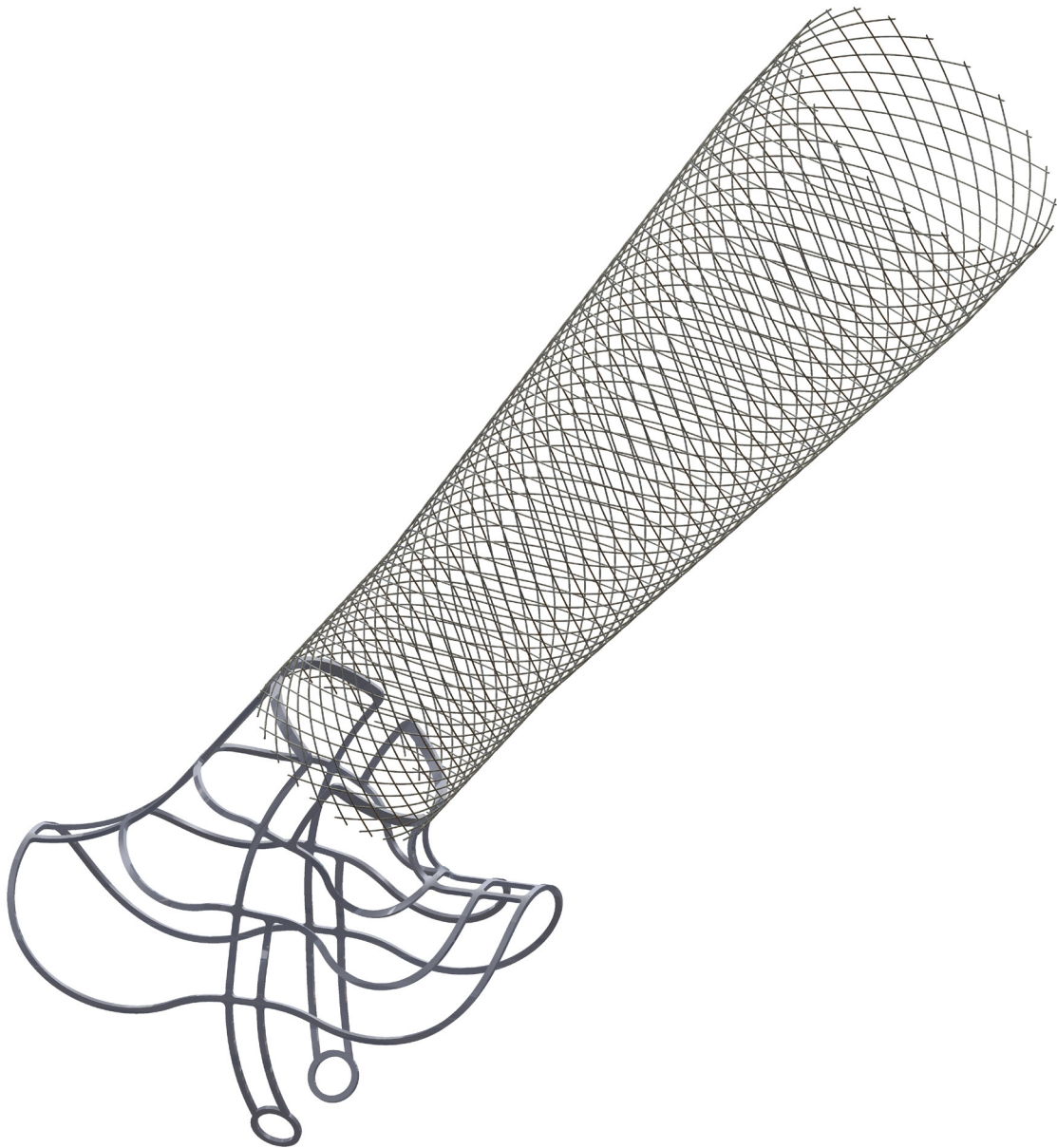




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# Innovative External Support for Outstanding AV-Fistula Performance



