Enter a New Era in Large Bore Closure

MANTA

Vascular Closure Device

Teleflex

A new era of simplicity and confidence in closure is here

The MANTA Device is the first commercially available biomechanical vascular closure device designed specifically for large bore femoral arterial access site closure.[1]

Simple deployment

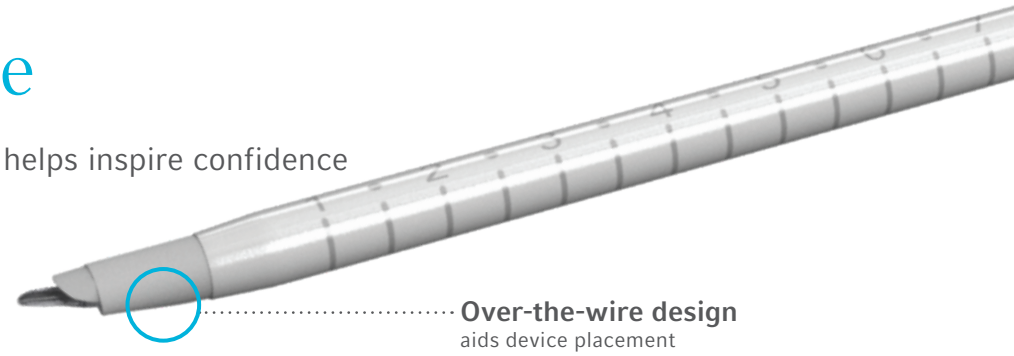
Addresses the challenges of large bore closure with a single easy-to-use device.[2a]

Rapid haemostasis

Reduces time to haemostasis without pre-closure, utilising the coagulation-inducing properties of collagen for rapid haemostasis to promote vessel healing.[2b,3-5]

Reliable closure

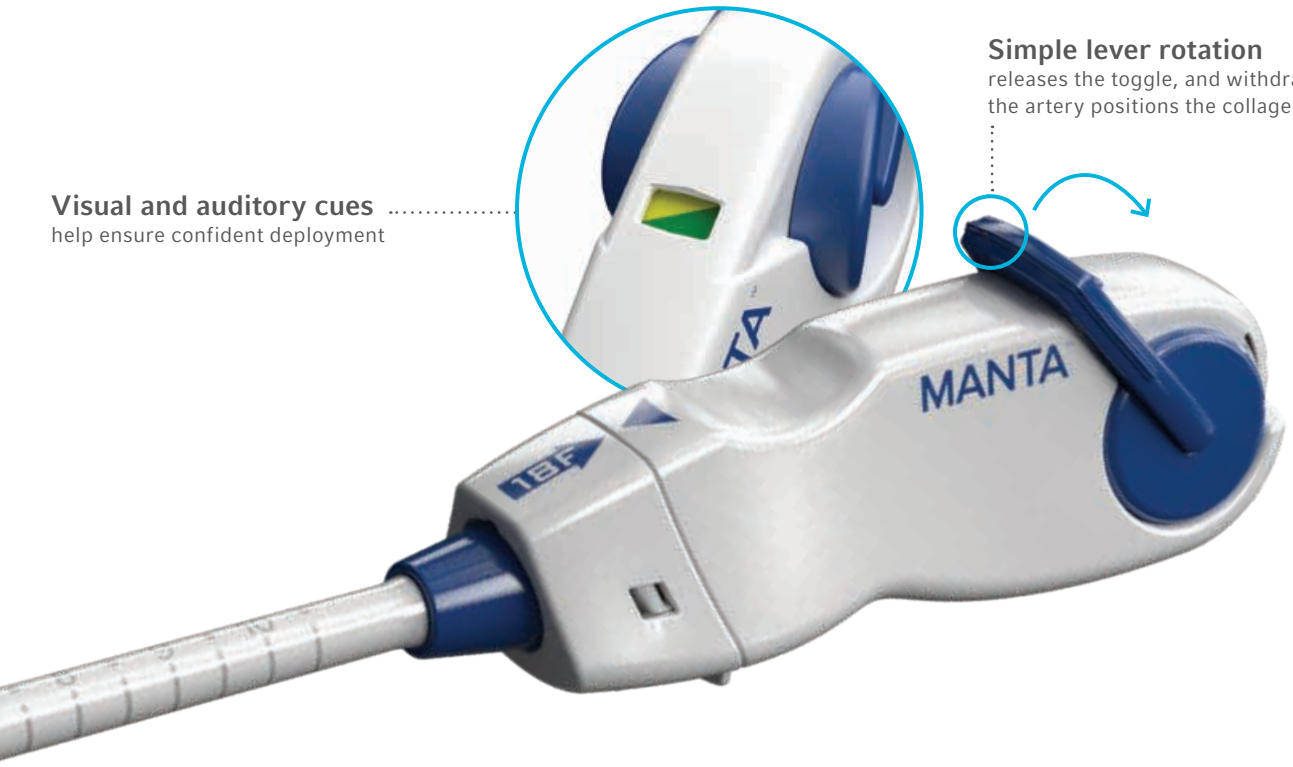
Delivers reproducible results and helps inspire confidence in achieving successful closure.[2c]



