



## Dear Readers,

All things considered, 2005 was a successful year for Berlin Heart: sales topped the EUR 14 million mark – up about 35 % on the previous year's results. The tremendous increase in demand for our EXCOR Pediatric System proved a major contributory factor to these excellent performance figures. We also booked numerous successful initial applications with the INCOR as well as EXCOR systems. In this edition of the Newsletter we would like to review some of the important highlights in the events of past year.

### Highly successful EXCOR pediatric applications

In 2005 the demand for our EXCOR system for children in the USA and Canada was greater than ever. We were able to add 14 new medical centers to the 7 centers already using our products, making a total of 21 centers in the North American continent alone. It is well worth mentioning here that 10 of these centers feature prominently in the top rankings of "U.S. News 2005" of the best US medical centers. The large number of applications in 2005 served to underline the urgent need to obtain a USA license for our EXCOR Pediatric system. This is particularly relevant in view of the outstanding 80% survival rate for this product.

Another success story for EXCOR Pediatric emerged on December 14 2005 in the Pedro de Elizalde Hospital de Niños (Children's Hospital) in Argentina. This implantation was performed by Dr. Florentino Vargas and was the first implant of a heart support system for a child in the whole country of Argentina.

The young patient was a 17 month old girl, weighing 8 kg and suffering from a primary AL-CAPA disorder with related cardiac insufficiency. The first part of the 4-hour operation involved repositioning the left coronary artery which had been defective since. This was followed by the implanting of a 9mm cannula in the left ventricular apex and the placement of a 6mm vascular cannula in the aorta ascendens. These were then connected by a 25 ml pump. Post implantation it was noted that right cardiac function was not so good during the first 48 hours, but this improved rapidly following the administration of adequate medicinal therapy. 24 hours later, in the absence of any obvious hemorrhage complications, anticoagulation was commenced.

On the third day the patient could be extubated and completely mobilized in the following days and weeks. During this period there was a welcome improvement in cardiac function, so much so that the small patient was successfully weaned after 25 days. On January 24 2006 she was released from hospital.



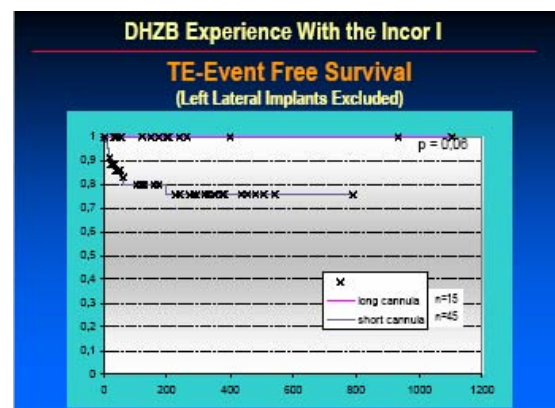
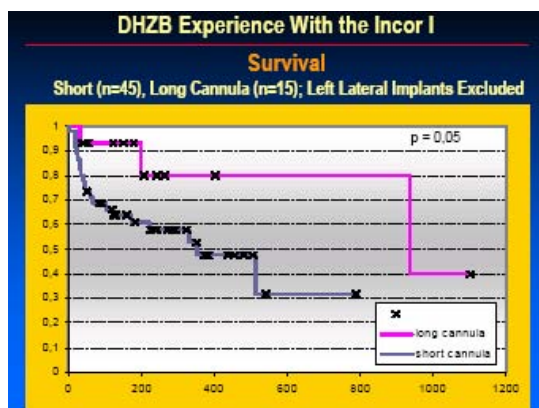
## Clinical results with INCOR

At the recent Berlin Heart International User Meeting on 14 and 15 October 2005 in Berlin, senior physician Dr. Michael Jurmann described the experiences made at the German Heart Centre Berlin (DHZB) with our INCOR® left ventricular support system.

He presented a consecutive analysis of the first 70 patients, beginning with the first world-wide INCOR implantation on 16 June 2002 and ending in August 2005 (the conclusion of this particular observation period). This means that the DHZB now disposes of the most comprehensive hands-on experience of any single clinic in the application of INCOR.

The analysis of these 70 patients showed a significantly more favorable survival rate among those patients younger than 55 (n=31) compared with patients older than 55 (n=39). In view of the underlying disorder (dilatative CMP, n=43 versus ischemic CMP, n=26), there was no significant differences in long term survival.

