HemCon® GuardIVa® Antimicrobial Hemostatic IV Dressing Obtains Additional FDA Clearance and HCPCS Reimbursement Codes

The Associated Press

PORTLAND, Ore.--(BUSINESS WIRE)--Sep 4, 2012--HemCon Medical Technologies (“HemCon”), a leading global developer of advanced medical technologies and products, announced receiving an additional U.S. regulatory clearance for the antimicrobial hemostatic IV dressing GuardIVa ®, that is part of its European subsidiary product portfolio.

GuardIVa ® Antimicrobial Hemostatic IV Dressing is an adjunct to infection control measures by providing sustained IV site protection. The dressing is a flexible, absorptive sponge disk that can be easily placed around catheters to absorb exudate, cover and protect sites such as central venous catheters (CVC) and peripherally inserted central catheters (PICC).

GuardIVa contains chlorhexidine gluconate (CHG), a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity. The CHG antimicrobial agent protects the dressing from microbial colonization and provides sustained effectiveness over seven days against a wide range of microorganisms*. GuardIVa is the only IV site dressing on the market that is indicated for control of surface bleeding thanks to HemCon’s proprietary hemostatic agent, microdispersed oxidized cellulose.

As part of its expanded cleared product information, GuardIVa is now supported by data demonstrating that the dressing does not adversely affect normal site healing and has a normal irritation response to CHG when compared to other commercially available CHG based dressings, which were found to adversely affect healing. GuardIVa also demonstrated the ability to suppress skin flora re-growth for up to ten days, maintaining skin flora at a level equivalent to that observed immediately following pre-operative skin preparation.

“We are thrilled to be able to supplement our GuardIVa product with additional product information that further demonstrates its safety and efficacy,” said Barry Starkman, CEO of HemCon. “GuardIVa has been having great success in the marketplace and this additional clearance by the FDA will serve to enhance the value of this important product for the patients we serve.” In addition, the Centers for Medicare and Medicaid Services (CMS) also confirmed GuardIVa’s HCPCS reimbursement codes for Durable Medical Equipment. These codes are used by Medicare and monitored by CMS, and allow wound dressings and other medical supplies to be tracked for reimbursement.

Starkman said that this addition of reimbursement codes further highlights the value of this important product to the current state-of the-art in catheter

management by assuring that patients and their providers will now be reimbursed for the use of GuardIVa.

* GuardIVa has not been clinically tested for its ability to reduce catheter related blood stream infections (CR-BSI).

HemCon Medical Technologies, Inc. (www.hemcon.com) founded in 2001, develops, manufactures, and markets innovative technologies for rapid delivery of plasma and hemostatic devices for the control of bleeding resulting from trauma or surgery. HemCon products are designed for use by military and civilian first responders as well as medical professionals in hospital and clinical settings where rapid supply of plasma and control of bleeding are of critical importance. HemCon is headquartered in Portland, Ore., with additional commercial operations in Ireland and the Czech Republic.

CONTACT: HemCon Medical Technologies, Inc.

Simona Buergi, 503-245-0459 simona.buergi@hemcon.com KEYWORD: UNITED STATES NORTH AMERICA OREGON INDUSTRY KEYWORD: SURGERY HEALTH BIOTECHNOLOGY MEDICAL DEVICES MANUFACTURING OTHER MANUFACTURING FDA MEDICAL SUPPLIES SOURCE: HemCon Medical Technologies, Inc. Copyright Business Wire 2012 PUB: 09/04/2012 06:00 AM/DISC: 09/04/2012 06:00 AM
http://www.businesswire.com/news/home/20120904005472/

Source URL (retrieved on *10/22/2014 - 11:17pm*):
http://www.mdtmag.com/news/2012/09/hemcon%C2%AE-guardiva%C2%AE-antimicrobial-hemostatic-iv-dressing-obtains-additional-fda-clearance-and-hcpcs-reimbursement-codes