Together, improving life

GORE® TAG®

Thoracic Branch Endoprosthesis

PROCEDURAL AID

The steps described here may not be complete, and are not intended to be a replacement for the *Instructions for Use* (IFU) or the education, training and professional judgment of health care providers (HCP). HCPs remain solely responsible for making decisions about patient care and the use of medical technologies.

ACCESS

Step		Action:	Reason:
1	Establish side branch wire.	Utilize catheter from arm while snaring and snare in the descending aorta.	Catheter protects the branch vessel while snaring and can remain for introduction of Aortic Component (AC) and Side Branch Component (SB).
		Select an appropriate side branch guidewire.	A stiffer Side Branch guidewire may help with rotational alignment of the portal during Aortic Component positioning. A softer Side Branch guidewire may be beneficial when advancing the Side Branch to the intended location.

AORTIC COMPONENT (AC)

Step		Action:	Reason:
2	Remove wire wrap.	Make sure the AC is outside of the introducer sheath.	Rotating the AC within the sheath can damage the AC.
		Advance or retract the AC while rotating the catheter.	Moving the AC while rotating can help translate the rotations of the handle to the constrained AC.
		Rotate AC in straight portion of anatomy.	Attempting to rotate the AC in a bend can lead to difficulty with AC rotation and can lead to premature partial deployment, which can potentially damage the AC.
		Be careful not to over-rotate the AC handle without visualizing the constrained AC rotation.	Over-rotating the AC delivery system can loosen the deployment line and lead to premature partial deployment.
3	Position the AC portal rotationally aligned with the target branch vessel.	A stiff branch wire can help rotationally align the AC.	A stiff wire can help align the portal. Deploying the AC with the portal misaligned can make completing the procedure with the SB Component difficult (See image glossary, *image A*).

Step		Action:	Reason:
4	Make sure the portal is not distal to the ostium of the target branch vessel.	Maximize proximal landing zone by deploying as proximal as possible, save enough room for the SB Component to exit the portal and enter the target branch vessel (See image glossary, *image B*).	Deploying as proximal as possible (but still within *Instructions for Use)* can help ensure a good seal with the AC and SB Component. Deploying too far distal can make completing the procedure with the SB Component difficult and may require more than one SB Component.
		If the portal cannot be advanced past the distal edge of the target branch vessel, consider a softer branch wire or reducing the tension on the through wire.	If the SB Component wire is too stiff, the wire may act as a barrier and prevent the AC from advancing further proximal.
5	AC deployment steps.	Advance device past target location.	The last movement of deployment needs to be distal to ensure stored energy is removed from the delivery system, so first the device must be advanced past the target location.
		Apply forward pressure on the guidewire to push AC to the outer curve.	The AC needs to be positioned along the outer curve to ensure accurate deployment.
		Retract AC to desired deployment location.	Retracting the device removes any stored energy in the delivery system to ensure an accurate deployment.
		Rapidly deploy using a two-person deployment technique.	Rapid deployment will prevent “windsocking,” which could lead to a distal inaccuracy. The two-person deployment technique ensures that the catheter does not move the device during deployment.

SIDE BRANCH COMPONENT (SB)

Step		Action:	Reason:
6	Advance SB Component into portal of AC.	Protect branch vessel with catheter or sheath from arm.	Utilizing a catheter or sheath from the arm helps protect the branch vessel from trauma, including new dissection. The catheter/sheath also prevents branch wire from prolapsing around proximal end of AC.
		If the SB Component does not go in portal right away, utilize catheter/ sheath to buttress tip of SB Component olive to guide SB Component into portal.	The catheter/sheath can guide the leading end of the SB Component into the portal. Requires coordinated effort with arm and leg manipulations.
		If getting the SB Component into the portal is still difficult, apply pressure on wire from both the arm and leg simultaneously to get the SB Component on the outer curve.	Creating an “S” shape with the wire can help to get the SB Component olive off the portal of the AC and allow entry into the portal.
		If getting SB Component into portal is still difficult, switch to softer wire.	Switching to a softer wire may help the SB Component find a better path into portal.
		Do NOT rotate the SB Component catheter.	Rotating the SB Component catheter may lead to premature deployment and/or catheter breakage.

