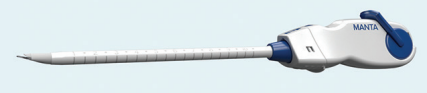
Manta Vascular Closure Device

Teleflex
www.teleflex.com/manta
(888) 413-3104

KEY FEATURES

- Fast, reliable biomechanical closure[2]
- Simple deployment with rapid hemostasis[2]
- Single device that doesn't require preclosure[2,3]
- Low complication rates[2]
- Saves time, potentially reducing costs[2]



The 14-F Manta vascular closure device is indicated for closure of femoral arterial access sites following the use of 10- to 14-F devices or sheaths (18-F maximum outer diameter/profile), and the 18-F Manta device is indicated for closure of femoral arterial access sites following the use of 15- to 18-F devices or sheaths (25-F maximum outer diameter/profile).

All study objectives were met in the Clinical Study to Evaluate the Safety and Performance of Manta Vascular Closure Device in support of CE Mark approval (NCT02521948). Median time to hemostasis (TTH) was 24 seconds (mean, 143 seconds; n = 50) and Valve Academic Research Consortium-2 (VARC-2) major vascular complications were 2% (1 out of 50 patients).[1]

The SAFE MANTA investigational device exemption (IDE) clinical trial* then 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 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 VARC-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.[2]

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

*The SAFE MANTA IDE clinical trial and the CE Mark Clinical Study to Evaluate the Safety and Performance of Manta Vascular Closure Device were sponsored by Teleflex Incorporated or its affiliates.

1. Van Mieghem NM, Latib A, van der Heyden J, et al. Percutaneous plug-based arteriotomy closure device for large-bore access: a multicenter prospective study. JACC Cardiovasc Interv. 2017;10:613-619.
2. SAFE MANTA IDE clinical trial. Data on file at Teleflex.
3. 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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