

INCRAFT® AAA Stent Graft System
English ONLY - *Instructions for Use*



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 |
|  | n units per box |
|  | Keep away from sunlight |
|  | Keep dry |
|  | Do not use if package is damaged |
|  | Serial number |
|  | OK for use |
|  | Do not use |

TABLE OF CONTENTS

| | | |
|-------|--|----|
| 1 | DEVICE DESCRIPTION..... | 8 |
| 1.1 | Stent Graft System | 8 |
| 1.1.1 | Aortic Bifurcate Prosthesis | 9 |
| 1.1.2 | Iliac Limb Prosthesis..... | 10 |
| 1.2 | Delivery System | 12 |
| 1.2.1 | Aortic Bifurcate Delivery System..... | 13 |
| 1.2.2 | Iliac Limb Delivery System | 13 |
| 2 | INDICATIONS FOR USE | 14 |
| 3 | CONTRAINDICATIONS | 14 |
| 4 | WARNINGS AND PRECAUTIONS..... | 14 |
| 4.1 | General | 14 |
| 4.2 | Patient Selection..... | 15 |
| 4.3 | Before the Implant Procedure | 17 |
| 4.4 | During the Implant Procedure | 17 |
| 4.5 | Treatment and Follow-up | 18 |
| 4.6 | Magnetic Resonance Imaging (MRI) Safety Information..... | 19 |
| 5 | ADVERSE EVENTS..... | 19 |
| 5.1 | Potential Adverse Events | 19 |
| 5.2 | Adverse Event Reporting | 20 |
| 6 | SUMMARY OF CLINICAL STUDY | 20 |
| 6.1 | Introduction | 20 |
| 6.1.1 | Endpoints | 20 |
| 6.1.2 | Secondary Endpoints | 21 |
| 6.2 | Study Results..... | 22 |
| 6.2.1 | Subject Accountability and Follow-Up | 22 |
| 6.2.2 | Subject Demographics | 26 |
| 6.2.3 | Baseline Medical History..... | 26 |

| | | |
|--------|--|----|
| 6.2.4 | Baseline Aneurysm Characteristics | 28 |
| 6.2.5 | INCRAFT Components Implanted | 30 |
| 6.2.6 | Acute Procedural Data | 31 |
| 6.2.7 | Safety Results..... | 32 |
| 6.2.8 | Effectiveness Results | 36 |
| 6.3 | Subject Accountability and Partial 5 Year Follow-Up Data | 54 |
| 7 | PATIENT SELECTION AND TREATMENT | 55 |
| 7.1 | Patient Selection..... | 55 |
| 7.2 | INCRAFT Stent Graft Sizing..... | 56 |
| 8 | PATIENT COUNSELING INFORMATION | 56 |
| 9 | HOW SUPPLIED | 57 |
| 9.1 | Package Contents | 57 |
| 9.2 | Sterilization, Storage and Handling | 57 |
| 10 | CLINICAL USE INFORMATION | 58 |
| 10.1 | Physician Training Requirements | 58 |
| 10.2 | Device Configuration and Sizing Guide | 58 |
| 10.3 | Recommended Devices, Supplies, and Equipment..... | 60 |
| 10.4 | MAGNETIC RESONANCE (MR) Imaging Safety Information | 61 |
| 11 | PREPARATION INSTRUCTIONS | 61 |
| 11.1 | Patient Preparation | 61 |
| 11.2 | Delivery System Preparation..... | 62 |
| 12 | IMPLANT INSTRUCTIONS..... | 63 |
| 12.1 | Implant the Bifurcated Aortic Prosthesis | 63 |
| 12.2 | Implant the Iliac Limb Prostheses | 66 |
| 12.2.1 | Implant the Ipsilateral Iliac Limb Prosthesis | 66 |
| 12.2.2 | Implant the Contralateral Iliac Limb Prosthesis | 68 |
| 12.3 | Complete the Procedure | 69 |
| 12.4 | Implant the Iliac Limb Prosthesis Used as Iliac Extension..... | 71 |
| 12.5 | Accessory Stent Placement | 74 |
| 13 | BAIL OUT TECHNIQUES..... | 74 |
| 13.1 | Delivery System Handle Disassembly | 74 |

| | | |
|------|---|----|
| 13.2 | Aortic Bifurcate Fixation Release Wire | 75 |
| 14 | FOLLOW-UP PROCEDURE..... | 75 |
| 14.1 | General | 75 |
| 14.2 | X-Ray | 76 |
| 14.3 | CT with Contrast | 76 |
| 14.4 | Non-Contrast CT | 76 |
| 14.5 | Duplex Ultrasound | 76 |
| 14.6 | MRI or MRA..... | 76 |
| 14.7 | Imaging Tests | 77 |
| 14.8 | Supplemental Imaging..... | 77 |
| 15 | ADDITIONAL SURVEILLANCE AND TREATMENT..... | 77 |
| 16 | DISCLAIMER OR WARRANTY AND LIMITATION OF REMEDY | 78 |
| 17 | PATENTS | 78 |

TABLE OF FIGURES

Figure 1. Components of the INCRAFT AAA Stent Graft System 8
Figure 2. Aortic Bifurcate 10
Figure 3. Iliac Limb 11
Figure 4. Prosthesis Marker Identification Guide 12
Figure 5. Delivery System Component Identification Guide..... 13
Figure 6. Kaplan-Meier Analysis: Freedom from All-Cause Mortality through 4 years 34
Figure 7. Kaplan-Meier Analysis: Freedom from Aneurysm-Related Mortality through 4 years.. 42
Figure 8. Location of All Stent Strut Fractures in INSPIRATION 50
Figure 9. Stent Graft Diameter and Length Identification 59
Figure 10. Illustration of Bifurcate Deployment Position..... 65
Figure 11. Illustration of the Aortic Bifurcate Sheath Pull-back for Limb Deployment..... 66
Figure 12. Placement of the Iliac Limb Extension 72
Figure 13. Disassembled Delivery System Handle 75

TABLE OF TABLES

| | |
|--|-----------|
| Table 1. Stent Graft Materials..... | 9 |
| Table 2. Potential Adverse Events | 19 |
| Table 3. Subject Imaging Accountability | 24 |
| Table 4. Subject Demographics | 26 |
| Table 5. Baseline Medical History | 27 |
| Table 6. Baseline Aneurysm Characteristics as Measured from CT Scan | 28 |
| Table 7. Distribution of Baseline Aneurysm Diameters..... | 29 |
| Table 8. Summary of INCRAFT Components Implanted | 30 |
| Table 9. Summary of INCRAFT Components Implanted by Size | 30 |
| Table 10. Acute Procedural Characteristics – U.S. and Japan | 31 |
| Table 11. Primary Safety Endpoint Results..... | 33 |
| Table 12. MAE Rate through 4 Years - Overall Rate and MAE Components | 33 |
| Table 13. Primary Effectiveness Endpoint Results | 36 |
| Table 14. Secondary Effectiveness Results..... | 38 |
| Table 15. Device Malfunctions through 4 Years..... | 42 |
| Table 16. Iliac Limb Migration through 4 Years..... | 43 |
| Table 17. Number of Subjects with Endoleaks Reported through the 4 Year Follow-Up Visit | 46 |
| Table 18. Aneurysm Diameter Change through 4 Year Follow-Up..... | 48 |
| Table 19. Aneurysm Enlargements through 4 year Follow-Up | 48 |
| Table 20. Summary of Stent Strut Fractures through 4 Years | 49 |
| Table 21. Subjects with Multiple Stent Strut Fractures at Follow-Up (N = 5) | 49 |
| Table 22. Patency Related Events through 4 Years | 52 |
| Table 23. Summary of Reasons for Secondary Interventions through 4 Years..... | 53 |
| Table 24. Aortic Bifurcate Prosthesis Dimensions Sizing Guide..... | 59 |
| Table 25. Iliac Limb and Limb Extension Prosthesis Dimensions Sizing Guide | 60 |
| Table 26 Minimum Overlap Recommendations When the Iliac Limb is Used as an Iliac Extension | 71 |

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 two 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 three main components: an aortic bifurcate prosthesis and two iliac limb prostheses. In addition, to extend the implant in a caudal direction, an iliac limb prosthesis can also be used as an 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.

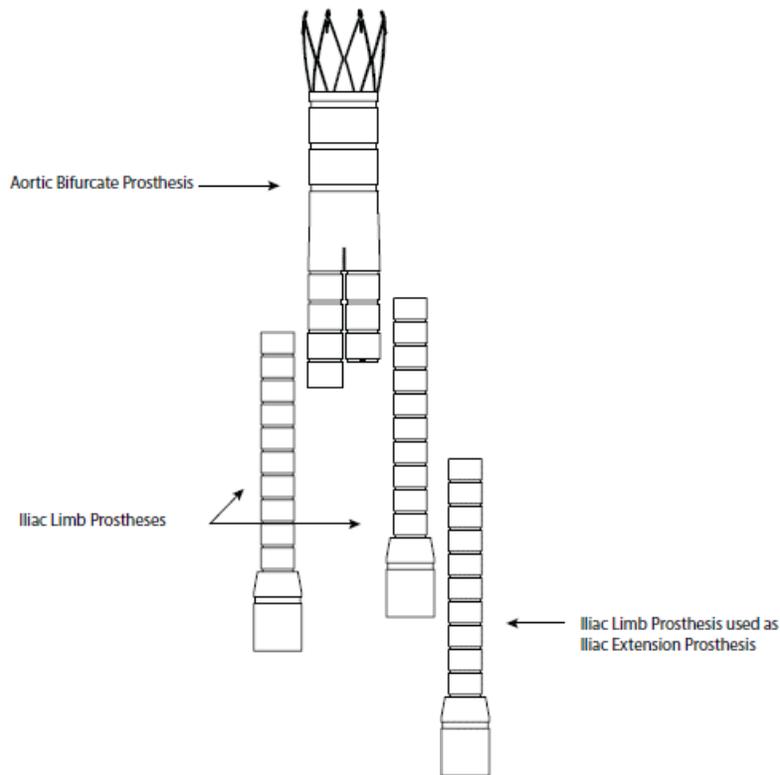


Figure 1. Components of the INCRAFT AAA Stent Graft System

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, as well as a small portion of the suprarenal 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 one main trunk with two 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 (Section 10.2, page 60)** for the aortic bifurcate prosthesis dimension sizing guide.

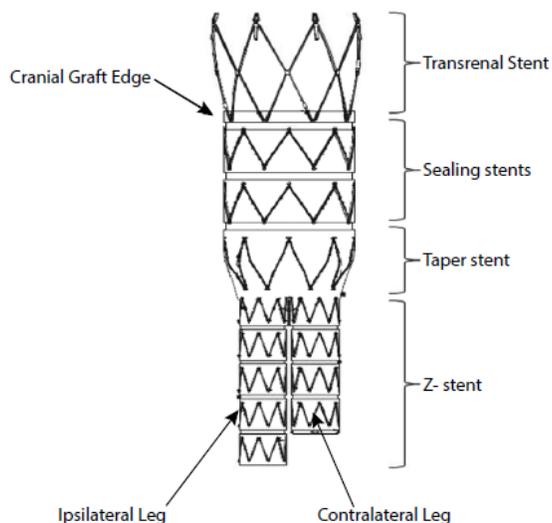


Figure 2. Aortic Bifurcate

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 one 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 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 product 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 24 (Section 10.2, page 60)** for the iliac limb sizing guide.

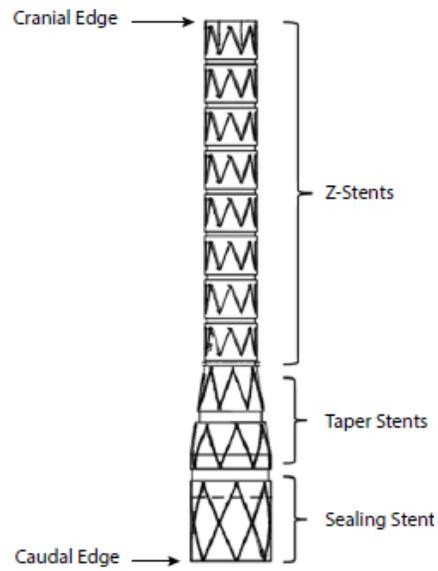
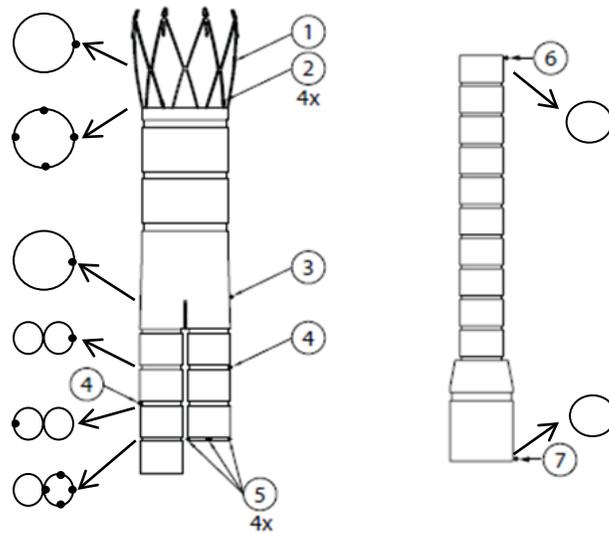


Figure 3. Iliac Limb

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

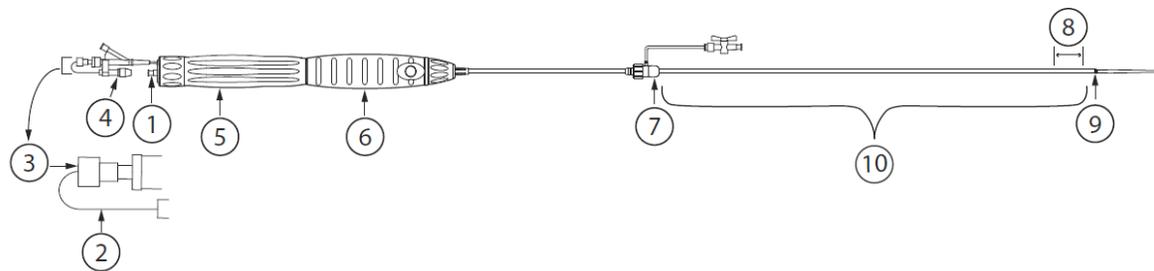


| Marker | Material | Configuration |
|-----------------------------------|------------------------|--|
| 1. Contralateral side marker | Tantalum | Cylindrical marker crimped onto stent strut |
| 2. Bifurcate cranial edge markers | Tantalum | Cylindrical marker crimped onto stent strut. Graft edge begins 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 0.035" (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) | 6. White handle component |
| 2. Fixation release wire | 7. Sheath hemostasis valve (aortic bifurcate only) |
| 3. Fixation release wire hemostasis valve | 8. Prosthesis location |
| 4. Release wire retainer | 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 two 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** found in **Section 10.2**, page 60). 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 prosthesis 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 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**

(Section 10.2, page 61).

