COOK MEDICAL

Zenith® Dissection Endovascular System

Zenith® TX2® Dissection Endovascular Graft with Pro-Form®

and

Zenith® Dissection Endovascular Stent

Instructions for Use

Patient I.D. Card Included

I-DISSECT-SYSTEM-441-01EN

441-01EN

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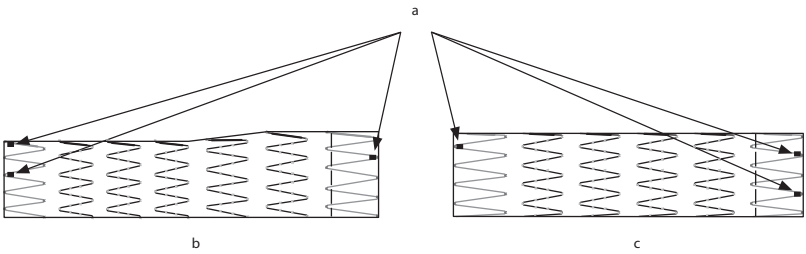

a. Radiopaque markers
b. Tapered component
c. Straight component

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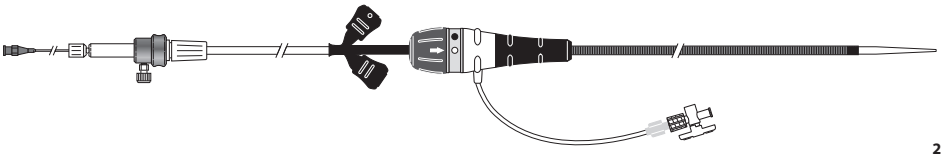

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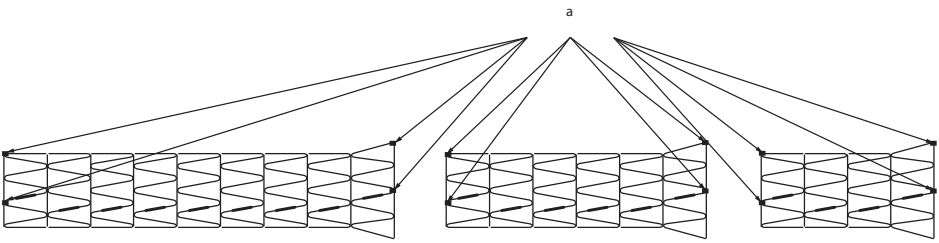

a. Radiopaque markers

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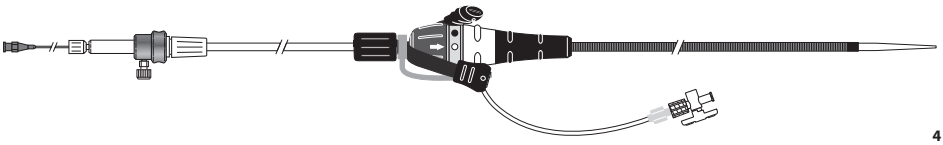

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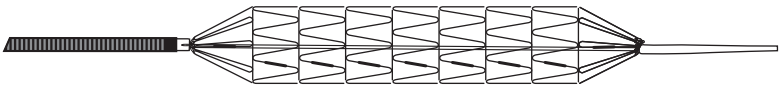

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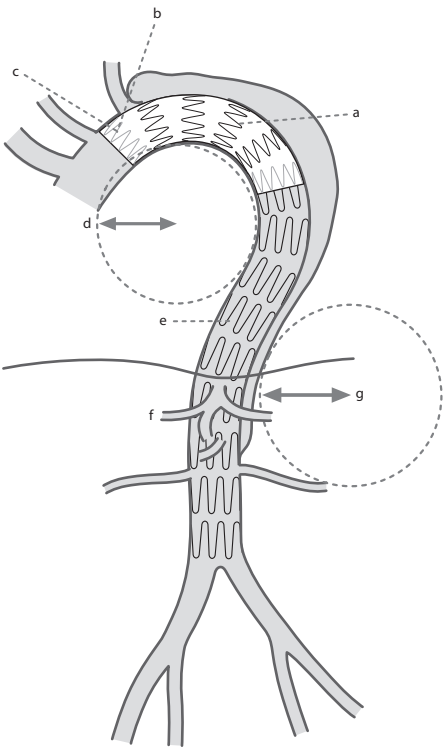

a. Zenith TX2 Dissection Endovascular Graft with Pro-Form Straight Component or Tapered Component
b. Proximal neck diameter 20-38 mm
c. Proximal neck length > 20 mm
d. Aortic radius > 35 mm
e. Zenith Dissection Endovascular Stent
f. Distal aortic diameter 20-38 mm
g. Aortic radius > 35 mm (endovascular stent component)

