COOK MEDICAL

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Patient I.D. Card Included

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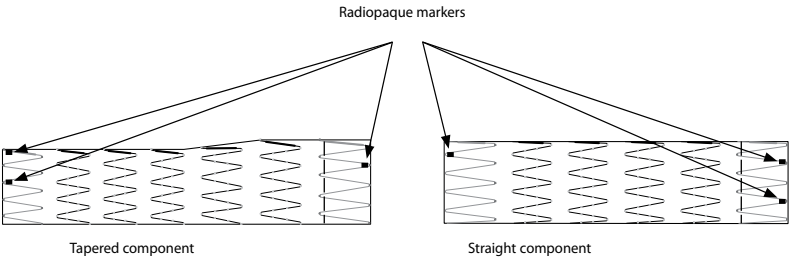

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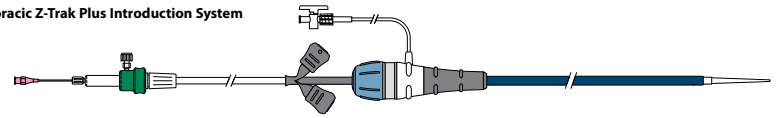

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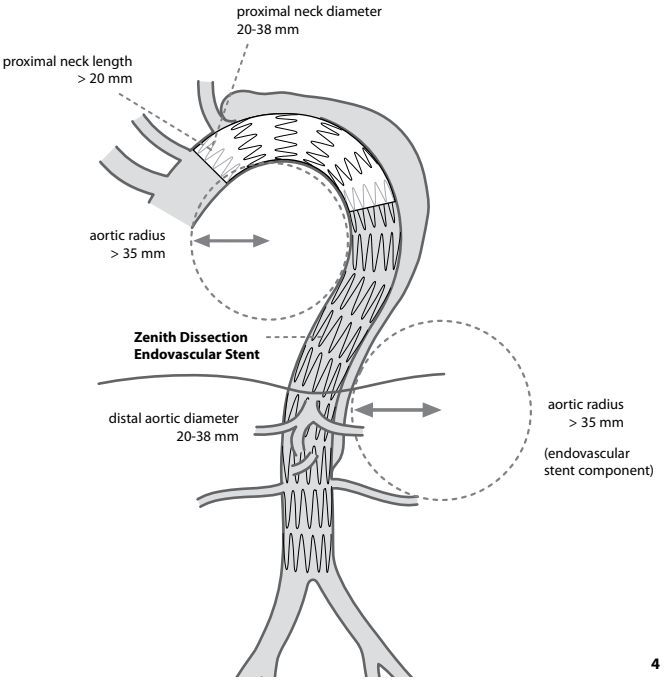

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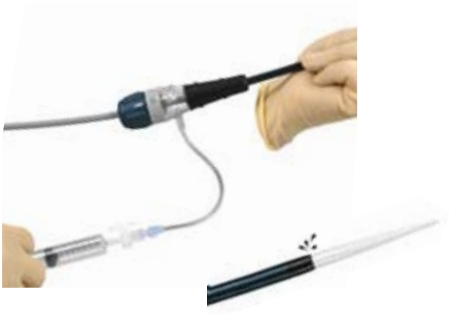

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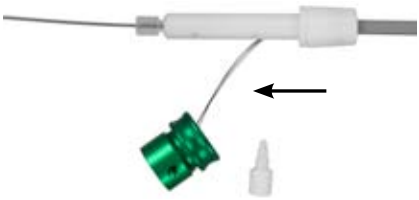

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ENGLISH

ZENITH® TX2® DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM® AND THE Z-TRAK® PLUS INTRODUCTION SYSTEM

Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CAUTION: All contents of the inner pouch (including the introduction system and endovascular graft) are supplied sterile, for single use only.

1 DEVICE DESCRIPTION

1.1 Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System

When treating dissections of the descending thoracic aorta, the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is typically used in conjunction with the Zenith® Dissection Endovascular Stent. The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is for sealing of entry tear(s). The Zenith Dissecton Endovascular Stent provides support to delaminated segments of the aorta. For information regarding the use and deployment of the Zenith Dissection Stents, please refer to the Instruction for Use.

The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System shortest Straight Components can be used to provide additional lenght to the endovascular graft , both proximal and distal. Ensure there is a minimum overlap of 2 stents. The stent graft is constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z stents with braided polyester and monofilament polypropylene suture (Figure 1). The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is fully stented to provide stability and the expansile force necessary to open the lumen of the graft during deployment. Additionally, the Cook-Z stents provide the necessary attachment and seal of the graft to the vessel wall.

To facilitate fluoroscopic visualization of the stent graft, four radiopaque markers are positioned on each end of the Straight Component or Tapered Component. These markers are placed in a circumferential orientation within 1 mm of the most proximal aspect of the graft material and within 1 mm of the most distal aspect of the graft material.

