



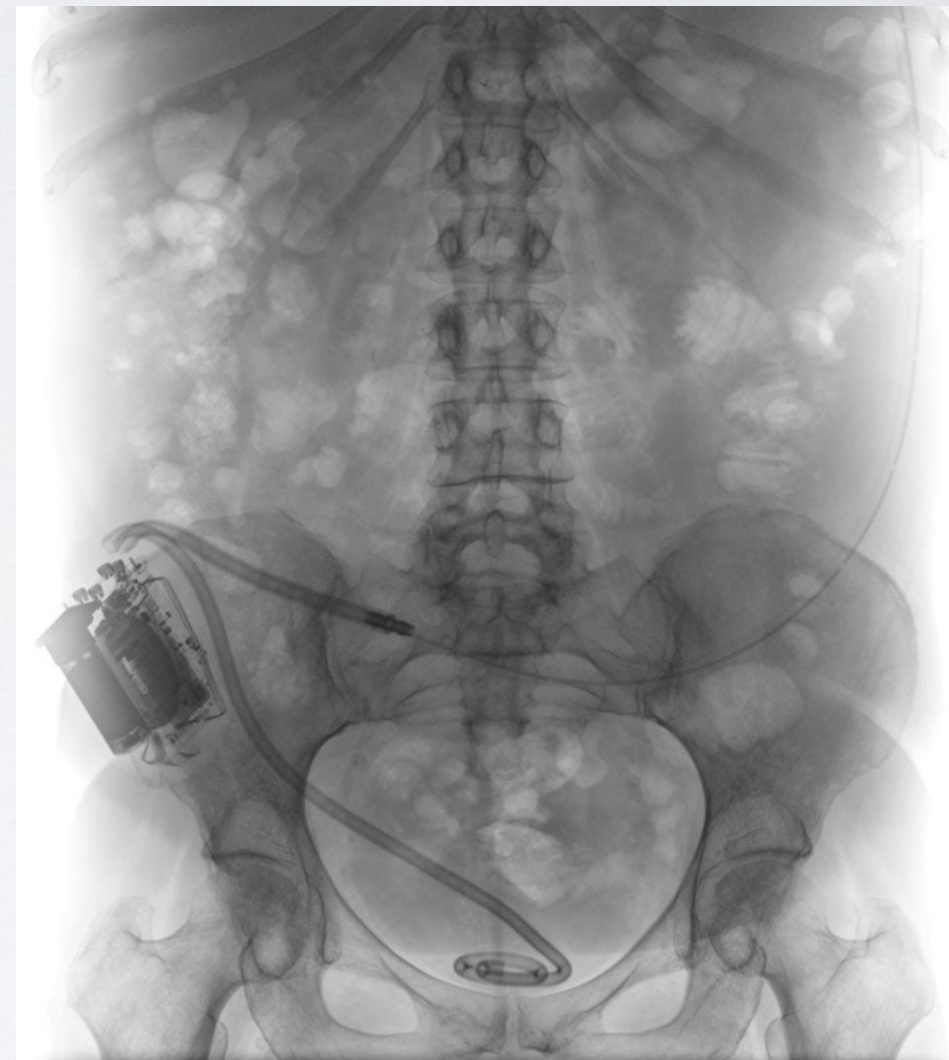
QUELLE: www.wohnmobilforum.de

THE ALFAPUMP[®] SYSTEM

A breakthrough in Ascites Management

SEQUANA MEDICAL

Dedicated to improving patient lives through development, manufacture & commercialisation of innovative implantable pump systems to manage fluid balance within the body.



