

Advancements in the Management of Refractory or Recurrent Ascites

Sammy Saab, MD, MPH [1]; Mangesh Pagadala, MD [2]; K. Rajender Reddy, MD [3];
M-Gracia Knuttinen, MD, PhD [4]; Steven Flamm, MD [5]; Eran Shlomovitz, MD [6];
Jasmohan S. Bajaj, MD [7]; Hugo Vargas, MD [8]; Florence Wong, MD [9]

[1] Departments of Medicine and Surgery, David Geffen School of Medicine at UCLA, Los Angeles, CA

[2] Liver Transplant Hepatology and Director for Hepatology Research, Liver Institute -Methodist Dallas Medical Center, Dallas TX;
Assistant Professor, TCU and UNT School of Medicine, Fort Worth TX

[3] Division of Gastroenterology and Hepatology, University of Pennsylvania, Philadelphia, PA

[4] Division of Interventional Radiology, Mayo Clinic, Phoenix, AZ

[5] Professor of Medicine, Rush University Medical School, Chicago, IL

[6] Associate Professor of Surgery and Medical Imaging. University Health Network, Toronto, Ontario, Canada

[7] Professor of Medicine, Virginia Commonwealth University and Richmond VA Medical Center, Richmond, VA

[8] Professor of Medicine, Transplant Center and Division of Gastroenterology and Hepatology, Mayo Clinic Arizona, Phoenix, AZ

[9] Division of Gastroenterology and Hepatology, University of Toronto, Ontario, Canada

Abstract

Refractory or recurrent ascites in patients with cirrhosis is a feature associated with poor prognosis, and the management can be challenging. Options include repeated large volume paracentesis (LVP) and transjugular intrahepatic portosystemic shunt placement in the appropriate patients and liver transplantation in eligible patients. More recently, the automated low-flow ascites pump (alfapump®) system (AS) has been added to the armamentarium for the treatment of refractory or recurrent ascites. This battery-powered, subcutaneously implanted device allows for a continuous transport of ascites from the peritoneal cavity to the urinary bladder, with elimination through urination. The software allows the physician to program an individualized schedule for fluid elimination and communicate with the pump, adjust the settings and retrieve data wirelessly. Data on the AS in patients with refractory or recurrent ascites demonstrate safe reductions in the need for LVP as well as improvements in quality-of-life and nutrition. In order to further define the proper utility of the AS, guidance is needed on this new device. This practical, evidence-based resource increases awareness of and discusses the utility of the AS, identifies where the AS fits into the treatment spectrum for refractory or recurrent ascites, and provides guidance on appropriate patient selection, implantation, management, and follow-up through a multidisciplinary team approach.

Introduction

One of the serious complications of decompensated cirrhosis is refractory ascites, defined as ascites that cannot be mobilized or whose early recurrence after paracentesis cannot be satisfactorily controlled by medical therapy [1]. Refractory ascites occurs in 5%–10% of patients with ascites, is associated with severe malnutrition, declining quality of life and sometimes serious life-threatening complications such as acute kidney injury (AKI), bacterial peritonitis and hyponatremia [2], with a survival rate as low as 50% 6–12 months after its appearance [3]. Recurrent ascites is defined as ascites that recurs at least three times within 1 year despite dietary sodium restriction and diuretic therapy. Recurrent ascites can be a precursor to refractory ascites [3].

The automated low-flow ascites pump (alfapump®) system (AS) represents a major advancement in the treatment of refractory or recurrent ascites. The Chronic Liver Disease Foundation, a nonprofit 501(c)(3) educational organization dedicated to raising awareness of liver disease, formed a multidisciplinary panel of hepatologists and interventional radiologists to discuss this novel medical device. The result is this practical evidence-based resource that increases awareness of and discusses the use of the AS, identifies where the AS fits into the treatment spectrum for refractory or recurrent ascites, and provides guidance on appropriate patient selection and evaluation.

Management of Refractory or Recurrent Ascites

In patients with ascites, the American Association for the Study of Liver Diseases recommends moderate sodium restriction (2 g or 90 mmol/day) to achieve a negative sodium balance and net fluid loss. In most patients with cirrhosis presenting with ascites, dietary sodium restriction alone is insufficient and diuretic therapy with aldosterone antagonists (eg, spironolactone) and loop diuretics (eg, furosemide, torsemide, bumetanide) is necessary. Diuretic therapy is often poorly tolerated as patients can develop muscle cramps, gynecomastia, electrolyte abnormalities, including hyponatremia or hyperkalemia, dehydration and AKI, such as pre-renal azotemia [3]. These adverse events can occur in up to 40% of patients with ascites [4].

