

## Abstract

*This annual clinical update provides a review of the ongoing experience with the GORE® EXCLUDER® AAA Endoprosthesis used in the treatment of infrarenal abdominal aortic aneurysms (AAAs). Five years of IDE clinical study data and 13 years of worldwide commercial performance are presented. Five year data representing outcomes of 565 patients enrolled through two Phase II pivotal studies are collectively presented as the combined IDE cohort. Outcomes from the clinical studies have been favorable for patients treated with the GORE® EXCLUDER® Device. These patients experienced fewer major adverse events compared to patients treated with open surgery.*

*Aneurysm-related mortality was similar between the two groups. Through five years, only one (0.2%) patient in the combined IDE cohort experienced an aneurysm rupture, 19 (3.4%) were converted to open surgery, and two explanted devices had stent fractures. At five-year follow-up, 40 (16%) patients had endoleaks and 79 (34%) had aneurysm enlargement. The 13 years of commercial experience represent more than 112,000 devices distributed worldwide. Worldwide commercial adverse event data represent all events reported to Gore between September 1997 and May 15, 2010. During this time, Gore has received reports of 56 ruptures,*

*358 conversions, 69 post-treatment migrations, 135 aneurysm-related deaths, 70 infections, 63 occlusions, 76 infolds and 9 stent fractures. The worldwide commercial adverse events support the low adverse event rates identified in the GORE® EXCLUDER® Device clinical trial data. Gore is pleased to offer you and your patients a device backed by strong long-term durability and clinical data. The data included within this annual clinical update reaffirm that Gore is committed to providing access to clinical results and data from our worldwide experience to assist you in making informed treatment decisions for your patients diagnosed with AAAs.*

## Introduction

Since the introduction of the GORE® EXCLUDER® Device, the Medical Products Division of W. L. Gore & Associates, Inc., (Gore) has demonstrated its commitment to keeping physicians up-to-date regarding product performance data. Gore is pleased to provide you with our latest GORE® EXCLUDER® Device annual clinical update. This update summarizes five years of clinical study data and 13 years of reported adverse event data from worldwide commercial experience with the GORE® EXCLUDER® Device. These data will assist you in making informed treatment decisions for your patients diagnosed with infrarenal abdominal aortic aneurysms (AAAs). Five year prospective, controlled clinical data and more than 13 years of worldwide commercial experience continue to support the safety and efficacy of treatment of abdominal aortic aneurysms with the GORE® EXCLUDER® Device. This report is divided into five primary sections:

- Section I summarizes the five year clinical study data from the combined IDE cohort. This is a comprehensive group of all patients enrolled under two Phase II clinical study protocols: 98-03 evaluating the Original GORE® EXCLUDER® Device and 99-04 evaluating the Modified GORE® EXCLUDER® Device. Clinical outcomes reported in this section include adverse events, mortality, and device-related events. Section I also contains data on the Low Permeability GORE® EXCLUDER® Device in the 04-04 post-approval clinical study. The Low Permeability GORE® EXCLUDER® Device is the only available design.
- Section II provides an update of worldwide commercial adverse events that have been reported to Gore from September 1997 to May 15, 2010. During this same period, approximately 112,000 devices were distributed worldwide. This section includes information on rupture, conversion, aneurysm morphology, migration, and occlusion.
- Section III provides an analysis of all explanted devices returned to Gore through May 15, 2010. Primary cause of explant and device durability data are reported.
- Section IV contains summary comments from the clinical study data as well as the worldwide experience with the GORE® EXCLUDER® Device.
- Section V details patient selection and follow-up guidelines for commercial use of the GORE® EXCLUDER® Device.

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† Data contained in this document is current through May 15, 2010, unless otherwise noted. All Adverse Event definitions follow those used in Gore's clinical study protocols.

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### Description of the US Clinical Studies

The Original GORE® EXCLUDER® Device was released in Europe in September 1997. Based upon the one-year follow-up data from a Phase II Pivotal Study conducted in the US (98-03), this device was approved for commercial distribution in the US in November 2002. During the 98-03 clinical study, Gore made three modifications to the Original GORE® EXCLUDER® Device. Changes included modifications for continuous wire diameters, standardizing anchor cut angles, and a change to the width and location of the proximal sealing cuff. In addition to these changes, new Trunk-Ipsilateral components were offered in shorter lengths. These changes did not affect the delivery system or operation of the Modified GORE® EXCLUDER® Device compared to the Original GORE® EXCLUDER® Device.

The Modified GORE® EXCLUDER® Device was released to the rest of the world in July 2002 and was approved for commercial distribution in the US in February 2004 based upon one-year follow-up data from a second Phase II Pivotal Study (99-04). Results demonstrated that there are no differences in clinical performance between the Original and Modified GORE® EXCLUDER® Devices.

Detailed clinical results for pivotal studies on the Original GORE® EXCLUDER® Device (98-03) and the Modified GORE® EXCLUDER® Device (99-04) on the treatment of patients for AAAs are pooled and reported as the combined IDE cohort for this annual update. This represents the largest collection of prospective, controlled, clinical data for the GORE® EXCLUDER® Device.

In June 2004, Gore launched a design enhancement to the GORE® EXCLUDER® Device in response to aneurysm enlargement concerns. This new device, the Low Permeability GORE® EXCLUDER® Device, differs from the Original and Modified GORE® EXCLUDER® Devices by the addition of an interior layer that decreases the overall graft permeability. The luminal and abluminal ePTFE surface materials, microstructure, and characteristics of the Low Permeability GORE® EXCLUDER® Device are equivalent to the Original and Modified GORE® EXCLUDER® Devices. The Low Permeability GORE® EXCLUDER® Device was designed to provide equivalent performance while minimizing the potential for serous fluid migration through the graft material. In June 2004, the Low Permeability GORE® EXCLUDER® Device was approved by the FDA and released worldwide. The Low Permeability GORE® EXCLUDER® Device is the only available design.

Gore conducted a post-approval clinical study (04-04) to evaluate the clinical performance of the Low Permeability GORE® EXCLUDER® Device. The study is complete and final data from this study are presented in this annual update.

The GORE® EXCLUDER® Device product line includes 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender sizes to treat patients with larger proximal aortic neck diameters. The larger size GORE® EXCLUDER® Devices were approved by the FDA in March 2009.

This section of the GORE® EXCLUDER® AAA Endoprosthesis annual clinical update will provide an overview of the results from the clinical studies discussed above. A detailed explanation of the design and enrollment of each of the clinical studies is provided.

### Pivotal Study Original GORE® EXCLUDER® Device (98-03)

This US Phase II Pivotal Study was designed to evaluate the safety and efficacy of the Original GORE® EXCLUDER® AAA Endoprosthesis. This multicenter (19 sites), non-randomized, prospective, controlled trial compared standard open surgical repair (Control, n = 99) to endovascular treatment with the GORE® EXCLUDER® Device (Test, n = 235) in the treatment of AAAs. An additional 49 Test patients were enrolled under the continued access protocol. Primary study endpoints were a comparison of major adverse event (MAE) rates between the Test and Control groups, and the assessment of aneurysm exclusion and major device events through one year post-treatment. Patients were enrolled into the 98-03 study from December 1998 to January 2000 and into the continued access study between November 1999 and April 2000. All Test and Control patients were followed through five years post-treatment. All 98-03 patients have completed five-year follow-up; this study has been closed. The 98-03 data included in the combined IDE cohort for this report represent the final study data.

**Section I – Clinical Experience****Pivotal Study Modified GORE® EXCLUDER® Device (99-04)**

The 99-04 clinical study was initiated to evaluate the Modified GORE® EXCLUDER® Device. The primary objectives of the study were to compare the safety of the Modified GORE® EXCLUDER® Device to open surgical repair and to evaluate the effectiveness compared to the Original GORE® EXCLUDER® Device in the treatment of AAAs. A total of 193 Test patients were enrolled in the study from April 2000 to April 2001. A total of 88 additional Test patients were enrolled from January 2001 to November 2002 under the continued access protocol. All patients were followed through five-year follow-up; this study has been closed. The 99-04 data included in the combined IDE cohort for this report represent the final study data.

**Combined IDE Cohort**

Test patient data from the 98-03 (n = 235), 98-03 continued access (n = 49), 99-04 (n = 193), and 99-04 continued access (n = 88) were combined and reported as a single group. These 565 patients are collectively referred to as the combined IDE cohort. Pooling of data from 98-03 and 99-04 is justified based on the following conclusions from a propensity score analysis<sup>1</sup>:

- No overall difference in survival was detected between the studies when controlling for propensity score quintiles
- No overall difference in major adverse events (MAE) was detected between the studies when controlling for propensity score quintiles
- No overall difference in major device events (MDE) (either total MDE, major endoleaks, or aneurysm increase with intervention) was detected between the studies when controlling for propensity score quintiles

**Post-Approval Study Low Permeability GORE® EXCLUDER® Device (04-04)**

The 04-04 post approval clinical study was initiated to assess aneurysm morphology changes through a two-year follow-up in patients treated with the Low Permeability GORE® EXCLUDER® Device in the treatment of AAAs. This study completed enrollment of 139 prospective and retrospective Test patients at eight sites in August 2006. Controls in the study are 120 randomly selected patients treated with the Original GORE® EXCLUDER® Device in the 98-03 clinical study. Two-year follow-up for the study was completed in February 2009. Final two-year follow-up results comparing the aneurysm morphology of the Test patients treated with the Low Permeability GORE® EXCLUDER® Device to the Control patients treated with the Original GORE® EXCLUDER® Device are shown in this report.

**31 mm GORE® EXCLUDER® Device Study (03-02)**

The GORE® EXCLUDER® Device product line includes a 31 mm Trunk-Ipsilateral Leg and 32 mm Aortic Extender to treat patients with larger proximal aortic neck diameters. The 03-02 study was initiated to evaluate the 31 mm GORE® EXCLUDER® Device compared to open surgical repair and to compare device performance to the Original GORE® EXCLUDER® Device in the treatment of AAAs with large proximal neck diameters. Enrollment of Test patients into this study was completed in January 2008 with a total of 35 patients enrolled. The larger size GORE® EXCLUDER® Devices were approved by the FDA in March 2009.