SEQUANA MEDICAL

COMPANY HISTORY

- 2000 Concept (American physician)
- 2006 Company founded in Switzerland
- 2007 Series A funding - 13.5 million CHF
- 2008 First implant
- 2010 Pioneer Study - 40 patients
- 2011 Series B funding - 26.6 million CHF
 - CE for liver disease
- 2012 Commercial Launch in DE, A, CH & UK
 - CE for cancer





ASCITES

- Accumulates in abdominal cavity
- Up to 2.5 litres every day
- Most common complication and main reason for hospitalisation
- Symptoms are painful, distressing and impact negatively quality of life



QUELLE: www.patient.co.uk/doctor/ascites.htm

STANDARD CURRENT TREATMENT

LARGE VOLUME PARACENTESIS

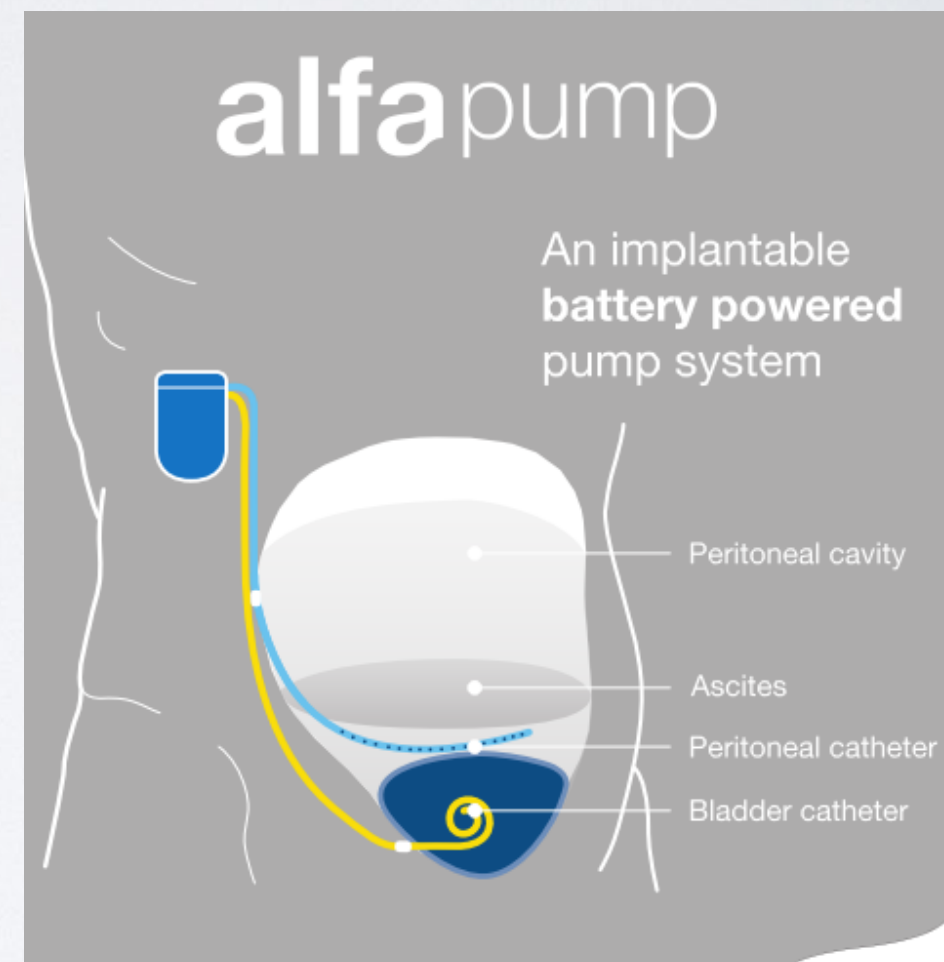
- Large bore needle drains up to 15 litres of Ascites over several hours
- Repeated every 7 to 10 days; often requiring overnight stay
- Highly unpopular with patients & physicians
- Expensive infusion of human Albumin to offset risk of renal failure (PICD)



