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 access$^{3-4}$

Patient expected to survive <2 years?

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior failed access?</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

F = Fistula recommended
G = Graft recommended

Probability of fistula non-maturation*$^*$

<table>
<thead>
<tr>
<th>Probability of fistula non-maturation*</th>
<th>No</th>
<th>Yes</th>
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<tbody>
<tr>
<td>≤25%</td>
<td>F</td>
<td>F</td>
</tr>
<tr>
<td>26-50%</td>
<td>F</td>
<td>F</td>
</tr>
<tr>
<td>51-74%</td>
<td>F</td>
<td>G</td>
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<tr>
<td>≥75%</td>
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* 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-maturation$^{1-5}$

- 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 care\(^\text{10}\)
  - Reliable performance for nursing staff and patients\(^\text{5,6}\)
  - Average outer porosity of 60 µm to promote tissue ingrowth\(^\text{10}\)

**3 Layer ePTFE graft**
- Large pore (nominal 60µm) surface layer, more receptive to tissue ingrowth\(^\text{1}\)
- Middle layer, reinforcing wrap for increased support\(^\text{10}\)
- Small pore base layer, inner graft surface porosity of nominal 20µm\(^\text{1}\)

- **Early cannulation**
  - An alternative to CVC catheters\(^\text{3,9}\)
  - Demonstrated as a safe and effective early cannulation option\(^\text{3,9}\)
Unique Graft Deployment System (GDS)

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

A choice of configurations

1. Graduated wall technology
   Reduced wall thickness on each end (length ≈8cm) for improved sutureability and handling

2. Tapered
   Designed to change flow dynamics
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 weeks\(^9\).
# Flixene

## Product Information

### Straight

<table>
<thead>
<tr>
<th>Diameter</th>
<th>Length</th>
<th>Wall Thickness</th>
<th>Slider GDS</th>
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<tbody>
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<td>SW</td>
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<td>25053</td>
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<tr>
<td>6 mm</td>
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<tr>
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<tr>
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<td>7 mm</td>
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### Tapered

<table>
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<th>Reference</th>
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<td>4-7 mm</td>
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<td>GWT-GW</td>
<td>Yes</td>
<td>25138</td>
</tr>
</tbody>
</table>

Graduated wall length is approximately 8 cm on each end.

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

2. KDOQI Clinical practice guideline
10. Data on file