# SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

## I. GENERAL INFORMATION

Device Generic Name: Stent, Abdominal Aneurysm

Device Trade Name: GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC)

Device Procode: MIH

Applicant's Name and Address: W. L. Gore & Associates, Inc.
32360 N. North Valley Parkway
Phoenix, AZ 85085

Date(s) of Panel Recommendation: None

Premarket Approval Application (PMA) Number: P200030/S014

Date of FDA Notice of Approval: April 5, 2024

The GORE EXCLUDER Conformable AAA Endoprosthesis original PMA (P200030) was approved on December 22, 2020 for treatment of infrarenal abdominal aortic aneurysm disease in patients with appropriate anatomy. The approved indications for use for the original PMA included treatment of patients with proximal aortic neck angulation $\leq 60°$ and minimum aortic neck length of 15 mm. The Summary of Safety and Effectiveness Data (SSED) to support the original approval is available on the CDRH website and is incorporated by reference here. The current supplement was submitted to revise the indications for use for the device to include anatomies with proximal aortic neck angulation of $\leq 90°$ and a minimum aortic neck length of $\geq$ 10 mm.

## II. INDICATIONS FOR USE

The GORE EXCLUDER Conformable AAA Endoprosthesis 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 16–32 mm and a minimum aortic neck length of $\geq$ 10 mm
- Proximal aortic neck angulation is $\leq 90^{\circ}$
- Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm.

The Gore EXCLUDER Iliac Branch Endoprosthesis may be used in conjunction with the Gore EXCLUDER Conformable AAA Endoprosthesis. For more information reference the Gore EXCLUDER Iliac Branch Endoprosthesis Instructions for Use.

## III. CONTRAINDICATIONS

The GORE EXCLUDER Conformable AAA Endoprosthesis is contraindicated in:

- Patients with known sensitivities or allergies to the device materials [expanded polytetrafluoroethylene (ePTFE), fluorinated ethylene propylene (FEP), nitinol, and gold].
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.

## IV. WARNINGS AND PRECAUTIONS

The warnings and precautions can be found in the GORE EXCLUDER Conformable AAA Endoprosthesis labeling.

## V. DEVICE DESCRIPTION

The GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC Device) provides endovascular treatment of infrarenal abdominal aortic aneurysms (AAA). The EXCC Device design consists of incorporating modifications to the current GORE EXCLUDER Trunk-Ipsilateral Leg components, Aortic Extender components, and their associated delivery systems. The EXCC Device consists of two modular components, which are the Trunk-Ipsilateral Leg Component (EXCC Trunk-Ipsi) and the Aortic Extender Component (EXCC AE) as shown in **Figure 1**. The EXCC Trunk-Ipsilateral Leg Component is designed to be used with GORE EXCLUDER Contralateral Leg Components and Iliac Extender Components, which provide additional extension and seal into the common iliac arteries (**Figure 2**).

### Stent-graft

The GORE® EXCLUDER® Conformable AAA Endoprosthesis is a multi-component system consisting of a Trunk-Ipsilateral Leg Endoprosthesis (**Figure 1** and **Figure 2**), a Contralateral Leg Endoprosthesis (**Figure 2**), an Aortic Extender Endoprosthesis for proximal extension (**Figure 1**), and an Iliac Extender Endoprosthesis for distal extension. The graft material for each component is expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) that is supported by nitinol (nickel titanium alloy) wire along its external surface. Nitinol anchors and an ePTFE / FEP sealing cuff are located at the leading (proximal) end of the trunk and a sealing cuff is located at the leading (proximal) end of the Aortic Extender. All components have gold radiopaque markers for visualization. An ePTFE / FEP sleeve is used to constrain the endoprostheses on the delivery catheter (**Figure 3**).

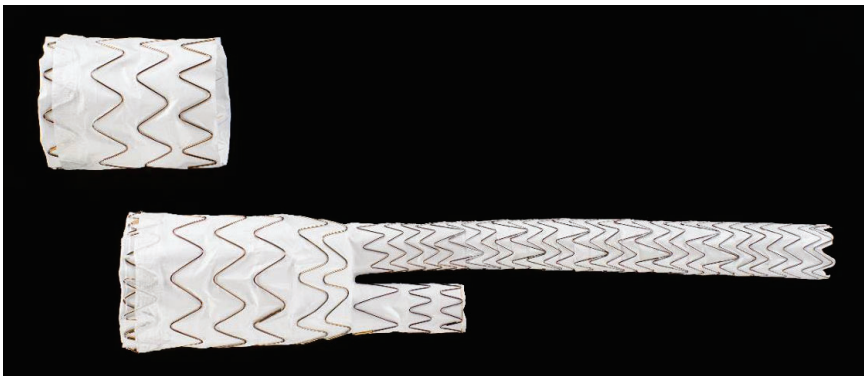

**Figure 1. GORE EXCLUDER Conformable AAA Trunk-Ipsilateral Leg Endoprosthesis (Bottom) and Aortic Extender Endoprosthesis (Top)**

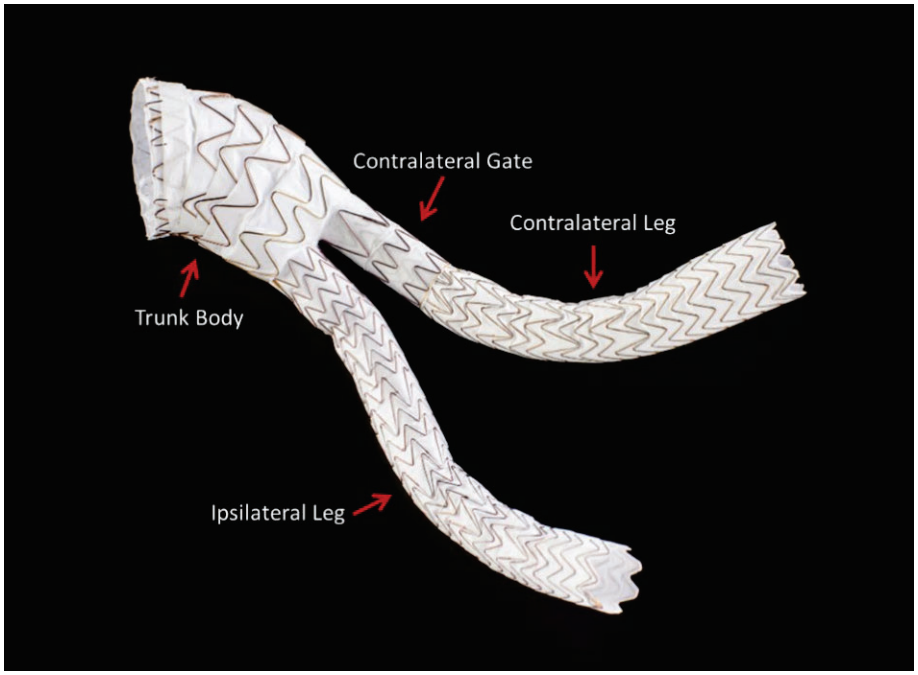


**Figure 2. GORE EXCLUDER Conformable AAA Trunk-Ipsilateral Leg Endoprosthesis with GORE EXCLUDER Contralateral Leg Endoprosthesis within Contralateral Gate**

**Delivery System**

The EXCC Trunk-Ipsilateral delivery system is similar to the GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery System in that it has a corresponding white handle with nested knobs for device deployment (**Figure 3**). The sewn sleeve incorporates the same sewn sleeve / deployment line mechanism as the GORE C3 Delivery System. The EXCC Trunk-Ipsilateral delivery system includes the constraining/unconstraining mechanism for device repositioning, which is part of the GORE C3 Delivery System. In addition, the EXCC Trunk-Ipsi handle has an Angulation Control Knob to aid in angulating the device on catheter, which is an optional device feature (**Figure 3**). The

catheter working length is 69 cm and the profiles are 15 Fr, 16 Fr and 18 Fr. Refer to the IFU for additional information.

Unique features to the EXCC delivery system are:

- Catheter angulation by rotating a gray knob on the delivery catheter handle for device positioning and deployment accuracy (optional feature)
- Secondary sleeve over the trunk body which constrains it to ~70% of its full diameter for improved device repositioning
- Longer and flexible leading tip to enhance trackability and deliverability in tortuous anatomy

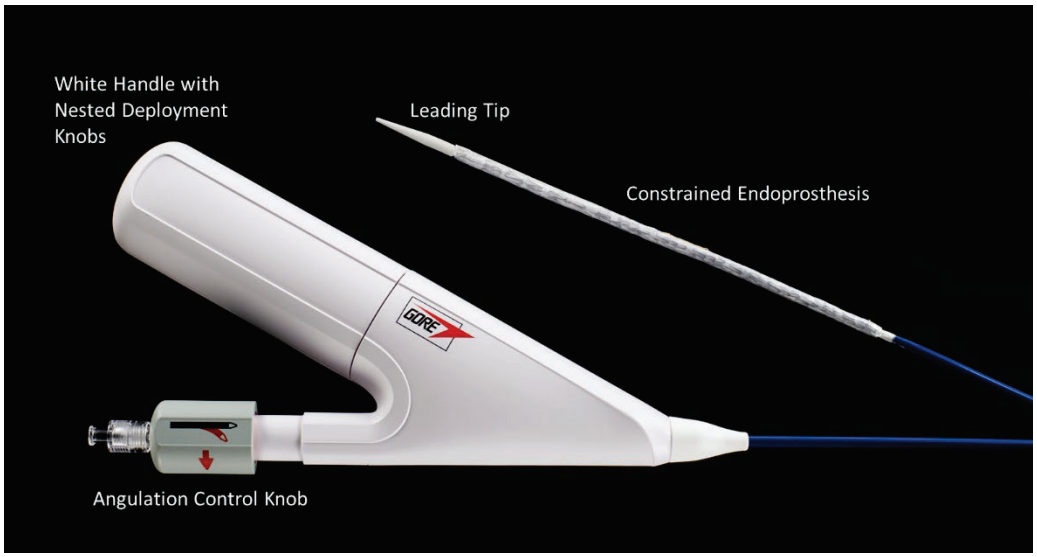


**Figure 3. GORE EXCLUDER Conformable AAA Trunk-Ipsilateral Leg Endoprosthesis Delivery System Handle and Constrained Endoprosthesis on Delivery Catheter**

**Product Size Availability**

**Table 1** summarizes the device sizes and delivery system compatibility.

**Table 1. GORE EXCLUDER Conformable AAA Endoprosthesis Trunk-Ipsilateral Leg and Aortic Extenders Sizing Summary**

| Part Number Trunk-Ipsilateral | Proximal Diameter | Overall Length | Ipsilateral Leg Diameter | Profile |
|---|---|---|---|---|
| CXT201212 | 20 mm | 12 cm | 12 mm | 15 Fr |
| CXT201214 | 20 mm | 14 cm | 12 mm | 15 Fr |
| CXT201216 | 20 mm | 16 cm | 12 mm | 15 Fr |
| CXT201412 | 20 mm | 12 cm | 14.5 mm | 15 Fr |
| CXT201414 | 20 mm | 14 cm | 14.5 mm | 15 Fr |
| CXT201416 | 20 mm | 16 cm | 14.5 mm | 15 Fr |
| CXT231212 | 23 mm | 12 cm | 12 mm | 15 Fr |

| Part Number Trunk-Ipsilateral | Proximal Diameter | Overall Length | Ipsilateral Leg Diameter | Profile |
|---|---|---|---|---|
| CXT231214 | 23 mm | 14 cm | 12 mm | 15 Fr |
| CXT231216 | 23 mm | 16 cm | 12 mm | 15 Fr |
| CXT231218 | 23 mm | 18 cm | 12 mm | 15 Fr |
| CXT231220 | 23 mm | 20 cm | 12 mm | 15 Fr |
| CXT231412 | 23 mm | 12 cm | 14.5 mm | 15 Fr |
| CXT231414 | 23 mm | 14 cm | 14.5 mm | 15 Fr |
| CXT231416 | 23 mm | 16 cm | 14.5 mm | 15 Fr |
| CXT231418 | 23 mm | 18 cm | 14.5 mm | 15 Fr |
| CXT231420 | 23 mm | 20 cm | 14.5 mm | 15 Fr |
| CXT261212 | 26 mm | 12 cm | 12 mm | 16 Fr |
| CXT261214 | 26 mm | 14 cm | 12 mm | 16 Fr |
| CXT261216 | 26 mm | 16 cm | 12 mm | 16 Fr |
| CXT261218 | 26 mm | 18 cm | 12 mm | 16 Fr |
| CXT261220 | 26 mm | 20 cm | 12 mm | 16 Fr |
| CXT261412 | 26 mm | 12 cm | 14.5 mm | 16 Fr |
| CXT261414 | 26 mm | 14 cm | 14.5 mm | 16 Fr |
| CXT261416 | 26 mm | 16 cm | 14.5 mm | 16 Fr |
| CXT261418 | 26 mm | 18 cm | 14.5 mm | 16 Fr |
| CXT261420 | 26 mm | 20 cm | 14.5 mm | 16 Fr |
| CXT281212 | 28.5 mm | 12 cm | 12 mm | 16 Fr |
| CXT281214 | 28.5 mm | 14 cm | 12 mm | 16 Fr |
| CXT281216 | 28.5 mm | 16 cm | 12 mm | 16 Fr |
| CXT281218 | 28.5 mm | 18 cm | 12 mm | 16 Fr |
| CXT281220 | 28.5 mm | 20 cm | 12 mm | 16 Fr |
| CXT281412 | 28.5 mm | 12 cm | 14.5 mm | 16 Fr |
| CXT281414 | 28.5 mm | 14 cm | 14.5 mm | 16 Fr |
| CXT281416 | 28.5 mm | 16 cm | 14.5 mm | 16 Fr |
| CXT281418 | 28.5 mm | 18 cm | 14.5 mm | 16 Fr |
| CXT281420 | 28.5 mm | 20 cm | 14.5 mm | 16 Fr |
| CXT321414 | 32 mm | 14 cm | 14.5 mm | 18 Fr |
| CXT321416 | 32 mm | 16 cm | 14.5 mm | 18 Fr |
| CXT321418 | 32 mm | 18 cm | 14.5 mm | 18 Fr |
| CXT321420 | 32 mm | 20 cm | 14.5 mm | 18 Fr |
| CXT361414 | 36 mm | 14 cm | 14.5 mm | 18 Fr |
| CXT361416 | 36 mm | 16 cm | 14.5 mm | 18 Fr |
| CXT361418 | 36 mm | 18 cm | 14.5 mm | 18 Fr |
| CXT361420 | 36 mm | 20 cm | 14.5 mm | 18 Fr |

