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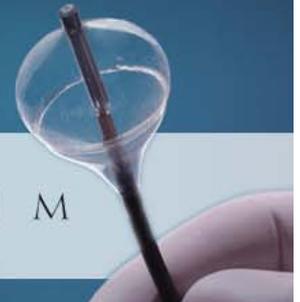
THE THERAPY WITH FOCUS

HIFU Ablation for the Treatment of AF Clinical Trial Experience

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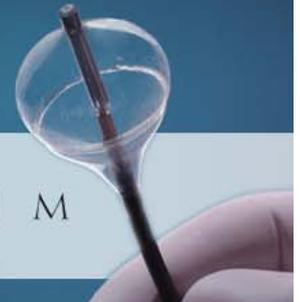
Focus AF Screening Results

- **Screening Data voluntarily collected by investigational sites (January – June, 2007)**
 - 1364 subjects screened
 - 158 subjects eligible
 - 93 (59%) of the eligible subjects refused randomization to an AAD



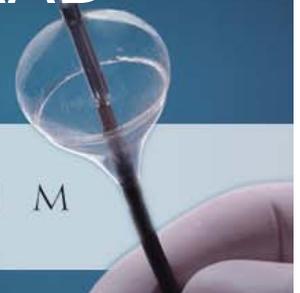
Focus AF Screening Results

- **Top 5 Reasons for Screen Failure:**
 1. Prior LA Ablation
 2. Persistent or Chronic AF
 3. No prior Class I or III AAD
 4. Not willing to be randomized to AAD
 5. Pacemaker/ICD



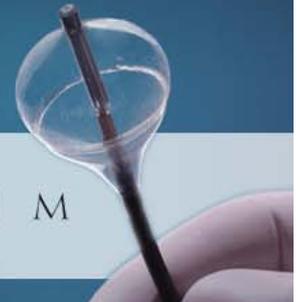
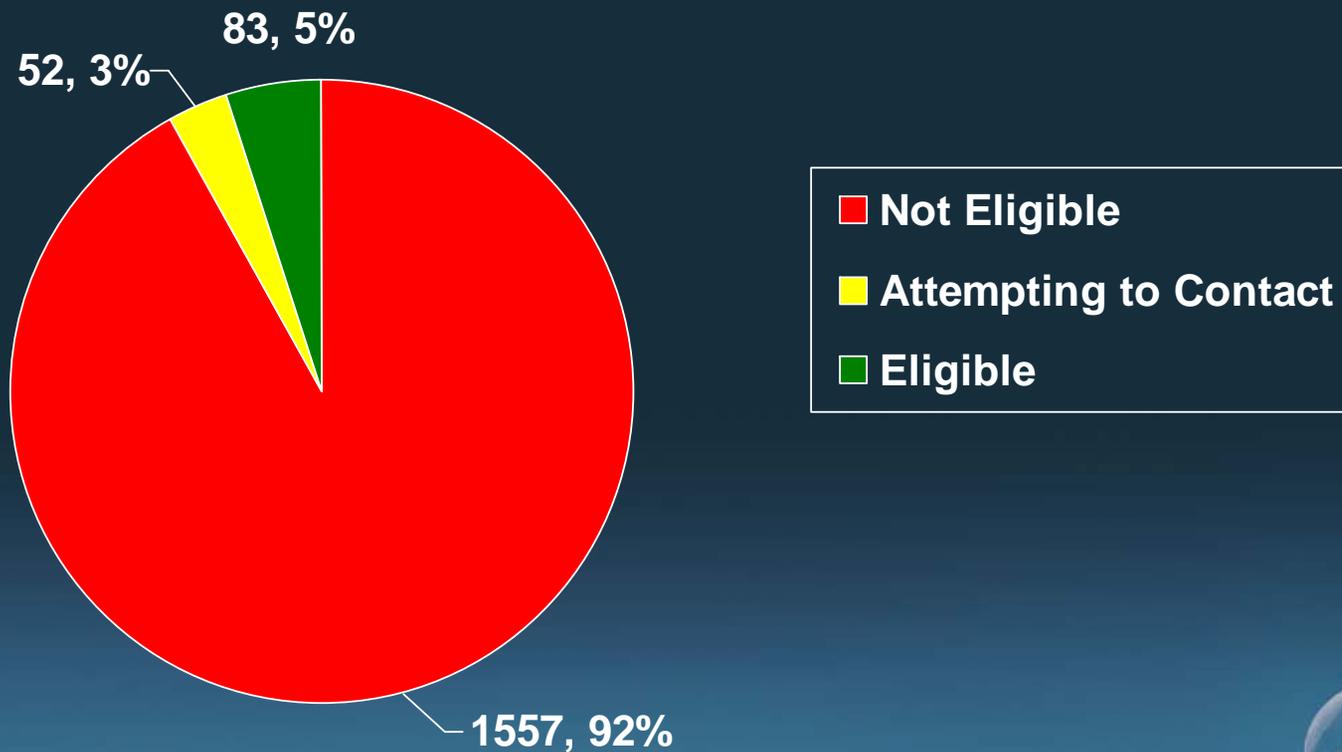
Focus AF Screening Results

