Technical Aspects of the *Rotarex® S* device

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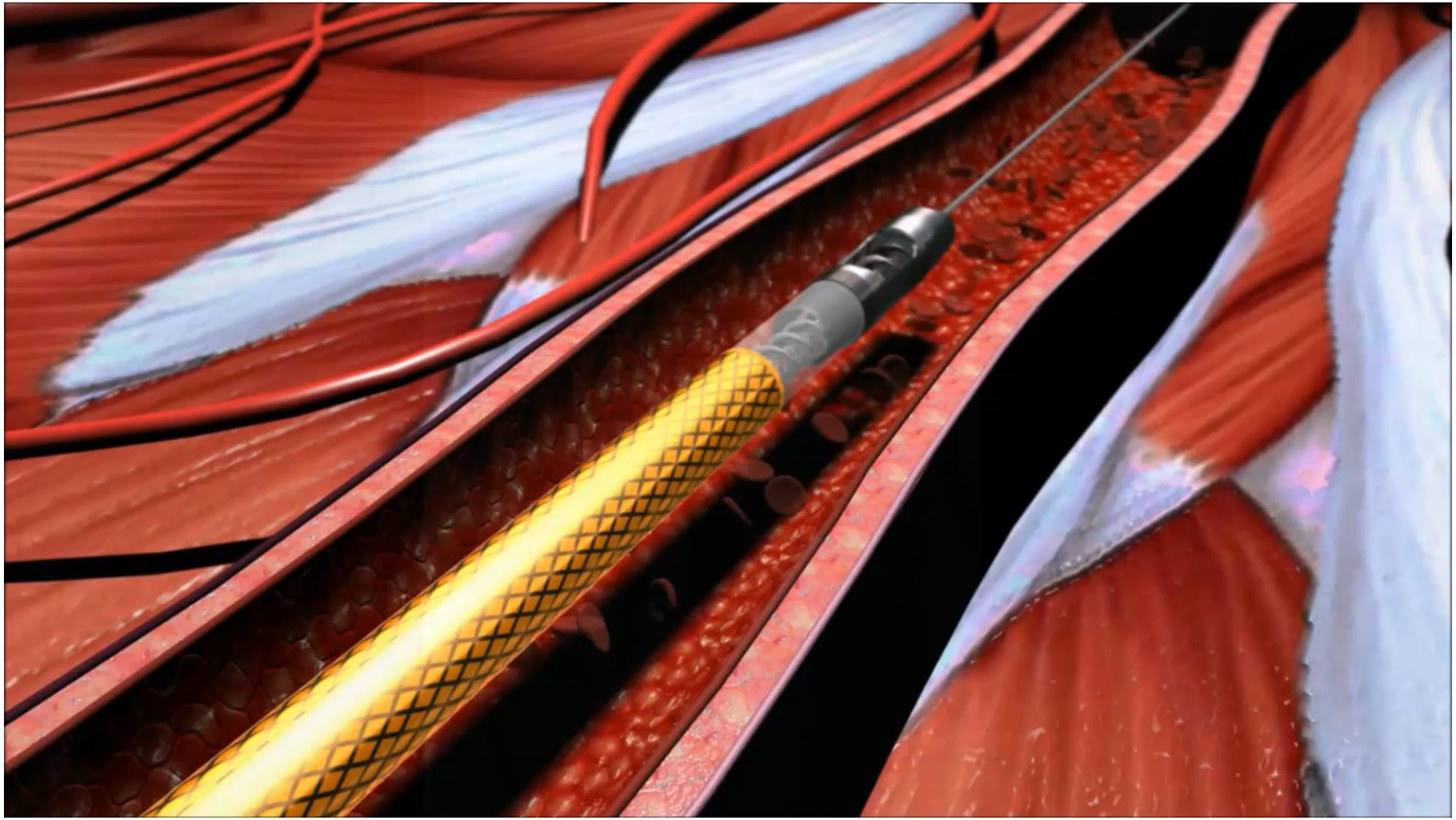
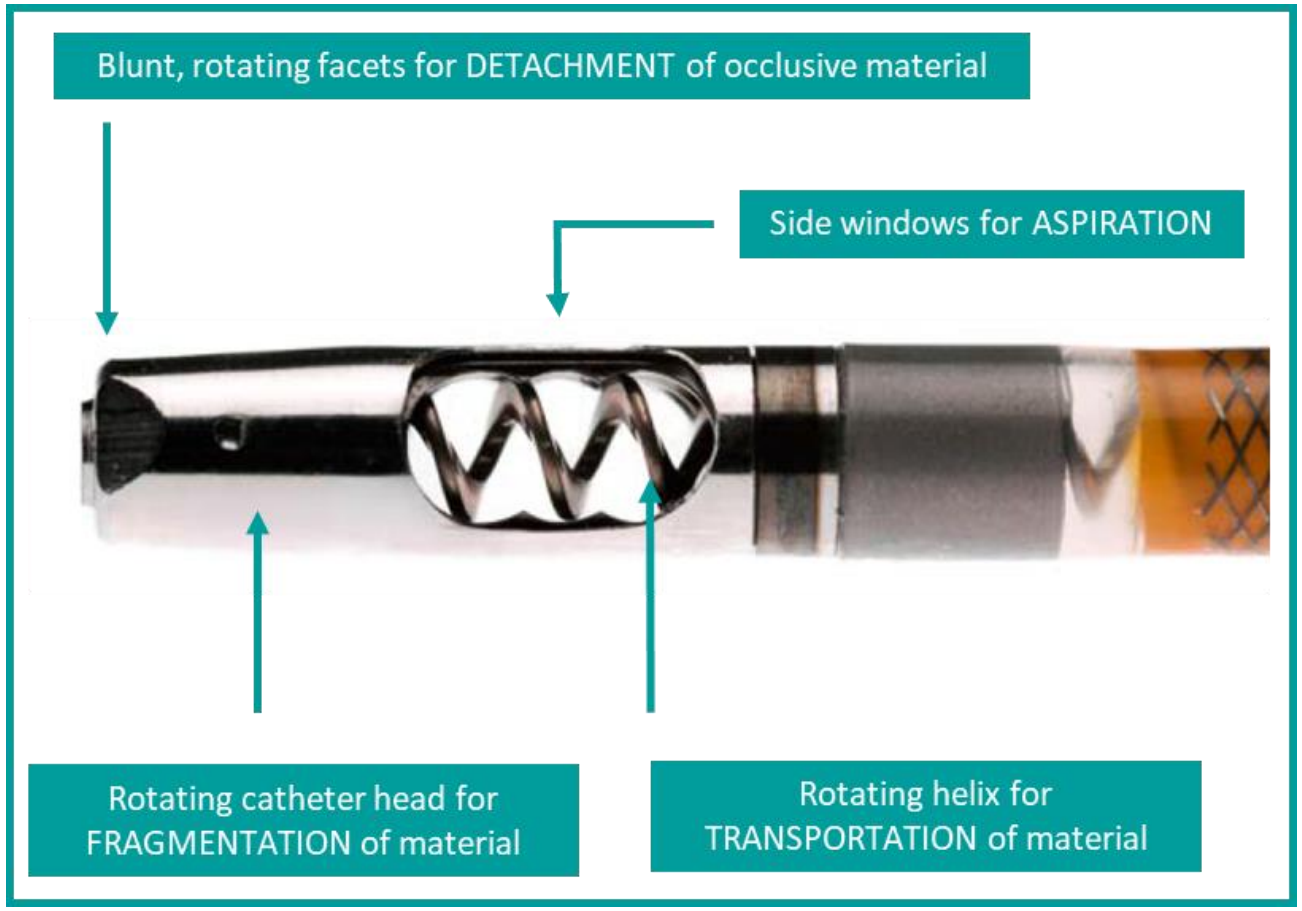
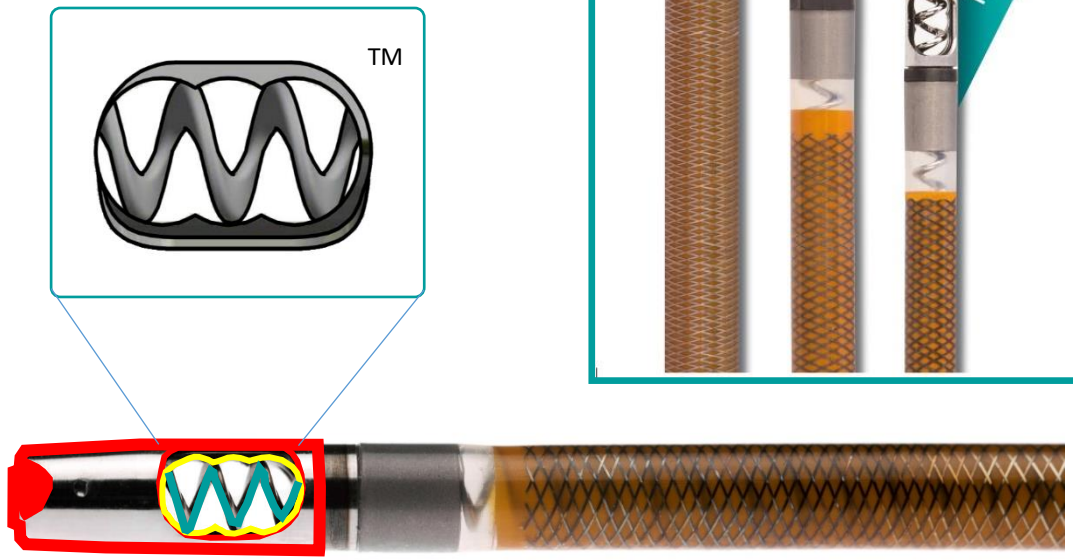
Rotarex