1.2 Thoracic Z-Trak Plus Introduction System

The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is shipped preloaded onto the Z-Trak Plus Introduction System. It has a sequential deployment method with built-in features to provide continuous control of the endovascular graft throughout the deployment procedure. The Z-Trak Plus Introduction System enables precise positioning before deployment of the Straight Component or Tapered Component. The straight and tapered graft components are deployed from a 20 Fr or 22 Fr Z-Trak Plus Introduction System. These systems use a single trigger-wire release mechanism to secure the endovascular graft onto the delivery system until released by the physician (**Fig. 2**). All introduction systems are compatible with a .035 inch wire guide. For added hemostasis, the Captor™ Hemostatic Valve can be loosened or tightened for the introduction and/or removal of ancillary devices into and out of the sheath. All introduction systems feature Flexor® introducer sheaths, which resist kinking and are hydrophilically coated. Both features are intended to enhance trackability in the iliac arteries and thoracic aorta.

To facilitate sheath withdrawal, each graft component is kept in a longitudinally stretched condition on the introduction system by locking trigger-wires (**Fig. 3**). These trigger-wires work in tandem to deliver sequential controlled release of the Zenith TX2 Dissection Endovascular Graft with Pro-Form during deployment (**Fig. 3**).

2 INTENDED USE

The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is indicated for the endovascular treatment of patients with symptomatic dissection of the descending thoracic aorta having vascular morphology suitable for endovascular repair (**Fig. 4**), including:

- Adequate iliac/femoral access compatible with the required introduction systems,
- Radius of curvature greater than 35 mm along the length of aorta intended to be treated by Straight or Tapered Component,
- Non-dissected/aneurysmal aortic segments (fixation sites) proximal to the entry tear:
  - with a length of at least 20 mm
  - with a diameter measured outer wall to outer wall of no greater than 38 mm and no less than 20 mm, and
  - with localized angulation less than 45 degrees.

3 CONTRAINDICATIONS

The Zenith TX2 Dissection Endovascular Graft with Pro-Form and with the Z-Trak Plus Introduction System is contraindicated in:

- Patients with known sensitivities or allergies to stainless steel, polyester, polypropylene, nitinol or gold.
- Patients with a systemic infection who may be at increased risk of endovascular graft infection.

4 WARNINGS AND PRECAUTIONS

4.1 General

- Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious consequences or injury to the patient.
- The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System should only be used by physicians and teams trained in vascular interventional techniques (catheter-based and surgical) and in the use of this device. Specific training expectations are described in **Section 10.1, Physician Training**.
- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, persisting flow in false lumen, or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 12, IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.**
- After endovascular graft placement, patients should be regularly monitored for perigraft flow or changes in the structure or position of the endovascular graft. At a minimum, annual imaging is required, including: 1) thoracic device radiographs to examine device integrity (separation between components or stent fracture); and 2) contrast and non-contrast CT to examine perigraft flow, patency, tortuosity, device position and progressive disease. If renal complications or other factors preclude the use of image contrast media, use of other imaging modalities (e.g., TEE, IVUS) should be considered in combination with non-contrast CT.
- The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is not recommended in patients unable to undergo, or who will not be compliant with, the necessary pre-operative and post-operative imaging and implantation studies as described in **Section 12, IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.**
- Additional endovascular interventions or conversion to standard open surgical repair following initial endovascular repair should be considered for patients experiencing unacceptable decrease in fixation length (vessel and component overlap) and/or endoleak.
- Patients experiencing reduced blood flow through the graft and/or leaks may be required to undergo secondary endovascular interventions or surgical procedures.
- Always have a qualified surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- Interventions such as defibrillation, cardioversion, or CPR, although not specifically evaluated in studies, may have the potential to disrupt position or seal of the endograft, and should be followed by imaging to confirm continued device function.

4.2 Patient Selection, Treatment and Follow-Up

- Access vessel diameter (measured inner wall to inner wall) and morphology (tortuosity, occlusive disease, and/or calcification) should be compatible with vascular access techniques and introduction systems of the profile of a 20 Fr or 22 Fr vascular introducer sheath. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude femoral introduction of the endovascular graft and/or may increase the risk of embolization.
- Key anatomic elements that may affect successful exclusion of the dissection include severe angulation localized angulation > 45 degrees); short proximal fixation site (< 20 mm); an inverted funnel shape at the proximal fixation site (greater than 10% increase in diameter over 20 mm of fixation site length); and circumferential thrombus and/or calcification at the arterial fixation sites. Irregular calcification and/or plaque may compromise the attachment and sealing at the fixation site. Necks exhibiting these key anatomic elements may be more conducive to graft migration.
- The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is not recommended for patients who cannot tolerate contrast agents necessary for intra-operative and post-operative follow-up imaging.
- The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is not recommended for patients whose weight or size would compromise or prevent the necessary imaging requirements.
- Graft implantation may increase the risk of paraplegia where graft exclusion covers the origins of dominant spinal cord or intercostal arteries.
- Patients with connective tissue disorders have not been evaluated.
- Highly patent intercostal aortic branches or large collateral vessels are likely to result in retrograde flow after thoracic graft implantation. Patients with uncorrectable coagulopathy may also have an increased risk of Type II endoleak or bleeding complications.

