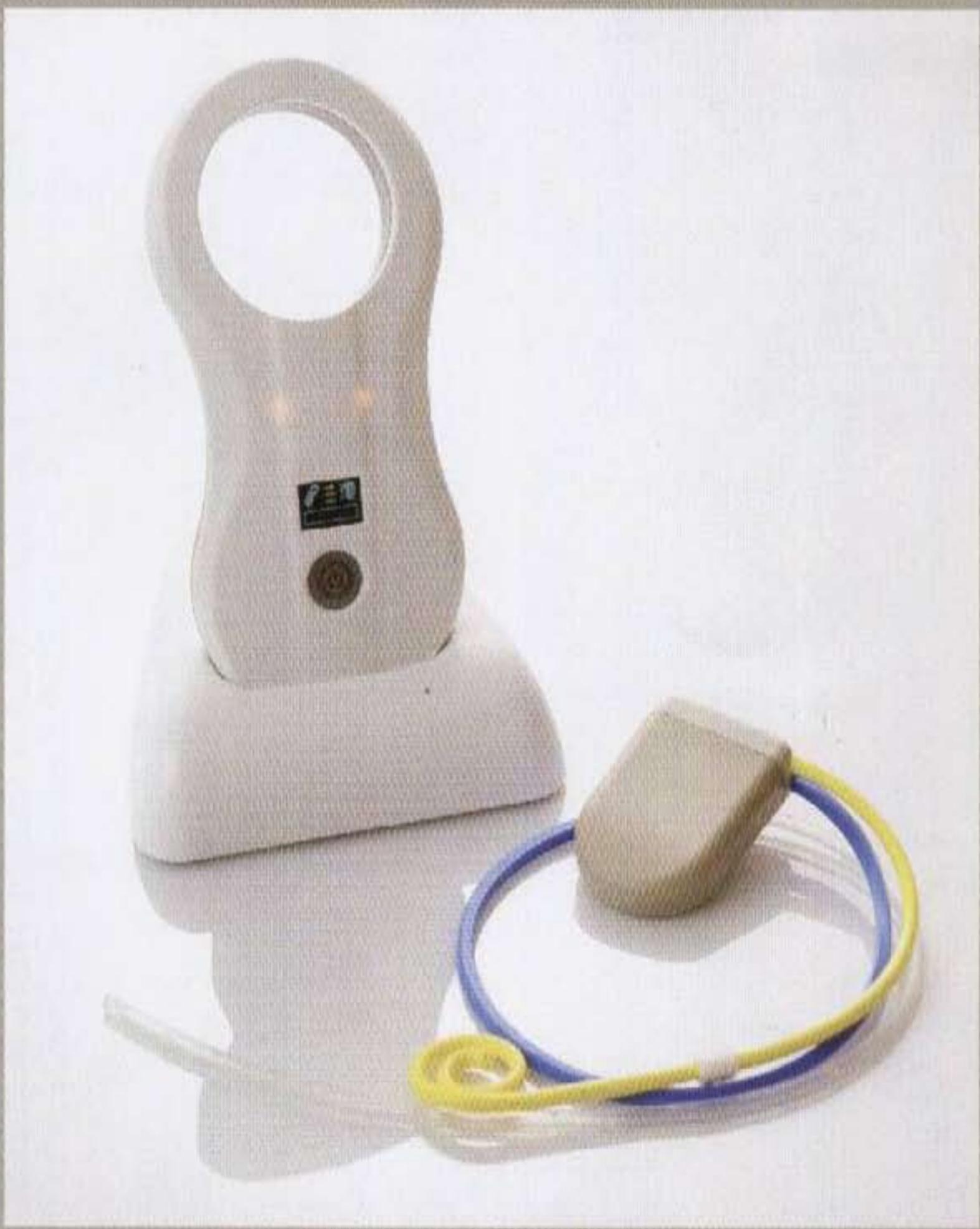




The ALFApump® System



An innovative solution
for patients with refractory ascites

ALFApump® System

The Automated Low-Flow Ascites Pump System is a fully implantable battery powered pump system that slowly removes ascites as it forms by transferring it to the bladder where it is eliminated through normal urination

THERAPY OBJECTIVES

- Eliminate pain
- Enhance quality of life
- Reduce the number of paracentesis

PERFORMANCES

The ALFApump System significantly reduces the number of required paracentesis and increases the interval between them.