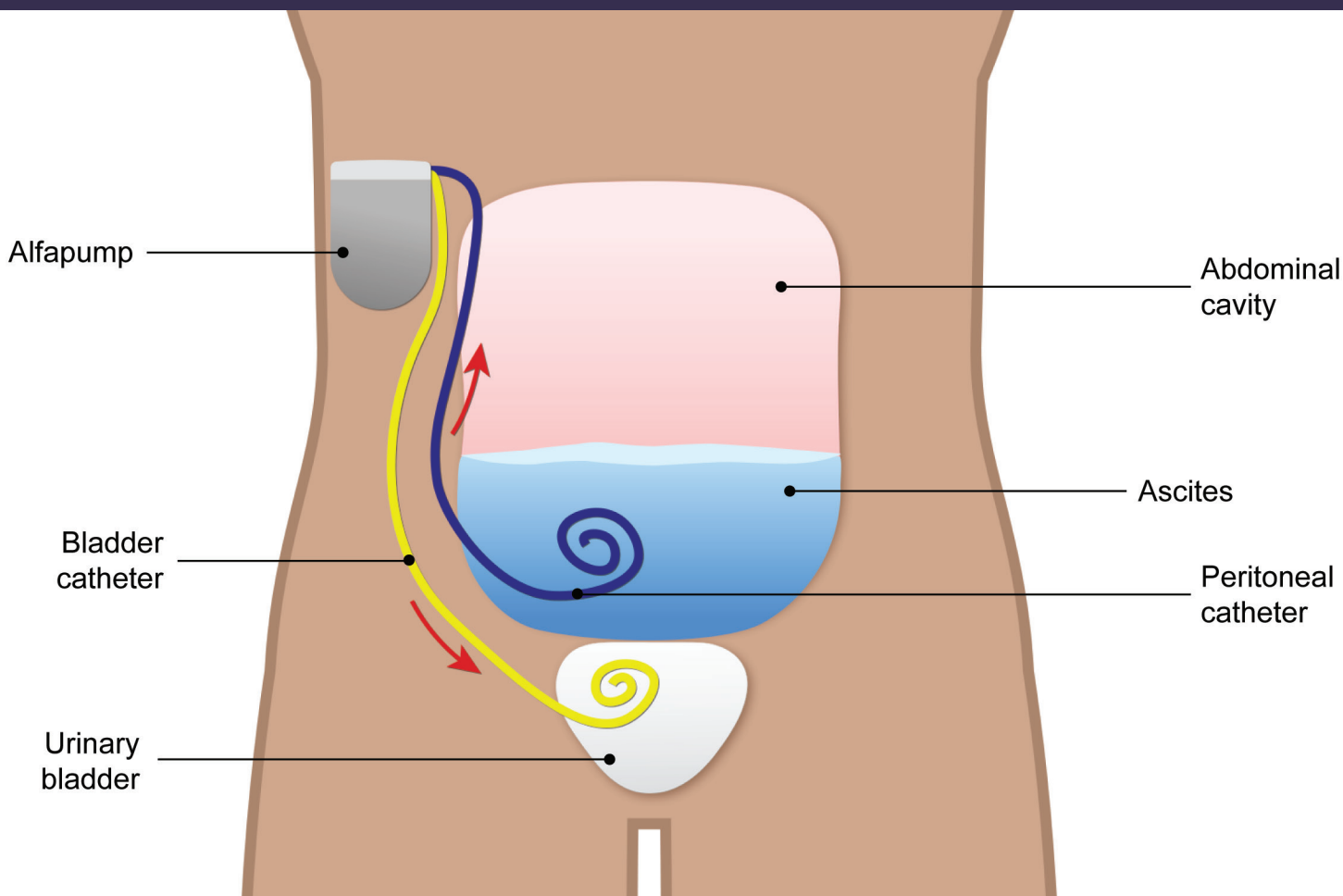
The standard of care for refractory ascites is large volume paracentesis (LVP) [3]. LVP is simple to perform in the outpatient setting, but usually needs to be repeated often [1] and is considered invasive. Moreover, there is rare risk of bowel puncture or bleeding, infection, and circulatory changes with LVP known as post paracentesis circulatory dysfunction, which can predispose patients to the development of renal dysfunction [5, 6]. A transjugular intrahepatic portosystemic shunt (TIPS) may also be an option in select patients with refractory ascites, but its utility limited by contraindications [7].

The use of TIPS is not recommended in patients at high risk for complications (patients with prior episodes of hepatic encephalopathy, high Model for End-Stage Liver Disease (MELD) score, age >65 years, platelets <125 g/L, glomerular filtration rate < 90 mL/min or low hemoglobin) [8-10]. Careful patient selection is the key to the success of TIPS, but, ultimately, only approximately 40% of patients with refractory ascites are candidates [2]. Liver transplant can also be considered in patients with refractory ascites and cirrhosis, but its availability is limited because the demand for liver transplant is greater than available organs.

