



INFINITY Angioplasty Balloon Co. (IABC) is an early commercial stage, medical device company that was founded in 2015 by serial entrepreneur and vascular surgeon, John Pigott, MD, FACS. Corporate offices are located on the ProMedica Innovations campus at 2865 N Reynolds Road, Suite 220, Toledo, OH 43615, while engineering and manufacturing is located on the Interplex Medical Campus in Milford, OH. The Company is focused on the design, development and commercialization of its innovative proprietary angioplasty balloon catheter platform for the treatment of peripheral and coronary atherosclerotic disease (PAD and CAD).

Customer Problem

Plain balloon angioplasty (POBA) is the most common procedure worldwide, for the treatment of PAD and CAD. Since the length and diameter of a diseased vessel is highly variable from patient to patient, providers must carry a large inventory of balloon sizes. Adding to this is that in 2010, drug coated balloons (DCB) entered the market to deliver drugs like paclitaxel or sirolimus to the arterial wall to reduce potential re-stenosis. The problem with current DCB's is that they lose a majority of the drug coating in route to the disease site – the exposed drug scrapes off upon insertion, through the sheath and even when crossing the occlusion. Drug loss also occurs by elution and can contribute to downstream and systemic adverse effects. Providers have had to significantly increase their inventory to include DCB.

INFINITY Solution

IABC has developed the first fully sheathed, operator adjustable, variable length, angioplasty balloon for POBA procedures in peripheral arteries. One highly cost-effective balloon to replace the majority of current peripheral balloon inventories. The INFINITY Precision Angioplasty Balloon® is cleared by the FDA to treat femoral, popliteal and infra-popliteal arteries with balloon lengths able to be adjusted to the “mm”, ranging from 20mm to 250mm in length.

The Company is now turning development efforts toward DCB. Taking the same intuitive and easy to adopt platform to deliver a protected drug coated balloon to the lesion, enabling the clinician to control a precise DCB therapy – the INFINITY Defender™. No scraping or wash off downstream, simply precision drug delivery.

Protected with a robust global IP portfolio, INFINITY's proprietary features address patient, provider and clinical needs, leapfrogging the current commercial fixed-length balloon platforms.

Target Market

According to Markets and Markets™, the total accessible market for angioplasty balloons is projected to reach \$1.1B by 2025 from \$800M in 2019, at a CAGR of 5.1% during the forecast period. The growing geriatric population and the increasing prevalence of PAD's, are major factors driving the growth in this market. DCB's represent approximately \$400M, projecting 6.7% CAGR, while POBA represents approximately \$700M at a 4% CAGR through 2025³.

INFINITY Angioplasty Balloon Co., LLC

2865 N. Reynolds Rd, Suite 220
Toledo, OH 43615
www.infinab.com

MANAGEMENT:

John P. Pigott, MD

Founder and Chief Medical Officer

jpigott@infinab.com

Gary L. Smith, MBA

CEO

gsmith@infinab.com

Open

VP Sales

Kerrie A Denman, CPA

Director Finance, Controller

kdenman@infinab.com

Angela Mallery, PhD

Director Regulatory (NAMSA)

Darci Diage, MS

Director Quality Systems

Craig Berkey, MME

Design, Mfg, Engineering

Interplex Medical

BOARD OF MANAGERS:

John P Pigott, MD

Gary L Smith, MBA

Lee Hammerling, MD

ADVISORY BOARD:

John Philips, MD

Ohio Health, Columbus

Jan Skowronski, MD.

Tenet Health, Birmingham, AL

David Paolini, MD

OBL, Scottsdale, AZ

LEGAL COUNSEL:

Thompson Hine

INTELLECTUAL PROPERTY:

Standley Law Group

Series A Raise: \$5.5 M

Customer Profile

INFINITY customers are defined by three medical specialties: vascular surgeons, interventional cardiologists and interventional radiologists - providing patient care in hospitals, outpatient facilities and private office-based labs facilities. Same profile applies in EU and ROW markets.

Business Model

IABC balloons are sterile, single patient use, disposable devices. Typically shipped in a five (5) pack container, product is competitively priced to support a blended 70-80% gross margin. Production, packaging and sterilization is managed by Interplex Medical and shipped in bulk to IABC for distribution to its customers. Quality systems in both Interplex and IABC facilities satisfy requirements of the FDA currently, and will expand when needed to serve EU and ROW markets.

Sales/Marketing Strategy

IABC will build a direct sales force to initially target high volume, KOL'S based in hospitals, teaching hospitals, and privately held, office-based labs in the US. The Company will seek early adopters interested in conducting registry studies and clinical research, generating podium presentations and marketing collateral.

Competitors/Acquirers

Strategic suppliers such as Boston Scientific, Bard/BD, and Medtronic dominate market share with large dedicated sales teams. These companies along with second tier endovascular companies are seeking new, innovative angioplasty technologies to displace their aging complicated and expensive platforms. INFINITY's platforms are seen as the game changers in balloon angioplasty and DCB technology.

Competitive Advantage

INFINITY's innovative and proprietary features address patient, provider and clinical needs, bypassing the currently available POBA and DCB offerings. INFINITY Precision™ assures providers a cost effective, inventory solution guaranteeing the intervention will never be without the right size balloon. DEFENDER DCB™ enables precise drug delivery without wash-out downstream and the potential for toxic side-effects

Series A Use of Funds

The Company is raising Series A of \$5.5 M in equity funding. These funds will be used to complete development of a below-the-knee balloon (fem-pop currently in limited mkt release) to enhance robust market entry of the POBA platform in early 2023, and to complete development of the Defender DCB BTK™ through pre-clinical. The Company has been financed to date through non-dilutive grant funding, private equity and convertible notes (Cleveland Clinic Global Cardiovascular Innovations, NW Ohio Tech Fund II).

Management Team

JOHN P PIGOTT, MD, FOUNDER, CMO, has been a vascular surgeon for 25+ years. He serves as Chief Innovation Officer at Promedica Health; Director, Jobst Vascular Institute and founder and CMO of VentureMed Group, Inc. Additionally, Dr. Pigott has 15+ Patents, Multiple 510(k)'s and raised over \$25M in capital.

GARY L SMITH, MBA, CEO. He has 30+ years in the medical device and diagnostics industry. He recently served as CEO of VentureMed Group, Inc., CEO of Clevex, Inc. and former VP Battelle Institute. Gary has launched dozens of technologies in global markets and has raised over \$50M in federal and venture funding.