CE 0344 CE 0297

The **VasQ** is not available in the US

Upper Arm Fistula Model Selection Table

Model	Vessel diameter D (mm)	PN
5B	2.5 ≤ D ≤ 4.8	FG0009
6B	4.8 < D ≤ 5.5	FG0010
7B	5.5 < D ≤ 6.0	FG0011

Forearm Fistula Model Selection Table

Model	Vessel diameter D (mm)	PN
1R	2.0 ≤ D ≤ 3.2	FG0018
2R	3.2 < D ≤ 3.7	FG0019
3R	3.7 < D ≤ 4.1	FG0020

Accessories

Description	PN
Laminate Model Selection Tool Upper Arm	FG0016
Laminate Model Selection Tool Forearm	FG0017

Israel
Laminate Medical
Technologies Ltd.
Tel: +972-3-6344246
Fax: +972-3-5561746
24 Raoul Wallenberg St.
Tel Aviv 6971921, Israel

USA
Laminate Medical
Technologies Inc.
Tel: +1-646-722-7346
411 Lafayette St.
6th Floor, Suite 628
New York, NY 10003, USA

Germany
Laminate Medical
Technologies GmbH
Tel: +49-30-408-192-398
Fax: +49-30-408-192-450
Europaplatz 2
10557 Berlin, Germany

LB0056Rev09

VasQ™

Improving Vascular Access

Support Better Maturation. Create More Usable Fistulas.

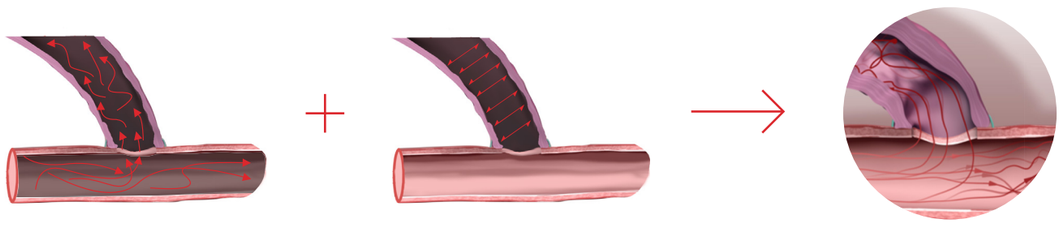
External support
for your anastomosis

Lamjnate | www.laminatemedical.com | info@laminatemedical.com

Arteriovenous Fistula (AVF) Failure Mode

A biological response to hemodynamic and mechanical stress

Hemodynamic Stress + **Mechanical Stress** → **Negative (Stenotic) Remodeling**



A turbulent flow profile leads to areas of low wall shear stress associated with development of stenosis or thrombosis[1]

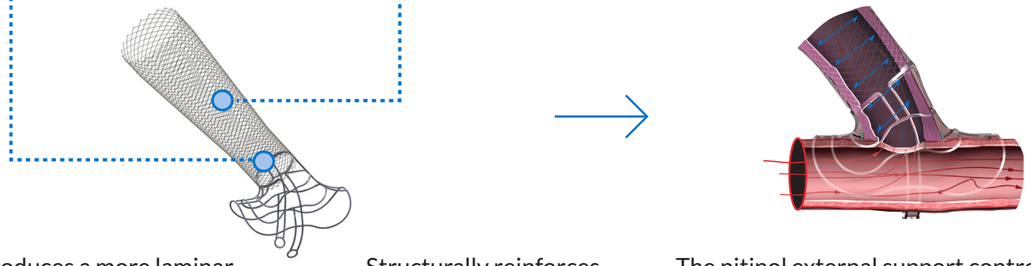
Excessive transmural pressure leads to medial hypertrophy[1]

The combined effect leads to a high propensity of inward wall thickening of the vein in response that results in AVF failure for many patients

Why VasQ

VasQ is the only solution currently available that addresses both hemodynamic and mechanical stress to create more usable fistulas

Optimal Hemodynamics + **Mechanical Support** → **Promotes Positive (Dilative) Remodeling**



