European Society of
Minimally Invasive Neurological Therapy

ESMINT-led European Multisociety Consensus Defines Clinical Evidence Standards for High-Risk Endovascular Stroke Devices

First physician-driven recommendations provide indication-specific guidance for the evaluation of thrombectomy devices under the European Medical Device Regulation (MDR)

Zurich, Switzerland – The European Society of Minimally Invasive Neurological Therapy (ESMINT) welcomes the publication of "Clinical Evidence Standards for High-Risk Endovascular Devices in Ischemic Stroke" in the Journal of NeuroInterventional Surgery (JNIS). Developed through a collaboration between ESMINT, the European Stroke Organisation (ESO), and the European Society of Neuroradiology (ESNR), the consensus document provides the first indication-specific recommendations for the clinical evaluation of high-risk endovascular stroke devices in Europe.

Mechanical thrombectomy has transformed the treatment of acute ischemic stroke and is now the standard of care for large-vessel occlusion. As new thrombectomy devices continue to enter clinical practice, questions remain regarding the level and type of clinical evidence required to demonstrate safety and performance under the European Medical Device Regulation (MDR).

To address this gap, the study group first reviewed the available scientific evidence with methodological support from the Institute for Evidence in Medicine at the University of Freiburg. Building on these findings, representatives of ESMINT, ESO, and ESNR took part in a structured, three-round consensus process to agree on key recommendations. These recommendations offer practical guidance for planning, conducting, and reporting clinical studies of single-use endovascular stroke devices to support regulatory approval.

Among the key findings, the panel concluded that prospective observational studies are appropriate for most regulatory scenarios involving thrombectomy devices, while acknowledging that conceptually novel devices may require more rigorous comparative evaluation. Consensus was also achieved on essential study design elements, including multicentre participation, operator and centre requirements, independent imaging adjudication, endpoint selection, safety monitoring, and data transparency.

The document identifies functional independence at 90 days, successful reperfusion, and symptomatic intracranial haemorrhage as core outcome domains for future device studies. It further provides recommendations on sample size planning, post-market evidence generation, comparator selection, and study governance.

This consensus represents an important milestone for our field," said Dr Anne Christine Januel, President of ESMINT. "Our objective was not to lower evidentiary standards, but to define study approaches that preserve scientific rigour while reflecting the realities of neurointerventional practice. The resulting framework supports robust and clinically meaningful evidence generation across a broad range of regulatory scenarios.

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Lead author Professor Christian A. Taschner, General Secretary of ESMINT and Vice-Chair of the European Medicines Agency (EMA) Expert Panel on Cardiovascular Implants, added:

“Current regulatory frameworks provide important general principles, but they do not address many of the specific challenges encountered in neurointerventional stroke research. Our goal was to translate these principles into practical guidance tailored to endovascular stroke therapy. We hope this framework will support investigators, manufacturers, notified bodies, and regulators alike.”

The authors emphasize that the recommendations complement existing MDR, ISO, and CORE-MD frameworks by translating general regulatory concepts into clinically meaningful standards for neurointerventional research. Beyond stroke therapy, the approach may serve as a model for developing physician-led, indication-specific guidance in other highly specialized medical fields.

Publication

Taschner CA, Fiehler J, Caso V, Möhlenbruch MA, Januel AC, Valvassori L, et al. Clinical evidence standards for high-risk endovascular devices in ischemic stroke: a European multisociety consensus. *J NeuroIntervent Surg* 2026;0:1–8. doi:10.1136/jnis-2026-025448

About ESMINT

The European Society of Minimally Invasive Neurological Therapy (ESMINT) promotes education, innovation, scientific excellence, and collaboration in the field of neurointervention. Through training, research, and international partnerships, ESMINT works to improve patient care and advance minimally invasive therapies for neurological diseases across Europe.

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