Over-the-wire design
aids device placement throughout deployment

References

1. Data on file at Teleflex.
2. Data on file at Teleflex. The SAFE MANTA IDE Clinical Trial.
   a. A single MANTA Vascular Closure Device was deployed in 99.6% of subjects in IDE trial.
   b. The MANTA Device demonstrated a time to hemostasis (TTH) of 24 seconds median time (65 seconds mean time) from deployment to hemostasis, which is lower than published rates for Perclose ProGlide® where Perclose ProGlide® demonstrated a TTH of 9.8 ± 17 minutes (588 ± 1,020 seconds).[3]
   c. 97.7% Technical Success, defined as percutaneous vascular closure obtained with the MANTA Device without the use of unplanned endovascular or surgical intervention.
   Study sponsored by Teleflex Incorporated or its affiliates.
3. Nelson PR, 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 May;59(5):1081-1193.
4. Farndale RW, et al. The role of collagen in thrombosis and hemostasis. J Thromb Haemost. 2004 Apr;2(4):564-573.
5. Nuyttens BP, et al. Platelet adhesion to collagen. Thromb Res. 2011;127(2): S26-S29.
6. Data on file at Teleflex. The SAFE MANTA IDE Clinical Trial.
   a.Percutaneous vascular closure obtained with the MANTA Device without the use of unplanned endovascular or surgical intervention.
   b.The MANTA Device demonstrated a time to hemostasis (TTH) of 24 seconds median time (65 seconds mean time) from deployment to hemostasis.
   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.
   Study sponsored by Teleflex Incorporated or its affiliates.
7. Généreux P, et al. Vascular complications after transcatheter aortic valve replacement. J Am Coll Cardiol. 2012 Sept 18;60(12):1043-1052.
8. 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.



Engineered for versatility

Available in 14 Fr. and 18 Fr., a single MANTA Device effectively closes femoral arterial access sites following the use of large bore sheaths ranging from 12 Fr. to 25 Fr. O.D.

Ordering Information

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

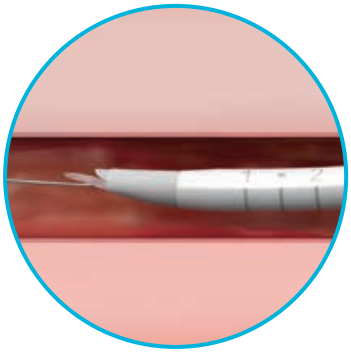
The Manta Vascular Closure Device

REF.	DESCRIPTION	SIZE
2156NE	14 Fr. MANTA Vascular Closure Device	14 Fr.
2115NE	18 Fr. MANTA Vascular Closure Device	18 Fr.
188F	MANTA 8 Fr. Depth Locator	8 Fr.
114F	MANTA 14 Fr. Depth Locator	14 Fr.

Packaged in quantities of 5 unit per box.

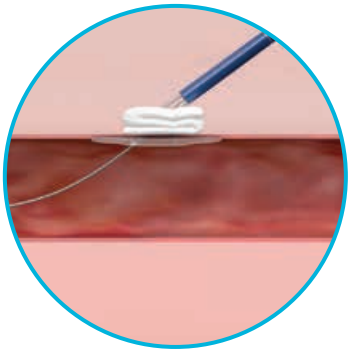
How it works

The MANTA Device facilitates biomechanical closure without pre-closure.

