The MANTA™ Device is the first commercially available biomechanical vascular closure device designed specifically for closure of large bore femoral arterial access sites. With simple deployment, a single MANTA™ Device achieves reliable closure with rapid hemostasis.¹⁻⁷c
MANTA™ Device
Simple Deployment

Visual and auditory cues ensure confident deployment with no pre-closure required

1. Insert the MANTA™ Device
2. Position and Release Anchor
3. Withdraw and Seal

Ordering Information

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.

<table>
<thead>
<tr>
<th>PRODUCT NUMBER</th>
<th>DESCRIPTION</th>
<th>SIZE</th>
</tr>
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<tbody>
<tr>
<td>2156</td>
<td>14 Fr. MANTA™ Vascular Closure Device</td>
<td>14 Fr.</td>
</tr>
<tr>
<td>2115</td>
<td>18 Fr. MANTA™ Vascular Closure Device</td>
<td>18 Fr.</td>
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</tbody>
</table>

Packaged in quantities of five units per box.

REFERENCES:
1. Data on file at Teleflex. SAFE MANTA (DE Clinical Trial).
2. The MANTA™ Device demonstrated a time to hemostasis (TTTH) of 24 seconds median time (65 seconds mean time) from deployment to hemostasis.
3. A single MANTA™ Device was deployed in 99.6% of subjects in the IDE trial.
4. Perforation of femoral or iliac artery wall, such as dissection.
5. Retroperitoneal bleeding as a result of access above the inguinal ligament or the most inferior border of the epigastric artery (IEA).
6. Perforation of iliofemoral arteries, causing pain, swelling, and difficulty with ambulation.
7. Do not use in patients who cannot be adequately anticoagulated for the procedure.
8. Do not use the MANTA Device in patients with known allergies to bovine products, collagen and/or collagen products, polyglycolic or polylactic acid polymers, stainless steel or nickel.
9. Do not use if there is difficulty dilation from initial femoral artery access (e.g., damaging or kinking dilators) while step dilating up to the large-bore device. Difficult dilation of the puncture tract due to scar tissue may lead to swelling of surrounding tissue, thus compromising the accuracy of the puncture site.
10. Do not use if the puncture site is proximal to the inguinal ligament or above the most inferior border of the epigastric artery (IEA), as this may result in retroperitoneal bleeding.
11. Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black. 5 Do not use if the package is damaged or any portion of the package has been previously opened.
12. Do not use if the items in the package appear damaged or defective in any way.
13. Do not REUSE or RESTERILIZE.
14. Do not use if the temperature indicator dot on package has changed from light gray to dark gray or black.
15. Do not use if the package is damaged or any portion of the package has been previously opened.
16. Do not inflate a contralateral balloon in the femoral or iliac artery during MANTA Sheath exchange or the MANTA Closure procedure.
17. Do not use if the patient has marked obesity or cachexia (BMI >40 kg/m² or <20 kg/m²).
18. Do not use if the patient has post-procedure blood pressure >180 mmHg that cannot be lowered prior to access site closure.
19. Do not use in patients who cannot be adequately anticoagulated for the procedure.
20. Do not use the MANTA Device in patients with known allergies to bovine products, collagen and/or collagen products, polyglycolic or polylactic acid polymers, stainless steel or nickel.

CONTRAINDICATIONS: There are no known contraindications to the use of this device.

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WARNING: 11 Do not use if the puncture site is proximal to the inguinal ligament or above the most inferior border of the epigastric artery (IEA), as this may result in retroperitoneal bleeding.

POTENTIAL ADVERSE EVENTS: The following potential adverse events related to the deployment of Vascular Closure Devices have been identified:

a. Ischemia of the leg or stenosis of the femoral artery.
   b. Nerve damage or neuropathy.
   c. Distal ischemia of the limb.
   d. Deep vein thrombosis.
   e. Necrosis.
   f. False aneurysm.
   g. Hematoma formation.
   h. Popliteal artery disease.
   i. Femoral artery rupture.
   j. Dissection.
   k. Nerve damage or neuropathy.
   l. Other adverse events include bleeding, hematoma, pseudoaneurysm, or arterio-venous fistula, possibly requiring blood transfusion, surgical repair, and/or endovascular intervention.

Please see the instructions for use for complete product information.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician. Teleflex, the Teleflex logo, and MANTA are trademarks or registered trademarks of Teleflex Incorporated or its affiliates, in the U.S. and/or other countries. Information in this document is not a substitute for the product Instructions for Use. Not all products may be available in all countries. Please contact your local representative. Revised: 02/2019. © 2019 Teleflex Incorporated. All rights reserved. MC-005323 Rev 0