

# OTHER DEVICES

## 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	.025	65, 120
Bacchus Vascular, Inc.	Trellis-8 Peripheral Infusion Catheter	8	.035	80 or 120 catheter length with treatment areas of 10, 15, or 30
	Trellis-6 Peripheral Infusion Catheter	6	.035	80 or 120 catheter length with treatment areas of 10 or 30
Concentric Medical, Inc.	Merci Retrieval System: X6 (1.5–3 mm diameter), L4 (2-mm diameter), L5 (2.5-mm diameter), L6 (2.7-mm diameter), K Mini (2.1-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 Firm (3-mm diameter)	7, 8, 9	.014	Balloon guide=95; microcatheter=150; retriever=180
Cordis Corporation	Hydrolyser Percutaneous Thrombectomy Catheter	6	.018	65, 100
Ekos Corporation	EkoSonic Endovascular System With Rapid Pulse Modulation	5.2	.035	106, 135 catheter length; treatment areas 6, 12, 18, 24, 30, 40, 50
	EkoSonic SV Endovascular System	3	.014	150

## OTHER DEVICES

Mode of Operation	CE Mark	FDA Indicated Use
Mechanical thrombectomy	Yes	Used in combination with the rotator drive, permits mechanical declotting of native AV fistulae and synthetic dialysis grafts
Isolated thrombolysis through introduction of lytic between two occlusion balloons; low frequency oscillation of dispersion wire increases the clot surface area to enhance the speed of thrombolytic therapy; aspiration port facilitates removal of remaining thrombolytic and lysed debris	Yes	Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature
Isolated thrombolysis through introduction of lytic between two occlusion balloons; low-frequency oscillation of dispersion wire increases the clot surface area to enhance the speed of thrombolytic therapy; aspiration port facilitates removal of remaining thrombolytic and lysed debris	Yes	
Mechanical thrombectomy with aspiration and proximal flow arrest	Yes	Restoring blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke; patients who are ineligible for IV tPA or who fail IV tPA therapy are candidates for treatment; retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and 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
Microsonic accelerate thrombolysis (MSAT) simultaneously delivers ultrasound and thrombolytics to target clot; the high-frequency, low-power microsonic energy loosens clot fibrin to increase clot permeability; sonic pressure waves radially drive the lytic agent deep into the clot for faster, more complete dissolution of thrombus	Yes	Intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature; it is 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.
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# OTHER DEVICES

## MECHANICAL THROMBECTOMY DEVICES (CONTINUED)

Company Name	Product Name	Sheath Size (F)	Guidewire (inch)	Working Length (cm)	
ev3 Inc.	X-Sizer Catheter System	6, 7	.014	135	
	Helix Clot Buster Thrombectomy Device (Amplatz Device)	7	None	75, 120	
	Rinspirator PR7-65		.014	N/A	
	Rinspirator PR7	7			
	Rinspirator CP5 (6-F guide compatible)	5		6	
	Rinspirator CP55 (7-F guide compatible)	6		7	
IDev Technologies, Inc.	AKónya Eliminator	6	None	60	
	AKónya Eliminator Plus		.018		
Medrad Interventional/Possis	XMI	4	.014	135	
	Spiroflex Rapid Exchange				
	SpiroflexVG Rapid Exchange	5	.014	135	
	XVG				140
	Xpeedior				6
	AVX	50			
	DVX	90			
OmniSonics Medical Technologies, Inc.	OmniWave Endovascular System	6	.018	100	
Penumbra, Inc.	Penumbra System	6	.01-.018	Separator length 200; reperfusion catheter length 137-150	
Rex Medical	Cleaner	6	N/A	65, 120	
Spectranetics Corporation	ThromCat Thrombectomy Catheter System	6	.014	150	

## OTHER DEVICES

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 grafts and native fistulae
65	No	Indicated to infuse physician-specified fluid and remove/aspirate fluid, fresh, soft thrombi from the peripheral vasculature
135		
135		Indicated to infuse physician-specified fluid and remove/aspirate fluid, fresh, soft thrombi from the coronary and peripheral vasculature
Combination of manual driven axial, rotational, and/or pulsatile motion	Yes	Indicated for use in the mechanical declotting of synthetic dialysis grafts
		Indicated for use in the mechanical declotting of synthetic dialysis grafts and native AV fistulae
High-velocity water jets enclosed in catheter utilize the Bernoulli principle for capture, microfragmentation, and removal	Yes	Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels $\geq 2$ mm in diameter before balloon angioplasty or stent placement
		Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels $\geq 2$ mm in diameter before balloon angioplasty or stent placement
		Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels $\geq 3$ mm in diameter before balloon angioplasty or stent placement
		Breaking apart and removing thrombus from infrainguinal peripheral arteries $\geq 3$ mm in diameter
		Breaking apart and removing thrombus from infra-inguinal peripheral arteries $\geq 3$ mm in diameter and upper extremity and infrainguinal lower extremity peripheral veins $\geq 3$ mm in diameter.
		Breaking apart and removing thrombus from AV access fistulae and synthetic conduits
		Breaking apart and removing thrombus from infrainguinal peripheral arteries $\geq 3$ mm in diameter
Patented, low-power, transverse ultrasonic energy over the entire length of the catheter's Active Zone is designed to rapidly dissolve thrombus and quickly restore blood flow without damaging surrounding structures	No	Indicated for the infusion of physician-specified fluids, including thrombolytics, and for the removal of thrombus in the peripheral vasculature
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 fistulae