



AngioDynamics Announces Publication of DIRECT Study Results and New Category I CPT Code for Pancreatic IRE

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Prospective, multicenter FDA IDE study found an IRE-based treatment strategy was associated with longer overall survival in Stage III pancreatic cancer; new Category I CPT code for open pancreatic IRE takes effect January 1, 2027

LATHAM, N.Y.--(BUSINESS WIRE)--Oct. 21, 2026-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options, and improving quality of life for patients, today announced two milestones for irreversible electroporation (IRE), the non-thermal ablation technology delivered by the NanoKnife System. The first is the publication of results from the DIRECT study in *The Oncologist*, in which an IRE-based treatment strategy was associated with longer overall survival in patients with Stage III pancreatic ductal adenocarcinoma (PDAC). The second is a new Category I CPT® code for open IRE ablation of pancreatic tumors, effective January 1, 2027.

DIRECT Study Publication

The peer-reviewed article reporting overall survival results from the DIRECT study was published in *The Oncologist* (DOI: 10.1093/oncolo/oyag416). DIRECT is a multicenter study conducted under a U.S. Food and Drug Administration Investigational Device Exemption at 18 U.S. sites. The analysis compared patients treated with standard-of-care systemic therapy plus IRE with patients who received standard-of-care systemic therapy without IRE for Stage III PDAC.

The analysis included 137 patients: 99 treated within an IRE-based strategy and 38 who received standard of care without IRE. Reported findings included:

- Patients treated within an IRE-based strategy had a median overall survival of 28 months from diagnosis, compared with 15 months for patients who received standard of care without IRE.
- After statistical adjustment for differences between the two groups, IRE remained associated with longer survival, including an average of five additional months of survival during the first 24 months.
- Median progression-free survival was 9 months in the IRE group and 6 months in the standard-of-care group. Serious adverse events, defined as Grade 3 or higher, were reported in 56% of patients in the IRE group and 71% of patients in the standard-of-care group.

DIRECT was a non-randomized study and the findings should be interpreted as an association between the IRE-based treatment strategy and longer survival, rather than definitive evidence that IRE caused the observed survival difference.

"Locally advanced pancreatic cancer remains a formidable clinical challenge, and defining the role of local therapy after induction chemotherapy is a critical priority," said Robert C.G. Martin II, M.D., Ph.D., Director of the Division of Surgical Oncology at the University of Louisville School of Medicine and an investigator in the DIRECT study. "DIRECT provides prospective, multicenter evidence that an IRE-based treatment strategy was associated with longer overall survival, including after analyses that accounted for measured differences in patient selection and treatment timing. Because this was a nonrandomized study, it cannot establish that IRE caused the survival difference. The findings support further prospective evaluation of IRE and its consideration within a multidisciplinary treatment plan for appropriately selected patients."

"Advancing pancreatic cancer research requires continued evaluation of multimodal treatment strategies that integrate local therapies with systemic therapy," said Rohan Jeyarajah, M.D., Chair of the Department of Surgery at TCU Burnett School of Medicine and Past President of the Americas Hepato-Pancreato-Biliary Association (AHPBA). "For locally advanced pancreatic cancer, generating meaningful clinical evidence is critical to informing future treatment strategies and improving the understanding of how these approaches may fit within multidisciplinary care."

New Category I CPT Code Established for Open Pancreatic IRE

The American Medical Association (AMA) CPT Editorial Panel approved a new Category I CPT code describing open ablation of pancreatic tumor(s) using IRE, including imaging guidance. The final code number and descriptor are expected to be published by the AMA, and the code is scheduled to become effective January 1, 2027.

The new Category I CPT code for open pancreatic IRE follows the January 1, 2026 implementation of Category I CPT codes for liver IRE (CPT 47384) and prostate IRE (CPT 55877). It also follows Palmetto GBAs final Local Coverage Determination L40205, effective July 5, 2026, for appropriately selected patients with favorable intermediate-risk prostate cancer and metastatic colorectal cancer to the liver who meet the policy criteria.

The new pancreatic IRE code establishes a standardized mechanism for reporting open pancreatic IRE procedures and represents continued progress in the coding infrastructure for IRE. The code does not determine coverage or guarantee payment. Coverage and payment decisions may vary by payer, plan and site of service.

"Prostate cancer remains our commercial priority for the NanoKnife System, and that is where our commercial investment is concentrated," said Juan Carlos Serna, Senior Vice President of Scientific and Clinical Affairs at AngioDynamics. "The DIRECT publication and new pancreatic Category I CPT code reflect important work that was initiated before we aligned our commercial strategy around prostate cancer. We are pleased to see that work reach peer-reviewed publication and provide surgeons with a defined way to report open pancreatic IRE procedures beginning in January. These milestones add to the clinical evidence base for IRE and support continued clarity in how the procedure is reported."

About the NanoKnife System

The NanoKnife System utilizes Irreversible Electroporation (IRE) technology to effectively destroy targeted cells without the use of thermal energy by delivering high-voltage electrical pulses, creating permanent nanopores within the cell membrane. This stimulus induces an apoptotic-like cellular

death in the targeted tissue, resulting in a complete ablation of the targeted tissue.¹ Visit nanoknife.com for full product information.

United States: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate tissue.

Canada: The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability.

European Union: The NanoKnife System is indicated for the ablation of soft tissue and tumors of the pancreas, kidney, liver, or prostate, including intermediate risk prostate cancer.

About AngioDynamics, Inc.

AngioDynamics is a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options, and improving quality of life for patients.

The Company's innovative technologies and devices are chosen by talented physicians in fast-growing healthcare markets to treat unmet patient needs. For more information, visit angiodynamics.com.

Safe Harbor

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¹ Lee EW, Thai S, Kee ST. Irreversible electroporation: a novel image-guided cancer therapy. Gut Liver. 2010;4 Suppl 1(Suppl 1):S99-S104. doi:10.5009/gnl.2010.4.S1.S99

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