- **Pre-screening performed by nurse staffed call center using IRB approved screening script (June – September, 2007)**
 - 1692 subjects screened
 - 181 subjects referred to sites
 - 83 subjects eligible
 - 39 eligible subjects disqualified because they have NOT been treated w/class I or III AAD



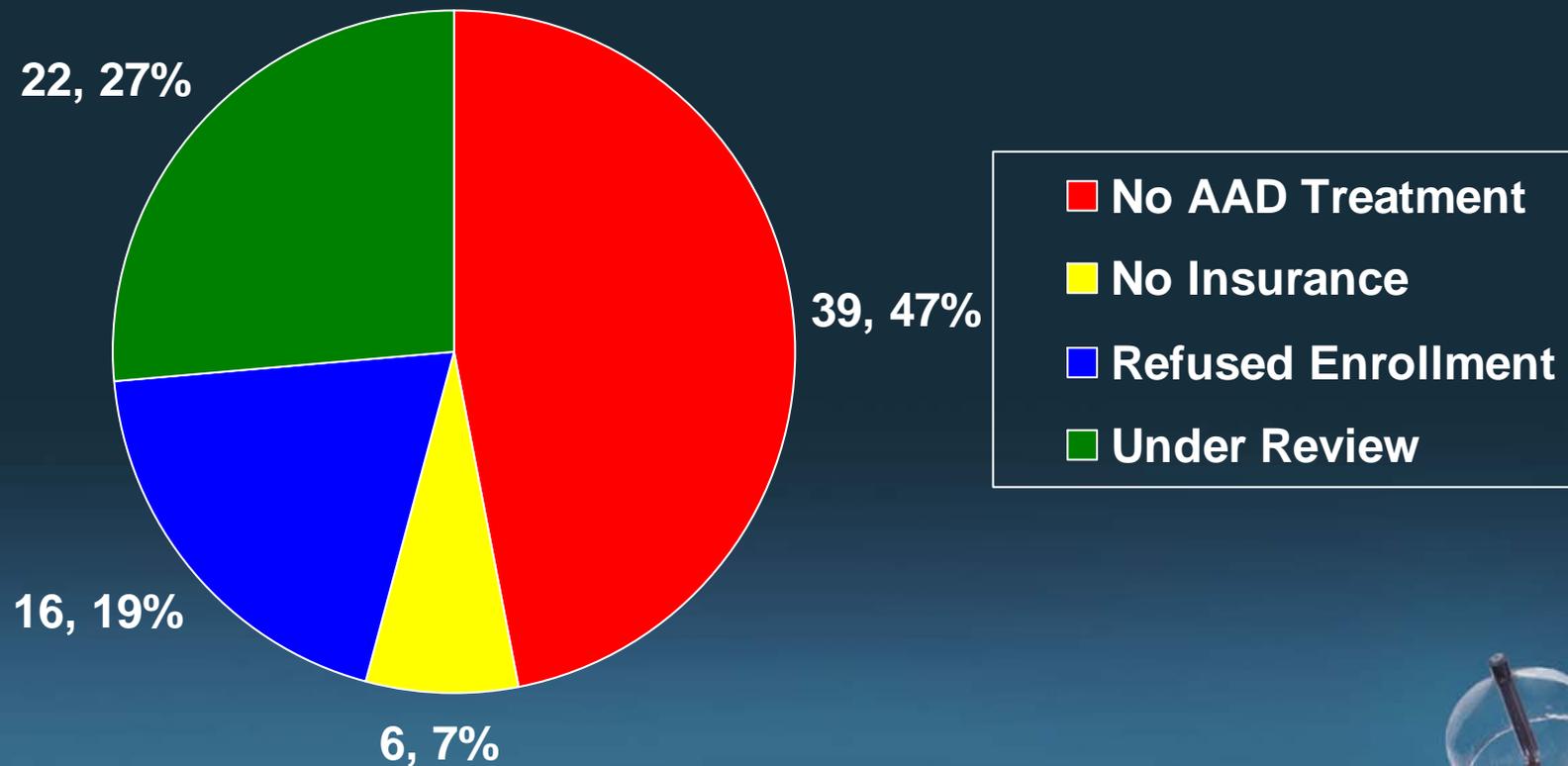
Pre-screening by Call Center

Total Subjects Pre-screened (n = 1692)



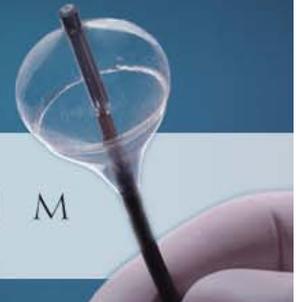
Disposition of Eligible Subjects

Total Eligible Subjects (n = 83)



Focus AF Enrollment Summary

- Over 3000 subjects screened in the past 8 months
- Total subjects enrolled = 41
- Percentage of screened patients enrolled – 1.4%
- Estimated number of subjects needed to screen to enroll 240 patients ~ 17,600
- Estimated minimum study duration ~ 5 years



Proposal for FDA Panel

- **Permit enrollment with failure of drugs routinely used but not indicated for the treatment of AF:**
 - Amiodarone
 - Beta-blockers
 - Calcium channel blockers
- ***Increase the number of eligible subjects***
- ***Broaden the range of 'indications for use'***