| Aortic Extenders | Proximal Diameter | Overall Length | Ipsilateral Leg Diameter | Profile |
|---|---|---|---|---|
| CXA200005 | 20 mm | 4.5 cm | N/A | 15 Fr |
| CXA230005 | 23 mm | 4.5 cm | N/A | 15 Fr |
| CXA260005 | 26 mm | 4.5 cm | N/A | 15 Fr |
| CXA280005 | 28 mm | 4.5 cm | N/A | 16 Fr |
| CXA320005 | 32 mm | 4.5 cm | N/A | 18 Fr |
| CXA360005 | 36 mm | 4.5 cm | N/A | 18 Fr |

## A. Accessories and Other Required Devices

The GORE EXCLUDER Conformable AAA Endoprosthesis is intended to be used with the following accessory devices for delivery or implantation:

- 0.035” (0.89 mm) ‘super stiff’ guidewire (or similar guidewire with a long floppy tip), 145 cm or longer
- Angiographic radiopaque marker catheter
- Contrast media
- Syringe
- Snare catheter
- Heparin and heparinized saline
- Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis
    - 12 Fr, 14 Fr, 15 Fr, 16 Fr, or 18 Fr introducer sheaths (reference IFU for sizing)
    - Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter IFU)
    - Percutaneous transluminal angioplasty (PTA) balloons (reference IFU for sizing)
- Aortic Extender Endoprosthesis
    - 15 Fr, 16 Fr, or 18 Fr introducer sheath (reference IFU for sizing)
    - Large diameter, low pressure aortic balloon (monitor balloon volumes and pressures as recommended in balloon catheter IFU)
- Iliac Extender Endoprosthesis
    - 12 Fr, 14 Fr, and 15 Fr introducer sheaths (reference IFU for sizing)
    - PTA balloon catheters (reference IFU for sizing)

## VI. ALTERNATIVE PRACTICES AND PROCEDURES

There are several other alternatives for the treatment of infrarenal abdominal aneurysms including:

- Medical management
- Open surgical repair of the aneurysm
- Endovascular Aneurysm Repair (EVAR) using other endovascular devices

Each alternative has its own advantages and disadvantages. A patient should fully discuss these alternatives with his/her physician to select the method that best meets expectations and lifestyle.

## VII. MARKETING HISTORY

The EXCC device is currently approved for use in the United States, Japan, Australia, New Zealand and the European Union (EU) which includes the following countries:

Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

The EXCC device has not been withdrawn from marketing for any reason related to its safety or effectiveness.

## VIII. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH

**Table 2** lists the potential adverse effects (e.g., complications) associated with the use of the device.

**Table 2. Potential Adverse Events**

| Adverse events that may occur and / or require intervention or additional intraoperative procedure time include, but are not limited to: |
|---|
| • allergic reaction and / or anaphylactoid response to x-ray contrast dye, anti-platelet therapy, device materials<br>• amputation<br>• anesthetic complications<br>• aneurysm enlargement<br>• aneurysm rupture and death<br>• arterial or venous thrombosis and / or pseudoaneurysm<br>• arteriovenous fistula<br>• bleeding, hematoma, or coagulopathy<br>• bowel complications (e.g., ileus, gastrointestinal bleeding, fistula, transient ischemia, infarction, necrosis)<br>• cardiac events (e.g., arrhythmia, myocardial infarction, congestive heart failure, hypotension or hypertension)<br>• claudication (e.g., buttock, lower limb)<br>• delivery catheter: damage, failure, difficulty / unable to remove<br>• death<br>• dissection, perforation, bleeding, or ruptures of the aortic vessel and surrounding vasculature<br>• edema<br>• embolization (micro and macro) with transient or permanent ischemia<br>• endoleak<br>• 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<br>• fever and localized inflammation<br>• genitourinary complications (e.g., ischemia, erosion, fistula, incontinence, hematuria, infection) |

- hemorrhage
- hepatic failure
- impotence
- infection (e.g., aneurysm, device or access sites)
- lymph fistula / complications
- multi-system organ failure
- neurologic damage, local or systemic (e.g., stroke, paraplegia, paraparesis)
- occlusion / stenosis of device or native vessel
- open surgical conversion
- paralysis/paresthesia/paraparesis
- post-implant syndrome
- pulmonary complications (e.g., pneumonia, respiratory failure)
- radiation injury, late malignancy
- renal (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- surgical cut down, bypass, or conversion
- tissue necrosis
- wound complications (e.g., infection, dehiscence, hematoma, seroma, cellulitis)
- • vascular spasm or vascular trauma (e.g., aorta dissection, aorta damage, ilio-femoral vessel dissection, bleeding, rupture, death)

For the specific adverse events that occurred in the clinical study, please see **Section X** below.

## IX. SUMMARY OF NONCLINICAL STUDIES

Nonclinical studies were completed to evaluate the EXCC device, including non-clinical bench testing, biocompatibility, sterilization, packaging, shelf-life, and animal studies. The SSED containing the nonclinical studies to support the original PMA is available on the CDRH website and is incorporated by reference here. No changes have been made to the EXCC device. Additionally, many of these studies were inclusive of $\leq 90°$ aortic neck angulation and $\geq 10$ mm aortic neck lengths. Therefore, these data remain applicable and support the revised indications for use.

Supplemental non-clinical testing executed can be found in **Table 3**.

**Table 3. Summary of Supplemental Nonclinical Studies**

| Test | Test Summary | Results |
|---|---|---|
| Angulated Durability Evaluation | To evaluate fatigue and durability of the EXCC Device at the indicated use anatomical limits using pulsatile fatigue testing.<br><br>**Acceptance Criteria:**<br>Each EXCC endoprosthesis on test shall demonstrate it is durable to physiologic motion/loading conditions for ten years of implantation without damage that would compromise endoprosthesis function. | **PASS** |

## X. SUMMARY OF PRIMARY CLINICAL STUDY

The applicant performed a clinical study (AAA 13-03) to establish a reasonable assurance of safety and effectiveness of endovascular repair of infrarenal abdominal aortic aneurysms with the GORE EXCLUDER Conformable AAA Endoprosthesis (EXCC device) in the US under IDE #G150057. A summary of the clinical study is presented below.

The study was a prospective, multi-center, non-randomized clinical study with two parallel substudies, designed to evaluate the safety and effectiveness of the EXCC device for the treatment of infrarenal AAA including in patients with short and/or angulated aortic necks. The substudies are described as follows:

- Short Neck (SN) Substudy: Subjects with AAA having aortic neck angulation ≤ 60˚ and infrarenal aortic neck length ≥ 10 mm

- High Neck Angulation (HNA) Substudy: Subjects with AAA having aortic neck angulation > 60˚ and ≤ 90˚ and infrarenal aortic neck length ≥ 10 mm

Data from the Short Neck Substudy were the basis for the original PMA approval decision. The SSED containing the clinical data to support the original PMA approval is available on the CDRH website and is incorporated by reference here.

Data from the HNA Substudy were the basis for the PMA Panel Track Supplement approval decision for the revised indications for use. Therefore, this SSED focuses on the results of the HNA Substudy. Additionally, there were subjects from the SN Substudy with aortic neck lengths between 10 – 15 mm with longer term follow-up. The data from these subjects was also used to support the revised indications for use and is discussed under Section XI. Summary of Supplemental Clinical Information section below.

### A. Study Design

Subjects were treated in the High Neck Angulation Substudy between January 22, 2018 and February 16, 2022. The database for this PMA reflected data collected through May 25, 2023 and included 95 subjects. There were 35 investigational sites in the US. Subjects were evaluated through hospital discharge and follow-up visits at one and six months, and annually through 5 years post treatment.

The study was a prospective, multi-center, non-randomized clinical study.

Primary Safety and Primary Effectiveness Endpoints were analyzed using frequentist one-sided exact binomial hypothesis testing ($\alpha = 0.05$).

The primary safety endpoint was a composite of procedural blood loss > 1000 mL and the following within 30 days of the initial procedure: death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, and thromboembolic events (including limb occlusion and distal embolic events). A performance goal of 79% of

freedom from procedural safety events was developed to evaluate safety using historical GORE® EXCLUDER® AAA device (EXC) data.

The analysis of the primary safety endpoint was intended to test the hypothesis that the proportion of subjects free from safety endpoint events ($P_{SE}$) exceeded the performance goal of 79%:

$$H_0 : P_{SE} \leq 0.79$$
$$H_A : P_{SE} > 0.79$$

The primary effectiveness endpoint was a composite of technical success (successful access and deployment of all required EXCC device components) and freedom from the following: Type I endoleak, Type III endoleak, migration (≥ 10 mm), and AAA enlargement (≥ 5 mm) with or without intervention at the 12-month evaluation, as well as freedom from AAA rupture and conversion to open repair through 12 months. A performance goal of 80% was developed to evaluate device effectiveness using historical EXC data.

The analysis of the primary effectiveness endpoint was intended to test the hypothesis that the proportion of subjects free from effectiveness endpoint events ($P_{EE}$) exceeded the performance goal of 80%:

$$H_0 : P_{EE} \leq 0.80$$
$$H_A : P_{EE} > 0.80$$

GORE® EXCLUDER® AAA Device (EXC) data was used to estimate primary safety endpoint success to be 91.0% and the primary effectiveness endpoint success to be 96.0%. The primary safety endpoint was limiting in terms of statistical power. Assuming 10% attrition, the minimum sample size required was 74 subjects. Because the High Neck Angulation substudy represented a novel subject population which could induce more variability in outcomes, a larger sample size of 95 subjects was utilized.

Evaluation groups used during the course of the pivotal study are described below:

- During the screening process, all patients who were assessed by an Investigator to meet all inclusion / exclusion criteria were submitted to Gore for review and case approval. The initial step in Gore's review included Gore Imaging Sciences (GIS) performing an angle assessment. Patients that passed the initial angle assessment were further evaluated by GIS to ensure that the anatomy, characterized by vessel diameters and sealing zone lengths, were within the intended use parameters of the EXCC Device. At the conclusion of the process, the site was notified by Gore on the patient's eligibility (Accept / Reject).
- An independent external Core Laboratory (Core Lab) was used to perform evaluations on all medical imagery submitted by clinical sites. The Core Lab reported all measurements and device assessments to Gore.
- An external Clinical Events Committee (CEC) adjudicated safety and certain effectiveness endpoint events. Effectiveness endpoint events not adjudicated by the CEC were determined by the Core Lab.

- An independent Data Safety Monitoring Board (DSMB) reviewed all available safety data on a regular basis and provided recommendations on the continuing safety, validity and scientific merit of the study.

1. Clinical Inclusion and Exclusion Criteria

   Enrollment in the AAA 13-03 HNA substudy was limited to patients who met the following inclusion criteria:

   - AAA meeting any of the following criteria:
     - Maximum diameter ≥ 50 mm
     - Rapid growth (> 5 mm in a 6-month period)
     - Non-ruptured AAA presenting with clinical symptoms
   - Adequate anatomy to receive the EXCC device, including:
     - Adequate iliac / femoral access
     - Infrarenal aortic neck diameter 16-32 mm
     - Infrarenal aortic neck length ≥ 10 mm
     - Aortic neck angle ≤ 90˚
     - Distal iliac artery seal zone ≥ 10 mm
     - Iliac artery diameter 8-25 mm
   - An Informed Consent Form (ICF) signed by subject
   - Male or infertile female*
   - Able to comply with Protocol requirements including following-up
   - Life expectancy > 2 years
   - Age ≥ 21 years

   * Infertile female – condition which prevents pregnancy e.g., hysterectomy, tubal ligation or post-menopausal for greater than 1 year

   Patients were not permitted to enroll in the AAA 13-03 HNA substudy if they met any of the following exclusion criteria:

   - Mycotic or ruptured aneurysm
   - Known concomitant thoracic aortic aneurysm which requires surgical intervention
   - Renal insufficiency defined as creatinine > 2.5 mg / dL or patient undergoing dialysis
   - New York Heart Association (NYHA) class IV
   - Aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone(s)
   - Severely tortuous or stenotic iliac and / or femoral arteries
   - Patient has body habitus or other medical condition which prevents adequate delineation of the aorta
   - Participating in another investigational device or drug study within 1 year of treatment
   - Systemic infection which may increase the risk of endovascular graft infection
   - Known degenerative connective tissue disease, e.g., Marfan or Ehler-Danlos Syndrome
   - Planned concomitant surgical procedure or major surgery within 30 days of treatment date

- Known history of drug abuse
- Known sensitivities or allergies to the device materials

2. Follow-up Schedule

All subjects were required to return for follow-up examinations at 1, 6, 12, 24, 36, 48 and 60 months.