# Arteriovenous (AV) Fistula

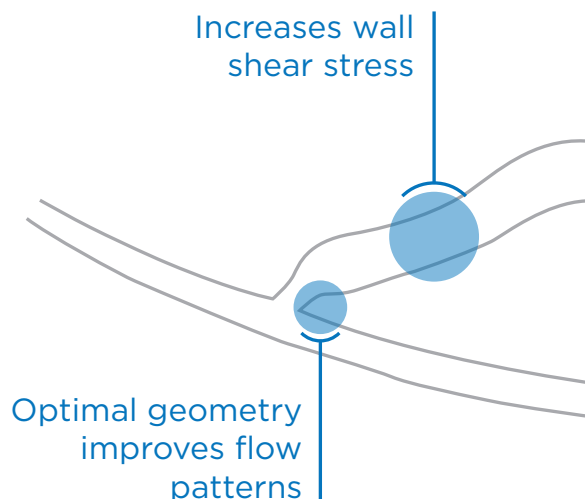
## The preferred vascular access

The surgically created arteriovenous (AV) fistula is the standard of care and preferred access for hemodialysis. The AV fistula is constructed by suturing together an artery and a vein so that the arterial pressure in the anastomosis dilates the vein, enabling accommodation of two needles needed for hemodialysis. A newly created fistula must mature (i.e., undergo dilation and remodeling) in order to be functional for dialysis, a process that takes 6-8 weeks.

## A clear unmet need

### AV fistulas often fail to mature

Studies over several decades have consistently demonstrated that native mature fistulas have superior longevity, spanning 4 to 5 years, and require minimal secondary interventions compared with other access types. However, despite the clear benefits of mature fistulas, early failure occurs in over 40% of fistulas. Early failure is often due to clotting and thrombosis of the fistula which is caused by turbulent flow patterns around the anastomosis region. Later failures are associated with exposure of the vein to high pressure and wall tension. These pressures cause a thickening of the intimal layer, called intimal hyperplasia, subsequently leading to a narrowing (stenosis) of the vessel lumen. Dember et al, 2008<sup>1</sup> report a failure rate of 53.4% at 120-150 days after fistula placement.



### The need for innovation

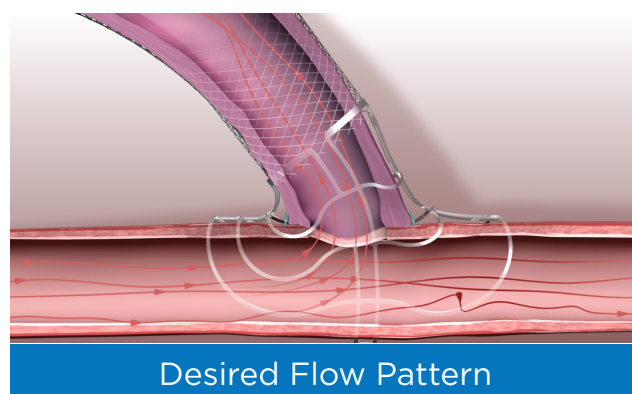
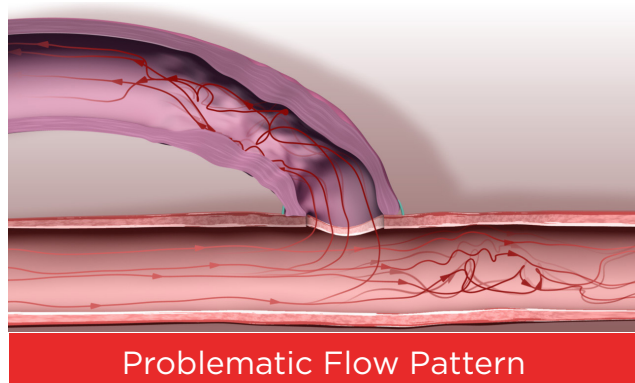
The technique for AV fistula placement has not changed significantly since its introduction in 1966. Given the high failure rates and the lack of a better vascular access, there is a strong need for a new solution that addresses the root causes of AV fistula failure.