THE ALFAPUMP® SYSTEM

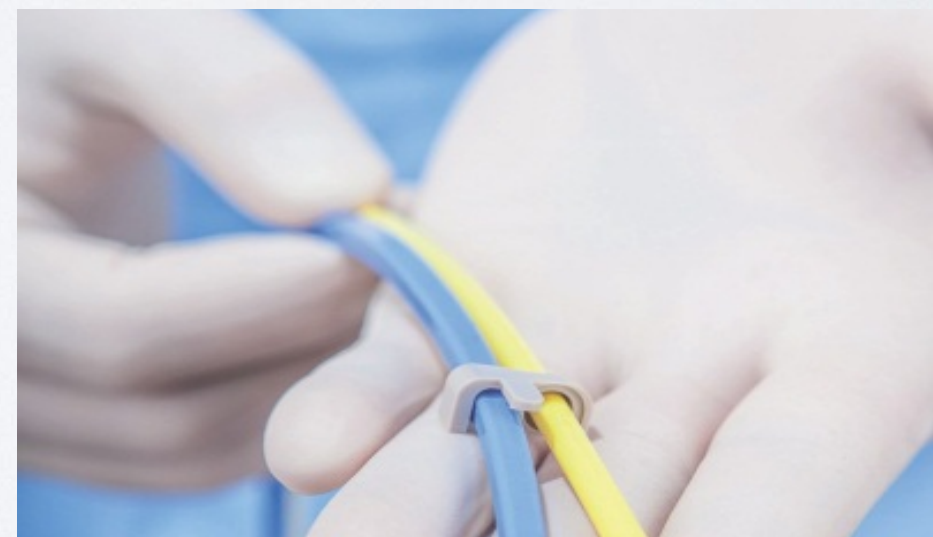
NEW REVOLUTIONARY TREATMENT OPTION

- Implanted into abdominal cavity
- Automatically and continually collects Ascites; moving it to the bladder
- Reduces need for large volume Paracentesis
- Reduces economic burden of Refractory Ascites
- Significantly improves quality of life



IMPLANTATION PROCEDURE

- Minimally invasive (> 1 hour)
 - General anaesthesia
- Procedure
 - Place Bladder Catheter
 - Place Peritoneal Catheter
 - Create standard pump pocket
 - Tunnel and connect Catheters
- Post Procedure
 - Program daily volume



AUTOMATED LOW-FLOW

ASCITES PUMP

- Custom designed & engineered
- Fully implanted
 - No external or visible components
- Individualised programming
- Wireless recharging by patient
- Unique mechanism
 - Unidirectional flow
 - Anti-blockage system
 - No pumping in absence of Ascites or when Bladder full



LIFE HAS CHANGED

PATIENT'S PERSPECTIVE

“I’m very satisfied with my pump.

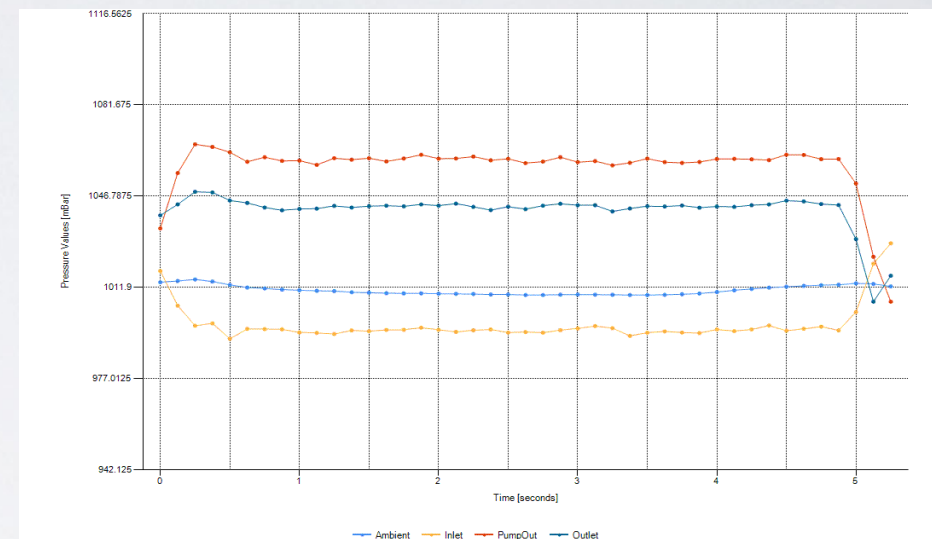
I enjoy my new life and like to be active. Now I can go swimming again and I take a walk every day. I have started to work again and I’m writing a new book with a friend of mine.”

