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1. DEVICE DESCRIPTION

1.1. Stent-Graft
The TREO Stent-Graft is a modular system designed to treat abdominal aortic aneurysms. It consists of a Main Bifurcated Stent-Graft and two Leg Extensions, each delivered via an endovascular approach using their own separate delivery system. All stent-grafts are comprised of self-expanding nitinol stents sutured to woven polyester fabric. The stent scaffold is a series of sinusoidal springs stacked in a tubular configuration. These stents are spaced along the length of the graft fabric to provide radial support and allow for the self-expansion of the stent-grafts. Radiopaque markers are placed on the stent-graft to aid visualization and accurate placement (Figures 1 and 2).

1.1.1. Main Bifurcated Stent-Graft
The Main Bifurcated Stent-Graft has an uncovered proximal stent that includes fixation barbs (suprarenal) for migration resistance. A second row of barbs are also located just distally to the start of the covered section, approximately at the middle of the first covered stent, to help provide infrarenal fixation. Each leg of the Main Bifurcated Stent-Graft is designed to accept a Leg Extension. The diameter of each leg of the Main Bifurcated Stent-Graft is always the same size (14 mm), regardless of proximal diameter or length. The legs of the Main Bifurcated Stent-Graft also have a stent that contains dull barbs to engage the Leg Extension in situ and help prevent separation of components. See Figure 3 and Tables 2a and 2b.

1.1.2. Leg Extensions
The proximal end of all catalog Leg Extension components is always of the same diameter (15 mm) to allow coupling with any cataloged Main Bifurcated Stent-Graft. It is configured as shown in Figure 1. In addition, the amount that each Leg Extension is inserted into the leg of the Main Bifurcated Stent-Graft is adjustable. The distal end configuration of the Leg Extension is available as a “closed end configuration”. See Figure 4 and Table 3a.

1.2. Delivery System for the Bifurcated Main Body and Cuff Delivery Systems
The TREO Main Bifurcated Stent-Graft and Cuff use the same delivery system, consisting of an introducer sheath attached to a main handle assembly (Figure 5). The handle assembly includes a Gray Turn Knob control system for accurate placement of the Main Bifurcated Stent-Graft and Cuff.

1.3. Delivery System for the Leg and Iliac Extension
The TREO Leg and Iliac Extensions use a similar version of the Delivery System as the Main Bifurcated Stent-Graft and Cuff. The only difference in the Delivery System for the Leg and Iliac Extensions is the absence of the clasp release mechanism at the distal end of the delivery system next to the guidewire flush port. See Figure 6.

1.4. Proximal Cuffs and Iliac Extensions
Additional ancillary endovascular components are also available. Proximal Extensions are available for all Main Bifurcate devices. The proximal end of the Proximal Extensions is configured identically to the proximal ends of the Main Bifurcated Stent-Grafts. The distal ends of the Proximal Extensions are “closed end configurations”. The Proximal Extension stent-graft is shown in Figure 1. Straight Iliac Extensions are available for Leg Extension Sizes with distal diameters of 9, 11 and 13mm. See Table 3b for details regarding Straight Iliac Extensions.

2. INDICATIONS FOR USE
The TREO Stent-Graft system is intended for the endovascular treatment of infrarenal abdominal aortic and aorto-iliac aneurysms in patients who have appropriate anatomy as described below:

- Adequate iliac or femoral access compatible with the required delivery systems
- Suprarenal neck angle of less than 45 degrees,
- Infrarenal landing neck length of:
  - 10 mm or greater with an infrarenal angle of less than 60 degrees and an inside diameter of 17 mm – 32 mm, or
  - 15 mm or greater with an infrarenal angle between 60 and 75 degrees and an inside diameter of 16 mm-30 mm

The introducer sheath and tip are hydrophilically coated. The sheath can be detached from the Black Stationary Grip and left in place while removing the rest of the delivery system so the Bifurcate Stent-Graft sheath can then be used as a vascular introducer for the ipsilateral Leg Extension. The tip of the delivery system and end of the introducer sheath are radiopaque for visibility during use.
• Distal iliac landing neck of inside diameter:
  - 8 mm – 13 mm and a length of at least 10 mm or
  - >13 mm - 20 mm and a length of at least 15 mm

3. CONTRAINDICATIONS OF USE FOR THE TREO SYSTEM

The AAA system is contraindicated when patients present with any of the following characteristics/conditions:
• Systemic infection.
• Hypersensitivity to polyester or Nitinol.

