

Device Schedule:

Device Name: Endurant

Intended Purpose as per the Instructions for Use:

The intended use of the Endurant stent graft system is to repair infrarenal abdominal aortic or aortoiliac aneurysms in an endovascular approach by providing an alternative conduit for blood flow within the patient's vessel (aorta and iliac arteries) by excluding the aneurysm (target lesion).

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00001977U

Type (Codes as per (EU) 2017/2185): MDN 1101

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Bifurcated	ENBF2313C120EE	23	13	120
	ENBF2316C120EE	23	16	120
	ENBF2313C145EE	23	13	145
	ENBF2316C145EE	23	16	145
	ENBF2313C170EE	23	13	170
	ENBF2316C170EE	23	16	170
	ENBF2513C120EE	25	13	120
	ENBF2516C120EE	25	16	120
	ENBF2513C145EE	25	13	145
	ENBF2516C145EE	25	16	145
	ENBF2513C170EE	25	13	170
	ENBF2516C170EE	25	16	170
	ENBF2813C120EE	28	13	120
	ENBF2816C120EE	28	16	120
	ENBF2820C120EE	28	20	120

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Bifurcated	ENBF2813C145EE	28	13	145
	ENBF2816C145EE	28	16	145
	ENBF2820C145EE	28	20	145
	ENBF2813C170EE	28	13	170
	ENBF2816C170EE	28	16	170
	ENBF2820C170EE	28	20	170
	ENBF3216C120EE	32	16	120
	ENBF3220C120EE	32	20	120
	ENBF3216C145EE	32	16	145
	ENBF3220C145EE	32	20	145
	ENBF3216C170EE	32	16	170
	ENBF3220C170EE	32	20	170
	ENBF3616C145EE	36	16	145
	ENBF3620C145EE	36	20	145
	ENBF3616C170EE	36	16	170
	ENBF3620C170EE	36	20	170
Aortic extension	ENCF2323C45EE	23	23	45
	ENCF2525C45EE	25	25	45
	ENCF2828C45EE	28	28	45
	ENCF3232C45EE	32	32	45
	ENCF3636C45EE	36	36	45

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Iliac extension	ENEW1010C80EE	10	10	80
	ENEW1313C80EE	13	13	80
	ENEW2020C80EE	20	20	80
	ENEW2424C80EE	24	24	80
	ENEW2828C80EE	28	28	80
Contralateral limb	ENLW1610C80EE	16	10	80
	ENLW1613C80EE	16	13	80
	ENLW1616C80EE	16	16	80
	ENLW1620C80EE	16	20	80
	ENLW1624C80EE	16	24	80
	ENLW1628C80EE	16	28	80
	ENLW1610C95EE	16	10	95
	ENLW1613C95EE	16	13	95
	ENLW1616C95EE	16	16	95
	ENLW1620C95EE	16	20	95
	ENLW1624C95EE	16	24	95
	ENLW1628C95EE	16	28	95
	ENLW1610C120EE	16	10	120
	ENLW1613C120EE	16	13	120
	ENLW1616C120EE	16	16	120
	ENLW1620C120EE	16	20	120
	ENLW1624C120EE	16	24	120
	ENLW1628C120EE	16	28	120

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Abdominal tube	ENTF2323C70EE	23	23	70
	ENTF2525C70EE	25	25	70
	ENTF2828C70EE	28	28	70
	ENTF3232C70EE	32	32	70
	ENTF3636C70EE	36	36	70
Aorto-Uni-Iliac (AUI)	ENUF2314C105EE	23	14	105
	ENUF2514C105EE	25	14	105
	ENUF2814C105EE	28	14	105
	ENUF3214C105EE	32	14	105
	ENUF3614C105EE	36	14	105

Device Schedule:

Device Name: Endurant II

Intended Purpose as per the Instructions for Use:

The intended use of the Endurant II/IIs stent graft system is to repair infrarenal abdominal aortic or aortoiliac aneurysms, or juxtarenal abdominal aortic or aortoiliac aneurysms (with a parallel graft technique), in an endovascular approach by providing an alternative conduit for blood flow within the patient's vessel (aorta and iliac arteries) by excluding the aneurysm (target lesion).

