

Dear reader,

four months ago, following the outstanding results of a nine-month clinical trials period, Berlin Heart received CE Mark certification for its implantable ventricular assist device INCOR®. After the successful launching of INCOR® in European Union member states, the company has now entered a new significant phase of its development. In the future, we want to achieve the same excellent results as we have done up to now. At the same time we continue to proceed along our course of becoming Europe's number-one VAD manufacturer and expert.

The first applications of our INCOR® system in Belgium and other European countries have been an important first step in this direction – but there are still tremendous challenges ahead, and we are happy to take these on.

Flexible concepts and activities, a healthy share of self-confidence and a strong, well-composed team are needed if one is to generate growth in times when money is short, particularly in the health and financial sectors. One of the major tasks Berlin Heart is facing at the moment is its transformation into an efficient operative unit, versatile in meeting its customers' needs and wishes and complying to market requirements in order to establish a strong competitive standing.

Supported by our partners, we are well-prepared for success. The entire company is engaged in a permanent learning process. We have spent a great deal of time talking to our customers and have listened to them very carefully. We know the clinical problems practitioners have to cope with when they use an assist device. We are aware of the problems physicians and nurses face in the post-operative care and follow-up treatment of our patients and we have integrated their ideas and observations into the development and manufacture of our products.

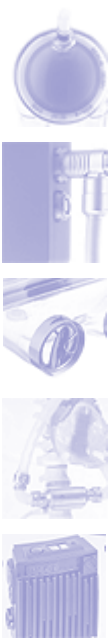
Your suggestions and your involvement are important incentives in helping us to maintain our success story.

We hope you enjoy reading this newsletter,

The Management Board, Berlin Heart AG



**Implantable Assist Device
INCOR® with continuous
blood flow - already used
more than 50 times
worldwide**



“The pump has become part of my everyday life”

INCOR® in long-term operation, has been Andreas Bidiak’s reliable companion for 400 days

For more than a year now, Andreas Bidiak, 41, has been borrowing on life thanks to his ventricular assist device. A good reason for us to visit the patient with the “longest” INCOR® system record, and to ask him about how he is getting along with the system:

Mr. Bidiak, last week you got a call from Berlin, telling you that a donor heart had become available, and were rushed off to the airport in an ambulance. What thoughts passed through your mind at that moment?

Well, it was certainly very exciting. Suddenly you don’t know what’s ahead of you any more. Even though you know that everything has been checked out thoroughly, there is still a certain amount of uncertainty on whether the new heart will really be suitable. With my pump, on the other hand, I know exactly where I’m at. However, the whole action was called off in the end and I went back home again. But I’m still on the waiting list and I’m sure that I will get a donor heart soon.

A year ago you were admitted to the German Heart Institute in Berlin with terminal cardiac insufficiency. How do you feel now, a year after the system was implanted?

It really was a last-minute affair. The doctors reckoned I only had a few more days to live. At the moment I’m fine. I’m feeling a lot better than I did in the five years before I had the pump fitted. During those five years I was constantly out of breath. And now I also have warm feet again at last. Basically, now I can do all the things that I used to do. I only miss out some of the things which might interfere with the pump. I’ve even replaced the aerial on our roof.

Do you have any difficulties with the pump?

The pump itself runs perfectly. I have no problems at all with it. Now that I’ve got used to living with the pump it’s become part of my everyday life.



INCOR® patient Andreas Bidiak, 41, lives with his mother in Salzgitter

How do your neighbours, your friends and family react to your situation?

Practically everybody knows me here in Salzgitter. My general practitioner, my neighbours, even the fire brigade know about me and my condition: I am one of those people who have to be treated differently. I have told them all what to do, and they know how to react if there is anything wrong with me. I have a doctor's note, which everybody knows about in the meantime, since I am constantly showing it in interviews. If you ever have to rescue me, I keep telling them, then don't forget the bag (*editor's note - with the energy supply*), you have to take that along as well.