4. WARNINGS AND PRECAUTIONS

• Placement of stent-grafts in the abdominal aorta often requires proximity to the renal arteries. The distal landing area of the leg extension may be very close to the internal iliac arteries. Care should be taken to not block these critical arteries during device deployment, with the exception of planned coverage of critical arteries.
• Proximal and distal landing zones need to be considered. They are specified in Tables 2a and 3a for each device.
• Excessive aortic tortuosity may result in not being able to properly position the stent-graft or result in the stent-graft kinking.
• Significant or circumferential calcification or mural thrombus in the proximal aortic neck or the distal iliac landing zones may adversely impact sealing
• Significant or circumferential calcification or mural thrombus within the treatment length may adversely impact device patency
• It is recommended that balloon modeling be done with a compliant balloon. Balloon inflation should not exceed 1 atm.
• Endovascular techniques such as kissing balloons should be considered in the graft flow divider and native aortic bifurcation zone as the anatomy warrants.
• Do not use power/pressure injections through the delivery systems.
• Care should be taken when treating morbidly obese patients as device visualization may be compromised.
• Careful consideration should be given to treating patients with pre-existing iliac endoprostheses.
• Care should be taken when treating women who are of childbearing age or are pregnant or lactating.

5. ADVERSE EVENTS

Adverse events that may occur in conjunction with endovascular procedures include, but are not limited to those listed in the following section.

<table>
<thead>
<tr>
<th>TABLE 1: Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adynamic Ileus</td>
</tr>
<tr>
<td>Anaphylaxis</td>
</tr>
<tr>
<td>Aneurysm / Lesion Rupture</td>
</tr>
<tr>
<td>Arteriovenous fistula / aorto-duodenal fistula</td>
</tr>
<tr>
<td>Blood Loss</td>
</tr>
<tr>
<td>Bowel Ischemia</td>
</tr>
<tr>
<td>Cardiac events</td>
</tr>
<tr>
<td>Cerebral vascular accident (stroke)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Delivery system failure</td>
</tr>
<tr>
<td>Deployment failure</td>
</tr>
<tr>
<td>Device dehiscence</td>
</tr>
<tr>
<td>Emboli</td>
</tr>
<tr>
<td>Endoleak</td>
</tr>
<tr>
<td>Fever</td>
</tr>
<tr>
<td>Hematoma</td>
</tr>
<tr>
<td>Hemorrhage</td>
</tr>
<tr>
<td>Hepatic failure</td>
</tr>
<tr>
<td>Impotence</td>
</tr>
</tbody>
</table>
For patient specific device selection, the following criteria shall be followed:

- Select the appropriate device size based on artery outer diameter measurement taken from CT images. Diometrical sizes of the proximal and distal landing zones are needed.

- Length of the stent-grafts should take into account tortuosity of vessels and minimum overlap requirements.

Patients considered for treatment with the TREO Stent-Graft shall meet the following criteria:

- Adequate access vessel size to accommodate the introducer sheath size of the device to be used as specified in Tables 2a, 3a and 3b.

- A total length of less than 49 cm length from infrarenal landing location to introducer vessel access site.

- Infrarenal landing neck having non-significant calcification or thrombus formation and having an outer diameter specified for the corresponding devices and neck anatomy listed in Table 2a.

- Infrarenal landing neck length of 10 mm or greater and an angle of less than 60 degrees relative to the long axis of the aneurysm and a suprarenal neck angle of less than 45 degrees relative to the infrarenal neck axis and an outer diameter specified for the corresponding devices and neck anatomy listed in Tables 2a and 2b.

- Distal iliac landing neck having non-significant calcification or thrombus formation, having a length and an outer diameter meeting the vessel size requirements specified for the corresponding devices in Tables 3a and 3b.

- Distal aorta with sufficient diameter to accommodate leg extension stent-grafts. Diameter recommended to be >70% of the sum of the two diameters anticipated passing through the native aortic bifurcation zone.