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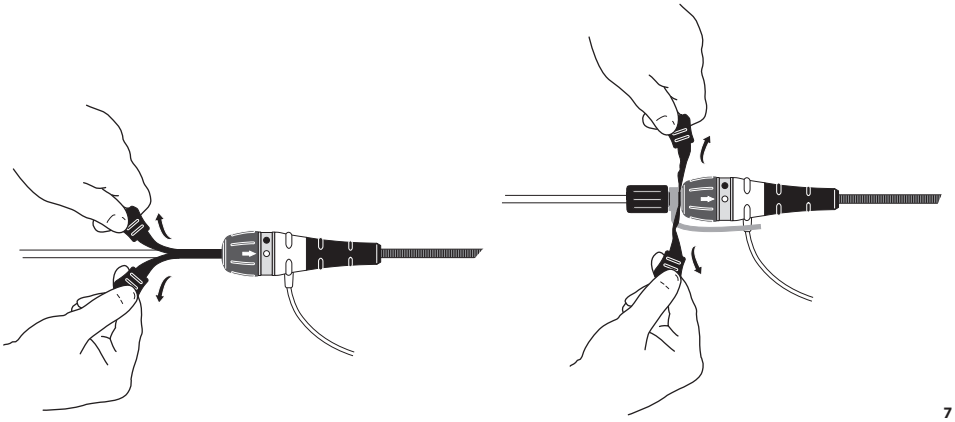

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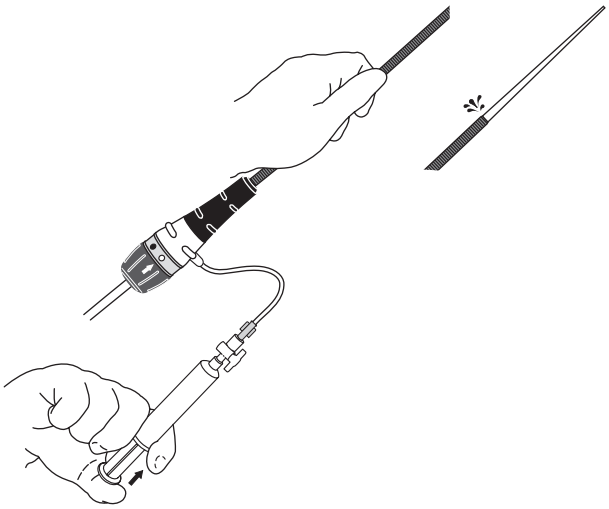

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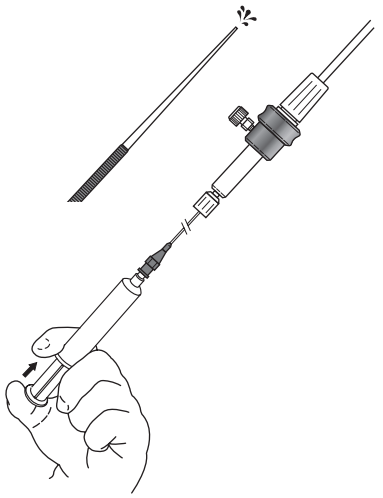

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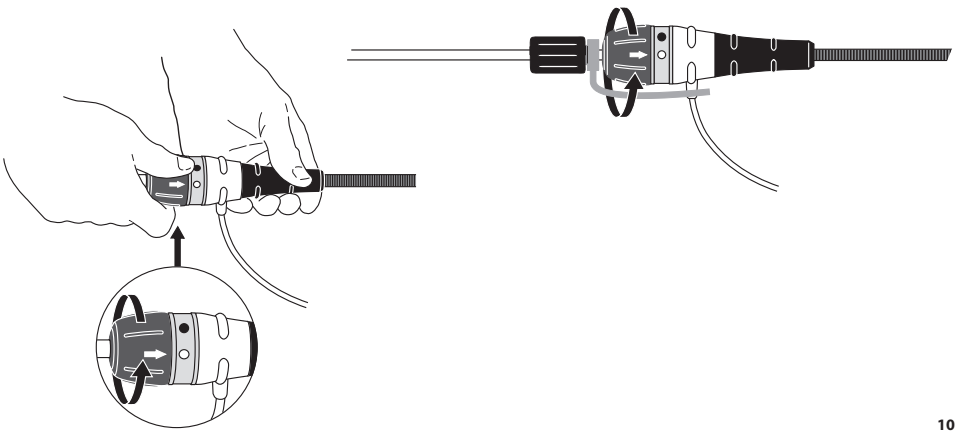

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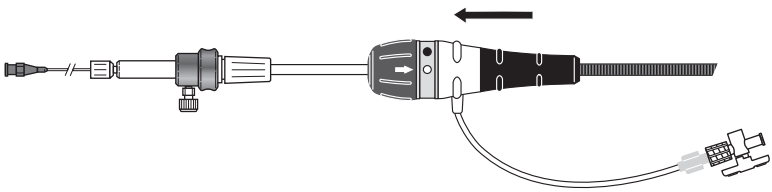

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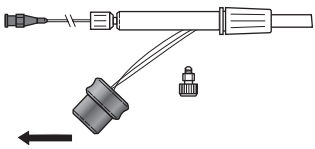

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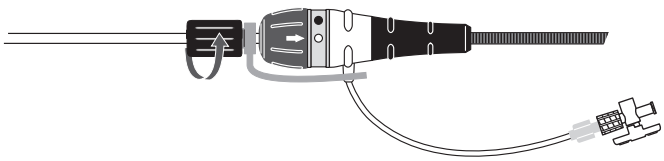