Step		Action:	Reason:
7	Position SB Component for deployment.	Align middle marker of SB Component with the trailing portal marker (See image glossary, *image C*).	Middle marker of SB Component should be aligned with portal marker or up to 5 mm outside of portal marker so the flared apex region of SB Component is outside the portal.
		Land leading end of SB Component in straight segment of branch vessel.	Ensure leading end of SB Component does not terminate in a bend of the branch vessel.
		If a second SB Component is needed, aligning the middle marker of the SB Component with the leading AC portal marker will achieve 15–20 mm extension, depending on deployment location of the first SB Component (See image glossary, *image D*).	Extending by > 20 mm could result in a Type III endoleak or other complication. Extending by ≤ to 20 mm is acceptable.

AORTIC EXTENDER (AE)

Step		Action:	Reason:
8a	AE orientation and alignment.	Ensure orientation marker in olive looks like a dot on the outer curve (See image glossary, *image E*).	AE must be rotationally aligned for accurate deployment. Recall that the orientation marker must be on the outer curve for the seamline to be on the inner curve.
		The AE may be deployed so that: Maximum extension: Up to half the length of the AE is past the proximal apices of the AC (See image glossary, *image F*). Minimum extension: The proximal gold band of the AE is flush with the proximal apices of the AC (See image glossary, *image F*).	Deploying the AE beyond the max extension may not provide adequate seal and could lead to Type III endoleaks. Deploying the AE below the min extension may result in wire fracture.

Step		Action:	Reason:
8b	AE deployment steps.	If the AE is hung up on the portal, retract device and advance again until the device is on the outer curve (See image glossary, *image G*).	If the AE is caught on the portal of the AC it is not on the outer curve, which may lead to inaccurate deployment.
		Advance device past target location.	The last movement of deployment needs to be distal to ensure stored energy is removed from the delivery system; therefore, the device must first be advanced past the target location.
		Apply forward pressure on the guidewire to push AE to the outer curve.	The AE needs to be positioned along the outer curve to ensure accurate deployment.
		Retract AE to desired deployment location.	Retracting the device removes any stored energy in the delivery system to ensure an accurate deployment.
		Rapidly deploy using a two-person deployment technique.	The two-person deployment technique ensures that the catheter does not move the device during deployment. Deployment must be rapid to ensure the AE opens all at one time.

AORTIC EXTENDER (AE)

Step		Action:	Reason:
8c	AE catheter removal.	First movement should be distal with catheter and wire.	This gets the olive off the outer curve to avoid the proximal apices of the AC.
		Once olive is clear of the proximal apices of the AC, push on wire to get catheter on outer curve for sleeve removal.	Catheter being on the outer curve will minimize sleeve interaction with the AE.
		Upon deployment, if the deployment line is not able to be removed completely, but the AE is fully deployed, the deployment line may still be engaged with the AE. If this occurs, follow these techniques to remove the catheter: – Rotate the catheter one full revolution before withdrawing catheter. – If distal movement of device occurs during catheter withdrawal, rotate the catheter one full revolution while pushing forward on catheter. – If catheter is still engaged with extender, rotate the catheter another full rotation while retracting catheter (See image glossary, *image H*).	If deployment line is not able to be completely removed, not rotating the catheter before retracting could cause distal movement of the AE. Note that the catheter is not mated to the AE. Be careful not to push the AE forward when pushing forward on the AE catheter. Recall that the AE sleeve is attached to the catheter and must be removed with the catheter. Note this has never occurred clinically but has been seen during testing.

Step		Action:	Reason:
8c	AE catheter removal. *(continued)*	Once the AE olive is past the partially uncovered stents, the trailing edge of the AE sleeve may engage with an SB component flared apex. If this occurs, the following techniques may be used to retract the AE catheter: – Push forward slightly on the AE catheter to disengage the AE sleeve from the SB Component flared apex. – If the AE sleeve is still engaged, rotate slightly (up to 180°) while pulling the catheter to disengage the AE sleeve from the SB Component flared apex (See image glossary, *image I*).	Retracting the AE catheter without first detaching from the SB Component could result in SB migration. Be careful not to push the AE forward when pushing forward on the AE catheter. Recall that the AE sleeve is attached to the catheter and must be removed with the catheter. Note this has never occurred clinically but has been seen during testing.

