

2019 Product Brief Point-of-Care Microfluidic Platelet Aggregometer



HEMOSTASIS MANAGEMENT

Bedside Results at 20% the cost.

MICELI is a new point-of-care platelet aggregometer that is reliable, portable, inexpensive, and easy to use. And since MICELI monitors at the bedside, decisions can be made in advance, enhancing the patients outcome, long-term prognosis, and reducing any unnecessary procedures or anti-platelet medications.



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PORTABLE

With portable aggregometry, we provide results at the point-of-care and when decisions need to be made. The MICELI is ideal for bedside, home, field, and within primary laboratory facilities.



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Platelet Monitoring, Simplified. Now.

The MICELI aggregometer provides portable monitoring for high-risk patients before, during, and after surgical procedures. With platelet count results readily available, MICELI advances reduces the probability of thrombotic events, unnecessary drugs, transfusion therapies, and added surgeries.

EASY TO USE

At 20% of the cost of aggregometers in the market, the MICELI also comes with the benefit of simplicity. MICELI was designed for ease-of-use and with the injection of a sample, and real-time impedance analysis, results are available in minutes.

The Market Problem: Platelet Testing Hasn't Changed in Over 50 Years **OBSERSONLY** TIME TO RESULTS COST OF DEVICES

- Transportation to labs with large devices installed
- May take 24 hours or more toand-from clinical laboratories...
- Limits impact on patient results



- Equipment is costly and only available in specialized labs.
- Most cost \$40,000 per device or more

- Highly sensitive device
- Requires significant training
- Difficult to operate in primary clinics, clinical departments, or in the field or home

LIMITED ASSESSMENT

- Limited
- biochemical/inflammatory data
- No platelet physiology
- No information on platelet activation & aggregation



Physician's Problem Advancing Decision Making and

 Predicting Surgical Bleeding and Transfusion Needs Reducing thrombotic events for patients with cardiac devices Anti-platelet therapy management ✓ Monitoring of platelet dysfunction after cardiopulmonary bypass and complications associated

Outcomes for High Risk Patients

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Platelet Assessment **Determines** Therapy

Platelet assessment determines therapy and the wrong therapy could cause dire consequences or death. Reasons for activation of clotting must be known.

MICELI

BIOCHEMICAL

MECHANICAL



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High-Risk Patients: Clotting & Bleeding

Pneumonia Cancer Pulmonary embolus Heart Attack (MI) Stroke Vulnerable plaque Mechanical Circulatory support o Ventricular Assist o Total Artificial Heart

Cardiac Implant Tx o TAVR/Mitral Coronary Stents Arterial Stents Stent Grafts Cancer Therapies Trauma Surgery Medications

16 M Peripheral Artery Disease 1 Million or more will be implanted with stents, and 340,000+ cardiopulmonary bypass patients will require transfusions







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Introducing MICELI The Ultra-Fast Solution With All The Data You Need.

MICELI is a point-of-care microfluidic platelet aggregometer (monitoring device).

It provides robust platelet data, including mechanical and inflammatory (biochemical) assessments to more readily make advanced patient care decisions...at the bedside.

As a first-to-market product, there is a significant cost savings of 80% for all...

✓ Patients
✓ Healthcare providers
✓ Insurance



Portability & Point-of-Care

MICELI is small, light, and Ideal for use in patient rooms, surgery, and in the field.



Ultra-Fast Testing

Platelet testing and results in under 6 minutes.

No more waiting. Get Real-Time Results.

Until now, real-time platelet function monitoring has not been available in the marketplace, and traditional methods and transfusion algorithms limit detection. The MICELI features stand alone.



Full Platelet Data and Assessment!

Advance patient decision making can now be made with biochemical, inflammatory, and mechanical data to address patient therapy.



80% cost savings for patients, healthcare providers, and insurance...with superior performance increases.



Inexpensive



Routine & Real-Time Monitoring

Ongoing platelet monitoring can now provide routine results or data required during high-risk procedures.

Semi-Automated and Easy to Use

Simple sample injection, simple device, and user-friendly software with dashboard-style data.

2015 Discovery & Founding

MICELI is a product developed by PlakDx, LLC, founded and co-invented by:

- o Frank LeDuca
- o Dr. Marvin Slepian
- o Dr. Alberto Redaelli
- o John Jackson, MBA

2017 Prototype and Intellectual Property

The MICELI Team worked with the University of Arizona IP development group – Tech Launch Arizona – to validate and patent, in collaboration with the co-inventing institution, Politecnico di Milano, Italy.



PlakDx and the creators of the MICELI will begin demonstration for acquisition, licensing, or to further development in partnership.

Research & Development

Product development is ongoing, with teams in Arizona and in Milan, working to commercialize the minimally viable prototype.

2018: REGULATORY Pre-Market FDA Submission

The MICELI will qualify as a premarket submission, avoid additional approval time, equivalent to marketed device (21 CFR §807.92(a)(3)), submitted and approved under 510(K) application # k103555.

2019: PRODUCT DEMONSTRATION Advancing Aggregometry





Frank LaDuca CEO



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Partner early and join us.

Our leadership team includes experienced founders of medical device companies, with extensive industry knowledge of diagnostic medicine, disease management, and commercialization of novel therapeutics. The PlakDx executive team has successfully delivered solutions to market, which are in clinical use today.





John Jackson, MBA COO

Is partners with







Dr. Marvin Slepian Chief Medical Officer

Center for Accelerated **BioMedical Innovation**

Dr. Alberto Redaelli **Co-Founder** & Board Member



Seed Opportunity

Capital Investment: Strategic Seed

Research operations, commercialization activities, and other market development, including regulatory needs are funded by research grants. Early seed funding is in need to support development until successful exit, with a target for acquisition or total licensing, within 24 months.

Commercialization Partnerships Technology Sensitive to Detect Platelet Aggregation or Miniaturized Systems / Lab-on-Chip for Platelet Function Analysis Partnerships are in discussion to accelerate development with strategic institutions and companies who are currently in-market. Opportunities are available on an institutional and private level, in concert with the Arizona Center for Biomedical Innovation in Arizona.

\$1.2 MM+

PROFILE OVERVIEW

Year Founded: 2018 Founders: 4 Co-Inventors: 2 Research Members: 6

Intellectual Property: Patent Pending

Location: Tucson, Arizona and Milan, Italy

Industry Market: Platelet Aggregation Devices; Hemotology diagnostics; hemostasis management

Partners: University of Arizona - Arizona Center for Accelerated Biomedical Innovation, Politecnico di Milano



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