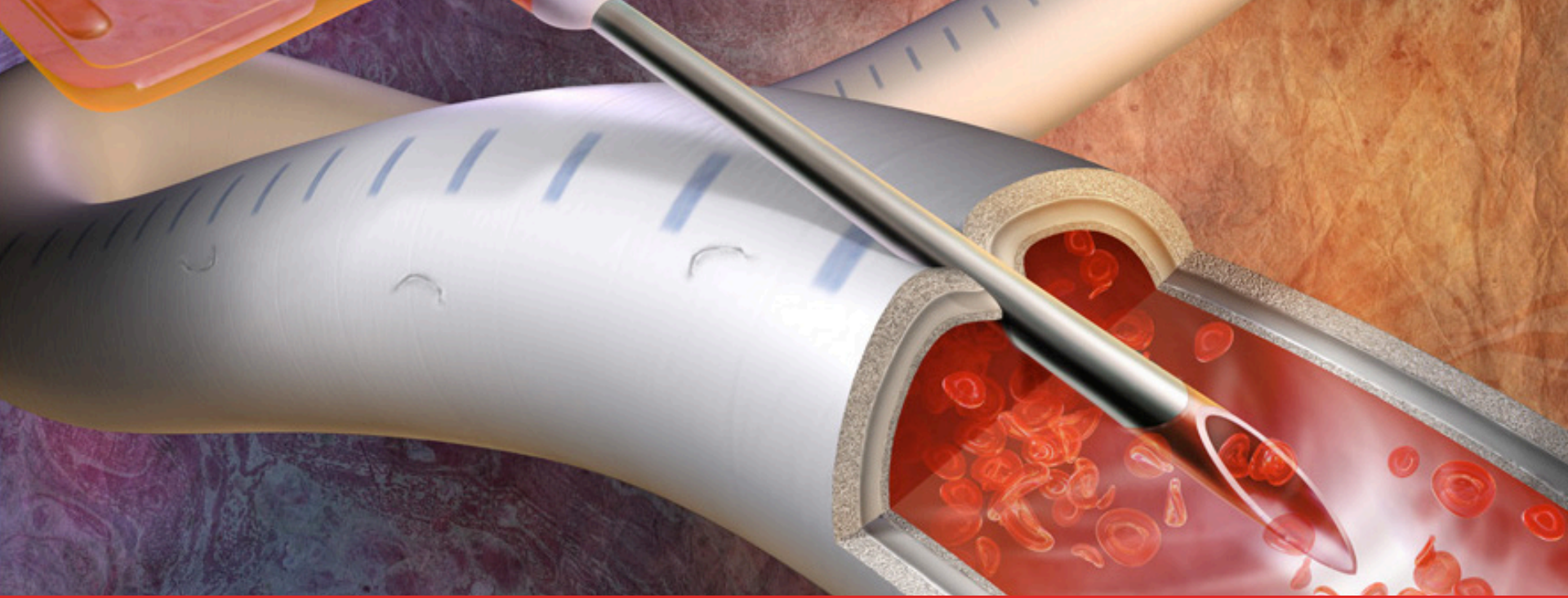


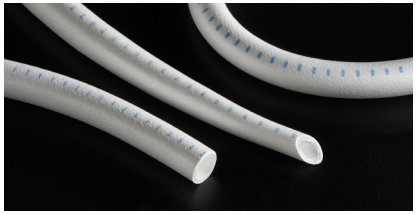
# Dialysis Access value with GORE® ACUSEAL Vascular Graft