CUSTOM DESIGNED AND ENGINEERED

- Controlled continual removal of ascites
- Fully implanted system, with no external or visible components
- Wireless programmable technology enables an easy connection to a computer
- Unique mechanisms ensure optimal performance including integrated pressure sensors and unidirectional flow components
- Extensive data capture capability enabling multi-center analysis
- Brief recharging using wireless smart charger
- One hour minimally invasive implantation procedure

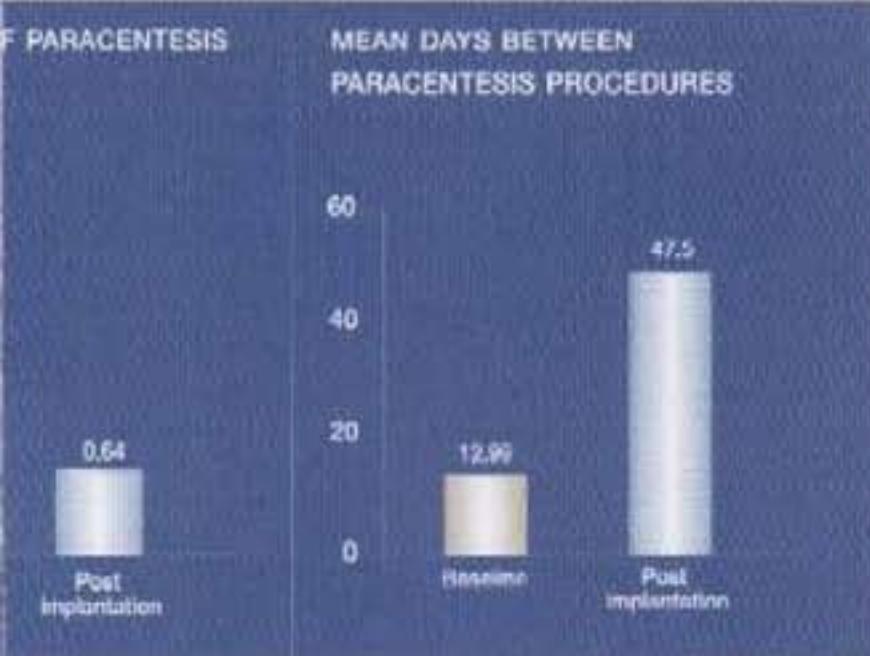
SURGICAL IMPLANTATION

The ALFApump System is subcutaneously implanted through a minimally invasive procedure. The bladder and peritoneal catheters are placed using standard surgical techniques. They are then tunneled to a small pump pocket located in the right upper abdominal quadrant where they are connected to the pump which is implanted under the skin.

REFRACTORY ASCITES

Refractory ascites is an accumulation of fluid in the peritoneal cavity which cannot be managed by medical treatment. Refractory ascites is associated with severe clinical complications, low quality of life, the requirement for repeated invasive interventions and high cost-of-care. The most common underlying cause of ascites is liver cirrhosis.