DEVICE BALLOONING

Step		Action:	Reason:
9	Device ballooning.	Balloon the AC and/or AE only if endoleak is present.	Ballooning should be kept to a minimum and only utilized when necessary for the AC and AE.
		Balloon entire length of SB Component.	The entire length of the SB Component must be ballooned to minimize risk of branch occlusion.
		Use only hand-inflation for ballooning the bend of the SB Component.	Using an inflation device or anything other than hand inflation in the bend of the SB Component may overly straighten the SB Component, causing AC and SB migration.
		The last thing that should be ballooned is the SB Component (If SB Component was already ballooned, but then the AC or AE was ballooned, the SB Component must be ballooned again).	Ballooning the SB Component last ensures it is patent and not affected by other ballooning.

GORE® TAG®
Thoracic Branch Endoprosthesis

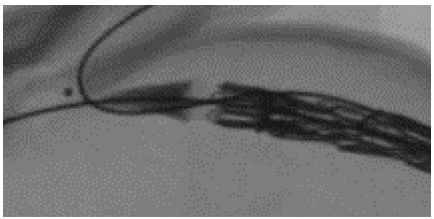
IMAGE GLOSSARY

IMAGE GLOSSARY

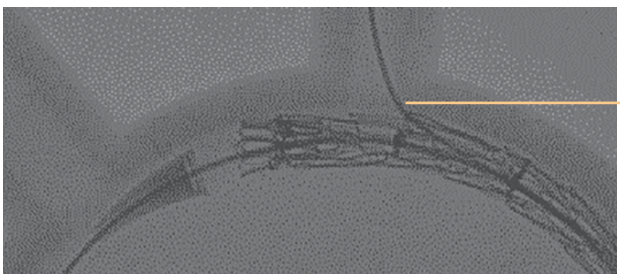
Aortic Component (AC)