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

The **INCRAFT® AAA Stent Graft System** is intended for the endovascular treatment of patients with infrarenal abdominal aortic aneurysms with the following characteristics:

- Adequate, but complex iliac or femoral vessel morphology (e.g., high tortuosity index, heavily calcified, small diameter), 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 $\leq 60^\circ$
- 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

The **INCRAFT® AAA Stent Graft System** is contraindicated for the following;

- Patients with a known allergy or intolerance to device materials listed in **Table 1** (**Section 1.1**, page 8).
- Patients who have a condition that threatens to infect the graft.

4 WARNINGS AND PRECAUTIONS

Carefully observe all warnings and precautions 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** (page 59).
- 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.

4.2 Patient Selection

- Inappropriate patient selection may result in poor device performance or device performance not otherwise in accordance with the specifications.
- **Note:** Key anatomic elements that may affect successful exclusion of the aneurysm include severe proximal neck angulation ($> 60^\circ$), 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.
- **Note:** Risks of patency-related events, aneurysm expansion and transrenal stent fracture observed in the U.S. clinical study (see **Section 6** Summary of Clinical Study, page 20) should be weighed against the risks associated with alternative treatment options for the indicated patient population.
- 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 exceeding weight or size limits necessary to meet imaging requirements.
- 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 stent graft in a patient with a narrowing of the distal aorta may result in reduced flow through the limbs.
- Pay close attention to the iliac graft landing zone morphology to assess for proper limb graft selection/suitability.
- When selecting an aortic 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.
- The 10 mm iliac limb prosthesis cannot be extended by design as the cranial diameter for all iliac limb prostheses is 13 mm.
- 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.
- 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 (**Section 4.5**, page 18 and **Section 14**, page 76).
- 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.
- **INCRAFT** is not recommended in patients who cannot tolerate contrast agents necessary for intraoperative and postoperative follow-up imaging.

- The **INCRAFT AAA Stent Graft System** 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/mm³) 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.

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 (**Section 9.2**, Sterilization, Storage and Handling, page 58).

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 (Section 1.1.2** page 12)).
- 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 delivery system's 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 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 the delivery system is removed 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. Carefully 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 performance 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 stent graft migration resulting in an inadequate seal zone should prompt further investigation and may indicate the need for additional intervention or surgical conversion.
- Patients experiencing reduced blood flow through the graft limb or leaks may be required to undergo secondary interventions or surgical procedures.
- 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.** (page 62). 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

| | | |
|--|---|---|
| <ul style="list-style-type: none"> ● Amputation ● Anesthesia complications ● Aneurysm enlargement ● Aneurysm sac rupture ● Aortic damage (perforation, dissection, bleeding, rupture) ● Aortocaval fistulae ● Aortoenteric fistulae ● Arterial or venous thrombosis ● Bleeding events ● 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 or thrombotic events | <ul style="list-style-type: none"> ● Endoleaks ● Fever ● Gastrointestinal complications ● Genitourinary complications (e.g., ischemia, erosion, fistula, incontinence, hematuria) ● Graft erosion ● Graft material wear ● Graft puncture ● Graft twisting or kinking ● Hematoma (surgical) ● Hepatic failure ● Impotence ● Improper stent graft placement ● Incomplete stent graft deployment ● Infection ● Insertion and removal difficulties ● Lymphatic complications ● Multiorgan system failure ● Neurological complications (e.g. CVA, TIA) | <ul style="list-style-type: none"> ● 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/occlusion of native vessel ● Stent fracture / separation / dislodgement of stent strut ● Suture break (endograft) ● Vascular access site complications occlusion/stenosis ● Vascular spasm/ trauma ● Wound complications |
|--|---|---|

5.2 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 U.S. 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, 1 year, and annually until 5 years post-procedure. A subset of subjects will be followed for an additional 5 years, for a total of 10 years post index procedure.

Although the primary effectiveness endpoint was at 1 year, at the time of the data lock, complete 4-year data were available and are described in subsequent sections.

6.1.1 Endpoints

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 ($\geq 1,000$ 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, aneurysm 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%.

6.1.2. Sample Size

The sample size for this study was based on the hypotheses for the primary safety and effectiveness endpoints.

Primary Safety Endpoint

A sample size of 180 subjects at 30 days was estimated to be required. The upper limit of the exact binomial 95% confidence interval should be lower than 20% to reject the null hypothesis.

Primary Effectiveness Endpoint

With a sample size of 150 evaluable subjects at 1 year, a one-sided exact binomial test using a nominal significance level of 0.05, will have approximately 90% power to reject the null hypothesis, when the successful aneurysm treatment rate at 12 months is 89%.

With expected attrition, a final sample size of 190 subjects satisfied the power requirements for both safety and effectiveness endpoints.

6.1.2 Secondary Endpoints

Secondary **safety** endpoints include the following:

- Major Adverse Events (MAEs) and individual components of the MAEs annually through 5 years; and
- Procedure-related complications through 30 days, 180 days, 360 days and annually to 5 years.

Secondary **effectiveness** endpoints include the following:

- Technical success at 30 days as confirmed by CT or other imaging modality;
- Aneurysm-related mortality annually through 5 years;
- Device-related events at 1 month, 6 months, 1 year and annually to 5 years;
- Incidence of secondary intervention or the need for secondary interventions, to repair vascular events or malfunctions which are related to device and/or peri-graft complications through 5 years. Secondary intervention is any vascular event which requires intervention to repair the AAA or device. Indications for secondary intervention may include endoleaks, stent graft migration, occlusion, or aneurysm sac rupture;
- The incidence of secondary interventions within 1 year post-procedure, needed to prevent the occurrence of a significant event. Significant event being defined as:

aneurysm enlargement (growth > 5 mm), stent graft migration (> 10 mm) compared to the one-month size, endoleak Type I / III, graft occlusion, sac rupture; and

- Clinical utility measures.

A Core Lab was utilized to evaluate Angiograms, CT and X-ray images from screening through the 5 year follow-up. They assessed the following events; aneurysm enlargement, endoleaks, stent fracture, and stent graft migration. The first imaging Core Lab was used through the first year and was replaced with a second Core Lab which reviewed all imaging after the first year through study completion. The second Core Lab re-reviewed all x-rays and re-calculated the 1-month baseline measurements due to changes in migration measurement process from the first Core Lab.

6.1.2.1 Patients

Patients enrolled in this study had an infrarenal aortic aneurysm that met the following anatomical characteristics:

- proximal aortic neck diameter (17-31 mm),
- infrarenal neck length (≥ 10 mm),
- infrarenal and suprarenal neck angulations (≤ 60 degrees),
- iliac landing zone length (≥ 15 mm) and diameter (7-22 mm),
- diameter at the aortic bifurcation > 18 mm, and
- minimum access vessels ≥ 5 mm.

Patients were excluded from the study if they met the following anatomic or physiologic characteristics:

- conical neck (defined as greater than 3 mm distal increase over a 10 mm length in planned seal zone),
- significant aortic or iliac mural thrombus, plaque or calcification that would compromise fixation and seal of the device, and
- coagulopathy, bleeding disorder, or other hypercoagulable state.

All patients enrolled in this study met these typical selection criteria based on site-reported CT measurements.

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. In order to confirm that only appropriate subjects would be enrolled, an independent reviewer reviewed all screening CT imaging to confirm the subject met eligibility criteria prior to enrollment. The team of independent reviewers were vascular surgeons, separate from the sponsor, Core Lab and sites. Each independent reviewer was trained to the protocol inclusion and exclusion criteria, the INCRAFT device and the imaging software. The most common reason for patients not being enrolled in the study include not meeting the protocol required imaging inclusion criteria (i.e., short or conical proximal neck; small, calcified iliac arteries; aortic bifurcate diameter <18 mm; infrarenal angulation >60°), based on assessment by the independent reviewer.

Ninety nine percent (99%) of the eligible subjects (189/190) completed the 1 month follow-up visit. One subject died 2-days post-operatively. The visit compliance rate was 97% (182/188) at 6

months, 97% (177/183) at 1 year, 94% (161/172) at 2 years, 92% (148/161) at 3 years, and 87% (129/148) at 4 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, 5 subjects withdrew after the 2 years but prior to the 3 years visit, 3 subjects withdrew after 3 years but prior to 4 years, and 5 subjects withdrew after 4 years.

There was at least 90% imaging compliance up to the 1 year visit with suitability for evaluating endoleaks, aneurysm 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. The subjects who underwent conversion did not have follow up imaging post-conversion as the INCRAFT device was no longer present; however, they continue annual clinical follow up. One subject who underwent an axillo-bifemoral bypass procedure to address a patency event at the 4 year timepoint (Stent Graft Patency **Section 6.2.8.2.9**) is continuing to be followed via clinical and imaging follow-up for endovascular graft assessment. Beyond the 1 year visit, there was at least 85% imaging compliance at 2 years, at least 82% imaging compliance at 3 years, and at least 70% imaging compliance at 4 years, with suitability for evaluating endoleaks, aneurysm enlargement, migration, and stent fracture. Detailed subject accountability and follow-up are presented in **Table 3**.

Table 3. Subject Imaging Accountability

| Visit | Number of Subjects (%) | | | | | Adequate Imaging to Assess the Parameter ⁶ # (%) (Core Lab data) | | | | Events Occurring before Next Interval # (%) | | | |
|------------------|-------------------------------------|---|-----------------|-----------------------|--|--|------------------------|---------------|----------------|--|--------------------|------------------|---------------------------------|
| | Eligible for follow-up ¹ | Subjects with clinical data for that visit ² | CT ³ | KUB XRAY ⁴ | Subjects with follow-up pending ⁵ | Endoleak | Aneurysm size increase | Migration | Stent fracture | Conversion ⁷ | Death ⁸ | LTF ⁹ | Not due for visit ¹⁰ |
| Procedure | 190 | 190 | N/A | N/A | 0 | 190/190 (100%) ¹¹ | N/A | N/A | N/A | 0 | 0 | 0 | 0 |
| Discharge | 190 | 190 | N/A | N/A | 0 | 190/190 (100%) ¹² | N/A | N/A | N/A | 0 | 0 | 0 | 0 |
| 1 Month | 190/190 ¹³ (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%) | 162/172 (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%) | 142/159 (89%) | 132/159 (83%) | 0 | 131/159 (82%) | 142/159 (89%) | 141/159 (89%) | 132/159 (83%) | 0 | 10/161 (6%) | 3/161 (2%) | 0 |
| 4 Years | 148/190 (78%) | 129/148 (87%) | 113/146 (77%) | 108/146 (74%) | 0 | 102/146 (70%) | 112/146 (77%) | 112/146 (77%) | 108/146 (74%) | 0 | 11/148 (7%) | 5/148 (3%) | 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).

¹Eligible for follow-up = (previous eligible for follow-up – previous death - previous LTF) – currently not due). Subject(s) not due for a visit are excluded from the denominator.

²Defined as subjects with either the scheduled study visit or subjects with an unscheduled study visit within the imaging window for the visit.

³Only images that pass QC are listed.

⁴Only images that pass QC are listed.

⁵Subjects still within follow-up window but have not had clinical follow up.

⁶Not the number of subjects with these reported events, but rather, the number with adequate imaging to evaluate the listed outcome.

⁷Subjects who converted to open surgery no longer completed imaging follow-up, only clinical follow-up.

⁸Deaths within imaging windows.

⁹Lost to Follow-up (LTF) are those subjects that are either withdrawn or classified as lost to follow-up in the EDC.

¹⁰Number 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).

¹¹Endoleak at procedure determined by angiogram. Adequate imaging count provided by sponsor, angiogram Core Lab data not received by NERI.

¹²Endoleak at discharge determined by CT. Adequate imaging count provided by sponsor, CT at discharge Core Lab data not received by NERI.

¹³The denominator for eligibility at 1 month is based on the 1 month imaging window defined as "post-procedure through 90 days." The 2 subjects died at 2 days and 78 days within the 1 month imaging window therefore they were included in the denominator.

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 U.S.

The subjects in the US cohort were slightly older (74.5 vs. 72.1 years) and taller (174.8 vs. 165.8) with a higher body mass index (28.6 vs. 24.6) as compared to the Japanese cohort. The percentage of women enrolled in the study was higher in the US (13.4%) as compared to Japan (1.8%).