Preoperatively, subjects were required to have a physical examination, serum creatinine concentration test and contrast enhanced spiral computed tomography (CT).

Operatively, subjects were required to have angiography performed at the conclusion of the procedure.

Post-operatively, subjects were required to have a physical examination and contrast enhanced CT scan at each visit interval. At the one-month interval, a non-contrast CT was also required. Adverse events and complications were recorded at all visits.

The key timepoints are shown below in the tables summarizing safety and effectiveness.

**Table 4** outlines the required screening evaluations and follow-up visit procedures for subjects.

**Table 4. Schedule of Events**

| Diagnostic Test | Pre-treatment | Treatment | Discharge | 1 month | 6 months | Annually for up to 5 years |
|---|---|---|---|---|---|---|
| Physical examination | X | | X | X | X | X |
| Serum creatinine concentration | X | | | | | |
| Spiral computed tomography (contrast) | X | | | X | X | X |
| Spiral computed tomography (non-contrast) | | | | X | | |
| Angiography | | X | | | | |

3. Clinical Endpoints

With regards to safety, the primary safety endpoint was a composite of procedural blood loss > 1000 mL and the following within 30 days of the initial procedure, based on the definitions provided by Chaikof et al.[1]

- Death
- Stroke
- Myocardial Infarction
- Bowel Ischemia
- Paraplegia
- Respiratory Failure
- Renal Failure

- Thromboembolic Events (including limb occlusion and distal embolic events)

With regards to effectiveness, the primary effectiveness endpoint was defined as a composite of technical success (successful access and deployment of all required EXCC device components) and freedom from:

- Type I endoleak in the 12-month window*
- Type III endoleak in the 12-month window*
- Migration (10 mm or more) between the post-operative baseline and the 12-month window*
- AAA enlargement ≥ 5 mm with or without intervention between the post-operative baseline and the 12-month window*
- AAA rupture through the 12-month window
- Conversion to open repair through the 12-month window

*A supplemental analysis was performed which considered all Core Lab reported imaging events (Type I/III endoleak, migration AAA enlargement) observed from the 1-month through the 12-month window (T12M) as endpoint events (See Effectiveness Results discussion below in Section 2).

With regard to overall study success, both the primary safety endpoint and primary effectiveness endpoint performance goals must be exceeded in order to achieve study success.

In addition to the primary effectiveness endpoints, a second group of effectiveness endpoints were assessed at each study follow-up interval and were reported descriptively. The secondary effectiveness endpoints were defined as the following:

- Aneurysm-related mortality
- Stent fracture based on Core Lab analysis
- Individual elements of the primary safety and effectiveness endpoints
- Reintervention
- Type II endoleak
- Type IV endoleak
- Index Procedure Blood Loss
- Index Procedure Time
- Length of Hospital Stay (initial hospitalization)

## B. Accountability of PMA Cohort

At the time of database lock, of the 95 subjects enrolled in the High Neck Angulation Substudy, 92 subjects were available for analysis of the primary safety endpoint at 1 month and 77 were available for analysis of the primary effectiveness endpoint at 1 year.

Compliance with the key endpoint follow-up visits is illustrated below in **Figure 4**. Three (3) subjects were not available for assessment of the primary safety endpoint at 1 month due to a missed physical exam. Eighteen (18) subjects were not available for assessment of the primary effectiveness endpoint at 12 months due to a missed contrast enhanced CT scan (CTA). Common reasons for missed CTA assessment include study discontinuation, death or renal insufficiency contraindicating the use of contrast dye.

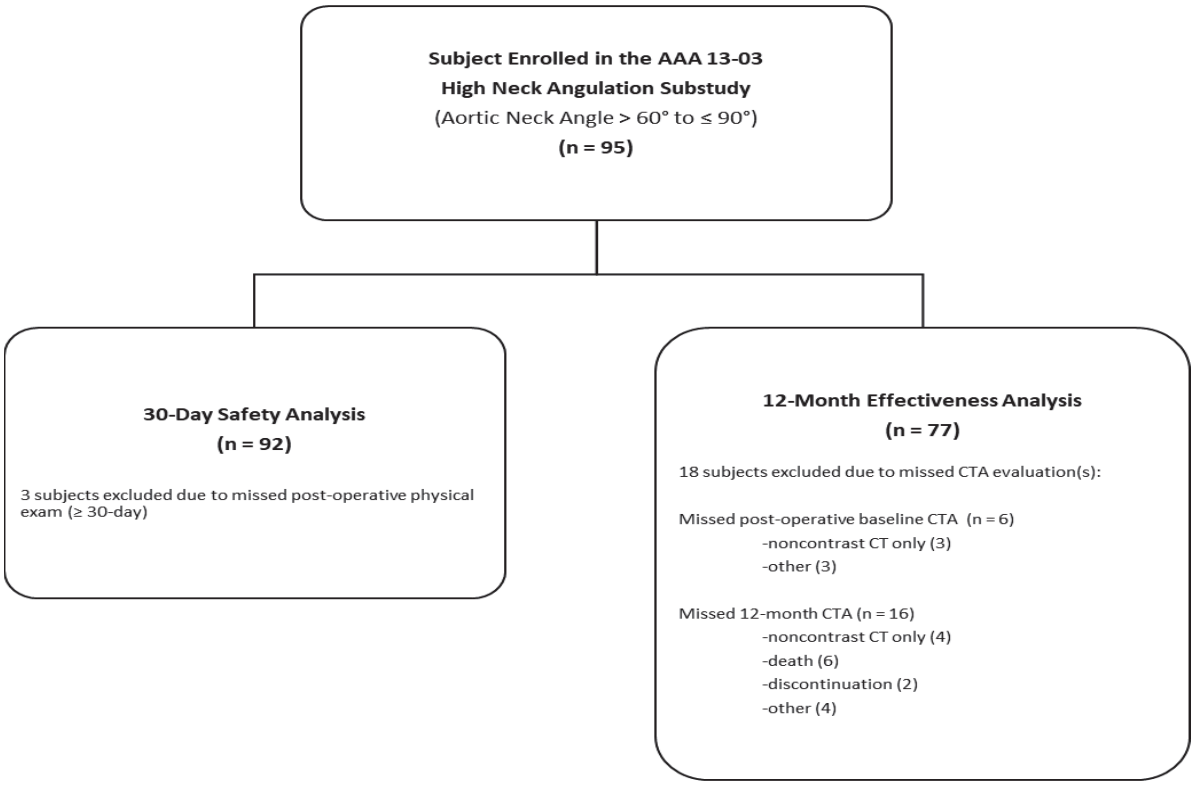


**Figure 4. Subject Compliance Flowchart for Endpoint Assessment**

At the time of the database lock, 52 subjects were actively undergoing 2-5 year follow-up, 1 subject has completed 5-year follow-up, 2 subjects have experienced conversion to open repair, and 40 subjects have discontinued the study due to death, withdrawal, or non-compliance. Visit compliance, imaging evaluability, and subject status is summarized in **Table 5** for all follow-up periods.

## Table 5. Subject Disposition and Compliance by Study Period in the High Neck Angulation Substudy

| | | Subjects with Data for Visit | | | | | Adequate Imaging to Assess Parameter[4] | | | | | Subject Status | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Visit | Eligible for Follow-Up[1] | Subjects with Data For That Visit[2] | Physical Exam | CT | CTA | Subjects with Follow-Up Pending[3] | Size Increase[5] (Aortic Enlargement) | Endoleak | Device Migration[5] | Wire Fracture[6] | Device Patency | Death | Conversion | LTF[7] | Not Due for Next Window[8] |
| Procedure | 95 | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| Post-Procedure[9] | 95 | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 1 Month | 95 | 87(91.6%) | 85(89.5%) | 84(88.4%) | 83(87.4%) | - | Baseline | 81(85.3%) | Baseline | 81(85.3%) | 83(87.4%) | - | 1(1.1%) | - | - |
| 6 Months | 94 | 83(88.3%) | 76(80.9%) | 81(86.2%) | 78(83.0%) | - | 76(80.9%) | 77(81.9%) | 77(81.9%) | 77(81.9%) | 78(83.0%) | 2(2.1%) | - | 1(1.1%) | - |
| 12 Months | 91 | 78(85.7%) | 71(78.0%) | 78(85.7%) | 73(80.2%) | - | 75(82.4%) | 73(80.2%) | 77(84.6%) | 73(80.2%) | 73(80.2%) | 6(6.6%) | - | 3(3.3%) | 1(1.1%) |
| 24 Months | 81 | 60(74.1%) | 54(66.7%) | 60(74.1%) | 55(67.9%) | 5(6.2%) | 58(71.6%) | 54(66.7%) | 60(74.1%) | 55(67.9%) | 55(67.9%) | 11(13.6%) | - | 5(6.2%) | 7(8.6%) |
| 36 Months | 58 | 46(79.3%) | 42(72.4%) | 44(75.9%) | 39(67.2%) | 5(8.6%) | 42(72.4%) | 38(65.5%) | 43(74.1%) | 43(74.1%) | 39(67.2%) | 2(3.4%) | 1(1.7%) | 5(8.6%) | 7(12.1%) |
| 48 Months | 43 | 18(41.9%) | 16(37.2%) | 16(37.2%) | 15(34.9%) | 21(48.8%) | 15(34.9%) | 14(32.6%) | 15(34.9%) | 14(32.6%) | 14(32.6%) | 3(7.0%) | - | 1(2.3%) | 26(60.5%) |
| 60 Months | 13 | 1(7.7%) | - | 1(7.7%) | 1(7.7%) | 11(84.6%) | 1(7.7%) | 1(7.7%) | 1(7.7%) | 1(7.7%) | 1(7.7%) | 1(7.7%) | - | - | 12(92.3%) |

[1]Eligible for follow-up eligible for follow-up from the previous interval – (death + conversion + LTF + not due) from the previous interval. All subjects that had an endovascular graft implanted are eligible for follow-up for the operative row. This is the denominator for all percentages in given study period.
[2]Either Physical Exam and/or CT scan.
[3]Subjects still within follow-up window, but data not yet available (neither physical exam or CT).
[4]Not the number of subjects with these reported events, but rather, the number with adequate imaging.
[5]Parameter requires both a post-operative baseline and follow-up evaluation to be considered evaluable.
[6]Wire fracture was considered evaluable if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed.
[7]In this table, lost to follow-up (LTF) includes all other reasons for study discontinuation including subjects that have withdrawn from the study.
[8]Those subjects that are "Not due for next visit" are those subjects that are not within the follow-up window for the next interval.
[9]No study visit was required in the Post-Procedure Analysis Window (Day 1-14)
Study period definitions: Procedure (0 days) Post-Procedure (1-14 days) 1 Month (15-59 days) 6 Months (60-242 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)

## C. Study Population Demographics and Baseline Parameters

### Demographics

The demographics of the study population are typical for an EVAR study performed in the US. The majority of subjects enrolled were male (74.7%)and white (91.6%). Enrolled subjects had a median age of 74 years and a median BMI of 28.5 kg/m$^2$. These observed demographic trends are also consistent with the commercial application of EVAR therapy[2]. A summary of subject demographics can be found in **Table 6**.

## Table 6. Subject Demographic Characteristics

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| **Number of Enrolled Subjects** | 95 |
| **Sex at Birth** | |
| Male | 71(74.7%) |
| Female | 24(25.3%) |
| **Ethnicity** | |
| Not Hispanic or Latino | 88(92.6%) |
| Hispanic or Latino | 3(3.2%) |
| Unknown | 4(4.2%) |
| **Race** | |
| White | 87(91.6%) |
| Black or African American | 3(3.2%) |
| Asian | 0(0%) |
| American Indian or Alaska Native | 1(1.1%) |

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| Hawaiian or Pacific Islander | - |
| Other | 4(4.2%) |
| **Age (yrs)** | |
| n | 95 |
| Mean (Std Dev) | 74.4(7.23) |
| Median | 74.0 |
| Range | (59,92) |
| **Weight (kg)** | |
| n | 95 |
| Mean (Std Dev) | 90.4(25.06) |
| Median | 87.4 |
| Range | (45.8,182.6) |
| **Height (cm)** | |
| n | 95 |
| Mean (Std Dev) | 173.1(9.78) |
| Median | 175.3 |
| Range | (152.4,200.0) |
| **BMI (kg/m$^2$)** | |
| n | 95 |
| Mean (Std Dev) | 30.1(7.93) |
| Median | 28.5 |
| Range | (16.9,66.3) |

Subject Baseline Medical History

A summary of subject baseline medical history is provided in **Table 7**. The majority of subjects had a history of hypertension (86.3%), hypercholesterolemia (73.7%), and/or tobacco use (69.5%).

**Table 7. Subject Medical History**

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| **Number of Enrolled Subjects** | 95 |
| | |
| Hypertension | 82(86.3%) |
| Hypercholesterolemia | 70(73.7%) |
| Tobacco Use | 66(69.5%) |
| Chronic Obstructive Pulmonary Disease | 31(32.6%) |
| Cardiac Arrhythmia | 29(30.5%) |
| Cancer | 28(29.5%) |
| Myocardial Infarction | 26(27.4%) |
| Peripheral Vascular Disease | 21(22.1%) |
| Diabetes Mellitus | 20(21.1%) |
| Cerebrovascular disease | 19(20.0%) |
| Congestive Heart Failure | 17(17.9%) |
| Coronary Artery Bypass Graft | 17(17.9%) |
| Renal Insufficiency | 12(12.6%) |
| Thromboembolic Event | 8(8.4%) |
| Other Concomitant Aneurysm | 6(6.3%) |

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| Paraplegia | 1(1.1%) |

Pre-Treatment Measurements

All subjects met anatomical criteria for inclusion based on Gore Imaging Sciences (GIS) and Site evaluations. Subjects were assigned to the High Neck Angulation Substudy based off of the infrarenal proximal aortic neck angle as measured by GIS (> 60° and ≤ 90°).

A summary of site, GIS, and Core Lab-reported pre-treatment measurements are provided in **Table 8**. The median infrarenal aortic neck angle measured by the site was 73.4˚ and the median proximal aortic neck length was 25.0 mm. The median infrarenal aortic neck angle measured by GIS was 68.0˚ and the median proximal aortic neck length was 22.0 mm. The median diameter of the abdominal aortic aneurysm measured by the site was 58.0 mm and by the Core Lab was 60.4mm.

**Table 8. Pre-Treatment Measurements**

| | Site | Gore Imaging Sciences (GIS)[1] | Core Lab (CL) |
|---|---|---|---|
| **Number of Enrolled Subjects** | 95 | 95 | 95 |
| | | | |
| **Proximal Aortic Neck Length (mm)[2]** | | | |
| Mean (Std Dev) | 26.4(11.9) | 23.2(10.1) | 21.5(10.6) |
| Median | 25.0 | 22.0 | 20.4 |
| Range | (10.0,77.0) | (10.0,57.0) | (4.0,58.8) |
| | | | |
| **Infrarenal Proximal Aortic Neck Angle (degrees)[3]** | | | |
| Mean (Std Dev) | 73.3(11.5) | 71.6(9.2) | - |
| Median | 73.4 | 68.0 | - |
| Range | (44.0,90.0) | (61.0,90.0) | - |
| | | | |
| **Maximum Abdominal Aortic Aneurysm Diameter (mm)** | | | |
| Mean (Std Dev) | 61.1(11.0) | - | 62.9(11.8) |
| Median | 58.0 | - | 60.4 |
| Range | (48.0,97.0) | - | (42.7,103.1) |
| | | | |
| **Length from Lowest Renal Artery to Native Aortic Bifurcation (mm)** | | | |
| Mean (Std Dev) | 132.6(24.6) | - | 148.2(21.2) |
| Median | 132.0 | - | 149.4 |
| Range | (13.0,187.0) | - | (103.3,207.5) |
| | | | |
| **Length from Lowest Renal Artery to Left Internal / External Bifurcation (mm)** | | | |
| Mean (Std Dev) | - | - | 211.0(27.7) |
| Median | - | - | 209.9 |

| | Site | Gore Imaging Sciences (GIS)[1] | Core Lab (CL) |
|---|---|---|---|
| Range | - | - | (122.3,276.4) |
| | | | |
| **Length from Lowest Renal Artery to Right Internal / External Bifurcation (mm)** | | | |
| Mean (Std Dev) | - | - | 210.9(27.3) |
| Median | - | - | 208.5 |
| Range | - | - | (159.0,275.8) |
| | | | |
| **Native Aortic Bifurcation Diameter (mm)** | | | |
| Mean (Std Dev) | 26.5(8.3) | - | - |
| Median | 25.0 | - | - |
| Range | (13.0,52.0) | - | - |
| | | | |
| **Aortic Diameter at Proximal Implantation Site (mm)** | | | |
| Mean (Std Dev) | 21.2(2.4) | - | - |
| Median | 21.0 | - | - |
| Range | (16.0,28.0) | - | - |
| | | | |
| **Aortic diameter - 10 mm Distal to Proximal Implantation Site (mm)** | | | |
| Mean (Std Dev) | 21.2(2.7) | - | - |
| Median | 21.0 | - | - |
| Range | (14.5,28.0) | - | - |
| | | | |
| **Left Common Iliac Diameter (mm)** | | | |
| Mean (Std Dev) | 14.7(3.6) | - | - |
| Median | 14.0 | - | - |
| Range | (9.0,24.0) | - | - |
| | | | |
| **Right Common Iliac Diameter (mm)** | | | |
| Mean (Std Dev) | 14.6(3.5) | - | - |
| Median | 14.0 | - | - |
| Range | (9.9,25.0) | - | - |
| | | | |
| **Left Access Vessel Diameter (mm)** | | | |
| Mean (Std Dev) | 9.5(1.8) | - | - |
| Median | 9.0 | - | - |
| Range | (6.0,14.3) | - | - |
| | | | |
| **Right Access Vessel Diameter (mm)** | | | |
| Mean (Std Dev) | 9.4(1.8) | - | - |
| Median | 9.0 | - | - |
| Range | (6.0,15.0) | - | - |

[1]Gore Imaging Sciences is comprised of film reading experts who reviewed pre-treatment images as a part of the screening process in support of the investigational trial.
[2]Proximal aortic neck length was measured at screening by sites and GIS and assessed by Core Lab after enrollment.
[3]Gore Imaging Sciences (GIS) angle assessment was the basis for substudy assignment.

Device Usage

**Table 9** describes device usage for subjects enrolled in the study. All subjects had a EXCC device implanted. Subjects received a median of 3.0 device components. Eighteen (18) subjects had an EXCC Aortic Extender (EXCC AE) implanted. A listing of EXCC Trunk device sizes used in the study are found in **Table 10**. A listing of EXCC AE device sizes used in the study are found in **Table 11**.

**Table 9. Summary of Device Usage Data at Initial Treatment**

| | **High Neck Angulation Substudy (> 60° and ≤ 90°)** |
|---|---|
| **Number of Subjects Enrolled** | 95 |
| | |
| **Number of Subjects with Devices Implanted at Initial Treatment** | 95 |
| | |
| **EXCLUDER Device Components** | |
| Subjects with Trunks Implanted | 95(100.0%) |
| Subjects with Contralateral Legs Implanted | 95(100.0%) |
| Subjects with Aortic Extenders Implanted | 18(18.9%) |
| Subjects with Iliac Extenders Implanted | 10(10.5%) |
| | |
| **Number of Components Implanted** | |
| 2 | 13(13.7%) |
| 3 | 45(47.4%) |
| 4 | 30(31.6%) |
| 5 | 5(5.3%) |
| 6 | 1(1.1%) |
| 7 | - |
| 8 | 1(1.1%) |
| | |
| **Number of Components Per Subject** | |
| n components | 320 |
| Mean (Std Dev) | 3.4(0.9) |
| Median | 3.0 |
| Range | (2,8) |

**Table 10. Distribution of Dimensions of EXCLUDER Trunks – Ipsilateral Legs Implanted at Initial Procedure**

| **Proximal Diameter (mm)** | **Distal Diameter (mm)** | **Length (cm)** | **Devices (N=95)[1]** |
|---|---|---|---|
| 20 | 12 | 12 | 1(1.1%) |
| 20 | 12 | 14 | - |
| 20 | 12 | 16 | 2(2.1%) |
| 20 | 14.5 | 12 | 1(1.1%) |
| 20 | 14.5 | 14 | 3(3.2%) |
| 20 | 14.5 | 16 | 1(1.1%) |
| **20 (Total)** | **-** | **-** | **8(8.4%)** |
| | | | |
| 23 | 12 | 12 | 0 |

| Proximal Diameter (mm) | Distal Diameter (mm) | Length (cm) | Devices (N=95)[1] |
|---|---|---|---|
| 23 | 12 | 14 | 1(1.1%) |
| 23 | 12 | 16 | 2(2.1%) |
| 23 | 12 | 18 | 3(3.2%) |
| 23 | 12 | 20 | 0 |
| 23 | 14.5 | 12 | 4(4.2%) |
| 23 | 14.5 | 14 | 5(5.3%) |
| 23 | 14.5 | 16 | 5(5.3%) |
| 23 | 14.5 | 18 | 7(7.4%) |
| 23 | 14.5 | 20 | 0 |
| **23 (Total)** | **-** | **-** | **27(28.4%)** |
| | | | |
| 26 | 12 | 12 | 0 |
| 26 | 12 | 14 | 1(1.1%) |
| 26 | 12 | 16 | 1(1.1%) |
| 26 | 12 | 18 | 1(1.1%) |
| 26 | 12 | 20 | 0 |
| 26 | 14.5 | 12 | 5(5.3%) |
| 26 | 14.5 | 14 | 10(10.5%) |
| 26 | 14.5 | 16 | 10(10.5%) |
| 26 | 14.5 | 18 | 3(3.2%) |
| 26 | 14.5 | 20 | 0 |
| **26 (Total)** | **-** | **-** | **31(32.6%)** |
| | | | |
| 28.5 | 12 | 12 | 0 |
| 28.5 | 12 | 14 | 1(1.1%) |
| 28.5 | 12 | 16 | 1(1.1%) |
| 28.5 | 12 | 18 | 0 |
| 28.5 | 12 | 20 | 0 |
| 28.5 | 14.5 | 12 | 5(5.3%) |
| 28.5 | 14.5 | 14 | 7(7.4%) |
| 28.5 | 14.5 | 16 | 6(6.3%) |
| 28.5 | 14.5 | 18 | 6(6.3%) |
| 28.5 | 14.5 | 20 | 0 |
| **28.5 (Total)** | **-** | **-** | **26(27.4%)** |
| | | | |
| 32 | 14.5 | 14 | 0 |
| 32 | 14.5 | 16 | 0 |
| 32 | 14.5 | 18 | 3(3.2%) |
| 32 | 14.5 | 20 | 0 |
| **32 (Total)** | **-** | **-** | **3(3.2%)** |
| | | | |
| 36 | 14.5 | 14 | 0 |
| 36 | 14.5 | 16 | 0 |
| 36 | 14.5 | 18 | 0 |
| 36 | 14.5 | 20 | 0 |
| **36 (Total)** | **-** | **-** | **0** |

[1]Denominator N = Total number of subjects with EXCLUDER Trunks – Ipsilateral Leg implanted

**Table 11. Distribution of Dimensions of EXCLUDER Aortic Extenders Implanted at Initial Procedure**

| Diameter (mm) | High Neck Angulation Substudy (> 60° and ≤ 90°) (N=18)[1] |
|---|---|
| 20 | 0 |
| 23 | 6(33.3%) |
| 26 | 5(27.8%) |
| 28.5 | 7(38.9%) |
| 32 | 0 |
| 36 | 0 |

[1]Denominator N Total number of subjects with EXCLUDER Aortic Extender s implanted

Procedure Characteristics

A summary of the index endovascular procedures is provided in **Table 12**. In the High Neck Angulation substudy the median procedure time was 110 minutes while in the Short Neck substudy the median procedure time was 84 minutes. The majority of subjects in the study had bilateral percutaneous femoral access. In the High Neck Angulation substudy the median blood loss was 50.0 mL as well as in Short Neck substudy with a median blood loss of 50.0 mL. Three (3) subjects experienced blood loss of 1000 mL or greater and subsequently received blood transfusions. During the index procedure, 12 subjects had additional procedures, including PTA (n=2), stent(s) (n=6), and/or embolization(s) (n=3), and/or endarterectomy with patch angioplasty n=1).

**Table 12. Procedure Characteristics**

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| **Subjects Initiating Procedure** | 95 |
| | |
| **Endovascular Access Method on Left Side** | |
| Percutaneous | 88(92.6%) |
| Cut-down | 7(7.4%) |
| Cut-down and Conduit | 0(0%) |
| | |
| **Endovascular Access Method on Right Side** | |
| Percutaneous | 89(93.7%) |
| Cut-down | 6(6.3%) |
| Cut-down and Conduit | 0(0%) |
| | |
| **Anesthesia Method[1]** | |
| General | 84(88.4%) |
| Regional | 4(4.2%) |
| Local | 5(5.3%) |
| | |
| **Procedure Time (minutes)[2]** | |
| n | 95 |
| Mean (Std Dev) | 119.0(56.7) |
| Median | 110.0 |
| Range | (40,358) |
| | |
| **Blood Loss (mL)** | |
| n | 93 |
| Mean (Std Dev) | 146.2(339.1) |
| Median | 50.0 |
| Range | (0,2700) |

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| | |
| **Total Fluoro Time (minutes)** | |
| n | 94 |
| Mean (Std Dev) | 28.2(18.9) |
| Median | 23.5 |
| Range | (9,140) |
| | |
| **Contrast Used During Procedure (mL)** | |
| n | 95 |
| Mean (Std Dev) | 108.6(55.8) |
| Median | 95.0 |
| Range | (23,315) |
| | |
| **Transfusion** | 3(3.2%) |
| | |
| **Procedure Survival** | 95(100.0%) |
| | |
| **Open Surgical Conversion** | 0(0%) |
| | |
| **Additional Procedures at Treatment** | 12(12.6%) |
| PTA | 2(2.1%) |
| Stent | 6(6.3%) |
| Embolization | 3(3.2%) |
| Other[3] | 1(1.1%) |

[1]Monitored anesthesia care (MAC) was used for an additional two (2) subjects
[2]Time from first arterial access to final closure.
[3]Other includes Endarterectomy with Patch Angioplasty n 1

Procedure Outcomes

A summary of procedure outcomes is provided in **Table 13**. The median hospital stay was 1.0 day.

**Table 13. Procedure Outcomes**

| | High Neck Angulation Substudy (> 60° and ≤ 90°) |
|---|---|
| **Subjects Initiating Procedure** | 95 |
| | |
| **ICU Stay** | 14(14.7%) |
| | |
| **ICU Duration (hours)** | |
| n | 14 |
| Mean (Std Dev) | 29.4(11.6) |
| Median | 25.0 |
| Range | (18,63) |
| | |
| **Hospital Survival** | 95(100.0%) |
| | |
| **Hospitalization Duration (days)** | |
| n | 95 |
| Mean (Std Dev) | 2.0(2.3) |
| Median | 1.0 |
| Range | (1,13) |

**Table 14** describes the summary of technical success results. Procedural technical success was achieved in 93 subjects (97.9%). A Type I endoleak was present upon completion angiography in two (2) subjects; in both cases the endoleak resolved spontaneously prior to the first post-operative (1-Month) CT scan.

**Table 14. Summary of Technical Success Results**

| | **High Neck Angulation Substudy (> 60° and ≤ 90°)** |
|---|---|
| **Number of Enrolled Subjects** | 95 |
| | |
| **Technical Success** | 93(97.9%) |
| Successful Access | 95(100.0%) |
| Successful Deployment of Devices in the Intended Location | 95(100.0%) |
| Successful Removal of All Delivery Catheters | 95(100.0%) |
| Patent Device Components on Completion Angiography | 95(100.0%) |
| Absence of Type I or Type III Endoleak on Completion Angiography | 93(97.9%) |
| Successful Access Site Closure | 95(100.0%) |

## D. Safety and Effectiveness Results

### 1. Safety Results

The key safety outcomes are presented below in **Table 15**. Adverse effects are reported from **Table 16** to **Table 18**. A listing of subject deaths is provided in **Table 19.**

The analysis of the primary safety endpoint was based on the cohort of 92 subjects available for the 30-day evaluation. The primary safety endpoint was a composite of procedural blood loss > 1000 mL and the following within 30 days of the initial procedure: death, stroke, myocardial infarction, bowel ischemia, paraplegia, respiratory failure, renal failure, and thromboembolic events including limb occlusion and distal embolic events. The primary safety endpoint was analyzed for eligible subjects receiving a 30-day adverse event assessment (physical exam) or experiencing an endpoint event.

In the High Neck Angulation Substudy 92 of the 95 enrolled subjects completed the required assessment to be evaluated for the primary safety endpoint. Three subjects experienced an endpoint event of procedural blood loss > 1000 mL. The percentage of subjects free from a primary safety endpoint event was 96.7%. The lower confidence limit for freedom from primary safety endpoint events was 91.8%, which exceeded the performance goal of 79%.

The result of the primary safety endpoint analysis is provided in **Table 15**.

**Table 15. Primary Safety Endpoint Result**

| **Primary Safety Endpoint Analysis** | **Endpoint Denominator** | **Endpoint Event** | **Percent Free from Endpoint Event (95% Exact LCL)[1]** | **Study Endpoint Met (LCL Exceeds 79% Performance Goal)** |
|---|---|---|---|---|
| **High Neck Angulation Substudy (> 60° and ≤ 90°)** | 92 | 3 | 96.7% (91.8%) | Yes |
| [1]95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method | | | | |

**Worst Case Sensitivity Analysis**

To account for subject attrition, a worst case sensitivity analysis was performed wherein subjects excluded from the primary analyses were considered to have experienced an endpoint event.

There were three (3) subjects ineligible for the primary safety analysis. The resulting freedom from a primary endpoint event was 93.7% (89/95), and the corresponding 95% lower confidence limit was 87.9% which exceeded the performance goal of 79%.

**Adverse effects that occurred in the PMA clinical study:**

Adverse events were defined as any untoward medical occurrence (that the investigator feels is a reportable event) experienced by a subject whether device related or not.

Adverse Device Effect were defined as any adverse event related to the use of an investigational medical device.

Major Adverse Events (MAE) were defined as adverse events meeting a safety endpoint definition extended for all study periods as shown in **Table 16**.

In the High Neck Angulation Substudy, 30 subjects experienced MAE(s). Three (3) subjects experienced procedural blood loss >1000 mL, one of which also experienced respiratory failure and death at 12 months. Eight (8) additional subjects experienced respiratory failure events, resulting in death for 7 subjects. One (1) subject experienced a cerebrovascular accident (stroke) resulting in death. Two (2) subjects experienced a myocardial infarction, one of which resulted in death. One (1) subject experienced end stage renal disease (renal failure). In total 25 deaths were reported, none of which were determined to be related to the device or procedure (See **Table 19** for cause of death listing).

**Table 16. Summary of Major Adverse Events for High Neck Angulation Substudy**

| | Follow-Up Period | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Procedure | 1 Month | 6 Months | 12 Months | 24 Months | 36 Months | 48 Months | 60 Months | Total |
| **Number of Subjects** | 95 | 95 | 95 | 93 | 89 | 67 | 47 | 14 | 95 |
| | | | | | | | | | |
| **Any Major Adverse Event** | 3(3.2%) | - | 1(1.1%) | 5(5.4%) | 8(9.0%) | 8(11.9%) | 4(8.5%) | 2(14.3%) | 30 |
| **Death** | - | - | 1(1.1%) | 4(4.3%) | 7(7.9%) | 8(11.9%) | 4(8.5%) | 1(7.1%) | 25 |
| **Stroke** | - | - | - | - | 1(1.1%) | - | - | - | 1 |
| **Myocardial Infarction** | - | - | - | 1(1.1%) | 1(1.1%) | - | - | - | 2 |
| **Bowel Ischemia** | - | - | - | - | - | - | - | - | 0 |
| **Paraplegia** | - | - | - | - | - | - | - | - | 0 |
| **Respiratory Failure** | - | - | - | 2(2.2%) | 1(1.1%) | 3(4.5%) | 2(4.3%) | 1(7.1%) | 9 |
| **Renal Failure** | - | - | - | - | - | - | - | 1(7.1%) | 1 |
| **Procedural Blood Loss >1000 mL** | 3(3.2%) | - | - | - | | - | - | - | 3 |
| **Thromboembolic Event** | - | - | - | - | - | - | - | - | - |

Death and Procedural Blood Loss are reported by the site. All other MAEs are reported by the site as adverse events and adjudicated by an independent Clinical Events Committee (CEC).

Column header counts and denominators are the number of subjects at risk at the start of each interval.
Study period definitions: Procedure (0 days) 1 Month (1-30 days) 6 Months (31-183 days) 12 Months (184-365 days) 24 Months (366-731 days) 36 Months (732-1096 days) 48 Months (1097-1461 days) 60 Months (1462-1826 days) Total (0-1826 days)

Adverse events were classified as serious and non-serious. Serious Adverse Events (SAEs) were defined as any event that: led to death; led to serious deterioration in the health of a subject that: resulted in a life threatening illness or injury, resulted in a permanent impairment of a body structure or a body function, required subject hospitalization or prolongation of existing hospitalization, resulted in medical or surgical intervention to prevent permanent impairment to a body structure or a body function; or led to fetal distress, fetal death, or a congenital abnormality or birth defect.

A summary of SAEs related to the study procedure in the study is found in **Table 17**. Six (6) subjects have experienced procedure-related SAEs. Three subjects experienced procedure-related SAEs on the day of the index procedure, including acute postoperative delirium, atelactasis, and external iliac artery injury. Post-operatively, one subject experienced acute kidney injury, hypotension, and a urinary tract infection, one subject experienced acute renal injury and chronic renal insufficiency, and one subject experienced a Type II endoleak.

**Table 17. Procedure-Related SAEs for High Neck Angulation Substudy**

| | Post Treatment Follow-up Period | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Procedure** | **1 Month** | **6 Months** | **12 Months** | **24 Months** | **36 Months** | **48 Months** | **60 Months** | **Total** |
| **Number of Subjects** | 95 | 95 | 95 | 93 | 89 | 67 | 47 | 14 | 95 |
| **Any Procedure-Related Serious Adverse Event** | 3 (3.2%) | 2 (2.1%) | 1 (1.1%) | 1 (1.1%) | 0 (0%) | 0 (0%) | 0 (0%) | 0 (0%) | 6 |
| | | | | | | | | | |
| **Infections and infestations** | - | 1 (1.1%) | - | - | - | - | - | - | 1 |
| **Urinary tract infections** | - | 1 (1.1%) | - | - | - | - | - | - | 1 |
| Urinary tract infection | - | 1 (1.1%) | - | - | - | - | - | - | 1 |
| **Vascular disorders** | - | 1 (1.1%) | - | - | - | - | - | - | 1 |
| **Vascular hypotensive disorders** | - | 1 (1.1%) | - | - | - | - | - | - | 1 |
| Hypotension | - | 1 (1.1%) | - | - | - | - | - | - | 1 |
| **Respiratory, thoracic and mediastinal disorders** | 1 (1.1%) | - | - | - | - | - | - | - | 1 |
| **Parenchymal lung disorders NEC[1]** | 1 (1.1%) | - | - | - | - | - | - | - | 1 |
| Atelectasis | 1 (1.1%) | - | - | - | - | - | - | - | 1 |
| **Renal and urinary disorders** | - | 2 (2.1%) | 1 (1.1%) | - | - | - | - | - | 2 |
| **Renal failure and impairment** | - | 2 (2.1%) | 1 (1.1%) | - | - | - | - | - | 2 |
| Acute kidney injury | - | 2 (2.1%) | - | - | - | - | - | - | 2 |
| Chronic kidney disease | - | - | 1 (1.1%) | - | - | - | - | - | 1 |
| **General disorders and administration site conditions** | - | - | - | 1 (1.1%) | - | - | - | - | 1 |
| **Vascular complications associated with device** | - | - | - | 1 (1.1%) | - | - | - | - | 1 |

| | Post Treatment Follow-up Period | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Procedure | 1 Month | 6 Months | 12 Months | 24 Months | 36 Months | 48 Months | 60 Months | Total |
| Stent-graft endoleak | - | - | - | 1 (1.1%) | - | - | - | - | 1 |
| **Injury, poisoning and procedural complications** | 2 (2.1%) | - | - | - | - | - | - | - | 2 |
| **Cardiovascular injuries** | 1 (1.1%) | - | - | - | - | - | - | - | 1 |
| Arterial injury | 1 (1.1%) | - | - | - | - | - | - | - | 1 |
| **Neurological and psychiatric procedural complications** | 1 (1.1%) | - | - | - | - | - | - | - | 1 |
| Postoperative delirium | 1 (1.1%) | - | - | - | - | - | - | - | 1 |

[1]Medical Dictionary for Regulatory Activities (MedDRA) abbreviation: 'Not Elsewhere Classified'
Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Numerators are the number of subjects with procedure-related serious adverse event as determined by site. Entries Represent MedDRA SOC, HLT and PT and are identified by increasing level of indentation. Dashes are used below headings with zero values.
Study period definitions: Procedure (0 days) 1 Month (1-30 days) 6 Months (31-183 days) 12 Months (184-365 days) 24 Months (366-731 days) 36 Months (732-1096 days) 48 Months (1097-1461 days) 60 Months (1462-1826 days) Total (0-1826 days)
MedDRA Version: 26.0

A summary of device related SAEs in the study is found in **Table 18**. Two (2) subjects have experienced a site reported device-related SAE, including device kink and a Type Ib endoleak. Both subjects have received reintervention for these events.

**Table 18. Device-Related SAEs for High Neck Angulation Substudy**

| | Post Treatment Follow-up Period | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Procedure | 1 Month | 6 Months | 12 Months | 24 Months | 36 Months | 48 Months | 60 Months | Total |
| **Number of Subjects** | 95 | 95 | 95 | 93 | 89 | 67 | 47 | 14 | 95 |
| **Any Device-Related Serious Adverse Event** | 0 (0%) | 0 (0%) | 1 (1.1%) | 0 (0%) | 0 (0%) | 1 (1.5%) | 0 (0%) | 0 (0%) | 2 |
| | | | | | | | | | |
| **General disorders and administration site conditions** | - | - | - | - | - | 1 (1.5%) | - | - | 1 |
| **Vascular complications associated with device** | - | - | - | - | - | 1 (1.5%) | - | - | 1 |
| Stent-graft endoleak | - | - | - | - | - | 1 (1.5%) | - | - | 1 |
| **Product issues** | - | - | 1 (1.1%) | - | - | - | - | - | 1 |
| **Device physical property and chemical issues** | - | - | 1 (1.1%) | - | - | - | - | - | 1 |
| Device kink | - | - | 1 (1.1%) | - | - | - | - | - | 1 |

Note: Column header counts and denominators are the number of subjects at risk at the start of each interval. Numerators are the number of subjects with procedure-related serious adverse event as determined by site. Entries Represent MedDRA SOC, HLT and PT and are identified by increasing level of indentation. Dashes are used below headings with zero values.
Study period definitions: Procedure (0 days) 1 Month (1-30 days) 6 Months (31-183 days) 12 Months (184-365 days) 24 Months (366-731 days) 36 Months (732-1096 days) 48 Months (1097-1461 days) 60 Months (1462-1826 days) Total (0-1826 days)
MedDRA Version: 26.0

**Mortality**

There have been 25 deaths in the High Neck Angulation Substudy (**Table 19**). All subject deaths were reviewed by an independent Clinical Events Committee (CEC) to determine causality. There have been no aneurysm-related deaths as adjudicated by the CEC.

**Table 19. Mortality in the High Neck Angulation Substudy**

| Study Day | Cause of Death (Lowest Level Term) |
|---|---|
| 122 | Idiopathic pulmonary fibrosis |
| 216 | Ventricular arrhythmia |
| 323 | Pneumonia |
| 329 | Unknown cause of death |
| 343 | Influenza A virus infection |
| 383 | Heart attack |
| 428 | Metastatic Gastric Adenocarcinoma |
| 453 | Congestive heart failure |
| 563 | Stroke |
| 591 | Intracranial hemorrhage |
| 722 | Cardio-respiratory arrest |
| 727 | Myelodysplastic syndrome |
| 741 | Respiratory failure |
| 760 | Metastatic squamous cell carcinoma |
| 782 | Unilateral pleural effusion |
| 817 | Congestive cardiac failure aggravated |
| 856 | Malignant neoplasm of descending colon |
| 874 | Unknown cause of death |
| 896 | COVID-19 pneumonia |
| 1007 | Unknown cause of death |
| 1259 | Progression of prostate cancer |
| 1277 | Cardiopulmonary failure |
| 1308 | Unknown cause of death |
| 1342 | Acute on chronic respiratory failure |
| 1708 | Acute hypoxic respiratory failure |

2. Effectiveness Results

Key effectiveness outcomes are presented in **Table 20** through **Table 23**.

The protocol analysis of the primary effectiveness endpoint was based on the 77 subjects evaluable at the 12-month time point. The formal effectiveness assessment for the study was based on the primary endpoint of treatment success. This was defined as a composite of technical success (successful access and deployment of all required EXCC device components) and freedom from:

- Type I endoleak in the 12-month window
- Type III endoleak in the 12-month window
- Migration (≥ 10 mm) between the post-operative baseline and at the 12-month window

- AAA enlargement ≥ 5 mm with or without intervention between the post-operative baseline and the 12-month window
- AAA rupture through the 12-month window
- Conversion to open repair through the 12-month window

In the High Neck Angulation Substudy, four (4) subjects experienced an endpoint event: technical success was not achieved in two (2) subjects due to the presence of Type Ia endoleak on completion angiography (both resolved prior to the 1-month follow-up without intervention, see **Table 14**), one (1) additional subject experienced AAA enlargement in the 12 month window, and a fourth subject experienced conversion to open repair (n=1) due to a Type A aortic dissection in the thoracic aorta resulting in abdominal stent graft occlusion (see Device Integrity discussion below). The percentage of subjects free from a primary effectiveness endpoint event was 94.8%. The lower confidence limit for freedom from a primary effectiveness endpoint event was 88.5%, which exceeded the performance goal of 80%.

An additional analysis was performed considering any Core Lab imaging event (Type I endoleak, Type III endoleak, migration, AAA enlargement) through 12 months (T12M) as an endpoint event. This T12M analysis considered all imaging events observed in the 1-month or 6-month visits as endpoint events, regardless of resolution status at 12 months. The T12M analysis of the primary effectiveness endpoint was based on the 78 subjects evaluable at the 12-month time point or with a prior endpoint event. In addition to the events described above, four (4) additional subjects had Type Ia endoleaks identified by Core Lab within the first 6 months. Resolution without reintervention or sac expansion was observed among the 3 subjects with available follow-up imaging (available follow-up through 12-, 48-, and 60-months). One subject died of coronary thrombosis (unrelated to device or procedure) prior to obtaining additional follow-up. One (1) additional sac expansion event was noted among a subject with a 7.6 mm increase in sac diameter observed at 6 months. The subject was free of sac expansion in the 12- month scan but an 8.5 mm increase in sac diameter (relative to baseline) was measured in the 24-month scan. No reintervention has been performed to date. In the original protocol analysis, this subject did not obtain treatment success due to a Type Ia endoleak observed by the investigator at completion angiography as described above. In the T12M analysis, the percentage of subjects free from a primary effectiveness endpoint event was 89.7%. The lower confidence limit for freedom from a primary effectiveness endpoint event was 82.3%, which exceeded the performance goal of 80%.

The results of the primary effectiveness endpoint analyses are provided in **Table 20**.

**Table 20. Primary Effectiveness Endpoint Results**

| Primary Effectiveness Endpoint Analysis | Endpoint Denominator | Endpoint Event | Percent Free from Endpoint Event (95% Exact LCL)[1] | Study Endpoint Met (LCL Exceeds 80% Performance Goal) |
|---|---|---|---|---|
| **Protocol Analysis** | 77 | 4 | 94.8% (88.5%) | Yes |
| **Through 12 Months Analysis** | 78 | 8 | 89.7% (82.3%) | Yes |
| [1]95% LCL represents one-sided 95% Lower Confidence Limit by exact Clopper-Pearson method | | | | |

Worst Case Sensitivity Analysis

Subjects were required to have a post-operative baseline contrast enhanced CT scan (CTA) and a 12-month CTA evaluation (or endpoint event) to be included in the primary effectiveness analysis. Death, discontinuation, and renal insufficiency contraindicating CTA imaging were common reasons for exclusion from the analysis. To account for subject attrition and noncompliance, worst case sensitivity analyses were performed wherein subjects who did not obtain the requisite imaging were considered to have experienced an endpoint event.

For the protocol analysis, eighteen (18) subjects were not eligible for primary effectiveness endpoint analysis. The resulting freedom from a primary endpoint event was 76.8% (73/95), and the corresponding 95% lower confidence limit was 68.6% which did not exceed the performance goal of 80%. For the T12M analysis, seventeen (17) subjects were not eligible for primary effectiveness endpoint analysis. The resulting freedom from a primary endpoint event through 12 months was 73.7% (70/95), and the corresponding 95% lower confidence limit was 65.2% which did not exceed the performance goal of 80%.

Tipping Point Analysis

To further contextualize the risk of noncompliance on the endpoint results, tipping point analyses were performed which incorporated simulated failure rates among the subjects with unknown endpoint outcomes into the effectiveness results. The failure threshold among the missing subjects, at which point the performance goal would not be met, was 9/18 (≥ 50.0%) in the protocol analysis and 5/17 (≥ 29.4%) in the T12M analysis.

Of note, none of the subjects excluded from the protocol or T12M analyses went on to have an event at a later time point. Additionally, none of the subjects missing the required baseline CT image (within the first 90 post-operative days) experienced migration or AAA expansion relative to their first available post-operative CT. Considering the absence of these events, along with the observed rate of primary effectiveness events (Protocol: 5.2%; T12M: 10.3%), it is unlikely the tipping point thresholds (Protocol: 50.0%, T12M: 29.4%) would be reached among the subjects not evaluated.

Device Effectiveness Outcomes

Key Device Effectiveness outcomes, including Core lab-evaluated imaging findings and CEC-adjudicated clinical events are summarized in **Table 21** through all available follow-up. Change in AAA diameter measured by Core lab at each follow-up period are summarized in **Table 22**. Reinterventions through all available follow-up are summarized by type in **Table 23**. Imaging Findings and Clinical Events observed through all available follow-up are as follows:

**Device Integrity**

There have been no (0) cases of wire fracture or extrusion/erosion, and one (1) case of device compression. This event was considered an unanticipated adverse device effect (UADE) and involved an acute Type A aortic dissection that extended down to the abdominal aorta. The resulting multi-lumen aorta compressed the study device and led to a loss of patency for all device

components. Treatment for this event included open surgical repair of the thoracic aorta in addition to bilateral axillofemoral bypass without device explant.

**Stent Graft Patency and Lumen Obstruction**
One (1) subject has experienced lumen obstruction and loss of patency (See 'Device Integrity' above).

**Migration**
There have been no (0) cases of prosthesis or intercomponent migration ≥ 10 mm as evaluated by the Core Lab.

**Endoleak**

**Type I Endoleak**
Four (4) subjects have experienced a Type Ia endoleak and no (0) subjects have experienced a Type Ib endoleak reported by the Core Lab. All Type Ia endoleaks were identified within the first 6 months and resolution without reintervention was observed among the 3 subjects with available follow-up imaging. None (0) have experienced Core lab reported aneurysm enlargement.

Procedural Type Ia endoleak was observed by investigators at completion angiography for two additional subjects (See Technical Success discussion above, **Table 14**). Both cases resolved without treatment prior to the first post-operative imaging assessment and were therefore not observed nor reported by the Core lab in the table below.

**Type II Endoleak**
In the High Neck Angulation Substudy, 52 subjects have experienced a Type II endoleak reported by the Core Lab. Among these subjects, 15 have experienced Core Lab reported aneurysm enlargement and 12 have undergone reintervention.

**Type III Endoleak**
There have been no (0) Type III endoleaks as evaluated by the Core Lab.

**Type IV Endoleak**
There have been no (0) Type IV endoleaks as evaluated by the Core Lab.

**Indeterminate Endoleaks**
Fifteen (15) subjects have had an indeterminate endoleak reported by the Core Lab at any point in the study.

**AAA Expansion (≥ 5 mm)**
There have been 16 subjects with a AAA expansion measured by the Core Lab relative to the post-operative baseline CT (≤90 days). Among these subjects, the Core Lab has reported 15 subjects with Type II endoleak and no (0) subjects with Type I, Type III, or Type IV endoleak. Six (6) subjects with reported an indeterminate endoleak also had sac expansion, five of which had Type II endoleak(s) reported at other imaging visit(s); the sixth subject had a one-time aneurysm increase of 5.1mm and subsequent aneurysm decrease (-3.7mm, relative to baseline) without treatment.

Eight (8) subjects with AAA enlargement have undergone reintervention.

Five additional subjects obtained their first post-operative baseline outside of the protocol-required 90-day window; none of the three subjects with a subsequent follow-up image experienced expansion relative to their first available CT.

**AAA Rupture**

No (0) subjects in the High Neck Angulation Substudy have experienced AAA rupture by either Core Lab or CEC adjudication.

**Reintervention**

Thirteen (13) subjects have undergone a total of 23 reinterventions as adjudicated by an independent Clinical Events Committee (CEC), with 3 of these subjects experiencing reintervention on more than one occasion. Ten (10) subjects have undergone embolization procedures to repair endoleak or pseudoaneurysm, and 6 subjects have received additional stenting for the treatment of endoleak, device kink, internal iliac pseudoaneurysm, renal artery occlusion, and/or superior mesenteric arterial stenosis.

**Conversion to Open Repair**

Two (2) subjects in the High Neck Angulation Study have undergone a reintervention which met the definition of conversion to open repair as adjudicated by an independent Clinical Events Committee (CEC). One subject underwent open surgical repair on POD 50 to treat an abdominal aortic graft occlusion in the context of a Type A aortic dissection. One subject experienced a conversion to open repair on POD 1266 for a persistent Type II endoleak.

