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First patient treated in Medtronic multi-organ SPYRAL GEMINI Pilot study

Medtronic advances pipeline with update on multi-organ denervation study and additional data recently presented at EuroPCR 2025

Medtronic, a global leader in healthcare technology, today announced that it has treated the first patient in its SPYRAL GEMINI Pilot program (including 'OFF MED' and 'ON MED' studies).* The first patient was treated by Dr. Barry Bertolet at Cardiology Associates of North Mississippi and North Mississippi Medical Center in Tupelo. With this trial, Medtronic intends to investigate the feasibility of combined denervation of both the renal and common hepatic (liver) arteries with the Symplicity Spyral™ catheter. The planned **G**lobal Pilot study of r**E**nal and hepatic co**M**b**IN**ed denervat**I**on (SPYRAL GEMINI Pilot study) will investigate the safety and potential efficacy of the multi-organ denervation (MDN) approach in uncontrolled hypertension patients who are both on and off medications.

“In addition to denervation of the renal arteries - where the blood pressure lowering clinical benefit has already been established through multiple rigorously designed clinical trials - targeting other richly innervated vascular areas such as the common hepatic artery is an emerging horizon for treating hypertension,” said Dr. David Kandzari, Chief of Piedmont Heart Institute and Cardiovascular Services and lead principal investigator of the SPYRAL GEMINI pilot study. “We look forward to learning more about the potential efficacy of denervation in both the liver and renal arteries from SPYRAL GEMINI.”

The SPYRAL GEMINI Pilot study is a prospective, multicenter, international, feasibility study in two parallel cohorts of hypertensive patients, including patients off anti-hypertensive medications and patients with high cardiovascular risk who are taking anti-hypertensive medications. The program will enroll up to 175 patients in the United States, Europe and Australia. Denervation will occur in both the common hepatic and main renal arteries and branches using the Symplicity Spyral catheter. Procedural safety and efficacy will both be evaluated starting at three months and continuing through 36 months post-procedure.

“As a pioneer in renal denervation, Medtronic is uniquely positioned to explore the clinical potential of multi-organ denervation with Symplicity Spyral’s low profile and single catheter design, and intellectual property in this field,” said Jason Weidman, senior vice president and president of the Coronary and Renal Denervation business within the Cardiovascular portfolio at Medtronic. “As a company, Medtronic is committed to investing in strategically important areas that hold promise for patients and the medical community."

Recently presented EuroPCR 2025 preclinical data showed a 90% significant reduction in norepinephrine (marker of sympathetic activity) with multiorgan denervation.[1] These findings suggest that multiorgan denervation using the Spyral system can successfully denervate within both the hepatic and renal arteries.

Hepatic denervation is limited by law to clinical investigation in all geographies. The generator and catheter used in the SPYRAL GEMINI Pilot study for hepatic denervation are not approved for sale or use in the U.S. or any other country.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission — to alleviate pain, restore health, and extend life — unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow on LinkedIn.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] Mahfoud F, et al. EuroPCR 2025

* SPYRAL GEMINI Pilot Study NCT06907147

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