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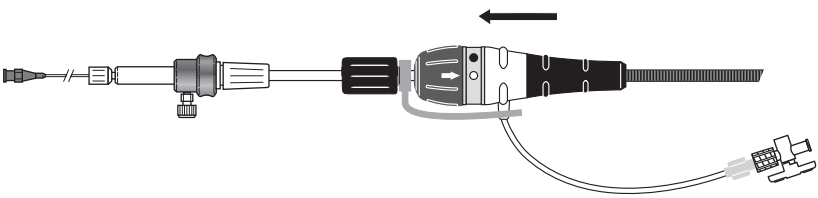

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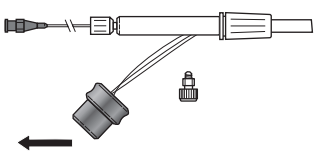

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ZENITH® DISSECTION ENDOVASCULAR SYSTEM (ZENITH® TX2® DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM® AND ZENITH® DISSECTION ENDOVASCULAR STENT)

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

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

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

1 DEVICE DESCRIPTION

1.1 Zenith Dissection Endovascular System

The Zenith Dissection Endovascular System consists of a stent-graft component and a bare stent component. The stent-graft component is the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Z-Trak Plus Introduction System. The bare stent component is the Zenith Dissection Endovascular Stent with the Z-Trak Plus Introduction System.

1.2 Zenith TX2 Dissection Endovascular Graft with Pro-Form

The Zenith TX2 Dissection Endovascular Graft with Pro-Form is a one-piece tubular endovascular graft that is intended to seal entry tears and to exclude aneurysms associated with chronic dissections. It is constructed of full-thickness woven polyester fabric sewn to self-expanding stainless steel Cook-Z stents with braided polyester and monofilament polypropylene suture. (**Fig. 1**) The graft is available in a straight or tapered configuration, both of which are 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 without the use of barbs. The proximal and distal ends of the graft have an internal sealing stent.

To facilitate fluoroscopic visualization of the stent graft, four radiopaque markers are positioned at each end of the graft. 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. The graft is available in diameters ranging from 22 mm to 42 mm, including non-tapered and tapered (4 mm and 8 mm tapered) configurations. There are multiple lengths available for each graft diameter, ranging from 79 to 218 mm.

1.3 Thoracic Z-Trak Plus Introduction System

The Zenith TX2 Dissection Endovascular Graft with Pro-Form is shipped preloaded onto the Z-Trak Plus Introduction System, which is 20 French (7.7 mm OD) or 22 French (8.5 mm OD). These systems use a single trigger-wire release mechanism to secure the endovascular graft onto the introduction system until released by the physician. (**Fig. 2**) All introduction systems are compatible with a .035 inch wire guide and use the Captor® Hemostatic Valve as well as Flexor® introducer sheath. There is hydrophilic coating on the introduction system tip and sheath.

1.4 The Zenith Dissection Endovascular Stent

The Zenith Dissection Endovascular Stent is a one-piece cylindrical device, with a slight flare in the stent at its proximal end, constructed from self-expanding nitinol z-stent segments sewn together with polyester suture. (**Fig. 3**) The Zenith Dissection Endovascular Stent is used as a distal component together with the Zenith TX2 Dissection Endovascular Graft with Pro- Form.

No graft material is used in this component to avoid coverage of spinal and visceral branch vessels. The Zenith Dissection Endovascular Stent is available in 2 diameters (36 mm and 46 mm), which come in multiple lengths. The 36mm diameter Dissection Stent is available in 80 mm, 120 mm, and 180 mm lengths, and the 46 mm Dissection Stent is available in 80 mm, 120 mm, and 185 mm lengths. To facilitate fluoroscopic visualization of the stent, four radiopaque markers are positioned on each end of the component. These markers are placed in a circumferential orientation at the most proximal end and most distal end of the Stent.

1.5 Thoracic Z-Trak Plus Introduction System

The Zenith Dissection Endovascular Stent is shipped preloaded onto a 16 French (6 mm OD) Z-Trak Plus Introduction System. (**Fig. 4**) The introduction system uses a single trigger-wire release mechanism to secure the endovascular stent onto the introduction system until released by the physician. (**Fig. 5**) The introduction system is compatible with a .035 inch wire guide and uses the Captor Hemostatic Valve as well as the Flexor introducer sheath

In addition, there is an anti-torque brace at the user interface (adjacent to the valve) to maintain rotational alignment of the sheath relative to the central carrier to which the stent component is attached. There is hydrophilic coating on the introduction system tip and sheath.

2 INTENDED USE

The Zenith Dissection Endovascular System (Zenith TX2 Dissection Endovascular Graft with Pro-Form and Zenith Dissection Endovascular Stent) is indicated for the endovascular treatment of patients with Type B aortic dissection. The Zenith TX2 Dissection Endovascular Graft with Pro-Form is intended to seal the entry tears and to exclude aneurysms associated with chronic dissections. The Zenith Dissection Endovascular Stent is intended to be used as a distal component to provide support to delaminated segments of non-aneurysmal aorta with dissection distal to a Zenith TX2 Dissection Endovascular Graft with Pro-Form. The system is indicated for use in patients having vascular anatomy suitable for endovascular repair, (**Fig. 6**) including:

- Adequate iliac/femoral access compatible with the required introduction systems
- For the Zenith TX2 Dissection Endovascular Graft with Pro-Form:
  - Non-dissected/aneurysmal aortic segments (fixation sites) distal to the left common carotid artery and proximal to the entry tear with a length of at least 20 mm,
  - Non-dissected/aneurysmal aortic segments (fixation sites) distal to the left common carotid artery and proximal to the entry tear with a diameter (measured outer-wall-to-outer-wall) of no greater than 38 mm and no less than 20 mm, and
- For the Zenith Dissection Endovascular Stent:
  - Diameter at non-aneurysmal intended implant site (measured outer-wall-to-outer-wall) of no greater than 38 mm (true lumen) and no less than 20 mm (total aortic diameter).

