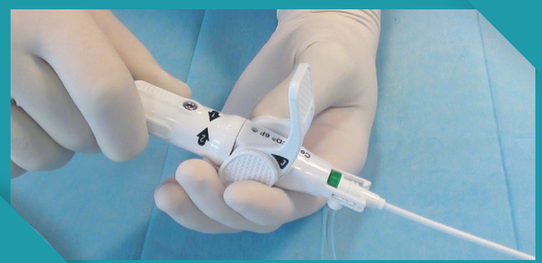
At the end of your recent hospital procedure, your doctor used a **Celt ACD®** Vascular Closure Device to seal the opening in the femoral artery in the groin.



Vasorum
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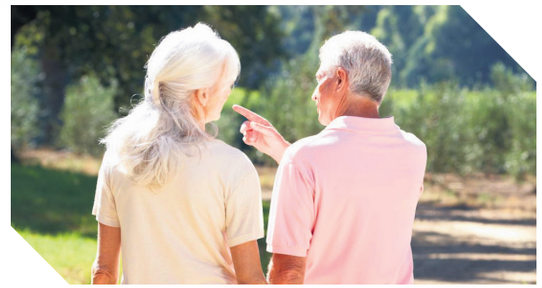

PATIENT INSTRUCTIONS:

Carry this Patient Information Card with you at all times. If necessary inform your doctor that you received the **Celt ACD®** device and show this leaflet to the doctor.

MRI SAFETY INFORMATION

Non-Clinical testing has demonstrated the **Celt ACD®** Vascular Closure Device is MR Conditional. A patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

Static magnetic field of 3-Tesla or less.
Maximum spatial gradient magnetic field of 1,500-gauss/cm (15-T/m) (extrapolated) or less.
Maximum MR system reported, whole body average 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 of operation for the MR system.

Under the scan conditions defined for the **Celt ACD®** is expected to produce a maximum temperature rise of 2.1°C after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact cause by the **Celt ACD®** extends approximately 10mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR-system.

MR
MR Conditional

PIL-TS-002 Rev 1 (SCR 205)

Celt ACD®
VASCULAR CLOSURE DEVICE

PATIENT INFORMATION BROCHURE

CE
0050

HOW DOES THE DEVICE WORK?

The **Celt ACD®** device is placed into your artery to close the opening created to carry out your procedure. The device is a very small permanent stainless steel implant. The **Celt ACD®** device closes the arterial opening quickly and securely in order to stop the bleeding and allow you to walk sooner following your procedure.

CARE OF SITE WHEN AT HOME

Following are the suggested patient guidelines for early post procedure site care and activities.

Note: These are guidelines only and not a substitute for doctor's advice. You should contact your doctor if you have any concerns.

- Avoid baths for 3-4 days until the puncture site is healed.
- No straining, lifting, driving for 48-72 hours post procedure.
- Bruising or discomfort is common during the healing process after the procedure; however if you experience any of the following contact your doctor immediately:
  - Fever
  - Bleeding
  - Persistent tenderness or swelling at the site
  - Pain, discomfort or irritation around the site
  - Redness and/or warm to the touch
  - Any other unusual symptoms

ADDITIONAL INFORMATION

Non-clinical testing has demonstrated that the **Celt ACD®** Vascular Closure Device is MR Conditional. A Patient with this device can be scanned safely in an MR system immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less.
- Maximum spatial gradient magnetic field of 1,500 - gauss/cm (15-T/m) (extrapolated) or less.
- Maximum MR system reported, whole body average 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 of operation for the MR system.

Under the scan conditions defined for the **Celt ACD®** is expected to produce a maximum temperature rise of 2.1℃ after 15 minutes of continuous scanning (i.e. per pulse sequence).

In non-clinical testing, the image artifact caused by the **Celt ACD®** extends approximately 10mm from the device when imaged using a gradient echo pulse sequence and a 3-Tesla MR-system.

If you need to undergo an MRI (Magnetic Resonance Imaging) please show this Patient Information Card to the person performing the scan.

PATIENT INFORMATION CARD

CELT ACD® Vascular Closure Device.

Patient Name: _____

Date of Implant placement: _____

Inserted ☐ Right Femoral Artery ☐ Left Femoral Artery (check one)

Lot#: _____ Size: _____

Implanting Physician: _____

Hospital Name: _____

Hospital Contact Number: _____

PLEASE KEEP THIS CARD WITH YOU AT ALL TIMES

Notes to Doctor/Nurse:

Please refer to the IFU for full details.

- The implant is visible under both X-Ray and Fluoroscopy.
- The implant is permanent and is made from biocompatible grade 316LVM stainless steel.
- The patient may have a further procedure through the same groin immediately.

PROCEDURE SUMMARY

Procedure Details

(To be completed by the Hospital prior to discharge)

Device: **Celt ACD®**

Inserted: ☐ RIGHT Femoral Artery ☐ LEFT Femoral Artery (check one)

Lot # : _____

Deployed by: _____

Deployment Date: _____

HOSPITAL CONTACT DETAILS: