7240201.3

Instructions for Use
INCRAFT® AAA Stent Graft System

Explanation of symbols on labels and packaging:

	**Manufacturer**
	**Use-by date**
	**Catalogue number**
	**Lot number**
	**MR Conditional**
	**Upper limit of temperature**
	**Sterilized using ethylene oxide**
	**Caution: Federal (USA) law restricts this device to sale by or on order of a physician.**
	**Do not re-sterilize**
	**Do not re-use**
	**Caution, consult Instructions for Use.**
	**Keep away from sunlight**
	**Keep dry**
	**Do not use if package is damaged**
	**Serial number**
	**OK for use**
	**Do not use**

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1 DEVICE DESCRIPTION

The **INCRAFT® AAA Stent Graft System (INCRAFT)** is a modular bifurcated endovascular stent graft system that is used for the treatment of infrarenal abdominal aortic aneurysms.

INCRAFT is comprised of 2 main types of devices: the **INCRAFT** Stent Graft and the **INCRAFT** delivery system. The stent graft is preloaded into the delivery system and advanced to the intended location under fluoroscopy where it is deployed to create a new blood flow channel that excludes the aneurysm from blood flow and pressure.

1.1 Stent Graft System

INCRAFT (**Figure 1**) is typically assembled from 3 main components: an aortic bifurcate prosthesis and 2 iliac limb prostheses. In addition, to extend the implant in a caudal direction, an iliac limb prosthesis can also be used as iliac extension prosthesis.

> **Note:** When describing the orientation of this product, cranial refers to the portion of the prosthesis that is closer to the head of the patient. Caudal refers to the portion of the prosthesis that is closer to the foot of the patient.

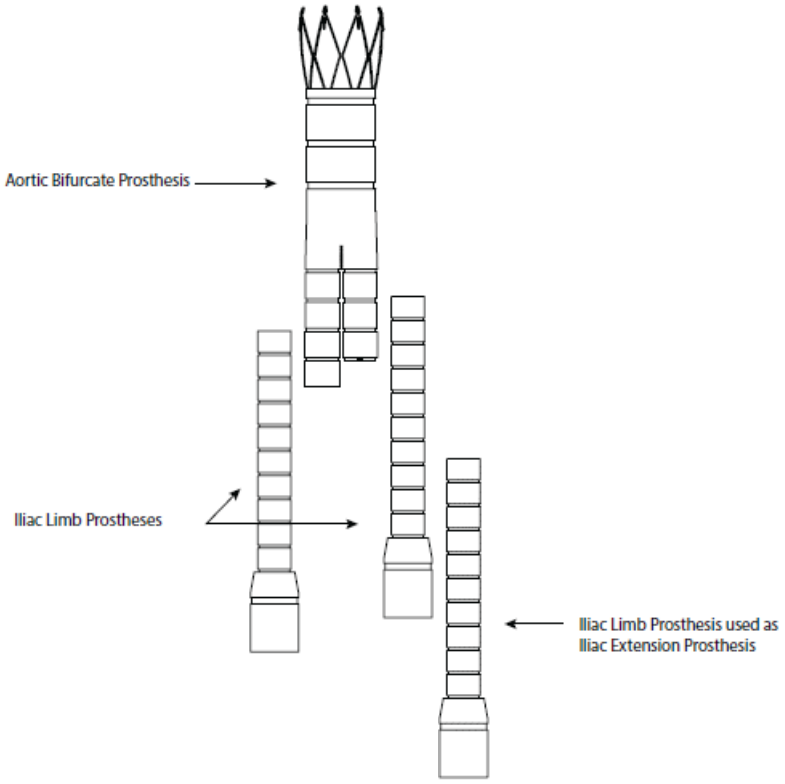


Figure 1. Components of the INCRAFT AAA Stent Graft System

Note: For illustration purposes only, the 16 mm iliac limb prosthesis is presented as the iliac extension prosthesis.

Each prosthesis is constructed of a seamless, low porosity, woven polyester graft supported by a series of short, electropolished, laser-cut, self-expanding Nitinol stent-rings throughout the entire

length. The Nitinol stent-rings are sutured to the inner surface of the graft material. In addition to the stents being visible under fluoroscopy, radiopaque markers are sewn onto each component to aid visualization and to facilitate accurate placement. **Table 1** provides a summary of the **INCRAFT** Stent Graft System materials.

Table 1. Stent Graft Materials

Implant Component	Material
Stent	Nickel-Titanium (Nitinol) Alloy
Graft	Polyethylene terephthalate (PET)
Sutures	Polyethylene terephthalate (PET) / Polytetrafluoroethylene (PTFE)
Marker Bands (AB / IL)	Tantalum
Marker Bands (AB)	Platinum-Iridium Alloy

Note: The stent graft is not made with natural rubber latex.

1.1.1 Aortic Bifurcate Prosthesis

The aortic bifurcate prosthesis (**Figure 2**) is deployed first into the cranial portion of the infrarenal aorta. It has a flared bare transrenal stent with 8 or 10 laser-cut barbs depending on the cranial diameter. The barbs help keep the prosthesis in place.

The aortic bifurcate prosthesis has 1 main trunk with 2 sealing stents and a taper stent that divides into the ipsilateral and contralateral legs, supported by a series of z-stents. While the diameter of the trunk varies by product code, the lengths of the trunk (49 mm) and legs (45 mm on the ipsilateral side and 37 mm on the contralateral side), as well as the diameters of the legs (11 mm) are constant. The aortic bifurcate prosthesis is manufactured in 4 trunk diameter sizes (22, 26, 30 and 34 mm). Refer to **Table 24** for the aortic bifurcate prosthesis dimension sizing guide.

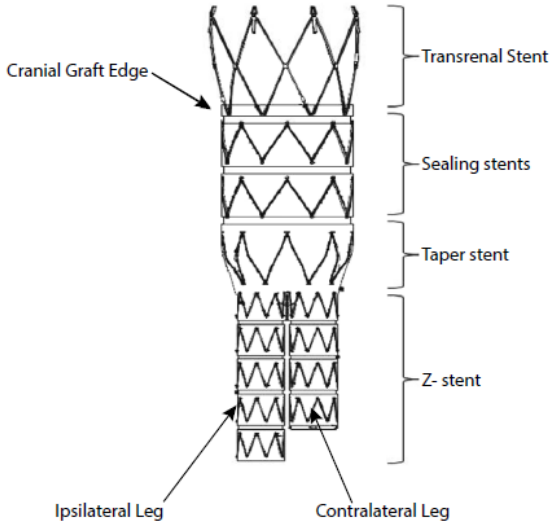


Figure 2. Aortic Bifurcate

1.1.2 Iliac Limb Prosthesis

The iliac limb prostheses (**Figure 3**) are deployed into the legs of the aortic bifurcate prosthesis and into the ipsilateral and contralateral iliac vessels. The overlap between the aortic bifurcate prosthesis and the iliac limb prosthesis can vary between 2 cm and 5 cm on the ipsilateral side, and between 2 cm and 4 cm on the contralateral side.

The iliac limb prostheses could also be used as iliac extensions by placing them into a previously deployed iliac limb prosthesis to gain additional exclusion length.

> **Note**: The 10 mm iliac limb prosthesis cannot be extended by design as the cranial diameter for all the iliac limb prostheses is 13 mm.

The iliac limb prosthesis has a series of z-stents cranially, 1 or more taper stents (if other than a straight configuration), and a diamond sealing stent caudally. The cranial diameter is always constant at 13 mm while the length and the caudal diameter of the iliac limb prosthesis could vary by code. The iliac limb prostheses are available in 5 different caudal diameters (10, 13, 16, 20 and 24 mm) and in 4 different lengths (8, 10, 12, and 14 cm) except for the 24 mm x 8 cm code that does not exist. Refer to **Table 25** for the iliac limb sizing guide.

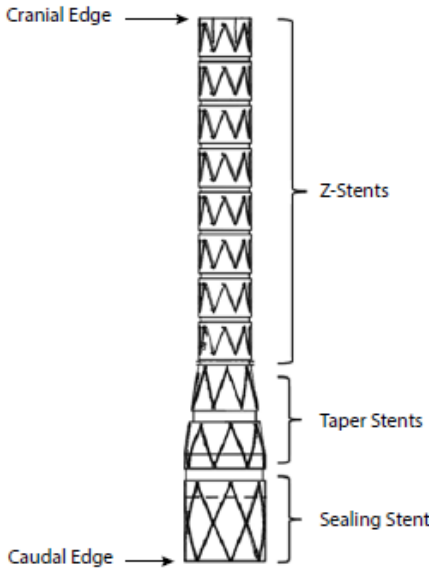
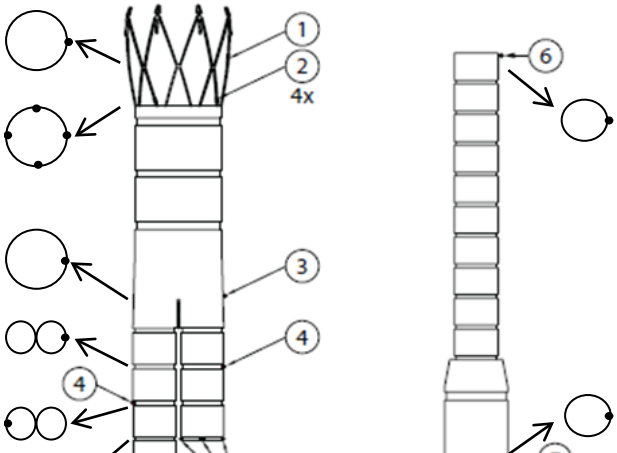


Figure 3. Iliac Limb

Radiopaque markers provide a reference for proper alignment when deploying the prosthesis components (**Figure 4**).

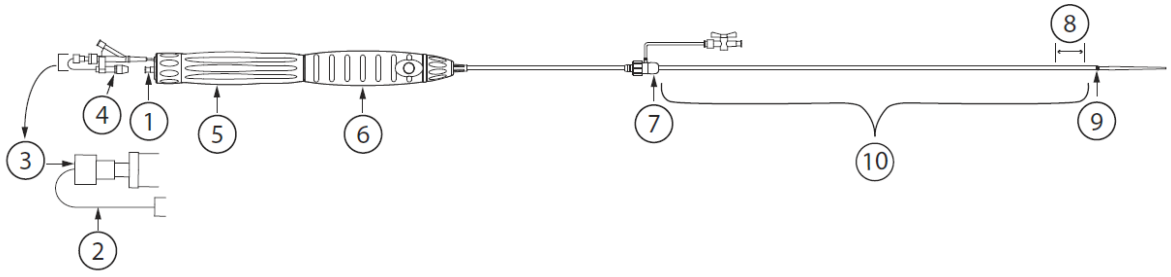


Marker	Material	Configuration
1. Contralateral side marker	Tantalum	Cylindrical marker crimped onto stent strut
2. Bifurcate cranial edge markers	Tantalum	Cylindrical marker crimped onto stent strut. Graft edge begins below and within 1 mm of the bottom edge of the marker.
3. Maximum overlap marker	Platinum-Iridium alloy	Cylindrical markers sewn onto the graft
4. Minimum overlap marker	Platinum-Iridium alloy	Cylindrical markers sewn onto the graft
5. Contralateral leg-gate markers	Platinum-Iridium alloy	Cylindrical markers sewn onto the graft edge
6. Limb cranial edge marker	Tantalum	Cylindrical marker crimped on the stent strut
7. Limb caudal edge marker	Tantalum	Cylindrical marker crimped on the stent strut

Figure 4. Prosthesis Marker Identification Guide

1.2 Delivery System

Each prosthesis is loaded into a delivery system which facilitates controlled deployment of the prosthesis into the intended locations under fluoroscopic guidance (**Figure 5**). Each delivery system is delivered over a .035" (0.89 mm) stiff guide wire and is operated to deploy the prosthesis by rotating the gold handle component (#5 in **Figure 5**) in a clockwise direction while firmly holding the white handle component (#6 in **Figure 5**). The deployment of each prosthesis is completed by pulling a secondary release mechanism (#4 in **Figure 5**).



1. Manifold assembly (manifold core with guidewire lumen flush connector and manifold shell)
2. Fixation release wire
3. Fixation release wire hemostasis valve
4. Release wire retainer
6. White handle component
7. Sheath hemostasis valve (aortic bifurcate only)
8. Prosthesis location
9. Sheath tip marker

5. Gold handle component (body) 10. Integrated sheath introducer (aortic bifurcate only)

Figure 5. Delivery System Component Identification Guide

There are 2 variations of the delivery system: one for the aortic bifurcate prosthesis, and one for the iliac limb prosthesis.

1.2.1 Aortic Bifurcate Delivery System

The aortic bifurcate delivery system has an integrated sheath introducer along with a hemostatic valve to facilitate component exchanges during the procedure. The working length of the aortic bifurcate delivery system is approximately 54 cm.

The size of the integrated sheath introducer varies depending on the diameter of the prosthesis it contains (refer to **Table 24**). For prosthesis diameters of 22, 26, and 30 mm, the inner diameter of the integrated sheath introducer is 13F (outer diameter of 14F). For the prostheses diameter of 34 mm, the inner diameter of the integrated sheath introducer is 15F (outer diameter of 16F). The outer surface of the integrated sheath introducer has a lubricious (hydrophilic) coating at the distal end to facilitate introduction into the vasculature.

Each aortic bifurcate delivery system handle is labeled with “AB” to indicate that it contains an aortic bifurcate prosthesis and a number that indicates the trunk diameter of the aortic bifurcate prosthesis.

1.2.2 Iliac Limb Delivery System

The delivery system of the iliac limb prosthesis is similar to that of the aortic bifurcate prosthesis except for its size, and that it does not have an integrated sheath introducer. The iliac limb delivery system has a working length of approximately 77 cm and can be delivered through the integrated sheath introducer of the aortic bifurcate system.

The iliac limb delivery system has a 12F outer diameter for prosthesis diameters between 10 mm and 20 mm, and a 13F outer diameter for the 24 mm diameter prosthesis (refer to **Table 25**).

The outer surface of each iliac limb delivery system has a lubricious (hydrophilic) coating at the distal end to facilitate introduction into the vasculature.

Each iliac limb delivery system handle is labeled with “IL” to indicate that it contains an iliac limb prosthesis and 2 numbers in the format AAxBB that indicate the size of iliac limb prosthesis where AA equals the limb diameter in mm and BB equals the limb length in cm.

2 INDICATIONS FOR USE

INCRAFT is intended for the endovascular treatment of patients with infrarenal abdominal aortic aneurysms with the following characteristics:

- Adequate iliac or femoral vessel morphology that is compatible with vascular access techniques, devices and accessories
- Proximal neck length ≥ 10 mm

- Aortic neck diameters ≥ 17 mm and ≤ 31 mm
- Aortic neck suitable for suprarenal fixation
- Infrarenal and suprarenal neck angulation ≤ 60°
- Iliac fixation length ≥ 15 mm
- Iliac diameters ≥ 7 mm and ≤ 22 mm
- Minimum overall AAA treatment length (proximal landing location to distal landing location) ≥ 128 mm

3 CONTRAINDICATIONS

INCRAFT is contraindicated for the following;

- Patients with a known allergy or intolerance to device materials listed in **Table 1**.
- Patients who have a condition that threatens to infect the graft.
- Patient selection information (Section 4.2) should also be considered.

4 WARNINGS AND PRECAUTIONS

Carefully observe all warnings and cautions noted throughout these instructions as failure to do so may result in injury to the patient.

4.1 General

- The use of **INCRAFT** requires that physicians be specially trained in endovascular abdominal aortic aneurysm repair techniques, including experience with high resolution fluoroscopy and radiation safety. Cordis Corporation will provide training specific to **INCRAFT**. Specific physician training requirements are provided in Section 10.1.
- A vascular surgical team should be available while the implant procedure is in progress in case a conversion to an open surgical repair is required.
- The 10 mm iliac limb prosthesis cannot be extended by design as the cranial diameter for all the iliac limb prostheses is 13 mm.

4.2 Patient Selection

- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.
- Do not use **INCRAFT** in patients unable to undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation procedures.
- **INCRAFT** is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging.
- **INCRAFT** is not recommended in patients exceeding weight or size limits necessary to meet imaging requirements.
- Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation (>60°), a short cranial aortic neck (<10 mm), short caudal landing zone (<15 mm), thrombus, or calcium especially at the cranial and caudal sealing zones and narrowing of the distal aorta at the bifurcation point. Thrombus, irregular calcification and/or plaque may compromise the fixation and sealing of the implant, especially at the cranial and caudal sealing zones. Inadequate seal zone length may result in increased risk of leakage into the aneurysm or migration

of the prosthesis. The use of a bifurcated device in a patient with a narrowing of the distal aorta may result in reduced flow through the limbs.

- When selecting a bifurcate prosthesis, attention should be given to the abdominal treatment length from the lowest renal artery to the aortic bifurcation. If this length is less than the length of the contralateral length of the aortic bifurcate prosthesis (8.6 cm) then it could result in increased difficulty when cannulating the contralateral gate.
- Iliac conduits may be used to ensure the safe insertion of the delivery system if the patient's access vessels, as determined by treating physician, preclude safe insertion of the delivery system.
- The safety and effectiveness of **INCRAFT** has not been evaluated in patients who:
    - are less than 21 years old,
    - are pregnant or lactating,
    - have an aneurysm that is:
        - suprarenal,
        - juxtarenal or pararenal,
        - isolated iliofemoral,
        - mycotic,
        - inflammatory or
        - pseudoaneurysm,
    - have a dominant patent inferior mesenteric artery and an occluded or stenotic celiac or superior mesenteric artery,
    - have an untreated thoracic aneurysm >4.5 cm in diameter,
    - requires emergent aneurysm treatment, e.g., trauma or rupture,
    - have a history of bleeding diathesis or coagulopathy,
    - have had a myocardial infarction (MI) or cerebrovascular accident (CVA) within 3 months prior to implantation,
    - have a reversed conical neck, which is defined as a >10% distal increase over a 10 mm length
    - have a known hypersensitivity or contraindication to anticoagulants, antiplatelets, or contrast media, which is not amenable to pre-treatment,
    - have significant (typically >25% of vessel circumference of aortic neck and iliac artery, or >50% of the length of the iliac artery) aortic mural thrombus at either the proximal or distal attachment location that would compromise bilateral fixation and seal of the device,
    - have ectatic iliac arteries requiring bilateral exclusion of hypogastric blood flow,
    - have arterial access site that is not expected to accommodate the diameter of the device due to size or tortuosity,
    - have active infection at the time of the index procedure documented by pain, fever, drainage, positive culture, or leukocytosis (WBC >11,000/mm^3) that is treated with antimicrobial agents (nonprophylactic),
    - have congenital degenerative collagen disease,
    - have a creatinine >2.0 mg/dl (or >182 µmol/L),
    - are on dialysis,
    - have a connective tissue disorder.

- All patients should be advised that endovascular treatment of infrarenal abdominal aortic aneurysms requires lifelong, regular follow-up to assess their health and the performance of the implanted endovascular prosthesis. Patients with specific clinical findings, e.g., endoleaks, enlarging aneurysms, or changes in structure or position of

the endovascular graft should receive enhanced follow-up.

- Patients experiencing reduced blood flow through the graft limb or leaks may be required to undergo secondary interventions or surgical procedures.
- Intervention or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing enlarging aneurysms or endoleak. An increase in aneurysm size or persistent endoleak may lead to aneurysm rupture.

4.3 Before the Implant Procedure

- Preoperative planning for access and placement should be performed before opening the device packaging.
- Before using the devices, carefully inspect all packaging for damage or defects. If the product or package has been damaged or the sterility of the contents is compromised, do not use the device. The product is provided double-pouched. Do not use if the outer pouch is opened, damaged, or missing. Handle the devices with care. Return the package and device to Cordis Corporation.
- For single use only. Do not resterilize or re-use. Re-use, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failures, which in turn may lead to injury, illness or death of the patient.
- Note product “Use By” date and do not use if the date has been exceeded.
- Note the temperature indicator on the pouch label and do not use if the indicator appears completely black. Please reference Section 9.2 Sterilization, Storage, and Handling.

4.4 During the Implant Procedure

- Exercise care in handling and delivery technique to help prevent vessel rupture.
- Renal complications may occur from an excessive use of contrast agents or as a result of embolic or misplaced stent graft.
- Non-straight catheters should be straightened with a guidewire prior to removal.
- Ensure that the delivery system handle and delivery system sheath are parallel with the patient’s leg. Excessive angulation where the white handle component meets the delivery system sheath may prevent delivery system sheath retraction.
- Do not handle the delivery system by the gold handle component since rotation of the gold handle component during positioning may cause premature deployment of the prosthesis.
- Before deployment ensure that the delivery system is straight and without any slack.
- Be aware that the delivery system should not be bent without an appropriate guidewire inserted into the guidewire lumen
- Do not torque the delivery system more than 90° without confirming rotational response at the distal end of the device (Contralateral Side Marker- **Figure 4**).
- Do not start deployment until the delivery system is accurately placed within the vasculature and ready for deployment.
- When positioning the loaded delivery system, hold only the white handle component.
- Do not rotate the gold handle component in a counter clockwise direction, as this may result in an inability to deploy the prosthesis.
- When deploying the prosthesis, be sure to hold the white handle component of the delivery system firmly against a stationary object (such as the patient's leg).
- Prosthesis components cannot be re-sheathed or drawn back into the delivery system without compromising the system, even if the prosthesis component is only partially

deployed.

- If the outer sheath is accidentally withdrawn exposing the prosthesis, the device will prematurely deploy and may be incorrectly positioned.
- Failure to position the bifurcate cranial edge markers within the healthy infrarenal aortic neck may result in prosthesis leaks or require a bail-out procedure.
- Failure to position the prosthesis below the lowest renal ostium may result in occlusion of the renal arteries.
- Failure to position the limb caudal edge marker limb caudal edge markers cranial to the internal iliac artery origin may result in occlusion of the internal iliac artery.
- Always use fluoroscopy to verify the prosthesis is completely released from the delivery system. Incomplete retraction of the delivery system Sheath or incomplete displacement (pull) of the fixation release wire could lead to dislodgement of the prosthesis when you remove the delivery system subcomponent from the patient.
- Use fluoroscopic guidance to advance the delivery system and to detect kinking or alignment problems with the stent graft system. Do not use excessive force to advance or withdraw the delivery system when resistance is encountered. If the delivery system kinks during insertion, do not attempt to deploy the stent- graft component. Remove the device and insert a new delivery system.
- An inadequate seal zone may result in increased risk of leakage into the aneurysm or migration of the stent graft.
- Prosthesis migration or incorrect prosthesis deployment may require surgical intervention.
- Exercise particular care in areas that are difficult to navigate, such as areas of stenosis, intravascular thrombus, calcification or tortuosity, or where excessive resistance is experienced, as vessel or catheter damage could occur. Consider performing balloon angioplasty at the site of a narrowed or stenotic vessel, and then attempt to gently reintroduce the catheter delivery system. Also exercise care with device selection and correct placement/positioning of the device in the presence of anatomically challenging situations such as areas of significant stenosis, intravascular thrombus, calcification, tortuosity and/or angulation which can affect successful initial treatment of the aneurysm.
- High pressure injections of contrast media made at the edges of the stent graft immediately after implantation can cause endoleaks.
- After use, all components used and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state and federal laws and regulations.

4.5 Treatment and Follow-up

- The long-term safety and effectiveness of **INCRAFT** has not yet been established.
- Any endoleak left untreated during the implantation procedure must be carefully monitored after implantation.
- All patients with endovascular aneurysm repair should undergo periodic imaging to evaluate the stent graft, aneurysm size, and occlusion of vessels in the treatment area. Significant aneurysm enlargement (>5 mm), the appearance of a new endoleak, evidence of perigraft flow, change in aneurysm pulsatility, or migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.
- Additional treatment including endovascular treatment or surgical conversion should be

strongly considered in the following cases:

- aneurysm growth >5 mm, with or without endoleak, since last follow-up,
- change in aneurysm pulsatility, with or without growth or endoleak,
- persistent endoleak, with or without aneurysm growth,
- stent graft migration resulting in an inadequate seal zone,
- decrease in renal function due to renal artery occlusion (migration or poor placement).

- Following endovascular aneurysm repair (EVAR), spinal cord ischemia (SCI) may result in a rare complication of paraplegia or paraparesis. Cerebrospinal fluid (CSF) drain is advised if spinal cord ischemia is suspected.

4.6 Magnetic Resonance Imaging (MRI) Safety Information

Nonclinical testing has demonstrated that **INCRAFT** is MR Conditional. It can be scanned safely in both 1.5T and 3.0T MR systems only, with the parameters specified in Section 10.4. Additional MRI safety information is provided in Section 10.4.

5 ADVERSE EVENTS

5.1 Potential Adverse Events

Potential adverse events include, but are not limited to those listed in **Table 2**. For the specific adverse events that occurred in the clinical study, please see **Section 6**.

Table 2. Potential Adverse Events

• Amputation • Anesthesia complications • Aneurysm enlargement • Aneurysm sac rupture • Aortic damage (perforation, dissection, bleeding, rupture) • Aortoenteric fistulae • Arterial or venous thrombosis • Bleeding • Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis) • Cardiac arrhythmia • Cardiac complications • Cardiac failure or infarction • Claudication • Coagulopathy • Component migration • Contrast toxicity / anaphylaxis • Death	• Edema • Embolism • Endoleak • Fever • Gastrointestinal complications • Genitourinary complications (e.g., ischemia, erosion, fistula, incontinence, hematuria) • Graft dilatation • Graft erosion • Graft material wear • Graft puncture • Graft twisting or kinking • Hematoma (surgical) • Hepatic failure • Impotence • Improper component placement • Incomplete component deployment • Infection • Insertion and removal difficulties	• Lymphatic complications • Neurological complications (e.g. CVA, TIA) • Open surgical conversion • Paralysis or paraparesis • Perigraft flow • Post-implant syndrome • Prosthesis occlusion/stenosis • Pseudoaneurysm • Pulmonary complications • Radiation complications • Renal failure/renal insufficiency • Sheath Leakage • Stenosis of native vessel • Stent fracture / break • Suture vreak • Vascular access site complications occlusion/stenosis • Vascular trauma • Wound complications

5.2 Potential Adverse Event Reporting

Any adverse event or clinical incident involving **INCRAFT** should be immediately reported to Cordis Corporation. To report an incident in the United States call 1 (800) 327-7714.

6 SUMMARY OF CLINICAL STUDY

6.1 Introduction

The primary objective of the INSPIRATION US pivotal clinical study was to evaluate the safety and effectiveness of **INCRAFT** in subjects requiring abdominal aortic aneurysm (AAA) repair. The study was a multicenter, prospective, open label, nonrandomized investigation. A total of 190 subjects were enrolled across 32 sites in the United States (27 sites with 134 subjects) and Japan (5 sites with 56 subjects). Subjects were evaluated at 1 month, 6 months, and 1 year post-procedure. Follow-up continues annually until 5 years post-procedure.

The primary safety endpoint was the incidence of major adverse events (MAEs) at 30 days post-procedure. A major adverse event was defined as any of the following:

- Death
- Stroke
- Myocardial infarction
- New onset renal failure (requiring dialysis)
- Respiratory Failure (requiring mechanical ventilation)
- Paralysis/ paraparesis
- Bowel Ischemia (requiring surgical intervention)
- Procedural Blood Loss (≥1,000 cc)

This primary safety endpoint was compared to a performance goal of 20%, which was derived from the open surgical control group in the Society of Vascular Surgery (SVS) Lifeline Registry (hereinafter referred to as SVS Controls).

The primary effectiveness endpoint was successful aneurysm treatment, which was a composite endpoint defined as the following.

- Technical success at the conclusion of the index procedure, that is, successful insertion of the delivery system through the vasculature and successful deployment of the device at the intended location. The endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, at the time of procedure completion as confirmed by angiography or other imaging modality.
- Absence of postoperative aneurysm enlargement (growth > 5 mm), or stent graft migration (> 10 mm), as compared to the 1 month size measurement at any time up to 1 year.
- Absence of postoperative conversion to open surgery, sac rupture, endoleak Type I/ III, or graft occlusion (including unilateral or bilateral limb occlusion) at any time up to 1 year.

This primary effectiveness endpoint was compared to a performance goal of 80%.

6.2 Study Results

6.2.1 Subject Accountability and Follow-Up

A total of 252 subjects were screened. Of the 252 subjects screened, 190 subjects were enrolled and underwent the index procedure. Ninety nine percent (99%) of the eligible subjects (189/190) completed 1 month follow-up visit. The visit compliance rate was 97% (182/188) at 6 months, 97% (177/183) at 1 year, 94% (161/172) at 2 years and 92% (148/161) at 3 years. Three (3) subjects withdrew consent after 6 months but prior to the 1 year visit, 5 subjects withdrew after the 1 year but prior to the 2 years visit, and 4 subjects withdrew after the 2 years but prior to the 3 years visit.

There was at least 90% imaging compliance up to the 1 year visit with suitability for evaluating endoleaks, enlargement, migration, and stent fracture. There were two (2) conversions to open surgery after the 6 month visit but prior to the 1 year visit and the devices were explanted in each case. Beyond the 1 year visit, there was at least 85% imaging compliance at 2 years and at least 79% imaging compliance at 3 years with suitability for evaluating endoleaks, enlargement, migration, and stent fracture. **Table 3** summarizes subject imaging accountability of the study.

Table 3. Subject Imaging Accountability

		Number of Subjects (%)				Adequate Imaging to Assess the Parameter [5] # (%) (Core Lab data)				Events Occurring before Next Interval # (%)			
Visit	**Eligible for follow -up [1]**	**Subjects with clinical data for that visit**	**CT[2]**	**KUB XRAY[3]**	**Subjects with follow -up pending [4]**	**Endoleak**	**Aneurysm size increase**	**Migration**	**Stent fracture**	**Conversion [6]**	**Death[7]**	**LTF [8]**	**Not due for visit [9]**
Procedure	**190**	**190**	**N/A**	**N/A**	**0**	**190/190 (100%)[10]**	**N/A**	**N/A**	**N/A**	**0**	**0**	**0**	**0**
Discharge	**190**	**190**	**N/A**	**N/A**	**0**	**190/190 (100%)[11]**	**N/A**	**N/A**	**N/A**	**0**	**0**	**0**	**0**
1 Month	**190/190 (100%)**	**189/190 (99%)**	**188/190 (99%)**	**183/190 (96%)**	**0**	**186/190 (98%)**	**188/190 (99%)**	**187/190 (98%)**	**183/190 (96%)**	**0**	**2/190 (1%)**	**0**	**0**
6 Months	**188/190 (99%)**	**182/188 (97%)**	**178/188 (95%)**	**173/188 (92%)**	**0**	**175/188 (93%)**	**176/188 (94%)**	**177/188 (94%)**	**172/188 (91%)**	**2/188 (1%)**	**2/188 (1%)**	**3/188 (2%)**	**0**
1 Year	**183/190 (96%)**	**177/183 (97%)**	**173/181 (96%)**	**164/181 (91%)**	**0**	**167/181 (92%)**	**173/181 (96%)**	**172/181 (95%)**	**163/181 (90%)**	**0**	**6/183 (3%)**	**5/183 (3%)**	**0**
2 Years	**172/190 (91%)**	**161/172 (94%)**	**155/170 (91%)**	**144/170 (85%)**	**0**	**149/170 (88%)**	**155/170 (91%)**	**154/170 (91%)**	**144/170 (85%)**	**0**	**6/172 (3%)**	**5/172 (3%)**	**0**
3 Years	**161/190 (85%)**	**148/161 (92%)**	**136/159 (86%)**	**131/159 (82%)**	**0**	**126/159 (79%)**	**136/159 (86%)**	**135/159 (85%)**	**131/159 (82%)**	**0**	**8/161 (5%)**	**3/161 (2%)**	**0**

-Visit windows are defined based on imaging windows:
Procedure (day 0), Discharge (1- discharge), 1 Month (discharge - 90 days), 6 Months (91 - 270 days), 1 Year (271 - 540 days), 2 Years (541 - 900 days), 3 Years (901 - 1260 days), 4 Years (1261 - 1620 days) and 5 Years (1621 - 1980 days).
1. Number of subjects who have reached the visit window, are alive, and are not LTF. Percent out of total subjects who are in the visit window.
2. Only images that pass QC are listed. Subject 200103105's 2 year image did not pass QC. Subject 200103408's 3 year image did not pass QC
3. Only images that pass QC are listed. Subject 200103408's 2 year image did not pass QC.
4. Subjects still within follow-up window, but have not had clinical follow up.
5. Not the number of subjects with these reported events, but rather, the number with adequate imaging to evaluate the listed outcome.
6. Subjects who converted to open surgery no longer completed imaging follow-up, only clinical follow-up.
7. Deaths within imaging windows.
8. Lost to Follow-up (LTF) are those subjects that are either withdrawn or classified as lost to follow-up in the EDC.
9. Number of subjects who are still alive and participating in the study, but have not had the device implanted long enough to be eligible for the follow-up visit. Percent of subjects is out of those who are still alive (not dead) and participating in the study (not LTF).
10. Endoleak at procedure determined by angiogram. Adequate imaging count provided by sponsor, angiogram core lab data not received by NERI.
11. Endoleak at discharge determined by CT. Adequate imaging count provided by sponsor, CT at discharge core lab data not received by NERI.

6.2.2 Subject Demographics

Subject demographics for the **INCRAFT** cohort and SVS controls are presented in **Table 4**. The **INCRAFT** cohort was older (73.8 years vs. 70.1 years SVS) and shorter in stature (172 cm vs. 174 cm SVS) than the SVS controls. In addition, the **INCRAFT** cohort included more males (90% vs. 83.3% SVS). The **INCRAFT** cohort was only 68.9% white/Caucasian as compared with the SVS controls (94.9%) because roughly one-third of the subjects in the **INCRAFT** cohort were from Japan while all the subjects in SVS controls were from the US.

Table 4. Subject Demographics

Patient Characteristics	INCRAFT ITT (N = 190)	SVS Controls (N = 323)
Age (years)		
Mean ± SD (N)	73.8 ± 7.56 (190)	70.1 ± 7.41 (323)
Median	74.0	70.7
Range (Min, Max)	51.0, 90.0	41.2, 86.1
Number of Men (%)	90.0% (171/190)	83.3% (269/323)
Height (cm)		
Mean ± SD (N)	172.1 ± 9.37 (190)	174.0 ± 9.26 (315)
Median	172.7	175.3
Range (Min, Max)	147.0, 196.0	135.0, 194.3
Weight (kg)		
Mean ± SD (N)	81.7 ± 17.27 (190)	82.9 ± 17.25 (318)
Median	80.5	83.0
Range (Min, Max)	35.9, 137.8	40.4, 151.5
BMI (kg/m^2)		
Mean ± SD (N)	27.4 ± 4.66 (190)	27.3 ± 5.07 (314)
Median	27.1	27.1
Range (Min, Max)	15.1, 40.0	15.8, 63.1
Race		
White/Caucasian	68.9% (131/190)	94.9% (244/257)
Non-White/Non-Caucasian	31.1% (59/190)	5.1% (13/257)

6.2.3 Baseline Medical History

Baseline clinical history for the study subjects is summarized in **Table 5** according to body system and/or medical condition. The cardiovascular comorbidities that were most commonly observed in the **INCRAFT** cohort were hypertension (77.9%) and hypercholesterolemia (72.1%).

A larger proportion of subjects in the SVS controls had angina (25.5% vs. 15.8%), coronary artery disease (53.3% vs. 40.5%), history of myocardial infarction (32.8% vs. 18.4%), and stroke (13.6% vs. 6.3%). In contrast, a larger proportion of subjects in the **INCRAFT** cohort had diabetes (25.3% vs. 12.7%), and history of cancer (32.6% vs. 23.6%). There was a high prevalence of smoking history in the **INCRAFT** cohort (92.6%) and the SVS controls (88.2%).

Table 5. Baseline Medical History

Body System/Medical Condition	INCRAFT ITT (N = 190)	SVS Controls (N = 323)
Cardiovascular		
Angina	15.8% (30/190)	25.5% (54/212)
Arrhythmia	18.4% (35/190)	13.9% (45/323)
Coronary Artery Disease	40.5% (77/190)	53.3% (172/323)
Myocardial Infarction	18.4% (35/190)	32.8% (106/323)
Hypertension	77.9% (148/190)	70.6% (228/323)
Hypercholesterolemia	72.1% (137/190)	NA
Congestive Heart Failure	2.6% (5/190)	6.5% (21/323)
Family History of Aneurysm	11.6% (22/190)	17.9% (38/212)
Peripheral Arterial Disease	14.7% (28/190)	18.0% (58/323)
Neurological		
Stroke	6.3% (12/190)	13.6% (44/323)
Endocrine		
Diabetes	25.3% (48/190)	12.7% (41/323)
Urinary		
Moderate Renal Insufficiency	5.3% (10/190)	3.1% (10/323)
Pulmonary		
Chronic Obstructive Pulmonary Disease	26.8% (51/190)	26.9% (87/323)
Other Medical Conditions		
Liver Disease	5.8% (11/190)	3.4% (5/146)
Cancer	32.6% (62/190)	23.6% (50/212)
Alcoholism	8.4% (16/190)	8.5% (18/212)
Smoking	92.6% (176/190)	88.2% (285/323)

6.2.4 Baseline Aneurysm Characteristics

Baseline aneurysm and anatomical measurements, as well as access vessel characteristics of the study population, were reported by both the core lab and site. The clinical sites evaluated 100% (190/190) of the baseline contrast CT scans. A CT scan without contrast at baseline was optional; however, 60.5% (115/190) of the subjects completed this scan. The core lab evaluated 98.9% (188/190) of the baseline contrast CT scans. Two CT scans were not evaluated by the core lab due to imaging quality. Baseline aneurysm characteristics are summarized in **Table 6.**

Table 6. Baseline Aneurysm Characteristics as Measured from CT Scan

Measure	INCRAFT ITT** (All Subjects)		SVS Controls
	Core Lab N = 188[†]	Site Reported N = 190	Site Reported N = 323
Supra-renal Aortic Diameter (mm)			
Mean ± SD (N)	23.6 ± 2.50 (188)	23.9 ± 2.56 (189)	NA
Median	23.50	24.00	NA
Range (min, max)	18.00, 31.50	17.00, 30.00	NA
Aortic Neck Diameter at start of cranial Attachment (mm)			
Mean ± SD (N)	21.7 ± 2.68 (188)	22.6 ± 2.70 (190)	NA
Median	22.00	23.00	NA
Range (min, max)	15.50, 30.00	17.00, 31.00	NA
Aortic neck Constant Reference Diameter at 10 mm inferior (mm)			
Mean ± SD (N)	22.2 ± 3.81 (188)	22.6 ± 3.03 (190)	NA
Median	22.00	22.50	NA
Range (min, max)	16.00, 50.00	16.00, 32.00	NA
Maximum aortic aneurysm Sac Diameter (mm)			
Mean ± SD (N)	54.9 ± 6.90 (188)	55.7 ± 6.58 (190)	58.7 ± 11.89 (292)
Median	53.95	54.00	56.9
Range (min, max)	43.30, 98.30	45.00, 100.00	31.0, 100.0
Aortic Diameter at Bifurcation (mm)			
Mean ± SD (N)	19.3 ± 5.50 (188)	25.2 ± 6.56 (190)	NA
Median	18.00	23.00	NA
Range (min, max)	11.00, 48.50	18.00, 52.00	NA
Right caudal landing zone Diameter (mm)			
Mean ± SD (N)	13.8 ± 3.15 (188)	13.5 ± 3.36 (190)	NA
Median	13.20	13.00	NA
Range (min, max)	7.50, 27.00	7.00, 22.00	NA
Left caudal landing zone Diameter (mm)			
Mean ± SD (N)	13.7 ± 2.91 (188)	13.0 ± 3.01 (190)	NA
Median	13.15	13.00	NA
Range (min, max)	8.00, 24.00	7.00, 21.00	NA
Right minimum vessel diameter (mm)			
Mean ± SD (N)	6.8 ± 1.53 (187)	8.1 ± 1.86 (190)	NA
Median	7.00	8.00	NA
Range (min, max)	2.80, 11.10	5.00, 17.00	NA
Left minimum vessel diameter (mm)			
Mean ± SD (N)	6.9 ± 1.50 (187)	8.1 ± 1.82 (190)	NA
Median	7.10	8.00	NA
Range (min, max)	3.30, 11.70	5.00, 14.00	NA

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.
[†] Two of the 190 CTs received by the core lab were deemed as not evaluable due to quality of the imaging.

The distribution of baseline aneurysm diameters is presented in **Table 7**.

Table 7. Distribution of Baseline Aneurysm Diameters

Measure	INCRAFT ITT (All Subjects)	
	Core Lab N = 188[†]	**Site Reported N = 190**
Maximum aneurysm Sac Diameter (%)		
< 30 mm	0% (0/188)	0% (0/190)
30-39 mm	0% (0/188)	0% (0/190)
40-49 mm	20.2% (38/188)	3.2% (6/190)
50-59 mm	63.8% (120/188)	76.8% (146/190)
60-69 mm	13.3% (25/188)	16.3% (31/190)
70-79 mm	1.6% (3/188)	2.1% (4/190)
80-89 mm	0.5% (1/188)	1.1% (2/190)
≥ 90 mm	0.5% (1/188)	0.5% (1/190)
Aneurysm Diameter < 50 mm (%)	20.2% (38/188)	3.2% (6/190)
Aneurysm Diameter ≥ 50 mm (%)	79.8% (150/188)	96.8% (184/190)

[†] Two of the 190 CTs received by the core lab were deemed as not evaluable due to quality of the imaging.

6.2.5 INCRAFT Components Implanted

The number and sizes of **INCRAFT** study device components implanted are summarized in **Tables 8** and **9.** The aortic bifurcate, ipsilateral limb and contralateral limb were implanted in all subjects. Iliac limb extensions were used when additional extension was required. The ipsilateral limb extension was implanted in 10 (5.3%) subjects while the contralateral limb extension was implanted in 9 (4.7%) subjects. Two subjects (2/190; 1%) were implanted with both an ipsilateral and a contralateral limb extension.

Table 8. Summary of INCRAFT Components Implanted

INCRAFT System Component	Overall (N = 190)
Aortic bifurcate	100.0% (190/190)
Ipsilateral limb	100.0% (190/190)
Contralateral limb	100.0% (190/190)
Ipsilateral limb extension	5.3% (10/190)
Contralateral limb extension	4.7% (9/190)

Table 9. Summary of INCRAFT Components Implanted by Size

INCRAFT System Component	Outer diameter	Overall (N = 190)
Aortic bifurcate		100.0% (190/190)
	22 mm	7.9% (15/190)
	26 mm	44.7% (85/190)
	30 mm	37.4% (71/190)
	34 mm	10.0% (19/190)
Ipsilateral limb		100.0% (190/190)
	10 mm	1.6% (3/190)
	13 mm	17.9% (34/190)
	16 mm	41.0% (78/190)
	20 mm	27.9% (53/190)
	24 mm	11.6% (22/190)
Contralateral limb		100.0% (190/190)
	10 mm	5.8% (11/190)
	13 mm	20.5% (39/190)
	16 mm	39.5% (75/190)
	20 mm	26.3% (50/190)
	24 mm	7.9% (15/190)
Ipsilateral Limb Extension		5.3% (10/190)
	13 mm	2.1% (4/190)
	16 mm	0.5% (1/190)
	20 mm	1.1% (2/190)
	24 mm	1.6% (3/190)
Contralateral Limb Extension		4.7% (9/190)
	10 mm	1.05% (2/190)
	13 mm	1.05% (2/190)
	16 mm	0.5% (1/190)
	24 mm	2.1% (4/190)

6.2.6 Acute Procedural Data

Table 10 provides the acute procedural data for the **INCRAFT** cohort including a breakdown of the data for subjects treated in the US vs. Japan. The mean duration of the procedure in the **INCRAFT** cohort was 102.7 minutes, a mean of 97 minutes for subjects treated in the US and a mean of 116 minutes for subjects treated in Japan. The mean time required to deploy the **INCRAFT** device, i.e., time from entry of delivery system to final imaging, was 47.5 minutes, which was similar in both US (48 minutes) and Japan (46 minutes). However, operators (study investigators) in Japan reported a higher fluoroscopy time and contrast volume compared to the operators (study investigators) in the US; 30 minutes vs. 23 minutes, and 136 mL vs. 124 mL respectively. Procedural estimated blood loss of ≥1000 mL was reported in 4 subjects (2.1%) in the **INCRAFT** cohort. Procedural blood loss of <500 mL among the subjects treated in Japan was 98.2%, while in the US it was 92.5%. While the estimated blood loss was different between US and Japan, the transfusion rates were similar (5.2% in US, 5.4% In Japan).

The main differences between the procedural data for US and Japan is related to subjects receiving general anesthesia, time in the ICU, and in overall length of hospital stay. A higher proportion of subjects (60%) treated in the US received general anesthesia compared to those that were treated in Japan (34%).

Table 10. Acute Procedural Characteristics - US and Japan

	INCRAFT ITT Subjects		
Acute Procedural Data	**Total (N = 190)**	**US (N = 134)**	**Japan (N = 56)**
Duration of Procedure (minutes)			
Mean ± SD (N)	102.7 ± 42.85 (190)	97.0 ± 41.44 (134)	116.4 ± 43.41 (56)
Median	95.5	86.5	115.0
Range (min, max)	30.0, 218.0	30.0, 211.0	44.0, 218.0
Duration of anesthesia (minutes)			
Mean ± SD (N)	179.2 ± 52.85 (99)	176.6 ± 56.46 (80)	190.5 ± 32.47 (19)
Median	169.0	163.0	195.0
Range (min, max)	47.0, 363.0	47.0, 363.0	130.0, 233.0
Total INCRAFT time (minutes)			
Mean ± SD (N)	47.5 ± 22.43 (189)	48.0 ± 22.88 (133)	46.2 ± 21.47 (56)
Median	45.0	45.0	44.5
Range (min, max)	15.0, 165.0	15.0, 165.0	17.0, 124.0
Subjects receiving general anesthesia (%)	52.6% (100/190)	60.4% (81/134)	33.9% (19/56)
Volume of contrast used (mL)			
Mean ± SD (N)	127.6 ± 52.24 (189)	124.0 ± 54.72 (133)	136.2 ± 45.12 (56)
Median	122.0	120.0	135.0
Range (min, max)	13.0, 300.0	13.0, 300.0	50.0, 240.0
Total Fluoroscopy Time (minutes)			
Mean ± SD (N)	25.0 ± 13.48 (190)	22.7 ± 12.60 (134)	30.4 ± 14.11 (56)
Median	21.0	20.0	26.5
Range (min, max)	7.0, 92.0	7.0, 92.0	13.0, 84.0

	INCRAFT ITT Subjects		
Acute Procedural Data	**Total (N = 190)**	**US (N = 134)**	**Japan (N = 56)**
Estimated blood loss (procedural)			
<500 mL	94.2% (179/190)	92.5% (124/134)	98.2% (55/56)
500-999 mL	3.7% (7/190)	4.5% (6/134)	1.8% (1/56)
≥1000 mL	2.1% (4/190)	3.0% (4/134)	0%(0/56)
Subjects requiring blood transfusion during procedure (%)	2.6% (5/190)	3.0% (4/134)	1.8% (1/56)
Subjects requiring blood transfusion after procedure (%)	2.6% (5/190)	2.2% (3/134)	3.6% (2/56)
Time in ICU (hours)			
Mean ± SD (N)	8.0 ± 10.59 (184)	4.8 ± 9.56 (128)	15.2 ± 9.25 (56)
Median	0.0	0.0	20.0
Range (min, max)	0.0, 48.0	0.0, 48.0	0.0, 25.0
Overall length of hospital stay (days)			
Mean ± SD (N)	2.7 ± 2.88 (190)	1.5 ± 1.12 (134)	5.6 ± 3.71 (56)
Median	1.5	1.0	4.0
Range (min, max)	1.0, 17.0	1.0, 8.0	2.0, 17.0

6.2.7 Safety Results

6.2.7.1 Primary Safety Endpoint

The primary safety endpoint of the specified analysis for the **INCRAFT** subjects met the pre-defined performance goal of 20%, demonstrating the safety of the **INCRAFT**. The primary safety results are presented in **Table 11**. The composite 30 day MAE rate was 3.2%. There was 1 subject that had a myocardial infarction (MI) which resulted in death. There were no incidences of renal failure, respiratory failure, paralysis/paraparesis, or bowel ischemia reported.

The analysis of safety was based on the intent-to-treat cohort of 190 subjects, available for the 1-month evaluation. The intent-to-treat cohort includes all subjects who had the aortic bifurcate device introduced into the body.

Table 11. Primary Safety Endpoint Results

	INCRAFT ITT**	
Primary Endpoint	**Total Subjects (N = 190)**	**95% CI**
Primary Composite Safety Endpoint*	3.2% (6/190)	(- , 6.1%)
MAE Component Rate at 30 days		
Death†	0.5% (1/190)	
Stroke	0.5% (1/190)	
Myocardial Infarction†	0.5% (1/190)	
New Onset Renal Failure (requiring dialysis)	0% (0/190)	
Respiratory Failure (requiring mechanical ventilation)	0% (0/190)	
Paralysis /Paraparesis	0% (0/190)	
Bowel ischemia (requiring surgical intervention)	0% (0/190)	

	INCRAFT ITT**	
Primary Endpoint	**Total Subjects (N = 190)**	**95% CI**
Procedural blood loss (≥ 1,000 cc)	2.1% (4/190)	

* Primary Composite Safety Endpoint includes all of the eight individual components listed in this table.
** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.
† A subject may report multiple MAEs; hence, number of subjects with any MAE may not be the sum of those in each MAE category. One subject experienced both a myocardial infarction and a death.

6.2.7.2 Secondary Safety Endpoints

Secondary safety endpoints include MAE and the individual components at 6 month and annually through 5 year; and procedure-related complications through 30 days, 6 months, and annually to 5 years. The overall rate of MAE and the components of MAE day post-procedure observed in the clinical study are provided in **Table 12**. The overall rate of MAEs is 7.0% at 6 month, 10.9% at 1 year, 18.8% at 2 years, and 23.1% at 3 years. The overall MAE rates are primarily driven by the incidence of death, stroke, and myocardial infarction, all deemed unrelated to the **INCRAFT** by the Clinical Events Committee (CEC).

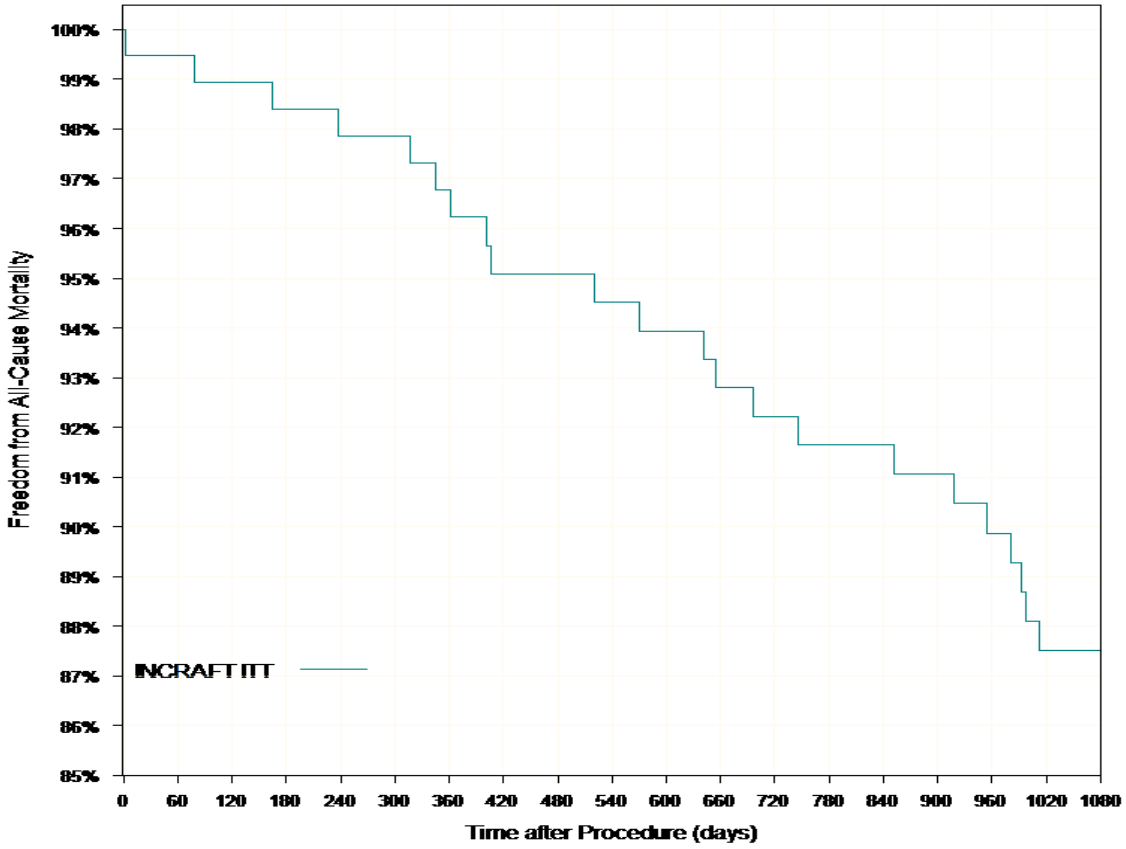
Table 12. MAE Rate through 3 Years - Overall Rate and MAE Components

Major Adverse Events *	**INCRAFT ITT ** Subjects (N = 190)**			
	6 Month	**1 Year**	**2 Years**	**3 Years**
MAE rate	7.0% (13/187)	10.9% (20/183)	18.8% (33/176)	23.1% (39/169)
Death	1.6% (3/187)	3.3% (6/183)	8.0% (14/176)	13.0% (22/169)
Stroke	1.6% (3/187)	2.2% (4/183)	5.1% (9/176)	7.7% (13/169)
Myocardial infarction	1.6% (3/187)	3.3% (6/183)	4.0% (7/176)	5.3% (9/169)
New onset renal failure (requiring dialysis)	0.0% (0/187)	0.0% (0/183)	0.0% (0/176)	0.0% (0/169)
Respiratory failure (requiring mechanical ventilation)	0.5% (1/187)	1.1% (2/183)	1.1% (2/176)	1.2% (2/169)
Paralysis / paraparesis	0.0% (0/187)	0.0% (0/183)	0.0% (0/176)	0.0% (0/169)
Bowel ischemia (requiring surgical intervention)	0.0% (0/187)	0.0% (0/183)	0.0% (0/176)	0.0% (0/169)
Procedural blood loss (≥ 1,000 cc)	2.1% (4/187)	2.2% (4/183)	2.3% (4/176)	2.4% (4/169)
MAE rate (excluding procedural blood loss)	4.8% (9/187)	9.3% (17/183)	17.6% (31/176)	21.9% (37/169)
Aneurysm-related mortality	0.5% (1/187)	0.5% (1/183)	0.6% (1/176)	0.6% (1/169)

* Safety endpoints presented in this table are cumulative.
** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

In addition, a Kaplan-Meier analysis of freedom from all-cause mortality was performed (**Figure 6**). For the **INCRAFT** cohort, freedom from all-cause mortality was estimated to be 99.5% at 30 days, 98.4% at 180 days, 96.8% at 1 year day, 92.2% at 2 years and 87.5% at 3 years.

Figure 6. Kaplan-Meier Analysis: Freedom from All-Cause Mortality through 3 Years



	Time after Procedure					
INCRAFT ITT**	**0 Days**	**1-30 Days**	**31-180 Days**	**181-360 Days**	**361-720 Days**	**721-1080 Days**
# At Risk	190	188	182	177	161	131
# censored	0	1	4	2	8	22
# Events	0	1	2	3	8	8
Survival (%)	100%	99.50%	98.40%	96.80%	92.20%	87.50%
Peto SE¥	0%	0.50%	0.90%	1.30%	2%	2.50%

****** Intent to treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body. All-cause mortality is defined as a death to any cause.

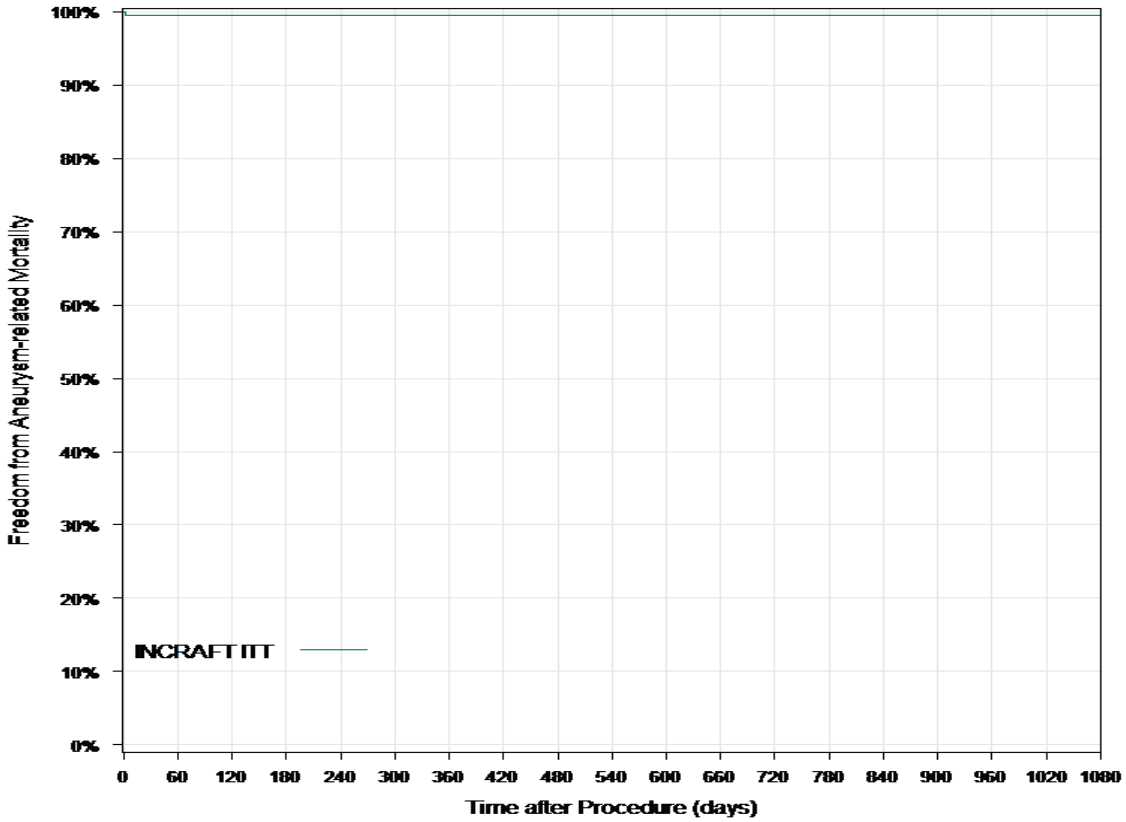
¥ Peto's formula utilizing non-parametric weights accounting for number of subjects at risk was used in calculating the standard error.

6.2.7.3 Aneurysm-Related Mortality

Aneurysm-related mortality was defined as a death from AAA rupture, or death within 30 days of open aortic surgical or endovascular repair, or death from any subsequent procedure required to

treat the same aneurysm. One subject died 2 days after the procedure due to a myocardial infarction. This incidence of death met the definition of aneurysm-related mortality because the death occurred within 30 days of the endovascular repair. A Kaplan-Meier analysis of freedom from aneurysm-related mortality was performed. For the **INCRAFT** cohort, freedom from aneurysm-related mortality was estimated to be 99.5% at each follow-up time point through 3 years post-procedure (**Figure 7**).

Figure 7. Kaplan-Meier Analysis: Freedom from Aneurysm-Related Mortality through 3 Years



	Time after Procedure					
INCRAFT ITT**	**0 Days**	**1-30 Days**	**31-180 Days**	**181-360 Days**	**361-720 Days**	**721-1080 Days**
# At Risk	190	188	182	177	161	131
# censored	0	1	6	5	16	30
# Events	0	1	0	0	0	0
Survival (%)	100%	99.50%	99.50%	99.50%	99.50%	99.50%
Peto SE¥	0%	0.50%	0.50%	0.50%	0.50%	0.50%

****** Intent to treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body. Aneurysm mortality is defined as a death from AAA rupture, or death within 30 days of open aortic surgical or endovascular repair, or death from any subsequent procedure required to treat the same aneurysm.

¥ Peto's formula utilizing non-parametric weights accounting for number of subjects at risk was used in calculating the standard error.

6.2.7.4 Aneurysm Rupture

No incidences of aneurysm sac rupture has been reported through 3 years post index procedure.

6.2.7.5 Conversion to Open Surgery

Two subjects underwent conversion to open surgery within the 3 years follow-up time point.

The first subject was a 68 year-old Caucasian male who, at 206 days post procedure, was noted to have a mural clot in both limbs of the endograft. Open surgical conversion, explant and embolectomy were performed. The conversion was successful and the subject was discharged.

The second subject was a 66 year-old Caucasian who had symptoms of numbness and pain in both legs reported approximately 4 months after the EVAR procedure. The subject was monitored and underwent imaging studies until 173 days post procedure when the subject underwent conversion to open surgery due to occlusion of the stent graft. The conversion was successful and the subject was discharged.

The subjects' medical history or prescribed medications might have predisposed the subjects to thrombosis of the stent graft. In the second subject, there were mild stenoses observed at the proximal limbs on the completion angiography at the index procedure which may have contributed to the subjects' thrombotic event. While the first subject had no clinical or anatomic findings identified as factors for the thrombotic event, extensive atherosclerotic popliteal disease was present in the second subject.

6.2.7.6 Serious Adverse Events

Twenty-two subjects experienced 23 procedure-related serious adverse events (SAE) within the first 30 days, 3 subjects experienced 3 procedure-related SAEs at 6 months, 2 subjects experienced 3 procedure-related SAEs at 1 year, 1 subject experienced 2 procedure-related SAEs at 2 years and 5 subjects experienced 7 procedure-related SAEs at 3 years, as summarized in **Table 13**.

Table 13. Site-Reported Procedure-Related SAEs through 3 Years Post Procedure

SAEs by MedDRA System Organ Class	Post Procedure Day 0		1 month		6 months		1 year		2 years		3 years	
	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=187)	Total # SAEs	# Subjects w/SAE (N=182)	Total # SAEs	# Subjects w/SAE (N=170)	Total # SAEs	# Subjects w/SAE (N=158)
Any SAE	**9**	**4.2% (8/190)**	**14**	**7.4% (14/190)**	**3**	**1.6% (3/187)**	**3**	**1.1% (2/182)**	**2**	**0.6% (1/170)**	**7**	**3.2% (5/158)**
Blood And Lymphatic System Disorders	**1**	**0.5% (1/190)**	**0**	**0% (0/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Anaemias Nonhaemolytic And Marrow Depression	1	0.5% (1/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Cardiac Disorders	**0**	**0% (0/190)**	**1**	**0.5% (1/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Coronary Artery Disorders	0	0% (0/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Gastrointestinal Disorders	**0**	**0% (0/190)**	**2**	**1.1% (2/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Gastrointestinal Motility And Defaecation Conditions	0	0% (0/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)

SAEs by MedDRA System Organ Class	Post Procedure Day 0		1 month		6 months		1 year		2 years		3 years	
	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=187)	Total # SAEs	# Subjects w/SAE (N=182)	Total # SAEs	# Subjects w/SAE (N=170)	Total # SAEs	# Subjects w/SAE (N=158)
Gastrointestinal Stenosis And Obstruction	0	0% (0/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
General Disorders And Administration Site Conditions	**2**	**1.1% (2/190)**	**1**	**0.5% (1/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**1**	**0.6% (1/170)**	**4**	**2.5% (4/158)**
Body Temperature Conditions	2	1.1% (2/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Complications Associated With Device	0	0% (0/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	3	1.9% (3/158)
Device Issues	0	0% (0/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	1	0.6% (1/170)	1	0.6% (1/158)
Injury, Poisoning And Procedural Complications	**2**	**1.1% (2/190)**	**1**	**0.5% (1/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Procedural Related Injuries And Complications NEC *	2	1.1% (2/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Investigations	**0**	**0% (0/190)**	**1**	**0.5% (1/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Renal And Urinary Tract Investigations And Urinalyses	0	0% (0/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Metabolism And Nutrition Disorders	**0**	**0% (0/190)**	**0**	**0% (0/190)**	**1**	**0.5% (1/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Electrolyte And Fluid Balance Conditions	0	0% (0/190)	0	0% (0/190)	1	0.5% (1/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)

SAEs by MedDRA System Organ Class	Post Procedure Day 0		1 month		6 months		1 year		2 years		3 years	
	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=187)	Total # SAEs	# Subjects w/SAE (N=182)	Total # SAEs	# Subjects w/SAE (N=170)	Total # SAEs	# Subjects w/SAE (N=158)
Nervous System Disorders	**1**	**0.5% (1/190)**	**1**	**0.5% (1/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Neurological Disorders NEC	0	0% (0/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Peripheral Neuropathies	1	0.5% (1/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Renal And Urinary Disorders	**2**	**1.1% (2/190)**	**4**	**2.1% (4/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Genitourinary Tract Disorders NEC	0	0% (0/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Renal Disorders (excl. Nephropathies)	1	0.5% (1/190)	1	0.5% (1/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Urethral Disorders (excl. Calculi)	1	0.5% (1/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Urinary Tract Signs And Symptoms	0	0% (0/190)	2	1.1% (2/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Respiratory, Thoracic And Mediastinal Disorders	**1**	**0.5% (1/190)**	**2**	**1.1% (2/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Respiratory Disorders NEC	1	0.5% (1/190)	2	1.1% (2/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Surgical And Medical Procedures	**0**	**0% (0/190)**	**0**	**0% (0/190)**	**0**	**0% (0/187)**	**0**	**0% (0/182)**	**0**	**0% (0/170)**	**0**	**0% (0/158)**
Vascular Therapeutic Procedures	0	0% (0/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)

SAEs by MedDRA System Organ Class	Post Procedure Day 0		1 month		6 months		1 year		2 years		3 years	
	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=190)	Total # SAEs	# Subjects w/SAE (N=187)	Total # SAEs	# Subjects w/SAE (N=182)	Total # SAEs	# Subjects w/SAE (N=170)	Total # SAEs	# Subjects w/SAE (N=158)
Vascular Disorders	**0**	**0% (0/190)**	**1**	**0.5% (1/190)**	**2**	**1.1% (2/187)**	**3**	**1.1% (2/182)**	**1**	**0.6% (1/170)**	**3**	**1.9% (3/158)**
Aneurysms And Artery Dissections	0	0% (0/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	2	1.3% (2/158)
Arteriosclerosis, Stenosis, Vascular Insufficiency And Necrosis	0	0% (0/190)	1	0.5% (1/190)	1	0.5% (1/187)	3	1.1% (2/182)	1	0.6% (1/170)	0	0% (0/158)
Embolism And Thrombosis	0	0% (0/190)	0	0% (0/190)	1	0.5% (1/187)	0	0% (0/182)	0	0% (0/170)	0	0% (0/158)
Vascular Disorders NEC	0	0% (0/190)	0	0% (0/190)	0	0% (0/187)	0	0% (0/182)	0	0% (0/170)	1	0.6% (1/158)

*: NEC is the abbreviation of “Not Elsewhere Classified”

6.2.8 Effectiveness Results

6.2.8.1 Primary Effectiveness

The primary effectiveness endpoint was met, demonstrating successful aneurysm treatment with **INCRAFT** at 1 year was greater than the 80% performance goal. The rate of successful aneurysm treatment to 1 year was 87.9% (152/173). There were no postoperative aneurysm enlargements, migrations, or sac ruptures noted, as is shown in **Table 14**.

Table 14. Primary Effectiveness Endpoint Results

	INCRAFT ITT**	
Primary Endpoint	**Total Subjects (N = 190)¥**	**95% CI**
Primary Composite Effectiveness Endpoint	87.9% (152/173)	(83.0%, -)
Successful Aneurysm Treatment to 1 year composite Rate†		
Technical Success (Peri-procedure) ‡	94.1% (176/187)	
Successful insertion of the delivery system	100.0% (190/190)	
Successful deployment of device at intended location	98.9% (188/190)	
Graft patency	100.0% (190/190)	
Absence of type I endoleak	95.2% (178/187)	
Absence of type III endoleak	100% (187/187)	
Absence of sac rupture	100.0% (190/190)	
Absence of postoperative aneurysm enlargement	100.0% (173/173)	
Absence of postoperative migration	100.0% (172/172)	
Absence of postoperative conversion	98.9% (173/175)	
Absence of postoperative sac rupture	100.0% (175/175)	
Absence of postoperative type I/III endoleak	98.3% (170/173)	
Absence of postoperative graft occlusion	96.0% (168/175)	

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

† Successful Aneurysm Treatment is described as the composite endpoint of the following:

- Absence of post-operative aneurysm enlargement (growth > 5 mm) or migration (> 10 mm), compared to the one month size measurement at any time up to 1 year;
- Absence of post-operative conversion to open surgery, sac rupture, endoleak Type I/III, or graft occlusion (including unilateral or bilateral limb occlusion) at any time up to 1 year;
- Considered a Technical Success as defined below.

‡ Technical Success at the conclusion of the index procedure, defined as successful insertion of the delivery system through the vasculature and successful deployment of the device at the intended location. The endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, at the time of procedure completion as confirmed by angiography or other imaging modality.

¥ Denominator is the number of subject evaluable for this endpoint.

The reasons that 21 subjects did not meet the primary effectiveness endpoint are summarized in **Table 15**. It should be noted that the protocol definition of graft occlusion implies that the vessel is 100% occluded.

Table 15. Summary of the 21 Subjects Who Did Not Meet the Primary Effectiveness Endpoint

Case	Successful Aneurysm Treatment to 1 year	Technical Success Peri Procedure	Reason Failed	Time to Failure from Index Procedure (days)
1	No	No	Deployment	0
2	No	No	Type I Endoleak	0
3	No	Yes	Conversion to Open Surgery	206
4	No	No	Deployment	0
5	No	Yes	Graft Occlusion	191
6	No	Yes	Type I Endoleak	373
7	No	Yes	Graft Occlusion	129
8	No	Yes	Graft Occlusion	171
9*	No	No	Type I Endoleak Type I Endoleak	0 366
10	No	No	Type I Endoleak	0
11	No	No	Type I Endoleak	0
12	No	No	Type I Endoleak	0
13	No	No	Type I Endoleak	0
14	No	Yes	Graft Occlusion	194
15	No	Yes	Graft Occlusion	98
16	No	Yes	Graft Occlusion	243
17*	No	Yes	Graft Occlusion Conversion to Open Surgery	126 173
18	No	Yes	Type I Endoleak	347
19	No	No	Type I Endoleak	0
20	No	No	Type I Endoleak	0
21	No	No	Type I Endoleak	0

* 2 subjects had 2 events that qualified them as not meeting the primary effectiveness endpoint: Case # 9 and 17 in this table.

6.2.8.2 Secondary Effectiveness Endpoints

Secondary effectiveness endpoints are summarized in **Table 16.** The data presented is the number of subjects with the events, not the number of incidence of the events.

The technical success at 1 month was 100% defined as graft patency with the absence of Type I or III endoleaks or sac rupture confirmed by imaging. There was 1 (0.5%) aneurysm-related mortality at 1 month and no more aneurysm-related mortality occurred after the 1 month time point through 3 years. The

At 1-month, there were no new Type I/III/IV endoleaks. All Type IV endoleaks observed post index procedure were resolved by 1 month. No incidences of aneurysm sac rupture, stent fracture, patency-related events, or conversion to open surgery were reported. No device malfunctions were reported by clinical sites. There was 1 secondary intervention performed for vascular injury post index procedure.

At 6-months, there were 3 stent fractures, 4 graft occlusions, 1 conversion to open surgery and 5 secondary interventions. There were no incidences of aneurysm sac rupture, type I or III endoleaks, aneurysm enlargement, or migration. Subjects with stent fractures and migration identified will continue to be included in the numerator and denominator for later time points.

At 1-year, there were 3 new type I endoleaks, 8 total stent fractures, 2 device malfunctions, 3 graft occlusions, 1 conversion to open surgery and 8 secondary interventions. There were no incidences of aneurysm enlargement, sac rupture or stent migration.

At 2 years, there were 11 aneurysm enlargement, 4 new type I endoleaks, 10 total stent fractures, 1 device malfunction, 1 graft occlusions, 1 limb migration and 7 secondary interventions. There was no incidence of sac rupture.

At 3 years, there were 23 total aneurysm enlargement (including 10 persistent aneurysm enlargement from 2 years), 2 new type I endoleaks, 1 new type III endoleak, 13 total stent fractures, 3 device malfunctions, 1 graft occlusion, 5 total limb migrations and 12 secondary interventions. There was no incidence of sac rupture.

