

GPX® Embolic Device meets Primary Endpoints in an Investigational Device Exemption (IDE) Pivotal Trial

Trial Reports 99% Successful Occlusion of Flow with 40 Investigators Delivering the New Embolic Through 20 Different Catheters

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Dr. Michael Darcy

Technology, Inc. announced the positive results from the Investigational Device Exemption (IDE) pivotal clinical trial evaluating the [GPX](#) Embolic Device. In the 114 patients that were treated in the trial, GPX achieved 100% success in delivery to the target vessel and 99.1% successful occlusion of flow, with 99.1% freedom from major adverse events. The data were presented at the Society of Interventional Radiology (SIR) annual meeting, as well as the Global Embolization Symposium & Technologies (GEST)

annual meeting where it was awarded a BEST of GEST abstract. The late-breaking abstract was also published in the Journal of Vascular and Interventional Radiology (JVIR Volume 37, Issue 5, 108719 abstract LBA20).

The GPX Embolic Device is a unique embolic technology that enables controlled, deep and durable embolization ideal for many applications, including oncology. Although more than \$3.5 billion is spent annually on embolic devices to treat tumors and other conditions throughout the body, many of these devices remain difficult to prepare, deliver, and control. The GPX technology is packaged in a ready-to-use syringe, can be prepped tableside by the clinician in less than 20 seconds, and may be delivered through standard microcatheters without complex mixing systems or special delivery catheters.

The IDE clinical study was a single-arm, open label, non-randomized, prospective, multi-center study and enrolled one hundred and fourteen patients at eighteen sites across the United States, Canada, and New Zealand, involving more than forty investigators. During the trial, GPX was delivered through over twenty different microcatheter configurations, (spanning sizes from 1.9Fr (0.025"/0.63mm) to 2.8Fr (0.037"/0.93mm) outer diameters and lengths from 110 cm to 165 cm), demonstrating broad compatibility across a wide range of commonly used delivery devices.

“These results are impressive and should help establish GPX as an important new tool in embolic therapy once approved”, said Michael Darcy, MD, National Principal Investigator and Professor of Radiology at Washington University in St. Louis. “The physician survey results are promising. It shows that the device preparation, delivery, and behavior were easy to incorporate into existing practice norms.”

Pathologies treated included pre-nephrectomy renal arteries, primary and metastatic bone tumors, renal cell carcinoma, hepatocellular carcinoma, renal angiomyolipoma, portal vein branches, and other vascular tumor or tumor metastases.

“We are excited about this data,” stated Libble Ginster, President and CEO of Fluidx Medical Technology, Inc. “The feedback has been overwhelmingly positive, and this is a major milestone for Fluidx. The GPX technology has the potential to revolutionize the interventional oncology category.”

The Fluidx GPX® Embolic Device is not approved or available for commercial distribution in any country. In the United States the device is being used under an Investigational Device Exemption (IDE) from the US Food and Drug Administration (FDA). Findings from the IDE study expand on results from the first-in-human study and support the Premarket Approval (PMA) application to the FDA for commercial use in the United States.

About Fluidx Medical Technology:

Fluidx Medical Technology, Inc. is a Salt Lake City-based medical device company advancing a portfolio of next-generation embolic technologies, including GPX, ULTRA, and IMPASS. The company's mission is to develop a new category of easy to use, controllable embolic gels that can treat the widest range of clinical conditions, effectively occluding the smallest vessels up to the largest vessels. www.FluidxMedical.com

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