straub MEDICAL

Rotarex®S



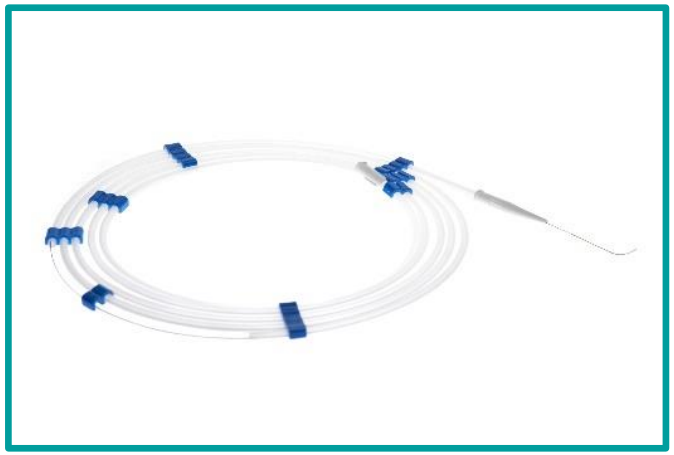


Technical Matrix (Outside of USA)

Rotarex®S	6F system	8F system	10F system
Vessel diameter	3-5 mm	5-8 mm	7-12 mm
Catheter type	0.018”/OTW	0.018”/OTW	0.025”/OTW
Usable length	110 cm, 135 cm	85 cm, 110 cm	85 cm
Catheter shaft	PEBAX, braided	PEBAX, braided	PEBAX, braided
Sheath compatibility	6F	8F	10F
Max. rotation speed	60,000 rpm	40,000 rpm	40,000 rpm
Max aspiration rate	45 ml/min	75 ml/min	130 ml/min
Catheter external diameter	2 mm	2.6 mm	3.3 mm

In USA only Rotarex®S 6F and 8F have 510k clearance

Images – Drive system, motor, guidewire



Indications for use (Outside USA)

Rotarex®S

- Rotarex®S catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of **thrombotic, thromboembolic and atherothrombotic** material from fresh, subacute and chronic occlusions of blood vessels outside the cardiopulmonary, coronary and cerebral circulations

- Native blood vessels or vessels fitted with stents, stent grafts or native or artificial bypasses outside the cardiopulmonary, coronary and cerebral circulations

In USA only Rotarex®S 6F and 8F have 510k clearance

Indications for use Technical matrix (USA)

Rotarex®S

- When operated with a Rotarex®S single use catheter, the Straub Endovascular System is intended for use as an atherectomy device and to break up and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, pulmonary, iliac or renal vasculature.

In USA only Rotarex®S 6F and 8F have 510k clearance