Table 16. Secondary Effectiveness Results

Secondary Effectiveness Endpoints	INCRAFT ITT** Subjects (N = 190)					
	Peri-Procedure	1 Month	6 Months	1-Year	2-Years	3-Years
Technical success at 1 month ‡	N/A	100.0% (188/188)	N/A	N/A	N/A	N/A
Aneurysm-related mortality§	N/A	0.5% (1/190)	0.5% (1/187)	0.5% (1/183)	0.6% (1/176)	0.6% (1/169)
Device-related events*	N/A	0.0% (0/181)	4.2% (7/167)	10.1% (16/159)	17.0% (24/141)	30.8% (40/130)
Aneurysm enlargement	N/A	N/A	0.0% (0/176)	0.0% (0/173)	7.1% (11/155)	16.9% (23/136)
Endoleaks (Type I)	N/A	0.0% (0/186)	0.0% (0/175)	1.8% (3/167)	2.7% (4/149)	1.6% (2/126)
Endoleaks (Type III)	N/A	0.0% (0/186)	0.0% (0/175)	0.0% (0/167)	0.0% (0/149)	0.8% (1/126)
Endoleaks (Type IV)	N/A	0.0% (0/186)	N/A	N/A	N/A	N/A
Aneurysm sac rupture	N/A	0.0% (0/189)	0.0% (0/183)	0.0% (0/176)	0.0% (0/161)	0% (0/146)
Fractures∞ ¥	N/A	0.0% (0/183)	1.7% (3/172)	4.9% (8/163)	6.8% (10/147)	9.6% (13/136)
Delivery system malfunction	4.2% (8/190)	N/A	N/A	N/A	N/A	N/A
Device malfunction¥	N/A	0.0% (0/189)	0.0% (0/183)	1.1% (2/176)	0.6% (1/161)	2.1% (3/146)
Stent graft migration***	N/A	N/A	0.0% (0/177)	0.0% (0/172)	0.6% (1/154)	3.7% (5/135)
Graft occlusion¥	N/A	0.0% (0/189)	2.2% (4/183)	1.7% (3/176)	0.6% (1/161)	0.7% (1/146)
Conversion to open surgery¥	N/A	0.0% (0/189)	0.5% (1/183)	0.6% (1/176)	0.0% (0/161)	0.0% (0/146)
Incidence of secondary interventions, or the need for secondary interventions, to repair vascular events or malfunctions	N/A	0.5% (1/189)	2.7% (5/183)	4.5% (8/176)	4.3% (7/162)	8.2% (12/146)
Incidence of secondary interventions, within 1 year post procedure needed to prevent the occurrence of a significant event	N/A	0.0% (0/189)	0.0% (0/182)	0.0% (0/176)	NA	NA

Secondary Effectiveness Endpoints	INCRAFT ITT** Subjects (N = 190)					
	Peri-Procedure	1 Month	6 Months	1-Year	2-Years	3-Years

* - For aneurysm enlargement, endoleaks, fractures, and migrations, denominators are based on evaluable core lab data within the imaging windows: 1 Month (post-procedure - 90 days); 6 Month (91 - 270 days); 12 Month (271 - 540 days) 2 Years (541 - 900 days), 3 Years (901 - 1260 days)
- For aneurysm sac ruptures, malfunctions, graft occlusions, conversions to open surgery, and secondary interventions, denominators are based on evaluable site reported data in follow-up windows: 1 Month (procedure - 30 days); 6 Month (31 - 180 days); 12 Month (181 - 360 days) 2 Years (361 - 720 days), 3 Years (721 - 1080 days)

** Intent-to-treat (ITT) analysis set includes all subjects who had the aortic bifurcate device introduced into the body.

∞ - Subjects with fractures and migration identified will continue to be included in the numerator and denominator for later time points

§ Aneurysm-related mortality was defined as a death from AAA rupture, or death within 30 days of open aortic surgical or endovascular repair or death from any subsequent procedure required to treat the same aneurysm.

‡ Technical success at 1 month was defined as a patent endovascular graft with absence of types I or III endoleaks or aneurysm sac rupture, up to 1 month post-procedure completion as confirmed by CT.

¥ A summary of conversions to open surgery, graft occlusions, device malfunctions and stent fractures are noted above table.

*** The migrations seen through 3 years only include limb migration, no migration of the bifurcate.

6.2.8.2.1 Technical Success

The INSPIRATION study evaluated technical success at the conclusion of the index procedure as one of the primary effectiveness endpoints and technical success at 1 month as one of the secondary effectiveness endpoints. The definition of technical success at the conclusion of the index procedure is successful insertion of the delivery system through the vasculature, successful deployment of the device at the intended location, the endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, as confirmed by the completion angiography or other imaging modality. The definition of technical success at 1 month, is the endovascular graft must be patent, with absence of types I or III endoleaks or aneurysm sac rupture, up to 1 month post procedure completion as confirmed by CT or other imaging modality.

At the conclusion of the index procedure the rate of technical success was 94.1%. The reasons for not achieving technical success were related to 2 devices that were deployed at the unintended location and 9 Type I endoleaks present at the conclusion of the procedure. Both a technical and clinical review of the 2 cases related to deployment were performed. It revealed that the user failed to stabilize the white handle component of the **INCRAFT**® delivery system during the pulling process of the fixation release wire. The Type I endoleaks all resolved by the 1 month follow-up time point.

The rate of technical success at 1 month was 100%. The grafts were patent. There were no incidences of Type I or III endoleaks or aneurysm sac ruptures.

6.2.8.2.2 Aneurysm-Related Mortality

Please refer to Section 6.2.7.3 for information regarding aneurysm-related mortality.

6.2.8.2.3 Device-Related Events

The post procedure device-related events at each follow up time points through 3 years are provided in **Table 16**. There were no device-related events at 1 month. There were 8 device-related events in 7 subjects at 6 months (3 stent fractures, 4 graft occlusions, and 1 conversion to open

surgery). There were 17 device-related events in 13 subjects at 1 year (3 Type I endoleaks, 8 stent fractures, 2 device malfunctions, 3 graft occlusions, and 1 conversion to open surgery). There were 28 device-related events in 22 subjects at 2 years (11 aneurysm enlargement, 4 Type I endoleaks, 10 stent fractures, 1 device malfunction, 1 stent graft migration, 1 graft occlusion). There were 48 device-related events in 39 subjects at 3 years (23 aneurysm enlargement including 10 persistent from 2 years, 2 Type I endoleaks, 1 Type III endoleaks, 13 stent fractures, 3 device malfunctions, 5 stent graft migration, 1 graft occlusion). Subjects with stent fractures and migration identified will continue to be included at later time points.

6.2.8.2.4 Endoleaks

In the INSPIRATION Study, the Clinical Events Committee (CEC) adjudicates Type I, III and IV endoleaks. Type II endoleaks are not adjudicated by the CEC. A summary of endoleaks present at the end of each follow up time point through 3 years is presented in **Table 17**.

The procedural Type IV endoleak occurrence rate, as adjudicated by the Clinical Events Committee, was 16.8% (32 Type IV endoleaks/190 total subjects). Seven of those Type IV endoleaks were resolved at discharge and the remaining 25 resolved by the 1 month time point. None of the Type IV endoleaks resulted in a conversion to a Type III endoleak. Type IV endoleaks generally resolve shortly after reversal of the patient's systemic anticoagulation and therefore do not present a concern long term as evidenced by the clinical data.

There were 9 Type Ia endoleaks reported at the index procedure and all spontaneously resolved by 1 month post-procedure. There were 3 Type Ia endoleaks reported at 1 year, 4 Type I endoleaks (3 Ia endoleaks and 1 Ib endoleak) at 2 years and 2 Type Ib endoleak at 3 years. All Type I endoleaks were resolved after the secondary interventions except for 1 Type Ia endoleak through 3 years.

There was 1 Type III endoleak reported related to a fabric tear in a stent graft limb at 3 years. It was resolved after the secondary intervention (placement of a competitor limb).

Most endoleaks reported were Type II endoleaks.

There was no aneurysm enlargement observed in the subjects with Type III endoleak. Two subjects with Type I endoleaks experienced aneurysm enlargement, however, the sac diameter subsequently decreased after the endoleak resolution.

Table 17. Number of Subjects with Endoleaks Reported through the 3 Year Follow-Up Visit

	Post-Procedure Day 0	Discharge	1 month	6 month	1 year	2 year	3 year
Endoleaks (Total) ∞	88	73	66	60	52	50	40
Type Ia Total	9 (10.2%, 9/88)	6 (8.2%,6/73)	0 (0%)	0 (0%)	1 (1.9%,1/52)	2 (4.0%, 2/50)	1 (2.5%,1/40)
Type Ib Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type II Total	42 (47.7%,42/88)	38 (52.1%,38/73)	66 (100%,66/66)	60 (100%,60/60)	51 (98.1%,51/52)	48 (96%,48/50)	39 (97.5%,39/40)
Type III Total	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type IV Total	32 (36.4%,32/88)	25 (34.2%,25/73)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Type V Total	2 (2.3%, 2/88)	2 (2.7%, 2/73)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Unknown * Total	3 (3.4%, 3/88)	2 (2.7%,2/73)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

∞ Total endoleaks at each time point is the sum of each type of endoleaks at that time point.

* Unknown: Other category includes one endoleak that was adjudicated as both Type II and Type IV and two endoleaks that were adjudicated as not Type I or Type III.

6.2.8.2.5 Change in Aneurysm Diameter

Per the study protocol, aneurysm enlargement is defined as growth of the aneurysm sac > 5 mm compared to the one month size measurement. Subjects with aneurysm expansion at any time point will continue to be reported in subsequent time points if the aneurysm size meets the definition of expansion. There were no aneurysm enlargement observed by the core lab at 6 months and 1 year. Eleven subjects (7.1%) were observed with aneurysm enlargement at 2 years. At 3 years, 23 subjects (17%) were observed with aneurysm enlargement, including 13 new enlargement and 10 ongoing enlargement from previous visit. Aneurysm regression (> 5 mm) is 22.2% at 6 months, 37.6% at 1 year, 36.8% at 2 years and 38.2% at 3 years. **Table 18** provides a summary of change in aneurysm diameter through 3 year follow-up as assessed by the core lab.

Table 18. Aneurysm Diameter Change through 3 Year Follow-Up

	6 Months	1 Year	2 Year	3 Year
Aneurysm diameter change from 1 month				
Aneurysm enlargement (increase > 5mm)	0% (0/176)	0% (0/173)	7.1% (11/155)	17% (23/136)
Aneurysm stable (≤5mm regression/ enlargement)	77.8% (37/176)	62.4% (108/173)	55.5% (86/155)	44.8% (61/136)
Aneurysm regression (decrease > 5mm)	22.2% (39/176)	37.6% (65/173)	36.8% (57/155)	38.2% (52/136)

6.2.8.2.6 Aneurysm Sac Rupture

Please refer to Section 6.2.7.4 for information regarding aneurysm sac rupture.

6.2.8.2.7 Device Malfunctions

A device malfunction is determined by the clinical site per the study protocol. Fourteen device malfunctions were reported by the clinical sites during the study through 3 years (**Table 19**). The data includes 8 delivery system malfunctions and 6 device malfunctions specific to the implanted components of **INCRAFT**.

Eight delivery system malfunctions were reported during the INSPIRATION clinical study at the time of the index procedure. Five of the 8 malfunctions were related to leakage in the aortic bifurcate hemostasis valve. Minor manufacturing process improvements have been implemented to reduce the potential for leakage in the aortic bifurcate hemostasis valve. The remaining 3 delivery system malfunctions were related to a high fixation release wire pull force, a component migration noted in the subject with deployment of the device not at the intended location, and a broken proximal sheath introducer respectively. The occurrence of these 3 malfunctions can be reduced through proper adherence to the information contained within these Instructions for Use.

The 2 subjects (1 event for each subject) with reported device malfunctions at 1 year pertained to patency issues. A patency issue can either be a stenosis or an occlusion. Stenosis refers to cases in which the stent graft component or vessel is not 100% obstructed. Complete obstruction is reported as a stent graft occlusion (summarized in Section 6.2.8.2.10 – Stent Graft Patency).

Beyond the 1 year time point, 1 device malfunction for stent fracture was reported at 2 years by clinical site. At 3 years, 1 device malfunction for stent fracture, 1 for device kink and 1 for type III endoleak were reported by clinical sites. The stent fracture were reported by clinical sites after the notification of the core lab findings. These events are also discussed in the appropriate section for each endpoint in this document.

Table 19. Device Malfunction through 3 Years

	Treatment to 12 Months % (n/N)	1 Month % (n/N)	6 Months % (n/N)	1 Year % (n/N)	2 Year % (n/N)	3 Year % (n/N)
Device or Delivery System Malfunction	5.3% (10/190)	0% (0/189)	0% (0/183)	1.1% (2/176)	0.6% (1/161)	2.1% (3/146)

6.2.8.2.8 Migration

No device migrations were observed by the 1 year follow up visit. Five device migrations were observed by the core lab beyond the 1 year time point through 3 years. All of the device migrations were limb migrations and no bifurcate migrations were observed. The migration status at each time point are based on the images reviewed by the core lab. One subject was initially observed with left limb migration at 2 years and bilateral limb migration at 3 years. Four subjects were observed with limb migration on only one side at 3 years.

The number and percent of device migrations at the study follow-up visits is presented in **Table 20**. The subjects with adequate imaging to assess the migration is used for the denominator for the percentage calculation.

Table 20. Stent Migration through 3 Years

	Treatment to 12 Months % (n/N)	1 Month % (n/N)	6 Months % (n/N)	12 Months % (n/N)	2 Year	3 Year
Stent Migration *	0% (0/187)	0% (0/187)	0% (0/177)	0% (0/172)	0.6% (1/154)	3.7% (5/135)

*: Subjects with migration identified will continue to be included in the numerator and denominator for later time points.

6.2.8.2.9 Stent Graft Integrity

Upon review of subject images by the Core Lab (central review), a total of 13 subjects with stent fracture were observed on the follow up imaging (X-ray) through 3 years. All of the fractures observed thus far are located in the transrenal stent. Three subjects with stent fracture were observed at 6 months, 8 were observed at 1 year, 10 were observed at 2 years and 13 were observed at 3 years. None of the subjects with stent fracture had clinical events associated with the stent fracture, specifically, no migration, potential stent segment embolization, Type I endoleak, aneurysm enlargement, sac rupture, vessel perforation, or death related to the stent fracture.

The number and percent of stent fractures at the study follow-up visits is presented in **Table 21.** The subjects with adequate imaging to assess the stent fracture is used for the denominator for the percentage calculation.

Table 21. Stent Graft Integrity through 3 Years

	Treatment to 12 Months % (n/N)	1 Month % (n/N)	6 Months % (n/N)	1 Year % (n/N)	2 Year % (n/N)	3 Year % (n/N)
Stent Fracture*	4.4% (8/183)	0% (0/183)	1.7% (3/172)	4.9% (8/163)	6.9% (10/144)	9.9% (13/131)

*Subjects with fractures identified will continue to be included in the numerator and denominator for later time points.

6.2.8.2.10 Stent Graft Patency

Per the INSPIRATION clinical study protocol, a stent graft occlusion was defined as a complete absence of flow within the stent graft. A stenosis was defined as patency within the graft that was less than 100% obstructed. A total of 9 stent occlusions, 14 stent stenoses and 1 limb kink were reported through 3 years. There were 4 stent graft occlusions and 2 stent graft stenoses were reported at 6 month. Three stent graft occlusions and 8 stent graft stenoses were reported at 1 year. One stent graft occlusion and 1 stent graft stenosis were reported at 2 years. One stent graft occlusion and 3 stent graft stenosis and 1 limb kink were reported at 3 years. All subjects with stent patency events underwent the secondary interventions resolving the patency events, except for 7 subjects with stent stenosis, for which the intervention was not required per the investigator. No recurrence of the patency events occurred after the secondary interventions.

A thorough analysis of the clinical and anatomical characteristics of all the subjects with patency events yielded potential contributing factors that could predispose the subjects to an occlusion or stenosis of the stent graft. Multiple factors contributed to thrombotic stenosis or occlusion of endograft limbs. These factors included landing the device within the external iliac artery (2 events), deployment of the device within a small diameter aortic bifurcation (2 events), severe iliac artery atherosclerotic disease (4 events), pre-existing thrombus at the iliac landing zone (1 event), long aortic neck with constrained iliac limbs (2 events in 1 subject), residual stenosis (1 event), and hypercoagulability syndromes including malignancy (5 events in 4 subjects). Patients not treated with aspirin or other antiplatelet agents may also be at increased risk for endograft thrombotic stenosis or occlusion (4 events).

The secondary interventions and outcomes associated with these patency events are presented along with the accessory device, affected site, reason for intervention and number of days post-procedure in **Table 22**. **Table 22** also includes one non-patency related secondary intervention, which related to a vascular injury during the procedure.

Table 22. Secondary Interventions through 3 Years

Accessory Device	Affected Site	Reason for Intervention	MAE	Days Post Index Procedure	Intervention Details
Procedures to Treat Patency-Related Events through 1 year follow-up					
Two stents placed Fem-fem crossover bypass	Left Limb	Occlusion	None	245	A CT scan was performed after the subject experienced left leg pain. A left limb occlusion was identified. The subject was not prescribed aspirin, clopidogrel, or other antiplatelet/ anticoagulants at the time of the occlusion. The subject underwent a mechanical thrombectomy of the left graft limb, bilateral iliac stent placement, balloon angioplasty of the left external iliac artery, left common femoral artery endarterectomy and patch angioplasty, left femoropopliteal thromboembolectomy, and a right to left femoral-femoral bypass resolving the occlusion.