4.3 Implant Procedure

- Systemic anticoagulation should be used during the implantation procedure based on hospital and physician preferred protocol. If heparin is contraindicated, an alternative anticoagulant should be used.
- Minimize handling of the constrained endoprosthesis during preparation and insertion to decrease the risk of endoprosthesis contamination and infection.
- To activate the hydrophilic coating on the outside of the sheath, the surface must be wiped with 4X4 gauze pads soaked in saline solution. Always keep the sheath hydrated for optimal performance.
- Maintain wire guide position during introduction system insertion.
- Do not bend or kink the introduction system. Doing so may cause damage to the introduction system and the Zenith TX2 Dissection Endovascular Graft with Pro-Form.
- Always use fluoroscopy for guidance, delivery, and observation of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System within the vasculature.
- The use of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure post-operatively. Care should be taken to limit the amount of contrast media used during the procedure.
- To avoid twisting the endovascular graft, never rotate the introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the vessels.
- As the sheath is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check position as necessary.
- Inaccurate placement and/or incomplete sealing of the Zenith TX2 Dissection Endovascular Graft with Pro-Form within the vessel may result in increased risk of endoleak, migration, or inadvertent occlusion of the left subclavian, left common carotid, and/or celiac arteries.
- Incorrect deployment or migration of the endoprosthesis may require surgical intervention.
- Do not continue advancing the wire guide or any portion of the introduction system if resistance is felt. Stop and assess the cause of resistance; vessel, catheter, or graft damage may occur. Exercise particular care in areas of stenosis, intravascular thrombosis, or calcified or tortuous vessels.
- Unless medically indicated, do not deploy the Zenith TX2 Dissection Endovascular Graft with Pro-Form in a location that will occlude arteries necessary to supply blood flow to organs or extremities. Do not cover significant arch or mesenteric arteries (exception may be the left subclavian artery) with the endoprosthesis. Vessel occlusion may occur. If a left subclavian artery is to be covered with the device, the clinician should be aware of the possibility of compromise to cerebral and upper limb circulation.
- Use caution during manipulation of catheters, wires and sheaths within a dissection. Significant disturbances may dislodge fragments of thrombus, which can cause distal or cerebral embolization.
- Avoid damaging the graft or disturbing graft positioning after placement in the event reinstrumentation (secondary intervention) of the graft is necessary.
- Do not attempt to re-sheath the graft after partial or complete deployment.
- Repositioning the stent graft distally after partial deployment of the covered proximal stent may result in damage to the stent graft and/or vessel injury.
- To avoid impaling any catheters left in situ, rotate the introduction system during withdrawal.

4.4 Molding Balloon Use - Optional

- Confirm complete deflation of balloon prior to repositioning.
- Do not inflate balloon in aorta outside of graft.
- Use caution during molding within a dissection
- For added hemostasis, the Captor™ Hemostatic Valve can be loosened or tightened to accomodate the insertion and subsequent withdrawal of a molding balloon.

4.5 MRI Information

Non-clinical testing has demonstrated that the Zenith TAA Endovascular Graft is MR Conditional according to ASTM F2503. A patient with this endovascular graft may be safely scanned after placement under the following conditions.

- Static magnetic field of 1.5 and 3.0 Tesla.
- Maximum spatial magnetic gradient field of 720 Gauss/cm
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode) for 15 minutes of scanning or less (i.e., per scanning sequence)

Static Magnetic Field

The static magnetic field for comparison to the above limits is the static magnetic field that is pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

MRI-Related Heating

1.5 Tesla Temperature Rise

In non-clinical testing, the Zenith TX2 TAA Endovascular Graft produced a temperature rise of 1.2°C (scaled to an SAR of 2.0 W/kg) during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 1.5 Tesla System (Siemens Magnetom, Software Numaris/4).

3.0 Tesla Temperature Rise

In non-clinical testing, the Zenith TX2 TAA Endovascular Graft produced a temperature rise of less than or equal to 1.3°C (scaled to an SAR of 2.0 W/kg) during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 3.0 Tesla System (General Electric Excite, HDx, Software G3.0-052B).

Image Artifact

The image artifact extends throughout the anatomical region containing the device, obscuring the view of immediately adjacent anatomical structures within approximately 20 cm of the device, as well as the entire device and its lumen, when scanned in nonclinical testing using the sequence: Fast spin echo, in a MR 3.0 Tesla System (General Electric Excite, HDx, Software G3.0-052B), with body radiofrequency coil.

For all scanners, the image artifact dissipates as the distance from the device to the area of interest increases. MR scans of the head and neck and lower extremities may be obtained without image artifact. Image artifact may be present in scans of the abdominal region and upper extremities, depending on distance from the device to the area of interest.