My family and my friends are a great help. I live with my mother and lead quite a normal life. Before, there was only one topic of conversation - my poor health. Nowadays, I think about other things as well.

What is your wish for the future?

That everything continues to run as smoothly as it is doing now.

15 years of experience with EXCOR® VAD

In 15 years of clinical use since 1988, the paracorporeal EXCOR® system for ventricular assistance has proven its benefits, its reliability and safety and has demonstrated its wide application range in a total of 800 cases. 500 patients of them alone have been treated at the German Heart Institute in Berlin (DHZB). The paracorporeal, pneumatically-driven ventricular assist device, EXCOR®, can be used to support patients of all ages, ranging from newly-born babies to adults, with left-ventricular, right-ventricular or biventricular failure.

The mobile driving unit Excor® was developed to allow patients as much freedom of movement as possible while undergoing treatment with the system. Since the unit was approved in 1999, 29 patients from the German Heart Institute alone have been discharged from in-patient care and have been using the system at home – in some cases for several years now.

This means that patients can enjoy a considerably higher quality of life while waiting for a heart transplantation. Moreover, this solution distinctly lowers



Paracorporeal ventricular assist device, Berlin Heart EXCOR® VAD, used to date in approx. 800 applications worldwide

the costs that society has to bear. Operating risks are very low thanks to the sophistication and safety of the system. In addition, allowing the patient to go home also minimizes the risk of infections which sometime develop during a long stay in hospital.

The safety of the system is enhanced by its design with backup redundancy and the provision of replacement components. Both the patients and members of their family are trained in emergency measures and how to exchange components. Furthermore, a 24-hour emergency telephone hotline provides assistance if technical problems do occur. In addition to treatment by their own general practitioner, the patients are subjected to regular out-patient monitoring at the hospital.

One example of successful implementation of this concept:

The 19 year-old patient, S.H., who was fitted with a biventricular EXCOR® system in November 2000, is a typical case for a bridge-to-transplant application. Quick action was needed after the diagnosis of suspected myocarditis with terminal heart insufficiency. Due to his age and the shortness of his illness prior to implantation, H. was able to leave the hospital and return home fairly soon after receiving the mobile driving system EXCOR®. During the waiting time of 15 months between obtaining the ventricular assist device and his heart transplantation, there were no complications – H. lived with his parents in a small town in Saxony, where he helped out in their bakery. To allow himself greater freedom of movement, S. carried his Excor® drive in a rucksack. “Admittedly, it was a bit strenuous, standing in front of the oven for 4 hours with the rucksack on my back...” he said with reference to his part-time job, where he worked daily between 5.00 and 10.00 am. He spent a lot of his free time tinkering with motorbikes – again with the Excor® on his back.



EXCOR® Assortment of cannulas



Mobile Driving System Excor®

Stationary Driving Unit Ikus



In February 2002, H. received a heart transplant and was able to leave the hospital three weeks later. According to his own accounts, it was more difficult adjusting to life after the transplant than to life with the pump strapped to his back. This is because he was able to continue with his usual everyday life while using the Excor® drive. After the transplantation, however, he was forced to leave home due to the potential risk of aspergillosis if he had continued working in his parents' bakery. He has been looking for a job since then, as it is not easy for someone who has received a heart transplant to find work or an apprenticeship.



**Mobile Driving System
Excor®**



New additional member appointed to Berlin Heart's Management Board

Berlin Heart AG's supervisory board has appointed a new member to the company's management board: On 12th June 2003, Dr. Manfred Elff joined Klaus Würtenberger and Dr. Johannes Müller as the new member of Berlin Heart's management board. Dr. Elff is responsible for Sales, Marketing and Public Relations.

Dr. Manfred Elff, 51, commands a wide range of experience gained over almost twenty years in the field of medical technology for invasive and non-invasive diagnostics and therapy. For the last 6 years he worked for Medtronic, his last post being that of Managing Director of Medtronic GmbH in Düsseldorf, as well as being Vice President of Cardiac Rhythm Management.