<sup>1</sup> Rosenbaum PR, Rubin DB. Reducing bias in observational studies using subclassification on the propensity score. *Journal of the American Statistical Association* 1984;79(387):516-524.

## Section I – Clinical Experience

### Clinical Study Data

#### Clinical Study Demographics

Demographic information and pre-procedural characteristics of patients enrolled in the 98-03 Control group and the combined IDE cohort are shown in **Table 1**. Overall, pre-procedural characteristics and pre-treatment risk assessments were similar between the 98-03 Control group and the combined IDE cohort. The combined IDE cohort patients were an average of three years older and there was a higher proportion of males.

**Table 1: Selected Demographic Information**

	98-03 CONTROL	COMBINED IDE COHORT
<b>TOTAL NUMBER OF PATIENTS ENROLLED</b>	99	565
<b>AGE AT TREATMENT (YEARS)</b>		
Mean (Std Dev)	70.6 (8.5)	73.9 (7.9)
Median	71.8	74.3
Range	(51.8, 87.6)	(48.9, 93.0)
<b>GENDER</b>		
Male	73 (73.7%)	456 (80.7%)
Female	26 (26.3%)	109 (19.3%)
<b>ETHNIC BACKGROUND</b>		
Caucasian	99 (100.0%)	553 (97.9%)
Black	0 (0.0%)	5 (0.9%)
Hispanic	0 (0.0%)	5 (0.9%)
Asian	0 (0.0%)	2 (0.4%)
<b>NYHA FUNCTIONAL CLASS</b>		
1	64 (64.6%)	289 (51.2%)
2	24 (24.2%)	201 (35.6%)
3	11 (11.1%)	48 (8.5%)
Missing	0 (0%)	27 (4.8%)
<b>ASA FUNCTIONAL CLASS</b>		
1	2 (2.0%)	8 (1.4%)
2	21 (21.2%)	111 (19.6%)
3	60 (60.6%)	373 (66.0%)
4	15 (15.2%)	73 (12.9%)
Missing	1 (1.0%)	0 (0.0%)
<b>SVS SUMMARY RISK SCORE</b>		
Mean (Std Dev)	4.6 (2.7)	4.9 (2.7)
Median	4.0	5.0
Range	(0.0, 12.0)	(0.0, 13.3)

Section I – Clinical Experience

**Compliance and Disposition**

The compliance and disposition of Control patients enrolled in the 98-03 clinical study and for the patients in the combined IDE cohort through five years post-treatment are shown in **Table 2**. CTs for the 98-03 Control group were only required at 12 months and annually thereafter. CTs for the combined IDE cohort were only required at the three-month interval if an endoleak was observed at one month. X-ray was not required at any interval for the 98-03 Control group. X-ray in addition to CT for the combined IDE cohort was required at the six-month visit and at the annual visits thereafter. All patients have completed their fifth and final year of follow-up.

Eligible patients are defined as those that are alive and participating in the study for that follow-up period. The number of ‘Patients with Visit in Window’ (compliance) is an exclusive category from the ‘Death’, ‘Discontinuation’, and ‘Not Due for Next Follow-Up’ (events prior to next interval) categories. It is possible for a patient to have a visit within the interval as well as expire or discontinue from the study. Therefore, it is not accurate to directly add entries in the table across the compliance and disposition sections.

These data show the level of follow-up compliance for the 98-03 Control groups and the combined IDE cohort. This consistent reporting of data through five years reaffirms the data integrity from these clinical studies.

**Table 2: Patient Compliance and Disposition by Study Period**

98-03 CONTROL			FOLLOW-UP COMPLIANCE			EVENTS PRIOR TO NEXT INTERVAL		
STUDY PERIOD	ELIGIBLE FOR FOLLOW-UP	PATIENTS WITH VISIT IN WINDOW	WITH CT <sup>a</sup>	WITH X-RAY <sup>a</sup>	WITH ABI <sup>a</sup>	DEATH <sup>a</sup>	DISCONTINUED <sup>a</sup>	NOT DUE FOR NEXT FOLLOW-UP <sup>a</sup>
Procedure	99	—	—	—	—	0 (0.0%)	0 (0.0%)	0 (0.0%)
Post-Procedure	99	—	—	—	—	0 (0.0%)	1 (1.0%)	0 (0.0%)
1 Month	98	89 (90.8%)	0 (0.0%)	0 (0.0%)	67 (68.4%)	1 (1.0%)	1 (1.0%)	0 (0.0%)
3 Months	96	11 (11.5%)	0 (0.0%)	0 (0.0%)	5 (5.2%)	1 (1.0%)	1 (1.0%)	0 (0.0%)
6 Months	94	81 (86.2%)	4 (4.3%)	0 (0.0%)	66 (70.2%)	2 (2.1%)	5 (5.3%)	0 (0.0%)
12 Months	87	83 (95.4%)	74 (85.1%)	4 (4.6%)	67 (77.0%)	1 (1.1%)	5 (5.7%)	0 (0.0%)
24 Months	81	70 (86.4%)	67 (82.7%)	6 (7.4%)	56 (69.1%)	2 (2.5%)	9 (11.1%)	0 (0.0%)
36 Months	70	52 (74.3%)	46 (65.7%)	4 (5.7%)	46 (65.7%)	3 (4.3%)	9 (12.9%)	0 (0.0%)
48 Months	58	47 (81.0%)	40 (69.0%)	5 (8.6%)	37 (63.8%)	3 (5.2%)	9 (15.5%)	0 (0.0%)
60 Months	46	40 (87.0%)	34 (73.9%)	7 (15.2%)	33 (71.7%)	1 (2.2%)	6 (13.0%)	—
COMBINED IDE COHORT			FOLLOW-UP COMPLIANCE			EVENTS PRIOR TO NEXT INTERVAL		
STUDY PERIOD	ELIGIBLE FOR FOLLOW-UP	PATIENTS WITH VISIT IN WINDOW	WITH CT <sup>a</sup>	WITH X-RAY <sup>a</sup>	WITH ABI <sup>a</sup>	DEATH <sup>a</sup>	DISCONTINUED <sup>a</sup>	NOT DUE FOR NEXT FOLLOW-UP <sup>a</sup>
Procedure	565	—	—	—	—	2 (0.4%)	1 (0.2%)	0 (0.0%)
Post-Procedure	562	—	—	—	—	1 (0.2%)	1 (0.2%)	0 (0.0%)
1 Month	560	545 (97.3%)	522 (93.2%)	103 (18.4%)	461 (82.3%)	6 (1.1%)	1 (0.2%)	0 (0.0%)
3 Months	553	94 (17.0%)	85 (15.4%)	11 (2.0%)	37 (6.7%)	6 (1.1%)	0 (0.0%)	0 (0.0%)
6 Months	547	507 (92.7%)	486 (88.8%)	411 (75.1%)	422 (77.1%)	7 (1.3%)	7 (1.3%)	0 (0.0%)
12 Months	533	501 (94.0%)	484 (90.8%)	412 (77.3%)	414 (77.7%)	37 (6.9%)	13 (2.4%)	0 (0.0%)
24 Months	483	441 (91.3%)	412 (85.3%)	360 (74.5%)	350 (72.5%)	25 (5.2%)	31 (6.4%)	0 (0.0%)
36 Months	427	340 (79.6%)	319 (74.7%)	274 (64.2%)	265 (62.1%)	28 (6.6%)	38 (8.9%)	0 (0.0%)
48 Months	361	306 (84.8%)	285 (78.9%)	240 (66.5%)	219 (60.7%)	26 (7.2%)	44 (12.2%)	0 (0.0%)
60 Months	291	255 (87.6%)	236 (81.1%)	185 (63.6%)	178 (61.2%)	11 (3.8%)	41 (14.1%)	—

<sup>a</sup> Denominators are based on the number of patients eligible for follow-up. Study period definitions: Procedure (0–0 days), Post-Procedure (1–14 days), 1 Month (15–60 days), 3 Months (61–120 days), 6 Months (121–242 days), 12 Months (243–546 days), 24 Months (547–911 days), 36 Months (912–1275 days), 48 Months (1276–1640 days), 60 Months (1641–2006 days)

## Section I – Clinical Experience

### Survival

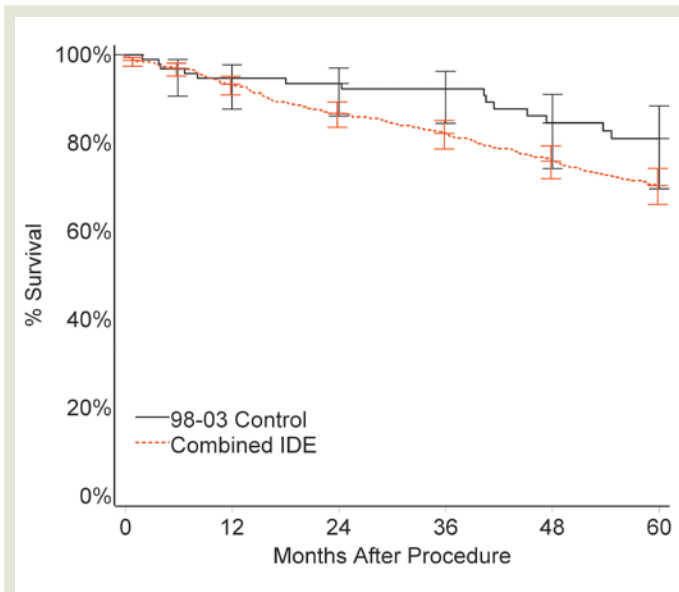
A Kaplan-Meier analysis of survival through five years for patients in the 98-03 Control group and the combined IDE cohort is shown in **Figure 1** and **Table 3**. At five years post-treatment, survival was 81% in the Control group and 70% in the combined IDE cohort (log rank p value = 0.049).

