Zenith® Dissection Endovascular System
Zenith® TX2® Dissection Endovascular Graft with Pro-Form®
and
Zenith® Dissection Endovascular Stent

Instructions for Use
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a. Radiopaque markers
b. Tapered component
c. Straight component

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)
The Zenith TX2 Dissection Endovascular Graft with Pro-Form: Key anatomic elements that may affect successful exclusion of the dissection include severe angulation (radius of curvature < 35 mm and localized angulation ≥ 45 degrees) and aortic tortuosity (true lumen diameter < 20 mm). 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, polypropylene, or gold
- bowel necrosis
- ASA Class ≥ V
- diabetes mellitus with suspected genetic connective tissue disease (e.g., Marfan or Ehlers-Danlos Syndrome)
- patients who are pregnant, breastfeeding, or planning to become pregnant within 60 days
- patients less than 18 years of age
- systemic infection (sepsis, pneumatosis)
- previous placement of thoracic endovascular graft
- prior open repair involving dissolving thoracic aorta (including surgical and/or endovascular)
- surgical or endovascular AAA repair within 30 days before or after deployment
- bleeding diathesis, uncorrectable coagulopathy, or refusal blood transfusion
- hemorrhagic stroke within 30 days or 14 days for embolic stroke
- unmetabolic reaction to contrast, which cannot be adequately tempered
- inability to preserve the native left common carotid artery and occipital artery origin
- presence 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 followed long-term to evaluate the efficacy and safety of the device. 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 comply with, the necessary preoperative and postoperative imaging and monitoring described in Section 12, IMAGING GUIDELINES AND POSTOPERATIVE FOLLOW-UP.

Graft implantation may increase the risk of paraplegia where graft exclusion threatens the compromise of vessel flow, which can lead to rupture. Further intervention should be considered for patients exhibiting continued flow in the false lumen of the dissection which may lead to rupture. Further intervention may include surgical repair to overcome compromise of organ vessel flows, or inadequate seal fixation proximal to the dissection.

4.2 Patient Selection, Treatment and Follow-Up

Access vessel diameter (measured external) and morphology (tortuosity, occlusive disease, and/or calcification) should be compatible with the vascular access technique used. The Zenith TX2 Dissection Endovascular Graft incorporates continued flow in the false lumen of the dissection which may lead to rupture. Further intervention may include surgical repair to overcome compromise of organ vessel flows, or inadequate seal fixation proximal to the dissection.
To eliminate the hydrophilic coating on the outside of the sheath, the surface may be wiped with an appropriate alcohol solution. Always keep the sheath hydrated for optimal performance.

- Maintain wire guide position during introduction system insertion.
- Do not bend or kink the guidewire. Doing so may damage the catheter and/or stent.
- Do not advance the guidewire or stent to its full length.
- Do not fully deploy the Zenith TX2 Dissection Endovascular Graft with Pro-Form.
- Always use fluoroscopy for guidance, delivery, and the position of the graft/stent within the vasculature.
- The use of the graft/stent requires administration of intravenous 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 traumatizing the endovascular graft and/or stent, never rotate the introduction system. Always 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 fluoroscopy images to check position as necessary.
- Incorrect deployment or migration of the 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. This may cause resistance of the catheter, or graft damage may occur. Ensure in particular any cares in aneurysm, stent thrombosis, or calcified or tortuous vessels.
- Use caution during manipulation of catheters, wires and sheaths within a dissection. Significant force may dislodge fragments of thrombus, which can cause distal or cerebral embolization.
- Avoid damaging the graft and/or stent during or stabilizing graft/stent positioning after placement in the primary access vessel or the primary (introducer) of the graft/stent is necessary.
- Do not attempt to re-shape 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 addressed immediately.

