Stainless Steels for Medical and Surgical Applications

EDITORS: Gary L. Winters and Michael J. Nutt

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Gary L. Winters and Michael J. Nutt, editors

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Foreword

This publication, *Stainless Steels for Medical and Surgical Applications*, contains papers presented at the symposium of the same name, held in Pittsburgh, Pennsylvania, on May 6 and 7, 2002. The symposium was sponsored by ASTM Committee F04 on Medical and Surgical Materials and Devices. Gary L. Winters of Cedar Creek, Texas, and Michael J. Nutt of Spinal Innovations, in Bartlett, Tennessee, presided as symposium chairmen and are editors of the resulting publication.

The editors would like to express their appreciation for the help provided by Markus Windler from Sulzer Orthopaedics, Winterthur, Switzerland, in promoting initially the need for such a symposium and in encouraging participation by several European research groups.

We, of course, want to thank all the authors who contributed to the research presented at the symposium and, in particular, we would like to thank the presenters, some of whom made the effort and sacrifice to travel to the United States from Brazil, France, Germany, Sweden, Switzerland, and the United Kingdom in order to attend the symposium.

We would also like to express our thanks to the ASTM staff that helped make the symposium and publication possible: most notably Dorothy Fitzpatrick for her help with the symposium planning and Maria Langiewicz for the handling of manuscript submission and review. We are also indebted to all the reviewers who volunteered their time and expertise for their careful consideration and critique of the manuscripts.

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The Symposium on Stainless Steels for Medical and Surgical Applications undertook to bring together, at one time, current research and development, recent clinical experience, and the substantial history of stainless steels in medical applications. This was done with the expressed purpose of bringing the attendees and participants of the symposium up to date on the current status of the latest technologies and to provide the most current information. Ultimately, this new information may stimulate further research and technical developments in the application of stainless steels for implantable medical devices and surgical instruments.

This Special Technical Publication (STP) furthers the aims of the symposium by documenting the entirety of the body of research that was presented in 20-minute synopses during the symposium. This information, which has not been previously published, is to be made available not only to the attendees and participants of the symposium, but also to the general public. In this manner, the information in the symposium can be distributed more widely and be more helpful in furthering research and technical developments in the application of stainless steels for implantable medical devices and surgical instruments.

This publication will be helpful to individuals engaged in the development of stainless steels for implant applications, or instrument applications in particular. It will also be of interest to other individuals, who are developing, making, or using implantable medical devices and/or surgical instruments in general. This publication may make both of these groups aware of alloys, testing, or applications that they had not previously considered.

This new information can stimulate new research or technical innovations. This information can also be used by individuals to contact researchers or producers with similar interests. Finally, this information may become part of the justifications for device approval by regulatory bodies, and for creation of material specifications by standards writing bodies, which can benefit producers, users, and regulatory bodies.

This publication addresses some of the issues in the medical uses of stainless steels, such as corrosion, wear, biological response, radiopacity, and the high cost of medical products. New alloys are discussed as solutions to some of these issues by offering more biocompatible, higher quality, radiopaque, or low cost alternatives for orthopaedic implants and stents. Several corrosion papers address this key concern for all medical devices. Some of these papers offer creative options for this field. Finally, there are other papers that deal with such timely issues as injuries due to the interaction of implants and MRI examinations.

This symposium covered a wide range of topics on stainless steels, with most of the presentations dealing with narrow segments of a specific topic. Therefore, a single theme of the presentations may be that work on stainless steels for medical uses continues and that stainless steels may be part of the answers for some of the issues facing the surgical community today, such as biological response, corrosion resistance, mechanical performance, quality, and cost.

Certainly, iron-base alloy systems offer excellent opportunities as implant and instrumentation alloys in the medical field to satisfy special needs such as radiopacity, wear resistance, superior me-
chanical properties, or freedom from allergic responses. As such, work should continue on increasing the corrosion resistance and mechanical properties of stainless steels, as well as the product forms and applications, while decreasing cost and any negative biological responses.

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