Produces a more laminar flow transition

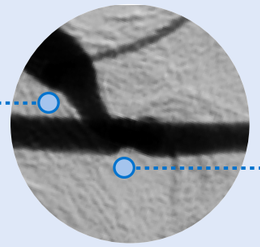
Structurally reinforces the juxta-anastomotic segment

The nitinol external support controls the remodeling at the anastomosis to promote outward wall thickening downstream for eventual use in hemodialysis

Retain Control Post-Surgery

Implanted during AVF creation surgery, VasQ retains the optimal configuration of the anastomosis during the critical weeks of maturation post-surgery and beyond

Venous Tapering
Smoothly transitions flow to the dilated fistula

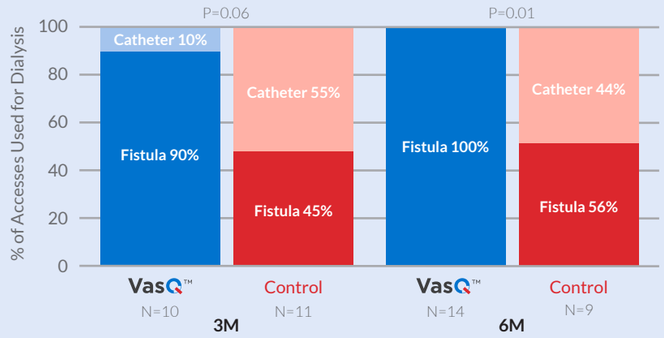


Example of 3-month VasQ supported fistula*

Arterial Arch
Designed to guide arterial flow towards the vein

Create More Usable Fistulas with VasQ

In a recent randomized, controlled multi-center study[2], more VasQ patients used their fistula for hemodialysis and could discontinue CVC use than patients treated without VasQ. VasQ patients also had a lower incidence of stenosis with consistent outward (dilative) remodeling leading to a greater mean diameter as compared to patients treated without VasQ



The high AVF usability was associated with:

- ✓ Greater freedom from >50% stenosis anywhere along the access vein (P=.04)
- ✓ Consistent venous dilation above 6 mm for each patient that led to a greater mean diameter (P=.03)

Building Consistent Clinical Success with VasQ

86% – 100% AVF Usability* at 6 months for multiple studies at a variety of clinics

FIM study
93% AVF Usability

20-pt prospective, single-center. Proof-of-Concept study in BCF Patients.

Chemla et al. J Vasc Access 2016; 17 (3): 243-248

EXT study
100% AVF Usability

40-pt multi-center, randomized controlled study demonstrating improvement over standard of care.

Karydis et al Am J Kidney Dis. 2020; 75(1): 45-53

Real-World Validation
≥86% AVF Usability†

5 separate single-center retrospective analyses of their first consecutive +6 cases.

Multiple conference presentations
Data on file.

RCF Analysis
86% AVF Usability

33-pt, single-center, retrospective RCF study with 17-pt historical control demonstrating improvement over standard of care.

Shahverdyan et al. J Vasc Access 2020 (online ahead of print)

VALUE Study
92% AVF Usability

80-pt RCF+BCF prospective multinational EU study.

Study on-going
Interim analysis data on file

US Pivotal Study
Data not yet available#

144-pt RCF+BCF prospective, multi-center US study.

Study on-going

1. Roy-Chaudhury P, Spergel LM, Besarab A, Asif A, Ravani P. Biology of arteriovenous fistula failure. J Nephrol 2007; 20: 150-163.
2. Karydis N, Bevis P, Beckitt T, Silverberg D, Halak M, Calder F. An Implanted Blood Vessel Support Device for Arteriovenous Fistulas: A Randomized Controlled Trial. Am J Kidney Dis. 2019. pii: S0272-6386(19)30845-5.

* AVF usability was defined as an AVF either used in dialysis or deemed usable for dialysis
† Data based on follow-up periods that vary between 6 weeks and 1 year
# Data not yet analyzed to be included in the usability range above