3 CONTRAINDICATIONS

The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent are 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/stent 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.
- DO NOT place the device in a dissected proximal landing zone. Placement of the device has resulted in proximal post-treatment dissection events (retrograde progression of pre-existing or new Type A dissection) when the dissection extends proximal to the LSA or the proximal landing zone is dissected.
- Always have a qualified surgery team available during implantation or reintervention procedures in the event that conversion to open surgical repair is necessary.
- The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent 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**.
- Additional/adjunctive endovascular and/or surgical interventions may be required to treat Type B dissections, including conversion to standard open surgical repair following initial endovascular repair should patients experience continued flow in the false lumen of the dissection which may lead to rupture. Further intervention should be considered for patients exhibiting compromise of organ vessel flow, or inadequate seal/fixation length proximal to the dissection.

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 French (7.7 mm OD) or 22 French (8.5 mm OD) vascular introducer sheath as is used for the Zenith Dissection Endovascular Graft, compared to 16 French (6.0 mm OD) for the Zenith Dissection Endovascular Stent. 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.
- **The Zenith TX2 Dissection Endovascular Graft with Pro-Form**: Key anatomic elements that may affect successful exclusion of the dissection entry tear include severe angulation (radius of curvature < 35 mm and localized angulation > 45 degrees); short proximal fixation site (< 20 mm of non-dissected aorta); necks > 38 mm or < 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 and or loss of seal.
- **The Zenith Dissection Endovascular Stent**: Key anatomic elements that may affect successful treatment of dissection include severe angulation (radius of curvature < 35 mm and localized angulation > 45 degrees) and aortic true lumen diameters > 38 mm or total aortic (true lumen plus false lumen) diameter < 20 mm.
- The safety and effectiveness of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent have not been evaluated in the following patient populations:
  - chronic Type B dissections
  - acute, uncomplicated Type B dissection
  - allergy to stainless steel, nitinol, polyester, polypropylene, or gold
  - bowel necrosis
  - ASA class V
  - diagnosed or suspected genetic connective tissue disease (e.g., Marfans or Ehlers-Danlos Syndrome)
  - females who are pregnant, breastfeeding, or planning to become pregnant within 60 months
  - patients less than 18 years of age
  - systemic infection (e.g., sepsis)
  - previous placement of thoracic endovascular graft
  - prior open repair involving descending thoracic aorta (including suprarenal aorta and/or arch)
  - surgical or endovascular AAA repair within 30 days before or after dissection repair
  - bleeding diathesis, uncorrectable coagulopathy, or refuses blood transfusion
  - hemorrhagic stroke within 30 days (or 14 days for embolic stroke)
  - untreatable reaction to contrast, which cannot be adequately premedicated
  - inability to preserve the native left common carotid artery and celiac artery origins
  - if occlusion of the left subclavian artery ostium is required to obtain adequate neck length for fixation and sealing, transposition or bypass of the left subclavian artery may be warranted.
- The long-term performance of the endovascular graft and stent 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 and/or stent. Patients with specific clinical findings (e.g., persisting flow in the false lumen, enlarging aneurysms, or changes in the structure or position of the endovascular graft and or stent) should receive enhanced follow-up. Specific follow-up guidelines are described in **Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP**.
- The graft and stent are not recommended in patients unable to undergo, or who will not be compliant with, the necessary preoperative and postoperative imaging and implantation studies described in **Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP**.
- The graft and stent are 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.
- 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

The following apply to both the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent:

- Strict adherence to the sizing guidelines provided in Sections 10.4 and 10.5 is strongly recommended in order to mitigate the risk for events that could result from selecting inappropriate device sizes. Undersizing has resulted in migration, endoleak/entry-flow and false lumen growth.
- **Table 1** incorporates appropriate graft oversizing. Sizing outside of the recommendations provided in **Table 1**, including that which could result from a difference in location of graft deployment relative to the location used for graft sizing, has resulted in false lumen expansion, endoleak/entry-flow, and migration. Fracture, device infolding, thrombosis, or compression may also result.
- 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 sterile 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 graft/stent.
- Always use fluoroscopy for guidance, delivery, and observation of the graft/stent within the vasculature.
- The use of the graft/stent requires administration of intravascular contrast. Patients with pre-existing renal insufficiency may have an increased risk of renal failure postoperatively. Care should be taken to limit the amount of contrast media used during the procedure.
- To avoid twisting the endovascular graft and/or stent, never rotate the introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the aorta.
- As the sheath is withdrawn, anatomy and graft/stent position may change. Constantly monitor graft position and perform angiography to check position as necessary.
- Incorrect deployment or migration of t he graft and/or stent 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.
- 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 and/or stent or disturbing graft/stent positioning after placement in the event reinstrumentation (secondary intervention) of the graft/stent is necessary.
- Do not attempt to re-sheath the graft or stent after partial or complete deployment.
- To avoid entangling any catheters left in situ, rotate the introduction system during withdrawal.
- Any sources for false lumen perfusion left untreated during the implantation procedure should be carefully followed after implantation.

