



2004-08-25

Techniques for Investigation of Surgical Cutting Instruments

Eamon Price

Institute of Technology, Sligo, Ireland

Ger Reilly

Dublin Institute of Technology, ger.reilly@dit.ie

Brendan McCormack

Institute of Technology, Sligo, Ireland

Andrew Macey

Sligo General Hospital, Sligo, Ireland

Follow this and additional works at: <http://arrow.dit.ie/engschmanconn>



Part of the [Biomedical Devices and Instrumentation Commons](#), and the [Vision Science Commons](#)

Recommended Citation

Price, E., Reilly, G., McCormack, B., Macey, A.: Techniques for Investigation of Surgical Cutting Instruments. Proceedings from the Materials & Processes for Medical Devices Conference, St. Paul, Minnesota, USA. August 25–27, 2004.

This Conference Paper is brought to you for free and open access by the School of Manufacturing and Design Engineering at ARROW@DIT. It has been accepted for inclusion in Conference Papers by an authorized administrator of ARROW@DIT. For more information, please contact yvonne.desmond@dit.ie, arrow.admin@dit.ie, brian.widdis@dit.ie.



This work is licensed under a [Creative Commons Attribution-NonCommercial-Share Alike 3.0 License](#)



Medical Device Materials II

Proceedings from the Materials & Processes for Medical Devices Conference 2004
August 25–27, 2004
St. Paul, Minnesota

Edited by
Mike Helmus
Dana Medlin

Sponsored by



ASM International®
Materials Park, OH 44073-0002
www.asminternational.org

Copyright© 2005
by
ASM International®
All rights reserved

No part of this book may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the written permission of the copyright owner.

First printing, May 2005

Great care is taken in the compilation and production of this Volume, but it should be made clear that NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE GIVEN IN CONNECTION WITH THIS PUBLICATION. Although this information is believed to be accurate by ASM, ASM cannot guarantee that favorable results will be obtained from the use of this publication alone. This publication is intended for use by persons having technical skill, at their sole discretion and risk. Since the conditions of product or material use are outside of ASM's control, ASM assumes no liability or obligation in connection with any use of this information. No claim of any kind, whether as to products or information in this publication, and whether or not based on negligence, shall be greater in amount than the purchase price of this product or publication in respect of which damages are claimed. THE REMEDY HEREBY PROVIDED SHALL BE THE EXCLUSIVE AND SOLE REMEDY OF BUYER, AND IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES WHETHER OR NOT CAUSED BY OR RESULTING FROM THE NEGLIGENCE OF SUCH PARTY. As with any material, evaluation of the material under end-use conditions prior to specification is essential. Therefore, specific testing under actual conditions is recommended.

Nothing contained in this book shall be construed as a grant of any right of manufacture, sale, use, or reproduction, in connection with any method, process, apparatus, product, composition, or system, whether or not covered by letters patent, copyright, or trademark, and nothing contained in this book shall be construed as a defense against any alleged infringement of letters patent, copyright, or trademark, or as a defense against liability for such infringement.

Comments, criticisms, and suggestions are invited, and should be forwarded to ASM International.

ISBN: 0-87170-824-8
SAN: 204-7586

ASM International®
Materials Park, OH 44073-0002
www.asminternational.org

Printed in the United States of America

Multiple copy reprints of individual articles are available from Technical Department, ASM
International.

CONTENTS

Keynote

Medical Device Failures – Can We Learn from Our Mistakes?	3
L.E. Eiselstein, B. James, Exponent Failure Analysis Associates, Menlo Park, California	

Nitinol Fatigue

Bending Fatigue Characteristics of Nitinol	14
A. Wick, X.Y. Gong, J. Fino, J. Sheriff, A.R. Pelton, Nitinol Devices & Components, Fremont, California	

High Strain Accelerated Fatigue Failure Testing of NiTi Implantable Devices.....	20
B. Shuman, C. Finger, Spiration Inc., Redmond, Washington K. Perry, Echobio, LLC, Bainbridge Island, Washington	

Cyclic Properties of Superelastic Nitinol Tubing.....	25
X.Y. Gong, A.R. Pelton, T. Duerig, Nitinol Devices & Components, Fremont, California A. Hall, California Polytechnic State University, San Luis Obispo, California	