Patient P I, implanted March 2009



SMART CHARGER & REMOTE PATIENT MONITORING SYSTEM

- Performance Data on ALFApump®
 - All events including all fluid cycles
- Data Transfer
 - Logs transferred to Charger
 - Logs uploaded to Server overnight
 - Logs analysed & alerts generated
- Launch Q1 2013



SOLID CLINICAL RESEARCH PLAN

2009 Feasibility Study 9 patients CZE, SWE

2010 Non randomised (Pioneer), 40 patients, safety and performance
(Prof. Such, Alicante)

2011 Non randomised, 12 patients, Hemodynamic & renal effect
(Prof. Gines, Hospital Clinic Barcelona)

Post Market Surveillance Registry

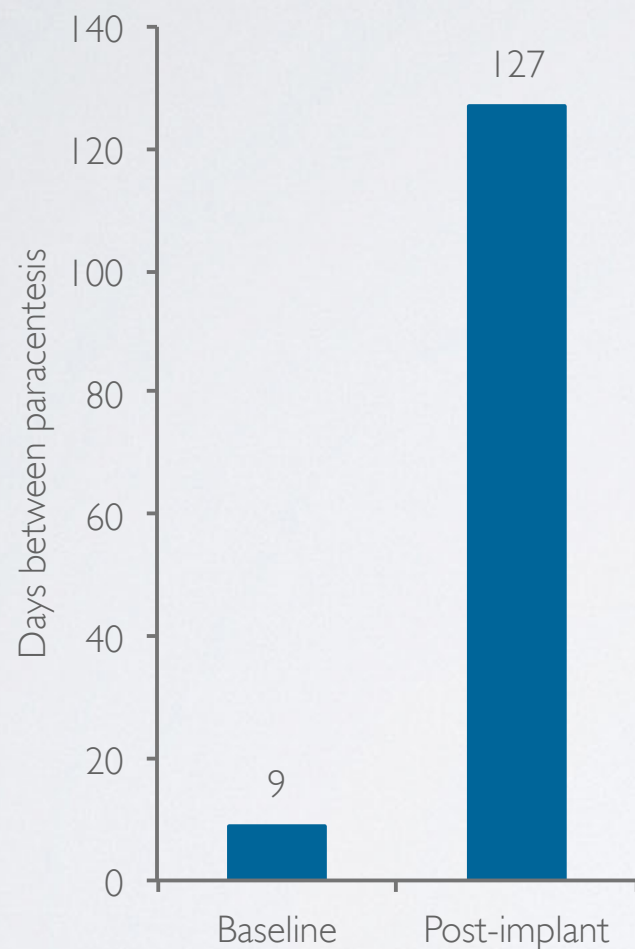
2012 Randomised, ALFApump® vs. Paracentesis, 60 patients
(Prof. Jalan, Royal Free London)

