Sequana Medical NV
Technoparkstrasse 1
8005 Zürich
Founded in 2006
35 employees

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The liver, seat of life

Just how important the liver is for the human body has been known since ancient times, when Mediterranean cultures regarded it as the seat of life. Archaeological finds from Mesopotamia, ancient Greece and the Etruscan civilization of central Italy show that people believed they could discover the will of the gods and gain a glimpse of the future by examining the surface of the liver. Patients with advanced cirrhosis of the liver caused either by alcohol or by viral hepatitis suffer from ascites, a build-up of fluid in the abdominal cavity. Suddenly intestinal bacteria are able to spread into the ascites intact and proliferate there. This is known as spontaneous bacterial peritonitis, and is generally fatal if left untreated. However, the alfapump® from Sequana Medical NV is now changing all that.

We are fully aware that overweight, diabetes, heart disease, excessive alcohol consumption and hepatitis are making life difficult for us. Our unhealthy lifestyle is one of the key reasons why liver disease is on the rise. In the USA, chronic liver disease and cirrhosis are the cause of an increasing number of deaths.

The liver – the problem child

Cirrhosis is a scarring of the liver. Non-functional connective tissue replaces normal, healthy liver tissue, and the largest detoxification organ in the human body stops working. Some 30–40 percent of the US population has non-alcoholic fatty liver disease, making the condition one of the major challenges facing the country's healthcare system and a major cause of cirrhosis. Sequana Medical NV, which is domiciled in the Belgian city of Ghent, has taken up this challenge. The company's aim is to develop innovative approaches to the treatment of liver disease, heart failure, malignant ascites and other disorders caused by fluid imbalance in the human body. It is now launching its Zurich-manufactured alfapump® implant for the treatment of refractory liver disease-related ascites and malignant ascites in Europe. As mentioned, ascites is an accumulation of fluid in the abdominal cavity that is associated either with liver disease or with cancer. As much as 15 litres of fluid may accumulate.

Over 650 alfapump® systems have already been implanted. A pivotal tri-

Left to right: David Knaus, Lies Vanneste, Dirk Fengels, Ian Crosbie, Daniel Bär.

al is in preparation in North America with the aim of achieving market launch in the second half of 2019. The US Food and Drug Administration (FDA) has granted the alfapump® Breakthrough Device Designation under the Breakthrough Devices Program it has set up to give seriously ill patients faster access to novel medical devices like the alfapump®.

A close look at an innovation

The alfapump® is fully implantable, programmable and wirelessly chargeable. The battery-powered device collects fluid as soon as it forms and conducts it to the bladder, from where it is discharged from the body by the natural process of urination. Pumps are implanted under local or general anaesthesia in less than one hour. Patients have minimal interaction with their alfapump® once it has been implanted. All they need to do is charge the pump through their skin by holding the wireless charger over it, a process that takes about 20 minutes, depending on how much fluid there is to remove. While the pump is charging, it transfers data to the charger. Doctors can then access this data during follow-up visits, and change settings as needed. The pump incorporates a special mechanism to ensure that fluid is only conducted to the bladder if the bladder has sufficient capacity to accommodate it. The pump shuts down automatically when there is no more fluid in the abdominal cavity. Patients can thus enjoy optimal fluid management without any inconvenience. In addition, the pump incorporates DirectLink technology to make it both comfortable and convenient for patients and doctors. Performance data from alfapump® is collected continuously and transferred to secure servers via the mobile phone network, which makes it possible to analyse data at any time and provide coverage 24 hours a day, 7 days a week. The alfapump® eliminates the need for repeated invasive procedures involving needles and external tubes, or for repeated paracentesis, a procedure in which the body is punctured to remove fluid.

The safety and efficacy of alfapump® in patients with ascites has been demonstrated in various clinical trials, the results of which have been published in peer-reviewed journals.

Broad recognition

Since April 2018, the alfapump® has been included in the EASL (European Association for the Study of the Liver) clinical practice guidelines for the treatment of decompensated cirrhosis. Furthermore, Sequana Medical NV recently announced that alfapump® has been included in the guidelines of the DGVS (German Gastroenterology, Digestive and Metabolic Diseases Society) for complications of liver cirrhosis. In November 2018, the UK National Institute for Health and Care Excellence (NICE) recommended use of the alfapump® under special arrangements for the treatment of refractory ascites caused by cirrhosis. The FDA granted the alfapump® Breakthrough Device Designation for the treatment of refractory liver ascites in January 2019.