In the days following the procedure, the access site will slowly heal. To encourage healing, it is important for you to properly care for the access site.

The following guidelines will aid with the recovery process:

- How do I care for the access site?
- What activities should I avoid?
- When can I resume activities?
- When should I contact my doctor?
- When do I need to carry my MANTA™ Device implant card?

Please detach and carry this card with you at all times.

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MANTA Vascular Closure Device

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14/18F Vascular Closure Device

PLEASE CARRY THIS CARD WITH YOU AT ALL TIMES.

If you require additional vascular access through your groin, tell your doctor that you have a MANTA™ Vascular Closure Device in your groin.
If you require a magnetic resonance imaging (MRI) examination, tell your doctor or MRI technologist that you have a MANTA™ Vascular Closure Device in your groin.

Patient Name:_____

Date of Implant:_____Implant Location:_____

Implanting Physician:_____

Hospital:_____Contact Number_____

Place patient label here

POTENTIAL ADVERSE EVENTS: The following potential adverse events related to the deployment of Vascular Closure Devices have been identified: 1) Inadequate blood supply to the leg or partial blockage of the femoral artery. 2) Injury to the femoral or iliac artery, such as splitting of the artery wall. 3) Bleeding into the pelvis as a result of the femoral artery access site being placed too high in the groin. 4) A hole in the iliac or femoral artery, causing bleeding. 5) Clot formation or circulation of a clot. 6) Nerve damage or nerve pain, weakness or numbness. 7) Other access site complications such as bleeding, a collection of blood under the skin but outside the blood vessel that may or may not have blood actively moving into it from the artery, or an abnormal connection between the femoral artery and the femoral vein, possibly requiring blood transfusion, surgery and/or a catheterization procedure. Potential Adverse Events associated with any large size catheter procedure, including the use of the MANTA Vascular Closure Device, include but are not limited to: Damage to the artery; An abnormal connection between the femoral artery and the femoral vein; Slow heart rate; Pressure within the muscles that causes pain and decreased blood flow; Death related to the procedure; Clot formation in the deep leg veins; Bruising; Swelling; Infection at the access site which may require antibiotics or a longer hospital stay; Adverse tissue response such as pain, heat, redness and/or swelling; Late bleeding from the access site; Oozing of blood from the access site; Sensation of pressure in the groin or area of the access site; Injury to an artery or vein; Re-opening of the wound site.

CAUTION: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

Essential Medical

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Exton, PA 19341
essmedclosure.com

MANTA™ Vascular Closure Device

Post-Procedure Care Guide

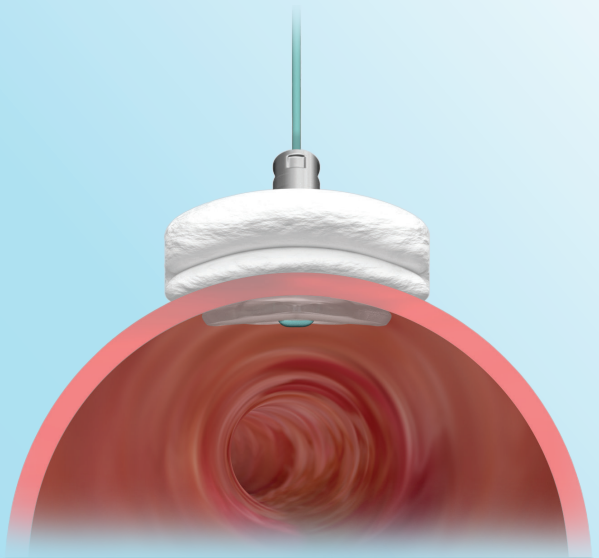
Following access site closure with the MANTA™ Vascular Closure Device

Essential Medical

Post-Procedure Care

Why did I receive a MANTA™ Vascular Closure Device?

During the interventional procedure, your doctor inserted thin tubes, called sheaths or catheters, into an artery in your groin. These devices provided access into your artery for your doctor to perform the interventional procedure. After the procedure, the devices were removed. Then, your doctor used the MANTA™ Vascular Closure Device to close the access site that was created for the procedure.



How does the MANTA™ Vascular Closure Device work?

The MANTA™ Device features a collagen plug and absorbable plastic anchor that close the hole created during your procedure. The collagen and anchor are connected by a suture and secured by a stainless-steel, radiopaque lock. Your body will slowly absorb the collagen plug and anchor after your procedure. The lock remains and is a helpful landmark if any interventions are needed in the future.

How do I care for the access site?

- Keep the access site clean and dry
- Clean the access site daily
- After showering, gently dry the access site before applying a bandage or dressing

Support the access site when coughing, sneezing or straining for a bowel movement by applying pressure with your hand over the bandage

What activities should I avoid?

- Avoid taking baths or swimming
- Do not wear tight fitting clothing to avoid irritating the access site
- Do not lift heavy objects
- Avoid vigorous activity or straining

When can I resume activities?

Your doctor can help you determine when you can resume additional activities. Your recovery time will vary depending on the nature of your activity level, previous procedures and any medications you are taking.

When should I contact my doctor?

If you experience any of the following symptoms after the procedure, immediately inform your doctor or hospital staff:

- Swelling, tenderness or pain at the access site
- Increased bruising or redness at the access site
- Drainage, oozing or bleeding from the access site
- Sensation of numbness or tingling in the leg
- Fever, chills or any other unusual symptoms

When do I need to carry my MANTA™ Device implant card?

Carry your MANTA™ Device implant card at all times in case you need an MRI or additional interventional procedure.

Contact your doctor if you have any questions regarding your procedure and post-procedure care.

Please detach and carry this card with you at all times.

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Rx Only

This patient has had a MANTA™ vascular closure device implanted at the location specified on the opposite side of this card. The MANTA device is bioresorbable with a radiopaque marker left behind to indicate the previous access site. If the patient requires an additional procedure, the company recommends that the doctor make the new puncture at least 2.5 cm above or below the previous MANTA site; the stainless steel MANTA lock can be seen on x-ray.

MRI Safety Information

Non-clinical testing demonstrated that the MANTA™ Device is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

MR CONDITIONAL

- Static magnetic fields of 1.5-Tesla and 3-Tesla
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode

Under the scan conditions defined above, the MANTA™ Device is expected to produce a maximum temperature rise of 2°C after 15 minutes of continuous scanning (i.e., per pulse sequence). In non-clinical testing, the image artifact caused by the MANTA™ Device extends approximately 10 mm from the MANTA™ Device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.