**EVOLVE Study Design**

- **Multicenter**, prospective, single arm, non randomized
- **Study centers**
  - Regensburg (P. Sick) 14
  - Prague (P. Neuzil, V. Reddy) 19
  - Frankfurt (H. Sievert, N. Wunderlich) 36
- **Main inclusion criteria**
  - Non valvular atrial fibrillation
  - CHADS$_2$ ≥ 1
- **Main exclusion criteria**
  - Contraindication for anticoagulation
  - Indications for Warfarin other than atrial fibrillation
  - Intracardiac thrombus or dense echo contrast
  - EF < 30% or NYHA IV
- **Primary endpoint**
  - Technical success without procedural or device related life- threatening event
- **Primary technical endpoint**
  - Successful implantation, including re-capture and retrieval if necessary
- **Secondary endpoints**
  - Procedure success defined as technical success and no procedure or device related serious adverse event within the hospital stay
  - Death, stroke, MI or any other serious adverse event related to the procedure or the device within the first 30 days or through hospital discharge
- **Study flow**
  - Device implantation under TEE control according to standard techniques
  - After device implantation
    - Coumadin for 45 days
    - TEE @ 45 days, 6 mo, 1 yr
  - If the LAA is closed after 45 days, Warfarin is replaced by Asprin and Clopidogrel
  - Clopidogrel will be stopped after 6 months
- **69 patients enrolled (August 2011)**
  - Age 71.7 ± 7.2 (56-85)
  - Female 36%
  - CHADS$_2$ Score 2.7 ± 1.3
    - CHF 39%
    - Hypertension 88%
    - Age ≥ 75 42%
    - Diabetes 33%
    - Prior Stroke or TIA 33%

**EVOLVE Study Results**

- **Successful implantation in 67/69 pts (97%)**
- **Device size used**
  - 22 mm 17
  - 26 mm 34
  - 31 mm 16
- **Mean follow up is 4.1 ± 4.0 months**
- **17 patients were followed to one year**
- **Procedure related serious adverse events**
  - Prolonged epistaxis requiring intubation 1
  - Epistaxis of unknown cause 2
  - Groin hematoma 2
  - No intervention 1
  - Groin bleeds requiring compression 2
  - Periprocedural stroke with dysarthria 1
  - Full recovery 1
- **No pericardial tamponade or device related complications**
- **Complete closure in all patients @ 45 days**
- **97% discontinued Warfarin at 45 days**
  - Warfarin discontinued > 45 days (<6mo) due to
    - Postprocedural stroke 1
    - New formation (thrombus) on the aortic valve 1
- **Thrombus on the device**
  - resolved under heparine, no sequelae 1

**EVOLVE Study Conclusion**

- LAA closure with the gen 4 WATCHMAN device is feasible and safe
- **Advantages of Gen 4**
  - Only 3 devices sizes needed
  - Device adapts better to anatomy
  - Atrumatic distal end

**New Size Ranges**

- Gen 4 implant allows for increased compression
- RESULT: 3 devices sizes versus 5

---

*This is the first LAA closure device which can not only be recaptured but also be redeployed!*