**Table 21. Summary of Device Effectiveness Outcomes (Core Lab/CEC-adjudicated)**

| | Post Treatment Follow-up Period | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Procedure / Post-Procedure[1]** | **1 Month** | **6 Months** | **12 Months** | **24 Months** | **36 Months** | **48 Months** | **60 Months** | **Total** |
| **Number of Subjects** | 95 | 95 | 95 | 92 | 79 | 55 | 24 | 4 | 95 |
| **Imaging Findings[2]** | | | | | | | | | |
| **Lumen Obstruction (i.e., Stenosis)** | | 1/83 (1.2%) | - | - | - | - | - | - | 1 |
| **Device Compression (i.e., Kink)** | | 1/84 (1.2%) | - | - | - | - | - | - | 1 |
| **Non-patent Component** | | 1/83 (1.2%) | - | - | - | - | - | - | 1 |
| Non-patent Trunk-Ipsilateral Leg | | 1/83 (1.2%) | - | - | - | - | - | - | 1 |
| Non-patent Contralateral Leg | | 1/83 (1.2%) | - | - | - | - | - | - | 1 |
| Non-patent Iliac Extension | | 1/67 (1.5%) | - | - | - | - | - | - | 1 |
| **Extrusion/Erosion** | | - | - | - | - | - | - | - | 0 |
| **Wire Fracture[3]** | | - | - | - | - | - | - | - | 0 |
| **Migration[4]** | | Baseline | - | - | - | - | - | - | 0 |

| | Post Treatment Follow-up Period | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | **Procedure / Post-Procedure[1]** | **1 Month** | **6 Months** | **12 Months** | **24 Months** | **36 Months** | **48 Months** | **60 Months** | **Total** |
| Prosthesis Migration≥ 10mm | | Baseline | - | - | - | - | - | - | 0 |
| Intercomponent Migration≥ 10mm | | Baseline | - | - | - | - | - | - | 0 |
| **Endoleak** | | 43/81 (53.1%) | 34/77 (44.2%) | 31/73 (42.5%) | 18/54 (33.3%) | 14/38 (36.8%) | 7/14 (50.0%) | 1/1 (100.0%) | 58 |
| Type I | | 1/81 (1.2%) | 3/77 (3.9%) | - | - | - | - | - | 4 |
| Type IA | | 1/81 (1.2%) | 3/77 (3.9%) | - | - | - | - | - | 4 |
| Type IB | | - | - | - | - | - | - | - | 0 |
| Type II | | 35/81 (43.2%) | 29/77 (37.7%) | 29/73 (39.7%) | 15/54 (27.8%) | 14/38 (36.8%) | 6/14 (42.9%) | 1/1 (100.0%) | 52 |
| Type III | | - | - | - | - | - | - | - | 0 |
| Type IV | | - | - | - | - | - | - | - | 0 |
| Indeterminate | | 7/81 (8.6%) | 5/77 (6.5%) | 2/73 (2.7%) | 3/54 (5.6%) | - | 1/14 (7.1%) | - | 15 |
| **AAA Expansion ≥ 5mm[4]** | | Baseline | 1/76 (1.3%) | 1/75 (1.3%) | 11/58 (19.0%) | 8/42 (19.0%) | 2/15 (13.3%) | - | 16 |
| **Clinical Events[5]** | | | | | | | | | |
| **Reintervention** | - | 2/95 (2.1%) | 2/95 (2.1%) | 3/92 (3.3%) | 5/79 (6.3%) | 4/55 (7.3%) | 1/24 (4.2%) | - | 13 |
| **Conversion to Open Repair** | - | 1/95 (1.1%) | - | - | - | 1/55 (1.8%) | - | - | 2 |
| **AAA Rupture[6]** | - | - | - | - | - | - | - | - | 0 |
| **Aneurysm-Related Mortality** | - | - | - | - | - | - | - | - | 0 |

[1]No imaging visit was required in the Procedure (Day 0) or Post-Procedure Analysis Window (Day 1-14); these windows have been combined as no clinical events were observed in either window (Day 0-14).
[2]Imaging findings are reported by an independent Core Lab. Denominators are number of subjects with an evaluable result for specified parameter (see **Table 5**). Per protocol, imaging findings for subjects who are post-conversion to open repair (as adjudicated by CEC) are not included. Numerators report any scan in window with a device event.
[3]Wire fracture was considered assessed and included in denominator if any fracture was present or at a minimum the non-overlap areas of investigational device could be assessed.
[4]Subject must have a post-operative baseline and post-baseline image to be evaluable.
[5]Clinical Events are site-reported adverse events adjudicated by an independent Clinical Events Committee. Denominator is the number of subjects at risk in window, inclusive of subjects who are post-conversion to open repair (as adjudicated by CEC).
[6]AAA Rupture may be reported by either Core Lab imaging evaluation or by site-reported, CEC-adjudicated adverse event.
Study period definitions: Procedure (0 days) Post-Procedure (1-14 days) 1 Month (15-59 days) 6 Months (60-242 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)

## Table 22. Change in Maximum Aortic Diameter from Baseline

| | 6 Months | 12 Months | 24 Months | 36 Months | 48 Months | 60 Months |
|---|---|---|---|---|---|---|
| **Number of Subjects with Available Data[1]** | 76 | 75 | 58 | 42 | 15 | 1 |
| | | | | | | |
| **Change in Maximum Abdominal Aortic Diameter from Baseline (Core Lab)** | | | | | | |
| ≥ 5mm Decrease | 22(28.9%) | 26(34.7%) | 27(46.6%) | 19(45.2%) | 8(53.3%) | 0 |
| No Change | 53(69.7%) | 48(64.0%) | 21(36.2%) | 15(35.7%) | 5(33.3%) | 1(100.0%) |

| | 6 Months | 12 Months | 24 Months | 36 Months | 48 Months | 60 Months |
|---|---|---|---|---|---|---|
| ≥ 5mm Increase | 1(1.3%) | 1(1.3%) | 10(17.2%) | 8(19.0%) | 2(13.3%) | 0 |

[1]Subjects must have post-operative baseline ≤90 days and a post-baseline measurement to be available for evaluation. Additional observations among 3 evaluable subjects with post-operative baseline >90 days include: 6 Months (No Change, n=2); 12 Months (No Change, n=2); 24 Months (≥5mm Decrease, n=1; No Change, n=1 ; 36 Months (≥5mm Decrease, n 1

Study period definitions: 6 Months(60-242 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)
If multiple observations are contained within a single study window, the observation closest to the target study window date is used. Per protocol, imaging findings for subjects who are post-conversion to open repair (as adjudicated by CEC) are not included.

## Table 23. Summary of Reinterventions for High Neck Angulation Substudy

| | Post Treatment Follow-up Period | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Procedure | Post-Procedure | 1 Month | 6 Months | 12 Months | 24 Months | 36 Months | 48 Months | 60 Months | Total |
| **Number of Subjects** | 95 | 95 | 95 | 95 | 92 | 79 | 55 | 24 | 4 | 95 |
| **Subjects with Any Reintervention** | 0(0%) | 0(0%) | 2(2.1%) | 2(2.1%) | 3(3.3%) | 5(6.3%) | 4(7.3%) | 1(4.2%) | 0(0%) | 13 |
| Conversion to open repair | - | - | - | - | - | - | 1(1.8%) | - | - | 1 |
| Open Surgical Repair without EXCC Device Explant | - | - | 1(1.1%) | - | - | - | - | - | - | 1 |
| Embolization[1] | - | - | - | 1(1.1%) | 3(3.3%) | 5(6.3%) | 2(3.6%) | 1(4.2%) | - | 10 |
| Stent | - | - | 1(1.1%) | 2(2.1%) | - | - | - | - | - | 3 |
| Stent Graft – Abdominal, Distal Extension | - | - | - | 1(1.1%) | - | 2(2.5%) | - | - | - | 3 |
| Stent Graft – Peripheral | - | - | - | 1(1.1%) | - | - | - | - | - | 1 |
| Other surgery, treatment, or procedure[2] | - | - | 1(1.1%) | - | - | - | 1(1.8%) | - | - | 2 |
| **Total Number of Reinterventions** | 0 | 0 | 3 | 5 | 3 | 7 | 4 | 1 | 0 | 23 |

[1] Includes: coil, glue, plug, and liquid embolic system
[2]'Other' includes Aorta-Femoral Bypass n 1 , Common Iliac Aneurysm Repair n 1
Adverse events and treatments are reported by Site and adjudicated by an independent Clinical Events Committee (CEC).
Column header counts and denominators are the number of subjects at risk at the start of each interval.
Study period definitions: Procedure (0 days) Post-Procedure (1-14 days) 1 Month (15-59 days) 6 Months (60-242 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)

Site Imaging Findings

The sites reported comparable incidences of endoleak and sac expansion relative to the Core Lab assessment reported previously (**Table 24**). The site reported 6 subjects with Type I endoleak, two of which had procedural endoleaks which resolved prior to the initial Core Lab imaging assessment performed at 1-month. Sites reported Type II endoleak in 47 subjects and Core Lab reported 52 subjects. No Type III or Type IV endoleak were reported by either assessor. Indeterminate endoleaks (site, n=1; Core Lab n=15) were a category used nearly exclusively by Core Lab as evaluations are done on a per image basis and independent of previous scans; whereas, site investigators are more likely to clearly attribute endoleak source by referencing prior images. The sites measured AAA expansion in 18 subjects and the Core Lab identified expansion in 16 subjects.

**Table 24. Comparison of Outcomes by Assessor (Cumulative)**

| | Site | Core Lab |
|---|---|---|
| **Endoleak[1]** | | |
| **Type I** | 6* | 4 |
| **Type II** | 47 | 52 |
| **Type III** | 0 | 0 |
| **Type IV** | 0 | 0 |
| **Indeterminate** | 1 | 15 |
| **AAA Expansion ≥ 5mm** | 18 | 16 |

[1]Sites reported endoleak as adverse events beginning at procedure, Core Lab performed CT imaging assessment beginning at the first post-operative (1-month) visit.
*includes two procedural endoleaks not present at the first post-operative scan (thus not available for Core Lab assessment)

Secondary Effectiveness Endpoint Results

In addition to the primary effectiveness endpoints, a second group of effectiveness endpoints was assessed for the study at each study follow-up interval. The endpoints were reported descriptively and independent of the performance goals. The secondary effectiveness endpoints were presented above:

- Aneurysm-related mortality (**Table 19**)
- Stent fracture based on Core Lab analysis (**Table 21**)
- Individual elements of the primary safety (**Table 16**) and effectiveness (**Table 21**) endpoints
- Reintervention (**Table 23**)
- Type II endoleak (**Table 21**)
- Type IV endoleak (**Table 21**)
- Index Procedure Blood Loss (**Table 12**)
- Index Procedure Time (**Table 12**)
- Length of Hospital Stay (initial hospitalization) (**Table 13**)

3. Subgroup Analyses

The following preoperative characteristics were evaluated for potential association with outcomes: sex at birth and race. Additionally, outcomes were examined among subjects presenting with both highly angulated (> 60°) and short (< 15 mm) necks. The study was not powered for these subgroup analyses.

Endpoint Analysis by Sex

Subject sex at birth was evaluated for potential association with endpoint success. There were no statistically significant differences in primary safety or primary effectiveness outcomes.

100% of females and 95.7% of males were free from a primary safety endpoint event p=1.000) and 89.5% of females and 96.6% of males were free from a primary effectiveness endpoint event (p=0.253).

Endpoint Analysis by Race

Descriptive analysis of the endpoints was performed by the Subjects' Race for U.S. Sites. For analysis of the 30-day Primary Safety Endpoint, 92 of 95 subjects were available for assessment. Eighty-nine subjects (89/92, 96.7%) experienced freedom from a primary safety event. Based on subject assessment availability for each race, 100% of Black or African American (2/2), American Indian or Alaska Native (1/1), and Other Race subjects (4/4), and 96.5% of eligible White subjects (82/85), experienced freedom from safety endpoint events.

For analysis of the 12-month Primary Effectiveness Endpoint, 77 of 95 subjects were available for assessment. Seventy-three subjects (73/77, 94.8%) experienced freedom from an endpoint event. Based on subject assessment availability for each race, 100% of American Indian or Alaska Native (1/1) and Other Race subjects (3/3), 95.8% of White subjects (68/71), and 50% of Black or African American subjects (1/2) experienced freedom from a primary effectiveness endpoint event.

Outcomes among HNA Substudy Subjects with Short (< 15 mm) Aortic Necks

There were 21 subjects enrolled with both highly angulated and short (< 15 mm) necks. All evaluable subjects experienced freedom from primary safety endpoint (100%, 20/20) and primary effectiveness endpoint (Protocol & T12M: 100%, 17/17) . Additional follow-up among this cohort (median 3.2 years) indicates that the EXCC device provides a repair option for this sub-population with on-going freedom from Type Ia endoleaks and device migration, failure modes of particular interest for patients with highly angulated and shorter aortic neck anatomy. One subject has received a reintervention (endovascular embolization procedure associated with Type II endoleak) and there have been no instances of conversion to open repair, AAA rupture, or aneurysm-related mortality across all follow-up periods.

4. Pediatric Extrapolation

In this premarket application, existing clinical data was not leveraged to support approval of a pediatric subject population.

## XI. Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 292 investigators of which 0 were full-time or part-time employees of the sponsor and 10had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: 0
- Significant payment of other sorts: 10

- Proprietary interest in the product tested held by the investigator: 0
- Significant equity interest held by investigator in sponsor of covered study: 0

The applicant has adequately disclosed the financial interest/arrangements with clinical investigators. Statistical analyses were conducted by FDA to determine whether the financial interests/arrangements had any impact on the clinical study outcome. The information provided does not raise any questions about the reliability of the data.