2013 Randomised, 50 patients, malignant Ascites
(Prof. Gabra, Imperial College London)

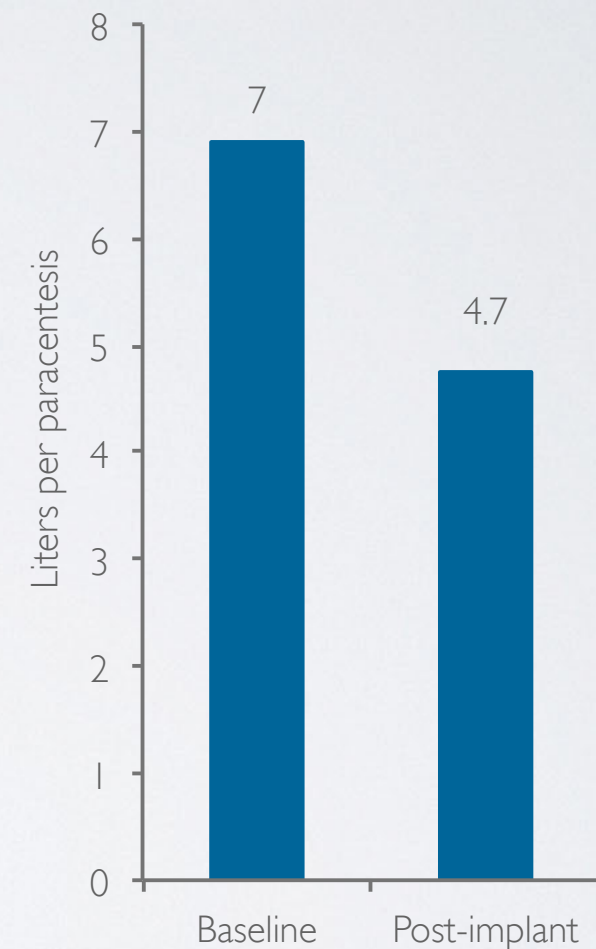
FDA Feasibility Study, 10 patients

PIONEER STUDY

