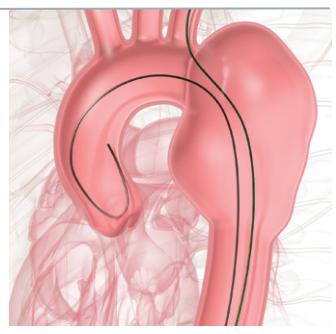
GORE® TAG®

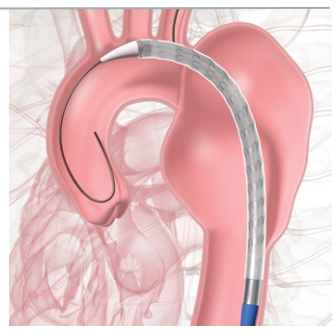
Thoracic Branch Endoprosthesis

DEPLOYMENT SEQUENCE

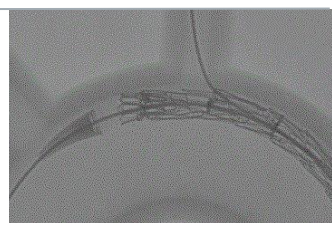
1 Establish necessary sheath and guidewires for the Aortic Component (AC) and Side Branch Component (SB) delivery.



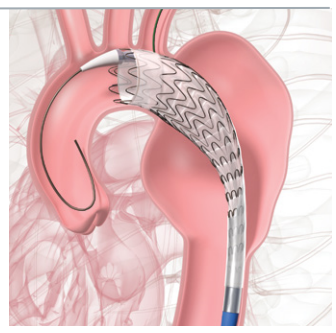
2 Advance the AC over both wires to intended treatment site.



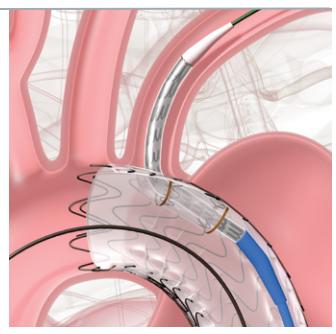
3 Remove wire wrap and ensure that the AC portal is rotationally aligned with the left subclavian artery.



4 Advance AC past target location, position the device on the outer curve of the aorta, then retract to desired deployment location, and deploy using a steady and continuous two-person deployment technique. Remove the AC catheter.

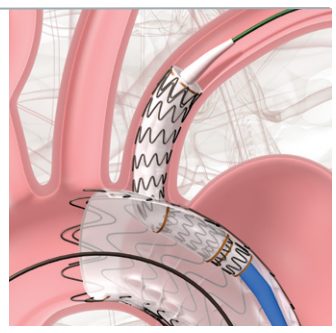


5 Advance SB Component into portal of AC, aligning middle marker of SB with trailing portal marker.



6 Deploy SB Component using a two-person deployment technique. Remove the side branch catheter.

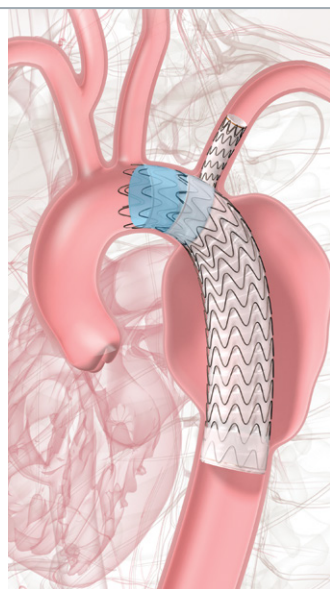
Balloon the entire length of the SB Component using a compliant or 2 cm long non-compliant balloon. Only use hand inflation when in the bend of the SB to avoid straightening the anatomy and potentially causing device migration.



OPTIONAL EXTENSION STEPS

A. Proximal aortic extension

If proximal extension is required, advance the Aortic Extender (AE) over the aortic guidewire and past the intended deployment location. Rotate the catheter such that the radiopaque olive marker appears as a circle adjacent to the aortic wall. Position AE on the outer curve of the aorta, then retract to desired deployment location and deploy using a steady and continuous two-person deployment technique. Remove the AE catheter.