For US Patients Only

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail:	MedicAlert Foundation International 2323 Colorado Avenue Turlock, CA 95382
Phone:	888-633-4298 (toll free) 209-668-3333 from outside the US
Fax:	209-669-2450
Web:	www.medicalert.org

5 POTENTIAL ADVERSE EVENTS

Adverse events that may occur and/or require intervention include, but are not limited to:

- Amputation
- Anesthetic complications and subsequent attendant problems (e.g., aspiration)
- Aneurysm enlargement
- Aneurysm rupture and death
- Aortic damage, including perforation, dissection, bleeding, rupture and death
- Aorto-bronchial fistula
- Aorto-esophageal fistula
- Arterial or venous thrombosis and/or pseudoaneurysm
- Arteriovenous fistula
- Bleeding, hematoma, or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent attendant problems (e.g., arrhythmia, tamponade, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Endoprosthesis: improper component placement; incomplete component deployment; component migration and/or separation; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture; perigraft flow; barb separation and corrosion
- Entry-Flow
- Fever and localized inflammation
- Genitourinary complications and subsequent attendant problems (e.g., ischemia, erosion, fistula, urinary incontinence, hematuria, infection)
- Hepatic failure
- Impotence
- Infection of the dissection, device or access site, including abscess formation, transient fever and pain
- Local or systemic neurologic complications and subsequent attendant problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis)
- Lymphatic complications and subsequent attendant problems (e.g., lymph fistula, lymphocele)
- Occlusion of device or native vessel
- Pulmonary/respiratory complications and subsequent attendant problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent attendant problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Vascular access site complications, including infection, pain, hematoma, pseudoaneurysm, arteriovenous fistula
- Vascular spasm or vascular trauma (e.g., ilio-femoral vessel dissection, bleeding, rupture, death)
- Wound complications and subsequent attendant problems (e.g., dehiscence, infection)

6 POTENTIAL RISKS AND BENEFITS

The device is an implantable endoprosthesis intended to reduce the risk of rupture. The hazards associated can be categorized as device-related (e.g., lack of sterility, toxicity, biodegredation of the device), deployment-related (e.g., failure to traverse the iliac arteries, misdeployment), performance-related (e.g., migration, stent fracture, graft infection, late endoleak), and disease-related (e.g., extension of the dissection, malperfusion, and aneurysm degeneration). The consequent risks to the patient depend on the incidence and effects of each hazard, which have been explored in a number of experimental and clinical insertions. These risks of endovascular repair must be weighed against the risks associated with the current alternative forms of thoracic aortic dissection management.

Implantation of the Zenith TX2 Dissection Endovascular Graft with Pro-Form is likely a less invasive procedure than open surgical repair. Therefore, potential clinical benefits to patients treated with the Zenith TX2 Dissection Endovascular Graft with Pro-Form may include a suitable dissection repair with less risk and fewer complications than those treated with open surgical repair. Zenith TX2 Dissection Endovascular Graft with Pro-Form patients may benefit from a reduced risk of serious treatment-related complications, shorter anesthesia times, shorter procedure times, reduced procedural blood loss and reduced need for blood products.

7 PATIENT SELECTION AND TREATMENT

(See **Section 4, WARNINGS AND PRECAUTIONS**)

7.1 Individualization of Treatment

Cook recommends that the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System component diameters be selected as described in Tables 1, 2 and 3. All lengths and diameters of the 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. This approach allows for greater intra-operative flexibility to achieve optimal procedural outcomes. The risks and benefits previously described in **Section 6, POTENTIAL RISKS AND BENEFITS** should be carefully considered for each patient before use of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System. Additional considerations for patient selection include but are not limited to:

- Patient's age and life expectancy.
- Co-morbidities (e.g., cardiac, pulmonary or renal insufficiency prior to surgery, morbid obesity).
- Patient's suitability for open surgical repair.
- Ability to tolerate general, regional, or local anesthesia.
- Ilio-femoral access vessel size and morphology (thrombus, calcification and/or tortuosity) should be compatible with vascular access techniques and accessories of the introduction profile of a 20 Fr to 22 Fr vascular introducer sheath, including:
  - Adequate iliac/femoral access compatible with the required introduction systems,
  - Radius of curvature greater than 35 mm along the length of aorta intended to be treated by Straight or Tapered Component,
- Non-dissected/aneurysmal aortic segment (fixation site) proximal to the dissection:
  - with a length of at least 20 mm
  - with a diameter measured outer wall to outer wall of no greater than 38 mm and no less than 20 mm, and
  - with localized angulation less than 45 degrees.

The final treatment decision is at the discretion of the physician and patient.

8 PATIENT COUNSELING INFORMATION

The physician and patient (and/or family members) should review the risks and benefits when discussing this endovascular device and procedure, including:

- Risks and differences between endovascular repair and open surgical repair.
- Potential advantages of traditional open surgical repair.
- Potential advantages of endovascular repair.
- The possibility that subsequent interventional or open surgical repair may be required after initial endovascular repair.