GORE
Creative Technologies Worldwide

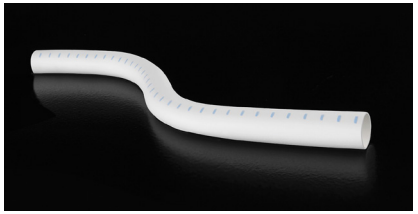
# About W. L. Gore & Associates

- **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

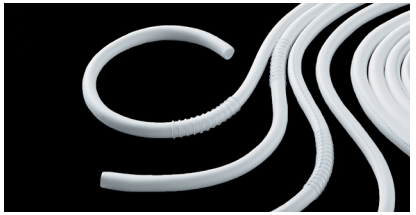
# Committed to Dialysis Access



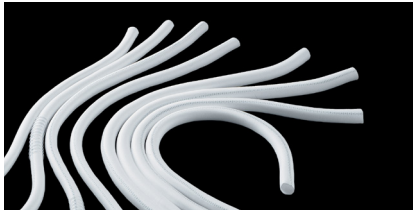
*GORE® ACUSEAL Vascular Graft*



*GORE® PROPATEN® Vascular Graft*

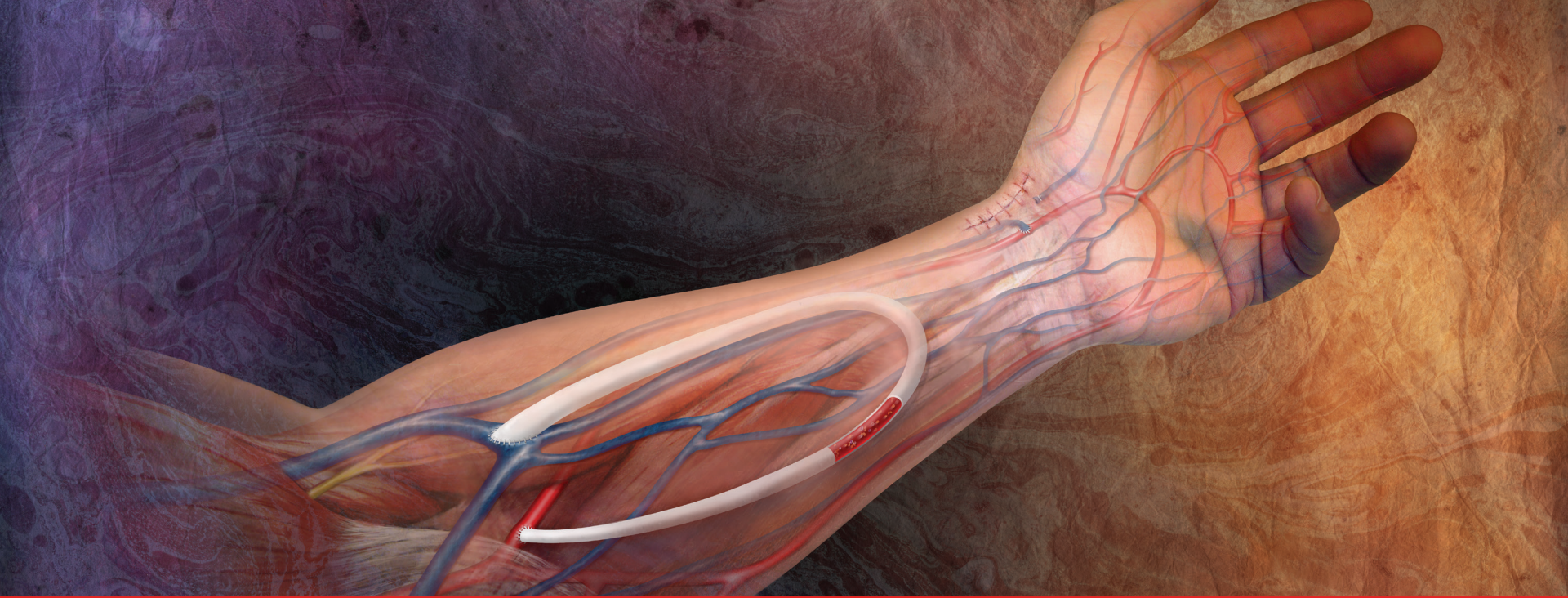


*GORE-TEX® Vascular Graft*



*GORE-TEX® Stretch Vascular Graft*

*GORE® VIABAHN® Endoprosthesis*



# Dialysis Access

## Prevalence and risks

GORE
Creative Technologies
Worldwide

# Prevalence

- 30 million people or 15% of U.S. adults are estimated to have Chronic Kidney Disease (CKD) [1]
- At the end of 2012, there were approximately 449,000 End-stage Renal Disease (ESRD) patients on some form of dialysis (409,000 hemodialysis, 40,000 peritoneal dialysis) [2]
- In 2012, 62% of new patients in the U.S. initiated dialysis via a catheter and, after three months, the percentage increased to a 75% Central Venous Catheter (CVC) rate due to failure of Arteriovenous Fistula (AVF) maturation [2]


1. Centers for Disease Control and Prevention. National Chronic Kidney Disease Fact Sheet, 2017. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2017. http://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf . Accessed December 19, 2018.
2. U.S. Renal Data System. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. USRDS 2014 annual data report: atlas of chronic kidney disease and end-stage renal disease in the United States. https://www.usrds.org/2014/view/Default.aspx . Published 2014. Accessed December 19, 2018.