### TABLE 2a: Main Bifurcated Stent-Graft and Cuff Proximal Extension Diameters

<table>
<thead>
<tr>
<th>Stent-Graft Proximal Diameter (mm)</th>
<th>Indicated Vessel OD for Infrarenal Neck Angle &lt; 60°</th>
<th>Seal Zone Neck Length Requirement for Infrarenal Neck Angle &lt; 60°</th>
<th>Indicated Vessel OD for Infrarenal Neck Angle from 60° to 75°</th>
<th>Seal Zone Neck Length Requirement for Infrarenal Neck Angle From 60° to 75°</th>
<th>Delivery System French Size (OD)</th>
<th>Delivery System Usable Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>17-18</td>
<td>10 mm</td>
<td>16-17</td>
<td>15 mm</td>
<td>18 Fr</td>
<td>49 cm</td>
</tr>
<tr>
<td>22</td>
<td>19-21</td>
<td>10 mm</td>
<td>18-19</td>
<td>15 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>21-23</td>
<td>10 mm</td>
<td>19-21</td>
<td>15 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>23-25</td>
<td>10 mm</td>
<td>21-23</td>
<td>15 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30</td>
<td>27-30</td>
<td>10 mm</td>
<td>25-27</td>
<td>15 mm</td>
<td>19 Fr</td>
<td>49 cm</td>
</tr>
<tr>
<td>36</td>
<td>30-32</td>
<td>10 mm</td>
<td>27-30</td>
<td>15 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Maximum infrarenal neck length restrictions do not apply if outer diameter of proximal neck is >28 mm.

### TABLE 2b: Main Bifurcated Stent-Graft Lengths

<table>
<thead>
<tr>
<th>Main body Contralateral Length (mm)</th>
<th>Minimum Renal-Aortic Bifurcation Length (mm)</th>
<th>Main Body Length (mm)</th>
<th>Maximum Infrarenal Neck Length (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>80</td>
<td>90</td>
<td>40</td>
<td>40</td>
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<tr>
<td>100</td>
<td>110</td>
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<tr>
<td>120</td>
<td>130</td>
<td>80</td>
<td>80</td>
</tr>
</tbody>
</table>

*Maximum infrarenal neck length restrictions do not apply if outer diameter of proximal neck is >28 mm.
### TABLE 3a: Leg Extension Sizes

<table>
<thead>
<tr>
<th>Proximal Graft Size (mm)</th>
<th>Distal Graft Size</th>
<th>Distal Vessel OD Size (mm)</th>
<th>Seal Zone Neck Length Requirement</th>
<th>Delivery System French Size (OD)</th>
<th>Delivery System Usable Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>8</td>
<td>10 mm</td>
<td></td>
<td>13 Fr</td>
<td>80 cm</td>
</tr>
<tr>
<td>11</td>
<td>9</td>
<td>10 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>10-11</td>
<td>10 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>12-13</td>
<td>10 mm</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>14-15</td>
<td>15 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>16-17</td>
<td>15 mm</td>
<td></td>
<td>14 Fr</td>
<td></td>
</tr>
<tr>
<td>24</td>
<td>18-20</td>
<td>15 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Straight extensions are only for use with previously placed Leg Extension stent-grafts with identical distal diameters.

### TABLE 3b: STRAIGHT EXTENSION SIZES

<table>
<thead>
<tr>
<th>Proximal Graft Size (mm)</th>
<th>Distal Graft Size (mm)</th>
<th>Distal Graft Length</th>
<th>Seal Zone Neck Length Requirement</th>
<th>Graft Length</th>
<th>Delivery System French Size (OD)</th>
<th>Delivery System Usable Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>9</td>
<td></td>
<td>10 mm</td>
<td>80 mm</td>
<td>13 Fr</td>
<td>80 cm</td>
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<tr>
<td>11</td>
<td>11</td>
<td></td>
<td>10 mm</td>
<td>80 mm</td>
<td>13 Fr</td>
<td>80 cm</td>
</tr>
<tr>
<td>13</td>
<td>13</td>
<td></td>
<td>10 mm</td>
<td>80 mm</td>
<td>13 Fr</td>
<td>80 cm</td>
</tr>
</tbody>
</table>

### 7. HOW PRODUCT IS SUPPLIED

The TREO Stent-Graft system is supplied as follows:

- Each Stent-Graft is pre-loaded in its individual delivery system and packaged using a double pouch system with peel-open end seals.

- Each package contains a label describing the device details such as catalog number, diameter, length, delivery system size, etc.

TREO is provided **STERILE: DO NOT RE-STERILIZE - SINGLE USE ONLY.**

The product is supplied with the following model designation identified on the label as shown in Table 4.

### TABLE 4

<table>
<thead>
<tr>
<th>Internal Code</th>
<th>Identifier</th>
<th>Internal Code</th>
<th>Stent Diameter</th>
<th>Stent Length</th>
<th>Device Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>28</td>
<td>X</td>
<td>XX</td>
<td>XXX</td>
<td>E: Clinical Use EC X: Clinical Use US S: Standard Catalog Product</td>
<td></td>
</tr>
</tbody>
</table>

*Stent diameter is for proximal diameter for Bifurcates.
Stent diameter is for distal diameter for Legs.
Stent diameter is for both the proximal and distal diameters for Cuffs and Straights.

