

## **ENVAST™ CORONARY THROMBECTOMY SYSTEM TECHNICAL SPECIFICATIONS**

Product Description	Product Number (SKU)	GTIN	Max Diamet er (mm)	Working Length (mm)	Total Basket Length (mm)	Num- ber of Drop Zones	Micro- Cath. Compa tibility	Indicated for vessel sizes (mm)
enVast 4.0 x 30 mm	EV-4030-F2RR	00851279008699	4.0	30	39	2	.021"	≥ 2.0 and ≤ 3.5
enVast 4.5 x 37 mm	EV-4537-F2RR	00851279008712	4.5	37	57	2	.021"	≥ 2.0 and ≤ 4.5
enVast 4.5 x 46 mm	EV-4546-F3RR	00851279008729	4.5	46	66	3	.021"	≥ 2.0 and ≤ 4.5
enVast 6.0 x 35 mm	EV-6035-F2RR	00851279008736	6.0	35	55	2	.027"	≥ 3.5 and ≤ 6.0

Parameter	Specifications				
Material	Basket: laser cut from Nitinol tube				
	Pusher wire: Nitinol				
	Fluoro-opaque Markers: Platinum & Tungsten				
Distal tip	Soft and flexible, platinum coil wind over tapered nitinol core				
Pusher wire length	180 cm				
Fluoro Markers	"Zebra" marker band on the pusher wire				
	10 x 1 cm shiny silver bands, separated 1 cm from each other				
	Max 130 cm from NeVa distal tip				
Radial Force	Radial force optimized: higher expansive forces for efficacy in clot interaction and lower				
	compressive forces for vessel safety				
Tensile Strength	.083" lbf (minimum)				
Torque Strength	10 cycles without damage to device				
Re-Sheathing	Up to 3 times				
Radio-Detectability	User should be able to easily visualize the NeVa device with smart markers at Proximal, drop				
	zones, and distal locations by fluoroscopy during deployment				
Packaging & Sterilization	Individually packaged and ETO sterilized per ISO 11135: 2014				
Shelf-life	2 years maximum from date of manufacture				
Corrosion Resistance	No sign of corrosion				
Biocompatibility	Must be biocompatible per ISO 10993-1				
Latex	No known latex material used in the manufacturing of the NeVa device				
Labeling	Device to have descriptive labels identifying the content in compliance with EN ISO 15223-1				
	and EN 1041				
Storage Conditions	Room temperature				