

Dear reader,

in the past few months, developments at Berlin Heart AG have made considerable progress. We have successfully forged ahead with our most important project – clinical trials of the INCOR implantable ventricular assist device, and are expecting to obtain sales approval for the whole of Europe in just a few months' time.

We are particularly pleased about our success story with the first INCOR patient, Holger Beckmann. Mr. Beckmann's heart recovered so well while he was being treated with the INCOR assist device that surgeons were able to remove the device again after 178 days. Now he can rely on his own heart again to keep him alive.

A further success story was the pediatric application of our paracorporeal EXCOR system in Indianapolis in the US, this being the fifth use of the system to date in North America. In mid-January, the Berlin Heart system provided an 18-month-old child with univentricular support, after the FDA had granted special permission. The little boy's condition is stable and he is now waiting for a heart transplant.

Other important events which have taken place in the past few weeks include:

- changes in the supervisory board at Berlin Heart
- visit by the German Minister of Finance, Hans Eichel
- results of the business year 2002

We invite you all to read on and find out more about our company.

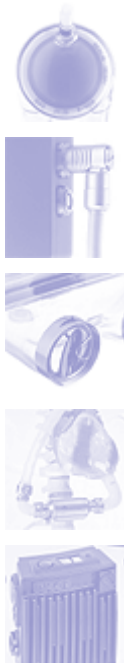
The Management Board of Berlin Heart AG

Almost a winter's tale – the first INCOR patient and his life-saving system are parted

We were able to celebrate one particularly good piece of news in December 2002 together with Holger Beckmann, a commercial driver from Berlin, and the first-ever patient to be implanted with an INCOR ventricle assist system at the German Heart Institute (DHZB) in Berlin. The 41-year-old patient was "weaned" from the system after a total of 178 days. "Now I can hear it beating again", a happy Mr. Beckmann told reporters at a press conference held at the DHZB. He was able to feel his pulse again where just a short time ago he could hear only the soft humming noise of the pump.



Berlin Heart INCOR
Implantable
Assist Device



Beckmann with
INCOR in his
hand, next to
Prof. Hetzer

Professor Dr. Roland Hetzer, Medical Director at the DHZB, who carried out both implantation and weaning, spoke of this as a milestone in the treatment of terminal myocardial insufficiency. "Things could not have gone better for the patient", Professor Hetzer said proudly.

Mr. Beckmann had been admitted to the DHZB in the previous summer with total occlusion of both main coronary arteries and in an advanced state of heart failure. Now his heart has almost totally recuperated. After the pump was removed, he was given two bypasses to ensure that his circulation works properly and his cardiac output is adequate. At the press conference, Prof. Dr. Hetzer, visibly thrilled, again pointed out the significance and advantages of circulation support pumps being used both to allow the natural heart to recover as much as possible, as well as a permanent replacement solution.

The DHZB registered its first success in Bridge-to-Recovery therapy, that is allowing the natural heart to recover by relieving it temporarily with an assist device, in 1995. Now, eight years later, the respective patient, who had been suffering from coronary heart disease, is in good overall shape.

**INCOR in clinical trials:
Excellent interim results –
INIT study still on-schedule**

To date (status: February 20, 2003), a total of seventeen patients have had the INCOR system implanted as left-ventricular support in the course of the approval INIT-study (INIT - INCOR initial trial). The operations have been carried out at five different hospitals: the DHZB, the Heart Institute Leipzig, the university teaching hospitals of Freiburg and Münster and the Shanghai East Hospital, China.

The clinical results so far are very satisfying. Cumulative experience is now 1522 patient days. The medium supporting period is 89 days, the longest 247 days.

The clinical data show that INCOR causes no haemolysis. Thrombembolic or bleeding complications can be minimized by accurate monitoring of the anti-coagulation therapy via certain laboratory tests.

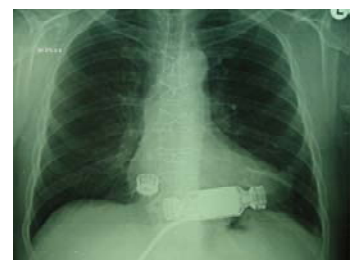
**Reduction of the
size of the heart –
an example of BTR**



Heart condition **prior**
to INCOR
implantation



Heart condition **14**
days after INCOR
implantation



Heart condition **90**
days after INCOR
implantation



From the technical aspect, the following results were obtained: the pump never stopped due to technical problems within the pump. When the explanted pump was examined after 178 days operation, no deposits of any kind were detected in the pump or the cannulas.

At present, we are still busy compiling all the data collected during the INIT trials to date, and shall be submitting these to the notifying body (LGA, Nürnberg) shortly. We currently expect market introduction for the second quarter of 2003.