**Stent length is for contralateral length on bifurcates.
Stent length is for total length on cuffs, legs and straights.
Product Size Availability

The TREO Stent-Graft is intended to be used as a three-piece modular system consisting of a Main Bifurcated Stent-Graft and two Leg Extensions. Each stent-graft is available as follows:

- The Main Body Bifurcated Stent-Grafts are available in proximal diameters ranging from 20 mm to 30 mm in 2 mm increments, 33 mm, and 36 mm as specified in Table 2a with the corresponding vessel size requirement. Each is available in 3 body lengths as shown in Figure 3 and Table 2b.

- Each leg of the Main Bifurcated Stent-Graft is always the same diameter, regardless of the proximal diameter size. This allows using any catalog Leg Extension with any catalog Main Body Bifurcated Stent-Graft.

- The Leg Extensions are available in distal diameters of 9, 11, 13, 15, 17, 20, and 24 mm. Available lengths range from 80 mm to 160 mm as shown in Figure 4 and Table 3a.

- The Proximal Cuff Extensions are available in proximal diameters ranging from 20 mm to 30 mm in 2 mm increments, 33 mm, and 36 mm as specified in Table 2a. Each is available in 3 body lengths of 40 mm, 55 mm, and 70 mm.

- Straight Extensions are available in diameters of 9, 11 and 13mm in 80mm lengths, and are intended for extending a previously placed leg extension that has an identical distal diameter. Straight Extensions are not intended for use directly with a Main Bifurcated Stent-Graft. See Table 3b.

8. CLINICAL USE INFORMATION

8.1. Case pre-planning & individualization of treatment

Practitioners using the TREO Stent-Graft with Delivery System should have a thorough understanding of endovascular procedures and techniques. In particular, the TREO Stent-Graft with Delivery System should only be used by physicians and teams with experience and training in vascular interventional techniques, including, but not limited to, training on the use of the TREO Stent-Graft system. Selecting the proper graft with the appropriate length and diameter is paramount to the successful exclusion of the aneurysm/lesion and to minimize endoleaks and migration. Measure all parameters needed for proper sizing of the graft carefully. Bolton Medical recommends evaluation of all imaging studies available, i.e., angiograms, CT scans, MRI scans, MRA scans and plain radiographs. Each imaging modality offers additional information to the sizing process. The physical characteristics of the vessel should be evaluated in addition to its size. Factors such as stenosis, atherosclerotic disease, ectasia and tortuosity may affect Stent-Graft selection and placement strategy. The final Stent-Graft selection will be the responsibility of the physician.

8.2. Device inspection prior to use

- Inspect the system packaging pouches for tears, punctures, breaks, or opening that would compromise the system sterility. WARNING: Do not use the system if the outer pouch has any punctures, tears or opening as this may have affected system sterility.

8.3. Materials required

- Fluoroscopic DSA equipment (ceiling/ pedestal mounted or portable image intensifier on a freely angled C-arm). It is desirable if the image intensifier has a complete range of motion.
- Minimum 260cm Guidewire/0.035” [0.89mm] (Super Stiff)
- Arterial puncture needles 18G or 19G
- Assorted vascular introducers and angiographic catheters
- Contrast media
- Syringes
- Heparinized saline solution
- Sterile gauze pads
- Inflation device with pressure gauge
- Guidewire torque devices
- Vascular Balloon-Catheters of the appropriate size
- PTA Balloons with diameters equivalent to the anatomical iliac diameters
- Gooseneck snare
- Extra leg extension products allowing for different length options

9. DIRECTIONS FOR USE

Patient and Device Preparation: (Steps 1 through 4)

Anticoagulation and anti-platelet therapies are used at the discretion of the physician. Similarly, arterial blood pressure adjustment and spinal cord protection measures are also at the discretion of the physician.

Position the patient on the surgical table where standard aseptic preparation of the surgical site is conducted. Drape the patient with sterile surgical drapes leaving exposed the bilateral groin access sites.
Main Bifurcated Stent-Graft identify the location of the contralateral gate within the delivery sheath. It may be necessary to move the sheath to a straight area of the aorta to facilitate rotation. (Figure 11)

Deployment of Main Bifurcated Stent-Graft
(Steps 11 through 15)

NOTE: Stent-Graft deployment should be done while observing the proximal end of the stent-graft under fluoroscopy.