Table 4. Subject Demographics

| Patient Characteristics | INCRAFT US (N=134) | INCRAFT Japan (N=56) | INCRAFT US & Japan (N = 190) | SVS Controls (N = 323) |
|--------------------------|-----------------------|-------------------------|------------------------------------|---------------------------|
| Age (years) | | | | |
| Mean ± SD (N) | 74.5 ± 7.48 (134) | 72.1 ± 7.55 (56) | 73.8 ± 7.56 (190) | 70.1 ± 7.41 (323) |
| Median | 75.0 | 71.0 | 74.0 | 70.7 |
| Range (Min, Max) | 51.0, 89.0 | 56.0, 90.0 | 51.0, 90.0 | 41.2, 86.1 |
| Number of Men (%) | 86.6% (116/134) | 98.2% (55/56) | 90.0% (171/190) | 83.3% (269/323) |
| Height (cm) | | | | |
| Mean ± SD (N) | 174.8 ± 8.96 (134) | 165.8 ± 7.09 (56) | 172.1 ± 9.37 (190) | 174.0 ± 9.26 (315) |
| Median | 177.8 | 166.0 | 172.7 | 175.3 |
| Range (Min, Max) | 150.0, 196.0 | 147.0, 179.5 | 147.0, 196.0 | 135.0, 194.3 |
| Weight (kg) | | | | |
| Mean ± SD (N) | 87.6 ± 15.78 (134) | 67.7 ± 11.87 (56) | 81.7 ± 17.27 (190) | 82.9 ± 17.25 (318) |
| Median | 86.2 | 69.9 | 80.5 | 83.0 |
| Range (Min, Max) | 48.6, 137.8 | 35.9, 96.2 | 35.9, 137.8 | 40.4, 151.5 |
| BMI (kg/m ²) | | | | |
| Mean ± SD (N) | 28.6 ± 4.49 (134) | 24.6 ± 3.74 (56) | 27.4 ± 4.66 (190) | 27.3 ± 5.07 (314) |
| Median | 27.9 | 24.9 | 27.1 | 27.1 |
| Range (Min, Max) | 19.7, 40.0 | 15.1, 34.4 | 15.1, 40.0 | 15.8, 63.1 |
| Race | | | | |
| White/Caucasian | 97.8% (131/134) | 0.0% (0/56) | 68.9% (131/190) | 94.9% (244/257) |
| Non-White/Non-Caucasian | 2.2% (3/134) | 100.0% (56/56) | 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%).

There were differences between the US patient population and the Japanese patient population with respect to their baseline medical histories as summarized in **Table 5**. The most commonly observed comorbidities were the same in the US and Japan; however, the rates were only similar for hypertension (78.4% vs. 76.8%) and were different for hypercholesterolemia (78.4% vs. 57.1%). The rates of comorbidities at baseline were higher in the US patient population as compared to the Japanese patient population, with the exception of angina (9.0% vs. 32.1%) and liver disease (4.5% vs. 8.9%).

Table 5. Baseline Medical History

| Body System/Medical Condition | INCRAFT US (N=134) | INCRAFT Japan (N=56) | INCRAFT US & Japan (N = 190) | SVS Controls (N = 323) |
|---|--------------------|----------------------|------------------------------|------------------------|
| Cardiovascular | | | | |
| Number of Subjects with at least one cardiovascular comorbidity | 97.0% (130/134) | 87.5% (49/56) | 94.2% (179/190) | 92.6% (287/310)* |
| Angina | 9.0% (12/134) | 32.1% (18/56) | 15.8% (30/190) | 25.5% (54/212) |
| Arrhythmia | 21.6% (29/134) | 10.7% (6/56) | 18.4% (35/190) | 13.9% (45/323) |
| Coronary Artery Disease | 47.8% (64/134) | 23.2% (13/56) | 40.5% (77/190) | 53.3% (172/323) |
| Myocardial Infarction | 20.1% (27/134) | 14.3% (8/56) | 18.4% (35/190) | 32.8% (106/323) |
| Hypertension | 78.4% (105/134) | 76.8% (43/56) | 77.9% (148/190) | 70.6% (228/323) |
| Hypercholesterolemia | 78.4% (105/134) | 57.1% (32/56) | 72.1% (137/190) | NA |
| Congestive Heart Failure | 3.7% (5/134) | 0.0% (0/56) | 2.6% (5/190) | 6.5% (21/323) |
| Family History of Aneurysm | 14.2% (19/134) | 5.4% (3/56) | 11.6% (22/190) | 17.9% (38/212) |
| Peripheral Arterial Disease | 18.7% (25/134) | 5.4% (3/56) | 14.7% (28/190) | 18.0% (58/323) |
| Neurological | | | | |
| Stroke | 6.7% (9/134) | 5.4% (3/56) | 6.3% (12/190) | 13.6% (44/323) |
| Endocrine | | | | |
| Diabetes | 26.9% (36/134) | 21.4% (12/56) | 25.3% (48/190) | 12.7% (41/323) |
| Urinary | | | | |
| Moderate Renal Insufficiency | 6.7% (9/134) | 1.8% (1/56) | 5.3% (10/190) | 3.1% (10/323) |
| Pulmonary | | | | |
| Chronic Obstructive Pulmonary Disease | 30.6% (41/134) | 17.9% (10/56) | 26.8% (51/190) | 26.9% (87/323) |
| Other Medical Conditions | | | | |
| Liver Disease | 4.5% (6/134) | 8.9% (5/56) | 5.8% (11/190) | 3.4% (5/146) |
| Cancer | 37.3% (50/134) | 21.4% (12/56) | 32.6% (62/190) | 23.6% (50/212) |
| Alcoholism | 11.2% (15/134) | 1.8% (1/56) | 8.4% (16/190) | 8.5% (18/212) |
| Smoking | 91.0% (122/134) | 96.4% (54/56) | 92.6% (176/190) | 88.2% (285/323) |

* There were 13 subjects who reported no other CV comorbidities but missing data for a prior history of angina or a family history of aneurysm for these subjects, therefore, they were not included in the denominator.

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**.

All subjects enrolled in this study met the inclusion criteria based on site-reported CT measurements. Subject eligibility was confirmed by the independent reviewer prior to enrollment. There were differences observed between the Core Lab and the site measurements for aortic diameter at the bifurcation (Core Lab: 19.3 ± 5.50 mm, Site: 25.2 ± 6.56) and minimum vessel diameter (Core Lab: right 6.8 ± 1.53 mm, left 6.9 ± 1.50 mm, Site: right 8.1 ± 1.86 mm, left 8.1 ± 1.82 mm). The variance between the Core Lab and the site measurements are due to differences in methodology when measuring aortic diameter at the bifurcation and the minimum vessel diameter. There were two different Core Labs used in the study; the measurements from baselines through 1-year were from the first Core Lab and follow-up measurements (after 1-year and beyond) were from the second Core Lab. The second Core Lab re-reviewed all x-rays and re-calculated the 1-month baseline measurements due to changes in migration measurement process from the first Core Lab. All measurement processes for the other parameters were uniform across the two Core Labs.

There were no significant differences between the U.S. cohort and the Japan cohort related to the baseline aneurysm and anatomical measurements.

Table 6. Baseline Aneurysm Characteristics as Measured from CT Scan

| Measure | INCRAFT (All Subjects) | |
|---|----------------------------------|--------------------------|
| | Core Lab N = 188 [†] | Site Reported N = 190 |
| Supra-renal Aortic Diameter (mm) | | |
| Mean \pm SD (N) | 23.6 \pm 2.50 (188) | 23.9 \pm 2.56 (189) |
| Median | 23.50 | 24.00 |
| Range (min, max) | 18.00, 31.50 | 17.00, 30.00 |
| Aortic Neck Diameter at start of cranial Attachment (mm) | | |
| Mean \pm SD (N) | 21.7 \pm 2.68 (188) | 22.6 \pm 2.70 (190) |
| Median | 22.00 | 23.00 |
| Range (min, max) | 15.50, 30.00 | 17.00, 31.00 |
| Aortic neck Constant Reference Diameter at 10 mm inferior (mm) | | |
| Mean \pm SD (N) | 22.2 \pm 3.81 (188) | 22.6 \pm 3.03 (190) |
| Median | 22.00 | 22.50 |
| Range (min, max) | 16.00, 50.00 | 16.00, 32.00 |
| Maximum aortic aneurysm Sac Diameter (mm) | | |
| Mean \pm SD (N) | 54.9 \pm 6.90 (188) | 55.7 \pm 6.58 (190) |
| Median | 53.95 | 54.00 |
| Range (min, max) | 43.30, 98.30 | 45.00, 100.00 |

| Measure | INCRAFT (All Subjects) | |
|--|----------------------------------|--------------------------|
| | Core Lab N = 188 [†] | Site Reported N = 190 |
| Aortic Diameter at Bifurcation (mm) | | |
| Mean ± SD (N) | 19.3 ± 5.50 (188) | 25.2 ± 6.56 (190) |
| Median | 18.00 | 23.00 |
| Range (min, max) | 11.00, 48.50 | 18.00, 52.00 |
| Right caudal landing zone Diameter (mm) | | |
| Mean ± SD (N) | 13.8 ± 3.15 (188) | 13.5 ± 3.36 (190) |
| Median | 13.20 | 13.00 |
| Range (min, max) | 7.50, 27.00 | 7.00, 22.00 |
| Left caudal landing zone Diameter (mm) | | |
| Mean ± SD (N) | 13.7 ± 2.91 (188) | 13.0 ± 3.01 (190) |
| Median | 13.15 | 13.00 |
| Range (min, max) | 8.00, 24.00 | 7.00, 21.00 |
| Right minimum vessel diameter (mm) | | |
| Mean ± SD (N) | 6.8 ± 1.53 (187) | 8.1 ± 1.86 (190) |
| Median | 7.00 | 8.00 |
| Range (min, max) | 2.80, 11.10 | 5.00, 17.00 |
| Left minimum vessel diameter (mm) | | |
| Mean ± SD (N) | 6.9 ± 1.50 (187) | 8.1 ± 1.82 (190) |
| Median | 7.10 | 8.00 |
| Range (min, max) | 3.30, 11.70 | 5.00, 14.00 |
| [†] 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**. All subjects enrolled in this study met the inclusion criteria based on site-reported CT measurements. As noted in **Table 7**, there were differences observed in the measurements for maximum aneurysm sac diameter between the Core Lab and the sites. This variance between the Core Lab and the site measurements are due to differences in methodology when measuring aneurysm sac diameter.

Table 7. Distribution of Baseline Aneurysm Diameters

| Measure | INCRAFT (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) |

| Measure | INCRAFT (All Subjects) | |
|--|----------------------------------|--------------------------|
| | Core Lab N = 188 [†] | Site Reported N = 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 **Table 8** and **Table 9**. The aortic bifurcate, ipsilateral limb and contralateral limb prostheses were implanted in all subjects. The most common aortic bifurcate diameters were 26 and 30 mm and the most common limb diameters were 13, 16 and 20 mm. 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) |

| INCRAFT System Component | Outer diameter | Overall (N = 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 U.S. 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 U.S. 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 U.S. (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 U.S. subjects (2.1%) in the **INCRAFT** cohort, while no estimated blood loss of ≥ 1000 mL was reported in the Japanese cohort. Procedural blood loss of < 500 mL among the subjects treated in Japan was 98.2% (55/56), while in the U.S. it was 92.5% (124/134). While the estimated blood loss was different between U.S. and Japan, the transfusion rates were similar (5.2% in U.S., 5.4% in Japan). The 3 Japanese subjects received a transfusion prophylactically due to advanced age and additionally due to presence of pre-procedure anemia (2 subjects). The main differences between the procedural data for U.S. 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%, 81/134) treated in the U.S. received general anesthesia compared to those that were treated in Japan (34%, 19/56).

Table 10. Acute Procedural Characteristics – U.S. and Japan

| Acute Procedural Data | INCRAFT Subjects | | |
|----------------------------------|-------------------------|------------------------|------------------------|
| | Total (N = 190) | U.S. (N = 134) | Japan (N = 56) |
| Duration of Procedure (minutes) | | | |
| Mean \pm SD (N) | 102.7 \pm 42.85 (190) | 97.0 \pm 41.44 (134) | 116.4 \pm 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 \pm SD (N) | 179.2 \pm 52.85 (99) | 176.6 \pm 56.46 (80) | 190.5 \pm 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) | | | |

| Acute Procedural Data | INCRAFT Subjects | | |
|---|---------------------|---------------------|--------------------|
| | Total (N = 190) | U.S. (N = 134) | Japan (N = 56) |
| 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 |
| 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%. The primary safety results are presented in **Table 11**. The composite 30 day MAE rate was 3.2% (6/190). There was 1 subject that had a myocardial infarction (MI) on post-operative day 2, which resulted in death. There was 1 subject that experienced a stroke (right occipital intraparenchymal hematoma) on post-operative day 16. The Clinical Events Committee adjudicated the event as unlikely related to the index procedure. Additionally, 4 subjects experienced procedural blood loss greater than 1,000 mL. There were no incidences of renal failure, respiratory failure, paralysis/paraparesis, or bowel ischemia reported.

The analysis of safety was based on the 190 subjects who had the aortic bifurcate component introduced into the body. Subjects who experienced at least 1 MAE through 30 days were included in the primary safety analysis even if the subject had not completed a 1-month follow up visit.