"In this important phase of the company's development I am happy to be able to contribute to Berlin Heart's efforts to improve the competitive standing of its wide portfolio of paracorporeal and implantable assist devices, particularly on the European market". A doctor of medicine and holding a higher degree in physics, Dr. Elff started his career at Philips Medizin Systeme in Hamburg in 1986, where he was Business Director for the marketing, development and production of radiofluoroscopy and innovative urology systems. From 1993 to 1996 he was Managing Director of Biotronik GmbH in Lörrach, where he was responsible for Germany and Switzerland.

Thus, the Management Board of Berlin Heart AG is now made up as follows:



Dr. Manfred W. Elff,
Berlin Heart, member
of the board,
(Sales, Marketing,
Public Relations)



Dr. Johannes Müller,
Berlin Heart, member
of the board,
(R & D, Production,
Clinical Affairs)



Klaus Würtenberger,
Berlin Heart, member of the board,
(Finances/Controlling, QM/Regulatory Affairs,
Purchase, IT, Office Management)



**Get to know our partners:
Our distributor in Belgium: QP & S**

Together with his wife, Caroline, Tom de Winter has been our distributor in Belgium for three years:

“QP & S was founded in 1999. As a salesman with more than 13 years of experience in the cardiothoracic field and in order to realise our common dream, my wife, Caroline, and I took this opportunity of founding our own company. It was our aim to dedicate ourselves fully to the cardiovascular sector.

Our products range from instruments to heart-lung disposables in the Belgian market. Caroline handles customer service and bookkeeping, while I am looking after sales.

We established contact with Berlin Heart in 2001. Soon after this an EXCOR[®] system was used in Hasselt (Virga Jesse Ziekenhuis): the patient was treated with the EXCOR[®] system for six months, and during this time his own heart recovered.



Caroline and Tom de Winter,
Berlin Heart's trading partners in Belgium since 2001

Only a month after the INCOR[®] system came onto the market, two INCOR[®] implantations were carried out in Hasselt. Thanks to the excellent support given by Berlin Heart, both operations were a great success.

At the moment we are doing everything we can to make sure that the costs of treatment with an INCOR[®] system are reimbursed. To this effect, we have to file a dossier both with the Ministry of Economic Affairs and with the Health Ministry. We have employed an additional member of staff for this purpose. We hope to have positive response by the end of the year.”



Third successful weaning of an INCOR[®] patient

At the beginning of July 2003, after only 97 days of treatment, it was possible to wean another INCOR[®] patient from the INCOR[®] system since his own heart had recovered sufficiently during this time. The entire system was removed, including the inflow conduit. Detlef S., 43, was admitted to the University Teaching Hospital in Münster at the beginning of April 2003 with inflammation of the heart muscle. A team led by Professor Hans-H. Scheld performed immediate surgery to implant an “artificial heart”. The team is now delighted about the results of its efforts. The patient has just been discharged and allowed to return home. His condition is good. In the meantime his ejection fraction is 80%. In all, nine patients have been fitted with the axial pump INCOR[®] in Münster already. Further transplantations are due in the near future.

The first two successful weanings of INCOR[®] patients were achieved at the German Heart Institute in Berlin under the supervision of the institute's Medical Director, Prof. Dr. Roland Hetzer.

Dr. Johannes Müller, Member of the Board, Berlin Heart AG receives award as pioneer in the field of artificial organs

At the 49th ASAIO Conference held in Washington on 18th June 2003, Dr. Johannes Müller received an award from the International Academy of Artificial Organ Pioneers of ICMT (International Center for Medical Technologies) for his pioneering work in the field of artificial organs with a view to improving the patient's quality of life.

3. "Long Night of the Sciences" at the German Heart Institute in Berlin – A lot of interested young people seek information at the Berlin Heart booth

Despite the tropical temperatures outside, droves of visitors with a great thirst for knowledge came to the German Heart Institute in Berlin again this year. On the "Long Night of the Sciences" on 14th June, the institute counted as many as 500 visitors, showing an interest not only in the heart catheter laboratory, magnetic resonance tomographies and "electronic noses", but also in the implantable ventricular assist device, INCOR®. They asked so many questions that some of the scientists explaining the system were in danger of losing their voices at one point.

