LivaNova

Health innovation that matters

NEWS RELEASE

# LivaNova Combats Leg Ischemia with Breakthrough Bidirectional Cannula

*CE Marked Bi-Flow is the only cannula designed to prevent leg ischemia during cardiac procedures requiring femoral artery cannulation*

**London, July 16, 2019** – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, today launched its innovative arterial femoral cannula, Bi-Flow, designed to prevent limb ischemia during cardiac surgery.

LivaNova Bi-Flow received CE Mark earlier this year and is the only bidirectional arterial cannula designed to prevent leg ischemia during cardiac surgery procedures requiring femoral artery cannulation. In a clinical study, Bi-Flow was easily inserted and removed without complications and was proven to provide simultaneous systemic and distal perfusion of the limb in a safe and reproducible way.[1]

Leg ischemia is caused by compromised blood flow to a lower limb and can affect up to 11% of patients undergoing complex cardiac surgery procedures.[2] Consequences can include higher mortality, higher morbidity and longer hospital stays.[3]

The first procedure in Europe using a Bi-Flow cannula was performed by Patrick Perier M.D., FACS, at the Cardiovascular Center of Bad Neustadt, Germany. “I truly believe that Bi-Flow has the potential to become the new standard of care to prevent limb ischemia and its devastating effects in complex cases requiring femoral cannulation,” said Dr. Perier. “Where other approaches act as mere workarounds, Bi-Flow ensures leg perfusion and through its unique features allows us to protect the leg in a safe, easy and reproducible way, further improving patient outcomes.”

*1. Marasco et al., A Phase 1 Study of a Novel Bidirectional Perfusion Cannula in Patients Undergoing Femoral Cannulation for Cardiac Surgery, Innovations, 2018*

*2. Hendrickson et al., A Method for Perfusion of the Leg During Cardiopulmonary Bypass via Femoral Cannulation, Ann Thorac Surg. 1998 Jun;65(6):1807-8*

*3. June et al., Acute Limb Ischemia After Cardiothoracic Surgery Is Associated With High Rates of Amputation and Mortality, Journal of Vascular surgery, 2015*

The innovative, patented and award-winning design of the bidirectional cannula incorporates a unique shoulder and downstream perfusion channel that enables continuous and reliable blood flow down the femoral artery. At the same time, an open tip design ensures adequate systemic perfusion for the whole body.

“Limb ischemia is an often-underestimated potential side effect of femoral artery cannulation, and it can have dramatic consequences,” said Alistair Simpson, LivaNova General Manager of Cardiac Surgery. “We are proud to launch this innovative cannula that offers a safe and easy way to prevent complications for our patients, especially during minimally invasive, redo and other complex cardiac surgery procedures.”

Bi-Flow is now available in Europe, Canada and other select countries in one size (19 fr), and is currently in pre-market notification for the U.S. The line will expand next year with more sizes and a version validated for Extracorporeal Life Support to address long-term procedures.

For more information on the Bi-Flow bidirectional cannula, visit www.bi-flow.livanova.com.

## Important Safety Information

For professional use. Please contact LivaNova through the Company website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.

## About LivaNova

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a relentless commitment to improve the lives of patients around the world. LivaNova’s advanced technologies and breakthrough treatments provide meaningful solutions for the benefit of patients, healthcare professionals and healthcare systems. Headquartered in London, LivaNova has a presence in more than 100 countries worldwide. The Company currently employs approximately 4,000 employees. LivaNova operates as two businesses: Cardiovascular and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

**For more information, please visit www.livanova.com.**

## Safe Harbor Statement

This news release contains forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as

amended. Forward-looking statements are not historical facts but are based on certain assumptions of management and describe LivaNova's future plans, strategies and expectations. Forward-looking statements can generally be identified by the use of forward-looking terminology, including, but not limited to, "may," "could," "seek," "guidance," "predict," "potential," "likely," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Forward-looking statements contained in this news release are based on information presently available to LivaNova and assumptions that LivaNova believes to be reasonable, but are inherently uncertain. As a result, LivaNova's actual results, performance or achievements may differ materially from those expressed or implied by these forward-looking statements, which are not guarantees of future performance or actions that may be taken by LivaNova and involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond LivaNova's control. You should carefully consider the risks and uncertainties that affect LivaNova, including those described in the "Risk Factors" section of LivaNova's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the United States Securities and Exchange Commission.

All information in this news release is as of the date of its release. LivaNova does not undertake or assume any obligation to update publicly any of the forward-looking statements in this news release to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to place undue reliance on any forward-looking statements, which are made only as of the date of this news release.

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