Table 11. Primary Safety Endpoint Results

| Primary Endpoint | INCRAFT | |
|--|-----------------------------|------------|
| | 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) | |
| Procedural blood loss (≥ 1,000 cc) | 2.1% (4/190) | |
| <p>£ The primary safety endpoint is the proportion of subjects with at least 1 MAE through 30 days post-procedure (numerator) over the number of subjects with an MAE plus the number of subjects without an MAE and with at least 23 days of post-procedure follow-up (denominator).</p> <p>* Primary Composite Safety Endpoint includes all of the eight individual components listed in this table.</p> <p>† 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.</p> | | |

6.2.7.2 Secondary Safety Endpoints

6.2.7.2.1 Major Adverse Events

Secondary safety endpoints include MAE and the individual components at 6 month and annually through 5 years; and procedure-related complications, defined as complications not attributed to the device but attributed to the procedure which arise following the procedure (e.g., renal insufficiency), through 30 days, 6 months, and annually to 5 years. The overall rate of MAE and the components of MAE 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, 22.8% at 3 years and 30.3% at 4 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 4 Years - Overall Rate and MAE Components

| Major Adverse Events * | INCRAFT Subjects (N = 190) | | | | |
|--|-------------------------------|----------------|----------------|----------------|----------------|
| | 6 Month | 1 Year | 2 Years | 3 Years | 4 Years |
| MAE rate** | 7.0% (13/187) | 10.9% (20/183) | 18.8% (33/176) | 22.8% (39/171) | 30.3% (50/165) |
| Death | 1.6% (3/187) | 3.3% (6/183) | 8.0% (14/176) | 12.9% (22/171) | 21.2% (35/165) |
| Stroke | 1.6% (3/187) | 2.2% (4/183) | 5.1% (9/176) | 7.6% (13/171) | 9.1% (15/165) |
| Myocardial infarction | 1.6% (3/187) | 3.3% (6/183) | 4.0% (7/176) | 5.3% (9/171) | 7.3% (12/165) |
| New onset renal failure (requiring dialysis) | 0.0% (0/187) | 0.0% (0/183) | 0.0% (0/176) | 0.0% (0/171) | 0.0% (0/165) |
| Respiratory failure (requiring mechanical ventilation) | 0.5% (1/187) | 1.1% (2/183) | 1.1% (2/176) | 1.2% (2/171) | 1.2% (2/165) |
| Paralysis / paraparesis | 0.0% (0/187) | 0.0% (0/183) | 0.0% (0/176) | 0.0% (0/171) | 0.0% (0/165) |
| Bowel ischemia (requiring surgical intervention) | 0.0% (0/187) | 0.0% (0/183) | 0.0% (0/176) | 0.0% (0/171) | 0.0% (0/165) |
| Procedural blood loss (≥ 1,000 cc) | 2.1% (4/187) | 2.2% (4/183) | 2.3% (4/176) | 2.3% (4/171) | 2.4% (4/165) |
| Aneurysm-related mortality | 0.5% (1/187) | 0.5% (1/183) | 0.6% (1/176) | 0.6% (1/171) | 0.6% (1/165) |

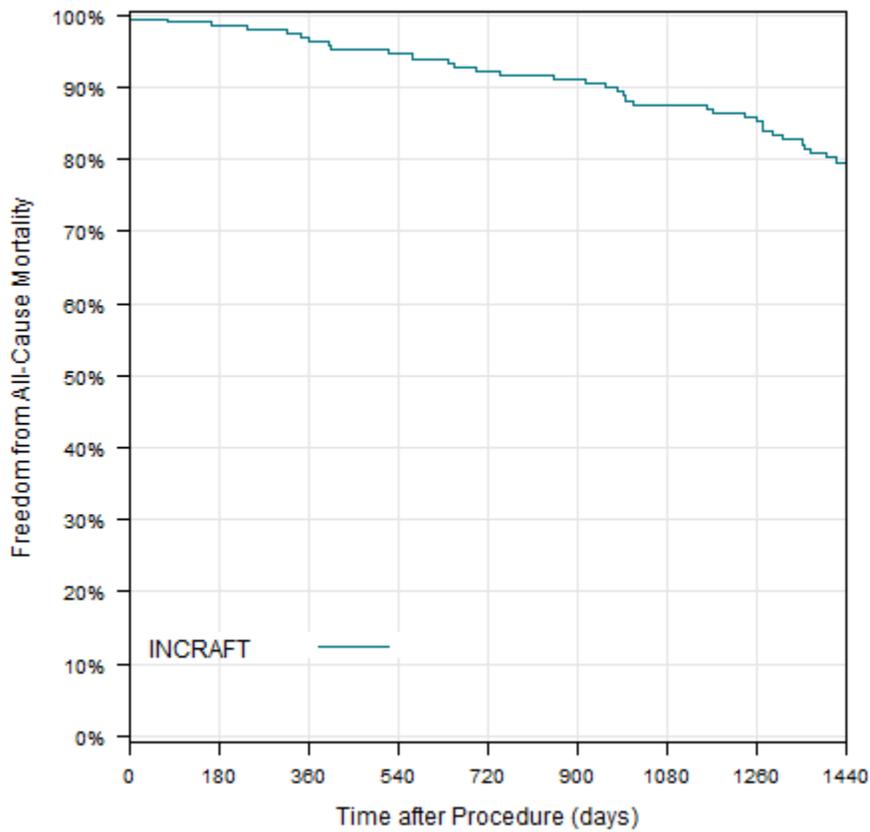
* Safety endpoints presented in this table are cumulative.

** Denominator is the number of subjects eligible for analysis includes subjects with a major adverse event or subjects with sufficient follow-up in the absence of a MAE for each study visit.

6.2.7.3 All-Cause Mortality

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, 87.6% at 3 years and 79.5% at 4 years. There was one aneurysm-related mortality, which occurred 2-days post-operatively (**Section 6.2.8.2.3**).

Figure 6. Kaplan-Meier Analysis: Freedom from All-Cause Mortality through 4 years



| INCRAFT | Time After Procedure | | | | | | |
|-------------------|----------------------|-----------|-------------|--------------|--------------|---------------|----------------|
| | 0 Days | 1-30 Days | 31-180 Days | 181-360 Days | 361-720 Days | 721-1080 Days | 1081-1440 Days |
| # At Risk | 190 | 188 | 182 | 177 | 161 | 149 | 115 |
| # Censored | 0 | 1 | 4 | 2 | 8 | 4 | 21 |
| # Events | 0 | 1 | 2 | 3 | 8 | 8 | 13 |
| Survival | 100.0% | 99.5% | 98.4% | 96.8% | 92.2% | 87.6% | 79.5% |
| Peto SE‡ | 0.0% | 0.5% | 0.9% | 1.3% | 2.0% | 2.5% | 3.1% |

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

6.2.8 Effectiveness Results

6.2.8.1 Primary Effectiveness

The primary effectiveness endpoint met the pre-defined 80% performance goal. The rate of successful aneurysm treatment to 1 year was 87.9% (152/173). There were no aneurysm enlargements, migrations, or aneurysm sac ruptures noted out to 1 year, as is shown in **Table 13**.

Table 13. Primary Effectiveness Endpoint Results

| Primary Endpoint | INCRAFT | |
|---|------------------------------|------------|
| | 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) | |

† 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.

Overall, twenty-one subjects did not meet the primary effectiveness endpoint. 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

Additionally, there were 2 conversions to open surgery, 3 Type I endoleaks, and 7 graft occlusions noted through 1 year. These events were all adjudicated by the Clinical Events Committee (CEC) to meet the definition of unsuccessful aneurysm treatment. It should be noted that the protocol

definition of graft occlusion implies that the vessel is 100% occluded. Additional information regarding these events is located in the respective sections below.

6.2.8.2 Secondary Effectiveness Endpoints

Secondary effectiveness endpoints are summarized in **Table 14** and discussed in the respective sections. The data presented are the number of subjects with the event observed during each time point. Subjects with fractures and migration identified in earlier time points will continue to be included in the numerator and denominator for later time points; however, data are not cumulative.

Table 14. Secondary Effectiveness Results

| Secondary Effectiveness Endpoints | INCRAFT Subjects | | | | | | | |
|--|------------------|------------------|--------------|----------------|----------------|----------------|----------------|----------------|
| | (N = 190) | | | | | | | |
| | Peri-Procedure | 1 Month | 6 Months | 1-Year | 2-Years | 3-Years | 4-Year | Total |
| Technical success at 1 month ‡ | N/A | 100.0% (186/186) | N/A | N/A | N/A | N/A | N/A | N/A |
| Device-related events* | N/A | (0/181) | 4.2% (7/167) | 10.1% (16/159) | 17.0% (24/141) | 30.5% (40/131) | 37.8% (42/111) | 30.5% (58/190) |
| Device malfunction¥ | N/A | (0/189) | (0/183) | 1.1% (2/176) | 1.2% (2/161) | 2.0% (3/148) | 2.4% (3/127) | 5.3% (10/190) |
| Aneurysm sac rupture | N/A | (0/189) | (0/183) | (0/176) | (0/161) | (0/148) | (0/127) | (0/190) |
| Stent graft migration*** | N/A | N/A | (0/177) | (0/172) | 0.6% (1/154) | 3.5% (5/141) | 4.5% (5/112) | 2.6% (5/190) |
| Endoleaks (Type I) | N/A | (0/186) | (0/175) | 1.8% (3/167) | 2.7% (4/149) | 1.5% (2/131) | 1.0% (1/102) | 5.3% (10/190) |
| Endoleaks (Type III) | N/A | (0/186) | (0/175) | (0/167) | (0/149) | 0.8% (1/131) | (0/102) | 0.5% (1/190) |
| Endoleaks (Type IV) | N/A | (0/186) | N/A | N/A | N/A | N/A | N/A | N/A |
| Aneurysm enlargement | N/A | N/A | (0/176) | (0/173) | 7.1% (11/155) | 16.2% (23/142) | 20.5% (23/112) | 14.7% (28/190) |
| Fractures° ¥ | N/A | (0/183) | 1.7% (3/172) | 4.9% (8/163) | 6.8% (10/147) | 9.5% (13/137) | 14.9% (17/114) | 8.9% (17/190) |
| Graft occlusion¥ | N/A | (0/189) | 2.2% (4/183) | 1.7% (3/176) | 0.6% (1/161) | 0.7% (1/148) | 0.8% (1/127) | 5.3% (10/190) |
| Conversion to open surgery¥ | N/A | (0/189) | 0.5% (1/183) | 0.6% (1/176) | (0/161) | (0/148) | (0/127) | 1.1% (2/190) |
| Aneurysm-related mortality§ | N/A | 0.5% (1/190) | - | - | - | - | - | 0.5% (1/190) |
| Delivery system malfunction | 4.2% (8/190) | N/A | N/A | N/A | N/A | N/A | NA | 4.2% (8/190) |
| 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) | 8.1% (12/148) | 6.3% (8/127) | 17.9% (34/190) |
| Incidence of secondary interventions, within 1 year post procedure needed to prevent the occurrence of a significant event | N/A | (0/189) | (0/182) | (0/176) | NA | NA | NA | N/A |

| Secondary Effectiveness Endpoints | INCRAFT Subjects | | | | | | | Total |
|--|------------------|---------|----------|--------|---------|---------|--------|-------|
| | (N = 190) | | | | | | | |
| | Peri-Procedure | 1 Month | 6 Months | 1-Year | 2-Years | 3-Years | 4-Year | |
| <p>* - For aneurysm enlargement, endoleaks, fractures, and migrations, denominators are based on evaluable data in CORE 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), 4 Years (1261 - 1620 days);</p> <p>- For aneurysm sac ruptures, malfunctions, graft occlusions, conversions to open surgery, and secondary interventions, denominators are defined based on evaluable 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)</p> <p>∞ - Subjects with fractures and migration identified will continue to be included in the numerator and denominator for later time points</p> <p>§ 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. Not defined as device-related event as per protocol.</p> <p>‡ 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.</p> <p>¥ A summary of conversions to open surgery, graft occlusions, device malfunctions and stent fractures are noted above table. Refer to Section 6.2.8.2.2 for a summary of device malfunctions.</p> <p>*** The migrations seen through 4 years only include proximal limb migration, no migration of the bifurcate prosthesis.</p> | | | | | | | | |

Technical success at 1 month, defined as graft patency with the absence of Type I or III endoleaks or aneurysm sac rupture confirmed by imaging was 100%. There was 1 (0.5%) aneurysm-related mortality at 1 month and no additional aneurysm-related mortality occurred after the 1 month time point through 4 years.

At 1 month, there were no new Type I/III/IV endoleaks. The Type Ia endoleaks observed in 9 subjects at the procedure (9/190, 4.7%) were resolved by 1-month. 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. There was 1 secondary intervention performed for vascular injury post index procedure.

For the duration of the study, no subjects with stent fracture had clinical sequelae attributable to stent fracture(s). There were no aneurysm sac ruptures. Reported device malfunctions are not included in this summary (See **Section 6.2.8.2.2**). The following paragraphs describe observations through 4 years:

At 6 months, there were 3 subjects with at least 1 transrenal stent fracture (total of 7 fractures), 4 stent graft occlusions (1 complete device occlusion, 3 occlusions of 1 iliac limb), 1 conversion to open surgery and 5 secondary interventions. There were no incidences of Type I or III endoleaks, aneurysm enlargement, or migration. The 4 subjects with stent graft occlusion resolved with secondary intervention. The subjects identified with stent fractures and migration 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 subjects with at least 1 transrenal stent fracture (total of 14 fractures), 3 stent graft occlusions of an iliac limb, 1 conversion to open surgery and 8 secondary interventions. The 3 subjects with stent graft occlusions of an iliac limb resolved with secondary intervention. There were no incidences of aneurysm enlargement or stent migration.

At 2 years, there were 11 new aneurysm enlargements, 5 Type I endoleaks (including 1 persistent), 10 subjects with at least 1 transrenal stent fracture (total of 22 fractures), 1 stent graft occlusion of an iliac limb, 1 proximal limb migration and 7 secondary interventions. The 1 subject with stent graft occlusion of an iliac limb resolved with secondary intervention.

At 3 years, there were 23 total aneurysm enlargements (including 10 aneurysm enlargements persisting from 2 years), 3 Type I endoleaks (including 1 persistent), 1 new Type III endoleak, 13 subjects with at least 1 transrenal stent fracture (total of 26 fractures), 1 subject with complete device graft occlusion, 5 subjects with proximal limb migrations and 12 secondary interventions. The 1 subject with stent graft occlusion resolved with secondary intervention.

At 4 years, there were 23 total aneurysm enlargements (including 19 aneurysm enlargements persisting from 3 years), 2 Type I endoleaks (including 1 persistent), 17 subjects with at least 1 transrenal stent fracture (total of 31 fractures), 1 subject with complete stent graft occlusion, 5 subjects with proximal limb migrations and 8 secondary interventions. The 1 subject with stent graft occlusion resolved with secondary intervention.

Type II endoleaks, stenoses and kink events were not defined as secondary effectiveness outcomes per the protocol. Through 4 year follow-up, 101 subjects (101/190, 53.2%) were observed with 108 Type II endoleaks, 15 subjects (15/190, 7.9%) were observed with 17 stent graft

stenosis, and 1 subject (1/190, 0.5%) was observed with 1 limb kink. Refer to the Endoleaks (**Section 6.2.8.2.6**) and Stent Graft Patency (**Section 6.2.8.2.9**) for discussion of these events.