A

✗ NO

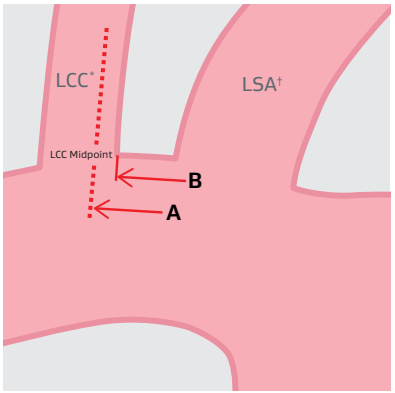


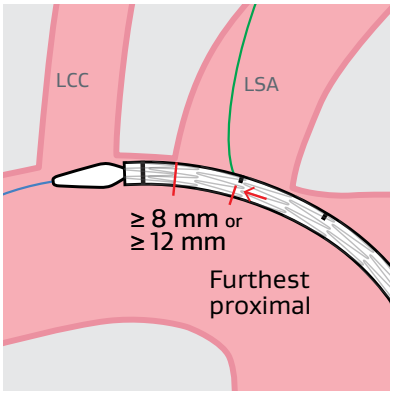
✓ YES

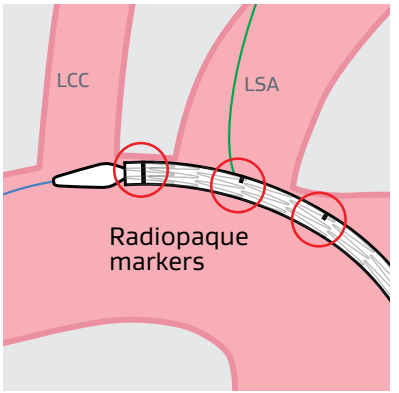


Branch guidewire extending from the delivery catheter

B





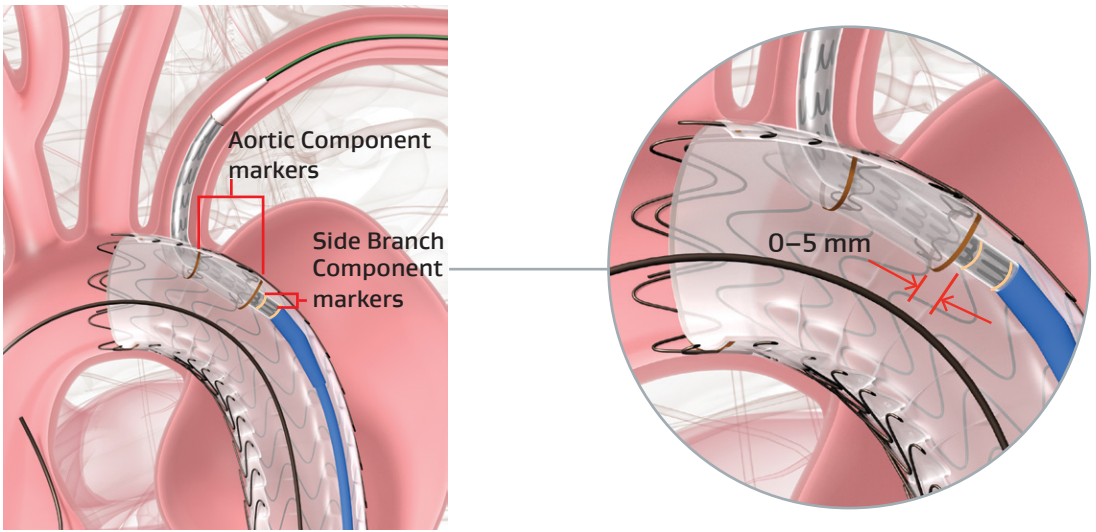


* Left common carotid (LCC)
† Left subclavian artery (LSA)

IMAGE GLOSSARY

Side Branch Component (SB)

C



Side Branch Component (SB)

D

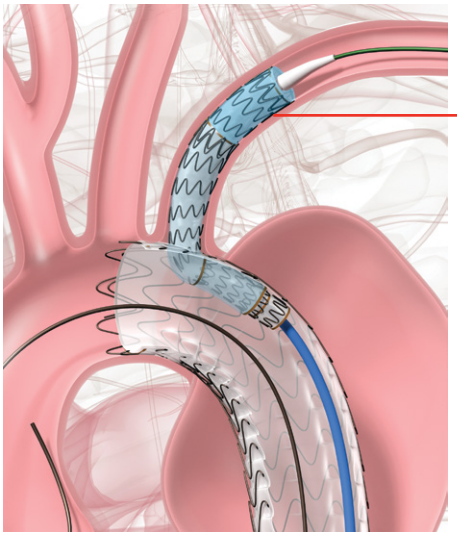
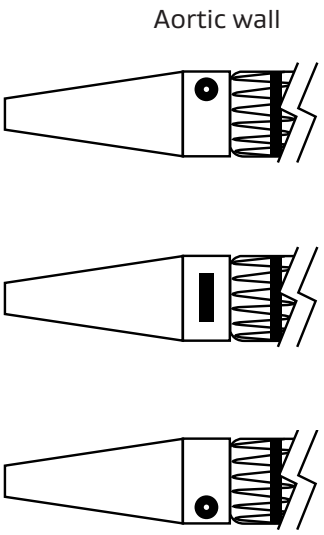
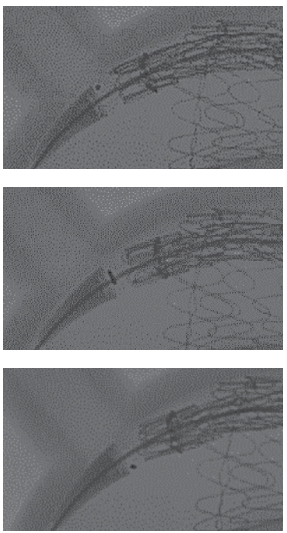


IMAGE GLOSSARY

Aortic Extender (AE)

E





Aortic Extender (AE)