11. Holding the Black Stationary Grip so that the stent-graft does not move, rotate the Gray Turn Knob in the direction of the arrow to start the deployment of the stent-graft (Figure 12). Observe the proximal end of the stent-graft as it starts to expand, noting any longitudinal or radial movement that may require adjustment.

12. Continue turning the Gray Turn Knob until the proximal stent is expanded. (Figure 13) At this time, if needed, adjust the longitudinal location of the stent-graft by moving the Black Stationary Grip as required.

13. Continue to deploy the stent-graft until the contralateral gate is exposed, leaving the sheath over the remaining stents on the ipsilateral side. (Figure 14). This secures the distal end of the main bifurcated stent-graft by still capturing the end of the ipsilateral leg.

WARNING: DO NOT ROTATE THE BLACK STATIONARY GRIP ONCE POSITION HAS BEEN CONFIRMED AND THE STENT-GRAFT FINAL DEPLOYMENT IS STARTED.

14. At this time, make any final longitudinal adjustments to the stent-graft by moving the Black Stationary Grip as required.

15. Release the bare stent by retracting the release grip. To do this, first hold either the blue handle tube or black stationary grip with one hand. While pushing (1) the grey knob towards the black release grip, turn the grey knob (2) [Figure 15]. The black release grip will partially move back from the grey knob (Figure 16 [NOTE: The bare stent is still fully clasped at this point]). To release the bare stent, move the Black Release Grip completely towards the Guidewire Flush Port while observing the clasp under fluoroscopy. The operator will feel two sets of clicks, which will ensure the black release grip is fully seated in the grey knob. (Figure 17).

WARNING: DO NOT HOLD GREY TURN KNOB WHILE RELEASING THE CLASP.

WARNING: WHEN POSITIONED AS SHOWN IN FIGURE 17, THE CLASP IS LOCKED. DO NOT ATTEMPT TO RE-ADVANCE THE CLASP.
RE- ADVANCEMENT OF THE CLASP MAY CAUSE CAPTURE OF A BARE STENT STRUT RESULTING IN AN UNINTENDED MOVEMENT OF THE STENT- GRAFT DURING SYSTEM WITHDRAWAL. THE DEVICE IS DESIGNED TO WITHDRAW WITH THE CLASP FULLY OPEN.

Contralateral Leg Extension Deployment
Preparation of the Contralateral Leg Extension (steps 16 through 20)

16. Cannulate the contralateral gate of the bifurcated stent-graft with a guidewire. Advance the guidewire and a catheter through the bifurcated stent-graft into the descending thoracic aorta.

17. Exchange the guidewire for a .035” super stiff wire, then remove the catheter while ensuring the super stiff wire remains in the descending thoracic aorta.

NOTE: Care should be taken to ensure the guidewire and catheter do not pass between the struts of the proximal bare stent.

18. Check the proximal end of the delivery system to ensure that the delivery system tip is properly seated in the outer sheath. If it is not seated properly as shown in Figure 7, the device should not be used.

19. Flush the guidewire flush port (Figure 8) with minimum of 5 cc of heparinized saline. Flush the leg delivery system with minimum of 20 cc of heparinized saline through the two way flush port (Figure 9) to purge air from the inside of the sheath. Ensure that saline can be seen exiting from the tip area. Visually inspect the system for remaining air and repeat if necessary.

20. Activate the hydrophilic coating by wetting the tip and introducer sheath with saline.

Introduction/Advancement of the Contralateral Leg Extension (steps 21 through 24)

21. Advance the introducer sheath into the artery over the super stiff guidewire.

NOTE: The guidewire should always remain in the delivery system while inside the patient.

22. Advance the Leg Delivery System through the contralateral gate of the Bifurcated Stent-Graft. Pay close attention as the tip of the Leg Delivery System advances into the contralateral gate to ensure that the Main Bifurcated Stent-Graft is not moved proximally. (Figure 18)

23. Continue to advance the Leg Delivery System noting the markers on the proximal end of the Leg Extension. The contralateral side of the Main Bifurcated Stent-Graft has two markers that indicate the overlap region. The radiopaque markers on the proximal end of the Leg Extension must be advanced so that they are within these two markers. (Figure 18)

24. Once the proximal end markers of the Leg Extension are past the minimum overlap marker on the contralateral side of the Main Bifurcated Stent-Graft, confirm that the distal markers of the Leg Extension are aligned with the target distal landing location. Confirm the proximal markers of the Leg Extension remain within the overlap zone. (Figure 18).

