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AAMI / FDA Summit Highlights Narrow Lumens as One of the Biggest Challenges in Medical Device Reprocessing

At a two day summit in October 2011 The Association for the Advancement of Medical Instrumentation (AAMI), the U.S. Food and Drug Association (FDA) and industry representatives debated the main challenges in medical device reprocessing. Among the list of the biggest design issues that the experts said need to be addressed were small angled lumen devices and an inability to determine if a device is clean.

The summit took place in response to growing concern over patient safety following reports about patients becoming sick after exposure to contaminated instruments.

Experts at the summit focused on the challenging and skilled nature of Sterile Processors job, especially when instruments are not designed with reprocessing in mind. When a device does not come apart, how do we ensure that lumens and crevices are clean? Romona Conner, Manager of Standards and Recommended Practices with the Association of periOperative Registered Nurses said "We are asking people...to do high-risk, highly technical and challenging processes under adverse conditions with little training, and little support,"

Medical devices can pose significant hazards to patients if they are inadequately or inappropriately reprocessed. The summit identified that a key step in the reprocessing cycle of any reusable medical device is inspection after cleaning and that many Sterile Processing Departments rely on visual inspection in order to determine whether an instrument is clean. Victoria Hitchins, Research Microbiologist at the Office of Science and Engineering Laboratories in FDA's Center for Devices and Radiological Health, said "Today, you can't see if the inside of the device is visibly clean due to long and/or narrow, opaque lumens and hinges."

Mike Waller, a Consultant for Single Use Surgical, commented "Central Sterile Departments tell our distributors that they struggle to process suction tubes and that they feel uneasy that they cannot be certain that the internal lumen is clean but their voice often goes unheard. Forward thinking hospitals have chosen to switch to single use suction tubes but there is still a lot of work to be done across the states. This summit raised the profile of the problems and should encourage other hospitals to look for a solution."

Single Use Surgical manufactures in the U.K. and entered the U.S. market in 2008 when they opened a warehouse in Pennsylvania to enable them to offer U.S. distributors and direct customers a safe and cost effective alternative to reusable fine lumen suction tubes. The company will be showcasing their range at the American Association of Neurological Surgeons (AANS) annual scientific meeting which will be held in Miami, April 14-18 2012.

The U.S. is about 10 years behind Europe, where it is widely accepted that narrow lumen instruments pose a significant infection risk and it is recommended that they are not reprocessed.

Attendees of the AMMI / FDA summit hope that the debates will bring about changes that will reduce hospital related infections and readmissions and improve patient safety. A list of priorities was collated from the debates and will be used by AAMI to create a comprehensive action plan to help improve reprocessing standards. AMMI President Mary Logan added "It's going to take an interdisciplinary conversation to make us move forward...We will make progress"

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About Single Use Surgical

Single Use Surgical provides an alternative to reprocessing instruments with narrow channels. They offer a wide range of disposable suction tube instruments for use in surgical procedures across several specialties. The company's focus on high quality, ergonomic design and customer support provides hospitals with a cost-effective alternative to reprocessing devices that carry a risk of being inadequately cleaned due to instrument design and inappropriate manufacturer's instructions. Switching to single use devices also reduces the volume of difficult to clean devices that pass through Central Sterile on a daily basis, helping to alleviate time constraints and ultimately to reduce Hospital-Acquired Infection rates.

About AAMI

Founded in 1967, the Association for the Advancement of Medical Instrumentation (AAMI) is a nonprofit organization representing a unique alliance of over 6,000 members from around the world united by one mission to increase the understanding and beneficial use of medical instrumentation through effective standards and educational programs, and publications.

About the U.S. FDA

The U.S. Food and Drug Association (FDA) is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. FDA also has responsibility for regulating the manufacturing, marketing and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.