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

- Laddening the proximal end of the device in dislocated tissue can increase the risk of damage to the septum and could lead to new tears, aortic rupture, retrograde dissection, or other complications.
- Inaccurate placement, incomplete sealing, inadequate overlying, or lack of compression may occur in difficult cases, especially if the width of the Zenith TX2 Dissection Endovascular Graft with Pro-Form within the vessel may result in risk of endoleak, migration, or inadvertent occlusion of the left subclavian, left common carotid or left vertebral arteries.
- Consider the potential effects of hypotension 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 exclude arteries necessary to supply blood flow to organs or extremities. Do not cover significant vessel with a component or device (e.g., the left subclavian artery) with the endovascular prosthesis. Vessel occlusion may occur. If a left subclavian artery is not left patent after deployment of the device, the clinician should be aware of the possibility of compromise to cerebral and upper limb circulation. Alternatively, the deployment of the distal portion of the deployment, the proximal stent may result in damage to the graft and/or lesion injury.
- Molding balloon use is optional, and if used, it should not be inflated in the aorta outside of the graft.
- Additionally, complete definition of the balloon should be confirmed prior to repositioning. For added hemostasis, the Celax Hemostaic Valve or a covered or self-expanding balloon may 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, consider the overlap of 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 is not recommended. Component is left to the discretion of the implanting physician. Factors affecting whether or not to overlap with a component device (e.g., the left subclavian artery) may vary in the left subclavian artery) with the endovascular prosthesis. Vessel occlusion may occur. If a left subclavian artery is not left patent after deployment of the device, the clinician should be aware of the possibility of compromise to cerebral and upper limb circulation. Alternatively, the deployment of the distal portion of the deployment, the proximal stent may result in damage to the graft and/or lesion injury.
- Molding balloon use is optional, and if used, it should not be inflated in the aorta outside of the graft.
- Additionally, complete definition of the balloon should be confirmed prior to repositioning. For added hemostasis, the Celax Hemostaic Valve or a covered or self-expanding balloon may accommodate the insertion and subsequent withdrawal of a molding balloon.

Devicel Related Adverse Event Reporting

Any adverse event (clinical or device) involving the Zenith Dissection Endovascular Graft (graft or stent) should be reported to Cook immediately. To report an incident, call the Customer Relations Department at 860-457-5450 (24 hours per day, 7 days per week).
Table 1 – Straight Component and Tapered Component Graft Diameter Sizing Guide

### Form and the Zenith Dissection Endovascular Stent are outlined below:

The Zenith TX2 Dissection Endovascular Graft with Pro-Form or the Zenith Dissection Endovascular Stent are loaded into a 16 French (7.7 mm OD) Flexor introducer sheath. Introducer sheaths are treated with a hydrophilic coating that, when hydrated, enhances trackability. To activate the hydrophilic coating, the surface must be seared with a sterile gazette pad soaked in saline solution.

### Table 1 – Straight Component and Tapered Component Graft Diameter Sizing Guide

<table>
<thead>
<tr>
<th>Intended Aortic Vessel Diameter (mm)</th>
<th>Graft Diameter (mm)</th>
<th>Overall Length of Straight Component (mm)</th>
<th>Overall Length of 4 mm Tapered Component (mm)</th>
<th>Overall Length of 8 mm Tapered Component (mm)</th>
<th>Introducer Sheath ID (Fr/mm)</th>
<th>Introducer Sheath + Valve Length (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>22</td>
<td>79/117</td>
<td>20/7</td>
<td>20/7</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>20/7 (92.6)</td>
</tr>
<tr>
<td>21</td>
<td>24</td>
<td>79/117</td>
<td>20/7</td>
<td>20/7</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>20/7 (92.6)</td>
</tr>
<tr>
<td>22/23</td>
<td>24</td>
<td>79/117</td>
<td>20/7</td>
<td>20/7</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>20/7 (92.6)</td>
</tr>
<tr>
<td>25</td>
<td>30</td>
<td>82/142/202</td>
<td>162/202</td>
<td>158/196</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>20/7 (92.6)</td>
</tr>
<tr>
<td>26</td>
<td>30</td>
<td>82/142/202</td>
<td>162/202</td>
<td>158/196</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>20/7 (92.6)</td>
</tr>
<tr>
<td>27</td>
<td>30</td>
<td>82/142/202</td>
<td>162/202</td>
<td>158/196</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
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</tr>
<tr>
<td>28</td>
<td>30</td>
<td>82/142/202</td>
<td>162/202</td>
<td>158/196</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
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</tr>
<tr>
<td>30</td>
<td>34</td>
<td>79/154/204</td>
<td>159/199</td>
<td>159/199</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>22/7 (95.3)</td>
</tr>
<tr>
<td>31</td>
<td>36</td>
<td>79/154/204</td>
<td>159/199</td>
<td>159/199</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>22/7 (95.3)</td>
</tr>
<tr>
<td>32</td>
<td>36</td>
<td>79/154/204</td>
<td>159/199</td>
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<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
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<td>33</td>
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</tr>
<tr>
<td>35</td>
<td>40</td>
<td>81/164/218</td>
<td>160/210</td>
<td>165/205</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
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<tr>
<td>38</td>
<td>42</td>
<td>81/164/218</td>
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<td>165/205</td>
<td>0.035 inch (0.89 mm) Flexor introducer sheath</td>
<td>22/7 (95.3)</td>
</tr>
</tbody>
</table>