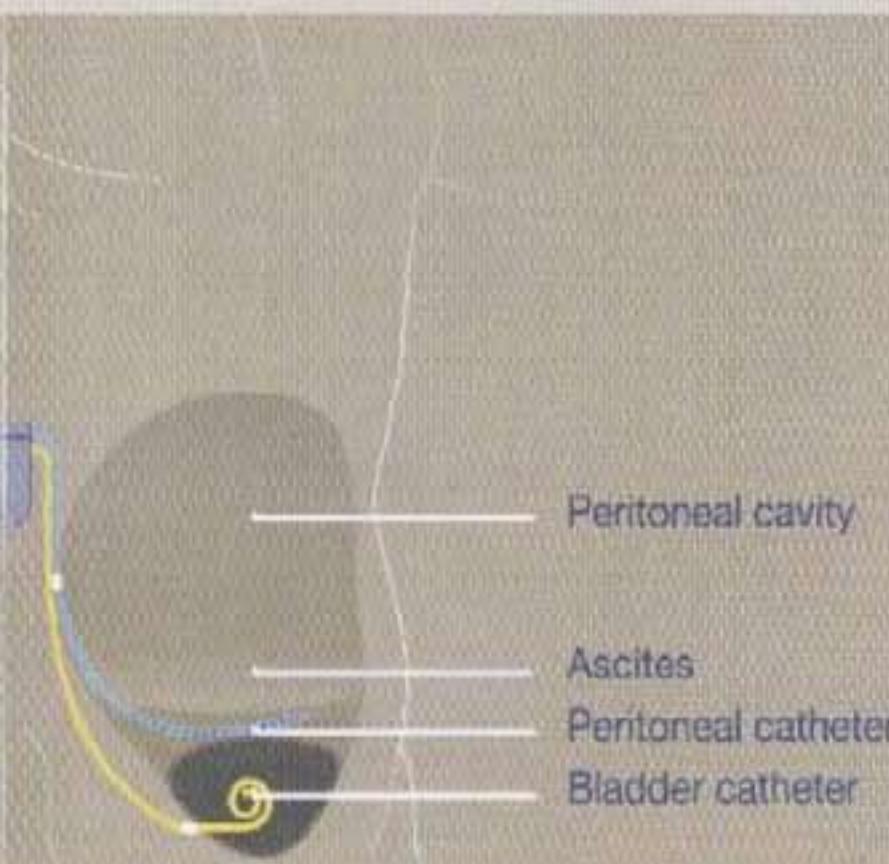
the need for repeated Large Volume Paracentesis
Patient Quality Of Life
overall burden for the healthcare system



DESIGNED FOR REFRACTORY ASCITES

le components
ndividualized flow algorithm
e including anti-blockage system, bladder and abdominal
nents
-criteria analysis and pump program optimization

ture



COMPONENTS

ALFApump



The ALFApump is a subcutaneously implanted battery powered pump that can be charged through the skin. It ensures controlled and continuous removal of ascites according to a programmed schedule set by the physician. Pressure sensors monitor pressure in the peritoneal cavity and bladder to ensure optimal fluid management. The ALFApump can move up to four liters of ascites per charge.

SMART CHARGER

The handheld SMART CHARGER is used by the patient to charge the ALFApump through the skin. During charging the SMART CHARGER collects records of all pump activity which can be transferred to the physician during follow-up visits.



CATHETERS



Standard implantable grade silicon catheters are utilized to collect ascites from the peritoneal cavity and transport it into the bladder. The bladder catheter features a pigtail design that rests inside the bladder. Dacron[®] cuffs facilitate tissue ingrowth and aid in securing the catheters after implantation.

ALFApump PROGRAMMER

Physicians use the notebook and integrated software to download pump data and to change settings according to patient needs. Unique flow control software enables quick and easy adaptation of patient specific pumping programs.



Sequana Medical is a Swiss medical device company dedicated to improving patient lives through innovative technologies to manage fluid within the body. Sequana Medical was founded in the Silicon Valley in 2004 and established in Switzerland in 2006.

ORDERING INFORMATION

PRODUCT DESCRIPTION	REFERENCE NUMBER
ALFApump® System	00777
ALFApump	00840
Bladder Catheter	00866
Peritoneal Catheter	00864
Tunneling Rod	00823
Implantation Accessories	00835
Smart Charger	00817
ALFApump Charging Kit	00816
ALFApump Programming Kit	00827



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The ALFApump System is indicated for the management of abdominal and ascitic fluid via an abdominal catheter.

Refer to package insert provided with the product for complete instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using the product. Information in this may not align with individual health authority product regulations.

All trademarks shall be used under license of their respective owners.

Caution: The law restricts this device to sale on the prescription of a physician.

Testing completed by Sequana Medical based on the German test regulation for laboratory performance.