

Mentice Launch the latest version of Ankyras® in the United States Following FDA Clearance, Advancing Patient-Specific Aneurysm Planning for Neuro interventions

Gothenburg, Sweden, May 13, 2025, – Mentice, a globally recognized leader in simulation solutions for image-guided interventional therapies, announces that Ankyras® 4.0, its neurovascular clinical decision-support platform for patient-specific flow diverter planning, is now FDA 510(k) cleared and available for clinical use in the United States.

Following its successful release in Europe, and recent launch in Brazil, Ankyras® continues its global rollout with clinical availability now expanding into the U.S. The US market is the largest and most advanced neurovascular market worldwide.

This latest version introduces enhanced capabilities, including DICOM node integration, redesigned user interface, and expanded accessibility via both an online platform and a mobile app. Additionally, its unique integration with the VIST® simulation platform enables case rehearsal in a virtual environment. These enhancements accelerate decision-making, improve team collaboration whether on-site or remotely. With this release, U.S. physicians now gain access to a fully validated platform for patient-specific aneurysm treatment planning and procedural rehearsal.

The U.S. intracranial aneurysm treatment market, valued at USD 369 million in 2024, is high-volume and projected to grow at a CAGR of 9% in the coming years[1], driven by increased detection of unruptured aneurysms, widespread imaging access, and a growing preference for minimally invasive therapies such as flow diverters. With an estimated 25,000–30,000 flow diverter procedures performed annually, reflecting a prevalence of 1 in 50 Americans affected by aneurysms[2], there is a clear need for validated digital planning solutions that improve accuracy, efficiency, and personalized care in neurointervention.

Ankyras® is a neurovascular clinical decision-support application that enables clinical teams to plan, size, and simulate flow diverter treatments of intracranial aneurysms using patient-specific vascular models. Its predictive simulation supports clinical decision-making by visualizing device deployment, improving confidence in sizing, placement, and procedural strategy before entering the angiosuite. In contrast to traditional planning methods, Ankyras® offers a dedicated clinical environment that allows physicians to assess how different devices behave in a given anatomy before entering the angiosuite. This level of pre-procedural insight improves clinical confidence, facilitates collaborative case review, and reduces the variability often associated with complex aneurysm treatment.

"With streamlined DICOM integration and advanced simulation tools, we're bridging imaging and procedural planning, enabling smarter, more efficient care," added Martina Andreasson, Global Product Manager, Neurovascular and Ankyras, Mentice.



The U.S. release of Ankyras® is guided by Mentice's Strategic Advisory Board, comprising leading interventional neuroradiologists, neurosurgeons, and neurovascular experts. Additionally, Ankyras® has been co-developed through a long-standing research partnership with the Yatiris Lab (UNICEN—CONICET) in Argentina, led by Dr. Ignacio Larrabide.

Following FDA 510 (k) clearance, Ankyras® 4.0 is now available for clinical use in the United States. The platform is accessible via cloud-based services, local desktop installations, and mobile devices via the App Store and Google Play.

Disclaimer & Regulatory Information Ankyras is manufactured by Mentice Spain S.L. ANKYRAS and is intended to be used by physicians trained in medical procedures involving percutaneous and intravascular interventions. All operators must read the complete User manual before using Ankyras. Ankyras v4.0 is 510 (k) cleared by the DA.

[1] https://www.grandviewresearch.com/horizon/outlook/intracranial-aneurysm-market/united-states [2] https://www.grandviewresearch.com/industry-analysis/us-intracranial-aneurysm-market-report

For media inquiries, clinical demos, or partnership opportunities, please contact: Martina Andreasson, Global Product Manager for Neurovascular and Ankyras at Mentice E-post: martina.andreasson@mentice.com

Mobile: +46 733 660 247

About Mentice

Mentice (STO: MNTC) is the world leader in proficiency based simulation solutions for image guided interventional therapies. Our solutions help healthcare professionals acquire, retain, and enhance their procedural skills driving improved productivity and outcomes. Mentice solutions are scientifically validated and have been specifically developed for healthcare providers and the medical device industry. Neurovascular, cardiovascular, and peripheral interventions are just some of the clinical areas covered by our solutions. Learn more about the features and benefits of Mentice solutions at: www.mentice.com

Marketplace| Nasdaq First North Growth Market, Stockholm | Ticker symbol MNTC Certified Adviser| FNCA Sweden AB

Attachments

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