This event has already been marked as a fixed item in Berlin Heart's calendar for next year.



Dr. Johannes Müller, Senior Physician, German Heart Institute Berlin, Dr. Ewald Hennig, Technical Manager, Assist Program

Building up a „Berlin Heart family“

We are continuing to expand our circle of distributors: We have now gained the company "Medical Systems Ltda" as our partner for operations in Brazil.

The company has its headquarters in Sao Paulo and specializes in the cardiovascular surgery field. Medical Systems was founded in Sao Paulo in 1991, Managing Director Ademar Araujo having more than 18 years of experience in this sector. The company employs a staff of 20, 7 of them working in the field. Medical Systems cooperates with numerous hospitals throughout the country and achieved a turnover of \$ 2.4 million in 2002.



Klaus Würtenberger, Member of the Board, Berlin Heart AG, Ademar Felipe de Araujo, Managing Director of Medical Systems



According to Medical Systems' own reports, it covers approx. 90% of the potential Brazilian market.

Our presentations:

In the next few months, Berlin Heart will be present at the following congresses:

**11th Congress of the
International Society of Rotary Blood Pumps**
**31st August - 2nd September 2003 in Bad Oeynhausen,
Germany**
Heart and Diabetes Center, North Rhine-Westphalia
www.rotarybloodpump.org

**30th Congress of
ESAO (European Society for Artificial Organs)**
**3rd - 6th September 2003 at the University Hospital,
Aachen, Germany**
www.esao.org

**16th Congress of
EACTS (European Association for Cardio-Thoracic
Surgery)**
12th - 15th October in Vienna, Austria Center
www.eacts.org

At all these events, we shall be showing our entire product portfolio, with special emphasis on our implantable axial pump INCOR® and our experience with the system up to now. In his lectures, Dr. Johannes Müller will be presenting the latest clinical results achieved with INCOR®.



Introducing Berlin Heart (IV): INCOR® / EXCOR® / Iku drive production

This sector manufactures the drive units for the paracorporeal system EXCOR® VAD and the electronic components of INCOR® and is subjected to the highest possible quality requirements. The quality demands are similar for all individual product lines: Excor® stationary, Excor® mobile and INCOR®, but those on INCOR® production are particularly high, since this is an active implanted device. This means that all members of staff must be highly qualified in their respective field and carry a high degree of responsibility. This is to achieve the highest possible safety of every single product. It is the task and duty of all persons working in the drive units sector to achieve zero-defect production.

Close cooperation with the Research and Development and Clinical Affairs departments ensures that new ideas and findings are immediately implemented in production.



Team Leader

Holger Lübke

luebke@berlinheart.de

EXCOR® mobil

Andreas Schütz

schuetz@berlinheart.de

Detlef Kemnitz

kemnitz@berlinheart.de

EXCOR® stationär

Hans-Dieter Kaul

kaul@berlinheart.de

Frank Hofmann

hofmann@berlinheart.de

INCOR®

Thomas Stuff
stuff@berlinheart.de

Eike Jeske
jeske@berlinheart.de



from l. to r.: Frank Hofmann, Eike Jeske, Andreas Schütz, Detlef Kemnitz, Holger Lübke, Hans-Dieter Kaul, Thomas Stuff

If you have any questions or suggestions, or if you require any information material, please contact us at:

Tel: ++49 (0)30. 8187-2678
Fax ++49 (0)30.8187-22 2678
info@berlinheart.de

Your person to contact:

Pia-Maria Görner
Public Relations
Marketing

Note: Both products INCOR® and EXCOR® are not commercially available in the US.

Berlin Heart AG · Wiesenweg 10 · 12247 Berlin · Germany ·

Tel +49 (0)30. 81 87 26 00 · info@berlinheart.de

