

# ARCA+

A FULLY IMPLANTABLE, DRAINAGE SYSTEM THAT TRANSFERS PERITONEAL FLUID FROM THE PERITONEAL CAVITY TO THE BLADDER FOR NATURAL EXPULSION THROUGH URINATION.



## ASCITES

Pathological buildup of fluid in the peritoneal cavity, most often due to advanced liver disease (cirrhosis), but also linked to cancer, and other conditions. Once ascites becomes refractory it signals advanced disease and very poor short-term prognosis.

Patients with refractory ascites undergo paracentesis, the standard of care.

This hospital-based procedure involves inserting a needle to drain peritoneal fluid. Only limited volumes can be removed per session to avoid acute kidney injury or albumin deficiency.



## HEALTH CONSEQUENCES

Because fluid reaccumulates, paracentesis is repeated once a week (on average) for the remainder of a patient's life. Average 2-year mortality rate.

10% of patients develop Spontaneous Bacterial Peritonitis (SBP), the most severe complication with a mortality rate of 90%

The only curative option is liver transplantation, but most patients are ineligible due to donor availability and compatibility.

## ECONOMIC CONSEQUENCES

Each paracentesis session takes ~4 hours, costs around \$1,600, and provides only temporary relief.

Patients may undergo a transjugular intrahepatic portosystemic shunt (TIPS), which is limited to those with portal hypertension (~\$35k).

Liver transplantation costs (~\$800k+)

DISEASE NUMBERS

+60.000  
CASES

Prevalence: Affects an estimated 5–10% of patients with chronic liver disease annually; in the U.S., over 60,000 cases occur each year.

80%  
RELATED TO LIVER  
CIRRHOSIS

80% of ascites cases are linked to liver cirrhosis, while the remaining 20% stem from cancers, hepatitis B/C, and other causes. The rising prevalence of metabolic dysfunction-associated steatohepatitis (MASH) is driving a 4% CAGR in ascites cases in the U.S., indicating steady growth of this population.

ALLOWS PATIENTS TO DRAIN AT HOME, BY THEMSELF AND CONSTANTLY – AVOIDING ACCUMULATION OF PERITONEAL FLUID AND ITS ASSOCIATED SYMPTOMS.

ARCA+  
IS THE SOLUTION

## PATIENTS



It is safe and low risk. It does not need replacement or maintenance for the life of the patient. It does not require any external energy, software or batteries to operate, making it safer and easy to use.

With **ARCA+**, patients can drain continuously, anytime, and anywhere, reducing hospitalizations and enabling a faster return to normal life and work

Patients will no longer have to live with associated symptoms such as swelling in the legs and ankles, nausea, shortness of breath, and, in severe cases, umbilical or inguinal hernias.

## HOSPITALS



Hospitals spend less time and resources managing ascites patients.

Helps hospitals manage fewer emergencies and complications, easing clinical burden and improving patient outcomes.

