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FOR IMMEDIATE RELEASE

THE GORE RELIEF CLINICAL STUDY BEGINS RANDOMIZING PATIENTS TO EVALUATE PFO CLOSURE FOR MIGRAINE HEADACHE RELIEF

CAUTION: Investigational device. Limited by United States law to investigational use.

The Gore RELIEF Clinical Study is evaluating the safety and efficacy of transcatheter closure of patent foramen ovale (PFO) with the GORE® CARDIOFORM Septal Occluder for the relief of migraine headaches.

FLAGSTAFF, Ariz. (October 15, 2023) — W. L. Gore & Associates (Gore) announces that patients have passed through the multi-month enhanced screening process and have begun entering the final randomization phase of the Gore RELIEF Clinical Study, an investigational study to evaluate the safety and efficacy of transcatheter closure of patent foramen ovale (PFO) for the relief of migraine headaches utilizing the GORE® CARDIOFORM Septal Occluder, a permanently implanted device.

"The RELIEF Clinical Study investigates whether PFO closure may reduce the number of monthly migraine headache days for select patients. No previous PFO closure migraine trial has yet included such clearly defined selection criteria designed to identify those patients expected to most likely respond to this potential, PFO-mediated mechanism," said Robert Sommer, M.D., National Principal Investigator, RELIEF Clinical Study. "Clinical experiences have suggested a platelet-based connection between migraine and PFO, and there may be a correlation between PFO closure responsiveness and thienopyridine responsiveness. PFO closure may offer a mechanical method to reduce or eliminate this trigger factor."

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Gore has been actively screening patients in the United States since initiating the trial in November of 2022. The enhanced screening process identifies the targeted 150 patients found responsive to the study drug, with a documented PFO and history of more than one migraine headache day per week.

“The RELIEF Clinical Study is another example of Gore’s commitment to research with the goal of improving lives,” said Jake Goble, Ph.D., Cardiac Business Leader for Gore’s Medical Products Division. “The study incorporates the learnings from past PFO-migraine studies targeting a patient population we hypothesize may truly benefit. We are excited to reach this milestone as we continue to pursue a potentially impactful treatment option for migraine headache relief.”

The device in the study, the GORE CARDIOFORM Septal Occluder, combines unique materials and is designed to provide a soft and conformable option for PFO closure, currently indicated for secondary stroke prevention in select patients. With over 68,000 devices sold globally and 12 years* of clinical use, the GORE CARDIOFORM Septal Occluder is trusted by physicians and patients for its safety and performance in its approved indications. The GORE CARDIOFORM Septal Occluder received U.S. Food and Drug Administration premarket approval in 2018 for the percutaneous closure of PFO to reduce the risk of recurrent stroke in select patients. It is also approved in the European Union for percutaneous closure of PFO. Furthermore, it is approved in the United States and European Union for closure of a type of atrial septal defect.†

Additional information about the clinical study is available at www.clinicaltrials.gov

* Beginning in June 2011.

† For complete indications and other important safety information for Gore commercial products referenced herein, refer to the applicable *Instructions for Use* (IFU).

Gore engineers medical devices that treat a range of cardiovascular and other health conditions. With more than 55 million medical devices implanted over the course of more than 45 years, Gore builds on its legacy of improving patient outcomes through research, education and quality initiatives. Product performance, ease of use and quality of service provide sustainable cost savings for physicians, hospitals and insurers. Gore is joined in service with clinicians and through this collaboration we are improving lives. www.goremedical.com

About Gore

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With more than 13,000 Associates and a strong, team-oriented culture, Gore generates annual revenues of \$4.8 billion. [gore.com](https://www.gore.com)

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