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United Business Media

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MAQUET Cardiovascular Receives 510(k) Clearance to Market the CARDIOHELP System in U.S.

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WAYNE, N.J., April 28, 2011 /PRNewswire/ -- MAQUET Cardiovascular today announced that the U.S. Food and Drug Administration has granted the company 510(k) clearance to market its CARDIOHELP System in the United States as a cardiac and/or respiratory assist device for up to six hours. The CARDIOHELP System is the world's smallest portable heart-lung support system providing extracorporeal life support (ECLS) to replace or support a patient's circulation and respiration. The product is expected to be commercially available in the United States later this year.

"Cardiovascular disease is the leading cause of death globally, with an estimated 17.5 million deaths each year," said Jeremy Cannon, M.D., trauma surgeon at Brooke Army Medical Center in San Antonio, Texas. "Many of these individuals experience cardiogenic shock because vital organs are not adequately supplied with oxygen. By quickly connecting a patient to a cardiopulmonary support system, the CARDIOHELP System will allow clinicians to gain valuable time that could save the patient's life*."

The CARDIOHELP System, which includes the HLS Advanced Tubing Set, is the first support system approved for both ground and air transportation.** It is light enough to be carried by one person and compact enough to be transported in a helicopter or vehicle. With its disposables, integrated sensors and individual operating modes, the CARDIOHELP System provides new options for patients whose heart and/or lungs are failing despite other treatment options.

"The need for immediate, mobile, compact, life-sustaining resuscitation occurs on a daily basis, both in and outside the hospital," said Linda Mongero CCP, perfusionist at New York Presbyterian Hospital. "CARDIOHELP is a collective system of engineering that finally optimizes cardiopulmonary support in prime time."

"The FDA clearance of the CARDIOHELP System means that we can provide clinicians and rapid response teams with an option for patients who need cardiac and/or respiratory support during inter- and intra-hospital transport," said Raoul Quintero, President and CEO, MAQUET Cardiovascular U.S. Sales. "In its most complete configuration, the CARDIOHELP System allows important blood parameters to be monitored during life support, ensuring the patient's safety."

"Today is a very gratifying and exciting day for me and the rest of the team that played an integral role in developing CARDIOHELP from concept through today's approval," said Christian Keller, President of MAQUET Cardiovascular U.S. "CARDIOHELP is another example of our ongoing commitment to providing customers the latest and most innovative technology that enables the Gold Standard in patient care."

CARDIOHELP

The individual operating modes and disposables of the CARDIOHELP System make it suitable for conditions in which cardiac and/or respiratory support is needed. The CARDIOHELP System offers several applications to support patients who require veno-venous life support or veno-arterial life support; it can also be used during open heart surgery and for extracorporeal carbon dioxide (CO_2) removal up to six hours.

Veno-venous life support, or respiratory assistance for lung disorders, is primarily used when the heart is still able to pump blood through the circulatory system without any additional support, as in the case of acute respiratory failure or a massive pulmonary embolism. The blood is removed from the jugular vein or a femoral vein for enrichment with oxygen, after which it is returned to a vein.

Veno-arterial life support is used with patients whose hearts are not adequately supporting their circulation or have stopped, which may occur with a myocardial infarction. It is vital to ensure cardiopulmonary support as early as possible to prevent organ damage. The CARDIOHELP System can help increase survival by enabling revascularization by means of catheterization or cardiac surgery. In the case of a veno-arterial life support, the blood is removed from the right atrium or a femoral vein and is returned to the aorta or a femoral artery after oxygenation; some of the blood therefore bypasses the heart in a parallel circulatory system, thus relieving stress on the heart muscle.

In severe cases of respiratory failure, the CARDIOHELP System can be used to reduce the CO_2 level in the blood. High CO_2 levels (e.g., acidosis, pulmonary hypertension) in some cases can lead to complications, and some patients need low to normal CO_2 levels to protect the brain.

Minimal extracorporeal circulation (MECC) with the CARDIOHELP System makes life support for cardiopulmonary support during open heart surgery less stressful for the patient than with a conventional heart-lung machine.

Key CARDIOHELP Features

The CARDIOHELP System may be installed in ambulances or helicopters and can be connected to the on-board power supply. The integrated rechargeable battery also provides a minimum of 90 minutes of operation without an external power supply. The CARDIOHELP System is operated via an easy touch screen with user guidance and a rotary knob to allow medical personnel with minimal life support experience to safely use the unit after suitable training.

The CARDIOHELP System monitors important blood parameters, including venous oxygen saturation, hemoglobin, hematocrit and arterial and venous blood temperature. The complete sensor system, which also includes three pressure sensors, is integrated into

the HLS Module Advanced disposable.
The CARDIOHELP System can be configured to capture case data and data recording intervals can be set individually from 3 seconds to 10 minutes.

About MAQUET

As a trusted partner for hospitals and clinicians since 1838, MAQUET is a global leader in medical systems that advance surgical interventions, cardiovascular procedures and critical care. MAQUET develops and designs innovative products and therapeutic applications for the operating room, hybrid OR/cath lab, intensive care unit and patient transport within acute care hospitals, improving outcomes and quality of life for patients.
Cardiovascular specialties include intra-aortic balloon counterpulsation (IABC) therapy for cardiac assist; coronary artery bypass surgery; aortic and peripheral vascular surgery; and extracorporeal circulation. The Critical Care portfolio includes market-leading intensive care ventilators and anesthesia machines. MAQUET also equips Surgical Workplaces with critical infrastructure, such as flexible room design for OR and ICU; OR tables; lights and ceiling supply units; and OR integration for image data management.
MAQUET is a subsidiary of the publicly listed Swedish GETINGE GROUP. In 2010, MAQUET generated nearly half of the company's annual revenue of $3.2 billion. The company has 12,000 employees worldwide, including 5,000 employees in 36 international sales and service organizations, as well as a network of more than 250 sales representatives. For more information please visit www.maquet.com and www.getingegroup.com.
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*The opinions expressed by Dr. Cannon are solely his own and do not represent an endorsement by or the views of the United States Air Force, the Department of Defense, or the United States Government.
**The CARDIOHELP System complies with other national transportation regulations.
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