**1-hour-long surgery** performed by a general surgeon and outpatient/at-home treatment by themselves.

## HEALTHCARE SYSTEM

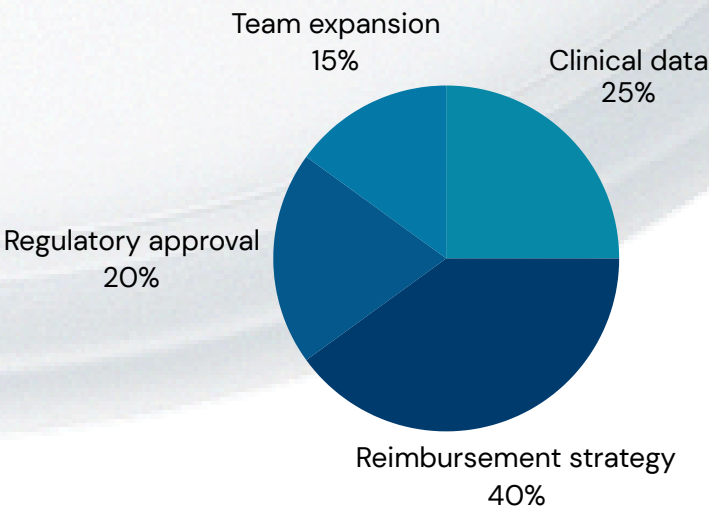


Paracentesis costs approximately **\$60,000** per patient per year, totaling nearly \$4B annually in the U.S. **ARCA+** is a one-time \$6,000 solution (excluding implantation costs)

Healthcare system spends approximately \$4B annually treating ascites patients. **ARCA+** offers an estimated \$3B in potential savings.

Ascites patients experience frequent hospitalizations due to infections, associated symptoms, and spontaneous bacterial peritonitis (SBP)

## USE OF CAPITAL



## ARCA+ VS COMPETITORS

- |   |   |
|---|---|
| <ul style="list-style-type: none"><li>• Painless</li><li>• Needle-free</li><li>• Low infection rate</li><li>• Constantly relieving symptoms</li><li>• No weekly hospital visits</li><li>• No eligibility criteria</li><li>• No long wait times</li><li>• Closed loop, fully implantable</li></ul> | <ul style="list-style-type: none"><li>• No external ports</li><li>• Improved life quality</li><li>• No clogging, 6 whole catheters</li><li>• Electricity-free</li><li>• Manual mechanism</li><li>• No skin erosion - no battery</li><li>• Low cost (\$6k)</li></ul> |
|---|---|

## INVESTMENT

Raising \$2.5M for 10% of ARCA + equity in seed round capital to prepare for U.S market entry in Q2 2027

## THIS IS ARCA+'S STATUS

### 2020-2021

- Idea development
- Prototyping, R&D, molding
- Q-sub with FDA

### 2022-2023

- Formulation Concept and Feasibility
- Patent Submitted
- Q-sub 2 with FDA

### 2024

- Biological Evaluation Plan (BEP)
- Pre-clinical testing started
- QMS, DHF, packaging

### 2025

- Final Validation / Product Launch Preparation
- Breakthrough Device Designation
- Reimbursement Pathway

### 2026

- Finalize Pre-clinical testing
- Distributor relationships
- FDA submission and approval

### 2027

- Patent Approval
- Product Launch

## SCALING + BUSINESS MODEL

### Business Model & scalability

**ARCA+** partners with established medtech distributors to drive commercialization and hospital access.

Distributors handle sales, logistics, and physician training, while **ARCA+** focuses on manufacturing, innovation, and quality control.

This model enables rapid market penetration with minimal in-house sales infrastructure.

### Revenue & financing structure

Bank-backed production financing:  
- **ARCA+** secures short-term loans based on letters of payment commitment from distributors, guaranteed by their banks.

- This ensures continuous production and on-time delivery while minimizing cash flow risk and capital strain.

- **ARCA+** pays only a small interest fee, leveraging external capital to fund production instead of equity dilution or delayed cash cycles.

### Scalability & growth

- Fast global expansion through additional distributor agreements across new regions.

- Low CapEx and operational leverage: growth in sales volume doesn't require scaling sales teams.

- Predictable revenue and efficient working capital management support sustainable long-term profitability.

## WHO WE ARE



Dr. Ernesto Andrade and his daughter, Gabriela Andrade, lead Laboratorios Vertex, combining medical expertise, business vision, and technological innovation. Together, they have turned the company into a benchmark in the development of medical devices that transform healthcare and aesthetic medicine. With over 30 years of experience as a surgeon, Dr. Andrade contributes his clinical knowledge and passion for innovation, while Gabriela, a professional in Entrepreneurship and Economics, leads strategic, financial, and operational growth. Their joint work reflects a family bond committed to improving people's quality of life and bringing science to its fullest potential.