Deployment of the Contralateral Leg Extension (steps 25 and 26)

Note: Deployment of the leg extension must be monitored under fluoroscopy at all times.

25. Begin deployment of the Contralateral Leg Extension by turning the Gray Turn Knob (clockwise with the arrow – Figure 12). Closely monitor the expansion of the Leg Extension under fluoroscopy to ensure proper location and adjust as necessary.

Note: Once the first stent of the Leg Extension is exposed, the Leg Extension should not be moved cranially.

26. Continue the deployment of the Leg Extension until the leg extension is fully deployed. Confirm that the distal markers of the Leg Extension remain within the overlap zone. (Figure 18).

Contralateral Leg Extension delivery system removal (Steps 27 through 36)

27. The Leg Extension Delivery System may be removed completely or may be disassembled, allowing for the sheath to remain behind as a working catheter.

28. To remove the system completely, the tip may be reseated onto the delivery sheath using steps 29-31.

29. Once the stent-graft is completely out of the delivery sheath, rotate the Gray Turn Knob in the opposite direction of the arrow until it is completely seated against the end of the Lead Screw.

30. Holding the Gray Turn Knob stationary, bring the Black Stationary Grip back to the Gray Turn Knob.

31. At this point, the delivery system tip is now seated properly with the sheath tip, and the entire delivery system can be removed.

32. To detach the sheath of the delivery system follow steps 33 – 36.

33. Ensure the Lead Screw is fully retracted by pulling the Gray Turn Knob all the way to the back end of the delivery system, such that the Lead Screw is against the end of the slot on the handle. The sheath release lever will now be exposed. It is not critical
where the Gray Turn Knob is relative to the Lead Screw. (Figure 20)

34. Lifting straight up, completely flip over the sheath release lever until it clicks in place next to the check valve. (Figure 21)

WARNING: WHEN DISENGAGING SHEATH RELEASE LEVER, HOLD THE BLUE HANDLE TUBE TO STEADY THE DEVICE. DO NOT HOLD BLACK GRIP.

CAUTION: For cases involving the detachment of the sheath, ensure that the tip of the leave behind sheath remains within the access artery at all times.

35. While holding the sheath with one hand, retract the Black Stationary Grip until the tip of the delivery system is seen at the hemostasis valve. It is advised that this be done under fluoroscopy to watch the tip of the delivery system as it is withdrawn through the Leg Extension. A dry gauze pad may be helpful to hold the sheath and keep it from moving. (Figure 22)

NOTE: If excessive force is needed or if tip snags on any of the devices, stop and evaluate the situation before proceeding.

36. While continuing to remove the delivery system, be sure to maintain control of the guidewire. Once the tip of the delivery system has cleared the hemostasis valve, the valve may be turned clockwise to maintain hemostasis if necessary.

Main Body Stent-Graft Deployment Completion (Step 37)

37. Release the ipsilateral side of the Bifurcated Stent-Graft by moving the Gray Turn Knob back until the Lead Screw is seated against the back end of the slot on the handle. (Figure 20)

Main Body Delivery System Removal (Steps 38 through 47)

38. The main delivery system may be removed completely or may be disassembled, allowing for the sheath to remain behind as a working catheter.

39. To remove the system completely, the tip may be reseated onto the delivery sheath using steps 40-42.

40. Once the Stent-Graft is completely out of the delivery sheath, rotate the Gray Turn Knob in the opposite direction of the arrow until it is completely seated against the end of the Lead Screw. Check to confirm that the bare stent clasp is still fully open.

41. Holding the Gray Turn Knob stationary, bring the Black Stationary Grip back to the Gray Turn Knob.

42. At this point, the delivery system tip is now seated properly with the sheath tip, and the entire delivery system can be removed.

43. To detach the sheath of the delivery system follow steps 44 – 47.

44. Ensure the Lead Screw is fully retracted by pulling the Gray Turn Knob all the way to the back end of the delivery system, such that the Lead Screw is against the end of the slot on the handle. It is not critical where the Gray Turn Knob is relative to the Lead Screw. (Figure 20)

45. Completely flip over the sheath release lever until it clicks in place next to the check valve. (Figure 21)

CAUTION: For cases involving the detachment of the sheath, ensure that the tip of the leave behind sheath remains within the access artery at all times.

46. While holding the sheath with one hand, retract the Black Stationary Grip until the tip of the delivery system is seen at the hemostasis valve. It is advised that this be done under fluoroscopy to watch the tip of the delivery system as it is withdrawn through the Main Body Stent-Graft. A dry gauze pad may be helpful to hold the sheath and keep it from moving. (Figure 22)

47. While continuing to remove the delivery system, be sure to maintain control of the guidewire. Once the tip of the delivery system has cleared the hemostasis valve, the valve may be turned clockwise to maintain hemostasis if necessary.