Fem-fem crossover bypass	Right Limb	Occlusion	None	211	The subject returned for the 6 month follow-up visit with new onset of severe right leg claudication with no palpable pulses of the leg. The CT revealed a right iliac limb occlusion with reconstitution of the right external and internal iliac and common femoral arteries. There was also mural thrombus present in the left limb of the endograft along the overlap zone with a residual luminal diameter under 6 mm. The subject was scheduled for a femoral-femoral bypass which was successfully completed resolving the occlusion. At discharge, the subject was prescribed enoxaparin, metoprolol extended release and warfarin.
One stent placed	Left Limb	Occlusion	None	196	The subject returned for the 6 month follow-up visit and had no complaints of claudication symptoms. An occlusion of the left iliac limb of the endograft was documented. The subject underwent successful thrombolysis followed by stent placement in the left iliac limb resolving the occlusion. The subject was discharged with an additional prescription for clopidogrel.
One stent placed in each limb	Left Limb	Occlusion	None	188	The subject returned for the 6 month follow-up visit and complained of 6 - 8 weeks of left leg claudication symptoms. An absence of pulses in the left leg was assessed on physical examination. CT angiogram showed that the left limb of the endograft was occluded. The subject underwent successful thrombolytic therapy of the left limb of the endograft. There was a residual stenosis in the proximal portion of the left limb and the subject underwent an interventional procedure three days later for placement of a stent in the limb, as well as left ilio-femoral thrombectomy resolving the occlusion. A second stent was placed in the right limb.
Fem-fem crossover bypass	Right Limb	Occlusion	None	179	The subject returned for the 6 month follow-up visit and imaging demonstrated an occlusion in the right iliac limb. A femoral-femoral bypass was performed to restore circulation to the right leg resolving the occlusion. At discharge, aspirin was continued and clopidogrel was prescribed.
Fem-fem bypass and device explant	Bifurcate and bilateral Limbs	Occlusion	None	173	The subject developed numbness and pain in both legs. Imaging demonstrated an occlusion of the bifurcate and both limbs of the device, beginning below the renal arteries and extending to the common iliac bifurcations bilaterally. Both hypogastric and external iliac arteries were reconstituted distal to the occluded limbs. The device was explanted and an aortobiliac bypass with left iliofemoral bypass was performed resolving the occlusion.
One stent placed	Left Limb	Occlusion	None	100	The subject came in for an office visit with complaints of pain and numbness in the left leg. ABIs were performed showing progressive left limb ischemia. An angiogram confirmed left iliac limb occlusion which was re-cannulated with angioplasty and stenting resolving the occlusion.
One stent placed	Right Limb	Stenosis	None	351	The subject complained of claudication. A mild to moderate narrowing of the right iliac limb due to inherent thrombus was noted. Angioplasty with stent placement was performed resolving the stenosis.
No device placed	Left Limb	Stenosis	None	211	The subject presented with diminished pulse on the left side and a CT scan revealed stenosis of the left limb. Subject underwent balloon angioplasty resolving the stenosis.
Surgical Graft	Bilateral Stent Graft Limb	Stenosis	None	206	The subject returned for the 6 month CT which exhibited a new mural thrombus in the left iliac limb. The subject was commenced on Plavix and Xarelto. The subject returned for follow up 3 months later and the device was explanted due to bilateral mural thrombus which resolved the stenosis.

One stent placed	Right Limb	Stenosis	None	199	The subject returned for the 6 month CT which exhibited decreased blood flow through the right iliac limb and the ABI was decreased. The subject also had symptoms of claudication. A stent was placed in the right iliac limb resolving the stenosis.
One stent placed	Left Limb	Stenosis	None	181	The subject returned for the 6 month follow up and CT exhibited narrowing in the proximal to mid left limb of the stent graft with thrombus present. A stent was placed in the left limb resolving the stenosis.
One stent placed	Left Limb	Stenosis	None	64	At follow up, a reduced ABI was observed and angioplasty of the left limb with stent placement was performed. The next day following the procedure, ABI was repeated which showed resolution of the stenosis.
Procedures to Treat Patency-Related Events through 2 year follow-up					
Fem-fem crossover bypass	Left limb	Occlusion	None	524	The subject returned for his 1 year follow-up. Device was intact and patent. Subject not taking aspirin, complained of left leg claudication starting about a month prior. Patient returned for follow-up 5 months later. Developed significant claudication on left. Angiography confirmed occlusion. Underwent right-to-left femoral-femoral bypass which restored adequate flow to left leg. Aspirin therapy started in hospital and patient discharged on clopidogrel.
Thrombectomy and three stents placed	Bilateral Limbs	Thrombus	None	499	The subject returned for his 1 year follow-up. Thrombus noted in the proximal left iliac limb. Six months later subject had claudication with new lower extremity symptoms. Subject underwent bilateral popliteal and tibial thrombectomy and placement of three stents. Thrombus was resolved and the patient was continued on aspirin and clopidogrel at discharge.
Procedures to Treat Patency-Related Events through 3 year follow-up					
Relining of prior Cordis INCRAFT stent graft using competitor limbs (2 on the right side and 2 on the left side)	aortoiliac stent graft	Occlusion	None	781	The subject returned for his 2 year follow-up. Imaging showed thrombosis of the entire stent graft. Underwent a successful revision of the endovascular repair to restore perfusion to the lower extremities. Subject started on clopidogrel.
One stent placed	stent graft limb	Kink	None	771	The subject returned for the 2 year follow-up. Device found to have kink at the left limb overlap zone. A stent was place in the left limb to resolve the kink.

6.2.8.2.11 Conversion to Open Surgery

Please refer to Section 6.2.7.5 for information regarding conversion to open surgery.

6.2.8.2.12 Secondary Intervention

A total of 28 subjects underwent 38 secondary interventions through 3 years to repair the device or aneurysm for vascular events or malfunctions which are related to device or peri-graft complications. A summary of the secondary interventions is presented in **Table 23.** The secondary interventions for patency events included in Table 22 are also included in the **Table 23**: Summary of Secondary Interventions through 3 Years.

Table 23. Summary of Secondary Interventions through 3 Years

Summary of Secondary Interventions through 1 year follow-up			
Reason for Intervention	**Type of Intervention**	**Days Post Procedure**	**Outcome**
Occlusions			
Right iliac limb occlusion	Fem-fem crossover bypass	211	Resolved
Left limb occlusion	One stent was placed in each limb of the stent graft and subject underwent a left iliofemoral embolectomy, Atrium iCAST 12x38 on left and Smart stent 14x40 on right	188	Resolved
Right iliac limb occlusion	Fem-fem crossover bypass	179	Resolved
Left iliac limb occlusion	Thrombolysis/ thrombectomy/ PTA and one stent was placed in the left iliac limb of the stent graft, 8 mm x 8 cm self-expanding Nitinol stent	196	Resolved
Left Limb Occlusion	Angioplasty with one stent placed in the left limb of stent graft, Cordis Smart Stent 14 x 80 and a second Cordis Smart Stent 14 x 80	100	Resolved
Occluded left limb of the EVAR graft	Two stents placed, Thrombolysis/ thrombectomy/ PTA, Fem- fem crossover bypass, Covered Stent ,Atrium Medical Corp., 38 x 35.3 mm and 59 x 56.9 mm- Viabahn Endoprosthesis, Gore, 10 mm x10 cm- Propaten Vascular Graft, Gore, 8 mm x 500 cm	245	Circulation resolved, Graft occlusion
Endograft occlusion	Fem-fem crossover bypass, device explanted	173	Resolved
Stenoses/Thrombus			

Summary of Secondary Interventions through 1 year follow-up			
Reason for Intervention	**Type of Intervention**	**Days Post Procedure**	**Outcome**
Bilateral iliac limb stenosis	Plavix and Xarelto were prescribed and device explant occurred three months later	206	Resolved
Left limb stenosis	Angioplasty of the left iliac limb of the stent graft	211	Resolved
Left limb of endograft stenosis	One stent was placed in the left limb of the stent graft, Viabahn endoprosthesis 10 mm X 5 cm	181	Resolved
Right Limb stenosis	One stent placed in the right limb of the stent graft, Cordis Smart Stent 14 x 80 and a second Cordis Smart Stent 14 x 80	199	Resolved
Right Iliac limb stenosis	Angioplasty with one stent placed in the right limb of stent graft	351	Resolved
Low ABI	One stent was placed	64	Resolved
Endoleak			
Type II endoleak	Embolization Coiling of AAA endosac and interior mesenteric artery	164	Resolved
Other			
Superior Mesenteric Artery intimal flap	One stent was placed in the Superior Mesenteric Artery. Abbott Herculink 7X15 mm	0	Resolved

Summary of Secondary Interventions through 2 year Follow-Up			
Reason for Intervention	**Type of Intervention**	**Days Post Procedure**	**Outcome**
Occlusions			
Left limb occlusion	Fem-fem crossover bypass	524	Resolved
Stenoses/Thrombus			

Summary of Secondary Interventions through 2 year Follow-Up			
Reason for Intervention	**Type of Intervention**	**Days Post Procedure**	**Outcome**
Thrombus of bilateral limbs of abdominal aortic endograft.	Thrombectomy and placement of three covered stents in the iliac limbs.	499	Resolved
Endoleak			
Endoleak (Type II)	Coil embolization	483	Resolved
Endoleak (Type II)	Coil embolization	402	Resolved
Endoleak (Type Ia)	Coil embolization	715	Resolved
Endoleak repair (Type I)	Proximal aortic cuff and eight EndoAnchors were implanted	410	Resolved
Endoleak repair (Type Ia)	Seven EndoAnchors were implanted at the proximal neck.	399	Resolved
Endoleak (Type Ia)	Excluder aortic extender cuff implanted	398	Resolved
Other			
Bleeding of suture site after the secondary intervention for the type II endoleak	A fem-stop device was applied to the site	485	Resolved

Summary of Secondary Interventions through 3 year Follow-Up			
Reason for Intervention	**Type of Intervention**	**Days Post Procedure**	**Outcome**
Occlusions			
Complete occlusion of the aortoiliac stent graft	Relining of prior Cordis INCRAFT stent graft using competitor limbs (2 on the right side and 2 on the left side) 2 Gore Viabahn/ 4 Gore Excluder	781	Resolved
Stenosis/Kink			
Kink of stent graft limb	Deployment of an iCAST covered stent ICast covered stent (10 mm x 38 mm)	771	Resolved
Endoleak			
Endoleak repair (Type 1b)	Limb extension placement and coil embolization	828	Resolved
Endoleak repair (Type 1a)	Proximal aortic cuff placement with left renal stent in chimney configuration, Gore Excluder Cuff 26-33 mm; Atrium	775	Resolved
Endoleak (Type II)	Coil embolization of IMA and coil and glue embolization of the aneurysm sac	877	Resolved
Endoleak (Type Ia)	Aortic cuff and stent placement, Excluder cuff,GORE,26 mmX3.3 cm	958	Resolved
Endoleak (Type III)	Gore Excluder Leg placed	1064	Resolved
Endoleak (Type II)	Coil embolization	1064	Resolved
Endoleak (Type II)	Coil embolization	742	Resolved
Endoleak (Type II)	Sac embolization using glue	743	Resolved
Endoleak (Type Ib)	A right limb extension applied	1063	Resolved
Endoleak (Type II)	Trans lumbar embolization with glue	1035	Resolved
Endoleak (Type II)	Supraselective embolization of the inferior lumbar and medial sacral arteries	1076	Resolved
Endoleak (Type II)	Coil embolization of inferior mesenteric artery	1077	Resolved

year

7 PATIENT SELECTION AND TREATMENT

Each **INCRAFT** AAA Stent Graft System must be ordered in the appropriate size to fit the patient's anatomy. Proper sizing of the device is the responsibility of the physician. Each stent graft component should be sized to the adventitia-to-adventitia measurement of the vessel at its intended landing zone. The stent graft configurations cover aortic diameters ranging from 17 to 31 mm and iliac diameters from 7 to 22 mm. The suprarenal aorta must be confirmed by measuring the diameter of the aorta 2 cm above the intended landing zone of the aortic bifurcate to confirm that the suprarenal aorta is no bigger that the labeled nominal diameter of the chosen aortic bifurcate. This will ensure proper engagement of the suprarenal barbs after deployment.

The recommended overall length of the stent graft including multiple deployed devices should extend from the lowest renal artery to just above the internal iliac or hypogastric artery. All lengths and diameters of the stent graft devices necessary to complete the procedure should be available to the physician, especially when pre-operative case planning measurements (treatment diameters/lengths) are not certain. Use of this approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes.

Cordis may consult with physicians to determine proper stent graft dimensions based on the physician's assessment of the patient's anatomical measurements. The benefits and risks previously described should be carefully considered for each patient before use of the stent graft system.

Caution: Vessel over-distension and damage, or partial stent graft in-folding, may be caused by excessive oversizing of the stent graft in relation to the diameter of the blood vessel.

8 PATIENT COUNSELING INFORMATION

The physician should review the following risks and benefits when counseling the patient about this endovascular device and procedure:

- Patient age and life expectancy
- Risks and benefits related to open surgical repair
- Risks and benefits related to endovascular repair
- Risks related to non-interventional treatment or medical management
- Risks of aneurysm rupture compared to endovascular repair
- Possibility that subsequent endovascular or open surgical repair of the aneurysm may be required
- The long-term safety and effectiveness of **INCRAFT** has not been established
- Long-term, regular follow-up is needed to assess patient health status and stent graft performance
- Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms) should be monitored closely
- Symptoms of aneurysm rupture

Cordis recommends that the physician disclose to the patient, in written form, all risks associated with treatment using **INCRAFT**. Details regarding risks occurring during and after implantation of the device are provided in adverse events (Section 5).

9 HOW SUPPLIED

9.1 Package Contents

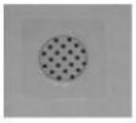
INCRAFT is available in the following packaging configurations.

- The aortic bifurcate prosthesis is supplied in the aortic bifurcate delivery system
- The iliac limb prosthesis (which also serves as an iliac limb extension) is supplied in the iliac limb delivery system

9.2 Sterilization, Storage and Handling

- The package contents of **INCRAFT** have been sterilized with ethylene oxide gas. The system is provided sterile for single use only. Do not resterilize any components of the system.
- Use prior to the “Use By” date specified on the package.
- Store the packaged **INCRAFT** to avoid exposure to extreme temperatures (above 60°C) and humidity.

Caution: The black dotted pattern on the grey temperature exposure indicator, located on the pouch label, must be clearly visible as shown below.



- Do not use if the temperature exposure indicator is completely black because the unconstrained prosthesis diameter may have been compromised, as illustrated below. A completely black indicator signifies that the product has been exposed to temperatures out of an acceptable temperature range. This indicates that the product should not be used.

OK for use

Do not use

- Before using the devices, carefully inspect all packaging for damage or defects.
- Handle the devices with care. Be aware that the delivery system cannot be bent without an appropriate guidewire inserted into the guidewire lumen.
- If the package has been damaged or the sterility of the contents is compromised, do not use the device. Return the package and device to Cordis Corporation.
- The product is provided double-pouched. Do not use if the outer pouch is opened, damaged, or missing.

10 CLINICAL USE INFORMATION

10.1 Physician Training Requirements

All physicians should be trained in the use of **INCRAFT** before using it.

> **Caution**: **INCRAFT** should only be used by physicians and teams trained in vascular interventional techniques and in the use of this device.

In addition, the following are the knowledge and skill requirements for physicians using **INCRAFT**:

- Natural history of abdominal aortic aneurysms (AAA), aortoiliac aneurysms, and comorbidities associated with AAA repair
- Radiographic, fluoroscopic, and angiographic image interpretation
- Appropriate use of radiographic contrast material
- General arterial cut down, arteriotomy, and repair or percutaneous access and closure techniques
- Nonselective and selective guidewire and catheter techniques
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Techniques to minimize radiation exposure
- Device selection and sizing

10.2 Device Configuration and Sizing Guide

The components of **INCRAFT** are shown in **Figure 8. Tables 24 and 25** provide information on the prosthesis dimensions and a sizing guide.

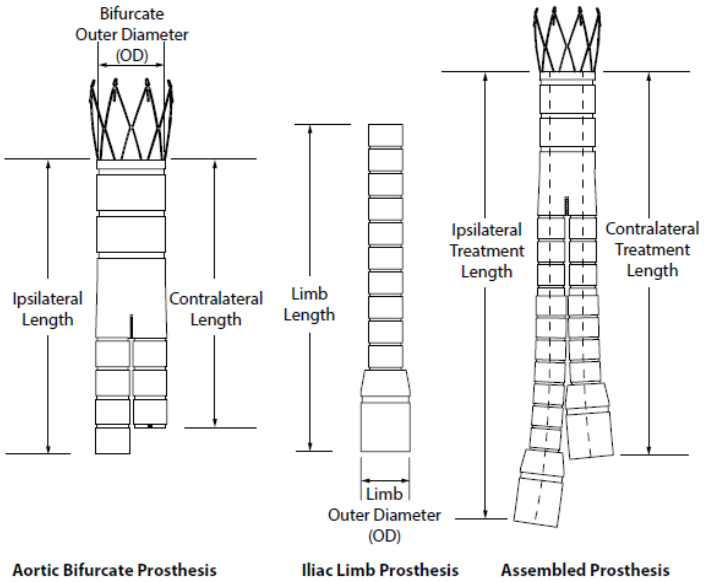


Figure 8. Stent Graft Diameter and Length Identification

Table 24. Aortic Bifurcate Prosthesis Dimensions Sizing Guide

Product Code	Bifurcate Main Diameter (mm)	Aortic Vessel Diameter Range Treated (mm)	Delivery System ID (F)	Delivery System OD		Ipsilateral Length (cm)	Contralateral Length (cm)
				F	mm		
AB2298	22	17.0 - 19.9	13	14	4.7	9.4	8.6
AB2698	26	20.0 - 22.9	13	14	4.7	9.4	8.6
AB3098	30	23.0 - 26.9	13	14	4.7	9.4	8.6
AB3498	34	27.0 - 31.0	15	16	5.3	9.4	8.6

Table 25. Iliac Limb and Limb Extension Prosthesis Dimensions Sizing Guide

Product Code	Limb Diameter (mm)	Iliac Vessel Diameter Range Treated (mm)	Limb Length (cm)	Delivery System OD		Ipsilateral Treatment Length (mm)	Contralateral Treatment Length (mm)
				F	mm		
IL1008	10	7.0 - 8.9	8.2	12	4.0	128-156	128-147
IL1010	10	7.0 - 8.9	10.1	12	4.0	147-175	147-166
IL1012	10	7.0 - 8.9	12.0	12	4.0	166-194	166-185
IL1014	10	7.0 - 8.9	13.8	12	4.0	184-212	184-203
IL1308	13	9.0 - 10.9	8.2	12	4.0	128-156	128-147
IL1310	13	9.0 - 10.9	10.1	12	4.0	147-175	147-166
IL1312	13	9.0 - 10.9	12.0	12	4.0	166-194	166-185
IL1314	13	9.0 - 10.9	13.8	12	4.0	184-212	184-203
IL1608	16	11.0 - 13.9	8.2	12	4.0	128-156	128-147
IL1610	16	11.0 - 13.9	10.1	12	4.0	147-175	147-166
IL1612	16	11.0 - 13.9	12.0	12	4.0	166-194	166-185
IL1614	16	11.0 - 13.9	13.8	12	4.0	184-212	184-203
IL2008	20	14.0 - 17.9	8.2	12	4.0	128-156	128-147
IL2010	20	14.0 - 17.9	10.1	12	4.0	147-175	147-166
IL2012	20	14.0 - 17.9	12.0	12	4.0	166-194	166-185
IL2014	20	14.0 - 17.9	13.8	12	4.0	184-212	184-203
IL2410	24	18.0 - 22.0	10.1	13	4.3	147-175	147-166
IL2412	24	18.0 - 22.0	12.0	13	4.3	166-194	166-185
IL2414	24	18.0 - 22.0	13.8	13	4.3	184-212	184-203

Warning: Failure to comply with sizing requirements outlined in the tables above may result in prostheses leaks, compromised flow, prostheses migration, compromised long term device durability or other complications or adverse events.

