Press Release
04 January 2024 15:30:00 CET

Mentice receives FDA 510(k) Clearance for ANKYRAS™

Mentice, a healthcare technology company, today announced that the clinical decision support application ANKYRAS™ has received 510(k) clearance from the U.S. Food and Drug Administration (FDA). The approval of our product by the FDA demonstrates the safety and effectiveness of Ankyras and confirms our commitment to providing innovative and high-quality healthcare solutions.

The software is designed to assist interventional neuroradiologists in selecting the most suitable flow diverter before interventional treatment of intracranial aneurysms. Ankyras offers an intuitive and precise solution for clinical treatment planning, leading to more accurate prediction than traditional methods.

In the United States, it is estimated that 6.7 million individuals have an unruptured brain aneurysm, meaning that 1 out of every 50 people may be affected. Shockingly, every year, approximately 30,000 people experience a rupture in their brain aneurysm. Unfortunately, this rupture is fatal in nearly 50% of cases. Of those who survive, about 66% suffer some permanent neurological deficit.[1]

Ankyras is a platform that provides users with various functionalities to investigate device and treatment options in greater detail. It offers unique morphological assessment metrics that provide customers with a comprehensive and interactive analysis of all artery segments, ensuring they are better equipped to handle real-life challenges. The platform has technology supported by a strong IP portfolio that enables users to evaluate final device length, local expansion and porosity[2], and precisely align the centerline to create accurate simulations for specific devices.

> *"Obtaining 510(k) clearance for Ankyras has been the number one priority since the beginning of last year, and we are pleased that we have achieved this major regulatory milestone,"* said Héctor Fernández, Director of Ankyras Development. *"The United States is the single largest market for flow diverters, and devices from all major manufacturers in the US will now be available through Ankyras. This demonstrates our unwavering committment to our expressed strategy of expanding into patient-specific decision support applications, which we believe will offer significant synergies with our existing training offering. By relying on a single provider for both pre-procedural clinical planning, 3D-printed physical simulation and virtual simulation, we can offer significant benefits to both hospitals and industry."*

Moving forward, Mentice plans to continue improving the Ankyras solution by incorporating advanced functionalities and more treatment modalities, as well as integrating it with other Mentice solutions, especially the recently acquired Biomodex line of biorealistic haptic simulators.

To stay up-to-date with the latest Ankyras advancements and its role in device development and treatment strategies for Intracranial Aneurysms, visit www.mentice.com/ankyras. Alternatively, click here to request a personalized demo session with our team of trusted solution experts.

[1] Brain Aneurysm Foundation. Statistics and Facts. Available at: https://www.bafound.org/statistics-and-facts/
*[2] * Porosity metrics not available for all devices.*

Disclaimer & Regulatory Information
Ankyras is manufactured by Mentice Spain S.L. and distributed by Mentice subsidiaries and partners in approved markets.

In the EU, ANKYRAS is a CE marked Class IIa medical device. ANKYRAS is an online medical software intended to assist healthcare professionals in the selection of a proper braided device for treatment of intracranial aneurysms, also allowing them to assess the fit of each particular braided device in the patients' anatomy. The software allows the prediction of the final position of the device after being placed inside the vascular patient anatomy, the changes in the braided device geometry after being placed inside the vascular patient anatomy and the geometrical characteristics of the braided device such as the radial expansion and the local surface porosity.
It is intended for use by qualified medical professionals experienced in examining and evaluating 3D rotational angiography images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.

ANKYRAS is intended to be used with 3D rotational angiography (3DRA) images and magnetic resonances (MR).

In the US, ANKYRAS is a FDA cleared Class II medical device. The ANKYRAS software is intended to be used by physicians trained in medical procedures involving percutaneous and intravascular interventions for preoperational planning and sizing and computational modelling of specific validated flow diverters for intracranial aneurysms treatment with endovascular braided devices.

ANKYRAS is intended to be used with 3D rotational angiography (3DRA) DICOM images.

The ANKYRAS software allows for segmentation of the target artery and measurement of the segment length to be treated with the implantable device and the cross-section diameters along the segmented vessel.

ANKYRAS uses the segmented vessel outline to computationally model the placement of specific validated braided endovascular devices selected by the user inside the target artery for preoperational planning of the intervention with endovascular braided device.

All operators must read the complete User Manual before using ANKYRAS. The product should be used only by physicians trained in medical procedures involving percutaneous and intravascular interventions and previously trained by an ANKYRAS expert from Mentice.

The ANKYRAS software is intended to assist the physician users in the preoperational planning and sizing of neurovascular interventions and surgery with specific validated flow diverters and cannot replace or substitute, in whole or in part, their clinical judgement and analysis of patient's condition.

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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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