The combined IDE cohort patients were approximately three years older than the 98-03 Control patients.

**When controlling for age, there is no difference in the survival between the combined IDE cohort and the Control group.**

A Kaplan-Meier analysis of aneurysm-related survival through five years for patients in the 98-03 Control group and the combined IDE cohort is shown in **Figure 2** and **Table 4**. Through five years post-treatment, aneurysm-related survival was 98% in the Control group and 98% in the combined IDE cohort.

**Figure 1: Survival Through Five Years**



Shown are 95% confidence limits at each time interval.

**When controlling for age using a Cox regression model, there is no difference in the survival between the combined IDE cohort and the Control group.**

**Table 3: Survival Through Five Years**

	DAY 0	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
<b>98-03 CONTROL</b>								
Patients at Risk	99	97	91	86	79	64	52	35
% Survival	100%	100%	97%	95%	94%	92%	85%	81%
<b>COMBINED IDE</b>								
Patients at Risk	565	556	545	512	457	401	332	196
% Survival	100%	99%	97%	93%	87%	82%	76%	70%

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Aneurysm-related death is defined as death within 30 days of initial procedure or prior to hospital discharge, death within 30 days of a secondary procedure to treat the original aneurysm, or death due to aneurysm rupture. In the 98-03 Control group, two aneurysm-related deaths were reported, both of which

occurred prior to hospital discharge. In the combined IDE cohort, 10 aneurysm-related deaths occurred; 7 within 30 days of treatment, 2 within 30 days of a secondary procedure, and 1 after a conversion to open surgery. No death was caused by aneurysm rupture in either treatment group.

Figure 2: Aneurysm-Related Death Through Five Years

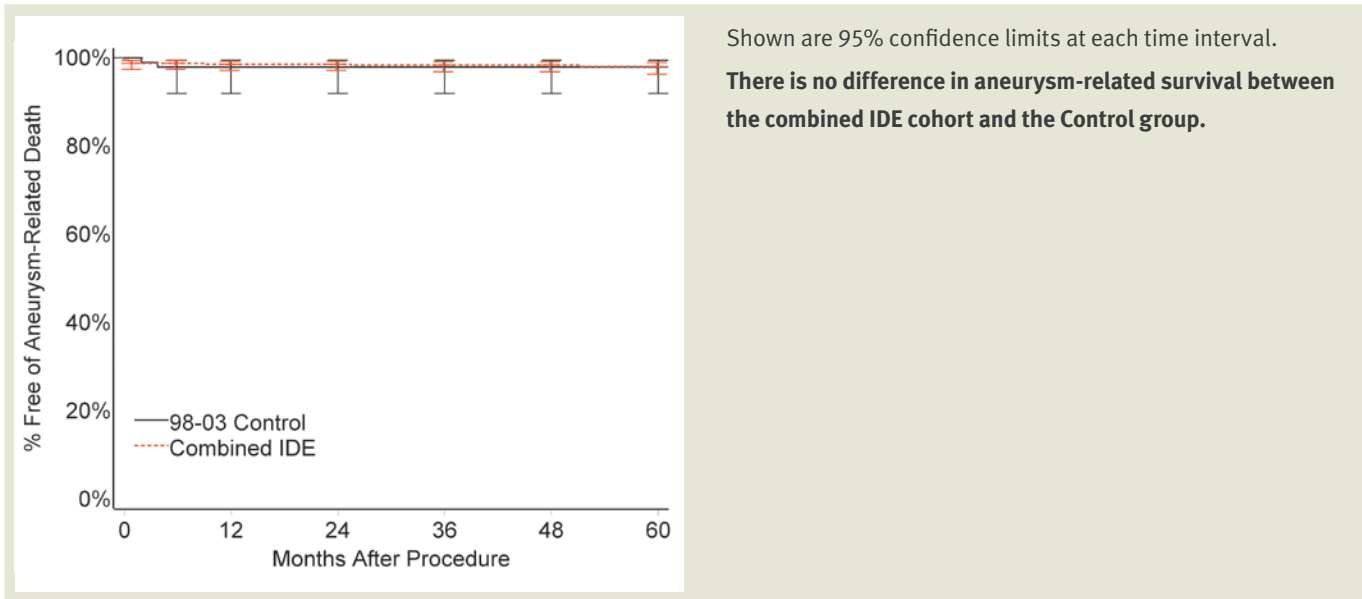


Table 4: Aneurysm-Related Survival Through Five Years

	DAY 0	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
<b>98-03 CONTROL</b>								
Patients at Risk	99	97	91	86	79	64	52	35
% Free of Aneurysm-Related Death	100%	100%	98%	98%	98%	98%	98%	98%
<b>COMBINED IDE</b>								
Patients at Risk	565	556	545	512	457	401	332	196
% Free of Aneurysm-Related Death	100%	99%	99%	99%	99%	98%	98%	98%

## Section I – Clinical Experience

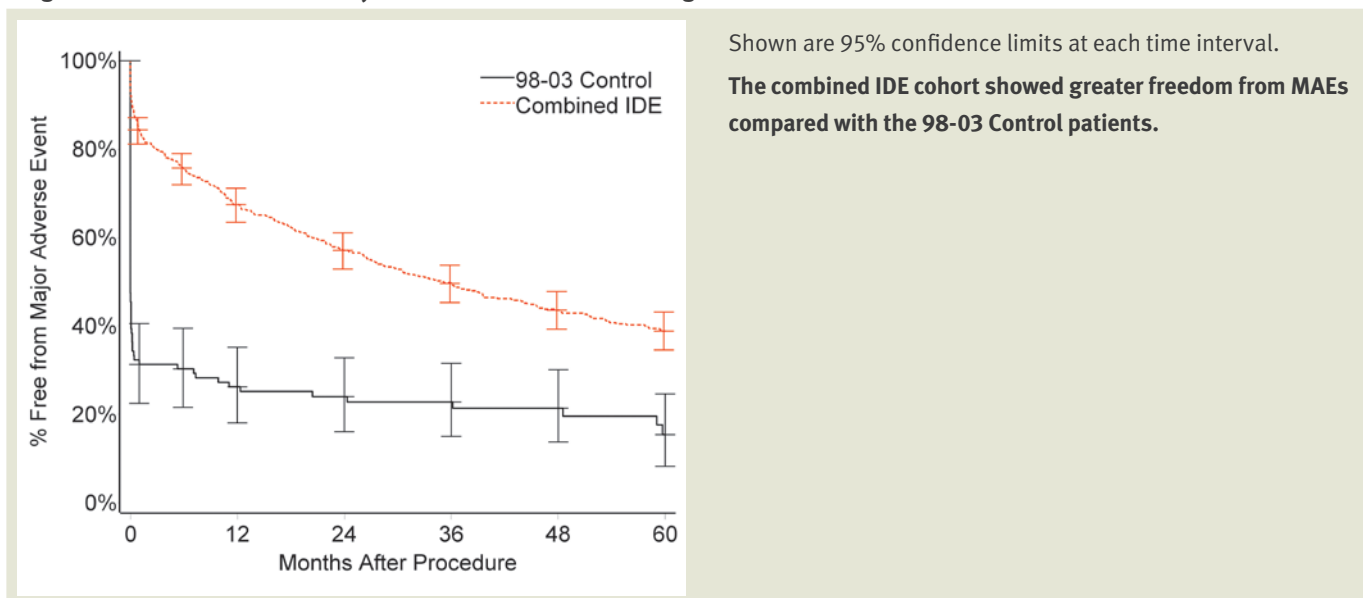
### Freedom from Major Adverse Events

Device safety was assessed by comparing the proportion of 98-03 Control patients and the combined IDE cohort patients who were free from any MAE. Adverse events were classified as major or minor according to pre-specified criteria<sup>1</sup>. An MAE was defined as an event that required therapy and short hospitalization (24 – 48 hours), major therapy, unplanned increase in level of care, blood loss  $\geq 1$  L, prolonged hospitalization (> 48 hours), or resulted in permanent adverse sequelae, or death. A minor adverse event required no therapy with no consequence, nominal therapy with no consequence, or included overnight admission for observation only. A patient experiencing more than one MAE is counted only once for the occurrence of the first MAE in the Kaplan-Meier analysis.

A Kaplan-Meier analysis of freedom from MAEs for patients enrolled in the 98-03 Control group and for the combined IDE cohort through five years post-treatment is shown in **Figure 3** and **Table 5**. Freedom from an MAE was 84% at 30 days for the combined IDE cohort and 31% for the 98-03 Control group. Through five years post-treatment the freedom from an MAE was 39% for the combined IDE cohort vs. 15% for the 98-03 Control group.

**Throughout the entire five-year follow-up period, the combined IDE cohort patients showed greater freedom from MAEs compared with the 98-03 Control patients. These data reaffirm the safety of the GORE® EXCLUDER® Device compared to open surgical repair for the treatment of AAAs.**

**Figure 3: Freedom from Major Adverse Events Through Five Years**



**Table 5: Freedom from Major Adverse Events Through Five Years**

	DAY 0	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
<b>98-03 CONTROL</b>								
Patients at Risk	99	32	30	26	20	16	12	7
% Free from Major Adverse Events	47%	31%	30%	26%	24%	23%	21%	15%
<b>COMBINED IDE</b>								
Patients at Risk	565	477	428	371	302	243	190	110
% Free from Major Adverse Events	94%	84%	76%	67%	57%	50%	44%	39%

<sup>1</sup> Sacks D, Marinelli DL, Martin LG, et al. Reporting standards for clinical evaluation of new peripheral arterial revascularization devices. *Journal of Vascular & Interventional Radiology* 1997;8(1)Part 1:137-149.