Preparation of the Ipsilateral Leg Extension (Step 48)

48. The ipsilateral leg extension is prepared and flushed in the same way as the Contralateral Leg Extension (steps 18 through 20).

Introduction and Advancement of the Ipsilateral Leg Extension Delivery System through Main Delivery System Introducer Sheath (steps 49 through 53)

49. While holding the hemostasis valve with one hand, advance the Leg Extension Delivery System over the wire until the tip of the Delivery System touches the hemostasis valve.

50. If closed, open the hemostasis valve by turning the knob counterclockwise. Insert the Leg Extension Delivery System through the hemostasis valve.

51. Continue to advance the Leg Extension Delivery System past the end of the introducer sheath while monitoring under fluoroscopy.

52. Advance the tip into the ipsilateral gate and into the Main Bifurcated Stent-Graft. Pay close attention as the tip of the Leg
Extension enters and advances into the Main Bifurcated Stent-Graft to ensure that the main stent-graft is not moved proximally. (Figure 23)

NOTE: The guidewire should always remain in the delivery system while inside the patient.

53. Continue to advance the Leg Delivery system noting the radiographic markers on the proximal end. The Main Bifurcated Stent-Graft has two markers that indicate the overlap region for the ipsilateral leg. The minimum overlap marker is located on the ipsilateral side of the main stent-graft, while the maximum overlap marker is the same maximum overlap marker as used on the contralateral side. Once the proximal end markers of the Leg Extension are past the minimum overlap marker on the ipsilateral side of the Main Bifurcated Stent-Graft, confirm that the distal markers of the Leg Extension are aligned with the target distal landing location. Confirm the proximal markers of the Leg Extension remain within the overlap zone.

NOTE: The distal radiographic markers on the Leg Extension must be beyond the end of the Main Introducer Sheath. If not, retract the Main Introducer Sheath while holding the Leg Extension Delivery System so that it does not move until the Main Introducer Sheath clears the distal markers of the Leg Extension.

Deployment of the Ipsilateral Leg Extension (steps 54 and 55)

Note: Deployment of the leg extension must be monitored under fluoroscopy at all times.

54. Begin deployment of the Ipsilateral Leg Extension by turning the Gray Turn Knob (clockwise with the arrow – Figure 12). Closely monitor the expansion of the Leg Extension under fluoroscopy to ensure proper location and adjust slowly as necessary. (Figure 24)

Note: Once the first stent of the Leg Extension is exposed, the Leg Extension should not be moved cranially.

55. Continue the deployment of the Leg Extension while observing the distal markers on the Leg Extension to ensure the sheath clears both. (Figure 25)

Ipsilateral Leg Delivery System Removal (steps 56 and 57)

56. Once the stent-graft is completely out of the delivery sheath, rotate the Gray Turn Knob in the opposite direction of the arrow until it is completely seated against the end of the Lead Screw.

57. Holding the Gray Turn Knob stationary, bring the Black Stationary Grip back to the Gray Turn Knob.

At this point, the delivery system tip is now seated properly with the sheath tip, and the entire delivery system can be removed.

Post Implant Procedure (Steps 58 through 63)

58. Balloon molding of the proximal and distal seal zones, as well as along the length of the limb extensions including the modular overlap, is recommended.

59. Kissing balloon technique should be considered in the areas of the prosthesis flow divider as well as in the area of the native aortic bifurcation.

60. Perform a final angiogram to assess for endoleaks, migration and aneurysm/lesion exclusion.

61. If a Type I endoleak is detected, consider balloon modeling to correct the leak. A Cuff device may also be considered to treat Type I endoleaks. For Cuff deployment see steps 64 through 71.

CAUTION: Do not exceed 1 atm. Balloon pressure. Always recheck position of stent-graft following balloononing.

62. Remove all catheters and sheaths from the access sites and perform standard surgical closure of the arteriotomy sites.

63. Assess blood flow to the distal extremities.

Cuff Device Deployment

The TREO system includes a Cuff that can be used in the following ways:

- To extend the system proximally.
- To resolve Type I endoleaks.
- As a stand-alone device used to treat focal lesions in the aorta. In order to use the Cuff Device as a stand-alone device, the following criteria must be met:
  - There must be a segment of aorta proximal to the lesion that meets the length and diameter requirements in Table 2a for the diameter device chosen.
  - There must be a segment of aorta distal to the lesion that meets the length and diameter requirements in Table 2a for the diameter device chosen.
  - The total length of the minimum required proximal seal zone, lesion and minimum required distal seal zone must be equal to or less than the covered length of the cuff device chosen.

