

HANDBOOK OF MATERIALS FOR MEDICAL DEVICES

**Edited by
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Preface

In January of 2000, the National Institutes of Health (NIH) estimated that 8 to 10% of Americans, or about 20 to 25 million people, had some sort of medical device implanted in their bodies (refer to the NIH Technology Assessment Conference on Implants, held 10–12 Jan 2000 in Bethesda, MD). In the United States, the market for orthopedic implant devices such as total knee and hip replacements, spinal implants, and bone fixation devices, exceeds two billion dollars per year. Worldwide, this market exceeds \$4.3 billion per year. These numbers, which clearly demonstrate the economic impact of the medical device industry, should continue to rise due to the combination of advances in the medical and materials science fields and an aging population (particularly in the United States, where some “baby boomers” are now in their sixties).

Humans have sought to restore function to the human body stricken by trauma or disease for thousands of years. For example, ancient civilizations such as the Phoenicians, Etruscans, Greeks, Romans, Chinese, and Aztecs used gold in dentistry as far back as 2700 BC. The use of sutures made from linen can be traced back to the Egyptians in circa 2000 BC. However, it has only been during the past 100 years that man-made materials and devices have been developed to the point where they can be used extensively to replace parts of living systems in the human body. These special materials—able to function in intimate contact with living tissue, with minimal adverse reaction or rejection by the body—are called *biomaterials*. Today, biomaterials play a major role in replacing or improving the function of every major body system (skeletal, circulatory, nervous, etc.). Some common implants include the orthopedic devices mentioned earlier; cardiac implants such as artificial heart valves and pacemakers; soft tissue implants such as breast implants and injectable collagen for soft tissue augmentation; and dental implants to replace teeth/root systems and bony tissue in the oral cavity.

Recognizing the growing importance of biomaterials and bioengineering, ASM International has published a number of reviews during the past 20 years that document the properties and failure mechanisms of metallic implant materials. The majority of these reviews can be found in various volumes of the *Metals/ASM Handbook* series. Until now, however, there was no single definitive source published by ASM that described the many important topics associated with the use of various implant materials (including metals, ceramics, polymers, composites, and coatings). These materials include:

- Implant material selection and applications
- The body/oral environment and its impact on implant material performance
- The basic concepts of biocompatibility
- Tissue attachment mechanisms
- Biophysical and biomechanical requirements of implant materials
- Corrosion and wear behavior, including degradation of polymeric materials

- Coatings technology, including the use of coatings to facilitate implant fixation and bone ingrowth, wear-resistant coatings, coatings to enhance blood clot resistance, antimicrobial action, and lubricity, and coatings for delivery of drugs
- Design considerations, particularly failures related to inadequate design

Each of these subjects is addressed in the *Handbook of Materials for Medical Devices*.

The genesis of this handbook can be attributed to the input of the ASM Handbook and Technical Books Committees, the ASM editorial staff (most notably, Scott Henry and Don Baxter), and the ASM Materials and Processes for Medical Devices Task Force. In particular, thanks are due to the following Task Force members for their thorough critique of the outline of the handbook at the outset of the project: Farrokh Farzin-Nia (Ormco Corporation), Darel E. Hodgson (Shape Memory Applications, Johnson Matthey), Terry C. Lowe (Los Alamos National Laboratory), and Sanjay Shrivastava (Edwards Lifesciences LLC). Their combined efforts led to the successful completion of this handbook.

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