Laminate
Medical Technologies

Executive Summary 2017

Company Mission

To improve the success rate of the arteriovenous fistula, as the gold standard for vascular access for hemodialysis treatment in kidney disease.

Company Milestones

2012 - Company founded; Developed computational fluid dynamics (CFD) model.
2013 - Design phase completed; Pre-Clinical Safety & Usability Evaluation; was found safe and effective.
2014 - Initiate human clinical study.
2015 - Completion of clinical study with promising results; Obtained CE approval.
2016 - Commercialization in major European markets; CFDA pathway kick-off.
2017 - Initiate FDA pivotal single-arm study in the US; Received reimbursement (NUB) approval in Germany and South Africa; Promising randomized controlled clinical data
2018 - Market application in the US; Initiate clinical study in China to support CFDA approval.
2019 - Commercialization in the US; CFDA approval.

The Opportunity

More than 2M individuals worldwide rely on vascular access, a site on the body where blood can be removed and returned, for hemodialysis treatment. This treatment serves as a "kidney replacement" therapy where a hemodialysis machine filters the blood and removes toxins. The arteriovenous fistula ('AV fistula' or 'AVF') is recognized as the preferred method for accessing the circulatory system, and has been in use since 1966. To create a fistula, a vascular surgeon joins an artery and a vein together through an anastomosis, being a junction between the blood vessels. This artery-vein junction bypasses the capillaries and enables rapid, blood flow through the fistula, leading to a very specific reconformation of the vein to make it suitable for hemodialysis access.

Although AV fistulas are the gold standard for vascular access for hemodialysis, more than 40% fail within one year of creation, necessitating re-interventions with high complication rates. This high failure rate is attributed to excessive remodeling and an over-thickening of the walls of the vein (intimal hyperplasia). With over 220,000 AVF procedures a year in the US alone, post-op complications cost Medicare upwards of $1 BN a year.

China Market

• China's Hemodialysis population has been climbing upwards over the past few years and growing steady due to better insurance system coverage and accessible medical services.
• It is estimated that by 2030, the number of ESRD patients in China will exceed 4 million.
• 70% of the ESRD patients will have AV Fistula creation surgical procedure..
• The overall dialysis treatment rate was estimated to reach 14%-15% in 2016, lower than the average global level of 38%-40%. These rates are dramatically lower than the common 90% treatment rate in developed countries.
• China had approximately 440,000 dialysis patients in 2016, which represents an increase of 80% over five years.
• Current market size of 14 billion RMB.
• Government initiatives to expand hemodialysis access suggest long term growth potential.
• In the next five years the hemodialysis market will enter an accelerated growth stage in which the market size is expected to exceed 45 billion RMB.

海思科药业 HAISCO PHARMACEUTICAL GROUP

Equity investment and exclusive distribution partnership singed on 2016, paved the way for the Company's promising market in China.

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The Laminate Innovation

Laminate Medical Technologies is developing a new, external support device for AV fistulas, to be implanted during the fistula creation surgical procedure. The VasQ alleviates wall tension and regulates fistula geometry where an undesired narrowing of the vein and/or frequent blockages of the blood vessels may occur during the first year. Use of Laminate Medical Technology's novel device aims to drive a change in the hemodialysis vascular access treatment paradigm and bring about a significant reduction in the annual fistula failure rate, thereby reducing kidney-failure related complications, re-interventions, and the cost burden of vascular access complications.

The Device

The VasQ is a nitinol braid surrounding the vein, welded to a nitinol brace "hugging" the artery near the junction site. It is supplied sterile and implanted over the junction during the surgical procedure to create the fistula. Implantation of the device does not interfere at all with the routine suturing of the vein to the artery and requires only minutes to complete. The VasQ targets the two main fistula failure modes: turbulent flow around the area of connection and increased venous wall tension due to the exposure to arterial circulation conditions. Disturbed fistula hemodynamics result in pathological thickening of the inner layer of the vein that leads to thrombosis and stenosis, a narrowing of the blood vessel.

