

Device Schedule:

Device Name: EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System

Type: MDN 1101

Intended Purpose as per the Instructions for Use:

The intended purpose of the EverFlex self-expanding stent with Entrust delivery system is for recanalization of stenoses or occlusions to restore blood flow to peripheral arteries. Implanting the EverFlex stent in the target vessel restores lumen patency and re-establishes blood flow in the artery through the gentle, outward force exerted by the stent.

Risk Classification: Class IIb Implantable

Basic UDI-DI: 0763000B00003327A

Model Number	Diameter (mm)	Length (mm)
EVX35-05-020-080	5	20
EVX35-05-040-080	5	40
EVX35-05-060-080	5	60
EVX35-05-080-080	5	80
EVX35-05-100-080	5	100
EVX35-05-120-080	5	120
EVX35-05-150-080	5	150
EVX35-06-020-080	6	20
EVX35-06-040-080	6	40
EVX35-06-060-080	6	60
EVX35-06-080-080	6	80
EVX35-06-100-080	6	100

Model Number	Diameter (mm)	Length (mm)
EVX35-06-120-080	6	120
EVX35-06-150-080	6	150
EVX35-07-020-080	7	20
EVX35-07-040-080	7	40
EVX35-07-060-080	7	60
EVX35-07-080-080	7	80
EVX35-07-100-080	7	100
EVX35-07-120-080	7	120
EVX35-07-150-080	7	150
EVX35-08-020-080	8	20
EVX35-08-040-080	8	40
EVX35-08-060-080	8	60
EVX35-08-080-080	8	80
EVX35-08-100-080	8	100
EVX35-08-120-080	8	120
EVX35-08-150-080	8	150
EVX35-05-020-120	5	20
EVX35-05-040-120	5	40
EVX35-05-060-120	5	60
EVX35-05-080-120	5	80
EVX35-05-100-120	5	100
EVX35-05-120-120	5	120

Model Number	Diameter (mm)	Length (mm)
EVX35-05-150-120	5	150
EVX35-06-020-120	6	20
EVX35-06-040-120	6	40
EVX35-06-060-120	6	60
EVX35-06-080-120	6	80
EVX35-06-100-120	6	100
EVX35-06-120-120	6	120
EVX35-06-150-120	6	150
EVX35-07-020-120	7	20
EVX35-07-040-120	7	40
EVX35-07-060-120	7	60
EVX35-07-080-120	7	80
EVX35-07-100-120	7	100
EVX35-07-120-120	7	120
EVX35-07-150-120	7	150
EVX35-08-020-120	8	20
EVX35-08-040-120	8	40
EVX35-08-060-120	8	60
EVX35-08-080-120	8	80
EVX35-08-100-120	8	100
EVX35-08-120-120	8	120
EVX35-08-150-120	8	150

Model Number	Diameter (mm)	Length (mm)
EVX35-05-020-150	5	20
EVX35-05-040-150	5	40
EVX35-05-060-150	5	60
EVX35-05-080-150	5	80
EVX35-05-100-150	5	100
EVX35-05-120-150	5	120
EVX35-05-150-150	5	150
EVX35-06-020-150	6	20
EVX35-06-040-150	6	40
EVX35-06-060-150	6	60
EVX35-06-080-150	6	80
EVX35-06-100-150	6	100
EVX35-06-120-150	6	120
EVX35-06-150-150	6	150
EVX35-07-020-150	7	20
EVX35-07-040-150	7	40
EVX35-07-060-150	7	60
EVX35-07-080-150	7	80
EVX35-07-100-150	7	100
EVX35-07-120-150	7	120
EVX35-07-150-150	7	150
EVX35-08-020-150	8	20

Model Number	Diameter (mm)	Length (mm)
EVX35-08-040-150	8	40
EVX35-08-060-150	8	60
EVX35-08-080-150	8	80
EVX35-08-100-150	8	100
EVX35-08-120-150	8	120
EVX35-08-150-150	8	150