The following apply to the Zenith TX2 Dissection Endovascular Graft with Pro-Form:

- Landing the proximal end of the device in dissected tissue could increase the risk of damage to the septum and could lead to new septal tears, aortic rupture, retrograde dissection, or other complications.
- Inaccurate placement, incomplete sealing, inadequate oversizing, or lack of complete circumferential wall contact along the entire length 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.
- Consider the potential effects of hypovolemia on aortic diameters when selecting the device size.
- If placing multiple grafts, ensure a minimum of 2 stent overlap.
- 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.
- 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.
- Molding balloon use is optional, and if used, it should not be inflated in the aorta outside of the graft. Additionally, complete deflation of the balloon should be confirmed prior to repositioning. For added hemostasis, the Captor Hemostatic Valve can be loosened or tightened to accommodate the insertion and subsequent withdrawal of a molding balloon.

The following apply to the Zenith Dissection Endovascular Stent:

- Use of the Zenith Dissection Endovascular Stent in an aneurysmal segment of a chronic dissection is not recommended.
- As the sheath is withdrawn, do not advance the introduction system. Doing so can cause the stent to become inverted.
- Overlapping of bare stent(s) or overlap with the Zenith TX2 Dissection Endovascular Graft with Pro-Form Straight Component or Tapered Component is left to the discretion of the implanting physician. Factors affecting whether or not to overlap, such as locations of reentries or expanded false lumen, should be judged by individual patient anatomy. When overlapping the bare stent within the stent graft component, no more than one-half of a partially overlapped bare stent body should be non-overlapped, so as to prevent flaring of the bare stent.
- If the distal end of the stent will be deployed in a funnel-shaped or angulated section of the aorta, or if the distal end of the stent appears conical in shape upon deployment, it is recommended to extend the treated segment distally with an additional stent, or choose a longer stent so it ends in a straight part of the aorta. Similarly, if the distal end of the stent will be deployed at the level of the diaphragm, or in a segment adjacent to the origin of the Celiac Trunk, Superior Mesenteric Artery and/or Renal Arteries, it is also recommended to extend the treated segment distally with an additional stent or choose a longer stent.
- Use of a molding balloon inside a section of aorta treated with the Zenith Dissection Endovascular Stent is not recommended.
- Avoid twisting or rotating the gray positioner against the introducer sheath assembly. Doing so may cause the loaded stent to become entangled and to deploy in a twisted state, or not to release from the introduction system.
- Exercise caution when manipulating a wire guide through an in-situ Zenith Dissection Endovascular Stent; the wire guide may become entangled with the stent.

4.4 MRI INFORMATION

Nonclinical testing has demonstrated that the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the nitinol Zenith Dissection Endovascular Stent is MR Conditional according to ASTM F2503. A patient with these devices can be scanned safely in a 1.5 T or 3.0 T MR system using the specific testing parameters described in **Section 12.4, MRI Information**.

5 POTENTIAL ADVERSE EVENTS

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

- Amputation
- Anesthetic complications and subsequent problems (e.g., aspiration)
- Aortic enlargement
- Aortic rupture and death
- Aortic damage, including perforation, dissection, bleeding, and rupture
- Arterial or venous thrombosis and/or pseudoaneurysm
- Bleeding, hematoma, or coagulopathy
- Bowel complications (e.g., ileus, transient ischemia, infarction, necrosis)
- Cardiac complications and subsequent problems (e.g., arrhythmia, tamponade, myocardial infarction, congestive heart failure, hypotension, hypertension)
- Claudication (e.g., buttock, lower limb)
- Death
- Dissection extension (i.e., either proximal or distal extension)
- Edema
- Embolization (micro and macro) with transient or permanent ischemia or infarction
- Endoleak
- Endoprosthesis: improper component placement; incomplete component deployment; poor conformability of the graft to the vessel wall; component migration and/or separation; suture break; occlusion; infection; stent fracture; graft material wear; dilatation; erosion; puncture and perigraft flow
- Fever and localized inflammation
- Fistula (e.g., aortobronchial, aortoesophageal, arteriovenous)
- Genitourinary complications and subsequent 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 problems (e.g., stroke, transient ischemic attack, paraplegia, paraparesis, spinal cord shock, paralysis)
- Lymphatic complications and subsequent problems (e.g., lymph fistula, lymphocele)
- Occlusion of device or native vessel
- Persisting flow in the false lumen
- Pulmonary/respiratory complications and subsequent problems (e.g., pneumonia, respiratory failure, prolonged intubation)
- Renal complications and subsequent problems (e.g., artery occlusion, contrast toxicity, insufficiency, failure)
- Surgical conversion to open repair
- Unintentional dissection septum rupture
- 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 problems (e.g., dehiscence, infection)

Device Related Adverse Event Reporting

Any adverse event (clinical incident) involving the Zenith Dissection Endovascular System (graft or stent) should be reported to Cook immediately. To report an incident, call the Customer Relations Department at 800.457.4500 (24 hour) or 812.339.2235.