- ***The VasQ as a** Brace will optimize geometrical parameters of the fistula. This will minimize flow disturbances around the anastomosis and mitigate the development of blood vessel disease.*
- ***The VasQ as a Braid** will guide reconfiguration of the vein through an external flexible support that allows the vein a constrained and controlled increase in diameter in a limited fashion, to accommodate the increase in flow rates, while absorbing elevated wall tension and maintaining the integrity of the vein.*

Advantages of the VasQ

- ***Less than 1 minute implementation, no other change in current procedures.***
- ***Mitigates the root causes that lead to failure during the 6-8 week post-op adjustment period.***
- ***Increases success rates of the AVF, where the vein accommodates up to 4x previous flow rate.***
- ***Increases life span of the AVF, by reducing stress on the AVF (current usefulness of 4-5 years).***
- ***Reduce medical costs and hospital stays.***
- ***No increased risk of infection, vs. alternatives to AVF such as bridge grafts and venous catheters.***

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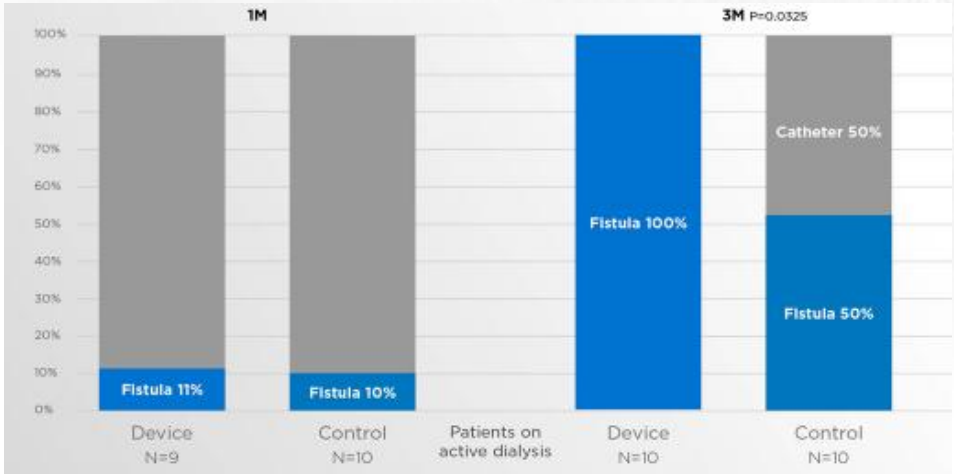
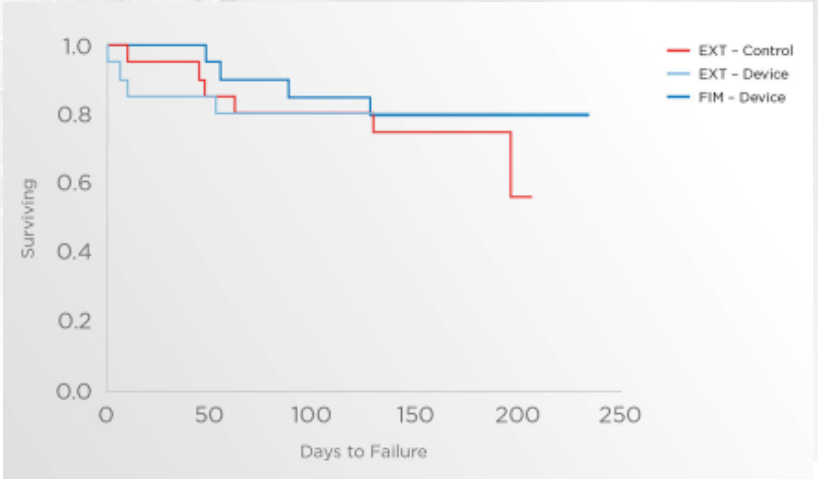
AVF – The Gold Standard that Requires Improvement

Lee at al., JASN, 2007, DAC Study – 877 patients from 9 academic centers

Favorable Functional Maturation in Vas Implanted Patients



Primary Patency Survival Analysis



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