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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](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.



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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.



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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
Brazil: +55 11 5502-7953, Fax: +55 11 5502-7965
EMEA: +49 89 4612 3440, Fax: +49 89 4612 43440

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,

Randall F. Ankeny, Ph.D.
Global Excluder Product Specialist

Kyle Marr
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

GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use Summary of Changes

GORE® EXCLUDER® AAA NEW WARNING

- RLT31/35 Page 27, 34, 35, 36, 44, 45, 46; RLT 23/26/28 Page 26, 33, 34, 35: **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).**

GORE® EXCLUDER® AAA Endoprosthesis MODIFIED WARNINGS

- RLT31/35 Page 27, 34, 35, 36, 40, 43, 45; RLT 23/26/28 Page 26, 32, 34: Do not advance the device outside of the sheath ~~the sheath will protect the device from catheter breakage or premature deployment~~ while tracking it into position. **Catheter breakage or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- RLT31/35 Page 27, 34, 35, 36, 40, 43, 45; RLT 23/26/28 Page 26, 32, 34: Do not rotate the Trunk, ~~or~~ Contralateral Leg, **Iliac Extender, or Aortic Extender** delivery catheter while the endoprosthesis is inside the introducer sheath. Catheter breakage **or separation** or premature deployment ~~may occur~~ **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- RLT31/35 Page 27, 34, 40, 43 Page 32; RLT 23/26/28 Page 26, 32: Do not rotate the Trunk delivery catheter beyond 360°. ~~to avoid~~ Delivery system damage and/or premature deployment **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- RLT31/35 Page 27, 35, 40, 45 Page 34; RLT 23/26/28 Page 26, 34: Do not rotate the Contralateral Leg, **Iliac Extender or Aortic Extender** delivery catheter during delivery, positioning or deployment. Catheter breakage **or separation** or premature deployment ~~may occur~~ **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- RLT31/35 Page 27, 34, 35, 36, 40, 43, 45; RLT 23/26/28 Page 26, 33, 34: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheath. The sheath and catheter must be removed together. **Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- RLT31/35 Page 27, 34, 35, 36, 40, 43, 45; RLT 23/26/28 Page 26, 32, 34: Do not continue advancing any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage ~~may occur or premature deployment~~ **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- RLT31/35 Page 27, 34, 35, 36, 40, 44, 45, 46; RLT 23/26/28 Page 26, 33, 34: Do not continue to withdraw the delivery catheter if resistance is felt during removal through the introducer sheath. Forcibly withdrawing the delivery catheter through the introducer sheath when resistance is encountered has resulted in adverse events including catheter **breakage or separation and reintervention** resulting in potential patient harms, see ADVERSE EVENTS.

GORE® EXCLUDER® AAA Endoprosthesis ADVERSE EVENTS (RLT31/35 Page 41; RLT 23/26/28 Page 31)

Adverse events that may occur and / or require intervention or **additional intraoperative procedure time** include, but are not limited to:

- amputation
- aneurysm enlargement
- aneurysm rupture and death
- arterial or venous thrombosis and / or pseudoaneurysm
- arteriovenous fistula
- bleeding, hematoma, or coagulopathy
- bowel (e .g ., ileus, transient ischemia, infarction, necrosis)
- cardiac (e .g ., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
- claudication (e .g ., buttock, lower limb)
- death
- dissection, perforation, or rupture of the aortic vessel and surrounding vasculature
- edema
- embolization (micro and macro) with transient or permanent ischemia
- endoleak
- endoprosthesis or **delivery system**: improper component placement; incomplete component deployment; **unintentional/premature component deployment; leading end catheter component retention**; component migration; separation of graft material from stent; occlusion; infection; stent fracture; graft material failure, dilatation, erosion, puncture, perigraft flow
- fever and localized inflammation
- genitourinary (e .g ., ischemia, erosion, fistula, incontinence, hematuria, infection)
- hepatic failure
- impotence
- infection (e .g ., aneurysm, device or access sites)
- lymph fistula / complications
- neurologic damage, local or systemic (e .g ., stroke, paraplegia, paraparesis)
- occlusion of device or native vessel
- pulmonary complications (e .g ., pneumonia, respiratory failure)
- renal (e .g ., artery occlusion, contrast toxicity, insufficiency, failure)
- surgical **cut down, bypass or** conversion
- wound (e .g ., infection, dehiscence)
- vascular spasm or vascular trauma (e .g ., ilio-femoral vessel dissection, bleeding, rupture, death)