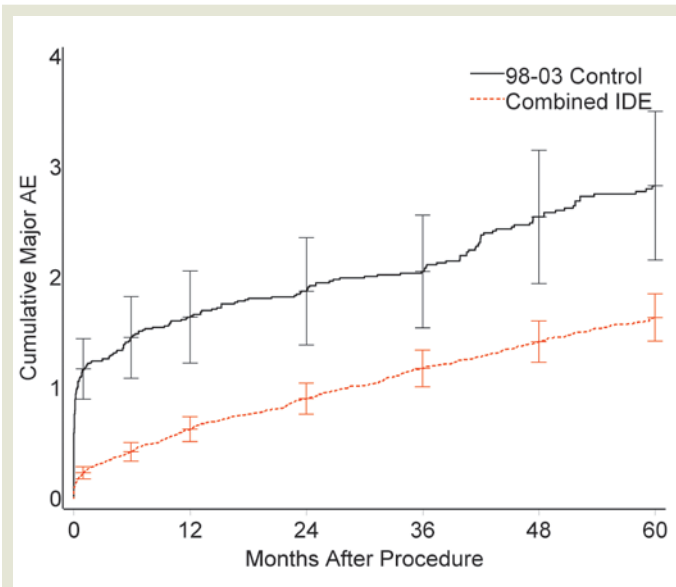
Section I – Clinical Experience

Cumulative Major Adverse Events

Safety of the GORE® EXCLUDER® Device was analyzed by reporting the cumulative number of MAEs per patient throughout the five-year follow-up period. The time-related accumulation of major adverse events for the 98-03 Control group and the combined IDE cohort are shown in **Figure 4** and **Table 6**. This figure represents average cumulative major adverse events a patient experienced through a given time point.

This analysis indicates that patients treated with the GORE® EXCLUDER® Device in the combined IDE cohort experienced fewer MAEs than patients undergoing open surgical repair in the 98-03 Control group. This trend was observed at the one-month interval and continued through five years of follow-up. **These data reaffirm the safety of the GORE® EXCLUDER® Device over open surgical repair for treatment of AAAs.**

Figure 4: Cumulative Major Adverse Events Through Five Years



Shown are 95% confidence limits at each time interval.

**The IDE cohort experienced fewer MAEs than patients undergoing open surgical repair in the 98-03 Control group.**

Table 6: Cumulative Major Adverse Events Through Five Years

	DAY 0	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
<b>98-03 CONTROL</b>								
Patients at Risk	99	97	91	86	79	64	52	35
Cumulative MAE / Patient	0.60	1.17	1.46	1.64	1.88	2.06	2.55	2.83
<b>COMBINED IDE</b>								
Patients at Risk	565	556	545	512	457	402	332	196
Cumulative MAE / Patient	0.08	0.24	0.43	0.63	0.91	1.18	1.42	1.64

## Section I – Clinical Experience

### Major Safety Adverse Events Summary

**Table 7** shows a summary of site-reported major safety AEs. Through five years post-treatment, 58% of patients in the combined IDE cohort and 81% of the 98-03 Control patients experienced a major safety adverse event. The most common types of AEs reported for the combined IDE cohort were cardiac, pulmonary, and other. The most common types of AEs reported for the 98-03 Control group were bleeding, cardiac, bowel, and pulmonary events.

**Table 7: Summary of Major Safety Adverse Events by Visit Interval**

	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS	OVERALL	
<b>98-03 CONTROL</b>									
Patients Available at Start of Interval <sup>a</sup>	99	96	87	81	70	58	46	99	
Patients with Any Major Safety Adverse Event <sup>b</sup>	68 (68.7%)	15 (15.6%)	10 (11.5%)	11 (13.6%)	12 (17.1%)	13 (22.4%)	3 (6.5%)	80 (80.8%)	
Complications	Bleeding	45 (45.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	45 (45.5%)
	Pulmonary	12 (12.1%)	3 (3.1%)	1 (1.1%)	2 (2.5%)	1 (1.4%)	4 (6.9%)	0 (0.0%)	19 (19.2%)
	Cardiac	16 (16.2%)	7 (7.3%)	7 (8.0%)	6 (7.4%)	6 (8.6%)	6 (10.3%)	1 (2.2%)	36 (36.4%)
	Renal Function	3 (3.0%)	0 (0.0%)	1 (1.1%)	0 (0.0%)	1 (1.4%)	3 (5.2%)	0 (0.0%)	7 (7.1%)
	Wound	4 (4.0%)	3 (3.1%)	0 (0.0%)	1 (1.2%)	2 (2.9%)	1 (1.7%)	0 (0.0%)	10 (10.1%)
	Bowel	17 (17.2%)	2 (2.1%)	1 (1.1%)	1 (1.2%)	2 (2.9%)	1 (1.7%)	1 (2.2%)	22 (22.2%)
	Vascular	7 (7.1%)	1 (1.0%)	3 (3.4%)	1 (1.2%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	12 (12.1%)
	Neurologic	3 (3.0%)	3 (3.1%)	2 (2.3%)	0 (0.0%)	0 (0.0%)	2 (3.4%)	0 (0.0%)	9 (9.1%)
	Genitourinary	1 (1.0%)	0 (0.0%)	2 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (3.0%)
	Sepsis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Neoplasm	0 (0.0%)	1 (1.0%)	2 (2.3%)	0 (0.0%)	3 (4.3%)	0 (0.0%)	0 (0.0%)	6 (6.1%)
	Death of Unknown Cause	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Other	1 (1.0%)	2 (2.1%)	2 (2.3%)	2 (2.5%)	2 (2.9%)	1 (1.7%)	0 (0.0%)	9 (9.1%)
<b>COMBINED IDE COHORT</b>									
Patients Available at Start of Interval <sup>a</sup>	565	553	533	483	427	361	291	565	
Patients with Any Major Safety Adverse Event <sup>b</sup>	105 (18.6%)	72 (13.0%)	91 (17.1%)	81 (16.8%)	64 (15.0%)	53 (14.7%)	22 (7.6%)	326 (57.7%)	
Complications	Bleeding	27 (4.8%)	2 (0.4%)	1 (0.2%)	3 (0.6%)	1 (0.2%)	5 (1.4%)	0 (0.0%)	38 (6.7%)
	Pulmonary	13 (2.3%)	13 (2.4%)	17 (3.2%)	10 (2.1%)	24 (5.6%)	10 (2.8%)	7 (2.4%)	81 (14.3%)
	Cardiac	22 (3.9%)	21 (3.8%)	24 (4.5%)	23 (4.8%)	23 (5.4%)	21 (5.8%)	10 (3.4%)	124 (21.9%)
	Renal Function	9 (1.6%)	6 (1.1%)	5 (0.9%)	6 (1.2%)	6 (1.4%)	1 (0.3%)	3 (1.0%)	30 (5.3%)
	Wound	22 (3.9%)	9 (1.6%)	3 (0.6%)	4 (0.8%)	1 (0.2%)	1 (0.3%)	0 (0.0%)	37 (6.5%)
	Bowel	12 (2.1%)	5 (0.9%)	10 (1.9%)	10 (2.1%)	4 (0.9%)	2 (0.6%)	2 (0.7%)	43 (7.6%)
	Vascular	16 (2.8%)	10 (1.8%)	9 (1.7%)	8 (1.7%)	5 (1.2%)	2 (0.6%)	2 (0.7%)	44 (7.8%)
	Neurologic	7 (1.2%)	5 (0.9%)	12 (2.3%)	9 (1.9%)	8 (1.9%)	3 (0.8%)	0 (0.0%)	38 (6.7%)
	Genitourinary	6 (1.1%)	5 (0.9%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	3 (0.8%)	1 (0.3%)	16 (2.8%)
	Sepsis	1 (0.2%)	2 (0.4%)	0 (0.0%)	2 (0.4%)	0 (0.0%)	2 (0.6%)	0 (0.0%)	7 (1.2%)
	Neoplasm	3 (0.5%)	8 (1.4%)	16 (3.0%)	10 (2.1%)	11 (2.6%)	14 (3.9%)	1 (0.3%)	61 (10.8%)
	Death of Unknown Cause	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	0 (0.0%)	1 (0.2%)
	Other	8 (1.4%)	12 (2.2%)	26 (4.9%)	19 (3.9%)	8 (1.9%)	11 (3.0%)	2 (0.7%)	77 (13.6%)

<sup>a</sup> Number of patients with study day of last contact  $\geq$  lower limit of specified time window. This is the denominator for all cells.

<sup>b</sup> Entries represent number of patients with the event (percentage). Time frames for each interval are as follows: 1 Month (0–60 days), 6 Months (61–242 days), 12 Months (243–546 days), 24 Months (547–911 days), 36 Months (912–1275 days), 48 Months (1276–1640 days), 60 Months (1641–2006 days), Overall (0–2006 days).

## Section I – Clinical Experience

**Combined IDE Cohort Reinterventions and Conversions**

**Table 8** summarizes the conversions and reinterventions for patients in the combined IDE cohort. The overall five year conversion incidence for the combined IDE cohort was 3.4% (19 total). The overall five year reintervention rate for the combined IDE cohort was 15.8% (89 total). Most of the reinterventions reported for the combined IDE cohort were post-treatment embolizations of Type II endoleaks.

Of the 19 conversions reported through five years post-treatment, 8 were due to aneurysm enlargement in the absence of endoleak, 3 due to aneurysm enlargement with endoleak, 3 due to access

problems, 1 due to endoleak without aneurysm enlargement, and 1 due to branch vessel occlusion. Other causes of conversion were urinary tract infection at four months post-treatment and infection and aorto-duodenal fistula of the aneurysm sac at 49 months post-treatment.

Only one conversion in the 60-month window was a result of an aneurysm rupture. This non-hemorrhagic rupture was identified when a patient from the 99-04 study was examined for a routine follow-up visit. The rupture did not cause a loss of hemodynamics and the patient was electively and successfully converted to open surgical repair.