# Dialysis catheters and patient risk

- **A study published in the *Journal of American Society of Nephrology*[1] 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

1. Ravani P, Palmer SC, Oliver MJ, *et al.* Associations between hemodialysis access type and clinical outcomes: a systematic review. *Journal of the American Society of Nephrology* 2013;24(3):465-473.

# ESRD and catheter-related sepsis

## Sepsis hospitalizations have been cited as the costliest condition to treat in the U.S. [1]

**$27,088 per admission [2]**

Cost for ESRD patient with CVC-related sepsis hospitalization

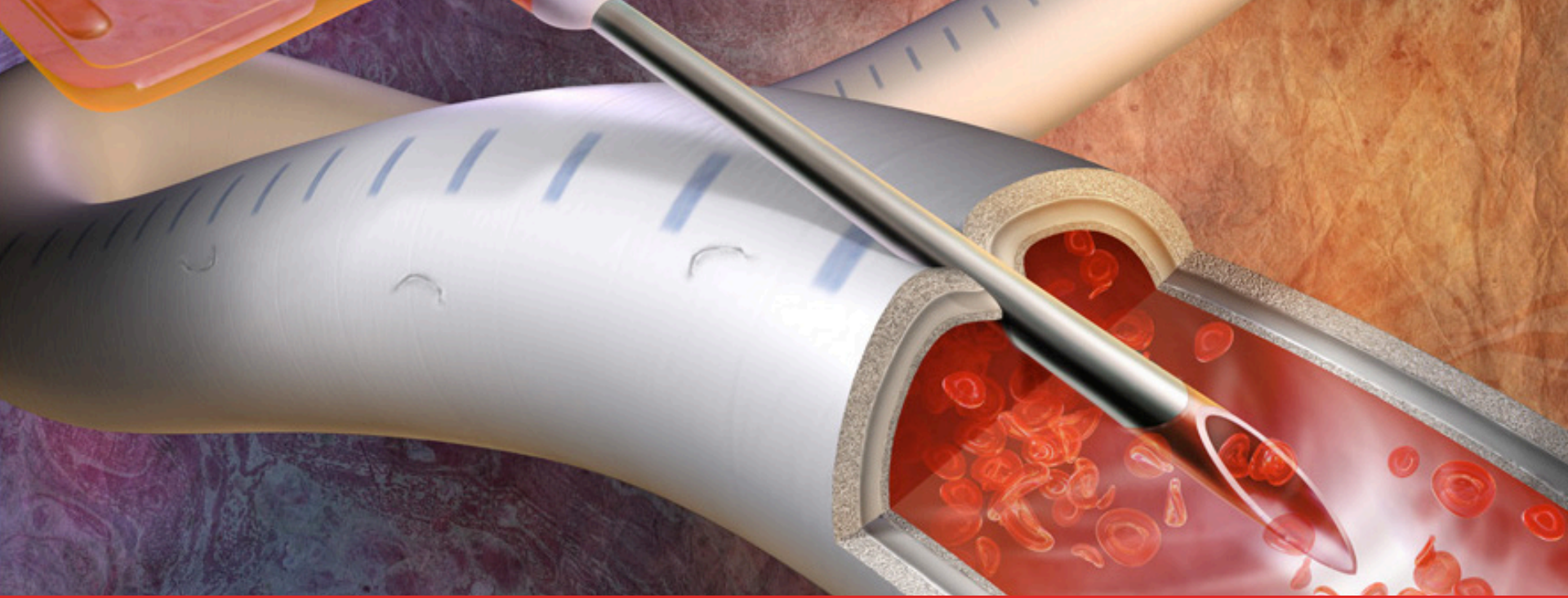
**7.6% mortality rate [2]**

In-hospital rate for ESRD patient with CVC-related sepsis

**2.32 sepsis infections per patient year**

Compared to arteriovenous grafts at .61 per patient year [3]


1. Torio CM, Andrews RM. Agency for Healthcare Research and Quality. Health Care Cost and Utilization Project H-CUP. National inpatient hospital costs: the most expensive conditions by payer, 2011. HCUP Statistical Brief #160. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf. Published August 2013. Accessed December 19, 2018.
2. HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality; 2010. www.hcup-us. ahrq.gov/nisoverview.jsp. Accessed January 10, 2019.
3. U.S. Renal Data System. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. USRDS 2011 annual data report: atlas of chronic kidney disease and end-stage renal disease in the United States. https://www.usrds.org/atlas11.aspx. Published 2011. Accessed January 10, 2019.
   *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.*