Notable differences in reported outcomes between the US and Japan are provided in the subsequent sections, as applicable. In general, device-related event rates were higher in the US; 13.2% vs. 3.8% at 1 year, 20.0% vs. 11.8% at 2 years, 33.7% vs. 25.0% at 3 years, and 43.3% vs. 29.5% at 4 years. The event driving the differences throughout the duration of the study was transrenal stent fracture(s).

6.2.8.2.1 Technical Success

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

6.2.8.2.2 Device Malfunctions

Device malfunction is defined as failure of a device to meet any of its performance specifications or otherwise perform as intended. In this study, a device malfunction was determined by the clinical site per the study protocol and may consist of a subset of events discussed in the sections for each endpoint in this document. Eighteen device malfunctions were reported by the clinical sites during the study through 4 years (**Table 15**). The data includes 8 delivery system malfunctions and 10 device malfunctions specific to the implanted components of the 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.

There were two devices deployed at the unintended location; however, only one was reported by the site as a delivery system malfunction. In one observed case of high fixation release-wire pull-force, the device was successfully deployed at the intended location with no procedure-related or device-related adverse events.

Ten device malfunctions specific to the implanted components of the INCRAFT were reported during the INSPIRATION clinical study at various time points. Device malfunctions were assessed at the discretion of the investigators; therefore, not all endpoint events were reported as device malfunctions. Please refer to the respective sections below for the totality of observations/events that occurred in the clinical study.

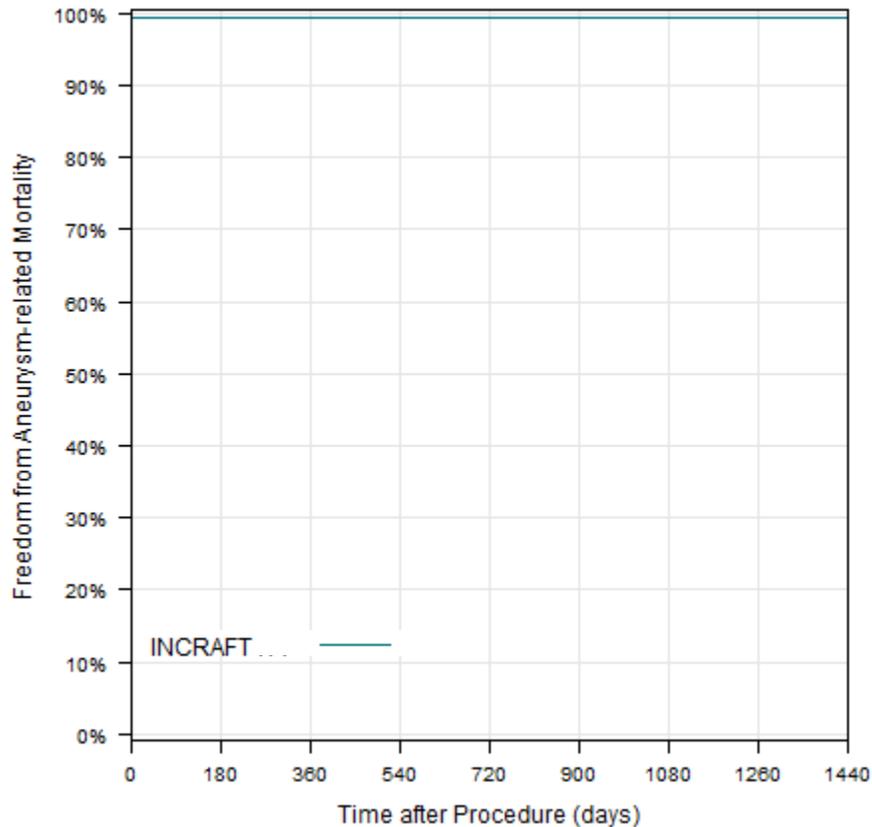
Table 15. Device Malfunctions through 4 Years

| | Peri-Procedure % (n/N) | 1 Month % (n/N) | 6 Months % (n/N) | 1 Year % (n/N) | 2 Year % (n/N) | 3 Year % (n/N) | 4 Year % (n/N) |
|---------------------------------------|---------------------------|--------------------|---------------------|-------------------|-------------------|-------------------|-------------------|
| Device or Delivery System Malfunction | 4.2% (8/190) | 0% (0/189) | 0% (0/183) | 1.1% (2/176) | 1.2% (2/161) | 2.0% (3/148) | 2.4% (3/127) |

6.2.8.2.3 Aneurysm-Related Mortality

Aneurysm-related mortality (ARM) 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. There was one (1/190; 0.5%) ARM observed. This subject died 2 days after the index 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 at each follow-up time point through 4 years post-procedure (**Figure 7**).

Figure 7. Kaplan-Meier Analysis: Freedom from Aneurysm-Related Mortality through 4 years



| INCRAFT ** | Time After Procedure | | | | | | |
|------------|----------------------|-----------|-------------|--------------|--------------|---------------|----------------|
| | 0 Days | 1-30 Days | 31-180 Days | 181-360 Days | 361-720 Days | 721-1080 Days | 1081-1440 Days |
| # At Risk | 190 | 188 | 182 | 177 | 161 | 149 | 115 |
| # Censored | 0 | 1 | 6 | 5 | 16 | 12 | 34 |
| # Events | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| Survival | 100.0% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% | 99.5% |
| Peto SE‡ | 0.0% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% | 0.5% |

** 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.

6.2.8.2.4 Aneurysm Sac Rupture

There have been no aneurysm sac ruptures reported in the study.

6.2.8.2.5 Migration

Device migration was defined as evidence of proximal or distal movement of the stent graft >10 mm relative to fixed anatomical landmarks compared with the 1-month imaging as assessed by the Core Lab. There were two different Core Labs used in the study; the measurements from baselines through 1-year were from the first Core Lab and follow-up measurements (after 1-years and beyond) were from the second Core Lab. The second Core Lab re-calculated the 1-month baseline measurements due to changes in migration measurement processes from the first Core Lab for all subsequent measurements after one year.

There have not been any aortic bifurcate migrations observed through 4 year follow-up that meet the protocol definition. However, there were 2 subjects that each had aortic bifurcate migration of 10 mm noted at the 3-year and the 4-year follow up visit respectively. Both migrations were likely associated with neck dilatation.

In addition to aortic bifurcate migration, limb migration was also investigated in the study. Proximal iliac limb migration was defined as proximal movement >10 mm of the distal margin of the iliac limb in relation to the hypogastric orifice. No limb migrations were observed by the 1 year follow up visit. Five limb migrations were observed by the Core Lab beyond the 1 year time point through 4 years. All of the limb migrations were proximal limb migrations and no limb separations were observed. The migration status at each time point are based on the images reviewed by the Core Lab. One of the subjects with limb migration at 3 years post procedure was observed with Type Ib endoleak which resolved following placement of an additional limb.

The number and percent of device migrations at the study follow-up visits is presented in **Table 16**. The subjects with adequate imaging to assess the migration is used for the denominator for the percentage calculation.

Table 16. Iliac Limb Migration through 4 Years

| | Treatment to 12 Months % (n/N) | 1 Month % (n/N) | 6 Months % (n/N) | 12 Months % (n/N) | 2 Year | 3 Year | 4 Year |
|------------------------|--------------------------------|-----------------|------------------|-------------------|--------------|--------------|--------------|
| Iliac Limb Migration * | 0% (0/187) | 0% (0/187) | 0% (0/177) | 0% (0/172) | 0.6% (1/154) | 3.5% (5/141) | 4.5% (5/112) |

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

6.2.8.2.6 Endoleaks

In the INSPIRATION Study, the Clinical Events Committee (CEC) adjudicated Type I, III and IV endoleaks. Types II and V endoleaks are not adjudicated by the CEC. A summary of endoleaks present at the end of each follow up time point through 4 years is presented in **Table 17**.

Fifteen subjects were observed with 16 Type Ia endoleaks. The Type Ia endoleaks observed in 9 subjects at the procedure (9/190, 4.7%) were resolved by 1-month with no secondary intervention. No aneurysm expansion attributable to Type 1a has been observed in the 9 subjects with procedural Type 1a endoleaks through 4 year follow-up. One subject with procedural Type 1a endoleak had aneurysm expansion attributed to Type II endoleak at 3-years.

A total of seven (7) subjects were observed to have Type Ia endoleaks during follow-up. Five (5) subjects who were observed with Type Ia endoleaks during follow-up underwent standard secondary interventions to resolve the endoleak, including coil embolization and/or placement of aortic cuff, EndoAnchors, chimneys (i.e., proximal placement of stent grafts parallel to an aortic cuff to facilitate branch vessel perfusion and exclusion of the aneurysm), and/or stents. No secondary interventions were performed on the remaining 2 Type Ia endoleaks that were observed during follow-up. These subjects have not had imaging since the last follow-up visit. Two aneurysm expansions were related to the observation of post-procedural Type Ia endoleaks. One subject had an aneurysm expansion with secondary intervention to address the Type Ia endoleak. The second subject had both a Type Ia and Type II endoleak which contributed to aneurysm enlargement; both endoleaks had a secondary intervention.

Three (3) subjects were identified with Type Ib endoleaks; 1 at 2-years and 2 at 3-years. One of the subjects that had limb migration noted at 3-years developed a Type Ib endoleak. This subject received an additional stent graft to resolve the endoleak. The other 2 Type Ib endoleaks observed underwent a secondary intervention to resolve the endoleak, namely placement of additional stent grafts. One subject had both a Type Ib and Type II endoleak which contributed to aneurysm enlargement; both endoleaks had a secondary intervention.

One hundred and eight (108) Type II endoleaks were identified in 101 subjects in the study through 4 years which account for majority of the endoleaks reported. Seventeen of the Type II endoleaks observed in 15 subjects (17/108, 15.7%) were treated with a secondary intervention that included coil and/or glue embolization. As noted in the aneurysm size section below (**Section 6.2.8.2.7**), 24 subjects with Type II endoleaks (24/101, 23.8%) were associated with aneurysm expansion greater than 5 mm. Eleven (11) of the 24 subjects with Type II endoleaks with aneurysm expansion have undergone a secondary intervention to address the observations.

One (1) subject was observed with a Type IIIb endoleak at the 3-year follow-up. The endoleak was related to a fabric tear in the left limb. The endoleak was successfully treated by placement of an additional limb component. The Medical Monitor stated that the limbs were in a “barber pole” configuration with the two limbs twisted about one another (i.e., limbs were crossed two times), which may have contributed to the fabric tear. No Type IIIa endoleaks have been observed through 4 year follow-up. There was no aneurysm enlargement observed in the subject with Type III endoleak.

The procedural Type IV endoleak occurrence rate, as adjudicated by the Clinical Events Committee, was 17.4% (33 Type IV endoleaks). Seven of those Type IV endoleaks were resolved

at discharge and the remaining 26 resolved by the 1-month time point without a secondary intervention.

There was 1 subject reported with a Type V endoleak at 3 years and currently persists through the latest follow-up visit. This subject had an aneurysm expansion greater than 5 mm, which was attributed to endotension.

There were some differences in the rates of reported Type I or III endoleaks between the US and Japan; 1.8% vs. 1.9% at 1 year, 4.1% vs. 0% at 2 years, 1.2% vs. 4.2% at 3 years, and 0% vs. 2.6% at 4 years.

Table 17. Number of Subjects with Endoleaks Reported through the 4 Year Follow-Up Visit

| | Post-Procedure Day 0 ^A | Discharge | 1-Month | 6-Month | 1-Year | 2-Year | 3-Year | 4-Year | Total |
|---|-----------------------------------|-----------|-----------|-----------|-----------|-----------|-----------|----------------|----------|
| Number of Subjects with Adequate Imaging to Assess Endoleaks | 190 | 190 | 186 | 175 | 167 | 149 | 131 | 102 | |
| Endoleaks (Total)^{B,C} | 90 | 74 | 72 | 68 | 64 | 66 | 58 | 49 | 167 |
| Type Ia | | | | | | | | | |
| <i>New</i> | 9 | - | - | - | 3 | 3 | - | 1 ^D | 15(16) |
| <i>Persistent</i> | - | 6 | - | - | - | 1 | 1 | 1 | |
| <i>Total (New + Persistent)</i> | 9, 4.7% | 6, 3.2% | -, -% | -, -% | 3, 1.8% | 4, 2.7% | 1, 0.8% | 2, 1.9% | |
| Type Ib | | | | | | | | | |
| <i>New</i> | - | - | - | - | - | 1 | 2 | - | 3(3) |
| <i>Persistent</i> | - | - | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | -, -% | -, -% | -, -% | -, -% | -, -% | 1, 0.7% | 2, 1.5% | -, -% | |
| Type Ic | | | | | | | | | |
| <i>New</i> | - | - | - | - | - | - | - | - | 0 |
| <i>Persistent</i> | - | - | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | |
| Type II | | | | | | | | | |
| <i>New</i> | 42(43) | 4 | 47 | 5 | 1 | 5 | 1 | 2 | 101(108) |
| <i>Persistent</i> | - | 34 | 25 | 63 | 60 | 56 | 52 | 44 | |
| <i>Total (New + Persistent)</i> | 42, 22.1% | 38, 20.0% | 72, 38.5% | 68, 37.8% | 61, 35.7% | 61, 39.1% | 53, 38.1% | 46, 39.3% | |
| Type IIIa | | | | | | | | | |
| <i>New</i> | - | - | - | - | - | - | - | - | 0 |
| <i>Persistent</i> | - | - | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | |
| Type IIIb | | | | | | | | | |
| <i>New</i> | - | - | - | - | - | - | 1 | - | 1(1) |
| <i>Persistent</i> | - | - | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | 1, 0.8% | -, -% | |

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English ONLY - Instructions for Use

| | Post-Procedure Day 0 ^A | Discharge | 1-Month | 6-Month | 1-Year | 2-Year | 3-Year | 4-Year | Total |
|-----------------------------------|-----------------------------------|-----------|---------|---------|--------|--------|---------|---------|--------|
| Type IIIc | | | | | | | | | |
| <i>New</i> | - | - | - | - | - | - | - | - | 0 |
| <i>Persistent</i> | - | - | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | |
| Type IV | | | | | | | | | |
| <i>New</i> | 33 | - | - | - | - | - | - | - | 33(33) |
| <i>Persistent</i> | - | 26 | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | 33, 17.4% | 26, 13.7% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | |
| Type V^E | | | | | | | | | |
| <i>New</i> | - | - | - | - | - | - | 1 | - | 1(1) |
| <i>Persistent</i> | - | - | - | - | - | - | - | 1 | |
| <i>Total (New + Persistent)</i> | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | 1, 0.8% | 1, 1.0% | |
| Unknown Causes^F | | | | | | | | | |
| <i>New</i> | 2 | - | - | - | - | - | - | - | 2(2) |
| <i>Persistent</i> | - | 2 | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | 2, 1.1% | 2, 1.1% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | |
| Other^G | | | | | | | | | |
| <i>New</i> | 3 | - | - | - | - | - | - | - | 3(3) |
| <i>Persistent</i> | - | 2 | - | - | - | - | - | - | |
| <i>Total (New + Persistent)</i> | 3, 1.6% | 2, 1.1% | -, -% | -, -% | -, -% | -, -% | -, -% | -, -% | |

^A Visits windows are defined as: At Procedure (0 days); At 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);

^B Endoleaks are presented in subsequent visit windows following discovery until resolved.