*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 is not a step-by-step 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, especially during the initial intervention (including transluminal) to prevent adverse outcomes. It is important to monitor blood loss from the hemostasis valve throughout the procedure as it is specifically releasable and after manipulation of the graft proponent. After the graft proponent has been removed, if blood loss is the case, consider placing an unflattened 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, iliac arteries
- Quality of the proximal and distal fixation sites
- Dimensions of proximal and distal fixation sites and distal iliac arteries
- Leaks around the introduction site

Patient Preparation

1. Refer to institutional protocols relating to anesthesia, anticoagulation, and monitoring of vital signs.
2. Position patient on the operating table allowing fluoroscopic visualization from the aortic arch to the femoral bifurcations.
3. Expose femoral artery in an appropriately technical fashion.
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 entryway. (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 heparinized saline to the device continuously and close stopcock on connecting tube.

NOTE: Golf flushing should be performed with saline solution is often used.

3. Attach syringe with heparinized saline to the hub on the inner cannula. Flush until fluid is returned to the syringe.
4. Soak sterile gauze pads in saline solution and use to wipe the Fexiou 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. Select the previously selected artery using standard technique with an 18 gauge needle access. Upon vessel entry, insert:
   - Wire guide – standard .035 inch, 260/300 cm, 15 mm J-tip or Bentson wire guide
   - Appropriatel size sheath (e.g., .5 French)
   - Pigtail flush catheter (often radiopaque-banded sizing catheter), i.e., Cook Centimeter Sizing CCI-20 catheter.

2. Perform angiography at the appropriate level if using radiopaque markers, adjust position as necessary.

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. (Fig. 9)
4. Give systemic heparin. Flush all catheters and all wire guides with a solution of heparin saturated with saline solution.
5. Replace the standard wire guide with a .035 inch, 260/300 cm.LESDC wire guide and advance through the catheter and up to the aortic arch.
6. Pigtail flush catheter and sheath.

NOTE: At this stage, the second femoral artery can be accessed for angiographic catheter placement. After angiography, a balloonnush approach may be considered.

7. Introduce the newly hydrated introduction system over the wire guide and advance until the desired graft position is reached.

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

NOTE: The dilator tip will swell at body temperature.

9. Ensure that the Captor Hemostatic Valve on the Fexiou Introducer Sheath is turned to the open position. (Fig. 10)
10. Stabilize the gray proponent [introduction system shall] and withdraw the sheath until the graft is fully expanded and the valve assembly docks with the handle control. (Fig. 11)
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 difficulties is encountered when attempting to withdraw

The Zenith Dissection Endovascular Stent is available in multiple lengths (4, 6 or 9 stent segments) and in two diameters (36 and 46 mm J tip or Benyon wire guide). TheZenith Dissection Endovascular Stent is constructed from a nitinol alloy conformed into the desired configuration.

11.1.2 Molding Balloon Insertion – Optional

1. Prepare the recently hydrated introduction system during the procedure. Allow the device to conform naturally to the curves and tortuosity of the vessel.
2. Insert the Captor Hemostatic Valve into the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent.
3. Attach syringe with heparinized saline
4. Remove all air from balloon.
5. In preparation for the insertion of the molding balloons, open the Captor Hemostatic Valve by turning it counter-clockwise.
6. Advance the molding balloons 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.
7. Tighten the Captor Hemostatic Valve around the molding balloon to gain pressure by turning it clockwise.
8. Expand the molding balloons 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.
9. CAUTION: Do not inflate balloons in aorta outside of graft. Use caution during molding within a dissection.
10. Confirm complete deflation of balloon prior to repositioning.
11. Open the Captor Hemostatic Valve, remove the molding balloon and replace it with an angiographic catheter to perform completion angiograms.
12. Tighten the Captor Hemostatic Valve to ensure the angiographic catheter with gentle pressure by turning it clockwise.
13. Remove or replace all stiff wire guides after aorta has resumed its normal position.

