**FEB 5, 2026**

# Medtronic EMBOLISE observational data demonstrates effectiveness and positive trend for hematoma improvement with MMA embolization

Feb. 5, 2026 – Medtronic plc, a global leader in healthcare technology, today announced additional data from the EMBOLISE trial, a clinical trial in the United States evaluating the performance of the Onyx™ Liquid Embolic System (LES) for middle meningeal artery (MMA) embolization for patients with symptomatic subacute or chronic subdural hematoma (cSDH).

**About the New Data**

The Medtronic-sponsored, multicenter, prospective and randomized EMBOLISE Trial compared MMA embolization using Onyx™ LES to observation only for subacute and chronic SDH.

The Observation cohort was a stand-alone trial for patients with smaller hematomas and no motor symptoms. The Test arm (Onyx MMA embolization) met the pre-specified 90-day primary effectiveness endpoint and showed a positive trend in 180-day imaging for hematoma improvement compared to the Control arm (observation only without any intervention). The use beyond surgical adjunct treatment is not approved by the FDA, but we look forward to those discussions based on this new data.

“These trial results clearly show that MMA embolization lowers the risk of surgical rescue, or a clinical deterioration at 90 days. At six months after enrollment, treated patients had half the amount of residual fluid compared to those who weren’t embolized,” said Jared Knopman, M.D., associate attending neurological surgeon at New York-Presbyterian Hospital and principal investigator of the trial. “Though there was a higher stroke and death rate in the Test group compared to the Control group, it is important to note that none of these were related to the Onyx device. Several of these clinical events were likely related to comorbidities, anti-platelet/anti-coagulant management and procedural factors.”

**About the EMBOLISE Trial**

EMBOLISE was initiated in 2020 and enrolled 600 patients, representing the largest IDE study in this space. It is a multi-center, prospective, randomized, interventional, controlled, open label, adaptive design IDE clinical trial in the United States - evaluating the performance of the Onyx™ Liquid Embolic System for MMA embolization for

patients with symptomatic subacute or chronic SDH. The trial is the only IDE with two statistically powered cohorts (Surgery Cohort and Observation Cohort).

- In the Surgery Cohort, subjects are randomized to receive either Surgery + MMA embolization or surgery alone
- In the Observation Cohort, subjects are randomized to receive either MMA embolization or observation only

In November 2024, the New England Journal of Medicine published findings of the Surgery Cohort of the study, indicating that treatment with Surgery + MMA embolization showed a 63% reduction in treatment compared to surgery alone. In December 2025, Medtronic announced the indication expansion in the U.S. for the Onyx 18 and 34 liquid embolic system for embolization of the MMA as an adjunct to surgery, signaling a significant step in cSDH patient treatment.

EMBOLISE IDE Surgical data has been published in scientific publications and highlighted at conferences, including:

- Three publications in notable, high–impact factor journals, including *NEJM*; *Radiology*; and *JNIS*.
- Presentations at more than 15 major Stroke, Neurosurgery, and INR conferences including, ISC, ESOC, CNS, AANS, SNIS, SVIN, ESMINT, WFITN, and WLNC.

In addition to EMBOLISE IDE, Medtronic supported three physician-initiated studies in chronic subdural hematoma with Onyx: MAGIC-MT (China), OTEMACS (France), and EMMA-Can (Canada). Collectively, Medtronic has supported clinical data collection on more than 1,700 patients with subacute or chronic subdural hematoma.

**About cSDH**

cSDH, or chronic subdural hematoma, is a collection of fluid 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. The aging population and increased use of antithrombotic medications are contributing to the rising incidence of chronic SDH worldwide. By 2030, cSDH is anticipated to be the most common cranial neurosurgical condition among adults globally.

**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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https://news.medtronic.com/Medtronic-EMBOLISE-observational-data-demonstrates-effectiveness-and-positive-trend-for-hematoma-improvement-with-MMA-embolization