The DuraGraft® Difference: Treatment For The Prevention Of Vein Graft Disease
The durability and patency of vein grafts are significantly compromised by Vein Graft Disease (VGD):
- The VGD process begins during the grafting surgery itself.\(^{(1)}\)
- VGD is the principal cause of both early (within 30 days) and intermediate/late Vein Graft Failure (VGF).
- VGD encompasses the pathophysiological changes that occur in vein grafts following their use in surgical grafting.

### Endothelial Damage, Manifested Within Minutes as Pro-inflammatory, Pro-thrombogenic, and Hyper-proliferative Changes Within the Graft, Leads to VGD

As VGD progresses, vein grafts lose their ability to adapt to the post-grafting environment, leading to:
- Thrombus formation
- Intimal hyperplasia
- Atherosclerosis

These may result in:
- Graft stenosis
- Occlusion
- Loss of graft patency

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**Human saphenous vein grafts treated with DuraGraft were found to maintain viability and structural integrity through extended storage times, while untreated vein grafts were extensively damaged and lost viability almost immediately.**

Multi-photon microscopy was used to generate images of vein grafts stained using "live/dead" staining technology. **Green** fluorescence indicates viable cells. **Red** fluorescence indicates dead cells.

EC = Endothelial Cells.

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VGD that progresses to VGF may result in death, myocardial infarction, the need for repeat revascularization and/or lower limb amputation. The success rate of revascularization or re-intervention of a failed graft is very poor\(^{(2)}\) and therefore addressing early vein graft disease in the primary graft is crucial.\(^{(3)}\)

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* Thatte et al., Ann Thorac Surg. 2003; 75:1145-1152
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DuraGraft® Treatment Improves Clinical Outcomes

DuraGraft is the 1st and only approved Endothelial Damage Inhibitor. It is a one-time intraoperative treatment of vascular grafts that preserves endothelial function and structure for the prevention of graft disease, thereby reducing graft failure rates and improving clinical outcomes.

DuraGraft treatment has been shown to significantly reduce major cardiac events such as repeat revascularization, myocardial infarction and MACE over five years plus post CABG.

Two Independent Large Studies Demonstrate Similar Reductions in Long-Term Clinical Events

**DuraGraft Clinical Study Summary**

U.S. Retrospective Study • 2436 CABG Patients • DuraGraft Treatment vs. No Treatment

Significant reductions in long-term clinical events with DuraGraft (5-year)

<table>
<thead>
<tr>
<th>Event</th>
<th>Reduction %</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction Rates</td>
<td>50%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Repeat Revascularization Rates</td>
<td>38%</td>
<td>0.03</td>
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<tr>
<td>MACE Rates</td>
<td>29%</td>
<td>0.02</td>
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</table>

**DuraGraft Pilot Study**

EU Retrospective Study • Five-year Study • 630 CABG Patients • DuraGraft Treatment vs. No Treatment

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<thead>
<tr>
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<th>Reduction %</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myocardial Infarction Rates</td>
<td>70%</td>
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<tr>
<td>Repeat Revascularization Rates</td>
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<tr>
<td>All Cause Death Rates</td>
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<tr>
<td>MACE Rates</td>
<td>37%</td>
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* Manuscript being prepared for publication.
DuraGraft® Reduces Complications, Which Leads to Potential Cost Savings

- Reduces incidence of clinical complications resulting from vein graft disease and vein graft failure
- Does not interrupt or modify existing surgical procedure
- Formulated into an intraoperative surgical treatment for storage and flushing

“According to data collected from UK NHS hospitals in 2014-15, each Myocardial Infarction demands on average seven days of hospitalization; taking up resources that could be used by hospitals to treat other patients and improve financial and operational efficiency.”*


Myocardial infarction patients post-CABG are more complex, therefore any improvement in graft patency and occlusions can lead to potential cost savings for health care systems.


**DuraGraft** is not available in all markets. Visit somahlution.com/distributors for availability.

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