**Table 8: Summary of Conversions and Reinterventions for the Combined IDE Cohort Through Five Years**

	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS	OVERALL
Patients Available at Start of Interval <sup>a</sup>	565	553	533	483	427	361	291	565
Conversions	4 (0.7%)	1 (0.2%)	1 (0.2%)	4 (0.8%)	1 (0.2%)	6 (1.7%)	2 (0.7%)	19 (3.4%)
Reinterventions <sup>b</sup>	18 (3.2%)	22 (4.0%)	25 (4.7%)	21 (4.3%)	6 (1.4%)	11 (3.0%)	4 (1.4%)	89 (15.8%)
Reinterventions Excluding Type II Endoleak	16 (2.8%)	8 (1.4%)	6 (1.1%)	10 (2.1%)	3 (0.7%)	10 (2.8%)	3 (1.0%)	49 (8.7%)

<sup>a</sup> Number of patients with study day of last contact  $\geq$  lower limit of specified time window. This is the denominator for all cells.  
<sup>b</sup> Reinterventions excluding conversions. Patients may have had more than one intervention.

Time frames for each interval are as follows: 1 Month (0-60 days), 6 Months (61-242 days), 12 Months (243-546 days), 24 Months (547-911 days), 36 Months (912-1275 days), 48 Months (1276-1640 days), 60 Months (1641-2006 days), Overall (0-2006 days).

## Section I – Clinical Experience

### Combined IDE Cohort Explant

**Table 9** shows the primary cause of explants for the combined IDE cohort. There have been a total of 18 cases of GORE® EXCLUDER® Devices explanted from the combined IDE cohort. Devices from 16 of these cases were available for evaluation of evidence of biologic response and material integrity. The primary cause of explant for Original GORE® EXCLUDER® Devices in the combined IDE clinical cohort was aneurysm enlargement with and without endoleak.

**Table 9: Primary Cause of Explant**

COMBINED IDE COHORT	
REASON FOR EXPLANT	NUMBER OF OCCURRENCES
Implantation Difficulties	1
Rupture	1
Infection	1
Aneurysm Enlargement without Endoleak	7
Aneurysm Enlargement with Endoleak	5
Aortoenteric Fistula	1
<b>TOTAL CASES</b>	<b>16</b>

Two patients in the combined IDE cohort had explants in which the devices were not returned to Gore for explant evaluation.

Two explanted devices from the combined IDE cohort have been identified with device integrity observations as shown in **Table 10**. Components from these two cases had at least one stent-wire fracture. These fractures did not cause perforations in the graft material, were not the cause of any adverse events, nor were they the primary cause of explant. Most (14 /16) explanted devices returned for the combined IDE cohort had no device integrity issues. Device integrity events remain rare with the GORE® EXCLUDER® Device.

**Table 10: Device Integrity Observations**

COMBINED IDE COHORT	
OBSERVATION	NUMBER OF OCCURRENCES (BY CASE)
Fracture	2
ePTFE Abrasion Holes	0
No Device Integrity Issues	14
<b>TOTAL CASES</b>	<b>16</b>

## Section I – Clinical Experience

## Major Device Events

Efficacy of the GORE® EXCLUDER® Device was analyzed by reporting the incidence of major device events throughout the five-year follow-up period (**Table 11**). Site-reported major device events for the combined IDE cohort through five years post-treatment are shown in **Table 11**. The percentage of patients experiencing a major device efficacy event at each follow-up visit was low (1.9 – 5.7%) through five years post-treatment. There was no report of a major deployment failure, material failure, extrusion / erosion, or prosthesis realignment for any patient in the combined IDE cohort.

Endoleaks requiring reintervention were the most common device event that the patients in the combined IDE cohort experienced. An endoleak requiring reintervention was reported in 0.3 – 4.2% of patients during each follow-up interval through five years. Aneurysm increase requiring reintervention for the combined IDE cohort was < 2% at each follow-up visit through five years. Endoleaks and aneurysm enlargement will be discussed in more detail later in this document.

Four patients experienced branch vessel occlusion requiring reintervention at treatment. The first patient experienced a left renal artery occlusion, which was treated with an iliac-to-renal artery bypass. A left hypogastric artery occlusion was reported for the second patient, which was repaired with a thromboendarterectomy. The third patient experienced occlusion of the hypogastric artery, which resulted in persistent buttock pain past 30 days. The patient continued without treatment and

reported slightly improved buttock pain. The aortic cuff occluded the renal arteries for the last patient and this patient was converted to open repair.

Through five years, only four patients experienced prosthesis migration. All were treated and repaired with graft extensions. None of the migrations resulted in clinical sequelae.

Access failure was reported in two cases. In the first case, the device could not be advanced through the left common iliac artery and resulted in an injury to the artery. This patient died from cardiac arrest during an attempt to convert to open surgery. In the second case, access could not be obtained due to the inability to place the right limb contralateral leg in the presence of significant thrombus; the patient recovered and continued in the study after a fem-fem graft was placed.

Two major lumen obstructions were reported for the combined IDE cohort. One patient died six months post-treatment due to an aortic dissection with complete compression of the true lumen and the stent-graft. The second patient experienced a vascular embolism six days post-treatment leading to a graft occlusion. The patient recovered fully after a thrombectomy of the right limb of the graft, placement of bilateral iliac stents, and angioplasty.

There were three major device events that were classified as “other.” The first was an infold of the proximal end of the graft resulting in endoleak within the one-month window. The second was a report that the graft was unstable at the proximal attachment site approximately two years post-treatment; this appeared to be a result of increased angulation and possible

**Table 11: Major Device Events Through Five Years for the Combined IDE Cohort**

	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS	OVERALL
Patients Available at Start of Interval <sup>a</sup>	565	553	533	483	427	361	291	565
Patients with Any Major Efficacy Adverse Event <sup>b</sup>	32 (5.7%)	16 (2.9%)	12 (2.3%)	18 (3.7%)	8 (1.9%)	9 (2.5%)	6 (2.1%)	81 (14.3%)
Branch Vessel Occlusion	4 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (0.7%)
Endoleak	24 (4.2%)	15 (2.7%)	7 (1.3%)	10 (2.1%)	3 (0.7%)	4 (1.1%)	1 (0.3%)	55 (9.7%)
Access Failure	2 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
Lumen Obstruction	1 (0.2%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (0.4%)
Aneurysm Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	1 (0.2%)
Other Device-Related Event	1 (0.2%)	0 (0.0%)	0 (0.0%)	2 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (0.5%)
Prosthesis Migration	1 (0.2%)	0 (0.0%)	2 (0.4%)	0 (0.0%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	4 (0.7%)
Aneurysm Increase with Reintervention	2 (0.4%)	1 (0.2%)	3 (0.6%)	8 (1.7%)	4 (0.9%)	7 (1.9%)	5 (1.7%)	29 (5.1%)

<sup>a</sup> Number of patients with study day of last contact  $\geq$  lower limit of specified time window. This is the denominator for all cells.

<sup>b</sup> Entries represent number of patients with the event (percentage). Time frames for each interval are as follows: 1 Month (0–60 days), 6 Months (61–242 days), 12 Months (243–546 days), 24 Months (547–911 days), 36 Months (912–1275 days), 48 Months (1276–1640 days), 60 Months (1641–2006 days), Overall (0–2006 days).

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growth of the proximal aortic neck. In both of these cases the patients were treated with proximal extender cuffs and recovered. In the third case, retraction of the iliac limb was identified at a 30-month interim visit. This patient recovered after reintervention, extending and relining the limb.

Only one aneurysm rupture was reported for the combined IDE cohort. This non-hemorrhagic rupture was identified when a patient from the 99-04 study was examined for a routine follow-up visit. The rupture did not cause a loss of hemodynamics and the patient was electively and successfully converted to open surgical repair.

### Endoleaks

Site-reported endoleak data on the combined IDE cohort through five years post-treatment are shown in **Table 12**. New endoleaks are those that have a start date in the visit window and ongoing endoleaks are those that were continuing from a previous follow-up window. **During the final visit window (60 months) 83.6% of the patients were free from endoleaks.**

Type II endoleaks accounted for the majority of the endoleaks. Type II endoleaks are a result of patient anatomy and are not indicative of device failure. No Type IV endoleaks were reported for the combined IDE cohort. Overall, the risk of endoleak resulting from implant technique or device integrity (i.e., Type I, III, and IV) is very low.

