



## **Announcement of Spryte Medical, a US Affiliate of NIPRO, First Participants Enrolled in the “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 ”), a consolidated subsidiary of NIPRO, has enrolled the first participants in the “INSYTE” US Pivotal Trial evaluating the nOCT Imaging System during brain aneurysm treatment.

Spryte issued a press release as follows.

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**Spryte Medical Announces First Participants Enrolled in the INSYTE Trial at Baptist Health Jacksonville**  
*FDA-approved IDE Study to evaluate the safety and effectiveness of the nOCTTM Imaging System to provide quality images for diagnostic assessment during endovascular intracranial aneurysm treatment and follow-up*

**Bedford, MA — March 3, 2026 — Spryte Medical**, a pioneer in intravascular neuro imaging, today announced the successful enrollment of the first participants in the **INSYTE Trial**, at **Baptist Health Jacksonville** which marks a major milestone in the clinical development of its neuro-optical coherence tomography (nOCT) imaging system. The study will assess the system’s ability to provide high-quality intravascular images to support diagnostic assessment during endovascular intracranial aneurysm treatment and follow-up procedures.

The INSYTE Trial — **Intravascular Neuro OCT Imaging System for Aneurysm Treatment Evaluation** — is a U.S. Food and Drug Administration (FDA)–approved Investigational Device Exemption (IDE) trial designed to evaluate the safety and effectiveness of Spryte Medical’s nOCT Imaging System.

Initial enrollments were completed with the neurointerventional team at Baptist Health Jacksonville led by **Ricardo Hanel, MD, PhD**, neurosurgeon, who serves as Co-Principal Investigator of the INSYTE Trial.

*“Despite advances in endovascular therapy, our ability to visualize the vessel wall and device–tissue interaction during aneurysm treatment remains limited,” said Dr. Hanel. “INSYTE represents a landmark study that will significantly increase our understanding of brain vessel wall pathologies. Intravascular neuro-OCT imaging will enhance real-time diagnostic insights during these complex procedures.”*

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The INSYTE Trial is the **first FDA-approved clinical trial of an intravascular optical imaging system designed specifically for the neurovasculature**. Additional clinical sites are expected to initiate enrollment as the trial progresses.

*“Initiating enrollment in the INSYTE Trial is a significant milestone for Spryte Medical and for the neurointerventional community,”* said **Demetrius Lopes, MD**, Co-Principal Investigator of the INSYTE Trial and neurosurgeon, Advocate Health. *“This technology has the potential to provide unprecedented image resolution within the neurovasculature, and this study will help rigorously evaluate its safety, performance, and clinical utility.”*

*“Reaching first participant enrollment in INSYTE reflects years of close collaboration between our clinical partners, engineers, physicians, and regulators,”* said **David W. Kolstad**, Chief Executive Officer of Spryte Medical. *“Our goal with nOCT is to provide clinicians with a new level of intravascular insight that may ultimately improve decision-making, procedural precision, and patient outcomes in the treatment of intracranial aneurysms.”*

*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.*

#### **About the INSYTE Trial**

The INSYTE Trial is a prospective, single-arm, unblinded, multicenter trial evaluating the Spryte Medical nOCT Imaging System for use during endovascular treatment and follow-up of intracranial aneurysms. The trial focuses on safety and imaging performance to support diagnostic assessment in the neurovasculature. Details of the study are available on [ClinicalTrials.gov](https://ClinicalTrials.gov).

#### **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.

This news release is meant to provide information on NIPRO's corporate activities and an overview of our initiatives to not only the press but also our many stakeholders, including shareholders and investors in a fair and timely manner. The information about NIPRO products and services included in this release is not intended for use in attracting customers or as medical advice.

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