40 Patients, 9 Centres, 4 Countries (EU)



Median days between
Paracentesis procedures



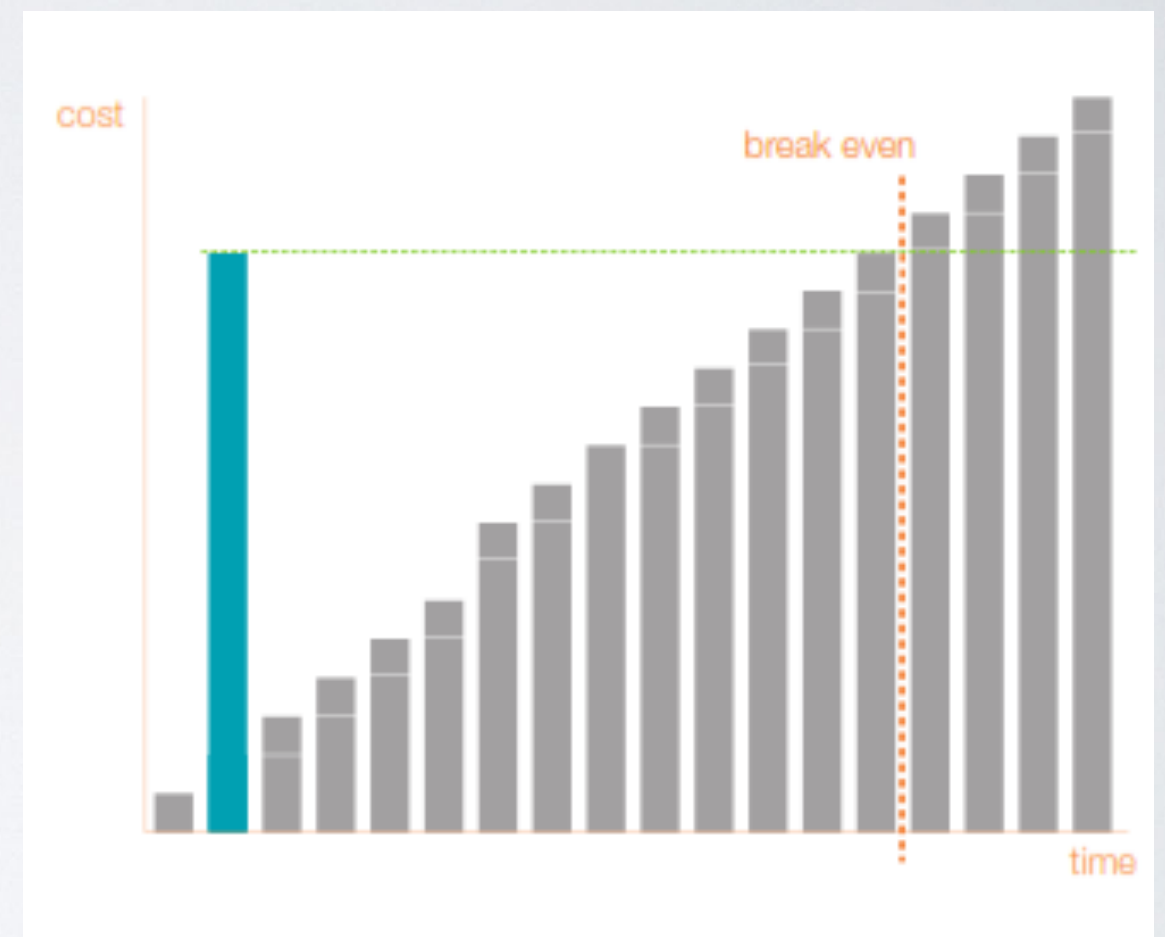
Mean volume of
Ascites removed per paracentesis