In addition to the risks and benefits of an endovascular repair, the physician should assess the patient's commitment to and compliance with post-operative follow-up as necessary to ensure continuing safe and effective results. Listed below are additional topics to discuss with the patient as to expectations after an endovascular repair:

- The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and the performance of their endovascular graft. Patients with specific clinical findings (e.g., endoleaks, persisting flow in false lumen or changes in the structure or position of the endovascular graft) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 12, IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP.**
- Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of dissections. At a minimum, annual imaging and adherence to routine post-operative follow-up requirements is required and should be considered a life-long commitment to the patient's health and well-being.
- The patient should be told that successful repair does not arrest the disease process. It is still possible to have associated degeneration of vessels.
- Physicians must advise every patient that it is important to seek prompt medical attention if he/she experiences signs of graft occlusion or rupture. Signs of graft occlusion include, but may not be limited to, pain in the hip(s) or leg(s) during walking or at rest, and discoloration or coolness of the leg(s). Rupture may be asymptomatic, but usually presents as pain, numbness, weakness in the legs, any back or chest pain, persistent cough, dizziness, fainting, rapid heartbeat, or sudden weakness.

The physician should complete the Patient Card and give it to the patient so that he/she can carry it with him/her at all times. The patient should refer to the card anytime he/she visits additional health practitioners, particularly for any additional diagnostic procedures (e.g., MRI).

9 HOW SUPPLIED

- The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System is supplied sterile using Ethylene Oxide and pre-loaded in peel-open packages.
- The device is intended for single use only. Do not re-sterilize the device.
- Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return to Cook Medical.
- Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

- The device is loaded into a 20 Fr or 22 Fr Flexor Introducer Sheath. Its surface is treated with a hydrophilic coating that, when hydrated, enhances trackability. To activate the hydrophilic coating, the surface must be wiped with a 4X4 gauze pad soaked in saline solution.
- Do not use after the "use by" (expiration) date printed on the label.
- Store in a dark, cool, dry place.

10 CLINICAL USE INFORMATION

10.1 Physician Training

CAUTION: Always have a qualified surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.

CAUTION: The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System should only be used by physicians and teams trained in vascular interventional techniques (endovascular and surgical) and in the use of this device. The recommended skill/knowledge requirements for physicians using the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System are outlined below:

Patient Selection:

- Knowledge of the natural history of thoracic dissections and co-morbidities associated with repair.
- Knowledge of radiographic image interpretation, patient selection, device selection, planning and sizing.

A multidisciplinary team that has combined procedural experience with:

- Femoral and brachial cutdown, arteriotomy, and repair
- Percutaneous access and closure techniques
- Non-selective and selective wire guide and catheter techniques
- Fluoroscopic and angiographic image interpretation
- Embolization
- Angioplasty
- Endovascular stent placement
- Snare techniques
- Appropriate use of radiographic contrast material
- Techniques to minimize radiation exposure
- Expertise in necessary patient follow-up modalities

10.2 Inspection Prior to Use

Inspect the device and packaging to verify that no damage has occurred as a result of shipping. Do not use this device if damage has occurred or if the sterilization barrier has been damaged or broken. If damage has occurred, do not use the product and return to Cook Medical.

Prior to use, verify correct devices (quantity and size) have been supplied for the patient by matching the device to the order prescribed by the physician for that particular patient.

10.3 Materials Required

(Not included with the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System). For information on the use of these products, refer to the individual product's instructions for use.

- Fluoroscope with digital angiography capabilities (C-arm or fixed unit)
- Contrast media
- Power injector
- Zenith Dissection Endovascular Stent
- Syringe
- Heparinized saline solution
- Sterile 4X4 gauze pads
- 0.035 inch (0.89 mm) extra stiff wire guide, 260/300 cm; for example:
  - Cook Amplatz Ultra Stiff Wire Guides (AUS)
  - Cook Lunderquist™ DC Extra Stiff Wire Guides (LESDC)
- 0.035 inch (0.89 mm) standard wire guide; for example:
  - Cook .035 inch Wire Guides
  - Cook .035 inch Bentson Wire Guide
  - Cook Nimble® Wire Guides
- Molding Balloons; for example:
  - Cook Coda® Balloon Catheter
- Introducer sets; for example:
  - Cook Check-Flo® Introducer Sets
- Sizing catheter; for example:
  - Cook Aurous® Centimeter Sizing Catheters
- Angiographic radiopaque marker catheters; for example:
  - Cook Beacon® Tip Angiographic Catheters
  - Cook Beacon® Tip Royal Flush® Catheters
- Entry needles; for example:
  - Cook Single Wall Entry Needles

10.4 Device Diameter Sizing Guidelines

The choice of diameter should be determined from the outer wall to outer wall vessel diameter and **not** the lumen diameter. Undersizing or oversizing may result in incomplete sealing or compromised flow, see **Table 1**.

Table 1 Straight Component and Tapered Component Graft Diameter Sizing Guide*

Intended Aortic Vessel Diameter[1,2] (mm)	Graft Diameter[3] (mm)	Overall Length of Straight Component (mm)	Overall Length of 4 mm Tapered Component (mm)	Overall Length of 8 mm Tapered Component (mm)	Introducer Sheath (Fr)
20	22	79/117			20
21	24	79/117			20
22/23	26	79/136			20
24	28	82/142/202			20
25	30	82/142/202			20
26	30	82/142/202			20
27	30	82/142/202			20
28	32	82/142/202	162/202	158/196	20
29	32	82/142/202	162/202	158/196	20
30	34	79/154/204	159/199	156/194	20
31	36	79/154/204	159/199	159/199	22
32	36	79/154/204	159/199	159/199	22
33	38	79/154/204	154/204	159/199	22
34	38	79/154/204	154/204	159/199	22
35	40	83/164/218	160/210	165/205	22
36	40	83/164/218	160/210	165/205	22
37	42	83/164/218	160/210	160/210	22
38	42	83/164/218	160/210	160/210	22

*All dimensions are nominal.

