GORE
Creative Technologies
Worldwide

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-EN1) 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.*

W. L. Gore & Associates, Inc.
Medical Products Division
3450 West Kiltie Lane
Flagstaff, Arizona 86001
Tel 928.779.2771 • Fax 928.779.3480

goremedical.com