Spring 2016

In This Issue

The Big Picture
7 Rising Stars among AAMI’s Sterilization Standards
Amanda Benedict

10 A Roundtable Discussion
Safer Sterilization and Reprocessing Require Systemwide Improvements

Research
18 Safe to Handle? Comparing Manually and Machine-Washed Medical Devices
Kaumudi Kulkarni, Dzelma Kaczorowski, Alex Bonkowski, Stephen Kovach, and Ralph Basile

Perspectives on Sterilization & Reprocessing
24 ST91: A Roadmap for Reprocessing Flexible and Semirigid Endoscopes
Mary Ann Drosnock

29 Bringing Order to Sterile Processing through Standardized Processes
Alison Sonstelie, Danae Dorval, and Susan Pfeifer

32 Lessons Learned from FDA’s Regulation of ‘Single-Use’ Device Reprocessing
Daniel J. Vukelich

Case Study
37 Barriers to Adopting FDA Guidance in Central Sterile Departments
Cheryl Kwinn

AAMI President
Mary Logan, JD, CAE

Vice President of Communications
Sean Loughlin

Managing Editor
Joseph Sheffer

Graphic Designers
Kristin Blair
Ruth Moyer

Copy Editor
Amber Bauer
Barbara Saxton

Editorial Board
Damien Berg
St. Vincent Hospital
Ramona Conner
Association of periOperative Registered Nurses
Jacqueline Daley
LifeBridge Health
Kevin Frey
Association of Surgical Technologists

Vicki Hitchens
Center for Devices and Radiological Health, Food and Drug Administration
Emily Mitzel
Nelson Laboratories, Inc.
Rodney Parker
Stryker Instruments
Janet Prust
3M Healthcare
Richard Schule
STERIS Corporation

Horizons is a supplement to Biomedical Instrumentation & Technology (ISSN 0899-8205) and is published twice a year by the Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633; 703-525-4890. © 2016, Association for the Advancement of Medical Instrumentation. Publishing services provided by Allen Press Publishing Services, a division of Allen Press Inc.

Membership: AAMI members receive a complimentary subscription. Contact membership at AAMI at 800-332-2264, ext. 1214.

Additional Copies: Visit www.aami.org/store or call 1-877-249-8226.


Mention of any commercial product, process, or service by trade name, trademark, manufacturer, or otherwise in Horizons does not constitute or imply an endorsement or recommendation by AAMI. The views and opinions of the authors in Horizons do not state or reflect the opinion of AAMI.

POSTMASTER: Send address changes to BI&T, 810 E. 10th Street, P.O. Box 1897, Lawrence, KS 66044-8897. AAMI members send changes to AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633; 703-525-4890. Nonmembers send changes to Kansas address above.