ECONOMIC BENEFITS

- Costs of Paracentesis can exceed €40,000 per year
- Cost of ALFApump[®] recovered after approx. 6 – 9 months
- NHS (UK) independent report
 - Paracentesis cost ca. £78,000 per year
 - ALFApump[®] could save £50 mio. per year

“Sequana Medical's ALFApump[®] system is a revolutionary fluid management solution for patients with Ascites which could save the NHS significant amounts of money by eliminating the costs associated with repeat medical interventions whilst significantly improving patients' Quality of Life.”

Head of the National Innovation Centre , October 2011



- ❖ One time cost of alfapump and surgery
- ❖ Cumulated cost of paracentesis and albumin

SUSTAINABILITY

- The ALFApump® System reduces number of patient hospital visits, reducing risk of hospital-acquired infection and burden on patient
- Frees up doctor and nurse time that can be put to use more efficiently
- Frees up hospital beds & resources



ALFAPUMP® MARKET

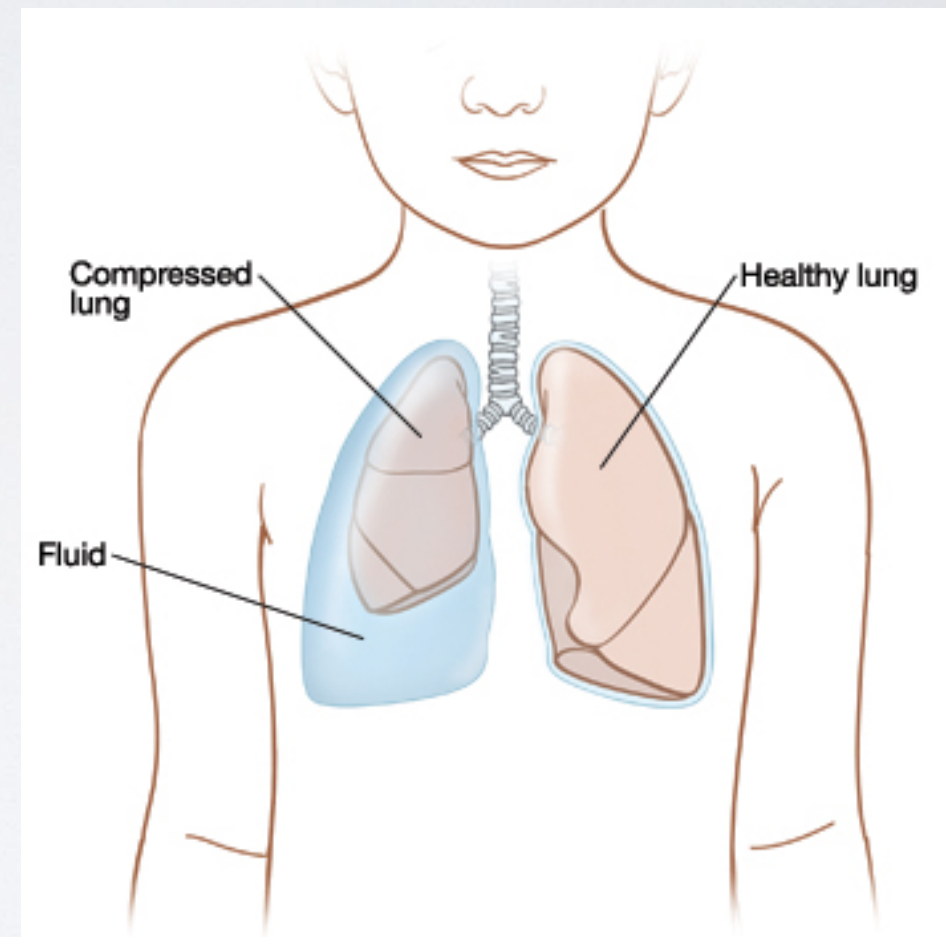
- Refractory Ascites in EU
 - Cirrhosis ~ 30'000 patients
 - Cancer ~ 12'000 patients
- Refractory Ascites in US
 - All types ~ 75'000 patients



BEYOND ASCITES MANAGEMENT

LEVERAGING TECHNOLOGY INTO NEW MARKETS

- Management of Refractory Pleural Effusion
 - Only minor modification required
 - Over 50'000 patients in the EU suffering from
 - Trapped lungs, length of hospitalisation
 - Complications, quality of life, body image
- Removal of excess fluid caused by late-stage renal disease or congestive heart failure
 - Pump delivers osmotic agent into the peritoneal cavity, causing fluid to move from the circulation into the peritoneal cavity due to the osmotic gradient
 - Over 500'000 patients with fluid overload
 - Most Swiss patients hospitalised due to fluid overload



MARKET & PRODUCT EXPANSION

ALFApump[®] System > 2 billion CHF

2012

Refractory Ascites due to Liver Cirrhosis
EU Market ~ 30'000 patients

2013

Refractory Ascites due to Cancer
EU Market ~ 12'000 patients

2014

Chronic Pleural Effusion
EU Market ~ 10'000 patients

US Market

All Applications ~ 100'000 patients

Osmotic System > 10 billion CHF

Congestive Heart Failure
with Fluid Overload
EU & US Markets ~ 500'000 patients

End Stage Renal Disease
Automated Peritoneal Dialysis
EU & US Markets ~ 70'000 patients