[1]Maximum diameter along the fixation site, measured outer wall to outer wall.

[2]Round measured aortic diameter to nearest mm.

[3]Additional considerations may affect choice of diameter.

11 DIRECTIONS FOR USE

The following instructions embody a basic guideline for device placement. Variations in the following procedures may be necessary. These instructions are intended to help guide the physician and do not take the place of physician judgment.

General Use Information

Standard techniques for placement of arterial access sheaths, guiding catheters, angiographic catheters and wire guides should be employed during use of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System. The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus introduction system is compatible with .035 inch diameter wire guides.

Endovascular stent grafting is a surgical procedure, and blood loss from various causes may occur, infrequently requiring intervention (including transfusion) to prevent adverse outcomes. It is important to monitor blood loss from the hemostatic valve throughout the prodecure, but is specifically relevant during and after manipulation of the gray positioner. After the gray positioner has been removed, if blood loss is excessive, consider placing an uninflated molding balloon or an introduction system dilator within the valve, restricting flow.

Pre-Implant Determinants

Verify from pre-implant planning that the correct device has been selected. Determinants include:

1. Femoral artery selection for introduction of the introduction system(s).
2. Angulation of aorta, aneurysm and iliac arteries.
3. Quality of the proximal and distal fixation sites.
4. Diameters of proximal and distal fixation sites and distal iliac arteries.

Patient Preparation

1. Refer to institutional protocols relating to anesthesia, anticoagulation, and monitoring of vital signs.
2. Position patient on imaging table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations.
3. Expose femoral artery using standard surgical technique.
4. Establish adequate proximal and distal vascular control of femoral artery.

11.1 The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System Preparation/Flush

1. Remove yellow-hubbed shipping stylet (from the inner cannula) and cannula protector tube (at the handle). Remove Peel-Away sheath from back of valve assembly (**Fig. 5**).
2. Elevate distal tip of system and flush through the hemostatic valve until fluid emerges from the tip of the introduction sheath (**Fig. 6**). Continue to inject a full 60 cc of flushing solution through the device. Discontinue injection and close stopcock on connecting tube.

   NOTE: Graft flushing solution of heparinized saline is often used.
3. Attach syringe with heparinized saline to the hub on the inner cannula. Flush until fluid exits the distal sideports and dilator tip (**Fig. 7**).
4. Soak 4X4 gauze pads in saline solution and use to wipe the Flexor Introducer Sheath to activate the hydrophilic coating. Hydrate both sheath and dilator liberally.

11.1.1 Placement of The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System

1. Puncture the selected artery using standard technique with an 18 gauge access needle. Upon vessel entry, insert:
   - Wire guide – standard .035 inch, 260/300 cm, 15 mm J tip or Bentson wire guide
   - Appropriate size sheath (e.g., 5.0 French)

- Pigtail flush catheter (often radiopaque-banded sizing catheters; i.e., Cook Centimeter Sizing CSC-20 catheter)

2. Perform angiography at the appropriate level. If using radiopaque markers, adjust position as necessary and repeat angiography.
3. Ensure graft system has been flushed and primed with heparinized saline (appropriate flush solution), and all air has been removed.
4. Give systemic heparin. Flush all catheters and wet all wire guides with a strong heparin solution. This should be repeated following each exchange.
5. Replace the standard wire guide with a stiff .035 inch, 260/300 cm LESDC wire guide and advance through the catheter and up to the aortic arch.
6. Remove pigtail flush catheter and sheath.

   NOTE: At this stage, the second femoral artery can be accessed for angiographic catheter placement. Alternatively, a brachial approach may be considered.
7. Introduce the freshly hydrated introduction system over the wire guide and advance until the desired graft position is reached.

   CAUTION: To avoid twisting the endovascular graft, never rotate the introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the vessels.

   NOTE: The dilator tip will soften at body temperature.

   NOTE: To facilitate introduction of the wire guide into the introduction system, it may be necessary to slightly straighten the introduction system dilator tip.
8. Verify wire guide position in the aortic arch. Ensure correct graft position.
9. Ensure that the Captor Hemostatic Valve on the Flexor Introducer Sheath is turned to the open position (**Fig. 8**).
10. Stabilize the gray positioner (introduction system shaft) and withdraw the sheath until the graft is fully expanded and the valve assembly docks with the control handle.

    CAUTION: As the sheath is withdrawn, anatomy and graft position may change. Constantly monitor graft position and perform angiography to check position as necessary.