Thermal Processing of Polycrystalline NiTi Shape Memory Alloys.....	31
C. Frick, K. Gall, A. Ortego, J. Tyber, University of Colorado, Boulder, Colorado H.J. Maier, A. El. M. Maksound, University of Paderborn, Paderborn, Germany Y. Liu, University of Western Australia, Chawly, Australia	

Hydrogen Effects on Nitinol Fatigue.....	37
J. Sheriff, A. R. Pelton, Nitinol Devices & Components, Fremont, California L.A. Pruitt, University of California, Berkeley, California	

Failure Analysis of NiTi Wires Used in Medical Applications	43
B. James, J. Foulds, L. Eiselstein, Exponent Failure Analysis Associates, Menlo Park, California	

Laser Technologies for Manufacturing Medical Devices

Corrosion of Laser Marks on Instruments.....	51
R. Peterson, J. Dickinson, Smith & Nephew, Inc., Memphis, Tennessee	

Effects of Oxygen Contamination in the Argon Shielding Gas in Laser Welding of Commercially Pure Titanium Thin Sheet.....	57
Y. Zhou, X. Li, University of Waterloo, Waterloo, Ontario, Canada J. Xie, St. Jude Medical Center, Sylmar, California	

Laser Drilling for Medical Device Manufacturing	63
T.L. VanderWert, Prima North America, Champlin, Minnesota	

Surface Engineering

Pulsed Laser Deposition of Diamondlike Carbon-Hydroxyapatite Composites	69
R J. Narayan, B.F. Ball, Georgia Institute of Technology, Atlanta, Georgia	
Metallographic Preparation of Orthopedic Medical Devices	73
G. Lucas, G. Vander Voort, Buehler, Ltd., Lake Bluff, Illinois D. Medlin, Zimmer, Inc., Warsaw, Indiana	
Structural Properties of PVD Coatings on Implants and their Influence on Stimulation Performance in Pacing Applications.....	79
H. Specht, F. Krüger, H. J. Wachter, O. Keitel, C. Leitold, M. Frericks, W. C. Heraeus GmbH & Co. KG, Hanau, Germany	
Characterization and Comparison of Coated Bone Drill Bits	83
L. Eschbach, W. Hirsiger, G. Biguin, B. Gasser, Dr. Robert Mathys Foundation, Bettlach, Switzerland	
The Challenge of Plasma Processing - Its Diversity.....	89
M. Larner, S. Kaplan, 4th State, Inc., Belmont, California	
Mechanical Properties of Calcium Phosphate Invert Glass-Ceramic Coated Ti-29Nb-13Ta-4.6Zr for Biomedical Applications.....	95
M. Niinomi, T. Akahori, T. Yamaguchi, Toyohashi University of Technology, Toyohashi, Japan T. Kasuga, Nagoya Institute of Technology, Nagoya, Japan A. Suzuki, Daido Steel Co., Ltd., Nagoya, Japan H. Fukui, Aichi-Gakuin University, Nagoya, Japan	
Modifying the Mechanical Properties of Porous Equiatomic Nickel-Titanium to Better Mimic Bone	101
A.P. Jardine, G. Baure, Shape Change Technologies LLC, Thousand Oaks, California	
Nitinol Properties and Manufacture	
Device Specific NiTi TTT Diagram: Lessons Learned	106
B. Shuman, C. Finger, Spiration, Inc., Redmond, Washington K. Perry, Echobio, LLC, Bainbridge Island, Washington	
Development and Testing of Manufacturable Thin Film TiNi for Medical Devices.....	109
A.P. Jardine, G. Baure, A. N. Le, Shape Change Technologies LLC, Thousand Oaks, California G.P. Carman, University of California, Los Angeles, California	
Clausius-Clapeyron Equations in Different Types of Nickel Titanium Shape Memory Alloy.....	113
S. Zhang, M. Denton, S. Fariabi, Edwards LifeSciences, Irvine, California	
An Investigation of the Effect of Drawing Temperature on Nitinol Processing.....	117
G.F. Archer, Johnson Matthey, San Jose, California	
Improved Fracture Healing with use of Shape Memory Alloys	121
J. Tyber, J. Toelle, C. Frick, A. Ortega, D. Steinke, E. Hardy, K. Gall, University of Colorado,	

