



Dear reader,

On On 21st March 2003 Regional Trade Inspection Office (LGA) Bavaria, Nuremberg, granted Berlin Heart AG the CE licence to sell INCOR, its implantable magnetically levitated cardiac system, within Europe. CE certification is the most significant milestone yet in the Company's six year existence.



INCOR can now be used for the long-term treatment of patients with heart problems who, for medical reasons or because of a shortage of donor organs, cannot receive a heart transplant.

The third edition of our newsletter is largely devoted to this great news. Happy reading!

We are proud to be the first European company to have developed the high tech blood pump – and this in a very short space of time.

The device is primed for launch on the open market and has massive commercial potential thanks to the unique technical characteristics and outstanding clinical results that set it apart from all competing products.

The entire Berlin Heart team is to be congratulated on its resounding success in bringing the company's most important project to fruition. Our heartfelt thanks go out to all team members, whose motivation and tireless dedication in their respective fields was evident from the outset.

CE certification does not simply represent official acknowledgement of endeavours and successes now confined to the past. We see it as a firm basis for our future and as an added incentive to expand our activities and raise the value of the company in general.

Board of directors
Berlin Heart AG

CE certification for the German-made High Tech Heart Pump – outstanding results in clinical tests

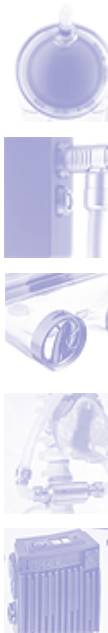
Approval for INCOR is based on clinical test findings that began on 16th June 2002 at the German Heart Institute Berlin (DHZB) and embraced 23 patients. When the study officially ends we will publish a report in conjunction with the centres which took part. We would like to set out the most significant results here:

For the INIT study (INCOR Initial Trial) 23 patients were fitted with the implantable INCOR system for left-heart support.

The patients were all in the terminal stages of cardiac insufficiency and had been hospitalised with one of the following diagnoses: myocarditis, cardiomyopathy or acute heart failure.



**Implantable Cardiac Assist Device
Berlin Heart INCOR**



Clinical data are impressive. Cumulative experience with INCOR (on 8th April 2003) stood at 2267 days (> 6 years), the mean period of study was 84 days; the longest: 294 days.

To date two patients could be “weaned” from the system after their hearts recovered during treatment. These patients can now rely again on the good functioning of their own hearts. Three further patients received successful heart transplants during the study and are now back home. Five patients have unfortunately died, an indication that Assist Devices are only being fitted to patients who are in the terminal stages of cardiac illness (NYHA IV) and are near death.

The INIT (INCOR Initial Trial) was conducted by Professor Dr. Yuguo Weng, senior physician at the German Heart Institute Berlin, and we would like to extend to him our sincere gratitude.

The study was carried out in six clinics: Bad Oeynhausen, Berlin, Freiburg, Leipzig, Münster and Shanghai. All teams applied themselves to the task at hand with exemplary devotion; our thanks go to them too.

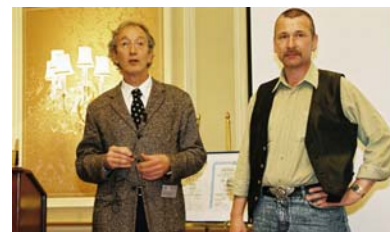
Berlin Heart is the sole company to offer a comprehensive portfolio of products

With the official stamp of approval for INCOR secured, Berlin Heart AG is now the only firm in the world offering both paracorporeal systems for patients of all ages and implantable assist devices for the treatment of patients with serious cardiac problems.

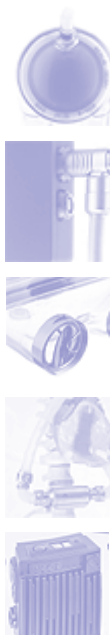
Berlin Heart systems are now available to provide univentricular and biventricular treatment to infants and elderly patients alike.

Official presentation of certificate by LGA management

Special events are marked in special ways. LGA managing directors Dr Klaus Höxer and Roland Bürger travelled to Berlin to attend the ceremony. The guests presented the certificate to Board directors Dr Johannes Müller and Klaus Würtenberger and congratulated them on the speed with which they overcame the obstacles involved.



Dr. Johannes Müller, Member of the Board of Berlin Heart AG, with Holger Beckmann, „weaned“ INCOR Patient



Left to right: Hans-Karl Herr, Dr. Peter Göttel, Klaus Würtenberger, Roland Bürger, Dr. Klaus Höxer, Dr. Johannes Müller, Dietmar Ries

Intensive marketing and distribution program bears initial fruits. First commercial application of INCOR in Erlangen

With the backing of an intensive marketing and distribution strategy we have begun introducing our INCOR system to the European market.

We recently sold our first INCOR system, to the University Clinic in Erlangen. Professor Dr Michael Weyand has already fitted two patients with our INCOR device and has recorded his experience using the product:

“Operation on patients with dilatory or anaemic cardiomyopathy was problem-free. The pump rate was 4.6 l./min, with revolutions set at 7,200 U/min, i.e. approximately 5 l/min at 8,000 U/min.

Patients could be extubated after only a few hours. In the post-operation phase there were also no complications. Patients were mobile within a short time and were able to receive coaching with their wives on how to use the device within the domestic environment.”

Professor Weyand went on: “We were particularly impressed by the simple and secure implantation technique with its practical insertion connectors. The small, compact design of the INCOR system also allows it to be implanted in the pericardial sac. Neither is it necessary to prepare any large aggregate bags, which is another important advantage.

The whole procedure went off without technical problems. Berlin Heart’s service is good and we work together very well.