Minimum extension

AE must extend minimally outside of aortic component such that leading gold marker of AE is aligned with bare apices of AC.

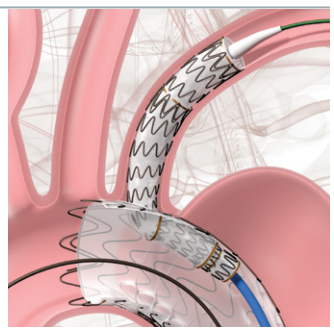
Maximum extension

AE may extend up to half device length outside AC.

B. Side branch extension

If a second SB Component is needed, it is recommended not to extend the SB Component by more than 20 mm.

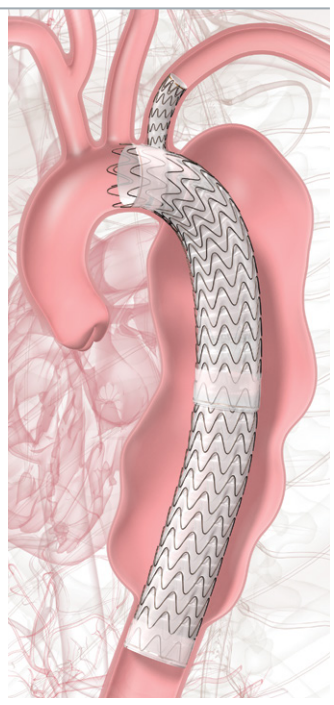
Alignment of the middle marker of the SB extension device with the leading marker of the AC portal indicates that extension is 15-20 mm beyond the first SB device.



C. Distal aortic extension

Distal extension can be achieved using the GORE® TAG® Conformable Thoracic Stent Graft. This device can be implanted before or after GORE® TAG® Thoracic Branch Endoprosthesis (TBE).

If distal extensions with the GORE® TAG® Conformable Device are implanted after TBE, the proximal edge of the GORE® TAG® Device extension should be at least 1 cm distal to the trailing end of the SB Component.



Physicians are responsible for completing prerequisite training and for subsequent device use.

Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® TAG® Thoracic Branch Endoprosthesis is indicated for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who have: **Adequate iliac/femoral access; Proximal Aortic Landing Zones:** For Isolated Lesion Patients: Proximal landing zone cannot be aneurysmal, dissected, heavily calcified, or heavily thrombosed; For Dissection Patients: Primary entry tear must be distal to the left subclavian artery and the proximal extent of the landing zone must not be dissected; Aortic inner diameter range 16-42 mm; Proximal segment length (length from distal edge of left subclavian artery to mid left common carotid ostium) of at least 2.0-4.0 cm, depending on Aortic Component selection; Proximal covered length (measured from distal edge of left subclavian artery to distal edge of left common carotid artery ostium) of at least 15–36 mm, depending on Aortic Component selection; For patients with prior ascending aorta or aortic arch repair with surgical graft: at least 2 cm landing zone proximal to the distal anastomosis; **Left Subclavian Landing Zone:** Landing zone cannot be aneurysmal, dissected, heavily thrombosed and severely tortuous (180 degree turn within the treated length); Left subclavian artery inner diameter of 6–18 mm, depending on Side Branch Portal diameter selected; Left subclavian artery minimum length of 2.5–3.0 cm, depending on Side Branch Portal diameter selected. **Distal Landing Zone (Isolated Lesion Patients only):** Outer curve length must be ≥ 2 cm proximal to celiac artery; Aortic inner diameter range 16-42 mm; Non aneurysmal, dissected, heavily calcified, or heavily thrombosed landing zone; Native Aorta or previously placed GORE® TAG® Conformable Thoracic Stent Graft. **CONTRAINDICATIONS:** The GORE® TAG® Thoracic Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials [ePTFE (polytetrafluoroethylene), FEP (fluoroethylpropylene), Nitinol (nickel, titanium), Gold, SB Component only - Heparin (CBAS® Heparin Surface]; Patients who have a condition that threatens to infect the graft; Patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II. Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $R_{X\ Only}$

Products listed may not be available in all markets.

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