    NOTE: If extreme difficulty is encountered when attempting to withdraw the sheath, place the device in a less tortuous position which enables the sheath to be retracted. Very carefully withdraw the sheath until it just begins to retract, and stop instantly. Move back to original position and continue deployment.
11. Verify graft position and adjust it forward, if necessary. Recheck graft position with angiography.

    NOTE: If an angiographic catheter is placed parallel to the stent graft, use this to perform position angiography.
12. Loosen the safety lock from the green trigger-wire release mechanism. Withdraw the trigger-wire in a continuous movement until the proximal end of the graft opens (**Fig. 9**). Do not rotate the green trigger-wire knob. Withdraw the trigger-wire completely to release the distal attachment to the introducer.

    NOTE: Check to make sure that all trigger-wires are removed prior to withdrawal of the introduction system.
13. Remove the introduction system, leaving the wire guide in the graft.

    NOTE: Leave the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System in place if intending to use a dissection stent.

11.1.2 Molding Balloon Insertion - Optional

1. Prepare molding balloon as follows and/or per the manufacturer's instructions.
   - Flush wire lumen with heparinized saline.
   - Remove all air from balloon.
2. In preparation for the insertion of the molding balloon, open the Captor Hemostatic Valve by turning it counter-clockwise.
3. Advance the molding balloon over the wire guide and through the hemostatic valve of the main body introduction system to the level of the proximal fixation site. Maintain proper sheath positioning.
4. Tighten the Captor Hemostatic Valve around the molding balloon with gentle pressure by turning it clockwise.
5. Expand the molding balloon with diluted contrast media (as directed by the manufacturer) in the area of the proximal covered stent, starting proximally and working in the distal direction.

   CAUTION: Do not inflate balloon in aorta outside of graft. Use caution during molding within a dissection.

   CAUTION: Confirm complete deflation of balloon prior to repositioning.
6. Open the Captor Hemostatic Valve, remove the molding balloon and replace it with an angiographic catheter to perform completion angiograms.
7. Tighten the Captor Hemostatic Valve around the angiographic catheter with gentle pressure by turning it clockwise.
8. Remove or replace all stiff wire guides to allow aorta to resume its natural position.

Final Angiogram

1. Position angiographic catheter just above the level of the endovascular graft. Perform angiography to verify correct positioning. Verify patency of arch vessels and celiac plexus.
2. Confirm that there are no endoleaks or kinks, and verify position of proximal and distal gold radiopaque markers. Remove the sheaths, wires and catheters.

   NOTE: If endoleaks or other problems are observed, refer to **Section 11.2, Additional Devices.**
3. Repair vessels and close in standard surgical fashion.

11.2 Additional Devices

Inaccuracies in device size selection or placement, changes or anomalies in patient anatomy, or procedural complications can require placement of additional endovascular grafts. Regardless of the device placed, the basic procedure(s) will be similar to the maneuvers required and described previously in this document. It is vital to maintain wire guide access.

12 IMAGING GUIDELINES AND POST-OPERATIVE FOLLOW-UP

12.1 General

The long-term performance of endovascular grafts has not yet been established. All patients should be advised that endovascular treatment requires life-long, regular follow-up to assess their health and performance of their endovascular graft and/or stent. Patients with specific clinical findings (e.g., endoleaks, persisting flow in false lumen or changes in the structure or position of the endovascular graft) should receive additional follow-up. Patients should be counseled on the importance of adhering to the follow-up schedule, both during the first year and at yearly intervals thereafter. Patients should be told that regular and consistent follow-up is a critical part of ensuring the ongoing safety and effectiveness of endovascular treatment of dissections.

Physicians should evaluate patients on an individual basis and prescribe their follow-up relative to the needs and circumstances of each individual patient. The recommended imaging schedule is presented in **Table 2**. This schedule continues to be the minimum requirement for patient follow-up and should be maintained even in the absence of clinical symptoms (e.g., pain, numbness, weakness). Patients with specific clinical findings (e.g., endoleaks, enlarging aneurysms, or changes in the structure or position of the stent graft or stent) should receive follow-up at more frequent intervals.

Annual imaging follow-up should include thoracic device radiographs and both contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, thoracic device radiographs and non-contrast CT may be used.

- The combination of contrast and non-contrast CT imaging provides information on endoleak, patency, tortuosity, progressive disease, fixation length, and other morphological changes.
- The thoracic device radiographs provide information on device integrity (separation between components and stent fracture).

Table 2 lists the minimum requirements for imaging follow-up for patients with the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System. Patients requiring enhanced follow-up should have interim evaluations.

Table 2 Recommended Imaging Schedule for Endograft Patients

	Angiogram	CT (contrast and non-contrast)	Thoracic Device Radiographs
Pre-procedure		X[1]	
Procedural	X		
Pre-discharge (within 7 days)		X[2]	X
1 month		X[2]	X
6 month		X[2]	X
12 month (annually thereafter)		X[2]	X

[1] Imaging should be performed within 6 months before the procedure.