Overview of the alfapump® System

In December 2024, the US Food and Drug Administration granted premarket approval to the AS for the treatment of recurrent or refractory ascites due to cirrhosis [11, 12]. The novel AS is a battery-powered, subcutaneously implanted device (with three implantable components) that allows for a continuous transport of ascites from the peritoneal cavity to the bladder, with elimination through normal urination (Figure 1 [12-14]). The software allows the physician to program an individualized schedule for fluid elimination and communicate with the pump, adjust the settings and retrieve data wirelessly. The battery, which is recharged daily by the patient, has a 3-year lifespan.

Figure. 1. The alfapump® System Components and Process to Remove Ascites [12-14]



The pump is subcutaneously implanted into the abdominal wall and is connected to a silicone peritoneal catheter, which aspirates ascitic fluid, and a silicone bladder catheter, which eliminates the fluid through the urine. Internal sensors in the AS monitor pressure in the peritoneal cavity and bladder and interrupt the pump cycles when peritoneal pressure becomes too low (indicating no ascites) and/or bladder pressure becomes too high (indicating a full bladder). The Smart Charger wirelessly charges the battery through the skin while gathering daily or weekly data from the alfapump® System.

Clinical Implications of the alfapump® System in Recurrent or Refractory Ascites

Data support the efficacy and safety of the pump. The pivotal POSEIDON study evaluated 40 patients with cirrhosis and refractory or recurrent ascites (mean $\pm$ standard deviation [SD] MELD-Na of 15 ± 4) who received an AS. The primary efficacy endpoint, a reduction in paracentesis requirement at 6 months, was met. Specifically, mean ($\pm$ SD) therapeutic paracentesis requirement was decreased from $3.2 (\pm 1.5)$ sessions per month preimplant to $0.2 (\pm 0.6)$ sessions per month at 6 months postimplant ($P < 0.001$), with 77% of patients having $\geq 50\%$ reduction. The primary safety endpoint was device-related adverse events resulting in intervention, AS removal, or death. Six pumps (15%) were removed within 6 months due to device-related adverse events, 3 (7.5%) due to pump-site skin erosion, and 3 (7.5%) due to bladder discomfort. The 5 deaths within 6 months post-implant were not directly related to the device or AS therapy. Physical but not mental components of the Short Form Health Survey (SF-36) improved ($P < 0.001$), with the greatest improvement in quality of life (QoL) associated with the reduction

in abdominal distention from elimination of ascites. The loss of abdominal fullness and reduction in back pain from not carrying the excess fluid, and the improvement in mobility led to an additional 10 good health days per month [15]. Twenty-four month data from POSEIDON demonstrated that use of the AS reduced the need for LVP by >50% (mean $\pm$ SD LVP per month reduced from 2.7 ± 1.3 to 0.1 ± 0.2 , $n = 39$). Overall survival on the pump was 71% and 62% at 12 and 24 months, respectively. There was one implant-related death caused by arterial bleeding. AKI ($n = 6$) and infections ($n = 5$) were events that could be successfully treated in most instances [16].

The result of a meta-analysis on the AS, consisting of nine studies (eight of which were case series), found that 62% of patients did not require LVP after AS insertion; the number of LVPs decreased by a mean of 2.1 per month with a resultant improvement in QoL. AKI, mostly stage 1, occurred in 30% of patients and creatinine levels increased by a mean of 23 $\mu\text{mol/L}$ after pump insertion. Bacterial peritonitis and urinary tract infection occurred in 27% and 20% of patients, respectively [17]. Additional studies also support the role of AS in the reduction in the need for LVP [18] and improvements in QoL [18, 19] and nutrition [18].

Patient Selection for the alfapump® System

The AS is intended for single patient use in adult patients with refractory or recurrent ascites due to cirrhosis. Eligibility requirements for AS are discussed in **Table 1** and mirror the inclusion and exclusion criteria used in the POSEIDON study. Many factors warrant consideration in these candidates, including MELD score, expected survival, renal function, urinary tract health, history of spontaneous bacterial peritonitis, and cognitive impairment/social support. Moreover, an estimated abdominal thickness and/or pannus greater than 3 cm may hinder proper charging of the pump [20]. In addition, patients with moderate-to-severe sarcopenia, risk of catheter erosion, coagulopathy (INR is ≥ 2), small bladder capacity and/or obstructive uropathy are contraindications to using the AS.