6 SUMMARY OF CLINICAL DATA

A summary of clinical data can be found on www.cookmedical.com.

7 PATIENT SELECTION AND TREATMENT

(See **Section 4.2, Patient Selection, Treatment and Follow-Up**)

7.1 Individualization of Treatment

The Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent

Cook recommends that the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent component diameters be selected as described in **Tables 1** and **2**. All lengths and diameters of the devices necessary to complete the procedure should be available to the physician, especially when preoperative case planning measurements (treatment diameters/lengths) are not certain. This approach allows for greater intraoperative flexibility to achieve optimal procedural outcomes. When treating a chronic dissection, do not plan to place the Zenith Dissection Endovascular Stent in an aneurysmal segment.

The risks and benefits should be carefully considered for each patient before use of the graft and/or stent. 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 introduction system with profile of 20 French (7.7 mm OD) to 22 French (8.5 mm OD), as is used for the Zenith Dissection Endovascular Graft, compared to 16 French (6.0 mm OD) for the Zenith Dissection Endovascular Stent.
- For the Zenith Dissection Endovascular Graft with Pro-Form, a non-dissected/aneurysmal aortic segment (fixation site) proximal to the dissection measured at any circumferential part of the aorta using a 3D reconstruction centerline:
  - 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
  - Radius of curvature greater than 35 mm and localized angulation less than 45 degrees along the length of aorta intended to be treated by either the graft or stent.
- For the Zenith Dissection Endovascular Stent, a diameter at the intended implant site for the stent (measured outer-wall-to-outer-wall) of no greater than 38 mm (true lumen) and no less than 20 mm (total aortic diameter).
- Cook recommends that the Zenith Dissection Endovascular Stent component lengths described in **Table 2** be selected to correspond to the length of dissection to be treated.
- The ends of the Zenith Dissection Endovascular Stent should not terminate in a curvature less than 35 mm and localized angulation greater than 45 degrees.

If the distal end of the stent will be deployed in a funnel-shaped or angulated section of the aorta, or if the distal end of the stent appears conical in shape upon deployment, it is recommended to extend the treated segment distally with an additional stent, or choose a longer stent so it ends in a straight part of the aorta. Similarly, if the distal end of the stent will be deployed at the level of the diaphragm, or in a segment adjacent to the origin of the Celiac Trunk, Superior Mesenteric Artery and/or Renal Arteries, it is also recommended to extend the treated segment distally with an additional stent or choose a longer stent.

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 the 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
- Potential advantages of medical therapy
- 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 postoperative 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 repair with the devices 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/stent. Patients with specific clinical findings (e.g., 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 POSTOPERATIVE 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 postoperative 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 dissection 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 decreased blood flow to organs or rupture. Signs of decreased blood flow to organs, such as due to occlusion of the graft or branch vessels include, but may not be limited to, nausea, vomiting, pain in the back, abdomen, 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 ID 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 Zenith Dissection Endovascular Stent are sterilized by ethylene oxide gas. Each device is preloaded onto an Z-Trak Plus introduction system, and is supplied in peel-open packages.
- The devices are intended for single use only. Do not re-sterilize the device.
- The product is sterile if the package is unopened and undamaged. 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.
- 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 Zenith TX2 Dissection Endovascular Graft with Pro-Form is loaded into a 20 French (7.7 mm OD) or 22 French (8.5 mm OD) Flexor Introducer Sheath.
- Introducer sheath and tip surfaces are treated with a hydrophilic coating that, when hydrated, enhances trackability. To activate the hydrophilic coating, the surface must be wiped with a sterile gauze pad soaked in saline solution.
- The Zenith Dissection Endovascular Stent is loaded into a 16 French (6 mm OD) Flexor introducer sheath.

  NOTE: The loaded stent is compressed lengthwise. Movement applied to the gray positioner as the stent is unsheathed may allow the deployed stent to lengthen.
- Do not use after the expiration date printed on the label.
- Store in a 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 device 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 Zenith Dissection Endovascular Stent 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 or conduit technique
- Percutaneous access and closure techniques
- Nonselective 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 devices 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.

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 or the Zenith Dissection Endovascular Stent). 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
- Syringe
- Heparinized saline solution
- Sterile gauze pads
- .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)
- .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 Torcon NB® Advantage Angiographic catheters
  - Cook Royal Flush® Plus Flush Catheters
- Entry needles; for example:
  - Cook Single Wall Entry Needles

10.4 Device Diameter Sizing Guidelines

The Zenith TX2 Dissection Endovascular Graft with Pro-Form

The choice of diameter should be determined from the outer-wall-to-outer-wall vessel diameter and not the lumen diameter. **Table 1** incorporates appropriate graft oversizing. Strict adherence to the sizing guidelines is strongly recommended. Undersizing has resulted in false lumen expansion, endoleak/entry-flow, and migration. Excessive oversizing could result in fracture, device infolding, thrombosis, or compression. The potential effects of hypovolemia on aortic diameters should also be considered when selecting the device size.