NOTE: If a dissection stent is placed, be placed beneath the sheath and wire guide

15. Confirm that there are no perigraft flow or leaks, and verify position of proximal and distal gold radiopaque markers. Remove the sheaths, wires, and catheters.
16. NOTE: Perigraft wire or other problems are observed, refer to Section 11.2, Additional Devices
17. Repair vessel, and close in standard surgical fashion.

11.1.3 Final Angiogram if not placing a Zenith Dissection Endovascular Stent

1. Position angiographic catheter just above the level of the endograft.
2. Perform angiography to verify correct position. Verify patency of arch vessels and celiac artery.
3. Confirm that there are no perigraft flow or leaks, and verify position of proximal and distal gold radiopaque markers.
4. Remove the sheaths, wires, and catheters.

NOTE: Perigraft wire or other problems are observed, refer to Section 11.2, Additional Devices.
5. Repair vessel, and close in standard surgical fashion.

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

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 all wire guides with a solution of heparin saturated with saline solution.
4. Replace the standard wire guide with a .035 inch, 260/300 cm LESDC wire guide and advance through the catheter and up to the aortic arch.
5. Introduce the Zenith Dissection Endovascular Stent introduction system over the wire guide through the Zenith TX2 Dissection Endovascular Graft with Pro-Form and advance until the desired device position is reached.
6. During coxial introduction of the Zenith Dissection Endovascular Stent Introducer Sheath in the Zenith TX2 Dissection Endovascular Graft with Pro-Form sheath, take care not to inadvertently advance the outer sheath. Dislodgement of the intimal Graft Component can occur.
7. CAUTION: Confirm complete deflection of balloon prior to repositioning. For devices, 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 swell at body temperature.

9. Ensure that the Captor Hemostatic Valve on the Fexiou Introducer Sheath is turned to the open position. (Fig. 11)
10. Just before withdrawing the sheath, 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 posterior (intrathoracic system shelf) and begin withdrawing the sheath while the stent is fully expanded and the valve assembly docks with the control handle. (Fig. 14) 

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. 18) 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 posterior 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 sheath.

Re-visualize 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.

12.1 General

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 resulting in growth of the false lumen) have interim evaluations.

Table 3 - Recommended Imaging Schedule for Endograft Patients

<table>
<thead>
<tr>
<th>Angiogram CT (contrast and non-contrast)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-procedure</td>
</tr>
<tr>
<td>Procedural</td>
</tr>
<tr>
<td>Pre-discharge (within 7 days)</td>
</tr>
<tr>
<td>1 month</td>
</tr>
<tr>
<td>6 month</td>
</tr>
<tr>
<td>12 month (annually thereafter)</td>
</tr>
</tbody>
</table>

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

² If type I or II 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 non-contrast CT imaging/image sets, as it prevents precise anatomical and morphological changes.

- Both non-contrast and contrast runs are required, with matching or corresponding table positions.

- Non-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.

12.3 Thoracic Device Radiographs

The following views are required if using a ray to evaluate device integrity:

- Four films, supra-axial (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 photos, thoracic spine technique, or manual technique should be used for all views to ensure adequate penetration of the medullary cavity. Ensure entire device is captured on each single image format lengthwise. Malignant photo will allow visualization of the device.

- If there is any concern about the device integrity (e.g., kinking, stent branches, 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 2X-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 F2050. 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 20 Gaus/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 T MRI 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:

<table>
<thead>
<tr>
<th>Mail:</th>
<th>MedicAlert Foundation International 2221 Colorado Avenue Turlock, CA 95382</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>888-633-4298 (toll free) 209-668-3333 from outside the US</td>
</tr>
<tr>
<td>Fax:</td>
<td>209-669-2450</td>
</tr>
<tr>
<td>Web:</td>
<td><a href="http://www.medicalert.org">www.medicalert.org</a></td>
</tr>
</tbody>
</table>

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.