Patient preferences should also be considered when managing refractory or recurrent ascites. In order to facilitate patient access to this new technology, the Centers for Medicare and Medicaid Services published the Final Rule for Fiscal Year 2026 Hospital Inpatient Prospective Payment System. Beginning October 1, 2025, the AS, when performed in the inpatient setting, is approved as a New Technology Add-On Payment [21]. It is also important to note that patients who are candidates for liver transplant are still able to receive the AS, which can be removed prior to or at the time of transplantation. If a patient is expected to have a transplant within 6 months, AS implementation is not recommended, as invasive procedures should be avoided during this time.

Table 1. Patient eligibility for the alfapump® system [19, 20]

Consider	✓ All patients with refractory or recurrent ascites ✓ Cirrhosis defined by histological and/or clinical, endoscopic, laboratory and radiological criteria ✓ Ascitic fluid consistent with cirrhosis ✓ Survival estimate >6 months ✓ Liver transplantation candidates who are likely to wait >6 months prior to surgery ✓ Screened for esophageal varices and on optimal management ✓ Absence of contraindications to prophylactic antibiotic use from time of pump implant ✓ Women of childbearing age on adequate contraceptives
Exclude	✗ <18 years of age ✗ Loculated ascites since the AS cannot access all areas of ascites accumulation ✗ >1 systemic or local abdominal infection in the previous 6 months ✗ ≥2 UTIs in the previous 6 months ✗ Recurrent SBP ✗ <i>Clostridium difficile</i> infection in the previous 12 months ✗ History of HCC exceeding Milan criteria, bladder cancer, or any other nonhepatic malignancy unless it had been adequately treated and was in remission for ≥3 years ✗ BMI >40 ✗ Evidence of urinary bladder outlet obstruction, presence of a functioning TIPS or a surgical shunt, previous solid organ transplant, or patients who had contraindication to general anesthesia ✗ Severe liver dysfunction (MELD-Na score ≥20) ✗ Moderate renal dysfunction (SCr >133 mmol/L (1.5 mg/dL)) ✗ Require hyperbaric oxygen therapy (environmental conditions entailed in this therapy are out of the defined range of use for the AS) ✗ Need for frequent MRI imaging due to device-related MRI incompatibility ✗ Contraindications to anesthesia

AS, alfapump® System; BMI, body mass index; HCC, hepatocellular carcinoma; MELD, Model for End-Stage Liver Disease-Sodium; MRI, magnetic resonance imaging; gradient; SBP, spontaneous bacterial peritonitis; UTI, urinary tract infection

Implantation, Use and Monitoring of the alfapump® System: Recommendations for the Inpatient and Outpatient

Once a patient is selected for the AS and the procedure is scheduled, a multidisciplinary care team should be formed that consists of hepatologists, who are essentially leading the team, and hepatology nurses or advanced practice providers (APP); these specialists would be responsible for setting and adjusting pump settings and monitoring for complications [20]. Placement of the AS using interventional radiology methods has been found to be both feasible and technically successful [22] and therefore interventional radiologists (IRs), with training on AS implantation, and IR support staff are a part of this team. Infectious disease specialists and urologists should be included in the event that related complications arise [20]. Sequana support staff can be consulted for implantation training, device trouble shooting, and rate adjustments [20].

Table 2 provides specific recommendations from pre-procedure, inpatient evaluation and implantation, to outpatient monitoring and follow-up. Once the device is implanted, the initial settings for programmed ascitic fluid output of the AS is estimated using the fluid volume removed by pre-implant paracentesis over a 30-day period. The daily AS output should be 1.2 times the amount of fluid removed in a 30-day period, divided by 30. For instance, if a patient had 24 liters of ascitic fluid drained, the AS should be programmed to drain 0.96 liters per day. These settings can be adjusted post-implant based on the actual volumes of ascites removed by the AS (as per the pump reports). As a general guideline, do not exceed 1.2–1.5 liters per day to minimize the risk of renal impairment and electrolyte disturbances, particularly in patients with marginal kidney function (eg, elevated creatinine). Albumin infusions, dosed according to guidelines are recommended if more than three liters of ascites is drained during the implant procedure [3].

Table 2. The alfapump® system inpatient work-flow and outpatient monitoring and follow-up

Inpatient	
Admission and pre-procedure evaluation	☐ Engage the multidisciplinary care team ☐ Perform CBC, INR and MSU to rule out UTI, group and screen ☐ Perform a diagnostic paracentesis to rule out SBP, leaving 0.5 L of fluid for ease of AS insertion ☐ Initiate IV broad-spectrum antibiotic coverage for 24 hours ☐ Infuse albumin according to local guidelines [3]
Implantation	☐ Trained/experienced interventional radiologist implants the AS
Post-procedure	☐ Monitor for hematuria on day 1 ☐ Start prophylactic antibiotics ☐ Albumin infusion, per local guidelines ☐ Initial pump programming and adjustment ☐ Patient education (see Table 5)
Discharge	☐ Daily bloodwork to assess renal function and for infection ☐ Continued pump titration as needed ☐ Patient discharge upon clinical stability ☐ Reinforcement of teaching and discharge instructions (see Table 5) ☐ Prescription of antibiotics (e.g., ciprofloxacin 500 mg/day) for infection prophylaxis

