Teleflex Receives FDA 510(k) Clearance for the ISO-Gard® Mask with ClearAir™ Technology

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LIMERICK, Pa.--(BUSINESS WIRE)--Apr. 11, 2013-- Teleflex Incorporated (NYSE:TFX), a leading global provider of medical devices for critical care and surgery, has announced that its Anesthesia and Respiratory business unit received 510(k) clearance[1] for the ISO-Gard® Mask with ClearAir™ Technology, the Company's novel product that helps to reduce clinician exposure to hazardous waste anesthetic gases.

The ISO-Gard Mask is designed to reduce waste anesthetic gas (WAG) within a nurse's breathing zone to minimize the cumulative effect of low-level exposure to these hazardous gases in the Post Anesthesia Care Unit (PACU). The multi-purpose mask scavenges WAG while simultaneously delivering oxygen to the patient. The patent-pending ClearAir technology provides unidirectional flow of oxygen through the mask to assure maximum FiO2.

Teleflex estimates that anesthetic gases are used in 20 million surgeries in the US annually and up to 100 million globally.[2] When patients are recovering in the PACU, they exhale these gases which are then released into the nurses' breathing zone and work environment. The Occupational Safety and Health Administration (OSHA) warns of several potential health effects from WAG exposure, including nausea, dizziness, headaches, and fatigue.[2]

The PACU is currently a non-scavenged environment so other less-effective methods of waste gas removal are often relied upon, making it more difficult to control clinician exposure.[3] "I was surprised at the level of nitrous oxide and sevoflurane in the PACU from patient off-gassing from a recent study we conducted in a hospital in the Midwest," said James D. McGlothlin, MPH, Ph.D., CPE.[4] "Based on what I personally experienced during this study, I believe that waste anesthetic gases should be controlled in the PACU by a combination of engineering controls (i.e., scavenging systems), including regular maintenance of such equipment, and best practices by those who care for patients in the PACU."

"As the only available solution for 'source control' of WAG in the PACU, the ISO-Gard Mask with ClearAir Technology is a simple, safe, and effective solution to a pressing need," said Cary Vance, President, Anesthesia and Respiratory Division. "By providing a means to reduce the amount of WAG within the breathing zone of the caregiver, hospitals can better comply with OSHA and NIOSH recommendations for workplace safety."[3,5]

The ISO-Gard Mask with ClearAir Technology is a featured addition to the Teleflex line of Hudson RCI® respiratory products. "This unique device exemplifies Teleflex's commitment to provide solutions that enhance provider safety," said Vance. Learn more at iso-gardmask.com.

About Teleflex Incorporated

Teleflex is a leading global provider of specialty medical devices for a range of procedures in critical care and surgery. Our mission is to provide solutions that enable healthcare providers to improve outcomes and enhance patient and provider safety. Headquartered in Limerick, PA, Teleflex employs approximately 11,600 people worldwide and serves healthcare providers in more than 140 countries. Additional information about Teleflex can be obtained from the company's website at teleflex.com.

About Dr. James D. McGlothlin

JAMES D. McGLOTHLIN is an Associate Professor of Health Sciences in the College of Health and Human Sciences at Purdue University. Dr. McGlothlin's research specializes in ergonomics, exposure assessment (focusing on Video Exposure Monitoring), occupational hygiene, engineering controls, and epidemiology. He has been conducting research in the areas of molecular diagnostics and molecular epidemiology, and is the Director of www.MolecularHub.org, a portal dedicated to advancing the science of molecular diagnostics. He is the Director of the Graduate Program in Occupational and Environmental Sciences, and Co-Director of the Center for Virtual Reality of Healthcare Center Design at Purdue University. He is one of the founders for the Regenstrief Center for Healthcare Engineering (RCHE). He served on the University Senate and on the Senate Advisory Committee to President Cordova and Provost Sands. Also, he has served on the Education Policy Committee as a member and as the chair. Prior to Dr. McGlothlin's appointment to Purdue University January 4, 1999 he was a senior researcher in ergonomics and occupational hygiene engineering controls with the Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (CDC/NIOSH).

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

References:

1. FDA 510(k) number K123176 – February 14, 2013

2. Inpatient Surgery data. Centers for Disease Control and Prevention. http://www.cdc.gov/nchs/fastats/insurg.htm.

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WHO Guidelines for Safe Surgery. WHO/IER/PSP/2008.08-1E http://gawande.com/documents/WHOGuidelinesforSafeSurgery.pdf. Accessed February 13, 2013.

3. Occupational Safety and Health Administration, Anesthetic Gases: Guidelines for Workplace Exposures. http://www.osha.gov/dts/osta/anestheticgases/index.html. Accessed February 13, 2013.

4. Study was funded by a grant from Teleflex. Study has not been peer reviewed or published. IRB study was not an outcome study to support an FDA submission. Sample size was not statistically significant.

5. Waste Anesthetic Gases–Occupational Hazards in Hospitals. Centers for Disease Control and Prevention. http://www.cdc.gov/niosh/docs/2007-151 Accessed February 13, 2013.

Source: Teleflex Incorporated

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