Although our clinical experience working with the system is limited we would stress that the linking of anticoagulant levels to a monitoring of thrombocytic function and aggregate collection is extremely important. We were pleased to note that on a strict anticoagulation regime the two patients gave no signs of thromboembolic complications.”



**Prof. Dr. Michael Weyand,
Medical Director of the
Cardiac Surgery Center,
Erlangen-Nuremberg**



**The two INCOR patients
in Erlangen with
Dr. Tandler**

“The beat goes on” – International Premiere gathering of all Berlin Heart AG distribution agents

The crowning event in the INCOR launch was the first gathering of our worldwide distributors (slogan: “The beat goes on”.) We invited the agents to Berlin for a meeting from 3rd to 6th April 2003 to decide on a common strategy for promoting the distribution in their respective countries not only of the INCOR system but also of the EXCOR paracorporeal Assist Devices and our aorta dissection glue, Gluetiss.

[19 dealers and their teams from 11 countries attended the 4-day conference in Berlin and were able to enjoy the city in all its multiplicity.

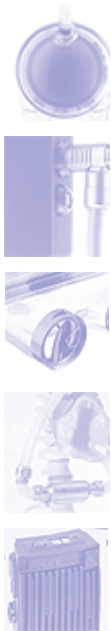
Beyond its launch of INCOR Berlin Heart was keen to familiarise its guests with the company, the staff and the entire range of products and to encourage an exchange of ideas with a view to strengthening the basis for successful distribution throughout individual countries.

A packed program

The program featured presentations by the Board and other Berlin Heart managers on technical and medical aspects of the INCOR system, clinical trials with INCOR, the paracorporeal EXCOR system, company strategies and ethos and sales topics. In the ensuing dialogues and during the tour round the production facility in the Lankwitz district of Berlin the guests demonstrated the depth of their interest, their questions revealing specialist knowledge of the field as well as their openness and hunger to know more.

A packed schedule of sightseeing was organised for the visitors so as to give them a lasting feel for Berlin to take away with them. The tourism side of the program included a visit to the Parliament, the glass cupola of the Reichstag and Potsdam’s Sanssouci Palace.

Gleaming climax to the conference was the gala dinner in the Palm Court of the Kaisersaal in the Sony Center. Conferring an added sheen on the occasion, honorary guest Professor Dr. Roland Hetzer spoke vividly in his address of how Berlin Heart had evolved.



**The spirit of the meeting:
„The beat goes on“**



**The distributing team
watch a presentation**



**Klaus Würtenberger, Member of
the Board of Berlin Heart AG,
explaining the production
process**



**Ceremonial speech by Prof. Dr.
Roland Hetzer, Medical Director of
the German Heart Institute Berlin**

Building up a “Berlin Heart family”

The success of the occasion and the positive feedback we have received since from all participants has given us an incentive to repeat the event at regular intervals of 15 to 18 months.

It is our aim to share our commercial experience within the “Berlin Heart family” and strengthen its internal ties.

We were very happy to be able to sign contracts with our partners in England, Iran and Taiwan during the meeting. In this regard we welcome APC Cardiovascular Ltd., Jahan Gostaresh Tejarat Co. Ltd. and Anson Health Care as confirmed partners of Berlin Heart and look forward to cooperating closely with them.



„Berlin Heart family“



Sara Carey, Derrick Ebdon
(UK), Klaus Würtenberger

Herbert Bogner, Iraj
Gardideh (Iran)

David Lu (Taiwan),
H. Bogner

Furthermore, in every new issue of this newsletter we intend to provide readers with a portrait of one of our distributors.

Introducing Berlin Heart:

ISHLT 23rd Annual Meeting & Scientific Sessions 9th to 12th April 2003 in Vienna

Our presence at the International Society for Heart and Lung Transplantation (ISHLT) Congress was designed to facilitate direct contact with potential clients. The congress was held in Vienna from 9th to 12th April: many heart surgeons from Austria and abroad gathered in the Vienna's Hofburg to present the latest results in the area of VAD and bring themselves up-to-date on the latest developments in the field.



**69th Congress of the German Cardiology Society - Heart and Circulation
23rd to 26th April 2003 in Mannheim,
Rosengarten Congress Centre.**



A host of German cardiologists and surgeons will deliver presentations in German on the broad subject of "Diagnosis and Therapy in Heart Illness". Professor Dr. E. Erdmann will be Congress president.

Dr. Johannes Müller, Member of the Board of Berlin Heart AG and Senior Physician at the German Heart Institute Berlin, will report on the clinical trials carried out with the INCOR implantable Assist Device.

You are cordially invited to visit us at our booth. We will be delighted to give detailed information of our entire range of products, our INCOR system, our EXCOR paracorporeal Assist Device for univentricular or biventricular application and our aorta dissection glue, Gluetiss.

You can locate us at Booth DO 5 in the Dorint Hotel, adjacent to the Rosengarten.

We look forward to talking with you!

Further information on the event:

www.dgkardio.de



Berlin Heart introduces itself (III): Quality Management / Regulatory Affairs

Quality management is largely concerned with assuring that all safety provisions associated with the INCOR system in its capacity as active implant are met. This entails all staff involved in the system's development and manufacture being given training in the product and its use. This complies with regulations laid down in the Medicinal Products Law, the product guidelines and meets the extremely high standards and additional norms of the American Licensing Authority, among other organisations.

Quality management is assessed on a zero-mistake basis and this approach is applied to all areas of the Company.

Quality management includes guaranteeing quality in the development phase of the products. This quality guarantee is achieved through the testing and licensing of the products and represents the second pillar of the department's activities. The licensing of medical products in particular requires detailed trials and documentation and is governed by the laws of the individual countries and economic areas. Adhering to these regulations is the second function of the QM and RA department.



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