GORE® EXCLUDER® AAA Endoprosthesis NEW DIRECTIONS FOR USE

- RLT31/35 Page 34, 35, 36, 44, 45, 46; RLT 23/26/28 Page 33, 34: **When withdrawing the device delivery system through the introduce sheath, verify all catheter components are intact.**
- RLT31/35 Page 36, 46; RLT23/26/28 Page 35: **Prior to removing wires and sheaths verify all catheter components have been withdrawn from the patient.**

Additional Recommended Materials (RLT31/35 Page 32, 42; RLT 23/26/28 Page 31)

- **Snare Catheter**

GORE® EXCLUDER® Iliac Branch Endoprosthesis Instructions for Use Summary of Changes

GORE® EXCLUDER® Iliac Branch Endoprosthesis NEW WARNING

- Page 9, 26, 27: **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).**

GORE® EXCLUDER® Iliac Branch Endoprosthesis MODIFIED WARNINGS

- Page 9, 25, 27: Do not advance the device outside of the sheath while tracking it into position. ~~The sheath will protect the device from~~ Catheter breakage or premature deployment **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- Page 9, 25, 26, 27: Do not rotate any delivery catheters while the endoprosthesis is inside the introducer sheath. Catheter breakage **or separation** or premature deployment ~~may occur~~ **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- Page 9, 25: Do not rotate the Iliac Branch Component (IBC) beyond 360°. ~~to avoid~~ Delivery system damage and/or premature deployment **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- Page 9, 26: Do not rotate the Internal Iliac Component (IIC) delivery catheter during delivery, positioning or deployment. Catheter breakage **or separation** or premature deployment ~~may occur~~ **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- Page 10, 26: Do not attempt to withdraw any undeployed endoprosthesis through the introducer sheaths. The sheath and ~~undeployed device catheter~~ must be removed together. **Catheter breakage or separation or premature deployment have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- Page 10, 25, 26, 27: Do not continue advancing ~~or withdrawing~~ any portion of the delivery system if resistance is felt during advancement of the guidewire, sheath, or catheter. Stop and assess the cause of resistance. Vessel or catheter damage **or premature deployment may occur** ~~may occur~~ **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**
- Page 10, 26: **Do not continue to withdraw the delivery catheter if resistance is felt during removal through the introducer sheath. Forcibly withdrawing the delivery catheter through the introducer sheath when resistance is encountered has resulted in adverse events including catheter breakage or separation and reintervention resulting in potential patient harms, see ADVERSE EVENTS.**
- Page 26: Do not advance the device **outside of** the sheath while tracking it through the IBC into the internal iliac artery. ~~The sheath will protect the device from~~ Catheter breakage or premature deployment **have occurred and may result in potential patient harms, see ADVERSE EVENTS.**

GORE® EXCLUDER® Iliac Branch Endoprosthesis MODIFIED Adverse Events Section (Page 10)

Adverse events that may occur and / or require intervention **or additional intraoperative procedure time** include, but are not limited to:

1. allergic reaction and / or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials
2. amputation
3. anesthetic complications
4. aneurysm enlargement
5. aneurysm rupture and death
6. arterial or venous thrombosis and / or pseudoaneurysm
7. arteriovenous fistula
8. bleeding, hematoma, or coagulopathy
9. bowel (e.g., ileus, transient ischemia, infarction, necrosis)
10. cardiac (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)
11. claudication (e.g., buttock, lower limb)
12. death
13. dissection, perforation, or rupture of the aortic vessel and surrounding vasculature
14. edema
15. embolization (micro and macro) with transient or permanent ischemia
16. endoleak
17. endoprosthesis **or delivery system**: improper component placement; incomplete component deployment; **unintentional/premature component deployment; leading end catheter component retention**; component migration; separation of graft material from stent; occlusion; infection; stent fracture; graft material failure, dilatation, erosion, puncture, perigraft flow
18. fever and localized inflammation
19. genitourinary (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection)
20. hepatic failure
21. impotence
22. infection (e.g., aneurysm, device or access sites)
23. lymph fistula / complications
24. multi-system organ failure
25. neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
26. occlusion of device or native vessel
27. post-implant syndrome
28. pulmonary complications (e.g., pneumonia, respiratory failure)
29. radiation injury, late malignancy
30. renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
31. surgical **cut down, bypass or** conversion
32. tissue necrosis
33. wound (e.g., infection, dehiscence)
34. vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, seroma, bleeding, rupture, death)

GORE® EXCLUDER® Iliac Branch Endoprosthesis NEW DIRECTIONS FOR USE

- **Page 26: When withdrawing the device delivery system through the introduce sheath, verify all catheter components are intact.**
- **Page 27: Prior to removing wires and sheaths verify all catheter components have been withdrawn from the patient.**