[2] If Type I or III endoleak, prompt intervention and additional follow-up post-intervention recommended, See **Section 12.5, Additional Surveillance and Treatment.**

12.2 Contrast and Non-Contrast CT Recommendations

- Film sets should include all sequential images at lowest possible slice thickness (≤ 3 mm). Do NOT perform large slice thickness (> 3 mm) and/or omit consecutive CT images/film sets, as it prevents precise anatomical and device comparisons over time.
- All images should include a scale for each film/image. Images should be arranged no smaller than 20:1 images on 14" x 17" sheets if film is used.
- Both non-contrast and contrast runs are required, with matching or corresponding table positions.
- Pre-contrast and contrast run slice thickness and interval must match.
- DO NOT change patient orientation or re-landmark patient between non-contrast and contrast runs.

Non-contrast and contrast enhanced baseline and follow-up imaging are important for optimal patient surveillance. It is important to follow acceptable imaging protocols during the CT exam. **Table 3** lists examples of acceptable imaging protocols.

Table 3 Acceptable Imaging Protocols

	Non-contrast	Contrast
IV contrast	No	Yes
Acceptable machines	Spiral capable of > 40 seconds	Spiral capable of > 40 seconds
Injection volume	n/a	150 cc
Injection rate	n/a	> 2.5 cc/sec
Injection mode	n/a	Power
Bolus timing	n/a	Test bolus: Smart Prep, C.A.R.E. or equivalent
Coverage - start	Neck	Subclavian aorta
Coverage - finish	Diaphragm	Profunda femoris origin
Collimation	< 3 mm	< 3 mm
Reconstruction	2.5 mm throughout - soft algorithm	2.5 mm throughout - soft algorithm
Axial DFOV	32 cm	32 cm
Post-injection runs	None	None

12.3 Thoracic Device Radiographs

The following views are required:

- Four films: supine-frontal (AP), cross-table lateral, 30° RPO, and 30° LPO.
- Record the table-to-film distance and use the same distance at each subsequent examination.
- Ensure entire device is captured on each single image format lengthwise.
- The middle photocell, thoracic spine technique, or manual technique should be used for all views to ensure adequete penetration of the medistinum.

Ensure entire device is captured on each single image format lengthwise. Middle photo cell should be used to fully penetrate the mediastinum and allow visualization of the device.

If there is any concern about the device integrity (e.g., kinking, stent breaks, relative component migration), it is recommended to use magnified views. The attending physician should evaluate films for device integrity (entire device length, including components) using 2-4X magnification visual aid.

12.4 MRI Information

Non-clinical testing has demonstrated that the Zenith TAA Endovascular Graft is MR Conditional according to ASTM F2503. A patient with this endovascular graft may be safely scanned after placement under the following conditions.

- Static magnetic field of 1.5 and 3.0 Tesla.
- Maximum spatial magnetic gradient field of 720 Gauss/cm
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode) for 15 minutes of scanning or less (i.e., per scanning sequence)

Static Magnetic Field

The static magnetic field for comparison to the above limits is the static magnetic field that is pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

MRI-Related Heating

1.5 Tesla Temperature Rise

In non-clinical testing, the Zenith TX2 TAA Endovascular Graft produced a temperature rise of 1.2°C (scaled to an SAR of 2.0 W/kg) during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 1.5 Tesla System (Siemens Magnetom, Software Numaris/4).

3.0 Tesla Temperature Rise

In non-clinical testing, the Zenith TX2 TAA Endovascular Graft produced a temperature rise of less than or equal to 1.3°C (scaled to an SAR of 2.0 W/kg) during 15 minutes of MR imaging (i.e., for one scanning sequence) performed in a MR 3.0 Tesla System (General Electric Excite, HDx, Software G3.0-052B).

Image Artifact

The image artifact extends throughout the anatomical region containing the device, obscuring the view of immediately adjacent anatomical structures within approximately 20 cm of the device, as well as the entire device and its lumen, when scanned in nonclinical testing using the sequence: Fast spin echo, in a MR 3.0 Tesla System (General Electric Excite, HDx, Software G3.0-052B), with body radiofrequency coil.

For all scanners, the image artifact dissipates as the distance from the device to the area of interest increases. MR scans of the head and neck and lower extremities may be obtained without image artifact. Image artifact may be present in scans of the abdominal region and upper extremities, depending on distance from the device to the area of interest.

For US Patients Only

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail:	MedicAlert Foundation International 2323 Colorado Avenue Turlock, CA 95382
Phone:	888-633-4298 (toll free) 209-668-3333 from outside the US
Fax:	209-669-2450
Web:	www.medicalert.org

12.5 Additional Surveillance and Treatment

Additional surveillance and possible treatment is recommended for:

- Migration
- Inadequate seal length

Consideration for reintervention or conversion to open repair should include the attending physician's assessment of an individual patient's co-morbidities, life expectancy, and the patient's personal choices. Patients should be counseled that subsequent reinterventions, including catheter-based and open surgical conversion, are possible following endograft placement.

13 REFERENCES

These Instructions for Use are based on experience from physicians and their published literature. Refer to your local Cook Technical Representative for information on available literature.

Manufacturer
WILLIAM COOK EUROPE ApS
Sandet 6, DK-4632
Bjaeverskov, DENMARK

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