

MECHANICAL THROMBECTOMY DEVICES

Company	Device	FDA Indicated Use	Sheath Size (F)	Guidewire (inch)	Working Length (cm)	Mode of Operation	CE Mark
Arrow International, Inc.	Arrow-Trerotola PTD (Percutaneous Thrombolytic Device)	Used in combination with the Rotator Drive, permits mechanical declotting of native arterio-venous fistulae and synthetic dialysis grafts.	5	None	65	Mechanical thrombectomy	Yes
	Arrow-Trerotola Over-The-Wire (OTW) PTD (Percutaneous Thrombolytic Device)	Used in combination with the Rotator Drive, permits mechanical declotting of native arterio-venous fistulae and synthetic dialysis grafts.	7	.025	65, 120	Mechanical thrombectomy	Yes
Bacchus Vascular	Trellis-8 Peripheral Infusion Catheter	Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.	8	None	80 cm or 120 cm catheter length with 15 cm or 30 cm treatment areas	Isolated thrombolysis	Yes
Cordis Endovascular, a division of Cordis Corporation	Hydrolyser Percutaneous Thrombectomy Catheter	Indicated to percutaneously remove soft, newly formed (<5 days old) thrombus from dialysis shunts of 3 to 6 mm.	6	.018	65, 100	Conventional contrast power injector is used to inject saline solution through the injection lumen. Resultant pressure reduction at the tip nozzle creates a 360-degree vortex that fragments and aspirates thrombus into the exhaust lumen. Thrombolytic material is discharged through the exhaust lumen into a collection bag.	Not provided

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Datascope	ProLumen	AV grafts	6	None	65	Wall contact with clot maceration properties	No
EKOS Corporation	Lysus Infusion System	Intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.	5	.035	106	Accelerate thrombolysis by coaxial delivery of high-frequency, low-energy ultrasound to increase clot permeability and disperse lytic agent into the clot	Yes
ev3	X-Sizer Catheter System	Dialysis grafts	6, 7	Not provided	145	Enclosed cutter with aspiration	Yes
	Helix Clot Buster Thrombectomy Device (Amplatz Device)	Dialysis graft and native fistulae	7	n/a	75, 120	Impeller device with fragmentation	Yes
ev3/MTI	Castaneda Over-The-Wire Brush	Synthetic AV grafts	6	.035	65	Wall contact with rotating brush	Yes
IDev Technologies, Inc.	AKónya Eliminator	Indicated for use in the mechanical declotting of synthetic dialysis grafts.	6	None	60	Combination of manual driven axial, rotational, and/or pulsatile motion.	Yes
	AKónya Eliminator Plus	Indicated for use in the mechanical declotting of synthetic dialysis grafts and native AV fistulae.	6	.018	60	Combination of manual driven axial, rotational, and/or pulsatile motion.	Yes
Kerberos Proximal Solutions	Peripheral Rinspiration System (7F Sheath Compatible)	Indicated to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the peripheral vasculature	7	.014	65, 135	Hand-held fluidic debris removal. Simultaneous rinsing to wash vessel walls and aspiration to evacuate debris.	No
	Rinspiration System (6F Guide Compatible)	Indicated to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature	5	.014	135	Hand-held fluidic debris removal. Simultaneous rinsing to wash vessel walls and aspiration to evacuate debris.	Yes
	Rinspiration System (7F Guide Compatible)	Indicated to infuse physician specified fluid and remove/aspirate fluid, fresh, soft emboli and thrombi from the coronary and peripheral vasculature	6	.014	135	Hand-held fluidic debris removal. Simultaneous rinsing to wash vessel walls and aspiration to evacuate debris.	Yes
OmniSonic Medical Technologies, Inc.	Resolution Endovascular System	Synthetic dialysis access grafts	5	None	60	Ultrasonic energy	No

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Possis	XMI	Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels ≥ 2 mm in diameter prior to balloon angioplasty or stent placement.	4	.014	135	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Yes
	XMI-RX	Removing thrombus in the treatment of patients with symptomatic coronary artery or saphenous vein graft lesions in vessels ≥ 2 mm in diameter prior to balloon angioplasty or stent placement.	4	.014	135	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal.	Yes
	Spiroflex Rapid Exchange	Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 2 mm in diameter.	4	.014	135	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	No

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Possis	XVG	Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 3 mm in diameter	5	.014	140	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Yes
	Xpeedior 120	Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 3 mm in diameter	6	.035	120	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Yes
	AVX	Breaking apart and removing thrombus from AV access conduits	6	.035	50	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Yes
	XMI-RX+	Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 2 mm in diameter	4	.014	135	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Yes
	DVX	Breaking apart and removing thrombus from infrainguinal peripheral arteries ≥ 3 mm in diameter	6	.035	90	High-velocity water jets enclosed in catheter utilize Bernoulli principle for capture, microfragmentation, and removal	Yes