Caution: Take care to avoid excessive oversizing in tapered aortic necks.

10.3 Recommended Devices, Supplies, and Equipment

For the procedure, it is recommended to have the following devices, supplies and equipment available.

- Devices – Redundant **INCRAFT** components of appropriate dimensions.
- Sterile hospital supplies including the following.
    - Heparinized saline solution
    - Introducer sheaths
    - Stiff guidewires
    - Radiopaque ruler with centimeter increments
    - Assorted balloon catheters
    - Compliant balloon catheters
    - Radiopaque contrast media
    - Sterile silicone lubricant or sterile mineral oil
    - Interventional snare devices
    - Endovascular coils and vascular plugs
- Non-sterile hospital equipment - Fluoroscope with digital angiography capabilities and the ability to record and recall all imaging.

10.4 MAGNETIC RESONANCE (MR) Imaging Safety and Compatibility

Non-clinical testing has demonstrated that **INCRAFT** is MR Conditional. A patient with this device can be scanned safely in an MR system meeting the following conditions.

- Static magnetic field of 1.5T or 3T
- Spatial gradient field ≤ 2500 Gauss/cm (25 T/m)
- Maximum whole-body-averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Mode)

Under the scan conditions defined above, the **INCRAFT** stent graft is expected to produce a maximum temperature rise of less than 6°C during 15 minutes of continuous MR scanning.

The calculations do not take into consideration the cooling effects of blood flow, and therefore, actual in-vivo rises are expected to be lower. The effect of heating in the MRI environment for fractured struts is not known.

In non-clinical testing, the image artifact caused by the device extends approximately 2 mm and 5 mm from the device, both inside and outside the device lumen when imaged with a spin echo and gradient echo pulse sequence respectively and a 3.0 T MRI system.

11 PREPARATION INSTRUCTIONS

Before you start the implant procedure, please read the following information to prepare the delivery

systems.

11.1 Patient Preparation

1. Systemic anticoagulation should be administered during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be considered.
2. Following standard practices, gain vascular access on both ipsilateral and contralateral sides.

   Note: For the purposes of this instruction for use, the side chosen for the implantation of the aortic bifurcate prosthesis is considered the ipsilateral side of the patient.

3. Following standard practices, perform angiography with a diagnostic catheter placed from the contralateral side (anteroposterior, oblique and lateral views as necessary) to confirm patient eligibility correct device component sizing and deployment locations. Leave the diagnostic catheter in place at the level of the renal arteries.
4. Always use fluoroscopy while advancing and removing guidewires, catheters, and **INCRAFT**.
5. From the ipsilateral side advance a 0.035" (0.89 mm) stiff guidewire to the level of the renal arteries.

Cautions:

- Failure to use a 0.035" (0.89 mm) stiff guidewire may result in vessel trauma and compromise deliverability and/or performance of the delivery system.
- Testing of **INCRAFT** devices was performed using an Amplatz Super Stiff™ guidewire. Use of a stiffer guidewire with the aortic birfurcate prosthesis may lead to increased degree of asymmetric deployment of the transrenal stent, particularly in angulated necks.
- When advancing the guidewires, catheters, and **INCRAFT** into the abdominal aorta, do not disturb the thrombus mass within the aneurysm. Doing so may dislodge emboli, which can cause distal embolization. If distal embolization should occur, use conventional treatment methods.

11.2 Delivery System Preparation

Prepare each delivery system as needed. Use **Figure 5** as a reference.

1. Remove the appropriately sized aortic bifurcate and two iliac limb delivery systems from their packaging and examine for possible damage such as kinks or separated components. Do not use if damage is suspected.

Cautions:

- Take care to maintain the sterility of the product during preparation. Do not bend, kink, or otherwise alter delivery system prior to implantation because it may cause deployment difficulties.
- Take care not to pull or snag the fixation release wire (refer to **Figure 5**) when handling and preparing the delivery system.
- Do not use the device if the fixation release wire is not clipped to the release wire retainer when product is removed from the package.

- Do not tighten the fixation release wire hemostasis valve. Tightening the fixation release wire hemostasis valve may increase the force necessary to pull the fixation release wire later in the procedure.

2. Prior to use, flush the guidewire lumen with heparinized saline through the Guidewire Lumen Flush Connector of the delivery system (refer to **Figure 5**) until saline is observed exiting through the distal end of the device.
3. Wet the aortic bifurcate delivery system (tip and approximately 25 cm of the sheath) with saline to activate the hydrophilic coating.
4. It is recommended before inserting the delivery system into the patient that the delivery system be examined under the fluoroscope on top of the patient to understand the orientation of the prosthesis and the configuration of the marker bands.

12 IMPLANT INSTRUCTIONS

12.1 Implant the Bifurcated Aortic Prosthesis

Perform the following steps using appropriate endovascular and surgical techniques.

1. Using the existing diagnostic catheter previously introduced in the contralateral side, locate the renal arteries, aortic bifurcation, and the iliac bifurcations.
2. If not already present on the ipsilateral side, insert a 0.035” (0.89 mm) stiff guidewire. Position the tip of the guidewire in the descending thoracic aorta. Wet the aortic bifurcate delivery system (tip and approximately 25 cm of the sheath) with saline to activate the hydrophilic coating.
3. Immediately prior to use, re-check that the sheath hemostasis valve screw cap is secure.

   Caution: Failure to ensure the sheath hemostasis valve screw cap is secure may result in connection separation and subsequent incomplete deployment of the prosthesis.

4. Insert the aortic bifurcate delivery system over the ipsilateral guidewire and, under fluoroscopy, advance the aortic bifurcate delivery system beyond the renal arteries and pull back such that the bottom end of the aortic bifurcate cranial edge markers are just below the lowest renal artery.

   Note: The aortic bifurcate graft edge is 0.0-1.0 mm below the bifurcate cranial edge markers.

   Cautions:
   - Once the cranial position of the aortic bifurcate prosthesis has been identified, do not move the patient or imaging equipment, as it may compromise accuracy of prosthesis placement.
   - The diagnostic catheter can be removed prior to deployment. However, if it is not removed until after deployment, ensure that the tip is straightened (for example, if it is pigtail catheter) with a guidewire before removal so that the prosthesis is not subject to migration.
   - When aligning the position of prosthesis, be sure the fluoroscope is angled perpendicularly to the center line of the infrarenal aorta to avoid parallax or other source of visualization error that could impact proper positioning. Some cranial-caudal

angulation of the image intensifier tube may be necessary to achieve this, especially if there is anterior angulation of the aneurysm neck.

5. Using the contralateral side marker (refer to **Figure 4**) as a reference, orient the aortic bifurcate prosthesis so that the contralateral side marker is aligned with either the contralateral iliac artery or the desired position
6. Ensure that the prosthesis position has been maintained with respect to the lowest renal artery. Confirm with injection through angiographic catheter as necessary. If needed, correct position of the bifurcate cranial edge markers under fluoroscopic guidance.

   Caution: Prior to deployment ensure that the sheath hemostasis valve screw cap is secure.

7. To deploy the aortic bifurcate prosthesis, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5**) of the aortic bifurcate delivery system to maintain the delivery system position with respect to the renal arteries (use fluoroscopy and / or angiography to confirm position). While holding the white handle component with one hand, slowly turn the gold handle component (refer to **Figure 5**) of the aortic bifurcate delivery system in the clockwise direction as indicated by the directional arrow on the gold handle component until the sheath begins to retract (use fluoroscopy to confirm that retraction has begun).

   Warning: Ensure that the position of the aortic bifurcate cranial edge markers does not change while retracting the sheath. Once the transrenal stent is unsheathed, the barbs on the transrenal stent are exposed and may be engaged with the aortic wall. Repositioning or rotating the aortic bifurcate delivery system with the barbs exposed may damage the transrenal stent or the aortic bifurcate delivery system, or cause injury to the artery or cause partial/complete coverage of aortic side-branches. Repositioning of the prosthesis may also result in peripheral and aortic side-branch vessel embolization. Failure to position the bottom edge of the aortic bifurcate cranial edge markers below the lowest renal ostium may result in occlusion of the renal arteries. Rotating the delivery system after the sheath has commenced retracting may compromise the operator's ability to pull the secondary release wire in step 9.

   Caution: Ensure that the delivery system handle and delivery system sheath are parallel with the patient's leg. Excessive angulation where the white handle component meets the delivery system sheath may prevent delivery system sheath retraction.

8. Under fluoroscopy, keep turning the gold handle component until the transrenal stent begins to expand. Assess device positioning relative to the renal arteries (refer to **Figure 9**) and make minor adjustments if needed. Continue retraction of the sheath until at least the Contralateral Leg of the aortic bifurcate prosthesis is unsheathed (refer to **Figure 4**) as confirmed by fluoroscopy where the sheath tip is just caudal to the four Contralateral Leg-Gate Markers.

   Warning: Do not retract the guidewire beyond the contralateral leg-gate marker, as guidewire access can be lost or result in a kink of the delivery system.

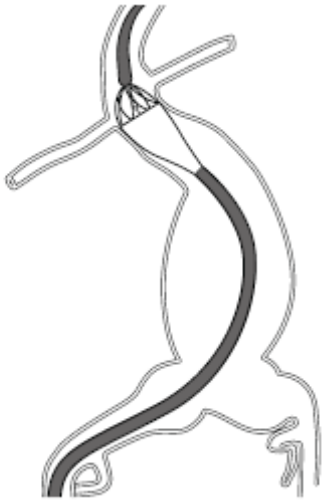


Figure 9. Illustration of Bifurcate Deployment Position

9. While holding the white handle component stationary, locate the fixation release wire on the handle of the aortic bifurcate delivery system (refer to **Figure 5**). Unclip the release wire retainer and pull the fixation release wire (refer to **Figure 5**) until the cranial end of the transrenal stent is released as confirmed by fluoroscopy.

   Caution: While activating the fixation release wire ensure that the white handle component is held against a steady object to avoid compromising placement of the stent graft.

10. Under fluoroscopy, If the prosthesis has not been completely unsheathed, continue turning the gold handle component (refer to **Figure 5**) until it is completely unsheathed. Use fluoroscopy to confirm complete deployment of the aortic bifurcate prostheses.
11. Using standard techniques, slowly reposition the diagnostic catheter from its current position to a location directly above the aortic bifurcation.
12. Upon full deployment of aortic bifurcate prosthesis, hold the integrated sheath introducer firmly to prevent movement while disconnecting the sheath hemostasis valve (refer to **Figure 5**) to separate the sheath into two parts. While holding the sheath firmly, remove the aortic bifurcate delivery system by the handle under fluoroscopic guidance to ensure safe removal of the device, leaving the integrated sheath introducer in place for use when deploying the ipsilateral limb and maintaining guidewire access.

    Note: Proper function of the integrated sheath introducer valve requires that the guidewire be centered within the valve gasket. The recommended technique for re-centering the guidewire if leakage occurs is 1-2 inch pull back of the guidewire followed by an equal push forward of the guidewire.

    Caution: If upon removal of the aortic bifurcate prosthesis delivery system excessive bleeding is seen through the valve, reposition the tip of the delivery system into the valve until the ipsilateral iliac limb prosthesis delivery system is inserted.

12.2 Implant the Iliac Limb Prostheses

The sequence of implanting the ipsilateral and contralateral iliac limb prostheses could vary based on local practice and clinical situation. The following description describes the situation where the ipsilateral iliac limb prosthesis is implanted first.

12.3 Implant the Ipsilateral Iliac Limb Prosthesis

1. Visualize the ipsilateral internal iliac artery origin and the caudal landing zone in the ipsilateral iliac artery by standard techniques.
2. Under fluoroscopic guidance, introduce the iliac limb delivery system over the 0.035" (0.89 mm) stiff guidewire through the integrated sheath introducer left in place from the aortic bifurcate prosthesis deployment so that the limb cranial edge marker of the iliac limb prostheses is aligned with the maximum overlap marker of the aortic bifurcate prostheses while ensuring that no cranial migration of the aortic bifurcate prosthesis occurs.

   Warning: Cranial migration of the aortic bifurcate prosthesis may result in renal occlusion.

3. Under fluoroscopic guidance pull the sheath hemostasis valve back until the tip of the integrated sheath introducer is at least 1 cm below the limb caudal edge marker to ensure that it does not interfere with deployment of the iliac limb prostheses while also ensuring that the delivery system sheath tip marker remains intravascular, particularly if in the proximity of the vascular access site (refer to **Figure 10**).

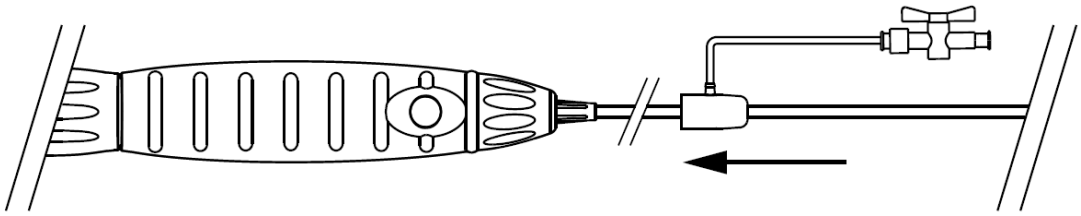


Figure 10. Illustration of the Aortic Bifurcate Sheath Pull-back for Limb Deployment

   Warning: Failure to pull the delivery system sheath back may result in incomplete deployment of the iliac limb prosthesis.

4. Under fluoroscopic guidance, make final caudal adjustment of the iliac limb delivery system by retracting the iliac limb delivery system to the desired deployment position in the iliac artery, ensuring that the limb caudal edge marker is aligned with the iliac landing zone and the limb cranial edge marker is located between the Ipsilateral minimum overlap marker and the maximum overlap marker (refer to **Figure 4**).

   Note: The Limb Caudal Graft Edge is 0.5-1.5 mm below the limb caudal edge marker.

Warning: The limb cranial edge marker of the ipsilateral iliac limb prosthesis must be between the minimum overlap marker and maximum overlap marker of the aortic bifurcate prosthesis. Failure to do so may result in prosthesis leaks or flow restrictions through one or both iliac limb prostheses.

Caution: Before deployment, ensure that the delivery system handle and delivery system sheath are parallel with the patient's leg. Excessive angulation where the white handle component meets the delivery system sheath may prevent delivery system sheath retraction.

5. To deploy the Ipsilateral iliac limb prosthesis, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5**) of the iliac limb delivery system to maintain the iliac limb delivery system position with respect to the distal landing zone (use fluoroscopy to confirm position). While holding the white handle component with one hand, slowly turn the gold handle component (refer to **Figure 5**) in the clockwise direction as indicated by the directional arrow on the gold handle component to retract the sheath.

   Caution: Ensure that the position of the limb cranial edge marker does not change while retracting the sheath.

   Warning: Do not advance the iliac limb delivery system once the distal tip of the sheath is retracted. Doing so could displace or damage the aortic bifurcate prosthesis.

6. Keep turning the gold handle component until the iliac limb prosthesis is fully deployed. Continue to turn the gold handle component until the sheath tip marker is at least 1 cm beyond the Limb Caudal Marker, as confirmed by fluoroscopy.
7. Unclip the release wire retainer and pull it (refer to **Figure 5**) until it comes completely out of the handle, thereby releasing and securing the cranial end of the iliac limb prosthesis.
   Warning: Do not advance or withdraw the iliac limb delivery system after the iliac limb prosthesis has been deployed until the fixation release wire has been retracted. Doing so could result in adverse events, including damage to the vessel wall or prosthesis.

   Note: Unlike with aortic bifurcate prosthesis, the fixation release wire for the iliac limb delivery system must be completely removed from the delivery system.

   Caution: Failure to remove the fixation release wire completely may result in caudal migration of the iliac limb during withdrawal of the delivery system.

8. Under fluoroscopy, carefully remove the iliac limb delivery system from the patient, ensuring that the iliac limb delivery system does not dislodge the prosthesis and guide wire access is maintained. Leave the delivery system sheath in place to use for balloon expansion after system deployment is completed.

12.4 Implant the Contralateral Iliac Limb Prosthesis

1. Using standard practice, cannulate the contralateral leg of the bifurcated aortic prosthesis guided by the contralateral leg-gate markers (refer to **Figure 4**).

   Note: Consider rotating the C-arm to a different angle to ensure that the contralateral leg of the aortic bifurcate can be uniquely visualized.

   Warning: Ensure the contralateral leg has been cannulated before contralateral iliac limb prosthesis deployment. Oblique imaging may be helpful in determining actual guidewire position relative to the leg opening. In the event that the contralateral leg is cannulated prior to placing the ipsilateral limb, ensure that the appropriate limb is cannulated prior to deployment.

2. Exchange the guidewire to a 0.035” (0.89 mm) stiff guidewire on the contralateral side.
3. Using standard techniques, visualize the internal iliac artery origin and the caudal landing zone in the side that you intend to deploy the contralateral limb.
4. Remove the diagnostic catheter, if used, under fluoroscopic guidance. Unless already present, introduce a diagnostic catheter in the other side of the patient.
5. Wet the outer sheath of the iliac limb delivery system sheath (tip to approximately 25 cm of the sheath) with saline to ensure activation of the hydrophilic coating.
6. Under fluoroscopic guidance, introduce the iliac limb delivery system over a 0.035” (0.89 mm) stiff guidewire slowly so that the cranial marker of the iliac limb prosthesis is aligned with the maximum overlap marker of the bifurcate prosthesis.

   Note: Carefully monitor the aortic bifurcate prosthesis to ensure that no migration occurs while introducing the iliac limb delivery system.

   Warning: Cranial migration of the aortic bifurcate prosthesis may result in renal occlusion.

7. Under fluoroscopic guidance, make final caudal adjustment of the iliac limb delivery system by retracting the iliac limb delivery system to the desired deployment position in the iliac artery, ensuring that the limb caudal edge marker is aligned with the iliac landing zone and the limb cranial edge marker is located between the contralateral leg minimum overlap marker and the maximum overlap marker (refer to **Figure 4**).

