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Medtronic announces US FDA approval for OnyxTM 12 Liquid Embolic System, with shorter prep time

Lower viscosity formulation designed to enable more distal penetration with 1-minute shake time

Medtronic, a global leader in healthcare technology, today announced U.S. FDA approval for the Onyx™ 12 Liquid Embolic System (LES). Onyx 12 LES is now indicated for embolization of middle meningeal artery (MMA) as an adjunct to surgery for the treatment of symptomatic subacute or chronic subdural hematoma (SDH).

About Onyx 12 LES

This marks the first US approval for Onyx 12 LES, which is the newest member of the Onyx LES family, joining Onyx 18 and 34. Onyx 12 LES has a lower viscosity and is specially designed to enable more distal penetration than Onyx 18 LES with comparable reflux. Additionally, the Onyx 12 LES shake time is only 1 minute, enabling faster procedure preparation time than the 20-minute shake time for conventional tantalum-based liquid embolic systems.

“Our Medtronic Neurovascular team is incredibly proud of this milestone,” said Linnea Burman, senior vice president and president, Medtronic Neurovascular. “This new formulation – building on 20 years of Onyx in the US – adds to our momentum, like our Onyx approval for cSDH last year and June’s closing of our acquisition of Scientia Vascular. These steps reflect our commitment to continuous innovation for physicians and contributing to better patient outcomes.”

“With a product like Onyx 12, we will increasingly be able to get to the membrane while managing reflux, which is needed for meaningful MMA embolization,” said Dr. Jason Davies, research director of the Jacobs Institute and assistant professor of Neurosurgery and Biomedical Informatics at the State University of New York at Buffalo and co-principal investigator on the EMBOLISE trial. “Liquid embolic technology – and this new formulation – can fundamentally change how we approach treating these challenging conditions and help improve outcomes for patients.”

“Targeting the membrane improves the efficacy of cSDH treatment,” said Dr. Jared Knopman, associate attending neurological surgeon at New York-Presbyterian Hospital and co-principal investigator on the EMBOLISE trial. “Onyx 12 LES’s lower viscosity will provide more tools for physicians to customize the approach based on patient

anatomy."

Onyx 12 LES will begin its initial market introduction in the coming days.

1 Minute Shake Time Across Onyx Product Line

Additionally, Onyx 18 and 34 LES are also now approved for a shake time of only 1 minute. Previously approved shake time for these products was 20 minutes. Onyx 18 and 34 LES will now use the same packaging as Onyx 12 LES for an improved user experience.

About cSDH

cSDH, or chronic subdural hematoma, is a collection of blood between the brain's dura and arachnoid mater that develops slowly over a period of days or weeks, usually following trauma. It commonly occurs in older people, and it can lead to severe complications if left untreated.

About the Neurovascular Business at Medtronic

Medtronic helped create the neurovascular market – introducing innovations like liquid embolic, stent retrievers, and flow diverters. Today, with products covering multiple conditions and disease states, we work to eliminate the burden of stroke and other neurovascular diseases globally by transforming care, one breakthrough at a time. Together with our partners, including physicians, hospitals, governments and patients, we're expanding into new disease states and stages of care. Our unwavering focus on better outcomes fuels our drive to deliver life-changing therapies and transform the future of care for patients worldwide. For more information, follow Medtronic Neurovascular on LinkedIn.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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