Teleflex Announces Publication of “Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device”

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Results from Multi-Center Study Demonstrated the Safety and Effectiveness of the MANTA™ Device

WAYNE, Pa., Aug. 01, 2019 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX) today announced the publication of the “Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device.” The SAFE MANTA IDE Clinical Trial, the largest U.S. prospective multi-center study of a purpose-designed large bore femoral arterial access site closure device to date, demonstrated the safety and effectiveness of the MANTA™ Device.[1,2] Results were published in Circulation: Cardiovascular Interventions.

The study demonstrated that, in a selected population, the MANTA™ Device can safely and effectively close large bore arteriotomies created by current generation transcatheter aortic valve (TAVR) replacement, percutaneous endovascular abdominal aortic aneurysm (EVAR) repair, and thoracic endovascular aortic aneurysm (TEVAR) repair devices.[1] The study authors noted that open surgical closure as well as adapted small-bore suture-based pre-closure devices have significant limitations.[1] The MANTA™ Device is innovatively designed to potentially reduce bleeding complications and offset other procedural costs.[1a]

“We created the MANTA™ Device to address a previously unmet clinical need for effective, reproducible, and safe closure of large bore femoral arterial access sites,” said Greg Walters, co-inventor of the MANTA™ Device and now Vice President of Access and Closure in the Interventional business unit of Teleflex. “We are excited to now have published data indicating that the MANTA™ Device can rapidly and effectively close large bore femoral arterial access sites with good safety. We believe this has important implications for the treatment of patients with current generation TAVR replacement, EVAR repair, or TEVAR repair.”

The study demonstrated that the median time from deployment to hemostasis was 24 seconds (65 second mean time).[1a] Technical success was achieved in 97.7% of patients, and a single device was deployed in 99.6% of cases.[1b] The IDE-defined major complications[1c], the primary safety end point for the study, occurred in 5.3% of patients and Valve Academic Research Consortium-2 (VARC-2) major vascular complications occurred in 4.2% of cases.[1] This VARC-2 rate is lower than published rates for suture-mediated closure.[2,3]

“This published data should give physicians the confidence they need to adopt the MANTA™ Device as their large bore femoral arterial access site closure device of choice,” said Dr. David A. Wood[4], Co-Principal Investigator of the SAFE MANTA IDE Clinical Trial and Director of the Vancouver General Hospital Cardiac Catheterization Laboratory in Vancouver, British Columbia. “As we discussed in the manuscript, the VARC-2 major vascular complications in this study included the use of balloon inflation or deployment of a covered stent at the access site regardless of the absence of any eventual adverse outcome. Many prior reports of other closure techniques have disregarded these additional, often prophylactic, interventions when reporting VARC-2 major vascular complications.”

“The publication of this data reflects our ongoing commitment to invest in and provide innovations that simplify interventions,” said Stewart Strong, President and General Manager of the Interventional business unit of Teleflex. “To further demonstrate this commitment to our customers, we are continuing to invest in the MANTA™ Device through additional studies in progress in Europe that will evaluate use of the device when encountering various clinical challenges, including patients with heavily calcified arteries not suited to suture-based devices.”

About the MANTA™ Device

The MANTA™ Vascular Closure Device is indicated for closure of femoral arterial access sites while reducing time to hemostasis following the use of 10-20F devices or sheaths (12-25F OD) in endovascular catheterization procedures.

With the MANTA™ Device, clinicians and hospitals can achieve:

- Successful large bore closure with a device that is simple to use and does not require preclosure, saving valuable time during the most delicate interventional procedures.
- Low complication rates for fast, reliable biomechanical closure with rapid hemostasis, potentially reducing costs.[1a,d]
- Reproducible results, inspiring confidence in achieving successful closure.[1b]

About Teleflex Incorporated

Teleflex is a global provider of medical technologies designed to improve the health and quality of people’s lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular access, interventional cardiology and radiology, anesthesia, emergency medicine, surgical, urology and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rusch®, UroLift®, and Weck® – trusted brands united by a common sense of purpose.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

References:

1. Wood D, et al. Pivotal Clinical Study to Evaluate the Safety and Effectiveness of the MANTA Percutaneous Vascular Closure Device: The SAFE MANTA Study. Circulation: Cardiovascular Interventions. 2019 July. Vol 12, Issue 7.
    a. MANTA™ Device demonstrated a time to hemostasis of 24 seconds median time (65 seconds mean time) from deployment to hemostasis.
    b. Percutaneous vascular closure obtained with the MANTA™ Device without the use of unplanned endovascular or surgical intervention.
    c. Major complications defined as composite of i) vascular injury requiring surgical repair/stent-graft; ii) bleeding requiring transfusion; iii) lower extremity ischemia requiring surgical repair/additional percutaneous intervention; iv) nerve injury (permanent or requiring surgical repair); and v) infection requiring IV antibiotics and/or extended hospitalization
    d. Rate of time to hemostasis for MANTA™ Device demonstrated from deployment to hemostasis.
    Study sponsored by Teleflex Incorporated or its affiliates.
2. Généreux P, et al. Vascular complications after transcatheter aortic valve replacement. J Am Coll Cardiol. 2012 Sept 18;60(12):1043-1052.
3. Lauten A, et al. Percutaneous left-ventricular support with the Impella 2.5®-assist device in acute cardiogenic shock: results of the Impella-EUROSHOCK-registry. Circ Heart Fail. 2013 Jan;6(1):23-30.
4. This statement reflects the personal experience and opinion of the physician.

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