New emergency application of a Berlin Heart EXCOR pediatric system in the USA – hope of a transplant for an 18-month-old boy

For the fifth time already, an EXCOR system has saved the life of a child in the USA following an emergency operation. Less than 24 hours after Berlin Heart received the request, a pediatric EXCOR system for left-ventricular support was implanted in the patient, a young boy, at the Riley Hospital for Children in Indianapolis, on the 13th January 2003. The operation had become necessary since the boy's main arteries, the pulmonary artery and the aorta, were mixed up and the pulmonary artery was also restricted. The restriction was eliminated in the operation, thus relieving the heart's right chamber. The boy's condition is now stable and is supposed to receive a donor organ very soon.



Berlin Heart EXCOR
blood pump for pediatric
applications

To date no system for pediatric use has been available in America.

All in all, there have been around 150 applications of special pediatric heart support systems world-wide so far.

Changes in the Supervisory Board

New composition of Berlin Heart AG's supervisory board as of 8th January 2003: Dr. Heribert Ballhaus and Mr. Michel Lendvai have been appointed as new members, and Dr. Thomas Brandkamp of the tbg and

Dr. Richard Reichel of the Global Vision AG/ Traunstein Group have left the board with closing of the Annual General Meeting on January 8, 2003.

Dr. Ballhaus, who is now chairman, belongs to the management of the Swedish Getinge Surgical Systems group. He is also Chairman of the Management Board of Maquet GmbH&Co.KG, Rastatt/Germany. Michel Lendvai was President, Europe and Senior Vice President of DePuy's New Business Development. Prior to that, he was President and Managing Director of Milex Medical Holding AG and Milex Consultants AG.

We are happy to have acquired these two experienced members, both of whom have extensive knowledge in the medical technology field as well as having spent many years in the top management of various companies on an international scale.

We would like to take this opportunity to thank Dr. Brandkamp and Dr. Reichel for their services and the close and friendly way they have accompanied our company in the past. We wish them both personally all the best for the future.



Dr. Heribert Ballhaus,
Chairman of Berlin Heart AG's



German Minister of Finance, Hans Eichel, drops in at Berlin Heart AG

High-ranking visitors shortly before Christmas: Minister of Finance Hans Eichel, accompanied by MP Klaus-Uwe Benneter, visited Berlin Heart AG on December 12th. During a tour of the company, members of the board Dr. Johannes Müller and Klaus Würtenberger, together with the "founding fathers" of the company, Professor Dr. Roland Hetzer and Hans-Karl Herr, elaborated on the various production stages – right up to the finished INCOR product. Minister Eichel showed particular interest in the financing terms which a medium-sized, high-tech company in the field of medical technology has to cope with.



German Minister of Finance, Hans Eichel, in conversation with Dr. Johannes Müller, Member of the Board of Berlin Heart AG

**Encouraging business results for 2002:
turnover increased to more than € 4 million**

With a 31% rise in earnings against the previous year to more than approx. € 4.1 million, Berlin Heart achieved a new turnover record in 2002. These results are fully in keeping with our expectations. Seen on a regional scale, we have expanded our turnover in all sales areas. The export rate is 49%, with a distinct emphasis on European countries. The equity rate was just under 20% on the cut-off date.

On the cut-off date a staff of 128 was employed at Berlin Heart AG.

Despite increasingly difficult framework conditions, we are expecting a distinct rise in turnover resulting from the imminent market launch of INCOR.

We shall be showing at:

**The 32nd Annual Meeting of the German Society for
Thoracic and Cardiovascular Surgery –
23rd –26th February 2003 in Leipzig, Congress Center**

The first of a series of national and international congresses in which Berlin Heart will be participating this year is the Annual Meeting of the German Society for Thoracic and Cardiovascular Surgery being held in Leipzig from 23rd to 26th February.

Many renowned speakers from Germany and abroad will be presenting their latest findings from research and development work as well as from clinical trials to specialist audiences. In his lecture: "Clinical results of the application of the first LVAD with a magnetically suspended bearing system", Dr. Johannes Müller, Member of Berlin Heart AG's Management Board and Senior Surgeon at the German Heart Institute, Berlin, will be reporting on latest developments in the clinical trials for the INCOR implantable assist device. Date: Tuesday, 25th February, 4.30 pm, Hall 1.

If you would like to learn more about our product range, our INCOR system, our paracorporeal assist device EXCOR for uni- or biventricular applications, or "Gluetiss", our surgical adhesive for use in aorta dissection, you are welcome to visit us at our booth in



Leipzig. You will find us in the East Hall (Halle Ost),
Stand No. 0.18.

We look forward to meeting you there!

For further information on this event, visit:

www.gstcvs.org

Introducing Berlin Heart (II): Clinical Affairs

The department's most important tasks are scientific marketing, customers' training and technical support regarding both the INCOR and EXCOR system. In addition, clinical affairs is in charge of planning, conducting and evaluating of clinical studies, as with the INIT study. The highly specialized staff provides support in technical as well as in medical issues. The customers' experiences are being evaluated and implemented into the ongoing development process.

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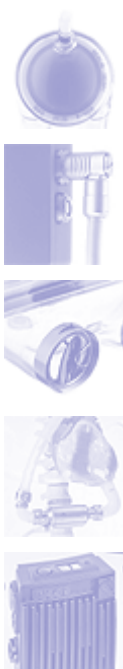
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