

## **Hemodynamic left heart support with the novel axial flow pump Heartmate II in heart failure – the European experience**

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### Objective

Small sized axial flow pumps were shown to provide effective hemodynamic left heart support in heart failure patients

The new HeartMate II LVAD was certified with the CE mark in Nov 2005, after having been under study in the United States and in Europe since Feb 2004. We report on the total European experience with this device.

### Methods

HeartMate II LVAD implantation was performed in 59 patients in 14 European institutions. 11 female and 48 male patients mostly with idiopathic dilated (30) or ischemic (17) cardiomyopathies, and 12 other for NYHA Class IV heart failure. All patients were on maximum medical therapy including inotrope infusion prior to implantation. The body surface area ranged from 1.58 to 2.40 m<sup>2</sup> (m) and the age from 14 to 71 years mean 47 years.

Intention for implant was bridge to transplant (n = 46), destination therapy (n = 12) and replacement of a failing LVAD (HeartMate I; n = 1)

### Results:

Mean support period was 108 (longest: 723) days. Total support time is 6383 days, 17, 5 years. Thirty eight (74.5%) were either transplanted (n=11) or still ongoing (n=32) and 15 patients (25, 4%) expired.

The discharge rate was 67%. A severe neurologic event occurred in one patient: An intracerebral bleeding was seen 223 days after implant. No stroke with permanent neurologic sequels was found in this patient group. Other major adverse effects were bleeding events, 2 hemolysis events infections and cardiac arrhythmias.

### Conclusion:

Heartmate II is an effective LVAD, restoring hemodynamics in heart failure patients with a relatively low incidence of neurologic and other adverse events. Long term results are limited to a low number of patients; however present data suggest long term reliability of the device as a bridge to transplant and possibly for destination therapy.