

Device Schedule:

Device Name: Protégé™ GPS™ Self-expanding Peripheral Stent System

Intended Purpose as per the Instructions for Use:

The intended purpose of the Protégé GPS stent system is to restore lumen patency and blood flow to peripheral arteries. Implanting the Protégé GPS 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: 0763000B00001927J

Type (per EU 2017/2185): MDN 1101

Model	Unconstrained Stent Diameter (mm)	Unconstrained Stent Length (mm)	Recommended Vessel Size (mm)	Delivery Catheter Length (cm)
SERP65-09-20-80	9	20	7.5-8.5	80
SERP65-09-30-80	9	30	7.5-8.5	80
SERP65-09-40-80	9	40	7.5-8.5	80
SERP65-09-60-80	9	60	7.5-8.5	80
SERP65-09-80-80	9	80	7.5-8.5	80
SERP65-09-20-120	9	20	7.5-8.5	120
SERP65-09-30-120	9	30	7.5-8.5	120
SERP65-09-40-120	9	40	7.5-8.5	120
SERP65-09-60-120	9	60	7.5-8.5	120
SERP65-09-80-120	9	80	7.5-8.5	120
SERP65-10-20-80	10	20	8.5-9.5	80

Model	Unconstrained Stent Diameter (mm)	Unconstrained Stent Length (mm)	Recommended Vessel Size (mm)	Delivery Catheter Length (cm)
SERP65-10-30-80	10	30	8.5-9.5	80
SERP65-10-40-80	10	40	8.5-9.5	80
SERP65-10-60-80	10	60	8.5-9.5	80
SERP65-10-80-80	10	80	8.5-9.5	80
SERP65-10-20-120	10	20	8.5-9.5	120
SERP65-10-30-120	10	30	8.5-9.5	120
SERP65-10-40-120	10	40	8.5-9.5	120
SERP65-10-60-120	10	60	8.5-9.5	120
SERP65-10-80-120	10	80	8.5-9.5	120
SERP65-12-20-80	12	20	9.5-11.0	80
SERP65-12-30-80	12	30	9.5-11.0	80
SERP65-12-40-80	12	40	9.5-11.0	80
SERP65-12-60-80	12	60	9.5-11.0	80
SERP65-12-80-80	12	80	9.5-11.0	80
SERP65-12-20-120	12	20	9.5-11.0	120
SERP65-12-30-120	12	30	9.5-11.0	120
SERP65-12-40-120	12	40	9.5-11.0	120
SERP65-12-60-120	12	60	9.5-11.0	120
SERP65-12-80-120	12	80	9.5-11.0	120

Sheath Compatibility: 6 (Fr)

Guidewire Acceptance: 0.89/0.035 (mm/in)

Outside Diameter: 0.0795 (in)