**Table 12: Summary of Endoleaks for the Combined IDE Cohort by Study Period**

	TREATMENT	1 MONTH	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
<b>Patients Available at Start of Interval</b>	565	562	553	533	483	427	361	291
<b>Patients with Endoleak Evaluation or Ongoing Endoleak</b>	565	538	509	489	425	335	297	244
<b>Patients with One or More Endoleak Adverse Events Ongoing in Window</b>	79 (14.0%)	147 (27.3%)	130 (25.5%)	110 (22.5%)	93 (21.9%)	74 (22.1%)	61 (20.5%)	40 (16.4%)
New	79 (14.0%)	83 (15.4%)	46 (9.0%)	26 (5.3%)	33 (7.8%)	11 (3.3%)	13 (4.4%)	6 (2.5%)
Ongoing	—	77 (14.3%)	90 (17.7%)	91 (18.6%)	72 (16.9%)	65 (19.4%)	51 (17.2%)	35 (14.3%)
<b>Type I</b>	11 (1.9%)	14 (2.6%)	6 (1.2%)	2 (0.4%)	4 (0.9%)	4 (1.2%)	3 (1.0%)	2 (0.8%)
New	11 (1.9%)	5 (0.9%)	1 (0.2%)	2 (0.4%)	2 (0.5%)	1 (0.3%)	0 (0.0%)	1 (0.4%)
Ongoing	—	9 (1.7%)	5 (1.0%)	1 (0.2%)	2 (0.5%)	3 (0.9%)	3 (1.0%)	1 (0.4%)
<b>Type II</b>	66 (11.7%)	123 (22.9%)	106 (20.8%)	99 (20.2%)	85 (20.0%)	65 (19.4%)	50 (16.8%)	30 (12.3%)
New	66 (11.7%)	61 (11.3%)	37 (7.3%)	24 (4.9%)	25 (5.9%)	8 (2.4%)	7 (2.4%)	4 (1.6%)
Ongoing	—	66 (12.3%)	72 (14.1%)	79 (16.2%)	66 (15.5%)	58 (17.3%)	44 (14.8%)	27 (11.1%)
<b>Type III</b>	1 (0.2%)	3 (0.6%)	6 (1.2%)	4 (0.8%)	2 (0.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
New	1 (0.2%)	2 (0.4%)	3 (0.6%)	2 (0.4%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ongoing	—	1 (0.2%)	3 (0.6%)	2 (0.4%)	1 (0.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
<b>Other</b>	3 (0.5%)	8 (1.5%)	6 (1.2%)	4 (0.8%)	0 (0.0%)	1 (0.3%)	3 (1.0%)	2 (0.8%)
New	3 (0.5%)	6 (1.1%)	1 (0.2%)	1 (0.2%)	0 (0.0%)	1 (0.3%)	2 (0.7%)	0 (0.0%)
Ongoing	—	2 (0.4%)	5 (1.0%)	3 (0.6%)	0 (0.0%)	0 (0.0%)	1 (0.3%)	2 (0.8%)
<b>Indeterminate</b>	3 (0.5%)	14 (2.6%)	15 (2.9%)	10 (2.0%)	13 (3.1%)	10 (3.0%)	11 (3.7%)	7 (2.9%)
New	3 (0.5%)	11 (2.0%)	5 (1.0%)	2 (0.4%)	7 (1.6%)	1 (0.3%)	4 (1.3%)	1 (0.4%)
Ongoing	—	3 (0.6%)	11 (2.2%)	8 (1.6%)	7 (1.6%)	9 (2.7%)	8 (2.7%)	6 (2.5%)
<b>Patients with No Endoleak Adverse Events Ongoing in Window</b>	486 (86.0%)	391 (72.7%)	379 (74.5%)	379 (77.5%)	332 (78.1%)	261 (77.9%)	236 (79.5%)	204 (83.6%)

Note: The total number of patients with an endoleak may not be equal to the sum of patients with new and ongoing endoleaks since a patient may be reported as having both a new endoleak and an ongoing endoleak at the same time.

Denominators are the number of patients with endoleak evaluation or ongoing endoleak at each interval.

Time frames for each interval are as follows: Treatment (0–0 days), 1 Month (1–60 days), 6 Months (61–242 days), 12 Months (243–546 days), 24 Months (547–911 days), 36 Months (912–1275 days), 48 Months (1276–1640 days), 60 Months (1641–2006 days).

## Section I – Clinical Experience

**Aneurysm Size Change**

A summary of aneurysm size changes in patients with the GORE® EXCLUDER® Device in the combined IDE cohort through five years post-treatment is shown in **Table 13**. Aneurysm size change was calculated by comparing the maximum aneurysm diameter at each follow-up visit to the baseline (one month).

At the five-year follow-up visit, aneurysm enlargement ( $\geq 5$  mm) was observed in 34.2% (79 / 231) of combined IDE cohort patients.

Only one patient with aneurysm enlargement experienced a rupture. This rupture was non-hemorrhagic in nature and the patient was electively and successfully converted to open surgical repair.

**Table 13: Change in Aneurysm Diameter from Baseline**

	6 MONTHS	1 YEAR	2 YEARS	3 YEARS	4 YEARS	5 YEARS
Patients Available at Start of Interval <sup>a</sup>	553	533	483	427	361	291
Patients with Aneurysm Evaluation <sup>b</sup>	476 (86.1%)	458 (85.9%)	397 (82.2%)	311 (72.8%)	279 (77.3%)	231 (79.4%)
$\geq 5$ mm Aneurysm Size Decrease <sup>c</sup>	66 (13.9%)	100 (21.8%)	100 (25.2%)	79 (25.4%)	65 (23.3%)	53 (22.9%)
No Change in Aneurysm Diameter	401 (84.2%)	335 (73.1%)	251 (63.2%)	174 (55.9%)	134 (48.0%)	99 (42.9%)
$\geq 5$ mm Aneurysm Size Increase <sup>c</sup>	9 (1.9%)	23 (5.0%)	46 (11.6%)	58 (18.6%)	80 (28.7%)	79 (34.2%)
Patients with Aneurysm Increase and an Endoleak	4	13	20	16	22	17
Type I	0	1	1	0	0	1
Type II	3	12	19	15	18	13
Type III	0	0	1	0	0	0
Indeterminate	1	0	2	1	4	3

<sup>a</sup> The number eligible for evaluation is based on the number of patients that enter the beginning of the follow-up interval alive and in the study.

<sup>b</sup> The denominator used to calculate percentages at each interval is based on the number of patients eligible for evaluation.

<sup>c</sup> The denominator used to calculate percentages at each interval is based on the number of patients with aneurysm evaluation at each timepoint.

Time frames for each interval are as follows: 6 Months (61–242 days), 12 Months (243–546 days), 24 Months (547–911 days), 36 Months (912–1275 days), 48 Months (1276–1640 days), 60 Months (1641–2006 days).

## Section I – Clinical Experience

### Low Permeability Post-Approval Clinical Study: 04-04 Clinical Study

Gore has completed a post-approval clinical study (04-04) to assess aneurysm morphology changes over time in patients treated with the Low Permeability GORE® EXCLUDER® Device. Follow-up is complete and a final study report was approved by the FDA. Patient visit compliance for the Test group was 96% at one month, 85% at six months, 95% at one year, and 98% at two years. Imaging compliance for these patients was 94% at one month, 82% at six months, 94% at one year, and 93% at two years. Seven patients in the 04-04 study died. Causes of death included myocardial infarction (2), lung cancer, esophageal cancer, pneumonia (2), and abdominal sepsis / bowel perforation.

One explant was performed four months post-treatment on an 04-04 Test patient as a result of an infected device in the presence of a mycotic aneurysm; this patient was successfully converted to open surgical repair. Explant analysis of the device showed no device integrity issues.

Patients in the 04-04 study were compared to 120 randomly selected patients treated with the Original GORE® EXCLUDER® Device in the 98-03 clinical study. Analyses of the pre-treatment

characteristics for both groups show a balanced population. The incidence of major device events, including reintervention, migration and patency through one-year post-treatment were similar for both groups. However, the incidence of minor Type II endoleaks (endoleaks requiring no reintervention) is higher for the Test group. Gore believes that this difference is a result of an improvement in imaging quality over time and not a clinically significant finding.

**Final data on aneurysm diameter and volume demonstrate that aneurysm enlargement is seen less in patients treated with the Low Permeability GORE® EXCLUDER® Device when compared to those treated with the Original GORE® EXCLUDER® Device (Control group).** Table 14 shows an overview of preliminary aneurysm diameter data, while aneurysm volume change data is presented in Table 15. Both of these measures show similar trends. Of the patients that showed aneurysm volume increase  $\geq 5\%$  at the two-year follow-up visit, 53% (25 / 47) of the Control group and 0% (0 / 17) of the Test group had enlargement without a reported Type II endoleak during the 04-04 study. Type II endoleaks are a result of patient anatomy and are not indicative of device failure.

**Table 14: Summary of the Proportion of Patients with Aneurysm Diameter Increase  $\geq 5$  mm by Study Visit**

	6 MONTHS		1 YEAR		2 YEARS	
	TEST	CONTROL	TEST	CONTROL	TEST	CONTROL
Number of Patients Enrolled	139	120	139	120	139	120
Patients with Available Data <sup>a</sup>	103	88	114	94	104	100
$\geq 5$ mm Decrease	25 (24.3%)	11 (12.5%)	45 (39.5%)	15 (16.0%)	51 (49.0%)	21 (21.0%)
No Change	76 (73.8%)	75 (85.2%)	69 (60.5%)	76 (80.9%)	50 (48.1%)	60 (60.0%)
$\geq 5$ mm Increase	2 (1.9%)	2 (2.3%)	0 (0.0%)	3 (3.2%)	3 (2.9%)	19 (19.0%)

<sup>a</sup> Patients are considered to be available for evaluation if they had both a baseline (one month) and post-baseline measurement.

**Table 15: Summary of the Proportion of Patients with Aneurysm Volume Change  $\geq 5\%$  by Study Visit**

	6 MONTHS		1 YEAR		2 YEARS	
	TEST	CONTROL	TEST	CONTROL	TEST	CONTROL
Number of Patients Enrolled	139	120	139	120	139	120
Patients with Available Data <sup>a</sup>	102	86	112	92	104	101
$\geq 5\%$ Decrease <sup>b</sup>	67 (65.7%)	34 (39.5%)	77 (68.8%)	35 (38.0%)	72 (69.2%)	31 (30.7%)
No Change <sup>b</sup>	29 (28.4%)	32 (37.2%)	26 (23.2%)	26 (28.3%)	15 (14.4%)	23 (22.8%)
$\geq 5\%$ Increase <sup>b</sup>	6 (5.9%)	20 (23.3%)	9 (8.0%)	31 (33.7%)	17 (16.3%)	47 (46.5%)

<sup>a</sup> Patients are considered to be available for evaluation if they had both a baseline (one month) and post-baseline measurement.

<sup>b</sup> Overall volume increase is computed as follows: if either distal renal to aortic bifurcation or right hypogastric to aortic bifurcation volume measurement increases  $\geq 5\%$  then the patient is considered an increaser. If either measure decreases  $\geq 5\%$  then the patient is considered a decreaser. Other non-missing combinations are considered No Change.

## Section II – Worldwide Commercial Experience

**Summary of Adverse Events**

From September 1997 through May 15, 2010, more than 112,000 GORE® EXCLUDER® Devices have been distributed. This includes more than 16,000 Original and Modified GORE® EXCLUDER® Devices and more than 96,000 Low Permeability GORE® EXCLUDER® Devices. The data presented in **Table 16** summarize adverse events from worldwide commercial experience.

