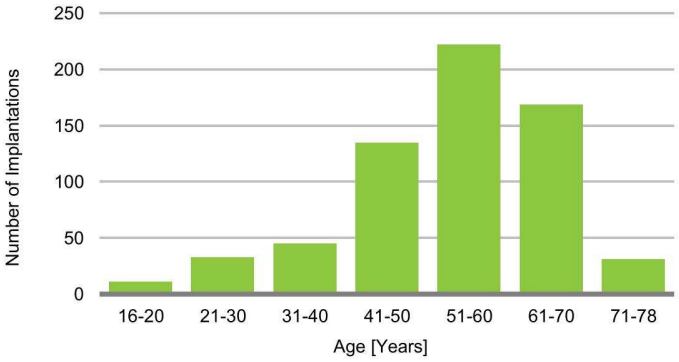
INCOR® Update

Clinical Experience with INCOR®

The INCOR® LVAD is the only CE-certified third generation axial flow pump. Its magnetically levitated impeller operates without any mechanical contact and ensures wear-free long-term support of patients with severe heart failure. Since June 2002 INCOR® LVAD has been successfully used at 69 heart centers in 19 countries.

1. More than 600 INCOR® Implantations documented in Database

Countries with INCOR® implantations.



Age distribution of INCOR® patients (n=646).

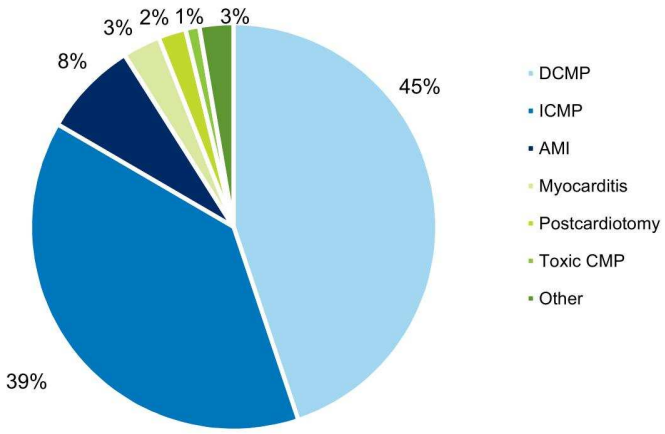
2. Demography

	Mean	Median
Age	53 years (16y - 78 y.)	55 years

Female	Male
12%	88%

3. Pre Operation Conditions*

- 29% emergency patients
- 81% NYHA level 4
- 44% INTERMACS level 1+2
- 20% on MCS
- 2.0 l/min/m² mean cardiac index
- 3.7 l/min mean cardiac output
- 17.1% LVEF

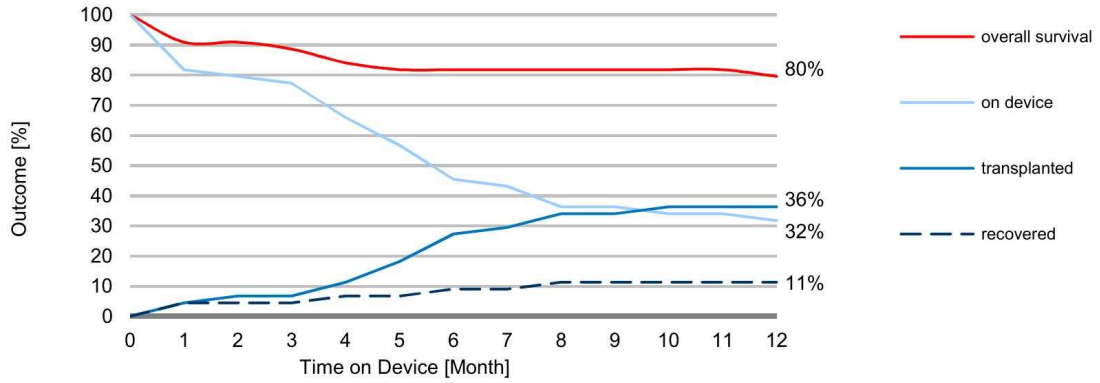


Diagnosis of INCOR® patients (n=646).

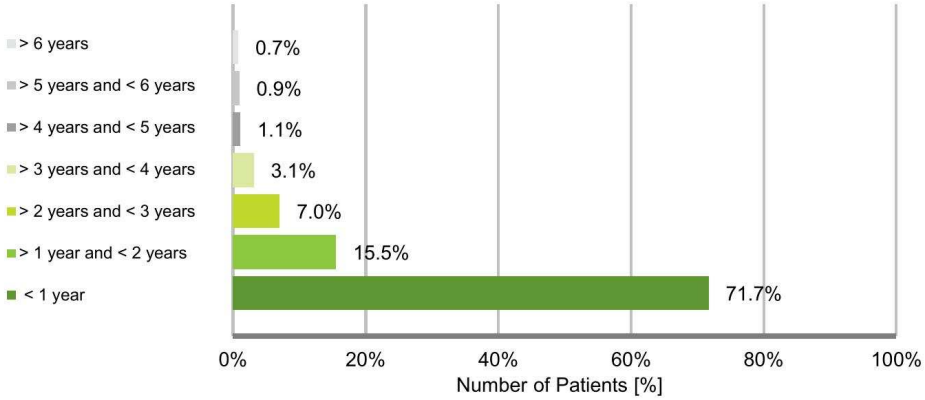
*of patients where data was given

4. Outcome

- Cumulative time on device: 546.1 years
- Mean time on device: 308.5 days (up to 2397 days)



Competing outcome of INCOR® patients in excellence centers (n=44).



Time on device of INCOR® patients (n=646).

5. Ongoing Clinical Trials

"INVASTOP" Reduction of driveline exit site infection rate with redesigned driveline
Study design: International, prospective, multi-center Clinical Study
Primary objective: Reduction of infections at driveline exit site.
Start enrollment: August 2011.
Investigator sites: Regensburg (Germany), Erlangen (Germany), Madrid (Spain), Udine (Italy), Barcelona (Spain), Gießen (Germany), Cordoba (Spain), Dresden (Germany), Marburg (Germany), Munich (Germany), Bergamo (Italy)
Interim results (March 2013)**:** n=13,
➔ actual overall survival: 92%,
➔ actual freedom from driveline infection: 92%.

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