

Figure 1: The inner life of the ALFapump. ©Sequana Medical

## Efficient pump system for improved quality of life.

**Implantable pump systems are used to treat many medical conditions – including ascites. Severe disorders are frequently the cause for this symptom. To control the fluid that has collected in the abdomen, Sequana Medical has developed an active implant. In these devices, maxon EC motors are responsible for trouble-free running and smooth pump motion.**

Ascites is a term that describes an accumulation of large quantities of fluid in the peritoneal cavity. In the vernacular, this symptom is also called “abdominal dropsy”. In approx. eight out of ten cases, the cause of ascites is decreased liver function, for example caused by cirrhosis of the liver. But ascites can also be caused by reduced myocardial function, kidney diseases or cancer. For most patients, medication and a special diet are adequate to drain this fluid again. However, for several thousand of patients per year in Europe and the USA, this therapy no longer works. Per day, an affected patient can accumulate up to two liters of fluid in the abdomen. For many patients, this accumulation of fluid in the abdomen is a big burden, as hitherto the only way to remove the fluid was by means of regular tapping.

The ALFapump System, an active implant from Swiss medical technology specialist Sequana Medical, ensures that patients with ascites can lead an uncomplicated life. The system monitors the fluid accumulation in the abdomen and, whenever necessary, pumps the fluid into the bladder of the patient, where it is excreted with the urine. The core component of the three-part system is the ALFapump implant with the two catheters for the peritoneal cavity and the bladder. The external SmartCharger with charging station is a mobile charging and communication unit that charges the battery of the ALFapump implant and enables communication. The lithium ion battery of the pump allows autonomous operation for several days. Due to the energy consumption of the pump (per day, 0.9 liter is pumped out on average), the battery has to be charged regularly. The battery is charged wirelessly through the skin of the patient.

For trouble-free monitoring, a notebook computer is used as an additional component. By means of special communication software the physician can program the implant for each patient individually. He can precisely define how much fluid should be pumped into the bladder per day. Furthermore, the physician can use the wireless connection to access the automatically recorded data of the patient.

### High material requirements

The ALFapump implant is inserted between the subcutaneous fat layer and the peritoneum and is made of PEEK (polyether ether ketone), a biocompatible plastic. The unique ambient conditions within the human body requires special motors and appropriately adapted electronics, as no hermetically sealed encapsulation is possible when plastic is used. Therefore, the materials used have to withstand permanent moisture exposure and an increased salt concentration. Additionally, a constant temperature of max. 40 °C has to be ensured. Due to the presence of humidity, the implant is sealed completely, the electronics are protected with an additional coating and a brushless motor is used.

The complex electronics handles low-level control of the motor, control of the pump drive, evaluation of the sensor signals, communication with the SmartCharger and the battery management. Thus the gear pump also has to pump enclosed air (e.g. after an operation) in addition to fluid. Therefore, it is very important that very narrow tolerances are maintained; this in turn results in a very high torque, also during normal operation. An additional complicating factor is the fact that the fluid in the peritoneal cavity contains high quantities of fibrin and protein from the blood plasma. These can easily clot and thus severely influence the pump operation. In the worst case, the pump can get blocked completely. To prevent this from occurring, the pump performs a short movement without volume transport at regular intervals.

### Drive for high precision in medical technology

The maxon EC 13 motor drives the pump gears of the ALFapump and is specially tailored to the requirements of the customer. The motor is equipped with Hall sensors that are important for position feedback. The motor controller uses these Hall sensors to achieve reliable and stable operation, in particular at low speeds and high load torques. In addition to the sterilizable motor having a special stator coating, the shaft is also made of bio-compatible materials. Additionally, special shaft geometry is required. With the compact design of the EC 13, its excellent low-noise and low-vibration running properties and the low heat emission, the drive is specially tailored to the requirements of medical technology. To increase patient safety and reduce the complexity of the ALFapump's programming, an own processor is used for the motor controller. The main processor configures the motor controller, to achieve the desired volume transport. This motor controller checks whether the respective parameters are valid.



Figure 1: The inside of the gear pump with electronics and the customer-specific EC13 motor. © 2012 Sequana Medical



Figure 2: The implant consists of a powerful pump (right) that is powered by a rechargeable battery. To enable increased mobility, the SmartCharger (left) is also operated with a battery. © 2012 Sequana Medical

If, for example, there is a deviation from the max. permissible pump duration, the main processor de-energizes the motor subsystem. Thanks to this dual processor system, maximum monitoring during the pumping procedure is guaranteed and the highest possible level of safety is provided.

### Successfully implanted pump systems

The first two commercial operations with the pump system were performed in October 2011 in Vienna (Austria). According to Prof. Markus Peck-Radosavljevic, Vice-Chairman of the Division of Gastroenterology and Hepatology at the Department of Medicine III of the Vienna General Hospital, both short operations were completed without complications. "I believe that the ALFApump system is a real breakthrough in the treatment of ascites. The patients can lead an easier life, as they do not need to go to hospital for the strenuous drainage procedure," says Peck-Radosavljevic.

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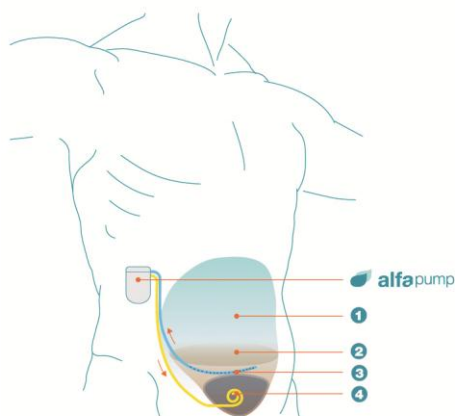


Figure 3: The automatic low-flow ascites pump (ALFApump®) is a fully implantable battery-operated pump that removes ascites by pumping the fluid into the bladder of the patient. © 2012 Sequana Medical

1: Peritoneal cavity 2: Ascites 3: Peritoneal catheter  
4: Bladder catheter

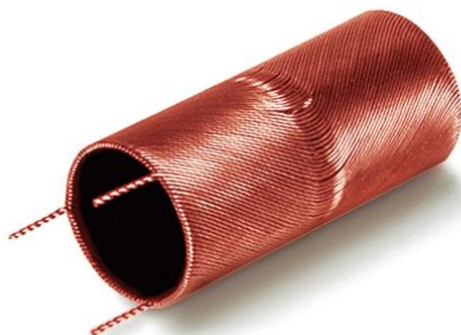


Figure 4: Self-supporting ironless winding, designed by maxon.© 2012 maxon motor ag

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