

#7 **TECHNICAL SUCCESS FROM ENDOVASCULAR ANEURYSM REPAIR
IN THE POST-MARKETING ERA: A MULTI-CENTER PROSPECTIVE
TRIAL**

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Objectives: Evaluation of the post-marketing experience with the Ancure endovascular graft (AEG) was accomplished in a multi-center prospective trial. Technical success, open conversion, intra-operative and perioperative adverse events of the AEG were assessed. Methods: 46 centers enrolled 163 patients AEG treatment of abdominal aortic aneurysm. Specific anatomic criteria used during pre-market trials were omitted to provide a better representation of post-marketing clinical experience. Intraoperative and 30 day post-operative outcomes were prospectively assessed.

Results: 158 (97%) of 163 patients had successful implants of the AEG over a 5 week interval. Four (2%) were converted to open repair and one was aborted. Device-related events included: wire caught on attachment hooks in 55 (35%), excessive jacket withdrawal force in 25 (16%), contralateral wire advancement difficulties in 11 (7%), delivery catheter retention in the ipsilateral limb in 21 (13%), limb stenoses-occlusion in 58 (37%) and no device related event in 35 (22%). 123 patients available for review 30 days post-operatively included 3 (2%) Type I leaks and 11 (9%) Type II leaks. Limb stenoses were found in five (4%) and limb occlusion in six (5%). There were no migrations, ruptures or operative deaths. High volume vs. low volume site enrollment did not influence device-related events or outcome.

Conclusions: The post-marketing AEG experience identifies potentially difficult technical features unique to the AEG implantation procedure. Recognition of these features provides opportunity to avoid deleterious consequences during AEG implantation. Results from this study demonstrate similar technical success, conversion and complication rates to those reported during the carefully controlled pre-market clinical trial.