The Zenith Dissection Endovascular Stent is intended for use as a distal component in combination with the Zenith TX2 Dissection Endovascular Graft with Pro-Form. Therefore, the diameter of the Zenith Dissection Endovascular Stent should be selected with consideration to the distal diameter of the Zenith TX2 Dissection Endovascular Graft. The 36 mm diameter stent is intended for use in conjunction with distal graft diameters ranging from 22 to 34 mm. The 46 mm diameter component is intended for use in conjunction with distal graft diameter ranging from 36 to 42 mm. Additional considerations may affect the choice of stent diameter.

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 ID (Fr/mm)	Introducer Sheath + Valve Length (cm)
20	22	79/117			20/6.7	96.2
21	24	79/117			20/6.7	96.2
22/23	26	79/136			20/6.7	96.2
24	28	82/142/202			20/6.7	96.2
25	30	82/142/202			20/6.7	96.2
26	30	82/142/202			20/6.7	96.2
27	30	82/142/202			20/6.7	96.2
28	32	82/142/202	162/202	158/196	20/6.7	96.2
29	32	82/142/202	162/202	158/196	20/6.7	96.2
30	34	79/154/204	159/199	156/194	20/6.7	96.2
31	36	79/154/204	159/199	159/199	22/7.3	96.2
32	36	79/154/204	159/199	159/199	22/7.3	96.2
33	38	79/154/204	154/204	159/199	22/7.3	96.2
34	38	79/154/204	154/204	159/199	22/7.3	96.2
35	40	83/164/218	160/210	165/205	22/7.3	96.2
36	40	83/164/218	160/210	165/205	22/7.3	96.2
37	42	83/164/218	160/210	160/210	22/7.3	96.2
38	42	83/164/218	160/210	160/210	22/7.3	96.2

*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.

10.5 Device Length Selection Guidelines

The Zenith Dissection Endovascular Stent

The choice of length should be determined from the pre-implant examinations, taking into consideration the fact that device length varies with vessel diameter, the degree of tortuosity and that components may be overlapped.

The Zenith Dissection Endovascular Stent is available in multiple lengths (4, 6 or 9 stent segments) and in two diameters (36 mm and 46 mm). Given the nature of the uncovered stent design, overall device length will vary in vivo with vessel diameter, see **Table 2**

Table 2 – Zenith Dissection Endovascular Stent Length Selection Guide

Stent Diameter (mm)	Introducer Sheath Size (ID Fr/OD mm)	Stent Length (at nominal diameter) (mm)	Stent Length Maximum (at 20/28 mm diameter) (mm)	Introducer Sheath Length (cm)
36	16/6.0	80	91 at 20	100
36	16/6.0	120	136 at 20	100
36	16/6.0	180	201 at 20	100
46	16/6.0	80	93 at 28	100
46	16/6.0	120	137 at 28	100
46	16/6.0	185	208 at 28	100

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 Zenith Dissection Endovascular Stent which are 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 procedure, 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:

- Femoral artery selection for introduction of the introduction system(s)
- Angulation of aorta, and iliac arteries
- Quality of the proximal and distal fixation sites
- Diameters of proximal and distal fixation sites and distal iliac arteries
- Length of proximal fixation site

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 Preparation/Flush of the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent

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. 7**)
2. Elevate distal tip of system and flush through the hemostatic valve until fluid emerges from the tip of the introduction sheath. (**Fig. 8**) Continue to inject a full 60 mL 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 dilator tip. (**Fig. 9**)
4. Soak sterile gauze pads in saline solution and use to wipe the Flexor Introducer Sheath and dilator tip to activate the hydrophilic coating. Hydrate both sheath and dilator tip liberally.

11.1.1 Placement of the Zenith TX2 Dissection Endovascular Graft with Pro-Form

1. Puncture the selected artery using standard technique with an 18 gage 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 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.
   NOTE: Confirm that the proximal landing zone is not dissected.
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.
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. 10**)
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. (**Fig. 11**)
    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 that 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.
    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. 12**) 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.
12. 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 introducer sheath 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.
   NOTE: If a dissection stent is to be placed leave the sheath and wire guide from the Graft in place, as the introducer for the Zenith Dissection Endovascular Stent is introduced through it coaxially. The ID of the Zenith TX2 Dissection Endovascular Graft with Pro-Form Introducer Sheath will accommodate introduction of the Zenith Dissection Endovascular Stent Introducer Sheath.

11.1.3 Final Angiogram (if not placing a Zenith Dissection Endovascular Stent)

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 artery.
2. Confirm that there are no perigraft flow or kinks, and verify position of proximal and distal gold radiopaque markers. Remove the sheaths, wires and catheters.
   NOTE: If perigraft flow or other problems are observed, refer to **Section 11.2, Additional Devices**.
3. Repair vessels and close in standard surgical fashion.