Boulder, Colorado
D. Pacaccio, Inova Fairfax Hospital, Falls Church, Virginia

Numerical Modeling

Phase Transformations in Nitinol and Challenges for Numerical Modeling 127

K.E. Perry, Echobio, LLC, Bainbridge Island, Washington
P.E. Labossiere, University of Washington, Seattle, Washington

Optimization of a Combined Nitinol/Polymer Device Using FEA..... 131

E. Konstantino, T. Feld, AngioScore, Inc., Alameda, California
S. Keidar, Tel Aviv, Israel
G. Gershony, John Muir Medical Center, Walnut Creek, California

A Numerical and Experimental Investigation into the Forces Generated when Cutting Biomaterials..... 136

C.T. McCarthy, E. O'Dwyer, M. Hussey, M.D. Gilchrist, University College, Dublin, Ireland
N.P. O'Dowd, Imperial College, London, United Kingdom

Process Simulation Applications in the Medical Industry 142

D. Lambert, J. Walters, Scientific Forming Technologies Corporation, Columbus, Ohio

Nano and Microfabricated Structures

Functionally Gradient Diamondlike Carbon Nanocomposites for Medical Applications..... 149

R.J. Narayan, D. Scholvin, Georgia Institute of Technology, Atlanta, Georgia

Material Design for Neural Applications Using Carbon Nanofibers 155

J.L. McKenzie, R. Shi, T.J. Webster, Purdue University, West Lafayette, Indiana

Healthy Aims - Development of Implantable Microsystems Medical Devices 161

S.B. Dunkerton, TWI Ltd/Medical Devices Faraday Partnership, Cambridge, United Kingdom
D. Hodgins, ETB Ltd., Cedicote, United Kingdom

Mechanical and Physical Properties of Medical Devices

Fluid Composition Influences Wear Testing of Artificial Knee Implants 169

T. Schwenke, M.A. Wimmer, Rush University Medical Center, Chicago, Illinois
C. Kaddick, EndoLab GmbH, Rosenheim, Germany

The Development of Wear Resistant Titanium-Ceramic Composites for Orthopaedic Implant Devices..... 174

S. Abkowitz, S. M. Abkowitz, H. Fisher, P.J. Schwartz, Dynamet Technology, Inc., Burlington, Massachusetts

Characterization of Biomedical Wire for Optimum Performance in Suture Needle Manufacture and Use 180

D. Bradley, S. Chaney, S. Fischer, Fort Wayne Metals Research Products Corporation, Fort Wayne, Indiana

The Effect of Bundle Type on Cerclage Cable Fatigue Life..... 185

R.W. Jones III, S. Tsai, W. Allen, A. Salehi, Smith & Nephew, Inc., Memphis, Tennessee

Effects of Surface Modification of Ti on Cement Bond Strengths 187

P. Agarwal, Y. Oshida, Indiana University School of Dentistry, Indianapolis, Indiana

M. Ito, Matsumoto Dental University, Shiojiri, Nagano, Japan

Stainless Steel, Titanium and Cobalt-Base Alloy Developments

Development of Beta Titanium Alloys with Low Young's Modulus 193

S. Hanada, T. Ozaki, H. Matsumoto, S. Watanabe, T. Miyazaki, M. Hasegawa, Tohoku University,
Sendai, Japan

Sandvik Bioline 1RK91 – an Advanced Material for Medical Device Manufacture 199

S. Cowen, N. Haworth, Sandvik Bioline, Sheffield, United Kingdom

J. O. Nilsson, Sandvik Materials Technology, Sandviken, Sweden

**Optimization of Melt Chemistry and Properties of Drawn Filled Tube (DFT®) Composite
Materials of 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy (UNS R30035)**

Medical Grade Wire with Silver Core 205

L. Kay, D. Bradley, Fort Wayne Metals Research Products Corporation, Fort Wayne, Indiana

Powder Injection Molding of Titanium Components 211

K.L. Simmons, E. A. Nyberg, K. S. Weil, Pacific Northwest National Laboratory,
Richland, Washington

M. Miller, University of Alabama, Birmingham, Alabama

**Desirable Biocompatible and Physical Characteristics of Selected Stainless Steel Alloys and
Specialty Wire Materials for Use in the Design and Manufacture of Implants and**

