



Flixene AV access graft

Premium performance for dialysis access

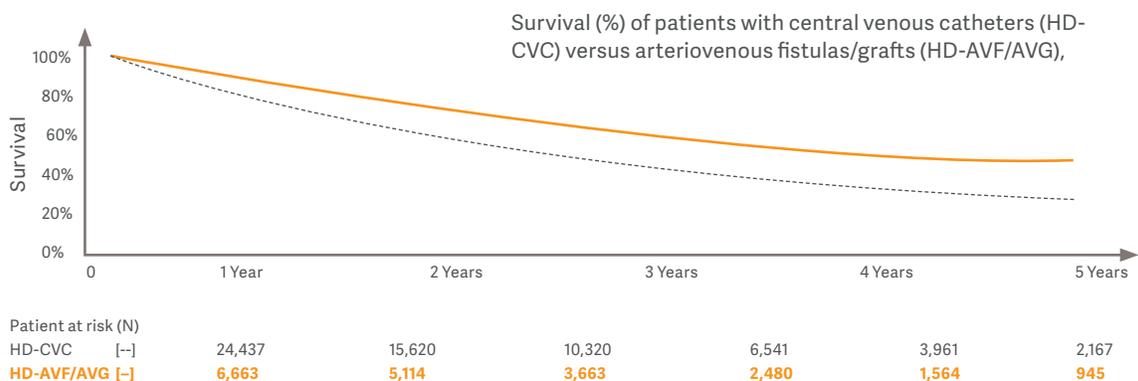
Dialysis burden

Facts and global trends

➔ More than 2 million people around the world receive dialysis treatment or are awaiting a kidney transplant. The number of patients diagnosed with the disease continues to **increase at a rate of 5-7% per year**.^{1,2}



➔ Central Venous Catheter (CVC) use is one of the growing problems globally which results in a **significantly higher morbidity and mortality rate** particularly due to the rate of infection.¹

