundamental principles and limits to capacitive sensing. In addition, a discussion on noise sources as well as several techniques (and electronic circuitry) that can be used for sensing capacitive changes and electrostatic force feedback is presented. The chapter on resonators extends these concepts by discussing in more detail the effects of geometry and structure on the resonant modes, the use of piezoelectric and capacitive sensing, device cascading, filtering, and losses. The chapter also gives a brief discussion on the use of SiGe resonators and contrasts their use with polysilicon.

In addition to the detailed treatment of capacitive sensors and resonators, the book includes an outstanding treatment of scanning probe microscopy. This section treats scanning tunneling microscopy, atomic force microscopy, near-field scanning optical microscopy, and combined scanning probe techniques (e.g., AFM-near field scanning optical microscopy) for materials analysis. Fabrication techniques of scanning probes and specialized applications such as AFM-SECM (scanning electrochemical microscopy), and NSOM-SICM (scanning ion conductance microscopy) for biological systems are presented. Additional topics that are covered very well are MEMS packaging, including the use of self-assembled monolayers and atomic layer deposition to increase reliability; a discussion of data storage using the latest MEMS-enabled techniques (e.g., thermal- and phase-change data storage); and fluid flow/molecular transport in nanochannels.

The book could use a stronger treatment of the nanotechnology and nanodevices that were alluded to in the title. The only major discussion given covers carbon nanotubes and nanotube sensors. While this particular chapter is good, the book does not capitalize on the opportunity to discuss other nanomaterials systems—such as semiconductors and metals—and techniques to integrate them into MEMS or create nanodevices or macroelectronics from them.

In general, this is an excellent book that gives a good overview and discussion of sensors and devices commonly found in the field of MEMS as well as more advance devices not typically covered in other references. The book is a good resource for MEMS researchers who are entry-level graduate students and beyond.

Reviewer: *Samuel Graham is an assistant professor in the Woodruff School of Mechanical Engineering at the Georgia Institute of Technology.*

Topics in the Theory of Solid Materials

J. M. Vail
(IOP Publishing, 2003)
368 pages; $44.99
ISBN 0–7503–0729–3

This book covers a collection of topics usually found under the titles of solid-state physics, physical metallurgy, and elasticity. The seemingly unrelated topics fall under two categories: the author's own research and standard topics covered in many textbooks. The latter category offers nothing new. The coverage is based on earlier works such as those by Landau and Lifshitz, Kittel, Huang, and the Weertmans.

What is missing is the connection between the topics. For example, the elasticity topics covered in Chapters 1, 2, 4, and 5 are barely mentioned in the rest of the book. One cannot help but wonder why all these topics should be covered in one book, particularly when others have succeeded in covering a similarly broad range of topics in a way that connects them and makes a coherent narrative (see, e.g., R. Phillips, *Crystals, Defects and Microstructures*, Cambridge University Press, 2001.)

The real value of this book is in several chapters (6, 11–14) that cover the author's own work as well as some of the background needed for understanding polarons, the foundations of quantum mechanical computations, and charge density waves. The minimum background for reading this book is a quantum mechanics course. An introductory solid-state physics course is desirable.

Not surprisingly, the last block of chapters (11–14) is a coherent exposition; these are well written, with rigorous—but not overwhelming—mathematical developments. The author has carefully chosen the mathematical topics that illuminate the subjects. Moreover, a textbook covering the mathematical background of quantum mechanical computations is needed. In light of that need, one regrets that the author did not choose to base the book on these topics and provide more detailed background instead of venturing into an unrelated topic in one chapter, then abandoning the topic altogether. Why cover dislocation mechanics unless one intends either to present quantum mechanical computations for electron density around a dislocation core, or to develop a crystal plasticity theory?

Despite its flaws, the book still serves as a valuable source. A physicist venturing into a growing realm of materials science and, in particular, the thermomechanical behavior of materials will find here a good introduction to selected topics and some pointers for further study. The usefulness of this book to materials scientists and engineers is limited to those who already have a background in quantum mechanics and solid-state physics.

Reviewer: *Sinisa Dj. Mesarovic is an assistant professor in the School of Mechanical and Materials Engineering at Washington State University. His main interests in micromechanics and multiscale modeling of materials lie between traditional disciplines: the mechanics of solids, materials science, and solid-state physics.*

Concise Encyclopedia of Materials Characterization, *2nd Edition*

R.W. Cahn, Editor
(Elsevier, 2005)
1024 pages; $310.00
ISBN 0-08-044547-0

This work, one of 11 "Concise Encyclopedias," is a collection of 186 articles, drawn from five different sources, expounding on various aspects of materials characterization such as composition, crystalline state, microstructure, and macrostructure. The five sources used are the 1986 *Encyclopedia of Materials Science and Engineering*, the 1988 and 1990 supplements thereto, and several specially commissioned papers (articles, selected from these four, collectively comprise the 1993 first edition of the *Concise Encyclopedia of Materials Characterization*), and, lastly, more recent articles appearing in the 2001 *Encyclopedia of Materials: Science and Technology* and on-line updates thereto. Review of the bibliographies appended to articles in the present work indicate that ~60% of the articles are current for the 1995–2003 period, but ~25% of them have apparently not been updated since 1985. Throughout, emphasis is on research techniques rather than methods for inspection and nondestructive evaluation. There is broad coverage with respect to materials types (e.g., metals, oxides, polymers, semiconductors, and amorphous materials).

Many, many different techniques are described and evaluated. For each technique, the underlying physical principles are explained, the required sample types defined, the typical data output illustrated, and the strengths and weaknesses of each technique compared. Cost and speed of analysis are additional considerations over and above mere applicability of the technique to the particular material and structure at hand. These matters are extensively reviewed in general terms in an excellent 10-page introductory essay by Eric Lifshin, but are treated in detail in each article.

Individual articles are usually illustrated, as appropriate, by line drawings, tables, halftones of equipment, and results of analysis. The various characterization techniques described include both the common and well-known (e.g., chromatography, photoelasticity, and scanning electron microscopy) as well as the unusual (e.g., acoustic microscopy, combinatorial screening, and perturbed angular correlations). The authorship of the articles comprises ~225 individual scientists and engineers, mostly from the United States and the United Kingdom but with 12 other countries represented as well. The individual articles, as well as the work as a whole, are designed to be freestanding. Each article has its own bibliography, including citations within the text as well as references for further reading. An extensive (~54 pages) three-level index is provided which has numerous "see also" entries.

The book should have appeal both to those in industry and in academia, either doing materials research or wishing to understand how various details of composition and structure affect properties and how they may best be determined.

Reviewer: *Jack H. Westbrook is owner of and principal consultant with Brookline Technologies, a consulting firm in Ballston Spa, N.Y., where he consults on materials and technical information systems. He is chair of the* MRS Bulletin *Book Review Board and serves on the* MRS Bulletin *Editorial Board.*