## VasQ™ Technology

### A revolution in AV fistula care

VasQ™ was designed to improve maturation and patency rates of AV fistulas. The VasQ™ provides external support thereby addressing the root causes of fistula failure:

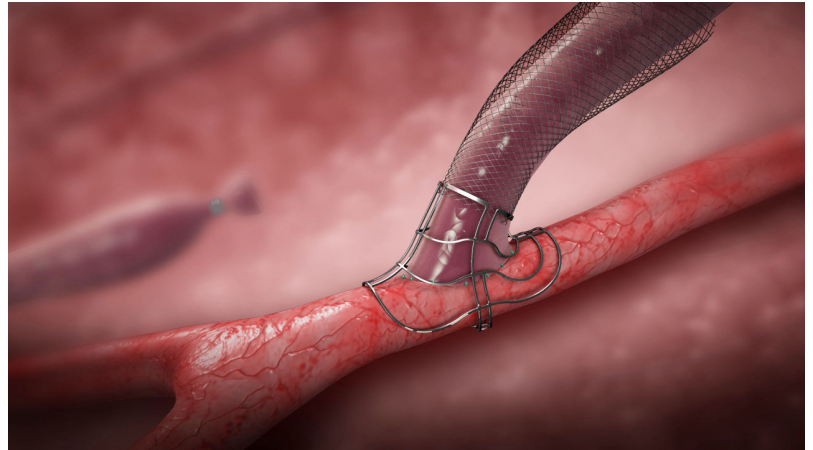
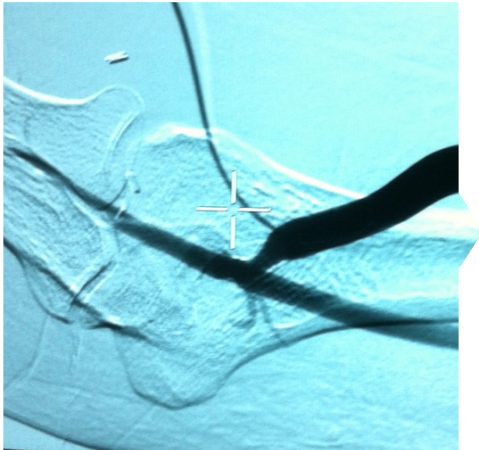
- **Regulate flow** by constraining and shaping optimal geometrical parameters of the fistula.
- **Reinforce and shield** the vulnerable perianastomotic vein against high pressure, wall tension, and flow levels.



## No change to current surgical paradigms

Designed for implantation during fistula placement, **VasQ™** can easily be incorporated into the current procedure.

- The anastomosis is constructed in a routine manner without any intervention or interference.
- The placement of the **VasQ™** around the anastomosis is quick and does not prolong procedure duration.
- There is no contact of the **VasQ™** with the blood circulation.



**VasQ™** targets vessel segments which are immediately proximal and distal to the anastomosis, where turbulent flow and intimal hyperplasia are most significant and where frequent occlusions occur, aiming to:

- **Control** geometrical configuration
- **Control** flow patterns
- **Reduce** wall tension in the vein
- **Increase** wall shear stress

Both of which:

Decrease damaging turbulent flow near the anastomotic region

Both of which:

Reduce intimal hyperplasia

Thus:

**An external support device *decreases* the fistula's early and late failures**

<sup>1</sup> Dember LM, Beck GJ, Allon M, Delmez JA, Dixon BS, Greenberg A, Himmelfarb J, Vazquez MA, Gassman JJ, Greene T, Radeva MK, Braden GL, Ikizler TA, Rocco MV, Davidson IJ, Kaufman JS, Meyers CM, Kusek JW, Feldman HI: Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. JAMA 299: 2164-2171, 2008



The VasQ is not available in the US

### Brachio Cephalic Fistula Model Selection Table

Model	Artery diameter D (mm)	PN
<b>5B</b>	$3.7 < D \leq 4.2$	FG0009
<b>6B</b>	$4.2 < D \leq 5.0$	FG0010
<b>7B</b>	$5.0 < D \leq 5.5$	FG0011

### Accessories

Description	PN
<b>Brachio Model Selection Tool</b>	FG0012

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