

AAA ENDOGRAFT FIXATION SYSTEMS

Company Name	Product Name	Components	Sizes	Description	FDA Indicated Use
Aptus Endosystems, Inc.	HeliFX Aortic Securement System	HeliFX Guide	16-F OD; 62-cm working length; 0.035-inch wire compatible	Deflecting guide catheter used to position HeliFX Applier to implant EndoAnchors	The HeliFX System is indicated for use in patients whose endografts have exhibited migration or endoleak, or are at risk of such complications, in whom augmented fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion; the EndoAnchor and HeliFX System have been evaluated via in vitro testing and determined to be compatible with the Cook Zenith, Gore Excluder, Medtronic AneuRx, Medtronic Endurant, and Medtronic Talent endografts; use with other endografts has not been evaluated
		HeliFX Applier	12-F OD; 86-cm working length	Battery operated delivery system with 2-stage EndoAnchor deployment with repositioning capability	
		EndoAnchor Cassette (contains 10 EndoAnchors)	0.5-mm round wire; 3-mm diameter X 4.5-mm length helix	Helical EndoAnchor implants designed to provide independent transmural fixation of an endograft to the aortic wall by augmenting the endograft's inherent sealing and fixation mechanisms	