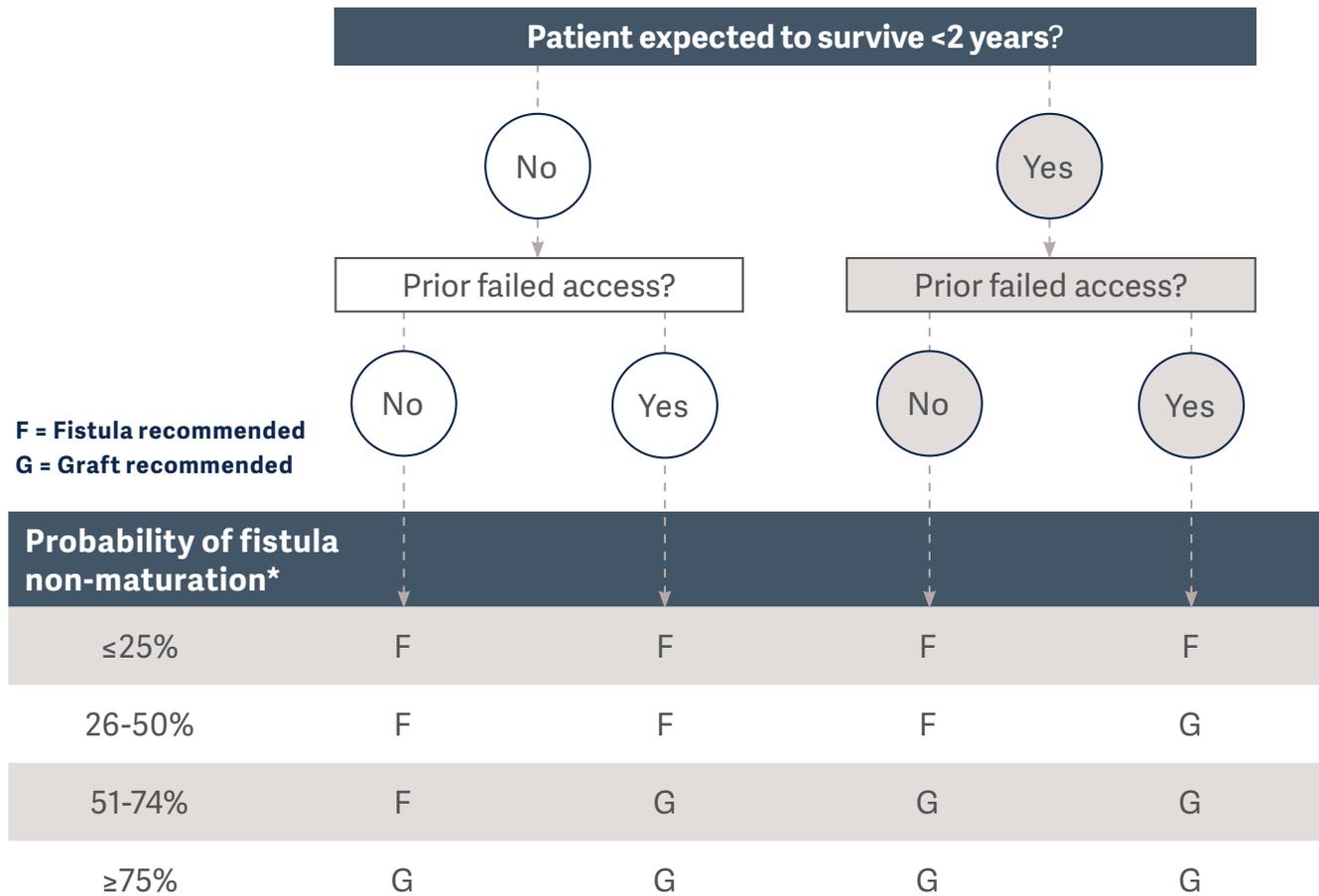


➔ Successful hemodialysis treatment is only possible with a well-functioning vascular access. The latest KDOQI and ESVS guideline recommend **grafts as a viable tier 2 option** and central venous catheters (CVCs) as a last alternative.^{1,2}

➔ Representing 25-30% in ESRD registries, **elderly patients may benefit from the use of AV Grafts** because of the high primary autogenous AVF failure rate. “Early stick grafts” may offer elderly patients the option to avoid CVCs with their inherent “high risk of infection”.¹

Vascular access

How to choose the right vascular access³⁻⁴



* The percentages correspond to the estimated risk of fistula non-maturation. The author states that the algorithm requires clinical skills and evidence based tools to determine the likelihood of fistula non-maturation.

➔ Risk factors for fistula non-maturation¹⁻⁵

- Age > 65
- Coronary Artery Disease (CAD)
- Poor vessel distensibility
- Peripheral Vascular Disease (PVD)
- Diabetic
- Small vein diameter

Flixene AV access graft

Premium performance

➔ Ongoing durability

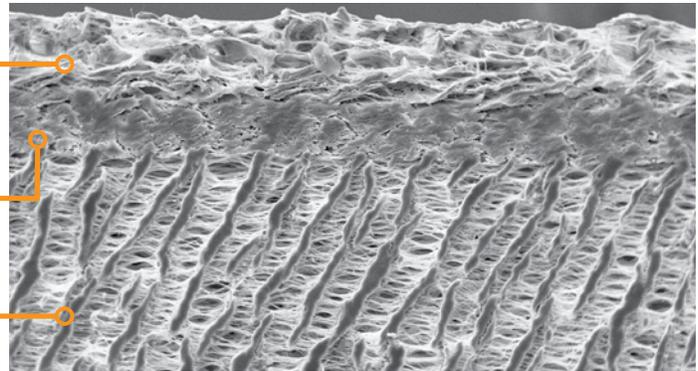
- Reinforced cannulation zone for greater durability
- Unique 3-layer ePTFE construction specifically designed to handle the rigors of multiple needle cannulations related to dialysis care¹⁰
- Reliable performance for nursing staff and patients^{5,6}
- Average outer porosity of 60 μm to promote tissue ingrowth¹⁰

