

Memo To File

To: C-48 V3.0

Subject: CONFORM Pivotal Trial Pre-randomization Screen Failures

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Date: March 27, 2026

Signed by:

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Conformal Medical Inc. (CMI) has identified language in the CONFORM clinical investigation plan (CIP) and the associated informed consent form (ICF) that can be interpreted in different ways by the reader. The purpose of this memo is to clarify the intent of this language, and outline steps that CMI intends to take to rectify the source of potential ambiguity.

CMI defines enrollment in CONFORM Pivotal Trial as a subject who has been consented, has met all inclusion criteria (including imaging review), meets none of the exclusion criteria, and has been randomized. If pre-procedure imaging is not available for a given subject, a TEE on the day of the procedure can be used to ascertain that the patient meets all imaging criteria. If the TEE imaging review confirms that the patient meets all study criteria, they are randomized and considered enrolled in the study. If the TEE imaging review reveals that the patient does not meet all study criteria, the subject fails screening, and are treated and followed per standard of care, consistent with consent provided by the patient to be treated outside the CONFORM study.

The intent of the CIP and ICF is to convey that subjects who have signed the ICF but fail to meet all inclusion criteria prior to randomization, including TEE the day of the procedure, are not considered enrolled in the study. These subjects are considered screen failures and are therefore not subject to any protocol-required follow-up, consistent with section 8.8.3 and 8.8.6 of the protocol. However, there is language in the CIP (section 9.5.7) and ICF (section titled “GENERAL FOLLOW-UP PROCEDURES – NON-IMPLANTED SUBJECTS”) that CMI believes could be interpreted differently, depending on how the reader understands what it means to be “enrolled” in the study.

After a subject is randomized, subjects are followed per the schedule of the CONFORM study. The follow-up schedule is dependent on whether the subject receives a device, and they are followed for either 18 months or for 5 years, per the protocol.

CMI is currently working on changes to the CIP and ICF to be submitted to FDA to clarify language so that both documents are unambiguously and clearly consistent with the intent described above. Once approved by FDA, applicable IRBs will also need to approve the changes.

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