GORE® EXCLUDER®
Iliac Branch Endoprosthesis

Product Overview

Frequently Asked Questions

Published Literature Summary

Clinical Data

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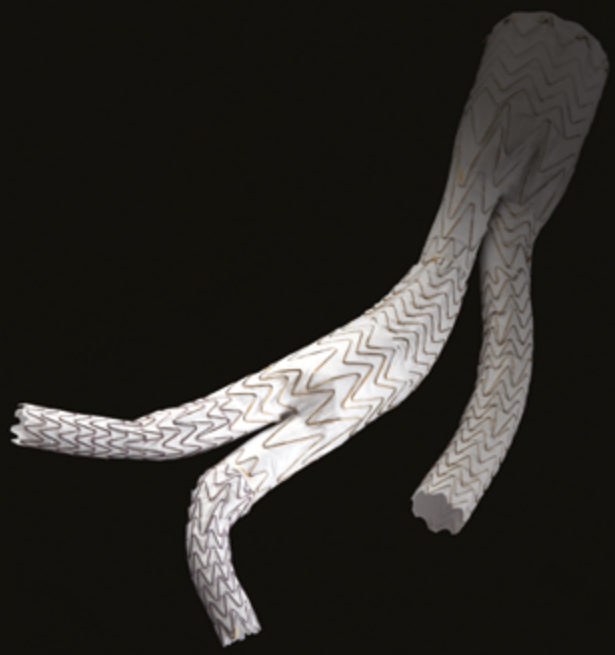

The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is used in conjunction with the GORE® EXCLUDER® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries.

General

- **Are there any storage requirements for this item?**
  There are no unique storage requirements for the IBE. Store in a cool, dry place.

- **Describe the advantages this product / service provides.**
  The advantage of the IBE is that it provides endovascular repair (EVAR) of common iliac artery aneurysms or aorto-iliac aneurysms while preserving blood flow to internal iliac arteries.

- **How will this product maintain or improve patient care?**
  Provide detail about efficacy and clinical outcomes
  The IBE can provide quality of life improvement over currently accepted treatment options for these patients, while potentially reducing cost associated with reintervention or increased level of care. Through six months follow-up, patients had 0% reported buttock claudication, 0% new onset erectile dysfunction, and 0% colonic ischemia in our clinical trial. View the Clinical Data section in this document for further information.

- **Is specific equipment or related products required for the use of this product?**
  i.e., sterile surgical instruments or instrument set
  No sterile surgical instruments or instrument set is needed. Standard endovascular ancillary devices are required to implant this product (i.e., guidewires, introducer sheaths, catheters, etc.)

- **What is the current product in use for this purpose?**
  While there are currently no other stent grafts approved by the FDA, there are currently two other stent grafts CE marked to preserve blood flow to the internal iliac arteries during EVAR. However, the Gore IBE is the only complete system fully engineered and tested for this purpose.

- **What routine maintenance cleaning / decontamination will be required and who will be expected to perform this?**
  There is no routine maintenance cleaning / decontamination required for the use of the IBE.

- **What support can Gore offer in terms of clinical support and training?**
  Our highly qualified clinical specialists and sales representatives will provide clinical case support. Furthermore, as part of our Gore Medical Mastery Series, we offer workshops on Iliac Branching Techniques and Case Planning. Please contact your sales representative for details.

General *(continued)*

- **Is this product and all packaging latex free?**
  Yes, the IBE and packaging is latex free.

- **Is this product sterile?**
  Yes, the IBE is preloaded on a delivery catheter and supplied sterile and non-pyrogenic.

- **What packaging does this product come in and what is the unit of measure (example: box of 5)?**
  The IBE is packaged and sold individually.

- **Is there a minimum order quantity for this product or for your company?**
  No, there is no minimum order quantity for the IBE.

- **Does your company supply free product and support for an evaluation?**
  No, there is no free product provided for evaluations. We provide free clinical support for all of our products.

Competitive Devices / Procedures

- **Will this device reduce the usage of item(s) currently in use?**
  The IBE may reduce the usage of vascular plugs and coils if currently used to embolize the internal iliac arteries during EVAR.

- **What devices compete against this device?**
  There are currently three devices available in the market that preserve flow to the IIA and which are approved for this indication but the GORE® EXCLUDER® Iliac Branch Endoprosthesis is the only easy to use, fully engineered ALL-IN-ONE device system for this purpose.

