

Watchman, watch out: Abbott challenges Boston



[Elizabeth Cairns](#)

The latest in Abbott's Amplatzer suite of heart defect repair devices has just gained US approval, and the company will be gunning for a market currently cornered by Boston Scientific. The Amplatzer Amulet is a catheter-mounted device designed to close off the left atrial appendage (LAA) in atrial fibrillation patients. The LAA is a small sac in the atrial wall; AF patients cannot pump blood out of their atria effectively, and there is a risk that blood can pool in the appendage, forming clots that can cause strokes. The leading product here is Boston's Watchman, forecast to do \$1.4bn of business in 2026, according to *Evaluate Medtech*. Watchman, which has [been on the market since 2015](#), has just escaped potential competition from Atricure's Lariat device after [that product's clinical trial failed](#). Exactly how well Amulet stacks up will become clear in a couple of weeks: full data from its [head-to-head trial versus Watchman](#) will appear on August 30 at the European Society of Cardiology meeting. This study was the basis for Amulet's approval, so Abbott's device clearly demonstrated non-inferiority at a minimum. But superiority might be necessary to persuade doctors to switch from the established product.

Abbott's Amplatzer devices

| Device | Indication | Pathway | US approval date | Review time (yr) |
|---|--|-------------------------------|------------------|------------------|
| Amplatzer Amulet left atrial appendage occluder | Closure of LAA in patients with atrial fibrillation at risk of ischaemic stroke | Premarket approval | Aug 2021 | 0.6 |
| Amplatzer post-infarct muscular VSD occluder | Closure of post-myocardial infarction VSD | Humanitarian device exemption | Jan 2017 | 9.6 |
| Amplatzer PFO occluder* | Closure of patent foramen ovale (PFO) in patients who have had a cryptogenic stroke | Premarket approval | Oct 2016 | 3.9 |
| Amplatzer muscular VSD occluder | Closure of congenital ventricular septal defect (VSD) in high-risk surgical patients | Premarket approval | Sep 2007 | 2.9 |
| Amplatzer duct occluder** | Closure of patent ductus arteriosus | Premarket approval | May 2003 | 0.9 |
| Amplatzer septal occluder | Closure of atrial septal defects or surgical openings | Premarket approval | Dec 2001 | 1.3 |

*Initially granted HDE in April 2002. **Duct occluder II and Amplatzer Piccolo also approved under supplements. Source: Evaluate Medtech & company release.

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