

OTHER DEVICES

NEUROVASCULAR LIQUID EMBOLIC					
Company Name	Product Name	Materials Used	Indication	Key Benefits	FDA Market Cleared
Codman Neurovascular	Trufill n-BCA Liquid Embolic System	n-BCA, tantalum, ethiodized oil	Embolization of cerebral AVMs when presurgical devascularization is desired	Trufill n-BCA is a clear, free-flowing liquid, which polymerizes quickly on contact with body fluid or tissue; offers convenient preparation and delivery, optimized radiopacity for visualization, and effective penetration of AVMs	PMA device
ev3 Inc.	Onyx Liquid Embolic System: Onyx 18 and Onyx 34	EVOH, dimethyl sulfoxide, tantalum	US: presurgical embolization of brain AVMs; EU: embolization of vascular lesions	Onyx Liquid Embolic System is an EVOH copolymer that provides full penetration and complete packing for neurovascular disorders, obliterating vascular lesions	PMA device
	Onyx HD-500		US: treating intracranial, saccular, sidewall aneurysms that present with a wide neck (≥ 4 mm) or with a dome-to-neck ratio < 2 that are not amenable to treatment with surgical clipping; EU: embolization of intracranial aneurysms	Onyx HD-500 is a high-viscosity formulation liquid embolic for the treatment of intracranial wide-necked aneurysms; provides complete volumetric filling to reduce recanalization and retreatment	HDE device
AVM, arteriovenous malformation; EVOH, ethylene vinyl alcohol; HDE, humanitarian device exemption; n-BCA, n-butyl cyanoacrylate; PMA, Premarket Approval.					