11.1.4 Placement of the Zenith TX2 Dissection Endovascular Stent

1. Perform angiography at the appropriate level. If using radiopaque markers, adjust position as necessary and repeat angiography.
2. Ensure system has been flushed with heparinized saline (appropriate flush solution), and all air has been removed.
3. Give systemic heparin. Flush all catheters and wet all wire guides with a heparin solution. This should be repeated following each exchange.
4. Remove pigtail flush catheter and leave the sheath and wire guide in place.
5. Introduce the Zenith Dissection Endovascular Stent introduction system over the wire guide through the Zenith TX2 Dissection Endovascular Graft with Pro-Form sheath and advance until the desired device position is reached. Make sure that the valve assembly of the Zenith Dissection Endovascular Stent sheath docks with the previously placed sheath.
6. During coaxial introduction of the Zenith Dissection Endovascular Stent Introducer Sheath inside of the Zenith TX2 Dissection Endovascular Graft with Pro-Form sheath, take care not to inadvertently advance the outer sheath. Dislodgement of the in-situ Graft Component can occur.
   CAUTION: To avoid twisting the device, never rotate the introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the aorta.
   NOTE: The dilator tip will soften at body temperature.
7. Verify wire guide position in the aortic arch. Ensure correct stent position.
8. Ensure that the Captor Hemostatic Valve on the introduction sheath is turned to the open position. (**Fig. 10**)
9. Just before withdrawing the sheath to deploy the stent, unlock the black cap on the anti-torque device by rotating it counter-clockwise. The anti-torque device is now released from the gray dilator and attached only to the Captor Hemostatic Valve. (**Fig. 13**)

10. Stabilize the gray positioner (introduction system shaft) and begin withdrawing the sheath until the stent is fully expanded and the valve assembly docks with the control handle. (**Fig. 14**)

    CAUTION: To avoid deploying the stent inside of the Zenith TX2 Dissection Endovascular Graft with Pro-Form sheath withdraw the two sheaths together.
11. Loosen the safety lock from the green trigger-wire release mechanism. Withdraw the trigger-wire until the proximal end of the device opens. Do not rotate the green trigger-wire knob. (**Fig. 15**) The distal end is still attached. Continue to withdraw the trigger-wire until the distal end opens. Withdraw the trigger-wire completely.

    As the distal end of the stent is still attached to the introduction system do not move the gray positioner until both ends of the stent are fully released.

    NOTE: Check to make sure that the trigger-wire is removed prior to withdrawal of the introduction system.

    NOTE: When using the sheath as a conduit through which other devices will be inserted, stabilize the sheath and remove the inner introduction system entirely, leaving sheath and wire guide in position. Remove the anti-torque device from the Captor Hemostatic Valve by twisting and removing it. Close the Captor Hemostatic Valve by turning it clockwise until it stops. Before any secondary procedure, open the Captor Hemostatic Valve by turning it counter-clockwise until it stops.
12. Remove the introduction system, leaving the wire guide in the graft.

11.1.5 Final Angiogram

Position angiographic catheter just above the level of the endovascular graft. Perform angiography to verify correct positioning. Verify patency of vessels inside the stented area.

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 POSTOPERATIVE FOLLOW-UP

12.1 General

The long-term performance of endovascular grafts and stents 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., persisting flow in the false lumen from any source 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 3**. 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., persisting flow in the false lumen 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 contrast and non-contrast CT examinations. If renal complications or other factors preclude the use of image contrast media, non-contrast CT may be used.

- The combination of contrast and non-contrast CT imaging provides information on device migration and integrity, perigraft flow, patency, progressive disease, fixation length, stent-to-vessel apposition and other morphological changes.

Table 3 lists the minimum requirements for imaging follow-up for patients with the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith TX2 Dissection Endovascular Stent. Patients requiring enhanced follow-up should have interim evaluations.

Table 3 – Recommended Imaging Schedule for Endograft Patients

	Angiogram	CT (contrast and non-contrast)
Pre-procedure		X[1]
Procedural	X	
Pre-discharge (within 7 days)		X[2,3]
1 month		X[2,3]
6 month		X[2,3]
12 month (annually thereafter)		X[2,3]

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

[2] If Type I or III sources for flow into false lumen are observed, prompt intervention and additional follow-up post-intervention recommended, see **Section 12.5, Additional Surveillance and Treatment**.

[3] If flow persists within the false lumen resulting in growth of the false lumen, prompt intervention and additional follow-up post-intervention is recommended.

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.
- 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 4** lists examples of acceptable imaging protocols.

Table 4 – 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 mL
Injection rate	n/a	> 2.5 mL/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 if using x-ray to evaluate device integrity:

- Four films: supine-frontal (AP), cross-table lateral, 30 degree RPO, and 30 degree 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 adequate penetration of the mediastinum.

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

Nonclinical testing has demonstrated that the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the nitinol Zenith Dissection Endovascular Stent is **MR Conditional** according to ASTM F2503. A patient with these devices can be safely scanned after placement under the following conditions:

- Static magnetic fields of 1.5 or 3.0 Tesla
- Maximum spatial magnetic gradient of 720 Gauss/cm or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) < 2.0 W/kg (Normal Operating Mode) for 15 minutes of continuous scanning

Under the scan conditions defined above, the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the nitinol Zenith Dissection Endovascular Stent is expected to produce a maximum temperature rise of less than 2.0 °C after 15 minutes of continuous scanning.

In nonclinical testing, the image artifact extends approximately 80 mm from the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the Zenith Dissection Endovascular Stent (ZDES) when imaged with a gradient echo pulse sequence and a 3.0 T MR system. The image artifact completely obscures the device lumen.

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
- Growth or extension of the false lumen
- Flow in false lumen of the dissection
- Obstruction/compromise of flow to end organs
- Inadequate stent-to-vessel apposition

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 (or) their published literature. Refer to your local Cook Technical Representative for information on available literature.

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2019-01
I-DISSECT-SYSTEM-441-01EN