FREQUENTLY ASKED QUESTIONS

How do I know if I qualify for the CONFORM Clinical Trial?

If you have non-valvular Afib and are on blood thinners, speak with your doctor to learn if you are eligible to participate in the CONFORM Clinical Trial.

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.

The CLAAS 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.

The risks of delivery of the CLAAS Implant 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. S.S. Chung, R. Havmoeller, K. Narayanan, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 study. Circulation, 129 (2014), pp. 837-847.

WOULD YOU BENEFIT FROM CLAAS?

Visit conformalmedical.com/clinical-trial/ to learn more

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Do you have atrial fibrillation and are you worried about your stroke risk?

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

claas®

Why are patients with atrial fibrillation at an increased risk of stroke?

Atrial fibrillation (Afib), or an irregular heartbeat, can cause blood to pool in a small pouch off the upper left chamber of the heart, known as the left atrial appendage (LAA). This pooling can cause the formation of blood clots which may lead to stroke.

CURRENT TREATMENT OPTIONS

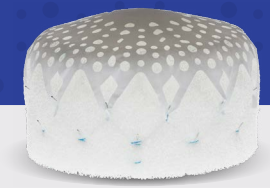
It is not necessary for you to be enrolled in this study to protect you from stroke or related complications from blood clots. Alternative therapies for your medical condition may include long term medication that thins your blood or commercially available left atrial appendage closure devices.

Discuss with your doctor to see what treatment option is best for you.

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

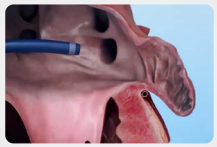
The CLAAS® System

is a permanent implant that uses a conformable foam designed to seal your LAA to reduce your risk of stroke, without the need for anticoagulants (blood thinners).

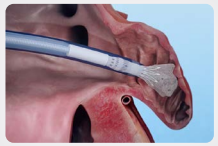


How is the CLAAS® implant placed?

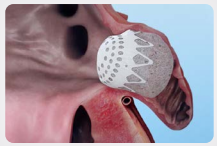
The Conformal CLAAS device is a permanent implant placed by your doctor using a standard minimally invasive procedure.



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® implant to your heart and into the LAA. Through the long, thin tube, the doctor will then guide the CLAAS® implant into your LAA.



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

WHAT IS THE PURPOSE OF THE

CONFORM Clinical Trial?

The CONFORM Clinical Trial has been reviewed by the FDA to evaluate the investigational CLAAS System compared to other commercially available left atrial appendage closure devices, in patients with non-valvular Afib. This trial is being performed to generate sufficient data for FDA approval.

All patients enrolled in the CONFORM Clinical Trial will be randomized to receive the investigational CLAAS implant or a commercially available device. The randomization process is used to assign a patient to a study group—like a coin toss.