The stent-graft uses the same type of delivery system as the Main Bifurcated Stent-Graft, and is implanted in the same way as the main stent-graft. The proximal extension is available in the same diameters as the main stent-graft and in three covered lengths, 40 mm, 55 mm and 70 mm.
Cuff Delivery System Preparation
(Step 64)
64. The Cuff delivery system is prepared in the same way as the main delivery system (steps 5 through 7).

Introduction and Advancement of Cuff Device (Steps 65 and 66)
NOTE: The main delivery system sheath must be removed prior to introducing the Cuff.
65. While holding and directing the tip and introducer sheath with one hand and holding the Black Stationary Grip with the other hand, advance the introducer sheath into the artery over the guidewire.
NOTE: The guidewire should always remain in the delivery system while inside the patient.
NOTE: Advancing the Cuff must be fluoroscopically monitored. When placing the cuff device into a previously placed device, ensure that the deployed stent-grafts are not moved by the Cuff delivery system.
66. Under fluoroscopic monitoring, advance the sheath until the delivery system tip is near the deployment site in the aorta. Continue advancing while observing the markers at the proximal end of the stent-graft. Advance until the proximal end of the stent-graft is at the deployment site.
NOTE: When placing the cuff device into a previously placed device, ensure that there is enough overlap between the Cuff and Main Bifurcated Stent-Graft by ensuring that the distal marker on the Cuff is at least 3 cm distal to the Main Stent-Graft’s proximal markers.

Deployment of Cuff
(Steps 67 through 71)
NOTE: Stent-graft deployment should be done while observing the proximal end of the stent-graft under fluoroscopy.
NOTE: The Cuff is deployed in the same way as the Main Stent-Graft.
67. Holding the Black Stationary Grip, rotate the Gray Turn Knob clockwise (in direction of arrow on the Turn Knob) to start the deployment of the Cuff. Observe the proximal end of the Cuff as it starts to expand, noting any movement of the Cuff that may have occurred.
68. Once the Cuff’s position is confirmed, continue to deploy the stent-graft until the sheath tip is distal to the end of the Cuff and allowing full expansion of the Cuff. This part of the deployment can be done by continuing to turn the Gray Turn Knob or pinning the Black Stationary Grip and pulling the Gray Turn Knob, without turning, as would be done in a typical “pin and pull” system.
69. Release the bare stent by retracting the release grip. To do this, first hold either the blue handle tube or black stationary grip with one hand. While pushing (1) the grey knob towards the black release grip, turn the grey knob (2) [Figure 15]. The black release grip will partially release from the grey knob [Figure 16 (NOTE: The bare stent is still fully clasped at this point.)]. To release the bare stent, move the Black Release Grip completely towards the Guidewire Flush Port while observing the clasp under fluoroscopy. The operator will feel two sets of clicks, which will ensure the black release grip is fully seated in the grey knob. (Figures 15 17and 16).
70. Rotate the Gray Turn Knob counterclockwise (opposite direction of arrow) as far as it will go. Then, pull back the Black Stationary Grip while holding the Gray Turn Knob stationary. The tip will move through the stent-grafts and must be monitored under fluoroscopy to ensure that the stent-grafts are not moved.
71. Continue pulling on the Black Stationary Grip until the tip is re- seated on the sheath and pull the delivery system out from the patient.

10. MRI SAFETY INFORMATION

MR Conditional
Non-clinical testing demonstrated that the TREO Abdominal Stent-Graft is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
- Static magnetic field of 1.5 Tesla or 3.0 Tesla, only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
Under the scan conditions defined above, the TREO Abdominal Stent-Graft is expected to produce a maximum temperature rise of 1.7ºC after 15 minutes of continuous scanning.
In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the TREO Abdominal Stent-Graft when imaged with a gradient echo pulse sequence and a 3 T MRI system. This artifact does not obscure the device lumen.
SYMBOLS/DEFINITIONS

- Do not Re-use
- Do not Re-Sterilize
- Model/Catalogue Number
- Use By
- Caution
- Consult Instructions for use
- Date of Manufacture
- Manufacturer
- Lot Number
- Store in a cool, dry place
- Do not use if package is damaged
- Sterilized by Irradiation

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