In the course of the clinical experience gathered over more than 38 months, it became apparent that a correlation exists between the actual intracardiac length of the apex cannula and the incidence of cerebrovascular occurrences: retrospective analysis of the results of all anteriorly (classically) implanted systems shows a cerebrovascular complication rate of 29% (this corresponds to 0.54 occurrences per patient year) for the 45 patients who were supplied with a short inflow cannula. By contrast, the clinical results with the new intracardiac, and almost 10 mm longer, inflow cannula are significantly better. In this instance, only 1 out of 15 patients (6.7%) suffered cerebrovascular complications, which corresponds to a rate of 0.09 occurrences per patient year. This is a reduction in the rate of cerebrovascular complications of about 83%.



Publication of the results with the kind approval of senior physician Dr. Michael Jurmann.



### Successful transplant after 1127 days

The June 2005 Newsletter Special featured an in-depth interview with Uwe Magdeburg. In the course of that summer he notched up more than 100 days on the INCOR LVAD System. In October, after more than 3 years of waiting, Uwe was given a successful transplant. His condition remains excellent and, more important for him, he is looking forward to being able to go swimming again soon - and he already has three birthday celebration lined up for this year... . All of us at Berlin Heart share his joy and wish him all the very best for the future!



### Berlin's governing mayor visits Berlin Heart

On August 4, 2005 Berlin's governing mayor, Klaus Wowereit, paid a visit to Berlin Heart. The visit was the result of an initiative by Dr. Bruno Broich, Chairman of the TSB Technology Foundation Berlin. Short talks held by Professor Dr. Dr. h.c. mult. Roland Hetzer, Medical Director of the German Heart Institute Berlin, who threw some light on the history of the development of heart support systems, and by our Chairman of the Board René Garo, who gave a detailed account of the



functional aspects of our products, provided Mister Wowereit with a clear picture of how Berlin Heart is setting an excellent example for successfully bridging the gap between science, clinical application and business in the world of medical technology. The event was also attended by one INCOR and one EXCOR patient, who were only too happy to demonstrate their heart support systems to an obviously enthusiastic governing mayor. The talks were followed by a detailed tour of the company during which Herr Wowereit learned much about the innovative technology behind the INCOR and EXCOR systems. The mayor's visit ended with a group photo featuring all the staff at Berlin Heart.



### The first Berlin Heart international user meeting

After the great success of the INCOR User Symposium last year we elected to organize a similar meeting again this year. The idea of sending out additional invitations to international users has already been instigated last year. Very good sales figures and the many positive reports on EXCOR this year, were contributory factors in our decision to give the user symposium the title of “Berlin Heart International User Meeting” and to invite users of both INCOR and EXCOR systems. The event took place in Berlin from 14 - 16 October. As last year, the symposium was held in the Grand Hyatt Hotel on Potsdamer Platz in the center of Berlin.

Of course, this year’s invitations again went out to the senior experts and decision makers in the German-speaking community. We were soon overwhelmed by the great response engendered by such an event, especially among those who had attended the 2004 user symposium. In a joint effort with our distributors, we were able to reach most of our international users or potential users. The feedback was really staggering. Having initially estimated an approximate 80 guests in total, we ended up more than 110 users or potential users attending the meeting.



The Berlin Heart International User Meeting began with a guided tour through the company’s operations in the Steglitz district of Berlin during which the guests were particularly impressed by the interaction of high-tech and intricate and painstaking manual work. Saturday’s symposium featured a broadly diversified scientific program incorporating a detailed analysis of the experiences made with the INCOR and EXCOR systems. A small supporting program rounded off the event and offered the guests the opportunity to compare notes on a more personal level.



## Berlin Heart goes West

On 1 October, 2005 Berlin Heart Inc. was set up in Northborough a small town to the west of Boston, Massachusetts. Berlin Heart Inc. is a 100% subsidiary of Berlin Heart AG in Germany. In response to last year's huge increase in demand from the USA for our EXCOR Pediatric VAD system, it was decided that we needed to be closer to the North American market, hence the foundation of Berlin Heart Inc.

Although approvals for our EXCOR Pediatric system have, up to now, only been granted by the FDA in individual "compassionate use" emergency cases, it is our aim to supply the 21 clinics with the best possible clinical support and the result was that we now employ two local representatives for this purpose. Both of them have undergone an intensive training program in Berlin and are being provided with extra support in the form of experienced colleagues from Germany who take turns to complete a three month stint with them in Northborough. We are also expecting our local representative to create optimal conditions for collaboration with the FDA in respect of our approval plans.

You can reach us at Berlin Heart Inc under the following address and telephone number:

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386 W. Main Street  
Northborough, MA 01532  
USA  
Tel. 001 50835 19440  
Fax 001 50835 19446

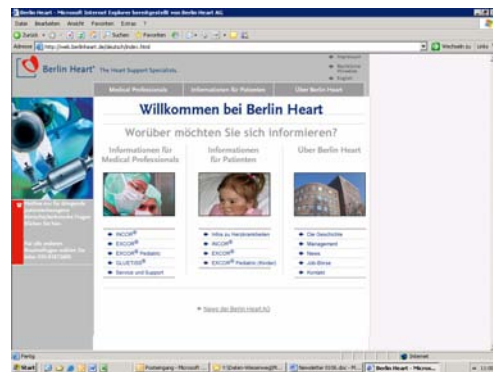
We are confident that during the next few weeks a highly motivated and dynamic small team will be ready for our North American clinics.

