alfapump® System

The innovative therapy for patients suffering from recurrent or refractory ascites due to liver cirrhosis.

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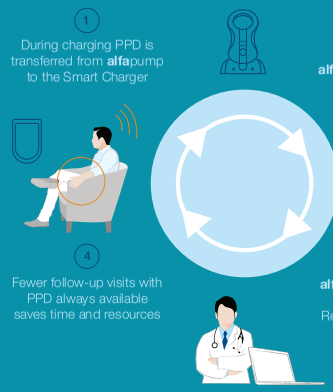
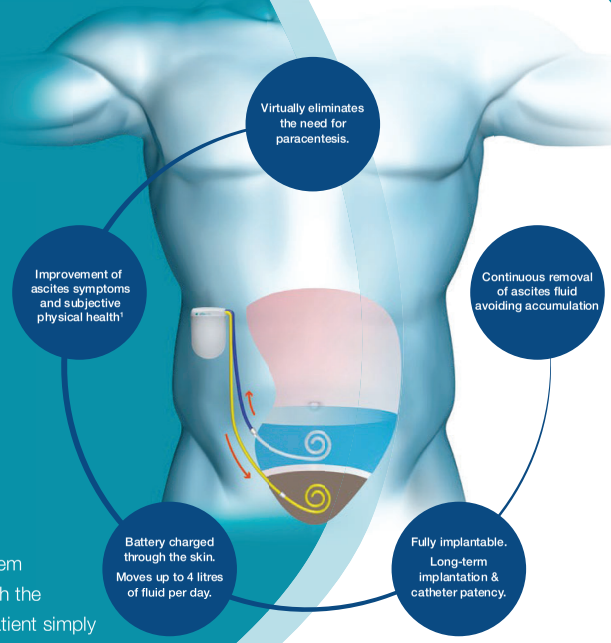
Demonstrated clinical benefit through reduced paracentesis

The **alfa**pump® system was designed and developed as an automated system to eliminate the need for repeated paracentesis helping keep patients out of the hospital while living a more free and independent life.





Once implanted, patient interaction with the **alfa**pump system is minimal. A training program is offered to help patients with the characteristics of the **alfa**pump and Smart Charger. The patient simply charges the **alfa**pump wirelessly through the skin by holding a hand-held charging device over the **alfa**pump.
While charging, Pump Performance Data (PPD) from the **alfa**pump is transferred to the Smart Charger. Settings can be changed by the treating physician as appropriate during follow-up visits.

1. While improvement in ascites symptoms was statistically significant, it might not be clinically significant

alfapump® System

The **alfa**pump® is a subcutaneously implanted battery-powered pump that ensures the controlled and continual removal of ascites according to a programmed schedule set by the doctor.

POSEIDON study observations at 6 months

Improvement of ascites symptoms and subjective physical health[1]

Strong efficacy

At 6 months, the POSEIDON study shows a strong efficacy with a **median per patient ratio reduction of therapeutic paracentesis of 100%** (N=40 P<0.001)

Virtually eliminates the need of therapeutic paracentesis

At 6 months follow up, **80.8% of the patients** that completed the follow up **had a 100% reduction of therapeutic paracentesis**. (N=26)

Manageable safety profile

At 6 months follow up, the POSEIDON study shows **a well characterized and manageable safety profile.**

Improvement of ascites symptoms and subjective physical health[1]

At 6 months follow up, the POSEIDON study **demonstrates a clinically significant improvement in the subjective physical health** as measured by SF-36 Physical Component Score and a **statistically significant improvement in ascites symptoms** as measured by Ascites-Q Score[1]

Ascites under control

At 6 months, **significant reduction of the monthly number of LVPs** from 2.3 to 0.1 (p<0.001). At 6 months, **significant reduction of the cumulative volume of ascitic fluid removed by needle** paracentesis in 3 months post-implant from 54.2L to 2.8L (p<0.001)

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alfapump® System

Benefits of the system

Improvement of ascites symptoms and subjective physical health[1]

The POSEIDON Study demonstrates that alfapump can virtually eliminate the need of paracentesis as well as improve subjective physical health (both clinically and statistically signficant) and ascites symptoms (statistically significant, may not be clinically significant).

Program your routine

Your doctor can program the **alfa**pump to meet your individual requirements and set it in accordance with your daily routine, for example to adapt to your work or sleeping pattern.

Patient choice

After consultation with the FDA, a quantitative Patient Preference study was designed based on recommended best-practices, CDRH guidelines, and current literature to understand how patients view the tradeoffs among the important benefits and risks of the **alfa**pump. The study included 125 patients, all candidates for an **alfa**pump, who were presented with a series of experimentally-designed hypothetical choices for an **alfa**pump with varying risks and benefits and asked to pick their preferred option. Analysis of their choices found that patients who are candidates for an **alfa**pump, on average, were willing to accept levels of risks associated with the **alfa**pump (e.g. mortality, major/minor surgical procedure, or infection or kidney injury requiring hospitalization) far greater than the rates observed in the POSEIDON trial to receive an **alfa**pump that reduces the need for paracentesis over continuing with regular paracentesis. Overall, a majority of patients selected an **alfa**pump over continued paracentesis.

Frequently asked questions

What do I have to do?
- Simply charge the battery for approximately 20 minutes a day.

Do I have to plug it in?
- Batteries are charged wirelessly through the skin.

How much liquid is pumped into my bladder?
- The volume transported is set to individual needs by the treating physician.

Can I travel by plane?
- Yes, you can travel by airplane.

Is it a long operation?
- Everything's done in just over 80 minutes.

Can you see the pump?
- No, the pump is implanted completely under the skin.

CONTRAINDICATIONS:

MRI Safety Information
- The **alfa**pump is MR unsafe.
- This diagnostic procedure is contraindicated due to possible movement of the alfapump, damage to the pump circuitry, tissue damage in the vicinity of the **alfa**pump and/or catheter dislocation.

Hyperbaric oxygen therapy

Hyperbaric oxygen therapy is contraindicated because the environmental conditions entailed in this therapy are out of the defined range of use for the **alfa**pump® System.

REFERENCES:

1. While improvement in ascites symptoms was statistically significant, it might not be clinically significant

https://www.easlcongress.eu/wp-content/uploads/2023/06/EASL_2023_Congress_Abstracts_version5_web4-compressed.pdf
Doc QCBD 30184 - Clinical Study report POSEIDON

WARNING. The implantation of the alfapump may result in infection that could delay liver transplant or impact transplant listing status.

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Sequana Medical is a Belgian medical device company dedicated to improving patient lives by providing innovative solutions to manage fluid balance within the body.

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