- **What procedures compete against this treatment?**
  There are two procedures which some may consider competing procedures. First is embolization (coiling and covering) of the internal iliac artery and the second is open surgical bypass of the internal iliac artery. In addition off label techniques are being used.

Schönhofer S, Mansour R, Ghotbi R. **Initial results of the management of aortoiliac aneurysms with GORE® Excluder® Iliac Branched Endoprosthesis.** *Journal of Cardiovascular Surgery* 2015;56(6):883-888.

Objectives

A prospective observation of the outcomes of all patients with an aortoiliac and a common iliac artery aneurysm who were electively treated with the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE).

Summary of Results

15 Patients, Mean follow-up of 9 months
93.3% (14 / 15) Procedural technical success
0% Perioperative mortality
0% Buttock claudication or any sign of pelvic ischemia was reported
0 IBE occlusions, **100%** Patency of internal iliac side branch
0 Type 1a, 1b, or III endoleaks were observed
20% Type II endoleak
0% Reintervention
5 Days mean hospital stay

Summarized Conclusion

The IBE provides a new and safe alternative for the management of complete endovascular repair of an extensive aortoiliac or common iliac aneurysm while maintaining pelvic blood flow in iliac branched devices. Due to the lower complexity if compared to previous endovascular or hybrid methods, it should be performed in every anatomically suitable case.

Millon A, Schiava ND, de Lambert A, et al. **Endovascular treatment of iliac aneurysms: short-term results of a new branched iliac stentgraft.** Presented at the 30th Annual Meeting of the French Society for Vascular Surgery (SCV); June 27-29, 2015; Montpellier, France. *Annals of Vascular Surgery* 2015;29(6):1045.

Objectives

A retrospective monocentric study to evaluate the short-term results of the new GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) for the treatment of common iliac artery (CIA) aneurysms without a distal neck.

Summary of Results

10 Consecutive Patients, 30-day Results Discussed
No technical failures observed
No perioperative complications observed
100% Patency of branches (internal and external) at 30 days
1 Type 1a endoleak identified on GORE® EXCLUDER® Device, treated with aortic extender POD3
0 Type 1b or III endoleaks
4 Days mean hospital stay

Summarized Conclusion

The technical success rate and the results at 30 days of this new stent graft are very encouraging. A long-term follow-up is necessary.

PUBLISHED LITERATURE SUMMARY

Published Literature Summary

Ferrer C, De Crescenzo F, Coscarella C, Cao P. **Early experience with the Excluder Iliac Branch Endoprosthesis.** *Journal of Cardiovascular Surgery* 2014;55(5):679-683.

Objectives

To evaluate early results with the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) in the treatment of iliac aneurysms associated or not with abdominal aortic aneurysms.

Summary of Results

7 IBE in 5 Patients, Reported up to 30 Days
100% Technical success
100% Branch patency
No 30-day mortality
In 1 of 2 bilateral cases, endovascular relining with bare stents was required due to compression of the iliac legs (of the GORE® EXCLUDER® AAA Endoprosthesis) at the level of the aortic bifurcation

Summarized Conclusion

Use of the IBE device in the treatment of aorto-iliac disease is feasible and safe. Late results are necessary to evaluate the performance of this endograft in the long-term.

Additional literature references available upon request.

U.S. IDE Clinical Trial

External Iliac Artery	Internal Iliac Artery
100% Patency 1 and 6 months	95% Patency 1 and 6 months

98.4% Freedom from Reintervention

0% Buttock Claudication

0% New Onset Erectile Dysfunction

0% Aneurysm Enlargement (> 5 mm) at 6 Months

152 Minutes Procedure Time

40 Minutes Fluoro Time	114 mL Contrast Used

95.2% Technical Success*

*Defined as successful implantation with lack of endoleaks

Primary enrollment of 62 patients. Data through six-month follow-up.

Global Registry for Endovascular Aortic Treatment (GREAT) Data*

100% Procedure Survival

0% Mortality	0% Aortic Rupture

100% EIA Patency *at 6 months*

0% Conversion to Open Repair	98% FREEDOM from Reintervention
0% Buttock Claudication Reported	0% Sexual Dysfunction Reported

0% Reintervention related to patency of IIA

* 58 patients enrolled in Europe and Australia through March 2016. Data through six months follow-up shown unless otherwise noted. Technical success: no device issues were reported as Serious Adverse Events related to elements of technical success definition.

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