

Medegen Receives FDA Clearance for MaxGuard[®] Advanced Luer-Activated Device with Antimicrobial Technology

First Positive Displacement Needleless Connector with Antimicrobial Technology

Ontario, Calif. (January 8, 2009)—Medegen <http://www.medegen.com/>, a leading innovator in infusion therapy products, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its new MaxGuard[®] Advanced Luer Activated Device featuring Agion[®] Antimicrobial Technology. MaxGuard is the first positive displacement needleless connector featuring impregnation of the antimicrobial additive into each of the components of the device. Laboratory testing has demonstrated this new antimicrobial device exhibits a kill rate of greater than 99.99 percent representing a 4+ log reduction on infection-causing organisms predominantly responsible for catheter related bloodstream infections.

Medegen routinely receives input from IV Therapy clinicians regarding unmet needs and new product concepts. In 2006 clinical end users requested that Medegen's leading device, the MaxPlus[®] Positive Displacement Connector, be offered with a clear housing to facilitate visualization of the fluid path. In February 2008, Medegen released the MaxPlus Clear[®] which quickly became a leading product for the company because of the consistent and dramatic bloodstream infection reduction results it has brought to hospitals nationwide. Last year, MaxPlus clinical users requested an antimicrobial version of the MaxPlus Clear device for use on immunocompromised patients. Today, Medegen is once again fulfilling the clinical users' requests by announcing FDA clearance of the new MaxGuard Advanced Luer Activated Device with Antimicrobial Technology.

"This is a significant achievement in Medegen's ongoing pursuit to develop programs and products that help clinicians prevent bloodstream infections," said Jeffrey Goble, President of Medegen. "Our goal has always been to provide clinicians with products that will significantly improve their efforts to enhance patient care and positive outcomes, and MaxGuard with Antimicrobial Technology meets that goal."

Many hospitalized patients receive medications and nutritional support intravenously. During the process of administering intravenous medication, environmental contaminants can be introduced into the bloodstream. This is of particular concern if proper infection prevention techniques are not followed. MaxGuard with Antimicrobial Technology helps prevent contamination and growth of microorganisms at the point of entry into the catheter and subsequently in the bloodstream. MaxGuard is new technology introduced to assist hospitals in reducing catheter related bloodstream infections.

The introduction of MaxGuard comes at a time when bloodstream infection rates continue to be a major concern among hospitals. With the new federal policy restricting reimbursement for healthcare-associated infections (HAIs), healthcare professionals are seeking techniques and technologies to assist in their bloodstream infection prevention efforts.

With the addition of antimicrobial technology, MaxGuard is an enhancement of the MaxPlus Clear, Medegen's leading positive displacement connector. It features Medegen's patented

positive displacement technology, which provides a bolus of fluid to clear the catheter tip upon disconnection from the device. It also features Medegen's patented Tru-Swab® top which acts as a double seal barrier to contamination and allows for true disinfection during pre-access swabbing. The translucent housing provides for visualization of the fluid path allowing for complete flushing of the device.

"Healthcare professionals and facilities are seeking new technologies and practices to assist in their efforts to reduce the occurrence of catheter related bloodstream infections (CRBSI)," said Goble. "In addition to the negative impact on the patient, the cost of treating a single CRBSI can reach \$56,000 or more according to the CDC and with changes in healthcare reimbursement practices, hospitals are looking for assistance in meeting infection reduction goals. We are very pleased to see the clinicians' fast rate of adoption of the MaxPlus Clear and more importantly to receive feedback from many hospitals regarding bloodstream infection rate reductions concomitant with use of the MaxPlus Clear device."

"We are excited to introduce MaxGuard and offer hospital clinicians yet another product to help prevent bloodstream infections, improve patient outcomes and reduce costs," said Goble.

MaxGuard Advanced Luer Activated device will be available second quarter 2009. Visit www.medegen.com <<http://www.medegen.com/>> for more information.

About Medegen, Inc. Medegen is a leading innovator in infusion therapy, focused on developing innovative product technologies that significantly improve patient safety and outcomes. Medegen founded is headquartered in Ontario, Calif. For more visit <http://www.medegen.com/>

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