

## Press Release

### **New ACCF/AHA/SCAI Guidelines with increased recommendations for the use of extracorporeal hemodynamic support in patients with cardiac or cardio-pulmonary failure.**

**Ampfing, Germany, 17-Januar 2012.** LIFEBRIDGE Medizintechnik AG today announces increased recommendations for hemodynamic support by guidelines for percutaneous coronary interventions (PCI). Issued by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA) and the Society for Coronary Angiography and Interventions (SCAI), guidelines provide expanded recommendations for hemodynamic support in patients with cardiogenic shock, during high-risk PCIs and to stabilize emergent patients in hospitals without on-site cardiac surgery. The portable LIFEBRIDGE® system, with its clinically proven capability to completely substitute cardiac function and oxygenate emergency patients, is the ideal cardiopulmonary support system for PCI centers to fulfill the updated guideline recommendations.

The 2011 ACCF/AHA/SCAI guidelines incorporate hemodynamic support for:

#### **Class I: Cardiogenic Shock**

“A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy.” (Level of Evidence B)

#### **Class IIb: Adjunctive Therapeutic Devices: Percutaneous Hemodynamic Support Devices:**

“Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients.” (Level of Evidence: C)

#### **Class III: HARM: PCI in Hospitals Without On-Site Surgical Backup:**

“Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer.” (Level of Evidence: C)

“Minimizing the time to initiation of cardiopulmonary bypass in patients requiring extracorporeal support now, for the first time, has been fully addressed by the updated PCI guidelines”, said Professor Hans-Reinhard Zerkowski, cardiac surgeon and CEO of LIFEBRIDGE Medizintechnik AG. “The portable LIFEBRIDGE® system is a unique solution for advanced life support in PCI centers and best suited to fulfill the updated guideline recommendations. Together with its unique safety features and usability LIFEBRIDGE® markedly will improve the standard of care in cardiac and respiratory emergencies.”

#### **ABOUT ACCF/AHA/SCAI Guidelines**

The 2011 ACCF/AHA/SCAI guidelines [1] incorporate several increased recommendations for hemodynamic support for:

#### **Class I: Cardiogenic Shock**

“A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy.” (Level of Evidence B)

#### **Class IIb: Adjunctive Therapeutic Devices: Percutaneous Hemodynamic Support Devices:**

“Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients.” (Level of Evidence: C)

**Class III: HARM: PCI in Hospitals Without On-Site Surgical Backup:**

“Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer.” (Level of Evidence: C)

Reference:

1. Levine GN et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. *Circulation* 2011, 124:e574-e651.

**ABOUT LIFEBRIDGE® SYSTEM**

The LIFEBRIDGE® system is a portable emergency system for extracorporeal heart lung support with unique safety features, automatic priming and air handling, intuitive user friendliness that allows a rapid initiation and a safe application of emergency cardiopulmonary bypass in patients with severe hemodynamic or respiratory crisis, especially in hospitals and locations without on-site cardiac surgery. It received CE certification and 510(k) FDA clearance. In contrast to current methods for hemodynamic support, the LIFEBRIDGE® system allows a complete temporary substitution of cardiac and pulmonary function. Thus LIFEBRIDGE® serves as the most powerful method to protect critical organs during acute episodes of cardiac or respiratory failure. The unique advantage of the LIFEBRIDGE® system is that hemodynamic support can be provided immediately where the hemodynamic crisis of the patient occurs. The primary usage of percutaneous cardiopulmonary bypass will be initiation in the emergency room, in the ICU or in the catheterization room by any trained health professional within minutes. The hemodynamic crisis can be reversed quickly and allows a rapid organ protection, which is the key for further therapy success and patient outcomes.

**ABOUT LIFEBRIDGE Medizintechnik AG**

Based in Ampfing, Germany, LIFEBRIDGE Medizintechnik AG is a leading provider of medical devices that provide circulatory support and extracorporeal oxygenation to patients in acute circulatory or respiratory failure. Our products are designed to enable the cardiovascular system as well as the critical organs to rest, heal and recover by improving blood flow and oxygenation. For additional information please visit: [www.lifebridge.com](http://www.lifebridge.com).

**FORWARD-LOOKING STATEMENTS**

This release contains forward-looking statements, including statements regarding development of LIFEBRIDGE's existing and new products, the company's progress toward commercial growth, and future opportunities. The company's actual results may differ materially from those anticipated in these forward-looking statements based upon a number of factors, including uncertainties associated with development, testing and related regulatory approvals, anticipated future losses, complex manufacturing, high quality requirements, dependence on limited sources of supply, competition, technological change, government regulation, future capital needs and uncertainty of additional financing, and other risks and challenges. Readers are cautioned not to place undue

reliance on any forward-looking statements, which speak only as of the date of this release. The company undertakes no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances that occur after the date of this release or to reflect the occurrence of unanticipated events.

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