^C The 'New' and 'Persistent' row results reported for each endoleak subtype represent the number of subjects with an endoleak in that category. In cases where a subject had more than one endoleak, the total number of endoleaks is presented in parentheses.

The 'Total (New + Persistent)' row results reported for each endoleak subtype represent the total number of subjects with a new and/or persistent endoleak in that category, the total number of endoleaks in parentheses, followed by the percentage out of the number of subjects with an endoleak of the specific subtype or subjects without an endoleak who were evaluated for endoleaks at that study visit.

The 'Total' column presents the total number of subjects with at least one endoleak in that category, with the total number of endoleaks in that category identified over the course of the study in parentheses.

^D CEC adjudication of the new Type 1A endoleak presented at the 4 year window was not finalized by the 29Dec17 database lock. Subtype information not reported by site. Categorization as a Type 1A based on preliminary adjudication data.

^E Type V endoleaks identified via Medical Monitor review of database.

^F Unknown Causes category includes two endoleaks at procedure, one endoleak in subject and one in subject where type could not be determined due to poor or inconclusive imaging.

^G Other category includes one endoleak that was adjudicated as both Type II and Type IV and two endoleaks in two subjects that were adjudicated as not Type I or Type III.

6.2.8.2.7 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 enlargements 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 (16.2%) were observed with aneurysm enlargement, including 13 new enlargements and 10 ongoing enlargements from previous visit. At 4 years, 23 subjects (20.5%) were observed with aneurysm enlargement, including 4 new enlargements and 19 ongoing enlargements from previous visit. Aneurysm regression (> 5 mm) was 22.7% at 6 months, 37.6% at 1 year, 36.8% at 2 years, 38.0% at 3 years, and 41.1% at 4 years. The majority of the aneurysm sac enlargements were deemed likely attributable to Type II endoleaks (24/28). Three aneurysm expansions were deemed likely attributable to Type I endoleak. One enlargement had no endoleak observed and was classified as endotension.

Table 18 provides a summary of change in aneurysm diameter through 4-year follow-up as assessed by the Core Lab. There were 2 Core Labs utilized during the study. The measurement processes for aneurysm enlargement were uniform across the two Core Labs. **Table 19** provides further detail on aneurysm enlargements.

Aneurysm enlargement was the only event that had a consistently lower rate in the US as compared to Japan; 0% vs. 0% at 1 year, 6.9% vs. 7.5% at 2 years, 14.0% vs. 20.4% at 3 years, and 17.9% vs. 24.4% at 4 years.

Table 18. Aneurysm Diameter Change through 4 Year Follow-Up

| | 6 Months | 1 Year | 2 Year | 3 Year | 4 Year |
|---|-----------------|-----------------|----------------|----------------|----------------|
| Aneurysm diameter change from 1 month | | | | | |
| Aneurysm enlargement (increase > 5mm) | 0% (0/176) | 0% (0/173) | 7.1% (11/155) | 16.2% (23/142) | 20.5% (23/112) |
| Aneurysm stable (≤5mm regression/enlargement) | 77.3% (136/176) | 62.4% (108/173) | 56.1% (87/155) | 45.8% (65/142) | 38.4% (43/112) |
| Aneurysm regression (decrease > 5mm) | 22.7% (40/176) | 37.6% (65/173) | 36.8% (57/155) | 38.0% (54/142) | 41.1% (46/112) |

Table 19. Aneurysm Enlargements through 4 year Follow-Up

| Measures | 1 Month | 6 Months | 1 Year | 2 Years | 3 Years | 4 Years | Total* |
|---------------------------------------|---------|--------------|--------------|---------------|----------------|----------------|----------------|
| Aneurysm diameter change from 1-Month | | | | | | | |
| Aneurysm enlargement (increase > 5mm) | N/A | 0.0% (0/176) | 0.0% (0/173) | 7.1% (11/155) | 16.2% (23/142) | 20.5% (23/112) | 14.7% (28/190) |
| Mean (SD) | | | | 9.0 (4.7) | 9.9 (4.6) | 11.1 (4.1) | 11.2 (4.8) |
| Median | N/A | N/A | N/A | 8.1 | 9.1 | 9.7 | 10.2 |
| Range (min, max) | | | | 5.3, 22.4 | 5.3, 26.0 | 6.6, 20.9 | (5.3, 26.0) |

* Descriptive statistics presented in the Total column are for the maximum change in aneurysm diameter observed among subjects with one or more value > 5 mm.

6.2.8.2.8 Stent Graft Integrity

Transrenal stent strut fractures were reported by the Core Lab based on the images received from the site. Upon review of subject images by the Core Lab, a total of 17 subjects with stent strut fractures were observed on the follow-up (X-ray) imaging through 4 years. Three subjects with stent strut fracture were observed at 6 months, five additional subjects at 1 year, two additional subjects at 2 years, three additional subjects at 3 years, and four more subjects at 4 years. A summary of the observed stent strut fractures through 4 years is presented in **Table 20**.

There were differences in the rates of reported fracture(s) between the US and Japan; 6.4% vs. 1.9% at 1 year, 9.6% vs. 1.9% at 2 years, 13.6 % vs. 2.0% at 3 years, and 21.7% vs. 4.4% at 4 years. There were 2 subjects with a reported fracture in Japan as compared to 15 in the US through 4 years.

Of the 17 subjects with stent strut fracture, confirmed by the Core Lab, one subject with stent strut fracture was initially identified by the site. For the remaining 16 subjects, stent strut fractures were identified by the Core Lab only.

Table 20. Summary of Stent Strut Fractures through 4 Years

| | 1 Month | 6 Months | 1 Year | 2 Year | 3 Year | 4 Year |
|--|---------|----------|--------|--------|--------|--------|
| Number of Subjects with Imaging adequate to assess Fractures | 183 | 172 | 163 | 144 | 132 | 108 |
| Number of Subjects Newly Identified with at least 1 fracture | 0 | 3 | 5 | 2 | 3 | 4 |
| Cumulative Number of Subjects with a fracture | 0 | 3 | 8 | 10 | 13 | 17 |
| Cumulative Number of Fractures | 0 | 7 | 14 | 22 | 26 | 31 |

Among the 17 subjects through 4 years, 12 subjects had a single fracture, 2 subjects had two fractures, 1 subject had three fractures and 2 subjects had six fractures. Among the 5 subjects with more than one stent strut fracture, 4 subjects were observed with additional stent strut fractures following the time point that initial fractures were first observed, as shown in **Table 21**.

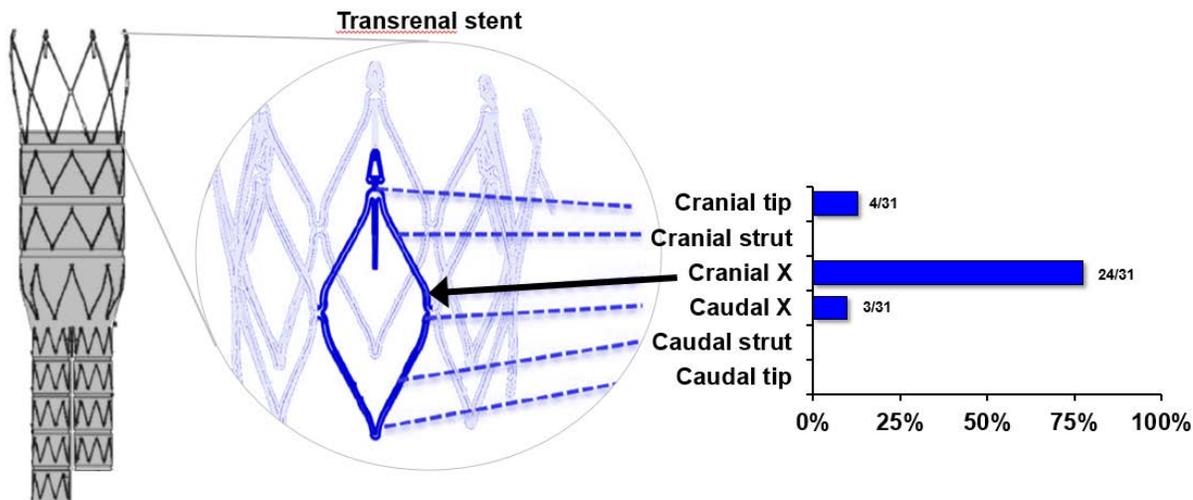
Table 21. Subjects with Multiple Stent Strut Fractures at Follow-Up (N = 5)

| | Total Number of Fractures at Each Follow Up Visit | | | | |
|-----------|---|--------|---------------|---------------|---------------|
| | 6 Months | 1 Year | 2 Year | 3 Year | 4 Year |
| Subject A | 1 | 1 | 1 | 1 | 2 |
| Subject B | 1 | 1 | 3 | Not available | Not available |
| Subject C | 0 | 1 | 5 | 6 | 6 |
| Subject D | 5 | 6 | Not available | Not available | Not available |
| Subject E | 0 | 2 | 2 | 2 | 2 |

All fractures observed were located at the transrenal stent, the stent component at the cranial end of the bifurcate implant which is not covered by the graft. Among the 17 subjects with fractures through 4 years, the majority of fractures (24/31) were located at the “Cranial X” location of the stent, with 4 fractures at the “Cranial tip” location and 3 fractures at the “Caudal X” location (**Figure 8**). In 3 of the 5 subjects with more than one stent fracture, the fractures resulted in disjointed stent segments (i.e., a stent segment that is not attached to the rest of the implant). There were total of five disjointed segments through 4 years, with one subject having one disjointed segment and two

subjects with two disjointed segments. Four of these five disjointed segments included the fixation barb and one disjointed segment was a linear portion of a stent strut. Across available imaging through 4 years, the disjointed segments remained at the original location and there was no strut embolization.

Figure 8. Location of All Stent Strut Fractures in INSPIRATION



There have been no clinical sequela or secondary interventions associated with the observation of stent strut fracture(s) reported through 4 year follow-up. Specifically, no aortic bifurcate migration, Type Ia endoleaks, aneurysm sac enlargements or aneurysm rupture were attributed to the presence of fractures. There were three subjects with stent strut fractures who had pre-existing and/or concurrent clinical events, which were assessed by the Medical Monitor to be independent of the transrenal stent strut fractures:

- Two subjects with stent strut fractures had aneurysm growth of > 5 mm during the study. In both subjects, the aneurysm enlargement was attributed to concurrent Type II endoleaks, independent of the strut fractures in the transrenal stent.
 - One subject had 6 fractures that developed from Year 1 through Year 4.
 - This subject had a non-INCRAFT aortic cuff/extension deployed during the initial procedure.
 - An aneurysm enlargement of > 5 mm and a Type II endoleak were detected at the 3-year visit. The Type II endoleak resolved without any intervention by the Year 4 visit.
 - A new Type Ia endoleak was detected at Year 4. The Type Ia endoleak, which remained untreated, and the aneurysm enlargement were ongoing as of the latest follow up. This endoleak was assessed by the Medical Monitor as not attributed to the stent strut fracture as it was unaccompanied by aortic bifurcate migration.
 - Two additional fractures were observed at Year 5 for a total of 8 fractures.
 - The second subject had a single stent strut fracture at Year 4, a Type II endoleak that was first detected at 6 months, and aneurysm enlargement that started in Year 3 which became > 5 mm by Year 4.
- One subject with a single stent strut fracture at Year 3 had aortic bifurcate movement of 10 mm in Year 4. This movement (just under the > 10 mm threshold of protocol-defined

migration) occurred steadily from 6 months through 4 years (7 mm of movement prior to stent fracture) and was attributed to dilatation of the aortic neck.

A root-cause investigation including non-clinical testing indicated that the primary cause of the observed transrenal stent fractures was cardiac-induced cyclic axial deformations. The root cause investigation has not identified any patient anatomical, demographic, or procedural related factors that may correlate with an increased risk of fracture or fracture propagation.

6.2.8.2.9 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 stent graft that was less than 100% obstructed. In the study, twenty-four subjects (24/189, 12.6%) were observed with an occlusion or other patency-related event.

Ten (10) subjects were observed by the site with stent-graft occlusions. Most of the occlusions occurred early (within 1 year). All subjects underwent secondary interventions, resolving the stent graft occlusions; no occlusions reoccurred after the interventions. Two subjects had complete occlusion of the aortic bifurcate component and both iliac limbs noted at 6 months and 3 years, respectively. One of the subjects was converted to open repair 173 days post procedure. Thrombosis of the entire stent graft was observed in the second subject at the 2 year follow-up, which progressed to complete occlusion of the implant, observed 781 days post procedure. The INCRAFT device was relined with commercially available devices to restore perfusion to the lower extremities. No additional secondary intervention was completed to address thrombosis or occlusion for this subject.

