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NIPRO CORPORATION

Announcement of Spryte Medical , a US Affiliate of NIPRO, Receives FDA IDE Approval to Initiate “INSYTE” US Pivotal Trial evaluating the nOCT Imaging System during Brain Aneurysm Treatment

NIPRO CORPORATION (Head office: Settsu, Osaka; President: Tsuyoshi Yamazaki) is pleased to announce that Spryte Medical (Head office: Massachusetts, USA; hereinafter “Spryte ”), an equity-method affiliate of NIPRO, has received U.S. Food and Drug Administration (FDA) Investigational Device Exemption (IDE) approval to initiate “INSYTE” US Pivotal Trial evaluating the nOCT Imaging System during Brain Aneurysm Treatment.

Spryte issued a press release as follows.

Spryte Medical Receives FDA IDE Approval to Initiate “INSYTE” US Pivotal Trial evaluating the nOCT Imaging System during Brain Aneurysm Treatment

Bedford, Mass — November 19, 2025 — Spryte Medical, a pioneer in intravascular neuro imaging, announced it has received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to initiate the INSYTE pivotal trial. The trial will evaluate the safety and effectiveness of Spryte’s neuro Optical Coherence Tomography (nOCT) imaging system for use during intracranial aneurysm treatment procedures.

INSYTE marks the first FDA-approved clinical trial of an intravascular optical imaging system designed specifically for the neurovasculature. The Spryte nOCT Imaging System uses high-resolution optical coherence tomography to provide clinicians with micron-level image resolution of intracranial vessel walls and therapeutic devices that, today, are limited by current imaging modalities.

INSYTE will be led by two of the world’s foremost experts in cerebrovascular disease, Dr. Demetrius Lopes (Chicago, Illinois) and Dr. Ricardo Hanel (Jacksonville, Florida), serving as co-principal investigators.

“We have long needed a way to truly see what’s happening inside the brain’s arteries,” said Dr. Demetrius Lopes, Director of Cerebrovascular Surgery and Neurointervention at Advocate Health. “nOCT intravascular imaging could fundamentally change how we assess and treat intracranial aneurysms – enabling us to optimize therapeutic device deployment with unprecedented precision.”

Dr. Ricardo Hanel, Director of the Baptist Neurological Institute, added: “The ability to visualize vessel disease, implanted devices and healing from inside the artery opens a completely new dimension for aneurysm treatment. The INSYTE trial will allow us to validate a technology that could redefine standards of care for patients with brain aneurysms.”

“FDA approval to initiate this study marks an important milestone for Spryte Medical and for the field of neurointervention,” said David Kolstad, Chief Executive Officer of Spryte Medical. “Our successful collaboration with the FDA through the Total Product Life Cycle Advisory Program (TAP) reflects their continued commitment to expedite patient access to innovative medical devices. We are excited to begin INSYTE, which we believe will further demonstrate the safety and effectiveness of our nOCT Imaging System in brain aneurysm treatment.”

Spryte Medical anticipates first patient enrollment of INSYTE in early 2026. Details of the study are available on ClinicalTrials.gov.

The nOCT Imaging System is an investigational product and has not been approved or cleared by the U.S. Food and Drug Administration. Its safety and effectiveness have not yet been established.

For more information about Spryte Medical and its breakthrough nOCT technology, please visit www.sprytemedical.com

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About Spryte Medical :
Spryte Medical is an intravascular imaging, AI, and data company headquartered in Bedford, MA. The unique imaging and data platform is purpose-built to accelerate understanding of target diseases, facilitate the development of novel therapies, and to provide information for optimal treatment delivery for the benefit of patients worldwide.