MECHANICAL THROMBECTOMY DEVICES

Company Name	Product Name	Sheath Size (F)	Guidewire (inch)	Working Length (cm)
Arrow International, a division of Teleflex Medical	Arrow-Trerotola PTD	5	None	65
	Arrow-Trerotola OTW PTD	7	0.025	65,120
Artegraft	D-Clot Thrombectomy Catheter	6	0.035	40
Concentric Medical, Inc.	Merci Retrieval System: X6 (3–1.5-mm diameter), L4 (2-mm diameter), L5 (2.5-mm diameter), L6 (2.7-mm diameter), V 2.0 Soft (2-mm diameter), V 2.0 Firm (2-mm diameter), V 2.5 Soft (2.5-mm diameter), V 2.5 Firm (2.5-mm diameter), V 3.0 Soft (3-mm diameter), V 3.0 Firm (3-mm diameter)	Balloon Guide Catheter (8 and 9 F)	0.014	Balloon Guide 8 and 9 F (80 and 95); MC14X, MC18L, and MC18 Plus (150); Retriever (180)
Cordis Corporation	Hydrolyser Percutaneous Thrombectomy Catheter	6	0.018	65, 100
Covidien	Trellis-8 Peripheral Infusion System	8	0.035	80, 120 catheter length; treatment areas 15, 30
	Trellis-6 Peripheral Infusion System	6		80, 120 catheter length; treatment areas 10, 30
Ekos Corporation	EkoSonic Endovascular System With Rapid Pulse Modulation	5.2	0.035	106, 135 catheter length; treatment areas 6, 12, 18, 24, 30, 40, 50
	EkoSonic SV Endovascular System	3	0.014	150

AV, arteriovenous; IV tPA, intravenous tissue plasminogen activator; USAT, ultrasound-accelerated thrombolysis.

Mode of Operation	CE Mark	FDA Indicated Use
Mechanical thrombectomy	Yes	Used in combination with the rotator drive, permits mechanical declotting of native arteriovenous fistulas and synthetic dialysis grafts
Patented agitator tip uses low torque to rotate at speeds > 10,000 rpm, creating a pumping action that positively pulls and holds the loosened clot material against the rotating tip until it is finely macerated; the macerated particles continue into and through the tube where the shaft's rotation prevents clogging, and the particles are extracted into a vacuum syringe	No	Nonautogenous grafts
Mechanical thrombectomy with aspiration and proximal flow arrest with Balloon Guiding Catheter	Yes	Restoring blood flow in the neurovasculature by removing thrombus in patients experiencing acute ischemic stroke (patients who are ineligible for IV tPA or who fail IV tPA therapy are candidates); for retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral, or coronary vasculature
Conventional contrast power injector is used to inject saline solution through the injection lumen; resultant pressure reduction at the tip nozzle creates a 360° vortex that fragments and aspirates thrombus into the exhaust lumen; thrombolytic material is discharged through the exhaust lumen into a collection bag	Yes	Indicated to percutaneously remove soft, newly formed (< 5 days old) thrombus from dialysis shunts of 3–6 mm
Isolated thrombolysis through introduction of lytic between two occlusion balloons; oscillation of dispersion wire increases clot surface area to enhance the speed of lysis; aspiration window facilitates removal of remaining thrombolytic and lysed debris	Yes	Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature
USAT simultaneously delivers ultrasound and thrombolytics to target clot; high-frequency, low-power transmits ultrasonic energy to loosen and thin the clot's fibrin, allowing thrombolytic agents to access more receptor sites; at the same time, it creates ultrasonic pressure waves that force the drug deep into the clot and keep it there so it does not escape downstream	Yes	Intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; also intended for the infusion of solutions into the pulmonary arteries; the safety and effectiveness of the EkoSonic Endovascular System for thrombolytic therapy administration in pulmonary embolus have not been established; in particular, the ultrasound energy delivered by the EkoSonic System is not intended to be therapeutic, nor has it been cleared with an indication for thrombolysis in pulmonary emboli
		Intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; regional infusion of contrast materials into selected vessels in the neurovasculature; delivering physician-specified fluids to the coronary vasculature

MECHANICAL THROMBECTOMY DEVICES (CONTINUED)

Company Name	Product Name	Sheath Size (F)	Guidewire (inch)	Working Length (cm)
ev3 Inc.	X-Sizer Catheter System	6, 7	0.014	135
	Helix Clot Buster Thrombectomy Device (Amplatz Device)	7	None	75, 120
	Rinspirator PR7-65		0.014	N/A
	Rinspirator PR7			7
	Rinspirator CP5 (6-F guide compatible)	5		6
	Rinspirator CP5 (7-F guide compatible)	6		7
Medrad Interventional/Possis	AngioJet Ultra XMI OTW	4	0.014	135
	AngioJet Ultra Spiroflex Rapid Exchange			
	AngioJet Ultra SpiroflexVG Rapid Exchange	5		
	AngioJet Ultra XVG OTW			140
	AngioJet Ultra Xpeedior 120 OTW	6	0.035	120
	AngioJet Ultra AVX OTW			50
	AngioJet Ultra DVX OTW			90
Penumbra, Inc.	The Penumbra System: Reperfusion Catheter and Separator 054, 041, 032, and 026	6	0.01–0.018	Separator length, 175–200; reperfusion catheter length, 137–150
Rex Medical	Cleaner	6	N/A	65, 135
Spectranetics Corporation	ThromCat Thrombectomy Catheter System	6	0.014	150

Mode of Operation	CE Mark	FDA Indicated Use
Enclosed cutter with vacuum aspiration	Yes	Mechanical removal of thrombus in synthetic hemodialysis access grafts
Wall-washing impeller technology for clot fragmentation		Dialysis graft and native fistulas
Hand-held fluidic debris removal; simultaneous rinsing to wash vessel walls and aspiration to evacuate debris	No	Indicated to infuse physician-specified fluid and remove/aspirate fluid, fresh, soft thrombi from the peripheral vasculature
Hand-held fluidic debris removal; simultaneous rinsing to wash vessel walls and aspiration to evacuate debris for peripheral and coronary use		Indicated to infuse physician-specified fluid and remove/aspirate fluid, fresh, soft thrombi from the coronary and peripheral vasculature
High-velocity water jets enclosed in the catheter utilize the Bernoulli principle for capture, microfragmentation, and removal	Yes	Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 2 mm in diameter
		Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 3 mm in diameter
		Breaking apart and removing thrombus from upper and lower extremity peripheral arteries, upper extremity peripheral veins, iliofemoral and lower extremity peripheral veins ≥ 3 mm in diameter
		Breaking apart and removing thrombus from AV access fistulas and synthetic conduits
		Breaking apart and removing thrombus from upper and lower extremity peripheral arteries, upper extremity peripheral veins, iliofemoral and lower extremity peripheral veins ≥ 3 mm in diameter
Separator-assisted clot debulking and aspiration	Yes	The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease within 8 hours of symptom onset
Battery-operated, hand-held drive unit initiates the mechanical rotation of an atraumatic, wall-contact, sinusoidal vortex wire for effective thrombus maceration	No	Indicated for use in the mechanical declotting of synthetic dialysis grafts currently pursuing native vessel indication
High-vacuum and saline jets disrupt thrombus and pulls into catheter; enclosed helix for maceration and removal	Yes	Indicated for removing thrombus from synthetic hemodialysis access; grafts and native vessel dialysis fistulas