Table 2. The alfaPump® system inpatient work-flow and outpatient monitoring and follow-up (cont'd)

Outpatient	
Day 2 Post-discharge	☐ Phone follow-up by the AS team to assess for early complications and patient comfort
Week 1, Ongoing monitoring	☐ Perform weekly blood work to decide whether the patient needs albumin infusion or adjustment of pump rate ☐ Check wound healing and change dressings ☐ Enquire about hematuria, dysuria ☐ Review weekly pump data, contacting the patient with any concerns and consulting with Sequana Medical for evaluation and rate adjustments
Week 2, In-person follow-up visit	☐ Clinical check-in (including an assessment of weight to make sure the patient is not losing too much weight) ☐ Check wounds and change dressings ☐ Evaluate labs and device ☐ Troubleshooting as needed
Monthly follow-up	☐ Clinical check-in ☐ Evaluate labs and device ☐ Troubleshooting as needed ☐ Continue following up monthly for the first three months

AS, alfaPump® System; CBC, complete blood count; INR, international normalized ratio; IV, intravenous; MSU, midstream specimen of urine; SBP, spontaneous bacterial peritonitis; UTI, urinary tract infection

The pump rate and potential development of volume depletion of each patient must be monitored by the treating physician to avoid the onset of AKI and systemic hypoperfusion. Weekly AS data will be provided by Sequana Medical and should be reviewed by the hepatology team. Adjustments should be made based on the match or mismatch between fluid formation and drainage rate (up-titrate if ascites accumulation exceeds pump drainage, down-titrate if minimal fluid is being produced or if clinical concerns arise). Patients should be instructed to follow a low sodium diet if ascites accumulation exceeds pump rate. Rate changes should always be guided by clinical status and basic metabolic panel results, with close attention to creatinine, sodium, and potassium levels.

Patients should be monitored for any potential adverse events (AEs) that might have occurred as a result of the implantation procedure (**Table 3A**) or from the device itself (**Table 3B**). Careful monitoring of and attention to wound care post implant and patient education on wound care is essential to minimize risk of implant site infection. It is recommended that patients be seen in the interventional radiology clinic for follow-up wound assessment after 1 week and that the stitches remain in place for at least 2 weeks. The development of infection may delay liver transplant or impact transplant listing status.

Table 3A. Potential adverse events associated with the procedures required for alfapump® placement^a

☐ Abdominal wall hematoma
☐ Adverse reaction to sedation, local or general anesthesia
☐ Bleeding
☐ Catheter track bleeding
☐ Cardiac or respiratory arrest connected to underlying medical problems (extremely rare)
☐ Injuries to blood vessels (extremely rare)
☐ Injuries to the digestive tract during placement (extremely rare in experienced hands)
☐ Pain
☐ Peritonitis
☐ Persistent leakage of ascitic fluid
☐ Urinary tract infections
☐ Wound dehiscence

^aIncluding the procedure to place the catheters and pump and local and/or general anesthesia

Table 3B. Potential adverse events that may be specifically associated with the alfapump® system

Category	Details
Pump pocket	☐ Hematoma ☐ Infection ☐ Pain ☐ Skin erosion above the AS ☐ Wound dehiscence ☐ Pump pocket fluid collection
Surgical	☐ Ascitic fluid leakage ☐ Bladder perforation ☐ Seroma ☐ Wound dehiscence (rupture)
Catheters	☐ Clogging ☐ Kinking
Catheter disconnection from pump	☐ Dislocation ☐ Infection ☐ Migration ☐ Tissue damage over catheter trajectory (including erosion)

Table 3B. Potential adverse events that may be specifically associated with the alfpump® system (cont'd)

Category	Details
alfapump® System	☐ Erosion ☐ Dysfunction ☐ Device migration ☐ Discomfort during pumping (sensation over the abdomen, filling of the bladder) ☐ Externally mediated damage (trauma, radiation) ☐ Clogging (prolonged shake mode) ☐ Shock-like sensation
Infection	☐ Peritonitis (abdominal inflammation) ☐ Pump pocket ☐ Skin ☐ Sepsis (including septic shock) ☐ Urinary tract ☐ Pneumonia ☐ Surgical incision
Reduced kidney function	☐ AKI ☐ Electrolyte disturbance ☐ Hepatorenal syndrome
Genito-urinary complications	☐ Bladder injury ☐ Bladder irritation/spasm ☐ Hematuria ☐ Incontinence/leakage ☐ Urethral stenosis ☐ Urinary retention
Systemic effects	☐ Circulatory dysfunction (similar to post paracentesis circulatory dysfunction) ☐ Dehydration ☐ Death ☐ Protein loss (hypoalbuminaemia)

AKI, acute kidney injury

Patients should be advised to keep the wound site dry, use water-proof dressings and change the dressings weekly. Potential medical therapy hazards are discussed in **Table 4**.

