Dialysis Access Value with
GORE® ACUSEAL Vascular Graft
About W. L. Gore & Associates

- Creative therapeutic solutions to complex medical problems for more than 40 years
- More than 40 million innovative Gore Medical devices have been implanted worldwide
- Extensive family of products:
  - Vascular grafts
  - Endovascular and interventional devices
  - Surgical meshes for hernia and soft tissue reconstruction
  - Staple line reinforcement materials
  - Sutures for use in vascular, cardiac, and general surgery
Committed to Dialysis Access

GORE® ACUSEAL Vascular Graft

GORE® Hybrid Vascular Graft

GORE® PROPATEN® Vascular Graft

GORE-TEX® Vascular Graft

GORE-TEX® Stretch Vascular Graft

GORE® VIABAHN® Endoprosthesis
Dialysis Access
Prevalence and Risks
Prevalence

• One in 10 American adults (more than 20 million adults) have some level of Chronic Kidney Disease \(^1\)

• At the end of 2012, there were approximately 449,000 ESRD patients on some form of dialysis (409,000 hemodialysis, 40,000 peritoneal dialysis) \(^2\)

• In 2012, 62% of new patients in the United States initiated dialysis via a catheter and, after three months, the percentage increased to a 75% CVC rate due to failure of AVF maturation \(^2\)

\(^1\) Centers for Disease Control and Prevention ESRD 2009
\(^2\) USRDS 2014 Annual Data Report
Dialysis Catheters and Patient Risk

- A study published in the Journal of American Society of Nephrology revealed that patients with a catheter had:
  - 38% greater risk for a major heart problem
  - 53% higher risk of dying
  - More than double the risk of developing a fatal infection than patients with fistulas

ESRD and Catheter-Related Sepsis

Sepsis hospitalizations have been cited as the costliest condition to treat in the US.

- **Cost for ESRD patient with CVC-related sepsis hospitalization**: $27,088 per admission.
- **In-hospital rate for ESRD patient with CVC-related sepsis**: 7.6% mortality rate.
- **Compared to arteriovenous grafts at .61 per patient year**.

2.32 sepsis infections per patient year compared to arteriovenous grafts at .61 per patient year.


*The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.*
GORE® ACUSEAL Vascular Graft
Value Summary
GORE® ACUSEAL Vascular Graft

- FDA Clearance – April 2013
- Early cannulation capable within 24 hours
- 78% cumulative patency at 12 months
- **Indications For Use**
  - GORE® ACUSEAL Vascular Grafts are intended for use as a vascular prosthesis in patients requiring vascular access.
- **Contraindications**
  - DO NOT use the GORE® ACUSEAL Vascular Graft in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of HIT type II.
  - DO NOT use GORE® ACUSEAL Vascular Grafts as a patch. If cut and used as a patch, GORE® ACUSEAL Vascular Grafts may lack adequate transverse strength.

Data on File.
## Product Configurations

<table>
<thead>
<tr>
<th>Catalogue Number</th>
<th>Diameter (mm)</th>
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# Clinical Study Overview

## Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access Study

<table>
<thead>
<tr>
<th>Objective</th>
<th>To establish the safety and efficacy of the GORE® ACUSEAL Vascular Graft for use in hemodialysis at any time post-implantation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>Non-randomized, multicenter, prospective GORE® ACUSEAL Vascular Graft compared to historical control.</td>
</tr>
<tr>
<td>Patient Population</td>
<td>ESRD patients either currently receiving hemodialysis or expected to require hemodialysis through a prosthetic vascular access graft within 30 days.</td>
</tr>
<tr>
<td>Primary Efficacy Endpoint</td>
<td>Cumulative patency at six months – Percentage of subjects free from complete loss of access for hemodialysis at the study access site.</td>
</tr>
<tr>
<td>Primary Safety Endpoint</td>
<td>Freedom from bleeding at six months – Percentage of subjects free from both major and minor bleeding events.</td>
</tr>
<tr>
<td>Sample Size</td>
<td>N = 138</td>
</tr>
<tr>
<td>Follow-Up</td>
<td>6 and 12 months</td>
</tr>
</tbody>
</table>
Primary Clinical Outcomes

Efficacy

<table>
<thead>
<tr>
<th>Cumulative Patency</th>
<th>GORE® ACUSEAL Vascular Graft</th>
<th>Historical Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-Month Follow-up</td>
<td>84%</td>
<td>75%</td>
</tr>
<tr>
<td>12-Month Follow-up</td>
<td>78%</td>
<td>66%</td>
</tr>
</tbody>
</table>