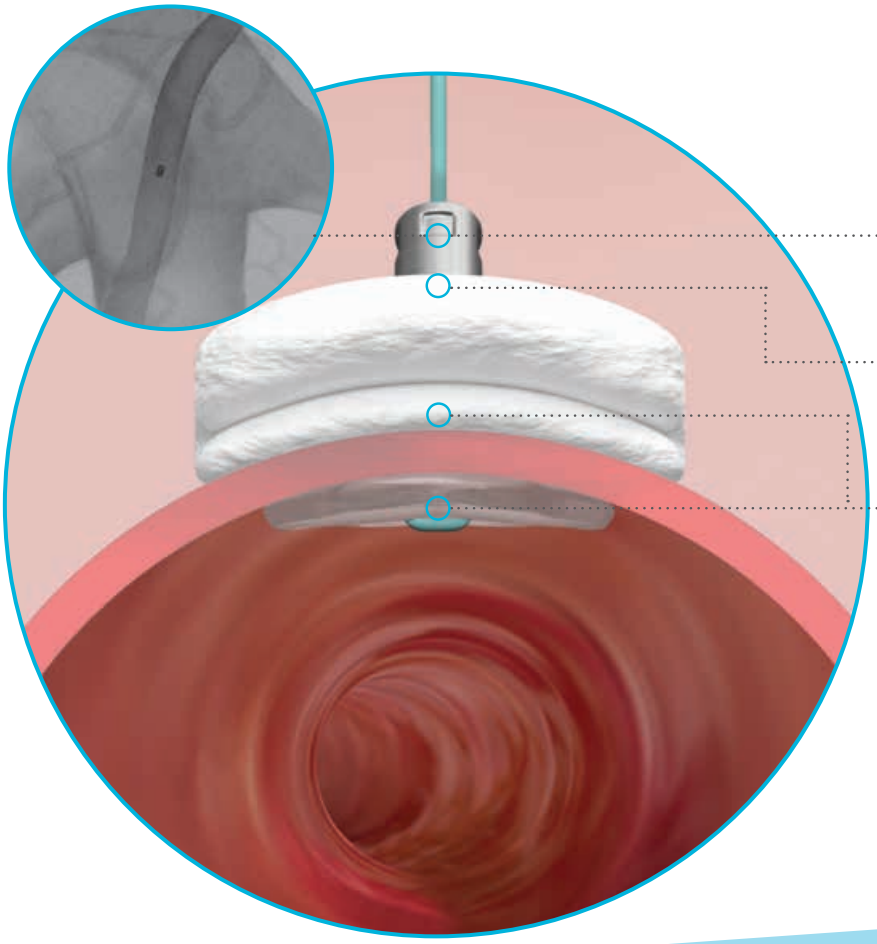


1. Insert the MANTA Device

2. Position and release toggle



3. Withdraw and seal



Front view

Radiopaque lock
secures the sliding suture knot without tamping and is a helpful landmark for future interventions

Sliding suture knot
provides initial compaction of the collagen

Resorbable collagen and toggle
sandwich the access site

Clinically proven

20
North American centres

263 patients

The SAFE MANTA IDE Clinical Trial - the largest U.S. prospective multi-centre study of a purpose-designed large bore femoral arterial access site closure device to date - demonstrated the safety and effectiveness of the MANTA Device.[6]

97.7%

Technical success rate[6a]

24 seconds

Median time from deployment to hemostasis (65 seconds mean time)[6b]

5.3%

Major Complications rate

Breakdown by most serious event or intervention:
Major Bleeding 2.3% (6/263)
Covered Stent 1.5% (4/263)
Balloon 0.8% (2/263)
Surgery 0.8% (2/263)

4.2%

VARC-2 Complications rate

Breakdown by most serious event or intervention:
Covered Stent 1.5% (4/263)
Major Bleeding 1.1% (3/263)
Balloon 0.8% (2/263)
Surgery 0.8% (2/263)

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 and interventional access, surgical, anaesthesia, cardiac care, urology, emergency medicine 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, QuikClot, Rüsch, UroLift, and Weck – trusted brands united by a common sense of purpose.

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INDICATIONS: The 14 Fr. MANTA is indicated for closure of femoral arterial access sites following the use of 10-14 Fr. devices or sheaths (maximum OD/profile or 18 Fr.), and the 18 Fr. MANTA device is indicated for closure of femoral arterial access sites following the use of 15-18 Fr. devices or sheaths (maximum OD/profile of 25 Fr.).

CONTRAINDICATIONS: 1) Severe calcification of the access vessel; 2) Severe peripheral artery disease; 3) Puncture in the origin of the profundal femoral artery, above the inguinal ligament, or above the most inferior border of the epigastric artery (IEA); 4) Sheath insertion in vessel other than the femoral artery; 5) Marked tortuosity of the femoral or iliac artery; 6) Marked obesity or cachexia (BMI >40 or <20); 7) Blood pressure >180 mmHg; 8) Patients who cannot be anti-coagulated for the procedure.

WARNINGS: Do not use: 1) if bacterial contamination of procedure sheath or surrounding tissues may have occurred; 2) if the procedure sheath has been placed through the superficial femoral artery and into the profunda femoris artery; 3) if the MANTA Device delivery system becomes kinked; 4) with a contralateral balloon inflated in the femoral or iliac artery during MANTA device use; 5) if there has been a femoral artery puncture in same vessel within prior 30 days, recent femoral artery puncture in same groin that has not healed appropriately, and/or recent (<30 days) vascular closure device placement in same femoral artery; 6) if puncture site is at or distal to bifurcation of superficial femoral and profunda femoris artery; 7) if the puncture site is proximal to inguinal ligament or above most inferior border of epigastric artery (IEA).

POTENTIAL ADVERSE EVENTS: 1) Failed hemostasis requiring manual or mechanical compression, application of balloon pressure from a secondary access site, placement of a covered stent or surgical repair. 2) Local trauma to the femoral or iliac artery wall, such as dissection. 3) Retroperitoneal bleeding as a result of access above the inguinal ligament or the most inferior border of the epigastric artery (IEA). 4) Perforation of ileofemoral arteries, causing bleeding/hemorrhage. 5) Accidental positioning of some or all of the collagen plug within the femoral artery, leading to ischemia or stenosis. 6) Thrombosis formation or embolism. 7) Nerve damage or neuropathy. 8) Other access site complications leading to bleeding, hematoma, pseudoaneurysm, etc., possibly requiring blood transfusion, surgical repair, and/or endovascular intervention.

Please see the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

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