   Warning: The limb cranial edge marker of the contralateral iliac limb prosthesis must be between the minimum overlap marker and maximum overlap marker (overlap zone) of the aortic bifurcate prosthesis. Failure to do so may result in prosthesis leaks or flow restrictions through one or both iliac limb prostheses.

   Note: If the contralateral iliac limb delivery system will not freely advance into the aortic bifurcate prosthesis, remove the contralateral iliac limb delivery system and re-introduce the guidewire into the contralateral leg. The guidewire may have been advanced between a stent and the graft material, or advanced into the ipsilateral leg.

   Caution: Ensure that the delivery system handle and delivery system sheath are parallel with the patient’s leg. Excessive angulation where the white handle component meets the delivery system sheath may prevent delivery system sheath retraction.

8. To deploy the contralateral iliac limb prosthesis, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5**) of the iliac limb delivery system handle to maintain the delivery system position with respect to the distal landing zone (use fluoroscopy to confirm position). While holding the white handle component with one hand, slowly turn the gold handle component (refer to **Figure 5**) in the clockwise direction as indicated by the directional arrow on the gold handle component to retract the sheath.

   Cautions:
   - Ensure that the position of the limb cranial edge marker does not change while retracting the sheath.
   - In the event that a contralateral catheter sheath introducer is used, ensure that the sheath tip is placed below the limb caudal edge marker to achieve proper deployment.

   Warning: Do not advance the iliac limb delivery system once the distal tip of the sheath is retracted proximally to the inner member tip. Doing so could displace or damage the aortic bifurcate prosthesis.

9. Keep turning the gold handle component until the iliac limb prosthesis is fully deployed. Continue to turn the gold handle component until the Sheath Tip Marker is at least 1 cm beyond the limb caudal edge marker, as confirmed by fluoroscopy.
10. Unclip the release wire retainer and pull it (refer to **Figure 5**) until it comes completely out of the handle, thereby releasing the cranial end of the iliac limb prosthesis.

    Warning: Do not advance or withdraw the iliac limb delivery system after the prosthesis has been deployed until the fixation release wire has been retracted. Doing so could result in adverse events including damage to the vessel wall or prosthesis.

    Note: Unlike with aortic bifurcate prosthesis, the fixation release wire for the iliac limb delivery system must be completely removed from the delivery system.

    Warning: Failure to remove the fixation release wire completely may result in caudal migration of the iliac limb during withdrawal of the delivery system.

11. Under fluoroscopy, carefully remove the iliac limb delivery system from the patient, ensuring that the delivery system does not dislodge the prosthesis and guide wire access is maintained. If a sheath introducer was used, leave the sheath in place to use for balloon expansion.

12.5 Complete the Procedure

Perform the following steps using appropriate endovascular and surgical techniques.

1. Under fluoroscopy, use an appropriately sized and compatible compliant balloon catheter to expand the cranial and caudal seal zones and the overlap regions of the modular components as well as any areas of potential restricted blood flow.

   Caution: Be careful not to displace the prostheses upon introducing and retracting the compliant balloon catheter.

Note: Care should be taken when inflating the compliant balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels. Ensure to not inflate the compliant balloon outside of the graft material. Inflate compliant balloon slowly. It is recommended that a backup compliant balloon be available.

Warnings:

- Over inflation of compliant balloon can cause graft tears and/or vessel dissection or rupture.
- When expanding the prostheses, there is an increased risk of vessel injury and/or rupture, and possible patient death, if the compliant balloon's proximal and distal radiopaque markers are not completely within the covered (graft fabric) portion of the prosthesis.
- Do not expand the transrenal stent of the aortic bifurcate prosthesis as it may cause vessel injury and vessel rupture and could snag onto the transrenal stent of the aortic bifurcate prosthesis.
- Do not use a balloon to expand the tapered portion of the aortic bifurcate prosthesis.
- Cranial migration of the aortic bifurcate prosthesis may result in renal artery occlusion. Caudal migration of the iliac limb prosthesis may result in occlusion of the internal iliac arteries.

2. At the completion of the procedure, perform angiography to assess the prosthesis for cranial, modular overlap and caudal endoleaks and to verify position of the implanted prosthesis in relation to the aneurysm, the renal as well as internal iliac arteries.

   Cautions:

   - High pressure injection of contrast media made at the edges of the prosthesis immediately after implantation may cause an endoleak.
   - Leaks at the attachment or connection sites should be treated using a compliant balloon catheter to remodel the prosthesis against the vessel wall. Major leaks that cannot be corrected by either re-ballooning may be treated by adding aortic or iliac extension components to the previously placed stent graft components or any other method per local practice and the clinical situation.
   - Any leak left untreated during the implantation procedure must be carefully monitored after implantation.

   Warning: Failure to diagnose renal artery flow-interruption and endoleaks post prosthesis deployment may result in renal failure or ruptured aneurysm. Failure to diagnose internal iliac artery interruption post prosthesis deployment may result in buttock claudication, bowel ischemia, or sexual dysfunction.

3. Remove all diagnostic catheters and guide wires under fluoroscopy
4. Close arterial access according to standard practice.

Note: If needed, a physician may choose to use an appropriately sized commercially available aortic accessory device/prosthesis for bail-out procedures.

12.6 Implant the Iliac Limb Prosthesis Used as Iliac Extension

Note: Similar to iliac limbs, the amount of overlap is adjustable, however, minimum overlap is

recommended as to prevent the potential multiple overlap of the bifurcate leg, iliac limb, and iliac extension, which may result in flow restrictions.

Note: When using iliac leg extension, the minimum overlap varies by the iliac limb size being extended as per **Table 26**.

Table 26. Minimum Overlap Recommendations When the Iliac Limb Is Used as an Iliac Extension

Limb Diameter Being Extended (mm)	Length of Iliac Limb Used to Extend (cm)	(Maximum) Length Extended (mm)
13	8	52
	10	71
	12	90
	14	108
16	8	16
	10	35
	12	54
	14	72
20	8	5
	10	24
	12	43
	14	61
24	8	N/A
	10	14
	12	33
	14	51

Note: The 10 mm iliac limb prosthesis cannot be extended by design as the cranial diameter of all the iliac limb prostheses is 13 mm.

1. Select the appropriate device as per **Tables 24 and 25.**
   Caution: After removal from the package take care not to pull or snag the fixation release wire (refer to **Figure 5**) when handling and preparing the delivery system.

2. Prior to use, flush the guidewire lumen with heparinized saline through the guidewire lumen flush connector of the iliac limb delivery system (refer to **Figure 5**) until saline is observed exiting through the distal end of the device.
3. Visualize the caudal landing zone in the iliac artery by standard techniques.
4. Wet the outer sheath of the iliac limb delivery system (tip and approximately 25 cm of the sheath) with saline to assure activation of the hydrophilic coating.
5. Under fluoroscopic guidance, introduce the iliac limb delivery system over the 0.035” (0.89 mm) stiff guidewire. If using the integrated Sheath introducer left in place from the aortic bifurcate prosthesis deployment, refer to steps 3-4 of the instructions provided in “Implant the Ipsilateral Iliac Limb Prosthesis” (section 12.3).

   Note: If deploying the iliac limb prosthesis near the vascular access site, take extra care to

ensure that sheath remains intravascular.

Caution: Ensure that the delivery system handle and delivery system sheath are parallel with the patient's leg. Excessive angulation where the white handle component meets the delivery system sheath may prevent delivery system sheath retraction.

6. Under fluoroscopy, advance the iliac limb delivery system beyond the targeted deployment site but not beyond the maximum overlap marker of the aortic bifurcate and pull back such that the Extension (Limb) Cranial Edge Marker is more cranial than three short non-tapered Z-stents (refer to **Figure 11**).

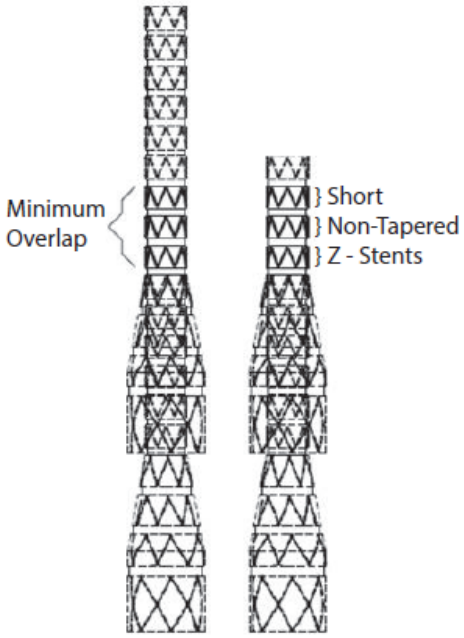


Figure 11. Placement of the Iliac Limb Extension

Caution: There is no minimum marker band on the iliac limb being extended.

7. If a catheter sheath introducer is used, ensure it is pulled back beyond the caudal edge marker of the iliac extension.
8. To deploy the Iliac limb prosthesis, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5**) of the iliac limb delivery system to maintain the iliac limb delivery system position with respect to the distal landing zone (use fluoroscopy to confirm position). While holding the white handle component with one hand, slowly turn the gold handle component (refer to **Figure 5**) in the clockwise direction as indicated by the directional arrow on the gold handle component to retract the sheath.

   Caution: Ensure that the position of the limb extension cranial edge marker does not change while retracting the sheath

   Warning: Do not advance the iliac limb delivery system once the distal tip of the sheath is retracted. Doing so could displace or damage the aortic bifurcate prosthesis or limb prosthesis previously deployed.

9. Keep turning the gold handle component until the iliac limb prosthesis is fully deployed. Continue to turn the gold handle component until the sheath tip marker is at least 1 cm beyond the limb caudal marker, as confirmed by fluoroscopy.
10. Unclip the release wire retainer and pull it (refer to **Figure 5**) until it comes completely out of the handle, thereby releasing and securing the cranial end of the iliac limb prosthesis.

    Warning: Do not advance or withdraw the iliac limb delivery system after the prosthesis has been deployed until the fixation release wire has been retracted. Doing so could result in adverse events including damage to the vessel walls or prosthesis.

    Note: Unlike with aortic bifurcate prosthesis, the fixation release wire for the iliac limb delivery system must be completely removed from the delivery system.
    Caution: Failure to remove the fixation release wire completely may result in caudal migration of the iliac limb during withdrawal of the delivery system.

11. Under fluoroscopy, carefully remove the iliac limb delivery system from the patient, ensuring that the iliac limb delivery system does not dislodge the prosthesis and guide wire access is maintained. Leave the delivery system sheath in place to use for balloon expansion.
12. Introduce appropriately sized and compatible compliant balloon and expand the overlap and seal areas of the iliac limb extension.

    Caution: Be careful not to displace the prosthesis upon introducing and retracting the compliant balloon catheter.

    Note: Care should be taken when inflating the compliant balloon, especially with calcified, tortuous, stenotic, or otherwise diseased vessels. Inflate slowly. Ensure to not inflate the compliant balloon outside the graft material. It is recommended that a backup compliant balloon be available.

    Warnings:
    - Over inflation of the compliant balloon can cause graft tears and/or vessel dissection or rupture.
    - When expanding the prosthesis, there is an increased risk of vessel injury and/or rupture, and possible patient death, if the compliant balloon's proximal and distal radiopaque markers are not completely within the covered (graft fabric) portion of the prosthesis.

13 BAIL OUT TECHNIQUES

In the unlikely event of delivery failure, the following bail-out techniques may be used.

13.1 Delivery System Handle Disassembly

If the **INCRAFT** delivery system handle locks up or ceases before stent graft deployment is complete the following steps can be used to remove the handle so that the stent graft can be

deployed using a "pin and pull" technique:

1. Use a Kelly Clamp or similar instrument to separate (starting at the distal end) and remove the white handle component at the seam where the parts are connected.
2. Starting at the distal end of the gold handle component, use a sharp instrument to separate and remove the Gold Handle Shell at the seam where the parts are connected.
3. Unclip and remove the white guide rail lock that is at the very distal end of the metallic guide rails of the internal handle assembly.
4. Unclip and remove the clear manifold shell that is at the very proximal end of the metallic guide rails of the internal handle assembly.
5. Move the gray sheath mount in the direction of the tip of the delivery system until the metallic guide rails come loose and can be removed.
6. At this point the stent graft delivery can be completed by holding the inner member and pulling back on the outer member.

13.2 Aortic Bifurcate Fixation Release Wire

If the deployment of the barbs using the Bifurcate Fixation Wire cannot be achieved, use the following steps on a step by step approach until barb deployment is achieved as necessary:

1. Check to make sure the delivery system is supported by a 0.035" (0.89 mm) stiff guide wire. If not, remove the guide wire and insert the stiffest guide wire available. Try to pull the fixation release wire again.
2. If fixation is still unreleased then check the plastic hemostatic valve that the fixation release wire comes out of at the very proximal end of the handle is completely loose (**see #3 in Figure 5**). Try to pull the fixation release wire again.
3. If fixation is still unreleased then fully deploy the aortic bifurcate stent graft. Try to pull the fixation release wire again.
4. If fixation is still unreleased detach the Sheath Hemostasis Valve (**see #7 in Figure 5**) to release any potential tension in the system. Try to pull the fixation release wire again. Pull the Release Wire as hard as possible until the fixation release is achieved or the wire breaks.
5. If fixation is still unreleased try inflating a compliant balloon inside the transrenal stent to achieve fixation release.
6. If these steps ha~~v~~e not worked then consider a conversion to open surgery.

13.3 Accessory Stent Placement

If placement of an accessory stent within an iliac limb is necessary due to tortuous anatomy, stenosis, an occlusion, or a kink, the following guidelines are recommended:

1. Avoid using stents with sharp cranial and/or caudal edges.
2. Avoid extending an accessory stent above the top of the ipsilateral or contralateral legs of the aortic bifurcate.
3. Avoid excessive oversizing of accessory stents.
4. Avoid excessive reduction of the lumen diameter.
5. Avoid placing a balloon expandable stent beyond the modular overlap of the aortic bifurcate and iliac limb.
6. Avoid placing the terminus of an accessory stent in a bend.

14 FOLLOW-UP PROCEDURE

14.1 General

Current imaging of stent graft patients includes abdominal X-ray and CT, with and without contrast medium. Alternative imaging modalities such as magnetic resonance imaging should be used in patients with impaired renal function or intolerance to contrast media. Imaging should be decided based upon the physician's clinical assessment of the patient pre- and post-implantation of the stent graft. After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including 1) abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable), and 2) contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide alternative means of providing some of this information.

14.2 X-Ray

Abdominal X-rays should be used to assess the presence of stent graft fracture. Four-view kidney, ureter, bladder (KUB) X-rays should be taken. Posterior/anterior (PA) and lateral images are recommended for visualization of the stent graft. Ensure the entire device is captured on images for device assessment.

14.3 CT with Contrast

Contrast-enhanced CT should be used to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, stent graft patency, AAA size, occlusion of branch vessels, and endoleak (including source and type if present). A pre-contrast scan of 5 mm thick slices is suggested to determine if there are calcifications or areas where metal artifacts may be misinterpreted as endoleak. Arterial and venous phase spiral CT scans with <3 mm slice thickness and overlapping images with coverage from the celiac artery to the common femoral artery beyond the end of the prosthesis to ensure that the entire endograft Is visualized are recommended. The venous phase scan may also be performed with thicker collimation (5 mm).

It is recommended that the source data set be archived in case specialized evaluation is needed later (volume measurements, 3-dimensional reconstruction, or computer-aided measurement software). If the aneurysm is not shrinking by more than 5 mm within the first year, volume measurements may be obtained as a more sensitive indicator of AAA size using 3-dimensional software. Patients who are allergic to contrast should be pre-medicated 12-24 hours prior to receiving the drug.

14.4 Non-Contrast CT

For patients with impaired renal function or those who are allergic to contrast medium, a spiral CT without contrast may be considered to assess stent graft fixation, deformation, apposition to the vessel wall at proximal and distal fixation sites, stent graft migration, occlusion of vessels, and size of the AAA diameter and volume measurements.

14.5 Duplex Ultrasound

For patients with impaired renal function or those who are allergic to contrast medium, a color-duplex ultrasound may be considered to assess size of AAA diameter, endoleaks, and stent graft occlusion and stenosis.

14.6 MRI or MRA

Patients with impaired renal function, i.e., renal insufficiency, may also be considered for magnetic resonance imaging or angiography (MRI, MRA) in facilities that have expertise in this area. Artifact may occur related to the stent, and care should be used to insure adequate imaging of the outer aneurysm wall to assess AAA size. Volume measurement may be helpful if the aneurysm is not clearly shrinking. If there are concerns regarding imaging of calcified areas, fixation sites, or the outer wall of the aneurysm sac, adjunctive CT without contrast may be needed.

14.7 Imaging Tests

It is recommended that physicians conduct regular examinations and imaging for the patient's lifetime. Follow-up imaging should be decided based upon the physician's clinical assessment of the patient pre- and post-implantation of the stent graft. After endovascular graft placement, patients should be regularly monitored for perigraft flow, aneurysm growth or changes in the structure or position of the endovascular graft. Annual imaging is recommended, including the following.

- Abdominal radiographs to examine device integrity (stent fracture, separation between bifurcated device and proximal cuffs or limb extensions, if applicable); and,
- Contrast and non-contrast CT to examine aneurysm changes, perigraft flow, patency, tortuosity and progressive disease. If renal complications or other factors preclude the use of image contrast media, abdominal radiographs and duplex ultrasound may provide similar information.

14.8 Supplemental Imaging

Note: Additional radiological imaging may be necessary to further evaluate the stent graft in situ based on findings revealed by one of the surveillance programs. The following recommendations may be considered.

- If there is evidence of poor or irregular position of the stent graft, severe angulation, kinking or migration of the stent graft on abdominal X-rays, a spiral CT should be performed to assess aneurysm size and the presence or absence of an endoleak.
- If a new endoleak or increase in AAA size is observed by spiral CT, adjunctive studies such as 3-D reconstruction or angiographic assessment of the stent graft and native vasculature may be helpful in further evaluating any changes of the stent graft or aneurysm.
- Spiral CT without contrast, MRI or MRA may be considered in select patients who cannot tolerate contrast media or who have renal function impairment. For centers with appropriate expertise, gadolinium or CO_2 angiography may be considered in patients with renal function impairment requiring angiographic assessment.

15 ADDITIONAL SURVEILLANCE AND TREATMENT

Additional endovascular repair or open surgical aneurysm repair should be considered for patients with an increase in AAA size > 5 mm or evidence of suboptimal stent graft fixation, proximal endoleak, distal endoleak, junction endoleak, unknown origin of persistent perigraft flow.

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