Medical Devices 217

G. Kurisky, R. D'Ambrisi, Maryland Specialty Wire, Cockeysville, Maryland

Precision of Fit of the Procera® One-Piece Machined Titanium Implant Framework 221

R.F. Wang, B.R. Lang, M.E. Razzoog, The University of Michigan, Ann Arbor, Michigan

In-Situ Formation of Ti Alloys Via Powder Injection Molding 225

K.L. Simmons, E.A. Nyberg, K. S. Weil, Pacific Northwest National Laboratory,
Richland, Washington

M. Miller, University of Alabama, Birmingham, Alabama

A Study on Low Modulus Titanium Alloys for Biomedical Applications..... 229

S.E. Kim, H. W. Jeong, Y.T. Hyun, Y.T. Lee, Korea Institute of Machinery and Materials,
Changwon, South Korea

Y.H. Park, J.H. Lee, Dong A University, Busan, South Korea

Imaging

**Quantitative Assessment of Radiofrequency Attenuation Associated With NiTi Stents
in Magnetic Resonance Imaging..... 235**

E. Walsh, A. Holton, University of Alabama, Birmingham, Alabama

R. Venugopalan, Codman and Shurtleff, A J&J Company, Raynham, Massachusetts

Tantalum Coated Carbon-Carbon Composite Material for Surgical Implants 241

S. Eriksen, E. Christensen, B. Gillesberg, L. N. Langmaack, Danfoss Tantalum Technologies,
Lyngby, Denmark

H. Li, M. Lind, C. Bünger, Aarhus University Hospital, Aarhus, Denmark

Radiopaque Marking of Devices for X-Ray Imaging	247
R. Dickenson, Noble-Met, Ltd., Salem, Virginia	

3D Imaging and Visualization of Engineering Materials via Medical and Industrial X-Ray Computed Tomography	253
J. M. Wells, JMW Associates, Mashpee, Massachusetts	

Three-Dimensional Atomic Structure and Compositional Analysis of Medical Devices with the Local Electrode Atom Probe	259
S.L. Goodman, T. J. Mengelt, M. Ali, S.L.P. Kostna, R.M. Ulfing, T.F. Kelly, Imago Scientific Instruments Corporation, Madison, Wisconsin	

A Femoral Canal Sizing Device for Hip Implants.....	263
T. Norman, R. Chasnov, A. Gianettino, A. Julian, M. Michonski, J. Proctor, T. Thompson, S. San Gregory, Cedarville University, Cedarville, Ohio J. D. Blaha, University of Michigan, Ann Arbor, Michigan	

Managing Post Production Change.....	267
C. Roy, J. Fessler, S. Medhekar, Exponent, Inc., Irvine, California	

Cardiovascular Device Applications

Comparing and Optimizing Co-Cr Tubing Properties for Stent Applications.....	274
P. Poncin, C. Millet, J. Chevy, Minitubes, Grenoble, France J. L. Proft, Metallurgical Solutions, Foster City, California	

Corrosion of the Nitinol Wire of Endovascular Prostheses: Does Nickel Ion Release Impair the Devices Performance?	279
R. Guidoin, Y. Douville, G. Dionne, Laval University, Quebec City, Quebec, Canada M. King, North Carolina State University, Raleigh, North Carolina A. P. Legrand, ESPCI, Paris, France P. Doppelt, CECM-CNRS, Vitry sur Seine, France	

Analysis of Nitinol Stents after Long Term in-Vivo Exposure	285
S. Walak, Boston Scientific Corporation, Watertown, Massachusetts	

A Biomimetic Stent Coating to Reduce Thrombosis and Inflammation.....	290
J. A. Neff, W. A. Takeguchi, T. Kupumbati, Allvivo, Inc., Lake Forest, California J. Andersson, B. Nilsson, University Hospital, Uppsala, Sweden F. Bexborn, K. Nilsson Ekdahl, University of Kalmar, Kalmar, Sweden	

Development of Iridium Oxide as a Cardiovascular Stent Coating	296
B. O'Brien, Boston Scientific Corporation, Galway, Ireland C. Chandrasekaran, Boston Scientific Corporation, Redmond, Washington	