## XII. SUMMARY OF SUPPLEMENTAL CLINICAL INFORMATION

Following initial device approval (Original PMA, P200030), subjects of the Short Neck Substudy continued to be followed longer term. Of particular interest for the current indication expansion were subjects who had neck lengths 10 mm to 15 mm. There were 23 subjects in this group as reported by Gore Imaging Sciences. With a median follow-up of 1446 days (4.0 years), device performance in the longer term included the following key outcomes of interest:

- No reported aneurysm-related mortality, AAA rupture, conversion to open repair, loss of patency, migration, or device integrity events.
- No reported Type I or III endoleaks.
- Reinterventions have been performed in two subjects each noted to have aneurysm enlargement in the presence of a Type II endoleak and treated with coil embolization(s). No other subjects have reported aneurysm enlargement.

## XIII. PANEL MEETING RECOMMENDATION AND FDA'S POST-PANEL ACTION

In accordance with the provisions of section 515(c)(3) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

## XIV. CONCLUSIONS DRAWN FROM PRECLINICAL AND CLINICAL STUDIES

### A. Effectiveness Conclusions

The primary effectiveness endpoint was analyzed for all evaluable subjects. The study successfully met the primary effectiveness endpoint performance goal of 80%. Per protocol analysis, the percentage of subjects free from a primary effectiveness endpoint event was 94.8% (lower confidence limit: 88.5%). Per the supplemental Through 12 Month (T12M) analysis, the percentage of subjects free from a primary effectiveness endpoint event was 89.7% (lower confidence limit: 82.3%).

Technical success was achieved in 97.9% of subjects, with two (2) subjects experiencing Type Ia endoleak observed by the investigator at the conclusion of the study procedure (both cases resolved without treatment prior to the first post-operative imaging assessment). One (1) subject was converted to open repair 50 days post-procedure due to a Type A aortic dissection in the thoracic aorta resulting in stent graft occlusion, and one (1) subject experienced sac expansion at 12 months associated with a Type II endoleak. Additional primary endpoint events evaluated by Core Lab through 12 months follow-up

included one (1) additional subject with sac expansion at 6 months associated with a Type II and indeterminate endoleak, and four (4) subjects with Type Ia endoleak. All Type Ia endoleaks were identified within the first 6 months and none had associated reintervention. Resolution without recurrence was observed among the 3 subjects with available follow-up imaging; the fourth subject died of coronary thrombosis prior to the next follow-up. Cumulative events observed through 12 months include (Core Lab reported): Type I endoleak in 4 of 75 subjects (5.3%), Type II endoleak in 50 of 83 subjects (60.2%), AAA expansion in 2 of 76 subjects (2.6%), and reintervention in 7 of 92 subjects (7.6%). Through 12 months, there were no Type III endoleaks, migration, wire fracture or rupture reported.

Mid-term (24-60 month) follow-up results include one (1) additional conversion to open repair to treat a persistent Type II endoleak. The Core Lab has not reported any Type I or III endoleaks, migration, or wire fracture in this period. The total number of subjects that have reported sac expansion through 60 months is 16, with the majority of sac expansions being attributed to a Type II endoleak.

While the High Neck Angulation (HNA) and Short Neck (SN) substudies (see P200030) both met the primary effectiveness endpoint performance goal of 80%, select events were reported more in the HNA substudy than the SN substudy: notably, post procedural Type Ia endoleaks (5.3% (4/75) vs 0.0% (0/67) and reintervention (7.6% (7/92) vs 2.5% (2/79)) through 12 month follow-up. As described above, the HNA post procedural Type Ia endoleaks resolved without reintervention and all (4/4) have stable or decreasing aneurysms through all available follow-up. For the HNA subjects that underwent reintervention in the first year, all (7/7) are free from aneurysm rupture and aneurysm-related mortality through all available follow-up.

Based on the clinical endpoint outcomes presented above, there is reasonable assurance of the effectiveness of the GORE® EXCLUDER® Conformable AAA Device for the proposed intended use.

## B. Safety Conclusions

The risks of the device are based on nonclinical laboratory and animal testing, as well as data collected in a clinical study conducted to support PMA approval as described above. The study successfully met the primary safety endpoint performance goal of 79%. The percentage of subjects free from a primary safety endpoint event was 96.7% (lower confidence limit: 91.8%), with three subjects experiencing procedural blood loss > 1000 mL.

There were 8 of 94 evaluable subjects (8.5%) who experienced MAE(s) in the first year, including death unrelated to device/ procedure (5/95, 5.3%), procedural blood loss >1000 mL (3/95, 3.2%), respiratory failure (2/95, 2.1%), and myocardial infarction (1/95, 1.1%). Twenty-two (22) additional subjects experienced events beyond 1-year including: death unrelated to device/procedure (n=20 , respiratory failure (n 7), myocardial infarction n=1), and renal failure (n 1).

There were 2 subjects who experienced a device-related SAE over the course of the study, including Type I endoleak (n=1 and device kink (n=1).

There was one observed event in the study that was in relation to device occlusion which is discussed in the study results section. This event involved an acute Type A aortic dissection that extended down to the abdominal aorta. The resulting multi-lumen aorta compressed the study device and led to a loss of patency for all device components. Treatment for this event included open surgical repair of the thoracic aorta in addition to bilateral axillofemoral bypass without device explant.

While the High Neck Angulation (HNA) and Short Neck (SN) (see P200030) substudies both met the primary safety endpoint performance goal of 79%, MAEs (8.5% (8/94) vs 3.8% (3/79)) and more specifically procedural blood loss > 1000 mL (3.2% (3/92) vs 0% (0/79) occurred more in the HNA substudy compared to the SN substudy through one year follow-up. As described above, the most common MAE within the first year was death unrelated to the device/procedure and may reflect the more advance state of disease among this patient subpopulation. All instances of procedural blood loss > 1000 mL in the HNA were attributed to the access site complications unrelated to the EXCC device and the median procedural blood loss was consistent between the HNA and SN substudies (50.0 mL vs 50.0 mL). While not linked to a safety endpoint, the median procedure time in the HNA substudy was longer than the SN substudy (110 minutes vs 84 minutes). The increased procedure time in the HNA substudy reflects the complexity of the treated anatomy and the increased component usage as required by patient anatomy.

The outcomes presented above demonstrate a reasonable assurance of the safety of the GORE EXCLUDER Conformable AAA Device for the proposed intended use.

## C. Benefit-Risk Determination

The probable benefits of the device based on the data collected in High Neck Angulation (HNA) substudy conducted to support PMA approval is described above.

The EXCC device (originally approved in P200030) consists of standard endovascular graft technology, that incorporates design modifications into the commercially available GORE Excluder device. The design modifications maintain an infrarenal AAA treatment option and incorporate delivery system features intended to aid stent graft repositioning and deployment accuracy in challenging anatomy. As such, the data provides reasonable assurance of safety and effectiveness in a broad range of AAA anatomy inclusive of patients with highly angulated necks that meet the study selection criteria.

As assessed by Core Lab and through the duration of available follow-up, there have been four Type I endoleaks, no Type III endoleaks, no device migrations, no stent fractures, no aneurysm ruptures, and two instances of conversion to open repair (discussed above). Additionally, there have been no instances of aneurysm-related mortality and the majority of subjects (72 of 88 subjects available for analysis) had aneurysms that decreased or remained stable in diameter.

The probable risks of the EXCC device are also based on data collected in the HNA substudy conducted to support PMA approval as described above. The most frequently observed procedure and device-related risks include Type II endoleaks, AAA expansion, and reinterventions as described above. Available clinical data lacks longer-term follow-

up information and limited usage of the large-diameter devices (due to limited anatomical applicability within the patients that participated in the study) and as such are sources uncertainty with respect to EXCC device performance.

Additional factors to be considered in determining probable benefits and risks for the EXCC device in patients with aortic neck lengths between 10mm and 15mm include:

Longer term data from 23 subjects in the Short Neck (SN) Substudy with aortic neck lengths 10mm to 15mm were provided. As assessed by Core Lab and with a median follow-up of 4.0 years, there have been no Type I endoleaks, no Type III endoleaks, no device migrations, no stent fractures, no aneurysm rupture, and no instances of conversion to open repair. Additionally, there have been no instances of aneurysm-related mortality and the majority of subjects (19 of 21 subjects available for analysis), had aneurysms that decreased or remained stable in diameter.

1. Patient Perspectives

This submission did not include specific information on subject perspectives

In conclusion, given the available information above, the data support that, for the endovascular treatment of subjects with infrarenal abdominal aortic and aorto-iliac aneurysms, the probable benefits outweigh the probable risks.

### D. Overall Conclusions

The data in this application support the reasonable assurance of safety and effectiveness of the device when used in accordance with the indications for use.

## XV. CDRH DECISION

CDRH issued an approval order on April 5, 2024. The final clinical conditions of approval cited in the approval order are described below.

Gore has agreed to provide a Clinical Update to physician users at least annually. At a minimum, this update will include a brief description of the IDE and Post-Approval studies, including study design, progress, and the results available to date for clinical evaluations of the device. This clinical update should also include a brief description of any recalls and safety notices. Additional learnings from commercial experience within and outside the United States, a summary of any explant analysis findings and a high-level discussion of any critical publications that discuss safety and performance of the device is also to be included. The clinical update for physician users and the information supporting the updates must be provided in the Annual Report.

In addition to the Annual Report requirements, Gore has agreed to provide the following data in post-approval study (PAS) reports.

1. *Continued Follow-up of the IDE Study Subjects*: This is a prospective, multi-center study that consists of continued follow-up of all available subjects from the AAA 13-03 pivotal study. A total of 175 subjects were enrolled in the study and remaining subjects will be followed annually for 5 years. Events reported through 5 years will

include major adverse events, all-cause mortality, aneurysm-related mortality, aneurysm rupture, secondary interventions, conversion to open surgery, losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (≥ 5 mm), stent graft migration (≥ 10 mm), all types of endoleaks, and other device-related events. No formal hypothesis testing will be performed for the longer-term follow-up. Outcomes will be reported using descriptive statistics annually.

2. *Post Approval Surveillance – Gore Together Registry*: This is a prospective, observational post-market registry collecting outcomes through 10-years post procedure for subjects treated with the EXCC device. The objective of the registry is to collect mid- and long-term post-market clinical follow-up data for the EXCC device used in real-world practice. The data collection will incorporate diversity, equity and inclusion concepts in supporting descriptions of underrepresented populations in EVAR; additionally, the effort will involve various institution types (e.g., urban, rural, academic, private), a wide geographic distribution, and physicians with a range of EVAR experience. The registry will consecutively enroll subjects treated with the EXCC device and meeting registry selection criteria at participating sites. To address outstanding uncertainty in certain populations, the following minimum enrollment numbers will be met:

   - US enrollment will include a minimum of 16% female and 7% non-white populations.
   - 40 subjects with 60°- 90° infrarenal aortic neck angulation.
   - 26 subjects with ≥ 10 mm to < 15 mm aortic neck length
   - 40 subjects implanted with either a 32 mm or 36 mm CEXC trunk (with or without an Aortic Extender).

Follow-up will be completed per each participating site's standard of care (SOC). Gore will encourage follow-up and imaging in alignment with the device labeling and professional society guidelines. Imaging outcomes will be site reported, unless a post-market signal is identified which warrants core lab review. The study will have a maximum of 110 clinical centers in North America, Europe and Asia-Pacific regions with a minimum of 40 US sites and 300 US patients. The data collection will include, but not be limited to, patient demographic, clinical, anatomic, and procedural characteristics, device-specific information such as device model (e.g., unique device identifier) and the following outcomes through 10-years (unless otherwise specified): technical success (index procedure), major adverse events (through 30-days), all-cause mortality, aneurysm-related mortality, secondary interventions (reason for and type), conversion to open surgery, losses of device integrity, device occlusions, stenosis or kink, aneurysm enlargement (> 5 mm), stent graft migration (> 10 mm), all types of endoleaks, and other device-related events. Data collection (i.e., case report forms) and endpoint definitions for relevant endpoints will be consistent with reporting standards with long-term outcome data focused on detecting notable rates of device events for further investigation. Gore will make available outcome data to EVAR-industry related reporting initiatives as they

are implemented. Together Registry data contributions should be similar to those available from the Long-term EVAR Assessment and Follow-up (LEAF) initiative. Outcomes will be reported using descriptive statistics. Subgroup analyses and missing data analysis will be prospectively planned.

The applicant's manufacturing facilities have been inspected and found to be in compliance with the device Quality System (QS) regulation (21 CFR 820).

## XVI. APPROVAL SPECIFICATIONS

Directions for use: See device labeling.
Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events in the device labeling.
Post-approval Requirements and Restrictions: See approval order.

## XVII. REFERENCES

1. Chaikof EL, Blankensteijn JD, Harris PL, White GH, Zarins CK, Bernhard VM, et al. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg. 2002;35(5):1048-60.

2. Goodney P, Mao J, Columbo J, Suckow B, Schermerhorn M, Malas M, et al. Use of linked registry claims data for long term surveillance of devices after endovascular abdominal aortic aneurysm repair: observational surveillance study. BMJ. 2022;379.