

Foreword

In 1997, the leadership of the American Society for Testing and Materials (ASTM International) Committee F04 on Medical and Surgical Materials and Devices created a broad-based standards development activity in Tissue Engineered Medical Products (TEMPs). This was a proactive initiative borne out of the realization that in the near future a large number of medical products will be introduced into the marketplace that are fundamentally different from the current generation of products fabricated from conventional engineering materials. These new products will be based on some combination of cells, growth factors, human tissue and biologic or non-biologic biodegradable scaffoldings. Unlike previous standards development activities, the TEMPs standards initiative is occurring prior to or concurrent with the commercial introduction of the vast majority of the products to be covered by the standards. This situation provides a unique opportunity for consensus standards to accelerate the product development phase and regulatory processes (by virtue of the establishment of a common nomenclature and standardized test methods) in order to bring these promising treatment modalities to the patient in an expeditious fashion.

To produce the most relevant and useful standards, it is critical that the best science and the latest scientific developments are brought to bear. Thus, ASTM Committee F04 regularly conducts workshops and scientific symposia in targeted areas where the science is rapidly evolving and the need for standards is pressing. This volume entitled “Bone Graft Substitutes,” edited by Dr. Cato Laurencin represents, in large part, the proceedings of a workshop held in November 2000 in Orlando, FL during ASTM committee week activities. Dr. Laurencin organized this workshop with help from Dr. Mohamed Attawia and recruited an impressive array of speakers, most of whom are recognized as leaders in their respective scientific, clinical and regulatory fields. The symposium organization effort was a cooperative endeavor between ASTM Committee F04 and the American Academy of Orthopaedic Surgeons Biological Implants Committee, and Biomedical Engineering Committee.

Bone defects resulting from traumatic, neoplastic, degenerative, inflammatory and congenital diseases are commonly seen in the clinical arena. Autologous bone grafting remains as the “gold standard” in treating such defects. In addition, autologous bone grafting is widely used to promote bone healing in the absence of bone defects in arthrodesis (fusion) procedures and in the treatment of delayed fracture healing. Unfortunately, only limited quantities of bone autograft are available and the harvesting of the graft can be associated with substantial morbidity. Thus, there is a great need for autologous bone graft substitutes—a need that can be filled by allograft tissue, synthetic bone graft substitutes, tissue-engineered bone products or a combination of the three. In this volume, the state of the art and science of bone grafting is presented in the context of the role of standards in the development, manufacturing, processing, testing, and regulation of bone graft substitute materials.

This monograph is divided into three sections. The first section presents a summary of the clinical use of bone allografts and allograft-based bone graft substitutes. This section includes a chapter on allograft tissue banking and safety and a chapter on potential areas of standards development. The second section addresses the use of cells

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and growth factors as bone graft substitutes. Representatives from academia, industry, and the regulatory communities present their perspectives on the exciting opportunities and formidable challenges involved in bringing scientific advances in the field of bone tissue engineering to the patient care arena. The final section addresses the use of synthetic materials, including polymers and ceramics, for bone graft substitutes. As in the other two sections, there is a chapter addressing the regulatory and standards issues involved. All sections begin with an overview by some of the leading authorities in the field.

Overall, this is a unique monograph exploring not only the clinical and scientific aspects of bone grafting, but also the practical issues of bringing promising new bone graft substitutes to the marketplace in a fashion which insures their safety and efficacy. Dr. Laurencin, the editor of this book, is to be commended for his tireless efforts in bringing this project to fruition. He has assembled an accomplished multidisciplinary panel of authors who collectively have produced a comprehensive and authoritative summary of a complex field. This volume will serve as a foundation for future standards development activities in this area.

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