3 Layer ePTFE graft

Large pore (nominal 60 μm) surface layer, more receptive to tissue ingrowth¹

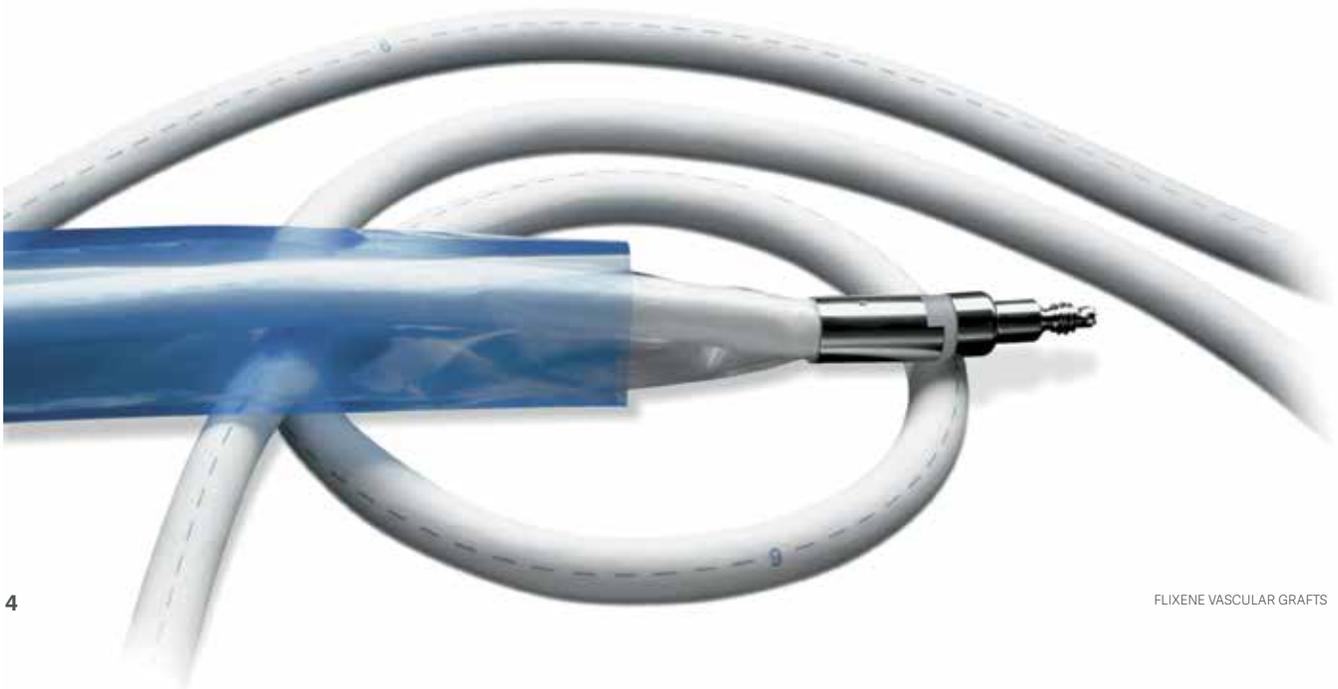
Middle layer, reinforcing wrap for increased support¹⁰

Small pore base layer, inner graft surface porosity of nominal 20 μm ¹



➔ Early cannulation

- An alternative to CVC catheters^{3,9}
- Demonstrated as a safe and effective early cannulation option^{3,9}





Unique Graft Deployment System (GDS)⁵

- Improved primary patency at 180 days
- Designed to make tunneling easier than conventional practices
- Minimize soft tissue trauma
- Reduce graft sweating



Flixene with GDS connects to tunneler rod



A choice of configurations

1. Graduated wall technology

Reduced wall thickness on each end (length ≈8cm) for improved suturability and handling

2. Tapered

Designed to change flow dynamics



Wall thickness of standard wall vs. graduated wall

Flixene can make a difference

Clinical evidence

- Flixene is shown to be a viable option for early cannulation within 3 days, reducing the need and risks associated with CVCs for patients^{6,7,8}
- Flixene includes a slider GDS system with plastic sheath for easy tunneling, reduced soft tissue trauma and targeted placement.^{1,5}
- Flixene offers successful treatment option for challenging patient population^{6,8}
- Secondary patency at 12 months ranged from 63% to 92%⁹
- Implantation of the Flixene graft followed by accessing the graft may reduce the need for temporary or permanent catheters.⁹
- One year patency and complication rates are equivalent to those of conventional grafts which can be cannulated only after 2 weeks⁹



Flixene

Product information

Straight

Inflow options		Cannulation zone	Outflow options	
				
Diameter	Length	Wall Thickness	Slider GDS	Reference
6 mm	10 cm	SW	No	25053
6 mm	30 cm	GW	Yes	25125
6 mm	30 cm	SW	Yes	25142
6 mm	40 cm	GW	Yes	25061
6 mm	50 cm	SW	Yes	25052
6 mm	50 cm	GW	Yes	25058
7 mm	10 cm	SW	No	25054
7 mm	30 cm	GW	Yes	25126
7 mm	40 cm	GW	Yes	25062
7 mm	50 cm	SW	Yes	25056
7 mm	50 cm	GW	Yes	25059
7 mm	80 cm	GW	Yes	25120
8 mm	50 cm	SW	No	25057
8 mm	50 cm	GW	Yes	25060
8 mm	80 cm	GW	Yes	25121

Tapered

Inflow options		Cannulation zone	Outflow options	
				
Diameter	Length	Wall thickness	Slider GDS	Reference
4-6 mm	35 cm	GWT-GW	Yes	25128
4-6 mm	45 cm	GWT	Yes	25134
4-6 mm	45 cm	GWT-GW	Yes	25137
4-7 mm	30 cm	GWT-GW	Yes	25141
4-7 mm	35 cm	GWT-GW	Yes	25129
4-7 mm	45 cm	GWT	Yes	25135
4-7 mm	45 cm	GWT-GW	Yes	25138
5-8 mm	35 cm	GWT-GW	Yes	25130
5-8 mm	45 cm	GWT-GW	Yes	25139

Graduated wall length is approximately 8 cm on each end.

SW = Standard wall | GW = Graduated wall | GWT = Graduated wall taper

References

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10. Data on file



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