## New Berlin Heart website

As of December last year, Berlin Heart is proud to present a newly designed website. The most significant innovation is the addressing of specific target groups and the new navigation set up. But why not just take a look for yourself under:

[www.berlinheart.de](http://www.berlinheart.de)

If you have other ideas and suggestions for our internet site, we would be more than happy to hear from you.



**Get to know our partners:**

**Our distributor in Argentina: Streamer s.r.l.**

Streamer is a Buenos Aires based company which was founded in 1988. Since May 2005 has been a distributor for Berlin Heart, Germany. Roberto Martinez is CEO of a small dedicated team.



Streamer specializes in the import and distribution of medical products covering four primary areas: heart surgery, angioplasty, interventional cardiology and heart support systems. The firm has been in the market for the past 18 years and boasts a wealth of valuable experience.

We would be more than happy to answer any questions, suggestions or information requirements you may have:

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Fax ++49 (0)30 - 8187- 22 - 2650  
[info@berlinheart.de](mailto:info@berlinheart.de)

Your contact person:

Katrin Neiß  
Marketing & Public Relations

*Note:*  
*Our products INCOR® and EXCOR® are not FDA approved..*



Berlin Heart will be participating as exhibitor at the following events in 2006:

<p>STS 42<sup>nd</sup> Annual Meeting 29. January– 1. February 2006 in Chicago, USA <a href="http://www.sts.org">www.sts.org</a></p>	<p>35. Internationale Fortbildungs- und Arbeitstagung der Deutschen Gesellschaft für Kardiotechnik 25. – 27. May 2006 in Ludwigshafen, Germany <a href="http://www.dgft.de">www.dgft.de</a></p>
<p>The San Diego Cardiothoracic Surgery Symposium 16. – 19. February 2006 in San Diego, USA <a href="http://www.amainc.com/cref_cardiothoracic.html">www.amainc.com/cref_cardiothoracic.html</a></p>	<p>59th Congress of the French Society for Thoracic and Cardiovascular Surgery 14. – 17. June 2006 in Bordeaux, France</p>
<p>35. Jahrestagung der Deutschen Gesellschaft für Thorax-, Herz- und Gefäßchirurgie, DGFTHG 19. – 22. February 2006 in Hamburg, Germany <a href="http://www.dgthg.infoworks.de/dt_index.php">www.dgthg.infoworks.de/dt_index.php</a></p>	<p>Heart Failure 17. – 20. June 2006 in Helsinki, Finland <a href="http://www.escardio.org">www.escardio.org</a></p>
<p>ISHLT Anniversary Meeting and Scientific Sessions 5. – 8. April 2006 in Madrid, Spain <a href="http://www.ishlt.org">www.ishlt.org</a></p>	<p>14th Congress of the International Society for Rotary Blood Pumps 30. August – 1. September 2006 in Leuven, Belgium</p>
<p>Cardiology in the Young 2006 19. – 22. April 2006 in London, GB</p>	<p>EACTS (European Association for Cardio-Thoracic Surgery) 9. - 13. September 2006 in Stockholm, Sweden <a href="http://www.eacts.org">www.eacts.org</a></p>
<p>Lange Nacht der Wissenschaften 13. May 2006 in Berlin, Germany <a href="http://www.langenachtderwissenschaften.de">www.langenachtderwissenschaften.de</a></p>	<p>Heart Failure Society of America 10. – 13. September 2006, Seattle, USA <a href="http://www.hfsa.org">www.hfsa.org</a></p>
<p>The Second International Conference on Pediatric Mechanical Circulatory Support Systems, Pediatric Heart Transplantation, and Pediatric Cardiopulmonary Perfusion 18. – 20. May 2006 in Toronto, Canada <a href="http://www.hmc.psu.edu/ce/pediatrics.htm">www.hmc.psu.edu/ce/pediatrics.htm</a></p>	<p>American Heart Association 12. – 15. November 2006 in Chicago, USA</p>
<p>Association for European Paediatric Cardiology 24. – 27. May 2006 in Basel, Switzerland <a href="http://www.akm.ch/aepec2006">www.akm.ch/aepec2006</a></p>	<p>6<sup>th</sup> Mechanical Circulatory Support 6. – 9. December 2006 in Bad Oeynhausen, Germany</p>