

! Indications, Safety, and Warnings

HEALTHCARE PROFESSIONALS

Onyx Liquid Embolic System

Peripheral Embolization



OVERVIEW

The Onyx™ liquid embolic system (LES) is an ethylene vinyl alcohol (EVOH) copolymer that provides complete filling and distal penetration¹ of peripheral and neurovascular lesions. Its non-adhesive properties permit more distal nidus embolization without significant risk of catheter entrapment, while higher viscosities allow for controlled deployment.²

INDICATIONS

Onyx 18 & 34 LES: Embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors.

Onyx 34L LES: Embolization of lesions in the peripheral vasculature, including endoleaks, arteriovenous malformations, portal veins, bleeding and tumors.

PRODUCT DETAILS

Onyx is a non-adhesive liquid embolic agent composed of EVOH dissolved in DMSO with suspended micronized tantalum powder. It is delivered through a microcatheter under fluoroscopic control.

Polymeric properties

- Precipitation occurs on contact with aqueous solution (e.g., blood, water, contrast)
- Flows like lava and solidifies from the outside in as solvent diffuses away
- Delivers in a cohesive manner, forming a spongy, coherent embolus

Controlled Delivery

- Slow controlled injection and delivery method
- Ability to start and stop injections (pauses should not exceed 2 minutes)
- Cohesive deposition and delivery
- Excellent visibility³
- Controlled angiography during embolic injection

Formulations

Onyx 18 and 34 LES for peripheral and neurovascular use:

- Onyx 18 LES (6% EVOH, viscosity of 18 cSt); will travel more distally and penetrate deeper into the targeted lesion due to its lower viscosity compared to Onyx 34, (i.e. peripheral AVM nidus)
- Onyx 34 LES (8% EVOH, viscosity of 34 cSt); with higher viscosity for more control in higher flow and large fistulous components

Onyx 34L LES for peripheral use:

- 8% EVOH, viscosity of 34 cSt
- Lower tantalum content than current version of Onyx 34 LES⁴
- Less streak artifact on CT with good visibility during injection⁴

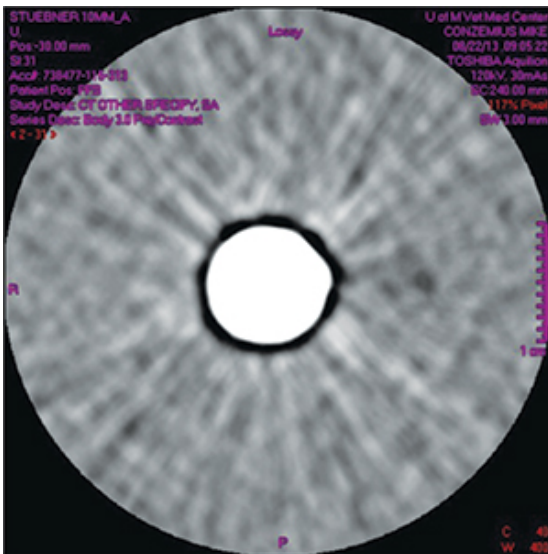
Onyx 34L LES packaging with 6 ml vial

- 6 ml vial provides ease of use for large volume treatments

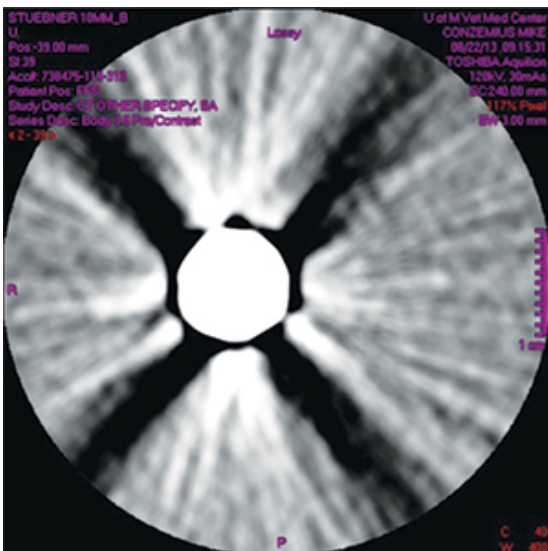
- Requires less storage space than four 1.5 ml vials of Onyx 34 LES
- Environmentally friendly packaging made from 98% recyclable content

CT VALIDATION*

- Onyx 34L LES has less streak artifact on CT with good visibility during injection in comparison to Onyx 34 LES⁴



Onyx 34L LES in 10mm vessel†



Onyx 34 LES in 10 mm vessel†

MANUALS AND TECHNICAL GUIDES

The technical manual includes indications, warnings, precautions, MRI information, and directions for use. Find it in the product labeling supplied with each device or call Medtronic at +1 763-526-7890.

MODEL SPECIFICATIONS

Onyx Liquid Embolic System

Product Code	Onyx Formulation
105-7200-060	Onyx 18 Peripheral Kit, 1.5 ml
105-7200-080	Onyx 34 Peripheral Kit, 1.5 ml
105-7315-080	Onyx 34L Kit, 1.5 ml
105-7360-080	Onyx 34L Kit, 6 ml

Onyx LES Accessories

Product Code	Onyx LES Accessory
103-1205-001	Vortex Genie 2 120v/60Hz with 1.5mL vial attachment
103-1205-002	Vortex Genie 2 240v/50Hz with 1.5mL vial attachment
103-1205-100	Mixer Attachment for 6mL and 1.5mL vials
103-1207	Syringe Catheter Interface Adapter (20 units/box)
103-1203	1 ml Luer-Lock Injector Syringe (10 units/box)

* CT artifact Validation in vitro using a water phantom tank to simulate body tissue and synthetic vessel Document TR_NV 11300 RevA

† Images are property of Medtronic.

¹ Jose Urbano, MD, PhD Selective Arterial Embolization with Ethylene–Vinyl Alcohol Copolymer for Control of Massive Lower Gastrointestinal Bleeding: Feasibility and Initial Experience. *J Vasc Interv Radiol* 2014.

² Ricardo Yamada, Andre Uflacker, Austin Bourgeois, Joshua D. Adams, Marcelo Guimaraes, ‘EVOH/DMSO in Peripheral Application’ in *Embolization Therapy: Principles and Clinical Applications*, ed. Marcelo Guimaraes, Riccardo Lencioni, and Gary P. Siskin (Philadelphia, Wolters Kluwer, 2015), 582 pp.

³ Perez-Higueras, A. et al. Endovascular Treatment of Cerebral AVM:Our Experience with Onyx. *Interventional Neuroradiology* 11:141-157,2005.

⁴ IFU 70721-001 Rev 01/13. 2 CT artifact validation in vitro using a water phantom tank to simulate body tissue and synthetic vessel Document TR_NV 11300 RevA 2013-08-20. All images property of Covidien.

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