**Aneurysm-Related Death**

A total of 135 aneurysm-related deaths have been reported worldwide in patients treated with the GORE® EXCLUDER® Device. Causes of aneurysm-related deaths are shown in **Table 17**.

The primary cause of aneurysm-related death is procedure-related complications. Procedure-related complications include 18 non-aneurysm aortic ruptures due to ballooning in the proximal aortic neck and 12 non-aneurysm iliac ruptures attributed to sheath insertion and withdrawal. Other less frequent procedure-related complications include embolic events, cardiac events, respiratory events, paralysis, reaction to contrast, aortic dissection, aortic perforation, and ischemic events.

**Table 16: Summary of GORE® EXCLUDER® Device Worldwide Performance**

Aneurysm-Related Death <sup>a</sup>	135
Post-Procedure Rupture	56
Aneurysm Enlargement <sup>b</sup>	342
Conversion	358
Migration <sup>c</sup>	69
Device Occlusion	63
Infection	70
Infolding	76

<sup>a</sup> Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion<sup>1</sup>.

<sup>b</sup> Aneurysm enlargement in this table is defined as any reported enlarging aneurysm with and without endoleak.

<sup>c</sup> During commercial use, migration is defined as any report of post-procedure device movement.

**Table 17: Aneurysm-Related Death<sup>a</sup>**

<b>Procedure-Related</b>	<b>64</b>
Non-Aneurysm Aortic Ruptures	18
Non-Aneurysm Iliac Ruptures	12
Other Complications	34
<b>Comorbidity<sup>b</sup></b>	<b>43</b>
<b>Aneurysm Rupture</b>	<b>12</b>
Endoleak	10
Indeterminate	2
<b>Occlusion</b>	<b>1</b>
<b>Infection</b>	<b>7</b>
<b>Indeterminate</b>	<b>8</b>
<b>TOTAL</b>	<b>135</b>

<sup>a</sup> Aneurysm-related deaths are defined as any deaths within 30 days or due to aneurysm rupture, a primary or secondary procedure, or surgical conversion<sup>1</sup>.

<sup>b</sup> Aneurysm-related death attributed to comorbidity is defined here as death that occurs within 30 days of a primary or secondary procedure; such death cannot be linked directly to the use of the device, but may be related to complications arising from the procedure.

## Section II – Worldwide Commercial Experience

### Post-Procedure Aneurysm Ruptures

There have been 56 commercial post-procedure aneurysm ruptures reported among patients treated with the GORE® EXCLUDER® Device since 1997. Post-procedure aneurysm rupture causes are shown in **Table 18**.

The primary cause of aneurysm rupture in patients treated with the GORE® EXCLUDER® Device is aneurysm enlargement with endoleak. Seven ruptures were caused by Type III endoleaks that were attributed to component disconnections following treatment. It is not known what specifically contributed to these disconnections, however, potential contributing factors may have included inadequate component overlap as well as placement in

**Table 18: Post-Procedure Aneurysm Rupture**

<b>Aneurysm Enlargement with Endoleak</b>	<b>30</b>
Type I	13
Type II	6
Type III	7
Unspecified	4
<b>Aneurysm Enlargement without Endoleak</b>	<b>5</b>
<b>Migration</b>	<b>4</b>
<b>Other<sup>a</sup></b>	<b>9</b>
<b>Indeterminate Cause</b>	<b>8</b>
<b>TOTAL</b>	<b>56</b>

<sup>a</sup> Other less frequent events that have contributed to post-procedure aneurysm rupture include post-procedure conversion and the disease state of the patient's aorta.

severely angulated anatomy. There were also reports of 13 Type I endoleaks, 6 Type II endoleaks, and 4 unspecified endoleaks that contributed to aneurysm ruptures. It is necessary to monitor patients presenting with endoleak, regardless of endoleak type. Five aneurysm ruptures were due to aneurysm enlargement in the absence of endoleak. These ruptures did not occur in patients with the Low Permeability GORE® EXCLUDER® Device. The ruptures were non-hemorrhagic and did not cause a loss of hemodynamics.

### Aneurysm Enlargement

Aneurysm enlargement, with and without endoleak, has been reported in a total of 342 patients treated with the GORE® EXCLUDER® Device worldwide, as shown in **Table 19**.

The Original GORE® EXCLUDER® Device was implanted in 193 of these patients. Of these patients, 65 reports were attributed to aneurysm enlargement with endoleak, while 119 reports were attributed to aneurysm enlargement without endoleak.

One hundred forty reports of aneurysm enlargement with the Low Permeability GORE® EXCLUDER® Device have been associated with an endoleak. There was not sufficient information to identify the exact cause for aneurysm enlargement in the indeterminate category.

**The stark contrast between enlargement without endoleak reports in the Original and Low Permeability GORE® EXCLUDER® Devices (119 versus 0) indicates that Gore's Low Permeability modification to the GORE® EXCLUDER® Device has significantly reduced the issue of sac enlargement via endotension.**

**Table 19: Aneurysm Enlargement**

	ORIGINAL GORE® EXCLUDER® DEVICE ( > 16,000 DEVICES )	LOW PERMEABILITY GORE® EXCLUDER® DEVICE ( > 96,000 DEVICES )	TOTAL
With Endoleak	65	140	205
Without Endoleak	119	0	119
Indeterminate	9	9	18
<b>TOTAL</b>	<b>193</b>	<b>149</b>	<b>342</b>

## Section II – Worldwide Commercial Experience

**Conversion**

Conversion to open surgical repair has been reported in 358 patients treated with the GORE® EXCLUDER® Device worldwide. The most common contributing factors to these reported conversions are shown in **Table 20**.

The primary causes for conversion were positioning difficulties related to unintentional proximal movement during deployment of the Trunk-Ipsilateral component and misidentification of component radiopaque markers. The second most common cause of implantation difficulties were those encountered during cannulation of the contralateral gate. Implantation difficulties can be minimized by careful pre-case planning and appropriate patient selection as indicated in the *Instructions for Use* (IFU).

Most of the 23 conversions attributed to non-aneurysm aortic ruptures occurred during ballooning of the proximal aortic neck during implantation of the Trunk-Ipsilateral Leg component. The 11 non-aneurysm iliac ruptures reported were attributed to sheath insertion and withdrawal.

**Migration**

During commercial use of the GORE® EXCLUDER® Device, migration is defined as any report of post-procedure device movement. There have been 69 commercial post-procedure migrations reported to Gore (**Table 16**). These migrations include reports of 50 migrations of the Trunk-Ipsilateral component, ten migrations of the contralateral leg and nine migrations of extender components. It is known that pre-case planning which includes appropriate patient anatomical measurements and device selection within the *Indications for Use* will minimize migration events. The low number of migrations reported during worldwide use of the GORE® EXCLUDER® Device reflects the low rate of migration experience in the GORE® EXCLUDER® Device clinical studies.

**Device Occlusion**

There have been 63 occlusions reported in patients treated with the GORE® EXCLUDER® Device worldwide. In the majority of these reports, the occlusions occurred shortly after the initial treatment. In many of these cases, the patient had narrow iliac arteries associated with calcification and thrombus. There were two reported incidents of a kink associated with the GORE® EXCLUDER® Device. The low number of occlusions reported during worldwide use of the GORE® EXCLUDER® Device reflects the low occlusion and high patency rates observed during the GORE® EXCLUDER® Device clinical studies.

**Table 20: Conversion**

<b>Aneurysm Rupture Post-Procedure</b>	<b>23</b>
<b>Aneurysm Enlargement with Endoleak</b>	<b>49</b>
<b>Aneurysm Enlargement without Endoleak</b>	<b>24</b>
<b>Endoleak</b>	<b>57</b>
<b>Implantation Difficulties<sup>a</sup></b>	<b>121</b>
Non-Aneurysm Aortic Rupture	23
Non-Aneurysm Iliac Rupture	11
Access Complications	11
Positioning Complications	40
Deployment Complications	7
Cannulation Difficulties	29
<b>Aortoenteric Fistula</b>	<b>5</b>
<b>Infection</b>	<b>40</b>
<b>Unsuitable Anatomy</b>	<b>14</b>
<b>Other</b>	<b>25</b>
<b>TOTAL</b>	<b>358</b>

<sup>a</sup> Any problems associated with implantation of any component during the procedure.

**Infection**

There have been 70 reported infections in patients treated with the GORE® EXCLUDER® Device worldwide. Many of these devices became infected due to systemic infection. Seven devices were infected due to aortoenteric fistula. Some of the infections were associated with secondary procedures, such as mastectomy, gallbladder removal, and bladder cancer treatment. In many cases, the exact cause of infection was unclear. The low number of infections reported during worldwide use of the GORE® EXCLUDER® Device reflects the low infection rates observed in the GORE® EXCLUDER® Device clinical studies.

**Device Infolding**

There have been 76 reported infolding events of the GORE® EXCLUDER® Device worldwide. Of these events, 55 occurred in the ipsilateral leg of the devices, 14 were cases of proximal trunk infolding and 9 cases were infolding of the contralateral leg. Two of the events had both a proximal trunk and a contralateral leg infolding event. Seven devices had reported occlusions, all of them ipsilateral legs. In every event where information was provided, the devices were excessively oversized. Typically, the infolding was resolved by ballooning or placing an additional stent or stent-graft. Surgical intervention was required in five cases where the devices became occluded. Device infolding can be avoided through proper pre-procedure case planning and device selection, and ballooning the device post-implantation. According to the GORE® EXCLUDER® Device IFU, the device should be oversized 10 – 21% based on aortic inner diameter and 7 – 25% based on iliac inner diameter.

## Section III – Explant Analysis and Device Durability

### Explant Analysis

There have been a total of 96 cases of GORE® EXCLUDER® Devices explanted and returned to Gore from worldwide commercial experience (Table 21). Gore has collected these devices for evaluation of evidence of biologic response, material integrity, and overall device durability. These 96 cases include a total of 237 GORE® EXCLUDER® Device components.

