claas® AcuFORM™

Next-Generation Left Atrial Appendage Occlusion Device

CONFORM PIVOTAL TRIAL REFERRAL FORM

Use this form to access which of your non-valvular atrial fibrillation (AFib) patients may be appropriate for a Left Atrial Appendage Occlusion (LAA) device and connect them with an implanter for a consultation about treatment options including the CLAAS AcuFORM LAAO device.

Patient Name | DOB

Phone Number | Email

OAC Regimen | CHA_2-DS_2-VASc

The CLAAS® AcuFORM™ implant has been designed to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

YES	NO	
○	○	Patient has documented non-valvular atrial fibrillation (paroxysmal, persistent, or permanent)
○	○	Patient has an increased stroke/systemic embolism risk and are recommended for OAC (As defined by $CHADS_2$/CHA_2DS_2-VASc of ≥ 3)
○	○	Patient is suitable for short-term OAC therapy
○	○	Patient has an appropriate rationale to seek a non-pharmacological alternative to OAC (Risk-benefit of OAC vs device considered)
○	○	Deemed appropriate for LAA closure by the site investigator and a clinician not a part of the procedural team using a shared decision-making process in accordance with standard of care
○	○	Able to comply with the protocol-specified medication regimen and follow-up evaluations

Referring Physician

Phone Number | Email

For more information about the CONFORM Pivotal Trial, please visit: conformtrials.com

CAUTION: Investigational Device.
The CLAAS System is limited by Federal (or United States) law to investigational use. MC-107.v1.0

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THE SHAPE OF STROKE PREVENTION

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CHA2DS2-VASC SCORE (STROKE RISK)[1]

	Condition	Points
C	Congestive heart failure	1
H	Hypertension	1
A	Age ≥ 75 years	2
D	Diabetes mellitus	1
S2	Prior stroke or TIA or Thromboembolism	2
V	Vascular disease	1
A	Age 65—75 years	1
Sc	Sex category	1
Total Points		

Score	Yearly Stroke Risk %)		
	No Warfarin	With Asprin[2]	With Warfarin[2]
0	0	0	0
1	1.3	1.0	0.5
2	2.2	1.8	0.8
3	3.2	2.6	1.1
4	4.0	3.2	1.4
5	6.7	5.4	2.3
6	9.8	7.8	3.4

HAS-BLED SCORE (BLEEDING RISK WITH WARFARIN)[3]

	Condition	Points
H	Hypertension	1
A	Abnormal renal/liver function (1 pt each)	1 or 2
S	Stroke	1
B	Bleeding history or disposition	1
L	Labile INR	2
E	Elderly (e.g. age > 65 years)	1
D	Current drugs (medication) or alcohol use (1 pt each)	1 or 2
Total Points		

Score	Yearly Major Bleeding Risk (%)*
0	1.13
1	1.02
2	1.88
3	3.74
4	8.70
5+	12.5

Choosing to participate in a clinical trial is an important personal decision. Talk with your patient and their loved ones about deciding to join a study. THIS IS NOT A FORMAL SHARED DECISION MAKING DOCUMENT AND SHOULD NOT BE USED AS A DECISION TOOL TO PARTICIPATE IN A CLINICAL TRIAL.

REFERENCES:

1. CHA2DS2-VASc: Chest. 2010;137(2):263-272.
2. Warfarin Stroke Reduction: Ann Intern Med. 2007;146:857-867.
3. HAS-BLED: Chest. 2010;138(5):1093-1100.

*Major Bleed = ICH or bleeding resulting in a hospitalization, a hemoglobin drop > 2 g/dL, or a blood transfusion.
NOTE: A high HAS-BLED score is ≥3.

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.

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For more information, please visit: clinicaltrials.gov (NCT05147792)

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