

STP 1452

Tissue Engineered Medical Products (TEMPs)

Eliane Schutte, Grace L. Picciolo, and David Kaplan, editors

ASTM Stock Number: STP1452



ASTM
100 Barr Harbor Drive
PO Box C700
West Conshohocken, PA 19428-2959

Printed in the U.S.A.

Contents

FOREWORD	iii
WHAT TECHNOLOGY DO WE HAVE AND HOW IS IT DOING?	
Measurement of Pore Size and Porosity of Tissue Scaffolds—P. TOMLINS, P. GRANT, S. MIKHALOVSKY, S. JAMES, AND L. MIKHALOVSKA	3
Development and Validation of a Detection Method for a Broad Range of Human Papillomavirus Types—D. N. GALBRAITH, T. COLLINS, J. BLACK, B. MC MANUS, D. MC MUTRIE, AND A. LOVATT	12
Bronchoscopic Lung Volume Reduction—A Novel Tissue Engineering Treatment for Advanced Emphysema—E. P. INGENITO, L. TSAI, R. L. BERGER, AND A. HOFFMAN	20
NIST and Standards for Tissue Engineered Medical Products—J. A. TESK AND L. R. KARAM	40
Mechanical Evaluation of Allograft Bone—M. C. SUMMITT, D. M. K. SQUILLACE, AND J. R. BIANCHI	47
Method to Determine Germicidal Inactivation in Allograft Processing—C. R. MILLS, M. R. ROBERTS, J. Y. CHANG, J. R. BIANCHI, AND M. C. SUMMITT	54
Towards <i>In-Situ</i> Monitoring of Cell Growth in Tissue Engineering Scaffolds: High Resolution Optical Techniques—M. T. CICERONE, J. P. DUNKERS, AND N. R. WASHBURN	59
Cartilage Mechanical Properties after Injury—D. D. D’LIMA, N. STEKLOV, A. BERGULA, P. C. CHEN, C. W. COLWELL, AND M. LOTZ	67
Age Related Differences in Chondrocyte Viability and Biosynthetic Response To Mechanical Injury—D. D. D’LIMA, A. BERGULA, P. C. CHEN, C. W. COLWELL AND M. LOTZ	77

A Comparative Study of Biomarkers of Oxidative DNA Damage Used to Detect Free Radical Damage in Tissue-Engineered Skin —H. RODRIGUEZ, P. JARUGA, M. BIRINCIOGLU, P. E. BARKER, C. O'CONNOR, AND M. DIZDAROGLU	84
Endpoint Verification of Bone Demineralization for Tissue Engineering Applications —C. B. THOMAS, L. JENKINS, J. F. KELLAM, AND K. J. L. BURG	90
Comparative Study of Bone Cell Culture Methods for Tissue Engineering Applications —C. B. THOMAS, J. F. KELLAM, AND K. J. L. BURG	100
A New Method for Real-Time and In-Situ Characterization of the Mechanical and Material Properties of Biological Tissue Constructs —G. ZHANG AND J. L. GILBERT	120
WHAT STANDARDS EXIST AND WHAT STANDARDS ARE NEEDED?	
Alginate and Chitosan Standards for Tissue Engineered Medical Products —M. DORNISH AND A. DESSEN	137
Biomolecules in Tissue Engineered Medical Products (TEMPS): a Case Study of recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) —T. J. PORTER, S. RATHORE, J. ROUSE, AND M. DENTON	150
Development of Standards for the Characterization of Natural Materials Used in Tissue Engineered Medical Products (TEMPS) —D. S. KAPLAN	172
Microbiological Safety and Adventitious Agents Standards for TEMPS —G. SOFER	176
Standards Used in Meeting Requirements for a Model Pre-Market Approval (PMA) of a Neural Guidance Conduit —L. STOVER AND L. HUBEL	182
Storage and Transport Issues for Tissue Engineered Medical Products —J. R. WALSH, M. J. TAYLOR, AND K. G. M. BROCKBANK	197
WHAT STANDARDS ARE USED GLOBALLY AND HOW BY THE REGULATORY BODIES FOR APPROVALS?	
The European Situation on Standards for Tissue Engineering Products —E. SCHUTTE	213
A European View on Risk Management Strategies for Tissue Engineered Medical Products (TEMPS) —R. E. GEERTSMA, M. KALLEWAARD, AND C. WASSENAAR	226
Molecular Biomarkers Used to Detect Cellular/Genetic Damage in Tissue-Engineered Skin —C. O'CONNELL, P. E. BARKER, M. MARINO, P. MC ANDREW, D. H. ATHA, P. JARUGA, M. BIRINCIOGLU, AND H. RODRIGUEZ	246
A Useful Marker for Evaluating the Safety and Efficacy of Tissue Engineered Products —T. TSUCHIYA	254
AUTHOR INDEX	263
SUBJECT INDEX	265