Cordella Heart Failure System

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KEY FEATURES

- Comprehensive heart failure management
- Enables guideline-directed medical therapy
- Streamlines clinical workflow for scale
- Seamlessly integrates PA pressure data*
- Supports chronic care management reimbursement

The Cordella System is a comprehensive heart failure management system that enables broad implementation of guideline-based management with a streamlined workflow, allowing physicians to scale effective heart failure management and improve patient outcomes.

The system extends clinical care into the home by collecting and securely transmitting daily patient data (blood pressure, SpO_2, heart rate, weight, symptoms) to the heart failure clinician to guide therapy and optimal dosing. Currently in clinical development, the system also includes a seamlessly integrated, implantable pulmonary artery (PA) pressure sensor* that will provide an earlier indication of worsening heart failure.

Designed to support patient care that impacts outcomes, the myCordella Patient Management Portal provides automated documentation for reimbursement with Medicare's chronic care management services.

*The Cordella PA pressure sensor is an investigational device and is not currently approved for clinical use in any geography. CAUTION. Investigational Device. Limited by Federal (or United States) law to investigational use.

Overhead Arm Support

Adept Medical
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KEY FEATURES

- Allows abdominal access
- Removes artifacts from the imaging site
- Quick placement and setup
- Optional strap placement for security
- Optimized design for patient comfort

The Overhead Arm Support is designed to comfortably support the patient's arms, eliminate extreme shoulder flexion, allow abdominal access, and remove unwanted artifacts when imaging with C-arm or CT machines.

The unique wing design can support one or both arms and will accommodate a wide range of patient sizes. The Overhead Arm Support facilitates improved patient comfort, procedural outcome, and repeatability. Designed for use with existing lab and imaging equipment, the wings have been engineered to fit inside the bore of standard CT machines and can be used with any C-arm imaging center.

Soft, pliable, latex-free polyurethane straps may be used for additional patient security and comfort. The straps are adjusted to loosely contain the patient's arms. Two strap mount locations for each arm ensure that the patient's arms are fully supported, thus reducing the risk of arm displacement and aiding patient assurance.

The Overhead Arm Support is crafted from high-performance engineering plastics for enhanced rigidity, durability, and resistance to chemical attack. At only 1.5 kg, it is lightweight and compact.

Adept Medical Limited is ISO 13485:2016 certified. The Overhead Arm Support is an FDA registered product and has European CE Mark approval. It is available to be sold globally.

Manta Vascular Closure Device

Teleflex
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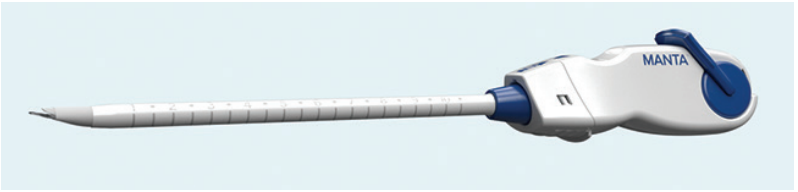
KEY FEATURES

- Fast, reliable biomechanical closure[1]
- Simple deployment with rapid hemostasis[1]
- Single device that doesn't require preclosure[1,2]
- Low complication rates[1]
- Saves time, potentially reducing costs[1]

The Manta vascular closure device is indicated for closure of femoral arterial access sites while reducing time to hemostasis (TTH) following the use of 10- to 20-F devices or sheaths (12- to 25-F outer diameter) in endovascular catheterization procedures.



The SAFE MANTA investigational device exemption (IDE) clinical trial* demonstrated that the Manta device successfully achieves fast, reliable biomechanical closure with rapid hemostasis (median TTH, 24 seconds [mean, 65 seconds]) and that all primary and secondary endpoints were met. A major complication rate, defined as a composite of vascular injury requiring surgical repair/stent graft, bleeding requiring transfusion, lower extremity ischemia requiring surgical repair/additional percutaneous intervention, nerve injury (permanent or requiring surgical repair), and infection requiring intravenous antibiotics and/or extended hospitalization, of 5.3% and a Valve Academic Research Consortium-2 major vascular complication rate of 4.2% were also reported. A single Manta vascular closure device was deployed in 99.6% of participants in the SAFE MANTA IDE trial. The device has the potential to reduce bleeding complications and offset other procedural costs.[1]

The Manta device has received CE Mark approval and FDA premarket approval. ■

*The SAFE MANTA IDE clinical trial was sponsored by Teleflex Incorporated or its affiliates.

1. SAFE MANTA IDE clinical trial. Data on file at Teleflex.
2. Nelson PR, Kracjer Z, Kansal N, et al. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). J Vasc Surg. 2014;59:1081-1193.

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