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PFO Closure in the Gore REDUCE Clinical Trial: Primary Results

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Disclosure of Financial Interest

- SEK, LS, JFR, and LT are national principal investigators for the REDUCE study and are compensated for their time by the sponsor, W. L. Gore & Associates.

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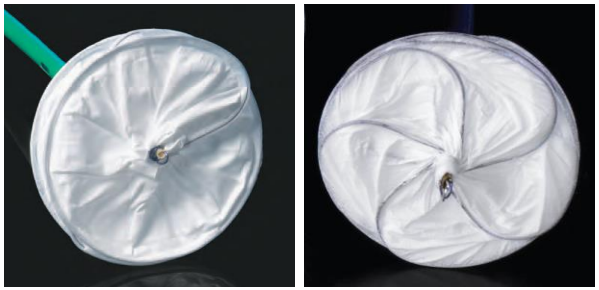
REDUCE Study



GORE® HELEX® (left) and GORE® CARDIOFORM (right) Septal Occluders

- Aim: establish superiority of PFO closure in conjunction with antiplatelet therapy over antiplatelet therapy alone in reducing the risk of recurrent clinical ischemic stroke or new brain infarct

- Randomized, controlled, open-label trial
- 664 subjects randomized in a 2:1 ratio to:
  - Closure: PFO closure with GORE® HELEX® Septal Occluder or GORE® CARDIOFORM Septal Occluder plus antiplatelet therapy
  - Medical therapy: antiplatelet therapy alone

- 63 sites in 7 countries
  - Canada, Denmark, Finland, Norway, Sweden, UK, US

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REDUCE Study Design

Medical Therapy

- Antiplatelet standardized options:
  - Aspirin alone (75-325 mg once daily)
  - Combination aspirin (50-100 mg) and dipyridamole (225-400 mg)
  - Clopidogrel (75 mg once daily)
  - Other combinations or the use of anticoagulants was not permitted
- Prescribed for all subjects for the duration of the study
- Each site was expected to treat all subjects with the same antiplatelet therapy

Follow-up

- Followed for up to 5 years
- Neurology assessments at 1, 6, 12, 18, 24, 36, 48, and 60 months
- Closure group also had echo with bubble study at 1, 12, and 24 months
- MRI imaging at baseline and 24 months (if not already performed for an endpoint event)

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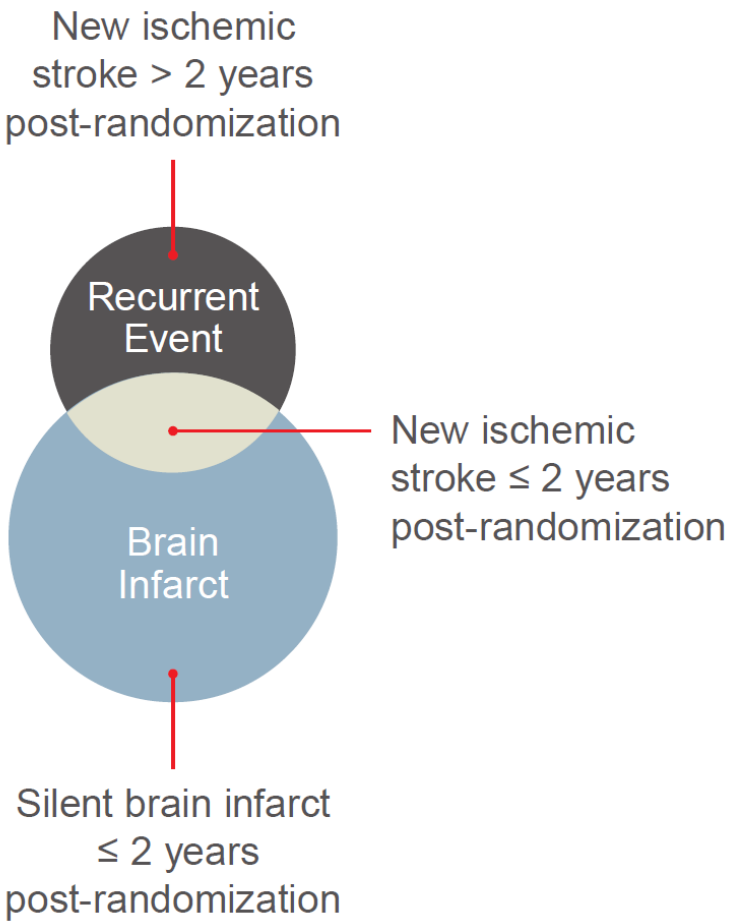
Co-Primary Endpoints

- Freedom from **recurrent clinical ischemic stroke** through at least 24 months

- Incidence of **new brain infarct** (defined as clinical ischemic stroke or silent brain infarct*) through 24 months



*New T2 hyperintense MRI lesion with diameter ≥3 mm; adjudicated by MRI core lab

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