WHO IS THE TRIAL FOR?

You may be eligible for the CONFORM Trial if you:

- Have non-valvular atrial fibrillation
- Are at increased risk for stroke
- Are currently taking or have been recommended to take oral anticoagulants (blood thinners)
- Are seeking a potential alternative to long-term blood thinner use

Participation in the trial is entirely voluntary and all qualified participants will be evaluated and cared for by a dedicated team of medical professionals.

1 OUT OF 3
people with AFib will have a stroke in their lifetime.[2]

15% OF STROKES
are due to AFib not caused by a non-valvular heart problem.[3]

5X HIGHER STROKE RISK
in people with AFib vs. people with a regular heart beat.[4]

WHY PARTICIPATE?

Participating in a clinical trial gives you access to innovative treatments, personalized care, and the chance to contribute to future medical advancements. You'll be closely monitored by a dedicated medical team focused on your health and safety. While there are risks, your involvement plays a vital role in shaping the future of care.

The CLAAS AcuFORM System is an investigational device in the United States, which means that it has not yet been approved by the Food and Drug Administration (FDA) for sale in the U.S.

WOULD YOU BENEFIT FROM CLAAS ACUFORM?

Visit conformtrial.com to learn more

The risks of delivery of the CLAAS device are similar to those of other procedures that require a transseptal puncture and transcatheter delivery of an implant through the venous system, across the interatrial septum, and into the left atrium using a specialized catheter (e.g., EP procedures and/or other LAA devices such as Watchman).

REFERENCES:

1. Gray W, Conformal Early Feasibility Study: 12 Months Results. TCT 2023
2. FAQ About AFib. American Heart Association, Inc., 2023. Available at: www.heart.org/-/media/Files/Health-Topics/Atrial-Fibrillation/FAQ-About-AFib.pdf. Accessed June 10, 2024.
3. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. Ann Thorac Surg. 1996;61:755-759.
4. Pfizer and Bristol-Myers Squibb. The Facts of AFib. March 2015.

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THE SHAPE OF STROKE PREVENTION

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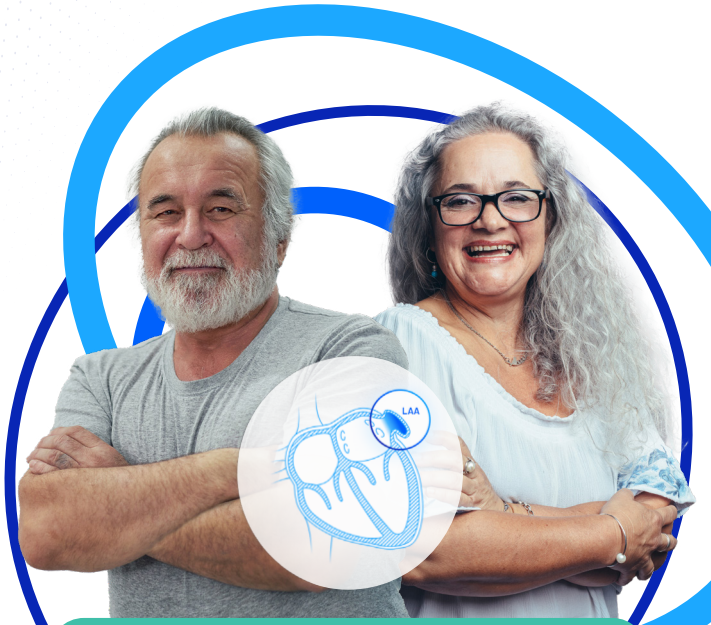
CONFORM
PIVOTAL TRIAL



LEFT ATRIAL APPENDAGE OCCLUSION

Personalized AFib Treatment for The Individual You Are.

FIND OUT IF THE CONFORM PIVOTAL TRIAL MAY BE RIGHT FOR YOU.

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WHAT IS THE PURPOSE OF THE

CONFORM
Pivotal Trial?

The CONFORM Trial has been reviewed by the FDA to evaluate the safety and efficacy of the CLAAS® AcuFORM™ device compared to other commercially available Left Atrial Appendage Occlusion (LAAO) devices in patients with non-valvular Atrial Fibrillation (AFib).

The CONFORM Trial offers patients an alternative to long-term use of blood thinners by permanently sealing off the left atrial appendage (LAA) — a common source of blood clots that can lead to stroke.

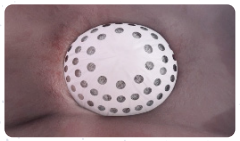
All patients enrolled in the CONFORM Trial will receive a LAAO device. One study group will receive the CLAAS AcuFORM device, and the other will receive a commercially available implant.

EARLY CLINICAL EXPERIENCE

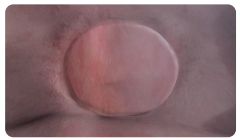
The CLAAS System is still under investigation, early clinical studies have shown

97.7% Closure Success

seal without significant (>3mm) leaks at 12 months, comparing favorably with marketed devices.[1]

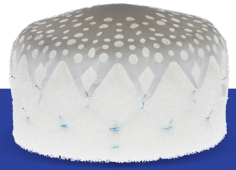


PRE-PROCEDURE



POST-PROCEDURE

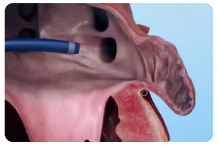
claas® AcuFORM™



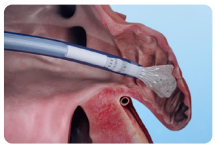
The CLAAS AcuFORM device is a foam-based implant that's engineered to conform to each patient's individual anatomy. The combination of a flexible nitinol frame with an expandable foam body helps ensure a secure fit and seal within the LAA.

How the device is implanted?

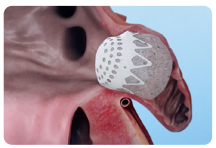
The CLAAS AcuFORM is a one time, permanent implant placed by your doctor using a minimally invasive procedure, without the need for open-heart surgery.



01 | Through a small incision in your groin, your doctor will insert a long, thin tube, and guide this tube into your left atrial appendage.



02 | The doctor will guide the CLAAS AcuFORM device to your heart and into the LAA. Through the long, thin tube, the doctor will then guide the implant into your LAA.



03 | The CLAAS AcuFORM device is then deployed to seal the LAA and prevent blood clot formation that can lead to stroke.

FREQUENTLY ASKED QUESTIONS

What should I expect if I participate?

As part of the trial, you will be asked to:

- Provide informed consent
- Adhere to medication therapy study requirements
- Commit to specific follow-up visits

What are my other treatment options?

If you are seeking therapy to reduce your AFib stroke risk your options include: anticoagulants (blood thinners), commercially approved LAA closure devices or participation in this study.

What are the risks?

Please discuss with your doctor the risks and benefits of participating in a clinical trial.

What happens if I decide to not participate?

Your participation in this trial is completely voluntary. If you decide not to participate, your doctor will continue to ensure you get appropriate care.

LEARN MORE

Scan the QR code to view the CLAAS AcuFORM animation overview.

CAUTION: Investigational Device. The CLAAS System is limited by Federal (or United States) law to investigational use.