Table 4. Medical therapy hazards associated with the alfapump® system

Medical Therapy Hazard	Recommendation
MRI	Contraindicated due to possible movement of the AS, damage to the pump circuitry, tissue damage in the vicinity of the AS and/or catheter dislocation
Hyperbaric oxygen therapy	Contraindicated because the environmental conditions entailed in this therapy are out of the defined range of use for the AS
Supersonic therapy and high-frequency heat therapy	<i>Should not be used</i> due to possible heating effects of the implanted AS, but <i>if the therapy must be performed</i>: ☐ Do not apply in the immediate vicinity of the AS or the surrounding areas ☐ Continuously monitor the AS during treatment ☐ Check AS functioning after treatment
TENS	<i>Should not be used but if the therapy must be performed</i>: ☐ the TENS electrodes should be placed as close as possible to each other to reduce the spread of electricity, and as far away as possible from the AS ☐ Check the AS function after stimulation
Lithotripsy	<i>Should not be used</i> due to possible electrical and/or mechanical interferences with the AS, but <i>if the therapy must be performed</i>: ☐ The selected site for electrical and mechanical stress should be as far as possible from the AS
Defibrillation	The circuitry of the AS is protected against the energies of normal defibrillation, but complete protection is not possible and <i>damage may occur</i>. <i>If defibrillation is needed</i>: ☐ Circumstances permitting the energy setting should not be higher than necessary for defibrillation ☐ The distance between the paddles and the AS should be at least 10 cm ☐ Check the AS function after stimulation
Radiation therapy	The electronic circuit elements of the AS can be damaged by radiation therapy. <i>If radiation therapy is needed</i> ☐ Shield the AS during therapy, if possible ☐ Check the AS function after treatment
Electrocautery	Electrocautery may damage the AS circuitry. <i>If electrocautery is needed</i>: ☐ Do not perform within 15 cm of the AS ☐ For trans-urethral electro-resection of the prostate, it is recommended to place the neutral electrode on the buttocks or upper thigh, but not in the thoracic area ☐ Check the AS function after treatment

AS, alfapump® System; MRI, magnetic resonance imaging; TENS, transcutaneous electrical nerve stimulation

Patient and caregiver education should begin in the hospital setting and reinforced at discharge. Patient interaction with the AS is minimal, but education is needed on monitoring for AEs and when to immediately report complications, use of the Smart Charger, diet, reinforcing antibiotic compliance, advice on monitoring weight and vitals daily and what to expect during follow-up appointments as discussed in **Table 2**. Some questions frequently asked by patients are addressed in **Table 5**.

Table 5. alfapump® system patient education: Answers to frequently asked questions

FAQ	Response
When should I immediately consult with my hepatologist?	☐ Wound leakage ☐ Implant site redness, swelling or pain ☐ Ascites accumulation ☐ Fever for > 2 days ☐ Urination problems or suspicion of a bladder infection ☐ Any visible erosion of the tunneled catheter through the skin or abnormalities at the catheter exit site ☐ Any shock-like, sharp, or twinging sensations in the abdomen should be reported, as they may indicate device-related complications
What do I need to know about the AS and the Smart Charger	☐ The device is monitored remotely ☐ Charge the AS every day for at least 15 minutes ☐ Training should be provided by your clinician on how to use the Smart Charger ☐ Each time the AS is charged, the data is automatically transferred to the Smart Charger ☐ Only use the provided Docking Station to charge the Smart Charger ☐ Only use the provided power cable to connect the Docking Station to a power outlet (do not use a multiple socket or extension cord) ☐ Bring the Smart Charger to each follow-up visit so that your doctor can transfer its pump data to the provided notebook or tablet (alfapump® Programmer IV) for review. ☐ Do not disassemble or attempt to repair any of the AS components ☐ Do not attempt to charge other implanted devices like hip implants or pacemakers with the Smart Charger ☐ Do not place the Smart Charger over other implanted devices while charging ☐ Report any device-related concerns
Do I have any dietary restrictions?	☐ Adherence to a low-sodium diet is strongly recommended; consult with your physician for guidance ☐ Ongoing dietary caution is advised even if the ascites and edema has improved
Is there anything specific I should know about taking other medications?	☐ Avoid use of NSAIDs (e.g., ibuprofen, ketoprofen, naproxen sodium) due to their effects on kidney function ☐ Compliance with prescribed antibiotics is important to prevent infection