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00001977U

Type (Codes as per (EU) 2017/2185): MDN 1101

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Bifurcated	ETBF2313C124EE	23	13	124
	ETBF2316C124EE	23	16	124
	ETBF2313C145EE	23	13	145
	ETBF2316C145EE	23	16	145
	ETBF2313C166EE	23	13	166
	ETBF2316C166EE	23	16	166
	ETBF2513C124EE	25	13	124
	ETBF2516C124EE	25	16	124
	ETBF2513C145EE	25	13	145
	ETBF2516C145EE	25	16	145
	ETBF2513C166EE	25	13	166
	ETBF2516C166EE	25	16	166
	ETBF2813C124EE	28	13	124
	ETBF2816C124EE	28	16	124
	ETBF2820C124EE	28	20	124

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Bifurcated	ETBF2813C145EE	28	13	145
	ETBF2816C145EE	28	16	145
	ETBF2820C145EE	28	20	145
	ETBF2813C166EE	28	13	166
	ETBF2816C166EE	28	16	166
	ETBF2820C166EE	28	20	166
	ETBF3216C124EE	32	16	124
	ETBF3220C124EE	32	20	124
	ETBF3216C145EE	32	16	145
	ETBF3220C145EE	32	20	145
	ETBF3216C166EE	32	16	166
	ETBF3220C166EE	32	20	166
	ETBF3616C145EE	36	16	145
	ETBF3620C145EE	36	20	145
	ETBF3616C166EE	36	16	166
	ETBF3620C166EE	36	20	166
Aortic extension	ETCF2323C49EE	23	23	49
	ETTF2323C70EE	23	23	70
	ETCF2525C49EE	25	25	49
	ETTF2525C70EE	25	25	70
	ETCF2828C49EE	28	28	49
	ETTF2828C70EE	28	28	70
	ETCF3232C49EE	32	32	49
	ETTF3232C70EE	32	32	70
	ETCF3636C49EE	36	36	49
	ETTF3636C70EE	36	36	70

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Iliac extension	ETEW1010C82EE	10	10	82
	ETEW1313C82EE	13	13	82
	ETEW2020C82EE	20	20	82
	ETEW2424C82EE	24	24	82
	ETEW2828C82EE	28	28	82
Aorto-Uni-Iliac (AUI)	ETUF2314C102EE	23	14	102
	ETUF2514C102EE	25	14	102
	ETUF2814C102EE	28	14	102
	ETUF3214C102EE	32	14	102
	ETUF3614C102EE	36	14	102
Limb	ETLW1610C82EE	16	10	82
	ETLW1613C82EE	16	13	82
	ETLW1616C82EE	16	16	82
	ETLW1620C82EE	16	20	82
	ETLW1624C82EE	16	24	82
	ETLW1628C82EE	16	28	82
	ETLW1610C93EE	16	10	93
	ETLW1613C93EE	16	13	93
	ETLW1616C93EE	16	16	93
	ETLW1620C93EE	16	20	93
	ETLW1624C93EE	16	24	93
	ETLW1628C93EE	16	28	93
	ETLW1610C124EE	16	10	124
	ETLW1613C124EE	16	13	124
	ETLW1616C124EE	16	16	124
	ETLW1620C124EE	16	20	124
	ETLW1624C124EE	16	24	124
	ETLW1628C124EE	16	28	124

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Limb	ETLW1610C146EE	16	10	146
	ETLW1613C146EE	16	13	146
	ETLW1616C146EE	16	16	146
	ETLW1620C146EE	16	20	146
	ETLW1624C146EE	16	24	146
	ETLW1628C146EE	16	28	146
	ETLW1610C156EE	16	10	156
	ETLW1613C156EE	16	13	156
	ETLW1616C156EE	16	16	156
	ETLW1620C156EE	16	20	156
	ETLW1624C156EE	16	24	156
	ETLW1628C156EE	16	28	156
	ETLW1610C199EE	16	10	199
	ETLW1613C199EE	16	13	199
	ETLW1616C199EE	16	16	199
	ETLW1620C199EE	16	20	199
	ETLW1624C199EE	16	24	199
	ETLW1628C199EE	16	28	199

Device Schedule:

Device Name: Endurant IIs

Intended Purpose as per the Instructions for Use:

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Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00001977U

Type (Codes as per (EU) 2017/2185): MDN 1101

Configuration	Model	Proximal Diameter (mm)	Distal Diameter (mm)	Total Length (mm)
Bifurcated	ESBF2314C103EE	23	14	103
	ESBF2514C103EE	25	14	103
	ESBF2814C103EE	28	14	103
	ESBF3214C103EE	32	14	103
	ESBF3614C103EE	36	14	103