### Primary Cause of Explant

The primary causes of explant for Original GORE® EXCLUDER® Devices from worldwide commercial experience were aneurysm enlargement with or without endoleak. **There have been no Low Permeability GORE® EXCLUDER® Devices explanted due to aneurysm enlargement without endoleak.** The primary causes of explant for the Low Permeability devices are unresolved endoleaks, implantation difficulties and ruptures.

**Table 21: Primary Cause of Explant**

REASON FOR EXPLANT	NUMBER OF OCCURRENCES		TOTAL
	ORIGINAL GORE® EXCLUDER® DEVICE (> 16,000 DEVICES)	LOW PERMEABILITY GORE® EXCLUDER® DEVICE (> 96,000 DEVICES)	
Implantation Difficulties	1	8	9
Rupture	4	9	13
Aneurysm Enlargement without Endoleak	17	0	17
Aneurysm Enlargement with Endoleak	11	17	28
Endoleak	2	8	10
Migration	0	3	3
Infection	0	5	5
Aortoenteric Fistula	1	2	3
Occlusion	1	0	1
Incidental Autopsy	1	0	1
Other	0	6	6
<b>TOTAL CASES</b>	<b>38</b>	<b>58</b>	<b>96</b>

## Section III – Explant Analysis and Device Durability

**Explant Analysis and Device Durability –****Device Integrity Observations**

Fourteen GORE® EXCLUDER® Devices explanted from worldwide commercial experience have been identified with device integrity observations as shown in **Table 22**.

Nine components had at least one stent-wire fracture. These fractures did not cause any perforations in the graft material, were not the cause of any patient adverse events and were not the primary cause of explant.

Five devices have been returned to Gore with a graft material hole due to abrasion. Three of these devices were the Original

GORE® EXCLUDER® Device and two were the Low Permeability GORE® EXCLUDER® Device. The holes on each of the devices were microscopic abrasion holes located under stent apices approximately two to five years post-treatment. It is unknown what caused these abrasion holes, however, they caused no patient adverse events and were not the cause of explant.

Most (82 / 96) explanted devices had no device integrity issues.

**The device integrity events identified during explant analysis did not cause adverse events and were not the cause of explant.**

**Table 22: Device Integrity Observations During Explant Analysis**

OBSERVATION	NUMBER OF OCCURRENCES		TOTAL
	ORIGINAL GORE® EXCLUDER® DEVICE	LOW PERMEABILITY GORE® EXCLUDER® DEVICE	
Fracture	8	1	9
ePTFE Abrasion Holes	3	2	5
No Device Integrity Issues	27	55	82
<b>TOTAL CASES</b>	<b>38</b>	<b>58</b>	<b>96</b>

## Section IV – Summary and Conclusions

### Overview

There have been more than 112,000 devices distributed worldwide, beginning in September 1997 through May 15, 2010. This includes more than 16,000 Original and Modified GORE® EXCLUDER® Devices and more than 96,000 Low Permeability GORE® EXCLUDER® Devices. Five year prospective, controlled clinical data and more than 13 years of worldwide commercial experience continue to support the safety and efficacy of treatment of abdominal aortic aneurysms with the GORE® EXCLUDER® Device.

### Summary of Clinical Experience

The clinical data presented in this report demonstrate the safety and efficacy of the GORE® EXCLUDER® Device when used to treat patients diagnosed with infrarenal AAAs. At five years, freedom from major adverse events was 39% for the patients treated with the GORE® EXCLUDER® Device as part of the combined IDE cohort as compared to 15% for the 98-03 Control patients.

The following is an overall summary of the Adverse Events data for the combined IDE cohort:

- 0.2% Post-Procedure Ruptures
- 3.4% Surgical Conversions
- 1.8% Aneurysm-Related Deaths
- 0.7% Post-Procedure Migration
- 5.1% Aneurysm Enlargement with Reintervention

Most endoleaks reported were Type II. Endoleaks requiring reintervention were reported in only 1 – 4% of patients during each follow-up interval through five years.

The observations associated with aneurysm enlargement in the 98-03 Phase II Clinical Study caused Gore to launch a design enhancement to the Original GORE® EXCLUDER® Device in June 2004. The modifications incorporated a low permeability interior layer while maintaining the same luminal and abluminal stent-graft surfaces. Gore has conducted a post-approval clinical study to evaluate aneurysm morphology with the Low Permeability GORE® EXCLUDER® Device. Final data demonstrate a lower incidence of aneurysm enlargement in patients treated with the Low Permeability GORE® EXCLUDER® Device when compared to patients treated with the Original GORE® EXCLUDER® Device.

The modifications made in the Low Permeability GORE® EXCLUDER® Device demonstrate Gore's commitment to improving patient outcomes in the treatment of AAA disease.

### Summary of Worldwide Commercial Experience

From the reported worldwide commercial experience through May 15, 2010, the following adverse events have been reported to Gore:

- 135 Aneurysm-Related Deaths
- 56 Post-Procedure Ruptures
- 342 Aneurysm Enlargement
- 358 Surgical Conversions
- 69 Post-Procedure Migrations
- 63 Device Occlusions
- 70 Infections
- 76 Infolding Events
- 9 Stent Fractures

### Conclusions

The combined IDE cohort represents the largest prospective, controlled clinical trial data set available for the GORE® EXCLUDER® Device. Worldwide commercial adverse events support the low adverse events identified in the GORE® EXCLUDER® Device clinical trial data. In addition, the 04-04 post-approval clinical study and peer-reviewed publications provide supporting evidence for improved performance with the Low Permeability GORE® EXCLUDER® Device over the Original GORE® EXCLUDER® Device in treatment of AAA disease. The GORE® EXCLUDER® Device continues to show acceptable durability. The GORE® EXCLUDER® Device remains a safe and effective device for the treatment of AAA disease.

## Section V – Patient Selection and Follow-Up

Regular follow-up of all patients treated with this device is required. As stated in the IFU, patients with specific clinical findings such as endoleak and / or aneurysm enlargement should receive enhanced follow-up. Physicians should tailor patient follow-up to the needs and circumstances of each individual patient.

As outlined in the IFU, critical factors for successful clinical outcomes include:

- Appropriate patient selection, including:
  - adequate iliac / femoral access
  - infrarenal aortic neck treatment diameter range of 19 – 29 mm and a minimum neck length of 15 mm
  - proximal aortic neck angulation  $\leq 60^\circ$
  - iliac artery treatment diameter range of 8 – 18.5 mm and iliac distal vessel seal zone length of at least 10 mm
- Device selection in accordance with the IFU
- Device deployment in accordance with the IFU
- Appropriate and timely patient follow-up

### Adverse Event Reporting

Any adverse event involving the GORE® EXCLUDER® Device should be reported to Gore immediately. To report an event in the US, call 800.437.8181. Outside the US, contact your local Gore technical representative.



### W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)    800.437.8181 (United States)  
00800.6334.4673 (Europe)    928.779.2771 (United States)

[goremical.com](http://goremical.com)

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### INDICATIONS FOR USE IN THE US

The GORE® EXCLUDER® Device is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: adequate iliac / femoral access; infrarenal aortic neck treatment diameter range of 19 – 29 mm and a minimum aortic neck length of 15 mm; proximal aortic neck angulation  $\leq 60^\circ$ ; iliac artery treatment diameter range of 8 – 18.5 mm and iliac distal vessel seal zone length of at least 10 mm. The GORE® EXCLUDER® Extender Endoprostheses (Aortic and Iliac) are intended to be used after deployment of the GORE® EXCLUDER® Device. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired.

### CONTRAINDICATIONS

The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials; Patients with a systemic infection who may be at increased risk of endovascular graft infection.

### WARNINGS AND PRECAUTIONS

The GORE® EXCLUDER® Device is intended to exclude the aneurysm from the blood circulation in those patients diagnosed with infrarenal AAA disease. The long-term performance of stent grafts has not been established. All patients should be advised that this treatment modality requires long-term, regular follow-up to assess patients' health status and stent-graft performance. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should receive enhanced follow-up. There was one incident of aneurysm rupture in all phases of the IDE cohort (1 / 594 or 0.17%). Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms and / or endoleak. An increase in aneurysm size and / or persistent endoleak may lead to aneurysm rupture.

The GORE® EXCLUDER® Device should only be used by physicians experienced in vascular interventional techniques, and who have successfully completed the physician training program. The GORE® EXCLUDER® Device is not recommended in patients unable to undergo, or who will not be compliant with the necessary pre and post-operative imaging and follow-up described in the IFU (refer to the Imaging Guidelines and Post-operative Follow-up section). Always have a vascular surgery team available during implantation or re-intervention procedures in the event that conversion to open surgical repair is necessary.

### PATIENT SELECTION, TREATMENT AND FOLLOW-UP

Refer to the IFU for additional information on Patient Selection. Treatment and Follow-Up. Ilio-femoral access vessel and morphology (minimal thrombus, calcium and / or tortuosity) should be compatible with vascular access techniques and accessories of the delivery profile of an 18 Fr (6.8 mm) and 12 Fr (4.7 mm) vascular introducer sheath. Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation, short proximal aortic neck and significant thrombus and / or calcium at the arterial implantation sites, specifically the proximal aortic neck and distal iliac artery interface. The US clinical studies quantify significant thrombus as thrombus = 2 mm in thickness and / or = 25% or the vessel circumference in the intended seal zone of the aortic neck. Irregular calcium and / or plaque may compromise the fixation and sealing of the implantation sites. The GORE® EXCLUDER® Device is not recommended in patients who cannot tolerate contrast agents necessary for inter-operative and post-operative imaging follow-up.

### POTENTIAL DEVICE OR PROCEDURE RELATED ADVERSE EVENTS

Adverse events that may occur and / or require intervention 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; edema; embolization (micro and macro) with transient or permanent ischemia; endoleak; endoprosthesis: improper component placement; incomplete component deployment; 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 conversion; wound (e.g., infection, dehiscence); vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture, death).