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URGENT Medical Device Safety Correction / Field Safety Notice
GORE® EXCLUDER® AAA Endoprosthesis and GORE® EXCLUDER® Iliac Branch Endoprosthesis

January, 2020

Medical Device Safety Correction / Field Safety Notice – Leading end catheter separation of the GORE® EXCLUDER® Endoprosthesis and the GORE® EXCLUDER® Iliac Branch Endoprosthesis (collectively "EXCLUDER Devices")

TARGET AUDIENCE: *Vascular Surgeons, Interventional Cardiologists, Interventional Radiologists, and other physicians implanting endovascular aortic devices, Health Care Facilities carrying the GORE® EXCLUDER® AAA Endoprosthesis and GORE® EXCLUDER® Iliac Branch Endoprosthesis.*

Event Number 8975 / 3007284313.12102019.001-C

Dear Health Care Provider:

W. L. Gore & Associates (Gore) would like to inform you of safety information related to the GORE® EXCLUDER® AAA Endoprosthesis and GORE® EXCLUDER® Iliac Branch Endoprosthesis (EXCLUDER Devices). Please carefully review this letter and the attached IFU Summary of Changes and follow all recommended actions described below.

Description of the Issue:

- From January 2013 to August 5, 2019, Gore received 346 reports of leading end catheter component separations of the EXCLUDER Device. Of the 346 events, 30 reported immediate health consequences and 1 long-term health consequence

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(pelvic ischemia). This represents a rate of 0.05% reported complaints of leading end catheter separation events over the last 6 years.

- Gore investigated these events and identified two (2) types of failure modes: unbonded leading end catheter components (olives) and breakage (separation) of leading end catheter components. It is important to note that these failure modes have not resulted in fragmentation of the separated component.
- Of the 30/346 events with reported health consequences, the majority occurred with:
    - failure modes other than confirmed unbonded leading end catheter component; and
    - devices utilized in challenging anatomies and/or with user actions that are warned against in the Instructions for Use (IFU).
- Potential device and/or procedure-related adverse events or patient risks related to leading end catheter component separation or breakage events may include but are not limited to: additional intraoperative procedure time, additional intraoperative and/or secondary surgical or endovascular procedures, iliac artery occlusion, iliac dissection, iliac rupture, leading end catheter component retention, pelvic ischemic events, surgical bypass, surgical cut downs, surgical conversion, unintentional/premature endoprosthesis deployment and wound infection at cut down site.
- Although premature deployments were reported in a few events, in all of the procedures the devices maintained their ability to exclude the aneurysm.
- To avoid premature deployments, please observe all warnings such as do not advance the device outside of the sheath while tracking it into position and do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together.
- Retrieval of the separated leading end catheter component (e.g. endovascular snaring or surgical cut downs) was achieved in the majority of events (286/346; 83%). The separated component was not retrieved in the remainder (60/346; 17%) based on medical judgment.[1]
    - No long term health consequences have been reported to Gore related to the patients with retained components.
    - Patient benefit/risk factors such as tortuous anatomy may have played a role in the physician's ability or decision to retrieve or not to retrieve the separated component.
    - Based on Physician input and an analysis of relevant literature, Physicians should consider additional follow-up as needed, for patients with retained components.

Gore Corrective Actions

Gore maintains its confidence in the safety and efficacy of the EXCLUDER Devices when used in accordance with the IFU. Gore will not be removing EXCLUDER product from the market because the patient benefits associated with EXCLUDER Devices being available for

[1] See https://www.jvascsurg.org/article/S0741-5214(12)01934-9/fulltext for a review of the management of iatrogenic retained foreign bodies in endovascular procedures.

use are much greater than the potential low patient risks and low frequency of leading end catheter component separation or breakage events described in this letter.

Unbonded Leading End Catheter Components

- In 2016 and 2019, Gore implemented manufacturing process improvements to reduce the rates of unbonded leading end catheter components. Currently, there are no devices in the field that were manufactured prior to the corrective actions implemented in 2016.
- Based on a frequency of 0.0080% or lower, Gore estimates that a very small number of the over 75,000 devices in the field globally may be potentially affected by this type of event.

Breakage of leading end catheter components

- Based on these events, Gore will be updating its Instructions for Use (IFU) to include:
  - a new Warning: **"Catheter leading end separation or breakage and related potential patient harms have occurred. See ADVERSE EVENTS. If catheter separation occurs, use best medical judgment to determine the appropriate course of action for the patient. Effective removal of the catheter component has been reported through both surgical (e.g. cut down) and endovascular techniques (e.g. snaring, sheath removal)."**
  - modified certain current warnings to emphasize that if these warnings are not followed then the **risk of catheter breakage and premature deployment have occurred and may result in potential patient harms**
    additional procedural steps related to **confirming that all catheter components are removed from the patient and recommended materials to have on hand**
  - updated adverse events

Immediate Recommended Actions for the Physician:

- Please review the attached Summary of IFU Changes and respond to the enclosed acknowledgement. This letter and Summary of IFU Changes will also be available on the Gore Medical website.
- Gore encourages physicians to adhere to these new and modified warnings in the IFU, as well as other current warnings. Please refer to the approved IFU for full indications, contraindications, instructions, warnings, and precautions, available at: https://eifu.goremedical.com/. Updated full IFUs will be available on the website.
- Gore recommends that physicians be familiar with snaring techniques and have a snare on-hand.

When faced with challenging anatomy or the potential use of the EXCLUDER Device that are against IFU warnings, physicians must balance the risks of treatment with the EXCLUDER Device, including risks of leading end catheter component separation events, with the risks of not treating the patient with this device. Gore is providing physicians with this safety risk-related data and information so that appropriate risk-related decisions can be made with the patient when considering the EXCLUDER Device.

This safety information serves as a supplement to the EXCLUDER Device training in which you participated, and any related educational material you received.

Please share this letter with others in your hospital or clinic as appropriate, and contact Gore Customer Service (email: MPDCustomerCare@wlgore.com or by phone at 800-528-8763) with any questions related to this letter.

In the event that an Adverse Event Occurs:

Any adverse event involving the GORE® EXCLUDER® AAA Endoprosthesis should be reported to the manufacturer and the country specific regulatory authorities immediately. To report an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com or contact:
USA: +1.800.528.1866, Ext. 44922, +1.928.864.4922, Fax: +1.928.864.4364
China: +86 21 5172 8237, Fax: +86 21 5172 8236
Japan: +81 3 6746 2562, Fax: +81 3 6746 2563
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Health care professionals and consumers may report adverse events or quality problems directly to FDA using the FDA MedWatch Website:
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

Sincerely,

… Global Excluder Product Specialist

… Global IBE Product Specialist

Attachments:
IFU Summary of Changes for the EXCLUDER Devices
Return Acknowledgement Form

Per MEDDEV 2-12-1 rev 8, EU National Competent Authorities have been advised of the FSCA

MD174657 Attachment 1