Determination of Constricting Forces Required for an Adjustable Systemic to Pulmonary Artery Shunt.....	302
N.V. Thuramalla, P. Rachakonda W. I. Douglas, C.F. Knapp, J.K. Knapp, University of Kentucky, Lexington, Kentucky	

Regulatory and Biocompatibility Issues for Medical Device Manufacturers

U.S. FDA Perspective on the Regulations of Cyanoacrylate Polymer Tissue Adhesives in Clinical Applications.....	309
G. J. Mattamal, U. S. Food and Drug Administration, Rockville, Maryland	

Advanced Manufacturing Technologies

Processing of Biocompatible Materials via Metal and Ceramic Injection Molding	318
J.L. Johnson, D.F. Heaney, The Pennsylvania State University, University Park, Pennsylvania	
Advanced Electrochemical Finishing Techniques for Medical Device Applications	324
A. Bonifas, E.J. Taylor, J. Sun, Faraday Technology, Inc., Clayton, Ohio	
CAD-CAM-Technology for Medical Components.....	330
W. Saxler, J. Strohmam, T. Simmich, Alfred H. Schuette GmbH, Cologne, Germany	

Non-Metallic Biomaterials

Mechanical Characterization of a Novel Biodegradable Composite for Use in Osteosynthesis Applications.....	336
S.D. Ramsay, L. Yang, R.M. Pilliar, J. P. Santerre, University of Toronto, Toronto, Ontario, Canada	

Advances in Surgical Instrument Technologies

Techniques for Investigation of Surgical Cutting Instruments	342
E. Price, G.A. Reilly, B.A.O. McCormack, Institute of Technology, Sligo, Ireland A.C. Macey, Sligo General Hospital, Sligo, Ireland	
A Durable and Lubricious Polymer Composite Coating for Medical Devices	348
J.G. Nawrocki, R. E. Maurer, Ethicon, Inc., a J&J Company, Somerville, New Jersey	
A Model of the Failure Process of Skin During Cutting.....	354
C. Doran, Waterford Institute of Technology, Waterford, Ireland B. McCormack, Institute of Technology, Sligo, Ireland A. Macey, Sligo General Hospital, Sligo, Ireland	

Corrosion

Interpretation of Corrosion Test Results and Prediction of Clinical Performance of Medical Devices.....	362
M. Marek, Georgia Institute of Technology, Atlanta, Georgia	
Passivation Stability of Titanium.....	368
Y. Oshida, Indiana University School of Dentistry, Indianapolis, Indiana F. Farzin-Nia, ORMCO Corporation, Glendora, California M. Ito, Matsumoto Dental University, Shiojiri, Nagano, Japan W. Panyayong, Prince of Songkla University, Songkhla, Thailand	

Effect of Grain Size on the Electrochemical Properties of Oxide Films on Titanium and

its Alloys For Orthopedic and Spinal Applications	373
I. Trausch, N. Istephanous, Medtronic Inc., Minneapolis, Minnesota	
H. Rack, J.I. Qazi, Clemson University, Clemson, South Carolina	
Effect of Radical Transfer Reaction by Free Oxygen on the Corrosion of Ti-Nb Implant Alloys.....	379
D. Zander, B. Heisterkamp, University of Dortmund, Dortmund, Germany	
Effect of Temperature and pH on Corrosion Resistance of Nitinol	385
A.R. Pelton, C. Trepanier, Nitinol Devices & Components, Fremont, California	
Galvanic Corrosion of Cobalt-Base and Titanium-Base Implant Material Couples.....	391
L. Zardiackas, M. Roach, University of Mississippi Medical Center, Jackson, Mississippi	
J. Disegi, Synthes, West Chester, Pennsylvania	
Acidic Fretting Tests of Oxidized Zr-2.5Nb, CoCr and SS Femoral Heads	396
V. Pawar, B. Jones, J. Sprague, A. Salehi, G. Hunter, Smith & Nephew, Inc., Inc., Memphis, Tennessee	
Electrolytic HA/ZrO₂ Double Layers Coating on Co-Cr-Mo Alloy for Orthopaedic Applications	402
S.K. Yen, C.M. Lin, G.S. Lin, S.H. Chen, National Chunghsing University, Taichung, Taiwan	

Preface

This publication, *Materials and Processes for Medical Devices (MPMD)*, contains papers presented at a conference sponsored by ASM International on August 25–27, 2004 in Saint Paul, Minnesota.