F

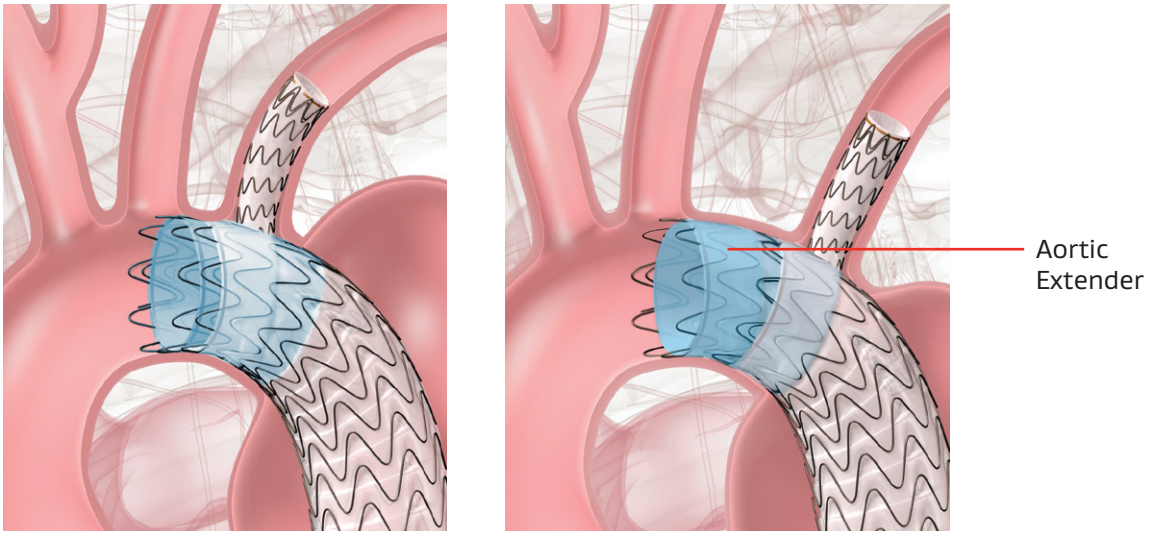
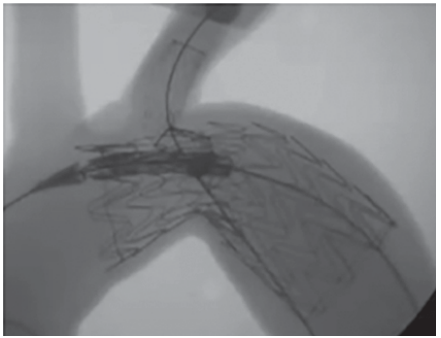


IMAGE GLOSSARY

Aortic Extender (AE)

G

✗ INCORRECT



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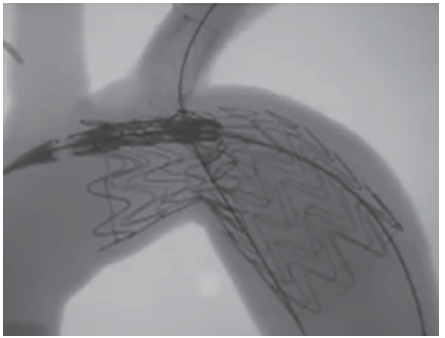

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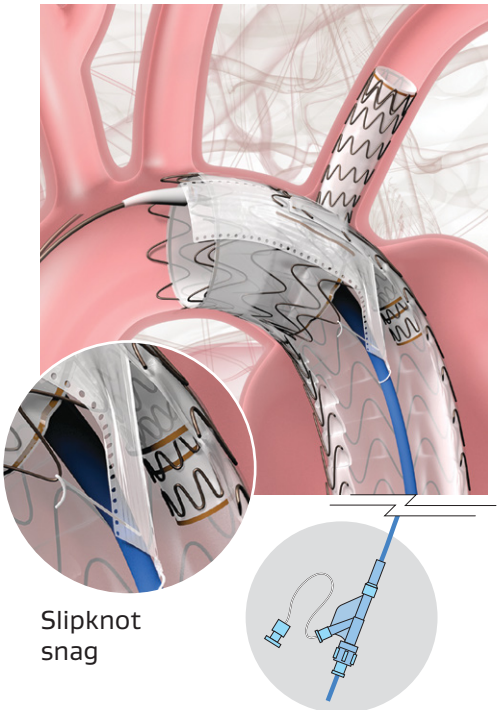
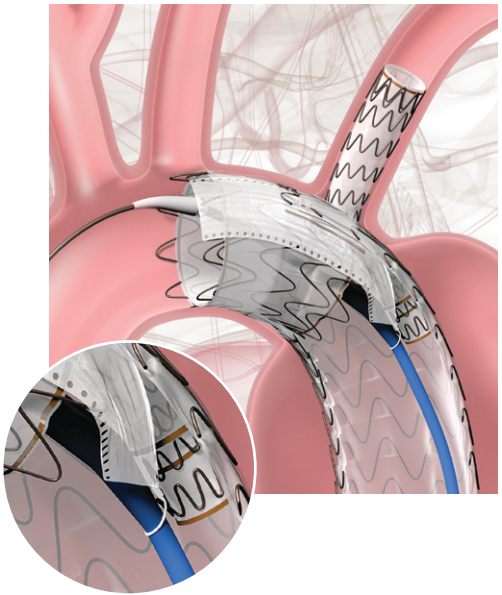


Slipknot
snag

I



Side Branch Component
interaction

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. ℞ Only

Products listed may not be available in all markets.

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