The other 8 subjects had limb occlusions with 7 subjects having single limb occlusion (3 at 6-months, 3 at 1 year, and 1 at 2 years). One subject at 4 years developed a bilateral limb occlusion and underwent an axillo-bifemoral bypass procedure to address the occlusion. The Medical Monitor reviewed the clinical and anatomical characteristics for this subject and determined that the modestly tight aortic bifurcation may have contributed to the occlusion. All occlusion subjects underwent secondary intervention, resolving the occlusion. The occlusions did not recur after the interventions. The secondary interventions completed to address the limb occlusions in the 8 subjects include the following: fem-fem bypass (3), right to left axillo-bifemoral bypass (1), relining of the INCRAFT device with competitor limbs (1), placement of 1 stent/embolectomy (1), placement of 1 stent/thrombolysis/thrombectomy/PTA (1), placement of 1 stent/angioplasty (1), and placement of 2 stents/thrombolysis/thrombectomy/PTA/fem-fem bypass (1).

There were some differences in the rates of reported occlusions between the US and Japan; 2.5% vs. 0% at 1 year, 0.9% vs. 0% at 2 years, 1.0% vs. 0% at 3 years, and 1.3% vs. 0% at 4 years.

Fifteen (15) subjects were reported by the site with 17 stent graft stenoses. All stent graft stenoses were observed in the iliac limbs. Seven subjects underwent secondary interventions to resolve the stenoses and 8 subjects did not require an intervention. The stenoses did not recur after the interventions. The secondary interventions completed to address stent graft stenosis or thrombus include the following: conversion to open repair (1), placement of 1 stent (3), placement of 1 stent/angioplasty (1), placement of 3 stents/thrombectomy (1), and angioplasty (1).

One (1) subject was observed with a limb kink by the site at the 3-year visit. The subject underwent stent placement to resolve the kink. The kink did not recur after the intervention.

All subjects met the selection criteria for the study, including absence of significant aortic or iliac mural thrombus, plaque, or calcification that would compromise fixation or seal of the device, as well as absence of coagulopathy, bleeding disorder, or other hypercoagulable state. A retrospective analysis of the clinical and anatomical characteristics of all subjects with patency-related events did not identify contributing causes unique to the subjects with patency-related events.

Table 22 provides a summary of all patients with patency-related events including stent graft occlusions, graft stenoses and limb kink.

Table 22. Patency Related Events through 4 Years

| n (m) ^a | INCRAFT | | | | | |
|---------------------------------|---------|-------|-------|-------|-------|-------|
| | 1M | 6M | 1Y | 2Y | 3Y | 4Y |
| Patients with Visit Data | 189 | 182 | 177 | 162 | 148 | 129 |
| Occlusion | 0 | 4 (4) | 3 (3) | 1 (1) | 1 (1) | 1 (1) |
| Stenosis | 0 | 4 (4) | 8 (8) | 1 (1) | 3 (3) | 1 (1) |
| Device kink | 0 | 0 | 0 | 0 | 1 (1) | 0 |

a. Results are presented as n, the number of patients with an event, and m, the number of events.

6.2.8.2.10 Conversion to Open Surgery

Two subjects underwent conversion to open surgery within the 4 years follow-up time point due to patency-related events, specifically complete device occlusion and mural clot in both iliac limbs of the INCRAFT, respectively. Additionally, an axillo-bifemoral bypass was completed to address a patency-related event. Please reference the stent graft patency **Section 6.2.8.2.9** for additional details regarding these interventions.

6.2.8.2.11 Secondary Intervention

A total of 34 subjects underwent 47 secondary interventions through 4 years to repair the device or aneurysm. The majority of secondary interventions were to address patency-related events and Type II endoleaks. A summary of the secondary interventions is presented in **Table 23**. Secondary interventions for patency-related events and endoleaks were discussed in their respective sections.

Two subjects underwent secondary interventions that were not discussed in the preceding sections: 1 for vascular injury and 1 for suture site bleeding. During the procedure, the first subject was treated for a superior mesenteric artery intimal tear with placement of a stent resolving the tear. The second subject underwent a secondary intervention for the Type II endoleak at 2-years post procedure. Following the secondary intervention, bleeding of vascular access site was observed and a fem-stop device was applied to the site resolving the bleed.

There were some differences in the rates of reported secondary interventions between the US and Japan; 6.6% vs. 0% at 1 year, 5.5% vs. 1.9% at 2 years, 8.1% vs. 8.2% at 3 years, and 6.3% vs. 6.4% at 4 years.

Table 23. Summary of Reasons for Secondary Interventions through 4 Years

| | 1-Month | 6-Month | 1-Year | 2-Year | 3-Year | 4-Year | Total |
|---|---------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|---------------------------------------|
| Number of Subjects Eligible | 189 | 182 | 177 | 162 | 148 | 129 | |
| Subjects with Any Intervention | 1 0.5% (1/189) | 5 2.7% (5/182) | 8 4.5% (8/177) | 7 4.3% (7/162) | 12 8.1% (12/148) | 8 6.2% (8/129) | 34 |
| Number of Interventions | 1 | 5 | 9 | 9 | 14 | 9 | 47 |
| Secondary Intervention for Stent graft occlusion* | 0 (0) 0% (0/189) | 3 (3) 1.6% (3/182) | 4 (4) 2.3% (4/177) | 1 (1) 0.6% (1/162) | 1 (1) 0.7% (1/148) | 1 (1) 0.8% (1/129) | 10 (10) [±] 5.3% (10/190) |
| Conversion to open surgery | 0 | 1 [±] | 0 | 0 | 0 | 0 | 1 |
| Fem-Fem Bypass | 0 | 1 | 1 | 1 | 0 | 0 | 3 |
| Right to Left Axillo-bifemoral bypass | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| 1 Stent/embolectomy | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 1 Stent/thrombolysis/thrombectomy/ PTA | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 1 Stent/angioplasty | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| 2 Stents/ thrombolysis/thrombectomy/PTA/ Fem-Fem Bypass | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Relining of INCRAFT graft with competitor limbs | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Secondary Intervention for Stent graft stenosis or thrombus* ,^β | 0 (0) 0% (0/189) | 1 (1) 0.5% (1/182) | 5 (5) 2.8% (5/177) | 1 (1) 0.6% (1/162) | 0 (0) 0% (0/148) | 0 (0) 0% (0/129) | 7 (7) 3.7% (7/190) |
| Angioplasty | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| Meds/Conversion to open surgery | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| 1 Stent | 0 | 1 | 2 | 0 | 0 | 0 | 3 |
| 1 Stent/Angioplasty | 0 | 0 | 1 | 0 | 0 | 0 | 1 |

INCRAFT® AAA Stent Graft System
English ONLY - *Instructions for Use*

| | 1-Month | 6-Month | 1-Year | 2-Year | 3-Year | 4-Year | Total |
|--|---------------------|---------------------|---------------------|-----------------------|-----------------------|-----------------------|---------------------------------------|
| Number of Subjects Eligible | 189 | 182 | 177 | 162 | 148 | 129 | |
| Subjects with Any Intervention | 1 0.5% (1/189) | 5 2.7% (5/182) | 8 4.5% (8/177) | 7 4.3% (7/162) | 12 8.1% (12/148) | 8 6.2% (8/129) | 34 |
| Number of Interventions | 1 | 5 | 9 | 9 | 14 | 9 | 47 |
| 3 Stents/thrombectomy | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Secondary Intervention for Type Ia Endoleak* | 0 (0) 0% (0/189) | 0 (0) 0% (0/182) | 0 (0) 0% (0/177) | 4 (4) 2.5% (4/162) | 2 (2) 1.4% (2/148) | 0 (0) 0% (0/129) | 5 (6) [∞] 2.6% (5/190) |
| Coil embolization | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Aortic cuff | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Aortic cuff/EndoAnchors | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Aortic cuff / chimney | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Aortic cuff / stent | 0 | 0 | 0 | 0 | 1 | 0 | 1 [∞] |
| EndoAnchors | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| Secondary Intervention for Type Ib Endoleak* | 0 0% (0/189) | 0 0% (0/182) | 0 0% (0/177) | 0 0% (0/162) | 2 1.4% (2/148) | 1 0.8% (1/129) | 3 1.6% (3/190) |
| Additional limbs placement | 0 | 0 | 0 | 0 | 2 | 1 | 3 |
| Secondary Intervention for Type II Endoleak* | 0 0% (0/189) | 1 0.5% (1/182) | 0 0% (0/177) | 2 1.2% (2/162) | 7 4.7% (7/148) | 6 (7) 4.7% (6/129) | 15 (17) [€] 7.9% (15/190) |
| Coil or/and glue embolization | 0 | 1 | 0 | 2 | 7 | 6 | 15 [€] |
| Secondary Intervention for Type III Endoleak* | 0 0% (0/189) | 0 0% (0/182) | 0 0% (0/177) | 0 0% (0/162) | 1 0.7% (1/148) | 0 0% (0/129) | 1 0.5% (1/190) |
| Additional limb placement | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Secondary Intervention for Stent graft kink* | 0 0% (0/189) | 0 0% (0/182) | 0 0% (0/177) | 0 0% (0/162) | 1 0.7% (1/148) | 0 0% (0/129) | 1 0.5% (1/190) |
| Stent | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| Secondary Intervention for Other** | 1 0.5% (1/189) | 0 0% (0/182) | 0 0% (0/177) | 1 0.6% (1/162) | 0 0% (0/148) | 0 0% (0/129) | 1 (2) 0.5% (1/190) |
| Stent placement for vascular injury | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| Fem-stop device for vascular access site bleeding | 0 | 0 | 0 | 1 | 0 | 0 | 1 |

* – Results through 4 year follow-up are presented as the number of subjects with an event (number of events), percent of total subjects at risk in the study.

β – One subject underwent a secondary intervention due to thrombus (thrombus of bilateral limbs of abdominal aortic endograft) during the 2-year window.

¥ – Other includes one secondary intervention which occurred at procedure due to a vascular injury and one secondary intervention which occurred at 2-years due to a procedure complication (bleeding of vascular access site after the secondary intervention for the Type II endoleak).

∞ – One subject underwent a secondary intervention in the 2-year window and 3-year window for the same Type Ia endoleak, however this subject is only counted once in the total column.

± – One subject underwent a secondary intervention in the 1-year window due to the occlusion which included both the fem-fem bypass and explant of the device, however, this subject is only counted once in the total column.

€ – One subject underwent a secondary intervention in the 3-year window and 4-year window for the same Type II endoleak, however this subject is only counted once in the total column.

6.3 Subject Accountability and Partial 5 Year Follow-Up Data

As of September 2018, one hundred fifteen (115) subjects have completed their 5-year follow-up visits. Of the 115 subjects, ninety-seven (97) subjects had CTs completed and assessed by the Core Lab and ninety-four (94) subjects had X-rays completed and assessed by the Core Lab. Study follow-up is ongoing.

Based on partial 5-year data, there were 20 aneurysm enlargements (18 persisting from 4 years, with 2 new identified expansions associated with Type II endoleaks), 1 persistent Type Ia endoleak from the 4 year visit, 6 new Type II endoleaks (41 persisting from the 4 year visit), and 4 secondary interventions for Type II endoleak repair (coiling/embolization).

Between 4-year and partial 5-year follow-up, there were three new subjects with stent strut fractures and three subjects (with prior stent fractures) observed with additional stent strut fractures. In all, there were twenty (20) subjects with a total of 40 transrenal stent fractures observed through (partial) 5 years:

- 13 subjects having a single fracture,
- 2 subjects having two fractures,
- 3 subjects having three fractures,
- 1 subject having six fractures, and
- 1 subject having eight fractures (including the 2 additional fractures identified at the 5 year visit).

Among the 7 subjects with more than one stent strut fracture, 5 subjects were observed with additional stent strut fractures following the time point that initial fractures were first observed. All subjects with stent fracture had no clinical sequelae attributable to stent fracture.

There was no incidence of aneurysm sac rupture. There were no additional reports of aneurysm-related mortality, additional endoleaks (Type Ib, Type IIIa, Type IIIb, Type V), device malfunctions, stent graft migration, stent graft patency related-events, or conversion to surgery beyond the 4-year follow-up.

7 PATIENT SELECTION AND TREATMENT

7.1 Patient Selection

Physicians should work with each patient to decide whether the INCRAFT would be an appropriate device to treat their aneurysm based on whether the patient meets the criteria specified in the indications for use, including:

- Adequate, but complex, iliac or femoral vessel morphology that is compatible with vascular access techniques, devices or accessories
 - NOTE – A physician may consider the access vessel morphology to be complex if in their experience the tortuosity index, amount of calcification, vessel diameters, and/or other factors may present an increased risk of access-related complications.
- Proximal neck length ≥ 10 mm;
- Aortic neck diameters ≥ 17 mm and ≤ 31 mm;
- Aortic neck suitable for suprarenal fixation;
- Infrarenal and suprarenal neck angulation $\leq 60^\circ$;
- Iliac fixation length ≥ 15 mm;
- Iliac diameters ≥ 7 mm and ≤ 22 mm; and

- Minimum overall AAA treatment length (proximal landing location to distal landing location) \geq 128 mm.

Considerations for patient selection include but are not limited to:

- Patient's age and life expectancy;
- Comorbidities (e.g., cardiac, pulmonary, or renal insufficiency prior to surgery, morbid obesity);
- Patient morphologic suitability for endovascular repair;
- Patient's suitability for open surgical repair;
- Risk of aneurysm rupture compared to the risk of repair with INCRAFT as compared to other marketed endovascular systems; and
- Ability to tolerate general, regional, or local anesthesia.

7.2 INCRAFT Stent Graft Sizing

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 than 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 and benefits related to **INCRAFT** as compared to other marketed endovascular systems
- 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 performance of the **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**, page 19).

