

Korea approves DeepQure's HyperQure™ for clinical trial in Atrial Fibrillation

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HyperQure is a next-generation laparoscopic RDN device



DeepQure has announced that South Korea's Ministry of Food and Drug Safety (MFDS) has approved a clinical trial of HyperQure™ RDN System, the company's novel laparoscopic renal denervation (RDN) system, for the treatment of atrial fibrillation (AF).

The trial is designed to evaluate the safety and efficacy of laparoscopic RDN in patients with recurrent AF following pulmonary vein isolation (PVI) and resistant hypertension. It will be conducted as a multicenter, prospective, single-arm, open-label exploratory study.

HyperQure is a next-generation laparoscopic RDN device developed over the past decade under the leadership of Professor Chang-Wook Jeong at Seoul National University Hospital. By adopting an extravascular approach, HyperQure™ addresses key limitations of conventional intravascular RDN, offering direct anatomical access to renal nerves with the potential for improved precision and outcomes.

DeepQure is also conducting RDN clinical trials for resistant hypertension in both South Korea and the United States. Patient enrollment is nearing completion domestically, while trials are actively underway at five major academic medical centres across the US.

The MFDS's approval for this new indication marks an important milestone, expanding HyperQure™'s potential from hypertension to atrial fibrillation and reinforcing its technical scalability and multi-disease therapeutic potential.

HyperQure™ is ISO 13485-certified, GMP-compliant, and was designated as Innovative Medical Device No. 36 by the MFDS, underscoring its clinical relevance and breakthrough innovation.