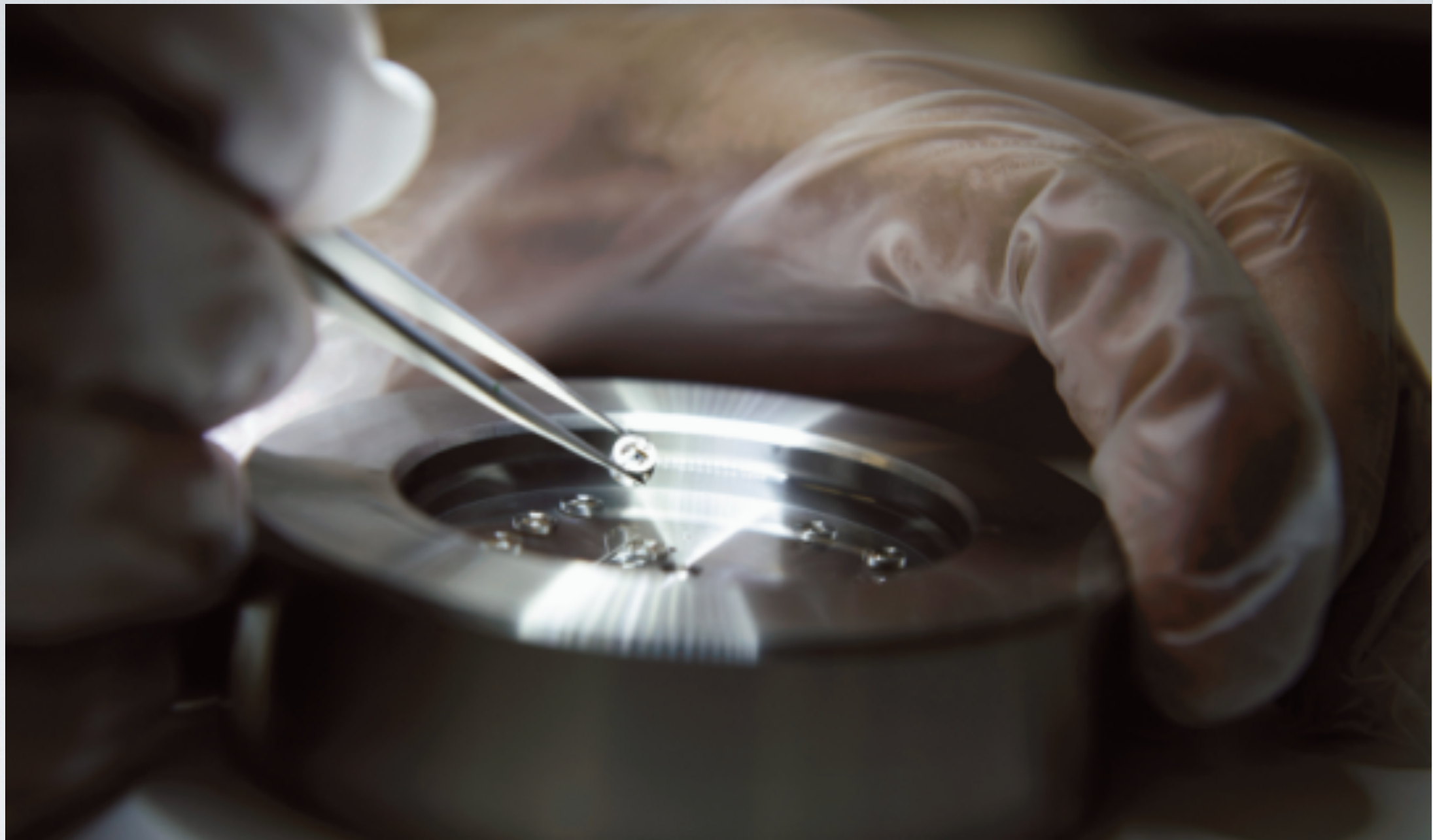
THE ALFAPUMP® SYSTEM

- The ALFApump® System
 - Battery (rechargeable) powered implantable pump
 - Smart Charger
 - Catheters
 - ALFApump® programmer
- Designed & Manufactured in Switzerland
 - World recognised engineering talent, especially with motors, gears, microelectronics, sensors and battery powered devices
 - Partnering with several Swiss companies
 - Art of Technology, Intersema, Maxon Motor, Microdul
- Generating sustainable economic growth & jobs in Switzerland



BEITRAG VON AoT

- Redesigned Electronics and Firmware for new Pump generation for Human Clinical Trials (based on working prototype used for animal studies)
- Software Development for Motor Controller (including recovery algorithm in case of Hall sensor failures)
- Design and Development of Wireless Charger (first 2 generations)
- Revision of Wireless Communication Protocol
- Optimisation of overall Energy Transfer System
- Generation of initial Technical Documentation for CE Submission
- As of today - punctual support (as and when required)



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