Product Safety Information

Conformable GORE® TAG® Thoracic Endoprosthesis

en English (Australia)

zh 简体中文 / China

GORE
Creative Technologies Worldwide

October 2017

URGENT RECALL FOR PRODUCT CORRECTION

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 (totalling 0.03% of 12,865 devices distributed*) that were manufactured in the prior year compared to those manufactured earlier.

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- Potential adverse events related to incomplete deployment may include, but are not limited to, additional procedures, open surgical conversion, or death.
- 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 manoeuvres.*

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 AUSTRALIA: 1800 680 424 **FAX:** 1800 810 520

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 (AW1576-EN2), also available at: goremedical.com/thoracic/ap.

There are no actions required for patients already implanted with a Conformable TAG® Device. Patients who

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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.

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 Associate or local Gore office at 1800 680 424 with any questions related to this letter.

This action has been undertaken following consultation with the Therapeutic Goods Administration (TGA).

If you have any questions regarding this notice, please contact Samantha Powis by phone on 1800 680 424 for further information.

Sincerely,

Samantha Powis
Aortic and Structural Heart Product Manager — South Asia Pacific

Enclosure: Changes to *Instructions for Use* (IFU) Document – AW1576-EN2

** 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 (AW1568-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.*

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重要安全信息

Conformable GORE® TAG® Thoracic Endoprosthesis

主题: 医疗器械安全性通告—腔内手术过程中 Conformable GORE® TAG® 支架不完全和/或部分释放

目标受众: 血管外科医生, 心胸外科医生, 心脏介入医生, 血管介入医生, 其他从事主动脉支架植入的医生, 和存有 Conformable GORE® TAG® Thoracic Endoprosthesis 的医疗机构

亲爱的医疗服务提供者:

基于病患安全考量, W. L. Gore & Associates, Inc. (Gore), 希望通报您有关 Conformable GORE® TAG® Thoracic Endoprosthesis (Conformable TAG® Device)的安全性信息.
请仔细阅读这封信并遵从以下的行动建议

事件概况:

- 自 2016 年 12 月, 戈尔公司收到4宗类似的有关 cTAG 支架不完全和/或部分释放的报告. 每个案例中,医生观 察到 cTAG 支架一半释放了，另一半仍被压缩在输送系统上. 以上的案例都是超适应症使用, 目前对于结果的影响仍不明朗。经过对退回的两条支架的技术分析显示其中一例部分释放是由于释放线的错误缝合造成，另一例是由于不明起源的释放线损坏。其余两条支架并未送回戈尔检测。
- 存在两例严重健康损害和一例死亡报告:
  - –一例患者需要术中转开放手术，随后死亡.
  - –一例患者需要术中转开放手术，且经历了短暂的肠缺血和肾缺血.
  - –一例患者需要额外的外科介入而且经历了短暂的肾缺血.
  - –一例患者在开放修复中支架打开，所以没有损害.
- 虽然在使用说明（IFU）里面已将不完全释放列为不良事件, 戈尔看到在已售 cTAG 支架中，去年生产的相对于更早期生产的，此不完全释放的发生频率有所增加 (在分销的 12,865 支架中，总计 0.03% *) .
- 不完全释放可能导致的不良事件，但不局限于, 额外的手术, 转开放手术, 或死亡.
- 戈尔已采取行动来应对这些事件的频率增加.

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- 目前，戈尔 不 打算从市场上撤回 Conformable TAG® Devices，因为此不完全释放发生的风险较低，且考量了如果不能供货而导致的潜在病人风险. 基于0.03%发生几率，戈尔预计目前市场上存留的预计大约6,300* 未植入的支架仅有很少部分的会受此类事件影响.
- 戈尔仍对 Conformable TAG® Device 的安全性和有效性保持足够信心.

建议措施:

基于这些事件，戈尔正在更新使用说明 (IFU) 包含以下新的警告和防范:

- 如果在释放初始阶段感觉到释放线阻力异常或不一致,请立即停止释放动作.如果支架维持在被压缩状态，将支架通过导引鞘撤出. 如果从鞘撤出时感受到阻力,请停止动作，然后将支架和导引鞘一起撤出.
- 如果支架处于部分释放状态且仍附着在导管上，医生应毫不犹豫的考虑立即转为开放手术修复，以避免额外的手术时间以及防止因其他的腔内操作而发生潜在伤害.

除这些措施之外，一旦手术结束，请通过以下的号码尽快向 Gore Product Surveillance 报告这个不良事件:

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

戈尔同时建议您遵从 Conformable TAG® Device 已获批的适应症和阅读 IFU 的警示事项. 戈尔着重强调现有 IFU 内的警示事项: 务必有一个外科团队可以在植入支架或再次介入时需要转开放修复时提供帮助. 请参考如下使用说明(IFU)改动，Document (AW1350-SZH1), 同时可以访问: goremedical.com/thoracic/ap
对于已植入 cTAG 支架的病人，不必采取任何的行动. 不必改动目前的随访计划，且需继续按常规监测.

戈尔正在提供这些安全信息来让您知晓这个在植入时可能发生的潜在伤害事件并帮助您决定.

这个安全信息将作为一个补充材料加入您之前参加过的 cTAG 产品培训中，和您接获过的教育材料中. 如果合适，请将此信件与您的同僚分享，如对此信件有任何问题，请联络当地戈尔销售同事或戈尔客服 (email: MPDCustomerCare@wlgore.com 或 电话 800.528.8763 or 928.864.2927.)

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对于不良事件或任何质量问题，医疗服务专业人员或病人可以通过 FDA MedWatch 网页直接报告给 FDA:
https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

此安全通告戈尔已经通知了相关的监管机构.

Sincerely,

Keith Flury
Thoracic Product Specialist

Michael Nilson
Thoracic Product Specialist

Enclosure: Changes to *Instructions for Use* (IFU) Document – AW1350-SZH1

** As of September 1, 2017*

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医疗器械安全性通告

GORE® TAG® Device在腔内手术时不完全和/或部分释放

使用说明 (IFU) 变更

基于 Medical Device Safety Notification (AW1346-SZH1)所描述的有关 Conformable TAG® Device 的四宗类似案例, 戈尔正在更新使用说明 (IFU) 包含以下新的警告和防范:

- 如果在释放初始阶段感觉到释放线阻力异常或不一致,请立即停止释放动作.如果支架维持在被压缩状态, 将支架通过导引鞘撤出. 如果从鞘撤出时感受到阻力,请停止动作，然后将支架和导引鞘一起撤出.

- 如果支架处于部分释放状态且仍附着在导管上, 医生应毫不犹豫的考虑立即转为开放手术修复，以避免额外的手术时间以及防止因其他的腔内操作而发生潜在伤害.

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Products listed may not be available in all markets.

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