In 2002 ASM International organized a Materials for Medical Devices (MMD) Task Force that evaluated the need and feasibility of sponsoring a conference on the topic area of biomaterials. After a year of analysis, organizing, and numerous teleconferences, the first *Materials and Processes for Medical Devices Conference* was held in Anaheim, California, on September 8–10, 2003. The number of technical presentations, exhibitors, and attendees at this conference exceeded the initial estimates and this gave the MMD Task Force an indication of the high level of interest in this technical subject matter. The MPMD Organizing Committee quickly responded by organizing a second conference described in these proceedings. Once again, the number of exhibitors and attendees exceeded the expectations, indicating the intense interest of this topic.

The overwhelming success of these two MPMD conferences is attributed to the organizing committee's balance of medical device technology, new materials, new processes, testing issues, regulatory issues, and specific device application concerns. These topical areas are likely to be of interest to material scientists, metallurgical engineers, medical device design engineers, regulatory professionals, government agencies, and medical practitioners involved with the vascular, dental, and orthopedic business segments. By bringing professionals from these diverse backgrounds together in a common forum, the opportunity to transfer new material and process technologies is one of the beneficial outcomes of this conference.

Many volunteers from the medical devices industry, suppliers, regulatory agencies, and academia participated by organizing and contributing to the development of this outstanding program. We sincerely thank them for their dedication and commitment. We also thank the staff of ASM International for their assistance in executing the vision and plan of the 2004 MPMD Organizing Committee, as well as the co-sponsors of this event: ASTM F04 Committee, Society for Biomaterials, AAOS, SMST, CRS, and Biomat.net.

Mike Helmus
Co-Chair, MPMD Organizing Committee
Committee
Boston Scientific Corporation
Natick, MA

Dana Medlin
Co-Chair, MPMD Organizing
Zimmer, Inc.
Warsaw, IN



ASM International is the society for materials engineers and scientists, a worldwide network dedicated to advancing industry, technology, and applications of metals and materials.

ASM International, Materials Park, Ohio, USA
www.asminternational.org

This publication is copyright © ASM International®. All rights reserved.

Publication title	Product code
Medical Device Materials II	05107G

To order products from ASM International:

Online Visit www.asminternational.org/bookstore

Telephone 1-800-336-5152 (US) or 1-440-338-5151 (Outside US)

Fax 1-440-338-4634

Mail Customer Service, ASM International
9639 Kinsman Rd, Materials Park, Ohio 44073, USA

Email CustomerService@asminternational.org

In Europe American Technical Publishers Ltd.
27-29 Knowl Piece, Wilbury Way, Hitchin Hertfordshire SG4 0SX, United Kingdom
Telephone: 01462 437933 (account holders), 01462 431525 (credit card)
www.ameritech.co.uk

In Japan Neutrino Inc.
Takahashi Bldg., 44-3 Fuda 1-chome, Chofu-Shi, Tokyo 182 Japan
Telephone: 81 (0) 424 84 5550

Terms of Use. This publication is being made available in PDF format as a benefit to members and customers of ASM International. You may download and print a copy of this publication for your personal use only. Other use and distribution is prohibited without the express written permission of ASM International.

No warranties, express or implied, including, without limitation, warranties of merchantability or fitness for a particular purpose, are given in connection with this publication. Although this information is believed to be accurate by ASM, ASM cannot guarantee that favorable results will be obtained from the use of this publication alone. This publication is intended for use by persons having technical skill, at their sole discretion and risk. Since the conditions of product or material use are outside of ASM's control, ASM assumes no liability or obligation in connection with any use of this information. As with any material, evaluation of the material under end-use conditions prior to specification is essential. Therefore, specific testing under actual conditions is recommended.

Nothing contained in this publication shall be construed as a grant of any right of manufacture, sale, use, or reproduction, in connection with any method, process, apparatus, product, composition, or system, whether or not covered by letters patent, copyright, or trademark, and nothing contained in this publication shall be construed as a defense against any alleged infringement of letters patent, copyright, or trademark, or as a defense against liability for such infringement.