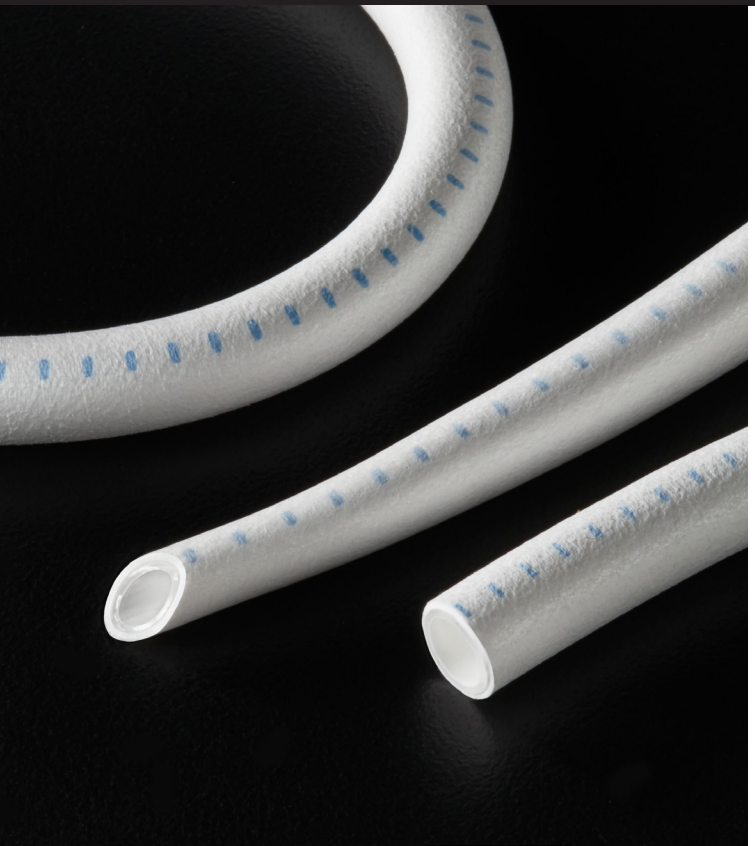


# GORE® ACUSEAL Vascular Graft

## Value summary

GORE
Creative Technologies
Worldwide

# GORE® ACUSEAL Vascular Graft



- **FDA clearance – April 2013**
- **Early cannulation capable within 24 hours**
- **78% cumulative patency at 12 months** [1]
- ***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.

1. W. L. Gore & Associates, Inc. Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access. ClinicalTrials.gov. Bethesda, MD: National Library of Medicine; 2013. https://clinicaltrials.gov/ct2/show/NCT01173718 . Published August 2, 2010. Updated July 26, 2013. Accessed December 17, 2018.

# Product configurations

| Catalogue number | Diameter (mm) | Length (cm) | Tapered |
|---|---|---|---|
| ECH060010A | 6 | 10 | |
| ECH060020A | 6 | 20 | |
| ECH060040A | 6 | 40 | |
| ECH060050A | 6 | 50 | |
| ECH470045A | 4–7 | 45 | X |

# Clinical study overview

## Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access Study [1]

| | |
|---|---|
| Objective | To establish the safety and efficacy of the GORE® ACUSEAL Vascular Graft for use in hemodialysis at any time post-implantation. |
| Design | Non-randomized, multicenter, prospective GORE® ACUSEAL Vascular Graft compared to historical control. |
| Patient population | ESRD patients either currently receiving hemodialysis or expected to require hemodialysis through a prosthetic vascular access graft within 30 days. |
| Primary efficacy endpoint | **Cumulative patency at six months** – Percentage of subjects free from complete loss of access for hemodialysis at the study access site. |
| Primary safety endpoint | **Freedom from bleeding at six months** – Percentage of subjects free from both major and minor bleeding events. |
| Sample size | N = 138 |
| Follow-up | 6 and 12 months |

1. W. L. Gore & Associates, Inc. Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access. ClinicalTrials.gov. Bethesda, MD: National Library of Medicine; 2013. https://clinicaltrials.gov/ct2/show/NCT01173718 . Published August 2, 2010. Updated July 26, 2013. Accessed December 17, 2018.