Safety

<table>
<thead>
<tr>
<th>Freedom from Bleeding</th>
<th>GORE® ACUSEAL Vascular Graft</th>
<th>Historical Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-Month Follow-up</td>
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</tr>
<tr>
<td>12-Month Follow-up</td>
<td>84%</td>
<td>66%</td>
</tr>
</tbody>
</table>

Data on File.
Secondary Clinical Outcomes

Early Access for Cannulation

<table>
<thead>
<tr>
<th>Time from Implantation to First Cannulation</th>
<th>Number of GORE® ACUSEAL Vascular Graft Cannulated†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 24 Hours</td>
<td>n = 30 (22.2%)</td>
</tr>
<tr>
<td>Within 48 Hours</td>
<td>n = 48 (35.6%)</td>
</tr>
<tr>
<td>Within 72 Hours</td>
<td>n = 54 (40.0%)</td>
</tr>
<tr>
<td>Within 7 Days</td>
<td>n = 70 (51.9%)</td>
</tr>
</tbody>
</table>

Time to Potential Central Venous Catheter (CVC) Removal

- Within 28 days of graft implantation 75.6% of the implanted GORE® ACUSEAL Vascular Grafts had been successfully cannulated three consecutive times.

Data on File.
## Economic Value Study Overview

**Economic value of preventing CVC sepsis infections with early cannulation arteriovenous grafts (ecAVGs) compared to non-ecAVGs**

<table>
<thead>
<tr>
<th><strong>Objective</strong></th>
<th>Compare CVC sepsis costs for patients implanted with the early cannulation GORE® ACUSEAL Vascular Graft to patients with non-early cannulation AVGs (ecAVGs)</th>
</tr>
</thead>
</table>
| **Methods**   | An economic cost model was estimated using:  
|               | • GORE® ACUSEAL Vascular Graft clinical study ¹  
|               | • Clinical literature for the non-ecAVG ², ³  
|               | • Publicly available cost sources ²⁴ |


## Economic Value Study Cost Savings Analysis

### Cost Savings

<table>
<thead>
<tr>
<th>GORE® ACUSEAL VASCULAR GRAFT</th>
<th>NON-ecAVG</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 CVC patients receive implant</td>
<td>100 CVC patients receive implant</td>
</tr>
<tr>
<td>2.32 CVC sepsis infection rate per patient year</td>
<td>2.32 CVC sepsis infection rate per patient year</td>
</tr>
<tr>
<td>15.5 days to potential CVC removal</td>
<td>34 days to potential CVC removal</td>
</tr>
<tr>
<td>= 9.9 potential CVC sepsis infections</td>
<td>= 21.6 potential CVC sepsis infections</td>
</tr>
<tr>
<td>× $27,088 / CVC sepsis infection</td>
<td>× $27,088 / CVC sepsis infection</td>
</tr>
<tr>
<td>= $268,171 total CVC sepsis costs and $2,682 CVC sepsis costs per patient</td>
<td>= $585,101 total CVC sepsis costs and $5,851 CVC sepsis costs per patient</td>
</tr>
</tbody>
</table>

1 Mohr BA, Trovillion PJ. Economic value of preventing central venous catheter sepsis infections with early cannulation arteriovenous grafts (ECAVGS) compared to non-ecavgs. Presented at the ISPOR 20TH Annual International Meeting; May 16-20, 2015; Philadelphia, PA. Value in Health 2015;18(3):A42. PMD27.
Average Sepsis Costs Per Patient

Average Sepsis Costs per Patient

Cost savings of $3,169 per patient with avoidance of 18.5 CVC-dependent days

1 Mohr BA, Trovillion PJ. Economic value of preventing central venous catheter sepsis infections with early cannulation arteriovenous grafts (ECAVGS) compared to non-ecavgs. Presented at the ISPOR 20TH Annual International Meeting; May 16-20, 2015; Philadelphia, PA. Value in Health 2015;18(3):A42. PMD27.
Value Summary

- 78% cumulative patency at 12 months
- Early cannulation capable within 24 hours
- Avoids 18.5 CVC-dependent days per patient
- $3,169 cost savings of CVC sepsis per patient
- Gore commitment to dialysis access
W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific) 800.437.8181 (United States)
00800.6334.4673 (Europe) 928.779.2771 (United States)
goremedical.com

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