Table 5. alfapump® system patient education: Answers to frequently asked questions (cont'd)

FAQ	Response
Is there anything I should know about electronics/mobile phones?	☐ Use of mobile phones near the AS during charging and programming has the potential to cause operational complications ☐ Do not carry mobile phones in pants pockets or on belt clips within 15 cm of the AS ☐ Temporary interference will resolve once the mobile phone is out of the immediate vicinity
Will any of my household appliances interfere with the AS?	☐ Electric household appliances (e.g., stoves, microwave ovens, radios, televisions, electric shavers and toothbrushes) <i>will not</i> generally affect AS operation if the appliances are in good condition and properly grounded and insulated.
Will strong electromagnetic fields interfere with my AS?	☐ Consult with your doctor before exposing your AS to electromagnetic fields (e.g., electric arc welders, electric melting furnaces, radio, radar and television transmitters, exposed ignition systems (e.g., internal combustion engines), electrical tools, high-voltage power lines and defective electrical equipment that is not properly grounded or sufficiently insulated) as operational complications may occur
Can I safely walk through the airport x-ray machine with an AS?	☐ Yes

AS, alfapump® system; NSAIDs, nonsteroidal anti-inflammatory drugs

Discharge may be considered once the patient is clinically stable. Discharge can be considered if no infections have occurred, oral intake is resumed, fluid status is satisfactory and the patient is ambulatory and is comfortable with charging the AS. Following discharge, the patient should be seen weekly for 2 weeks, followed by monthly appointments with the hepatologist and, if available, the hepatology APP for the first 3 months. Weekly bloodwork should be performed to decide whether the patient needs albumin infusion or pump rate adjustment. Patients should be checked for diarrhea from chronic antibiotic use.

Pump Removal and Replacement

The AS is designed for long-term implantation, but in certain cases explantation is warranted. **Table 6** lists indications for pump removal and replacement.

Table 6. Indications for pump removal and replacement

Indications for AS removal	☐ At the time of liver transplant or the immediate preoperative period ☐ Patient request ☐ Need for urgent or frequent MRI ☐ Need for hyperbaric oxygen therapy ☐ Infectious complications (e.g., SBP) ☐ Skin erosion by either device or catheter(s) ☐ Documented absence or significant reduction of ascitic fluid production based on AS data logs, despite proper device functioning (which may be due to clinical improvement) ☐ Death
Indications for AS replacement	☐ Technical or mechanical failure of the pump requiring replacement to restore function ☐ Skin erosion of the peritoneal or bladder catheter necessitating removal and re-implantation ☐ Dislodgement of the catheter from the urinary bladder, compromising fluid transfer and requiring repositioning or replacement ☐ Infections localized to the pump pocket that necessitate removal, followed by consideration for reimplantation on the opposite side of abdominal wall after infection resolution

AS, alfa pump system®; MRI, magnetic resonance imaging; SBP, spontaneous bacterial peritonitis

Conclusions

Refractory or recurrent ascites are serious complications of decompensated liver disease that put the patient at risk for severe complications and decreased QoL. The recent introduction of the AS, the first active, implantable medical device in the United States to be approved for the treatment of recurrent or refractory ascites due to cirrhosis, represents a significant milestone in ascites treatment. By reducing symptom burden and procedural frequency, the AS may meaningfully improve patient QoL and functional status. Multidisciplinary team knowledge on proper patient selection, device use, potential AEs, and methods for evaluation and monitoring for efficacy and preventing complications will further improve patient outcomes and define the success of the AS. Case studies indicate that the AS is effective in controlling ascites in a patient with an umbilical hernia [23] and a patient with an hepatic hydrothorax [24]. Future studies are warranted on the use of the AS in providing an opportunity for recompensation and in the management of ascites in other conditions, such as congestive heart failure and malignancy.

Acknowledgments:

This manuscript was supported by a grant from Sequana Medical. Rachel E. Bejarano, PharmD, provided medical writing assistance.