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 the **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 the **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 9**. **Table 24** and **Table 25** provide information on the prosthesis dimensions and a sizing guide.

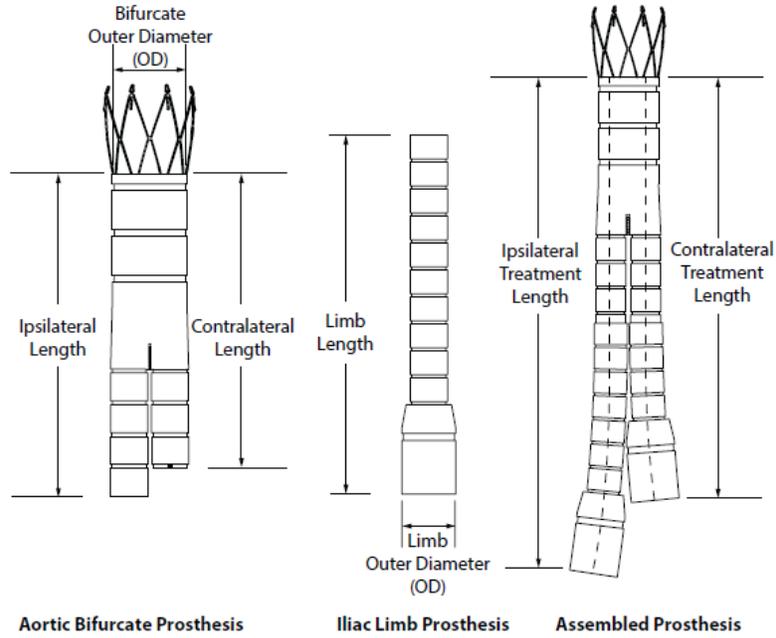


Figure 9. Stent Graft Diameter and Length Identification

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 | | |
| AB2298US | 22 | 17.0 - 19.9 | 13 | 14 | 4.7 | 9.4 | 8.6 |
| AB2698US | 26 | 20.0 - 22.9 | 13 | 14 | 4.7 | 9.4 | 8.6 |
| AB3098US | 30 | 23.0 - 26.9 | 13 | 14 | 4.7 | 9.4 | 8.6 |
| AB3498US | 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 | | |
| IL1008US | 10 | 7.0 - 8.9 | 8.2 | 12 | 4.0 | 128-156 | 128-147 |
| IL1010US | 10 | 7.0 - 8.9 | 10.1 | 12 | 4.0 | 147-175 | 147-166 |
| IL1012US | 10 | 7.0 - 8.9 | 12.0 | 12 | 4.0 | 166-194 | 166-185 |
| IL1014US | 10 | 7.0 - 8.9 | 13.8 | 12 | 4.0 | 184-212 | 184-203 |
| IL1308US | 13 | 9.0 - 10.9 | 8.2 | 12 | 4.0 | 128-156 | 128-147 |
| IL1310US | 13 | 9.0 - 10.9 | 10.1 | 12 | 4.0 | 147-175 | 147-166 |
| IL1312US | 13 | 9.0 - 10.9 | 12.0 | 12 | 4.0 | 166-194 | 166-185 |
| IL1314US | 13 | 9.0 - 10.9 | 13.8 | 12 | 4.0 | 184-212 | 184-203 |
| IL1608US | 16 | 11.0 - 13.9 | 8.2 | 12 | 4.0 | 128-156 | 128-147 |
| IL1610US | 16 | 11.0 - 13.9 | 10.1 | 12 | 4.0 | 147-175 | 147-166 |
| IL1612US | 16 | 11.0 - 13.9 | 12.0 | 12 | 4.0 | 166-194 | 166-185 |
| IL1614US | 16 | 11.0 - 13.9 | 13.8 | 12 | 4.0 | 184-212 | 184-203 |
| IL2008US | 20 | 14.0 - 17.9 | 8.2 | 12 | 4.0 | 128-156 | 128-147 |
| IL2010US | 20 | 14.0 - 17.9 | 10.1 | 12 | 4.0 | 147-175 | 147-166 |
| IL2012US | 20 | 14.0 - 17.9 | 12.0 | 12 | 4.0 | 166-194 | 166-185 |
| IL2014US | 20 | 14.0 - 17.9 | 13.8 | 12 | 4.0 | 184-212 | 184-203 |
| IL2410US | 24 | 18.0 - 22.0 | 10.1 | 13 | 4.3 | 147-175 | 147-166 |
| IL2412US | 24 | 18.0 - 22.0 | 12.0 | 13 | 4.3 | 166-194 | 166-185 |
| IL2414US | 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 Information



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 field gradient ≤ 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.

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 starting 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 delivery systems.

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 the **INCRAFT** devices was performed using an Amplatz Super Stiff™ guidewire. Use of a stiffer guidewire with the aortic bifurcate prosthesis may lead to increased degree of asymmetric deployment of the transrenal stent, particularly in angulated necks.
- When advancing the guidewires, catheters, and the **INCRAFT** delivery system 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 (Section 1.2, page 13)** 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 (Section 1.2, page 13)**) 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 (Section 1.1.2, page 12)**) 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 bifurcate 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 (Section 1.2, page 13)**) 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 below.

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

8. Under fluoroscopy, keep turning the delivery system's gold handle component until the transrenal stent begins to expand. Assess device positioning relative to the renal arteries (refer to **Figure 10**) 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 (Section 1.1.2, page 12)**) 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.

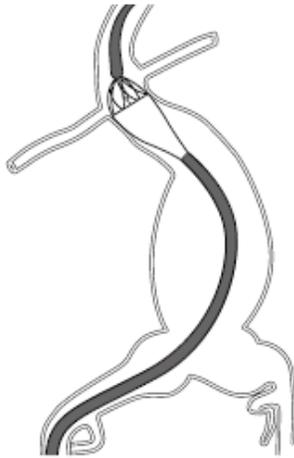


Figure 10. Illustration of Bifurcate Deployment Position

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 (Section 1.2, page 13)**). 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 (Section 1.2, page 13)**) until it is completely unsheathed. Use fluoroscopy to confirm complete deployment of the aortic bifurcate prosthesis.
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 (Section 1.2, page 13)**) to separate the sheath into two parts. While holding the sheath firmly, carefully 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.

12.2.1 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. Wet the outer surface of the iliac limb delivery system (tip to approximately 25 cm of the delivery system) with saline to ensure activation of the hydrophilic coating.
3. 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 prosthesis is aligned with the maximum overlap marker of the aortic bifurcate prosthesis while ensuring that no cranial migration of the aortic bifurcate prosthesis occurs.

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

4. 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 prosthesis 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 11**).

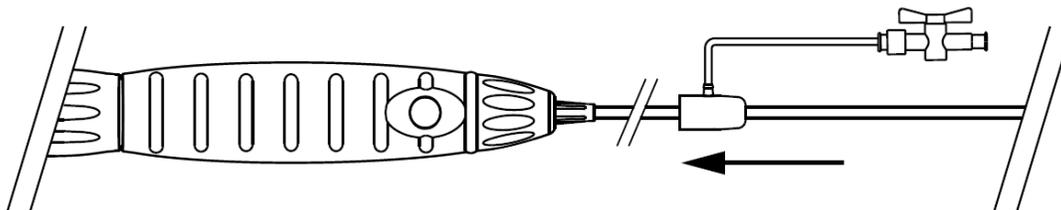


Figure 11. Illustration of the Aortic Bifurcate Sheath Pull-back for Limb Deployment

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

5. 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 (Section 1.1.2, page 12)**).

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.

6. To deploy the Ipsilateral iliac limb prosthesis, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5 (Section 1.2, page 13)**) 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.

7. 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.
8. Unclip the release wire retainer and pull it (refer to **Figure 5 (Section 1.2, page 13)**) 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.

9. 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.

12.2.2 Implant the Contralateral Iliac Limb Prosthesis

1. Using standard practice, cannulate the contralateral leg of the aortic bifurcated prosthesis guided by the contralateral leg-gate markers (refer to **Figure 4 (Section 1.1.2, page 12)**).

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 for 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. Place an adequately sized introducer sheath on the contralateral side.
6. Wet the outer surface of the iliac limb delivery system (tip to approximately 25 cm of the delivery system) with saline to ensure activation of the hydrophilic coating.
7. 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 aortic 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 artery occlusion.

8. 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 (Section 1.1.2, page 12)**).

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.

9. To deploy the contralateral iliac limb prosthesis, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5 (Section 1.2, page 13)**) 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.

10. Keep turning the delivery system's 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.
11. Unclip the release wire retainer and pull it (refer to **Figure 5 (Section 1.2, page 13)**) 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 deployed 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.

12. 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.

12.3 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 bifurcate and

limb 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 the 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 stent graft's 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 deployment may result in renal failure or ruptured aneurysm. Failure to diagnose internal iliac artery interruption post deployment may result in buttock claudication, bowel ischemia, or sexual dysfunction.

3. Carefully 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.

12.4 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 an 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 iliac limb as per **Table 25 (Section 10.2, page 61)**.

Caution: After removal from the package take care not to pull or snag the fixation release wire (refer to **Figure 5 (Section 1.2, page 13)**) 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 surface of the iliac limb delivery system (tip and approximately 25 cm of the delivery system) 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 12.2.1**, page 67).

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 12**) of the iliac limb graft previously deployed.

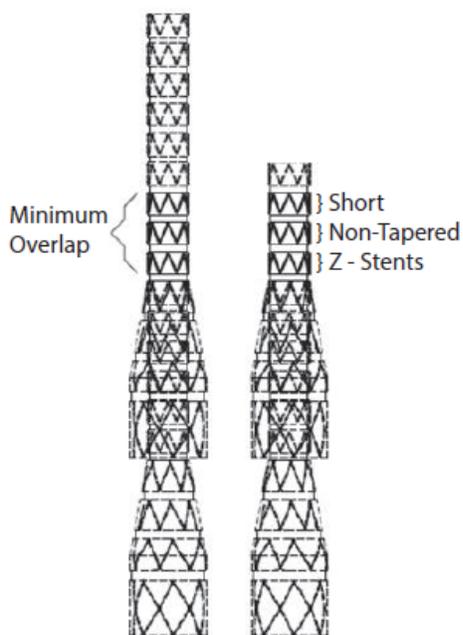


Figure 12. Placement of the Iliac Limb Extension

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 extension, proceed as follows: Place your hand firmly on the white handle component (refer to **Figure 5 (Section 1.2, page 13)**) 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 delivery system 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 (Section 1.2, page 13)**) until it comes completely out of the handle, thereby releasing and securing the cranial end of the iliac limb extension.

Warning: Do not advance or withdraw the iliac limb delivery system after the limb extension 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/extension 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 implanted graft components 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.

12.5 Accessory Stent Placement

If placement of an accessory stent within the stent graft 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. When placing an accessory stent in a limb, 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 the terminus of an accessory stent in a bend.

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 before stent graft deployment is complete, the following steps can be used to remove the handle (refer to **Figure 13**) so that the stent graft can be deployed using a "pin and pull" technique:

1. While maintaining the position and orientation of the delivery system, use a sharp 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. Reference **Figure 13** below.
3. Attempt completion of stent-graft deployment using "pin and pull" technique by holding the clear manifold shell located at the proximal end of the handle assembly and pulling back on the gray sheath mount toward the clear manifold shell to deploy the graft. If this is not successful, proceed to the steps below.
4. Unclip and slide the white guide rail lock (that is at the very distal end of the metallic guide rails of the internal handle assembly) slightly in the direction of the delivery system tip.
5. Unclip tabs of the clear manifold shell (without shifting its axial position) located at the proximal end of the handle assembly.
6. Slide the two metallic guide rails in the direction of the delivery system until they both come loose and can be removed. During this step, hold the grey sheath mount in the same axial position.
7. At this point, the stent graft delivery can be completed by holding the inner member and pulling back on the outer member.

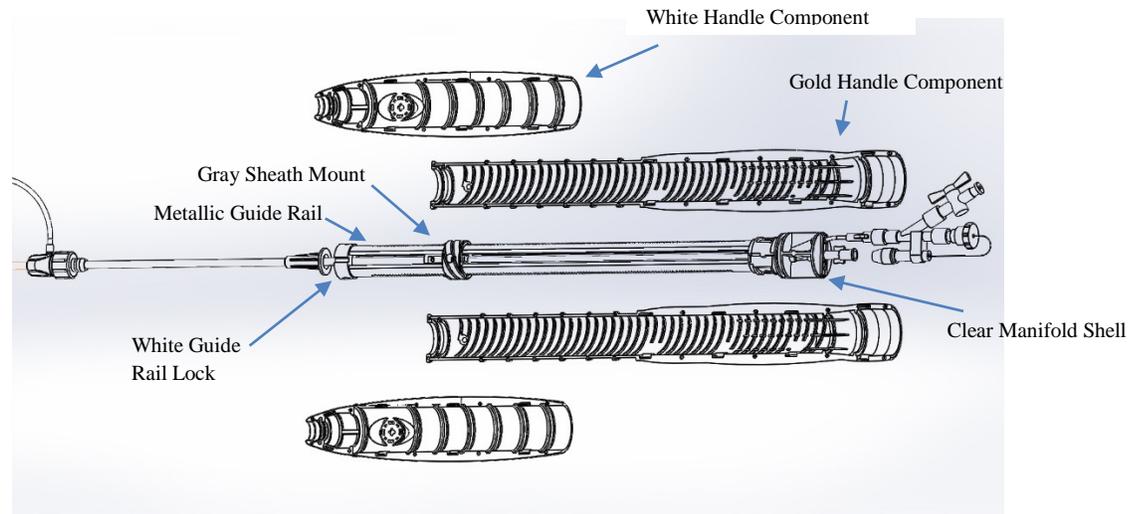


Figure 13. Disassembled Delivery System Handle

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 (Section 1.2, page 13)**). 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, unscrew 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 fixation release wire as hard as possible until the fixation release is achieved, or the wire breaks.
5. If these steps have not worked then consider a conversion to open surgery.

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 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 CO₂ 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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