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**~~ **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 patent 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.**