1. Salerno F, Guevara M, Bernardi M, et al. Refractory ascites: pathogenesis, definition and therapy of a severe complication in patients with cirrhosis. *Liver Int.* 2010;30:937-47.
2. Piano S, Tonon M, Angeli P. Management of ascites and hepatorenal syndrome. *Hepatol Int.* 2018;12:122-134.
3. Biggins SW, Angeli P, Garcia-Tsao G, et al. Diagnosis, Evaluation, and Management of Ascites, Spontaneous Bacterial Peritonitis and Hepatorenal Syndrome: 2021 Practice Guidance by the American Association for the Study of Liver Diseases. *Hepatology.* 2021;74:1014-1048.
4. Morando F, Rosi S, Gola E, et al. Adherence to a moderate sodium restriction diet in outpatients with cirrhosis and ascites: a real-life cross-sectional study. *Liver Int.* 2015;35:1508-15.
5. De Gottardi A, Thévenot T, Spahr L, et al. Risk of complications after abdominal paracentesis in cirrhotic patients: a prospective study. *Clin Gastroenterol Hepatol.* 2009;7:906-9.
6. Kumar K, Pillai VB. Improvement in Quality of Life and Decrease in Large-Volume Paracentesis Requirements With the Automated Low-Flow Ascites Pump. *Liver Transpl.* 2020;26:1539-1540.
7. Campbell MS, Brensinger CM, Sanyal AJ, et al. Quality of life in refractory ascites: transjugular intrahepatic portal-systemic shunting versus medical therapy. *Hepatology.* 2005;42:635-40.
8. Luca A, Miraglia R, Maruzzelli L, et al. Early Liver Failure after Transjugular Intrahepatic Portosystemic Shunt in Patients with Cirrhosis with Model for End-Stage Liver Disease Score of 12 or Less: Incidence, Outcome, and Prognostic Factors. *Radiology.* 2016;280:622-9.
9. Bureau C, Thabut D, Oberti F, et al. TIPS with PTFE-covered stent improves liver transplant free survival in patients with cirrhosis and recurrent ascites: results of a multicentre randomized trial. *Hepatology.* 2015; 62: 347A.
10. Hamel B, Guillaud O, Roman S, et al. Prognostic factors in patients with refractory ascites treated by transjugular intrahepatic porto-systemic shunt: From the liver to the kidney. *Dig Liver Dis.* 2014;46:1001-7.
11. Sequana Medical Announces US FDA Approval of alfapump® for the Treatment of Recurrent or Refractory Ascites due to Liver Cirrhosis. Available at: <https://www.sequanamedical.com/press-releases/sequana-medical-announces-us-fda-approval-of-alfapump-for-the-treatment-of-recurrent-or-refractory-ascites-due-to-liver-cirrhosis/>.
12. Weil-Verhoeven D, Di Martino V, Stirnimann G, et al. Alfapump® implantable device in management of refractory ascites: An update. *World J Hepatol.* 2022;14:1344-1356.
13. alfapump. Available at: <https://www.alfapump.com/alfapump/>.
14. Stirnimann G, Banz V, Storni F, et al. Automated low-flow ascites pump for the treatment of cirrhotic patients with refractory ascites. *Therap Adv Gastroenterol.* 2017;10:283-292.
15. Wong F, Vagas HE, Reddy KR, et al. The Effects of Alfapump on Ascites Control and Quality of Life in Patients With Cirrhosis and Recurrent or Refractory Ascites. *Am J Gastroenterol.* 2025.
16. Vargas H et al. ALFAPUMP SYSTEM IN REFRACTORY ASCITES: RESULTS FROM THE POSEIDON STUDY AT 24 MONTHS. *Hepatology.* 2024;80:2463-4.
17. Lepida A, Marot A, Trépo E, et al. Systematic review with meta-analysis: automated low-flow ascites pump therapy for refractory ascites. *Aliment Pharmacol Ther.* 2019;50:978-987.
18. Bureau C, Adebayo D, Chalret de Rieu M, et al. Alfapump® system vs. large volume paracentesis for refractory ascites: A multicenter randomized controlled study. *J Hepatol.* 2017;67:940-949.
19. Wong F, Bendel E, Sniderman K, et al. Improvement in Quality of Life and Decrease in Large-Volume Paracentesis Requirements With the Automated Low-Flow Ascites Pump. *Liver Transpl.* 2020;26:651-661.
20. Vargas HE, Knuttinen MG, Rotellini Colvet L, et al. How We Approach It: Alfapump. *Am J Gastroenterol.* 2025.
21. CMS Approves Additional Payment for Sequana Medical's alfapump® system in Hospital Inpatient Cases. Available at: <https://www.sequanamedical.com/press-releases/cms-approves-additional-payment-for-sequana-medicals-alfapump-system-in-hospital-inpatient-cases/>.
22. Bendel EC, Sniderman K, Shaw C, et al. Feasibility and Procedural Safety of alfapump System Implantation by IR: Experience from the MOSAIC Study, a Multicenter, Open-Label Prospective Study in Cirrhotic Patients with Refractory Ascites. *Journal of Vascular and Interventional Radiology.* 2020;31:1256-1262.e3.
23. Sioda NA, Vargas HE, Weidknecht JL, et al. Using the Alfapump® to control ascites enabling elective umbilical hernia repair: A case report. *Hernia.* 2025;29:209.
24. Tiwari N, Shlomovitz E, Capel J, et al. Innovative Management of a Difficult Case of Hepatic Hydrothorax. *ACG Case Rep J.* 2024;11:e01372.