conformal THE SHAPE OF STROKE PREVENTION	**CONFORM Patient Population** **Directions & Data Transfer Tool**
	Site Number: _____ Subject ID: _____

Did Subject meet eligibility criteria before Procedure Day ?	☐ **Yes** ☐ **No** *(Complete the Study Exit form accordingly. Classify subject as "Screen Failure" -- Subject did not meet I/E criteria prior to index procedure.)*
Did Subject undergo Procedure TEE ?	☐ **Yes** ☐ **No** *(Complete the Study Exit form accordingly. If the subject did not undergo the procedural TEE, the subject should be exited and classified as a "Screen Failure – Subject did not meet I/E criteria prior to index procedure" (or "Withdrawn" if the subject withdrew).*
Did Subject continue to meet eligibility criteria after the Procedural TEE ?	☐ **Yes** ☐ **No** *(Complete the study exit form accordingly. If the subject did not continue to meet eligibility criteria after the procedural TEE, subject should complete all visits through 45-Days with only Visit Information and QVSFS forms required. After completion of the 45-Day Visit, the subject should be exited and classified as "Screen Failure – Subject did not meet I/E criteria after the Index Procedure TEE was performed and prior to the Access Sheath crossed the body.)*
Did any component of the investigational or control device (e.g. access sheath) enter the subject's body ?	☐ **Yes** ☐ **No** *(Complete the study exit form accordingly. If the subject underwent procedural TEE but no component of the investigational or control device entered the subject's body, subject should complete all visits through 45-Days with only Visit Information and QVSFS forms required. After completion of the 45-Day Visit, the subject should be exited and classified as "Screen Failure – Subject did not meet I/E criteria after the Index Procedure TEE was performed and prior to the Access Sheath crossed the body.)*
Did the subject receive an LAAO implant?	☐ **Yes** (*If the subject underwent procedural TEE, AND a component of the investigational or control device entered the subject's body, AND received an implant, the subject should be followed for the **full 5-Year Protocol.)*** ☐ **No** *(Complete the study exit form accordingly. If the subject underwent procedural TEE, AND a component of the investigational or control device entered the subject's body, BUT the subject **DID NOT RECEIVE AN IMPLANT**, the subject should complete all primary safety and efficacy endpoints via phone call/telehealth (including Pre-Discharge, 7-Day, 45-Day, 6-Month, 12-Month, and 18-Month Visits Once the subject completes the 18-Month Visit, the subject should be exited as "Withdrawn – No Implant received at index procedure (after IMPLANT imaging, Access Sheath crossed the body)*
Did the subject receive the intended LAAO implant (e.g., the device they were randomized to)?	☐ **Yes** ☐ **No** (*If the subject underwent procedural TEE, AND a component of the investigational or control device entered the subject's body, AND received an implant, even if it was not the intended implant (e.g., a patient randomized to CLAAS was not able to get the CLAAS device and received a Control device), the subject **should be followed for the full 5-Year Protocol.**)* *Protocol Deviation should be entered for "Procedure /Assessment incomplete or not done" and, Additional Description of Deviation text box should include "Randomized to CLAAS – received CONTROL"*

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Site Personnel Signature **Date (DD/MMM/YYYY)**