

Device Schedule:

Device Name: Protégé™ RX Self-expanding Carotid Stent System and Protégé™ RX Tapered Self-expanding Carotid Stent System

Type: MDN 1101

Intended Purpose as per the Instructions for Use:

The intended purpose of the Protégé RX self-expanding stent system is to restore lumen patency and blood flow in the common carotid artery (CCA), internal carotid artery (ICA), or carotid bifurcation.

Implanting the Protégé RX stent in the target vessel restores lumen patency and reestablishes blood flow in the artery through the gentle, outward force exerted by the stent.

Risk Classification: Class III Implantable

Basic UDI-DI: 0763000B00001066X

Protégé RX Stent System (Straight) Device Configurations		
Model	Diameter (mm)	Length (mm)
SEPX-6-20-135	6	20
SEPX-6-30-135	6	30
SEPX-6-40-135	6	40
SEPX-6-60-135	6	60
SEPX-7-20-135	7	20
SEPX-7-30-135	7	30
SEPX-7-40-135	7	40
SEPX-7-60-135	7	60
SEPX-8-20-135	8	20
SEPX-8-30-135	8	30

Model	Diameter (mm)	Length (mm)
SEPX-8-40-135	8	40
SEPX-8-60-135	8	60
SEPX-9-20-135	9	20
SEPX-9-30-135	9	30
SEPX-9-40-135	9	40
SEPX-9-60-135	9	60
SEPX-10-20-135	10	20
SEPX-10-30-135	10	30
SEPX-10-40-135	10	40
SEPX-10-60-135	10	60

Protégé RX Stent System (Tapered) Device Configurations		
Model	Diameter (mm)	Length (mm)
SEPX-8-6-30-135	8-6	30
SEPX-8-6-40-135	8-6	40
SEPX-10-7-30-135	10-7	30
SEPX-10-7-40-135	10-7	40