



September 2017

Important Safety Information Conformable GORE® TAG® Thoracic Endoprosthesis

SUBJECT: Medical Device Safety Notification—Incomplete and / or partial deployment of the Conformable GORE® TAG® Device during the endovascular procedure

TARGET AUDIENCE: Vascular Surgeons, Cardiothoracic Surgeons, Interventional Cardiologists, Vascular Interventional Radiologists, other physicians implanting endovascular aortic devices, and Health Care Facilities carrying the Conformable GORE® TAG® Thoracic Endoprosthesis

Dear Health Care Provider:

In the interest of patient safety, W. L. Gore & Associates, Inc. (Gore), would like to inform you of safety information related to the Conformable GORE® TAG® Thoracic Endoprosthesis (Conformable TAG® Device). Please review this letter carefully and follow all recommended actions described below.

Description of the Issue:

- Since December 2016, Gore has received four similar reports of incomplete and / or partial deployments of the Conformable TAG® Device. In each event, the physician observed that half of the Conformable TAG® Device deployed and half remained constrained to the delivery catheter. Each of these events occurred during an off-label procedure, but it is unclear at this time how this may have affected the outcomes. Engineering evaluations for two returned devices indicate that one partial deployment was the result of an incorrect deployment line stitch pattern and another was the result of deployment line damage of unknown origin. The other two devices have not been returned to Gore for evaluation.
- There were two serious adverse health consequences and one death reported:
 - One patient required intra-operative surgical conversion and subsequently died.
 - One patient required intra-operative surgical conversion and experienced temporary mesenteric and renal ischemia.
 - One patient required an additional surgical intervention and experienced temporary renal ischemia.
 - One patient sustained no injuries due to deployment during an open repair.
- While incomplete deployments are known adverse events and identified within the *Instructions for Use* (IFU), Gore has seen an increased frequency of these partial deployment events in Conformable TAG® Devices sold (totaling 0.03% of 12,865 devices distributed*) that were manufactured in the prior year compared to those manufactured earlier.
- Potential adverse events related to incomplete deployment may include, but are not limited to, additional procedures, open surgical conversion, or death.

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- Gore has taken steps to address this increased frequency in events.
- At this time, Gore does NOT plan to remove Conformable TAG® Devices from the market due to the low risk of occurrence of incomplete deployments and potential patient risks if the Conformable TAG® Device is not available. Based on the frequency of 0.03%, Gore estimates that a very small number of the estimated 6,300* unimplanted devices remaining in the field may be affected by this type of event.
- Gore maintains its confidence in the safety and effectiveness of the Conformable TAG® Device.

Recommended Action:

Based on these events, Gore is updating its *Instructions for Use* (IFU) to include the following new warnings and precautions:

- *If abnormal or inconsistent deployment line resistance is felt during deployment initiation, STOP deployment action immediately. If device remains constrained, remove device through the introducer sheath. If resistance is felt during removal through the sheath, stop and withdraw device and introducer sheath together.*
- *If the device is in a partially deployed state and remains attached to the catheter, physicians should strongly consider conversion to immediate open surgical repair to avoid additional procedure time and potential harm from additional endovascular maneuvers.*

In addition to these actions, once the case is completed, report the adverse event to Gore Product Surveillance as soon as possible using the appropriate number below:

Contact Details:

PHONE ASIA PACIFIC: +86 21 5172 8235, **Ext.** 32235, **FAX:** +86 21 5172 8236

PHONE BRAZIL: +55 11 5502 7955, **Ext.** 35855, **FAX:** +55 11 5502 7965

PHONE EMEA: +49 89 4612 3440, **Ext.** 53440, **FAX:** +49 89 4612 43440

PHONE USA / OUS: 1 800 528 1866, **Ext.** 44922 or 1 928 864 4922, **FAX:** 1 928 864 4364

Gore also recommends adherence to the approved Conformable TAG® Device indications and review of current Conformable TAG® Device IFU warnings. Gore emphasizes the warning in the current IFU: *Always have a surgical team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.* Please refer to the enclosed *Changes to Instructions for Use* (IFU) Document (AW1350-EN3), also available at: goremedical.com/ctag

There are no actions required for patients already implanted with a Conformable TAG® Device. Patients who have been implanted with a Conformable TAG® Device do not require any change to their usual follow-up plan, and should continue to be monitored in accordance with your standard practice.

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Gore is providing this safety information to ensure that you are aware of this potentially harmful event during implantation of the device and to assist with your decision-making.

This safety information serves as a supplement to the Conformable TAG® Device training in which you should have participated, and any related educational material you received. Please share this letter with others in your hospital or clinic as appropriate, and contact your local Gore Sales Associates or Gore Customer Service (email: MPDCustomerCare@wlgore.com or by phone at 800.528.8763 or 928.864.2927 with any questions related to this letter.)

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>

Gore has notified the appropriate regulatory agencies of this Field Safety Notification.

Sincerely,

Keith Flury
Thoracic Product Specialist

Michael Nilson
Thoracic Product Specialist

Enclosure: Changes to *Instructions for Use* (IFU) Document – AW1350-EN3

* As of September 1, 2017

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Medical Device Safety Notification

Incomplete and / or partial deployment of the Conformable GORE® TAG® Device during the endovascular procedure

Changes to *Instructions for Use* (IFU)

Based on the four similar events described in the Medical Device Safety Notification (AW1346-EN3) for the Conformable TAG® Device, Gore is updating its *Instructions for Use* (IFU) to include the following new warnings and precautions:

- *If abnormal or inconsistent deployment line resistance is felt during deployment initiation, STOP deployment action immediately. If device remains constrained, remove device through the introducer sheath. If resistance is felt during removal through the sheath, stop and withdraw device and introducer sheath together.*
- *If the device is in a partially deployed state and remains attached to the catheter, physicians should strongly consider conversion to immediate open surgical repair to avoid additional procedure time and potential harm from additional endovascular maneuvers.*

Addendum to IFU Changes

Patient Counseling Addition:

Risk and benefit differences between endovascular repair and open surgical repair, **including potential emergency conversion to open surgical repair.**

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