# Primary clinical outcomes[1]

## Efficacy

| Cumulative patency | GORE® ACUSEAL Vascular Graft | Historical control |
|---|---|---|
| 6-month follow-up | 84% | 75% |
| 12-month follow-up | 78% | 66% |

## Safety

| Freedom from bleeding | GORE® ACUSEAL Vascular Graft | Historical control |
|---|---|---|
| 6-month follow-up | 88% | 78% |
| 12-month follow-up | 84% | 66% |

1. W. L. Gore & Associates, Inc. Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access. ClinicalTrials.gov. Bethesda, MD: National Library of Medicine; 2013. https://clinicaltrials.gov/ct2/show/NCT01173718 . Published August 2, 2010. Updated July 26, 2013. Accessed December 17, 2018.

# Secondary clinical outcomes

## Early access for cannulation

| Time from implantation to first cannulation | Number of GORE® ACUSEAL Vascular Graft cannulated * |
|---|---|
| Within 24 hours | n = 30 (22.2%) |
| Within 48 hours | n = 48 (35.6%) |
| Within 72 hours | n = 54 (40.0%) |
| Within 7 days | n = 70 (51.9%) |

## 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.

* Three ACUSEAL Grafts were not cannulated. The median days to first cannulation through the study graft was 5 days with a range of 0-116 days. For patients cannulated within the first 24 hours, the median time to first cannulation of the study graft was 21 hours with a range of 2 hours to 24 hours.

# Economic value study overview

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

**Objective**

Compare CVC sepsis costs for patients implanted with the early cannulation GORE® ACUSEAL Vascular Graft to patients with non-early cannulation AVGs (ecAVGs)

**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 [2–4]


1. W. L. Gore & Associates, Inc. Evaluation of the GORE® ACUSEAL Vascular Graft for Hemodialysis Access. ClinicalTrials.gov. Bethesda, MD: National Library of Medicine; 2013. https://clinicaltrials.gov/ct2/show/NCT01173718 . Published August 2, 2010. Updated July 26, 2013. Accessed December 17, 2018.

2. Quinn B, Cull DL, Carsten CG. Hemodialysis access: placement and management complications. In: Hallet JW Jr, Mills JL, Earnshaw J, Reekers JA, Rooke T, eds. *Comprehensive Vascular & Endovascular Surgery.* 2nd ed. Philadelphia, PA: Mosby; 2009;26:429-462.

3. Shingarev R, Maya ID, Barker-Finkel J, Allon M. Arteriovenous graft placement in predialysis patients: a potential catheter-sparing strategy. *American Journal of Kidney Diseases* 2011;58(2):243-247.

4. HCUP Nationwide Inpatient Sample (NIS). Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality; 2010. www.hcup-us. ahrq.gov/nisoverview.jsp. Accessed January 10, 2019.

# Economic value study cost savings analysis

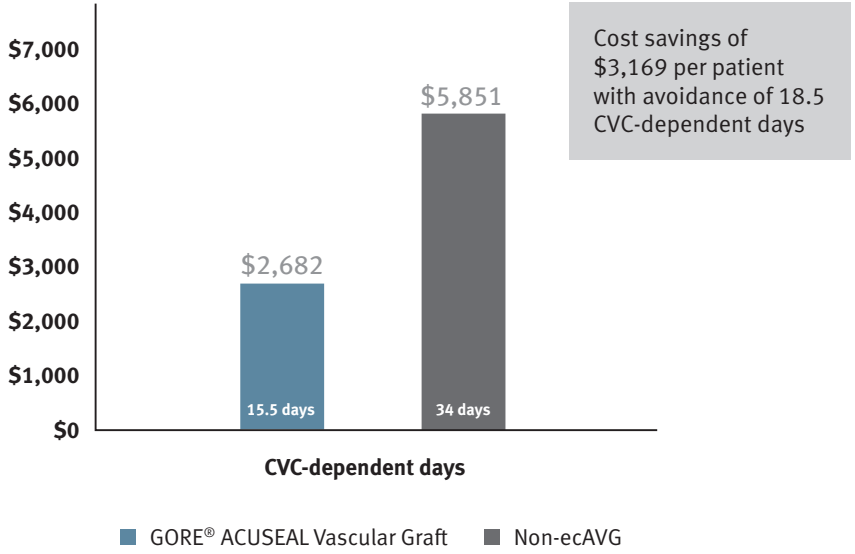
## Cost savings [1]

| GORE® ACUSEAL Vascular Graft | Non-ecAVG |
|---|---|
| 100 CVC patients receive implant<br>2.32 CVC sepsis infection rate per patient year<br>15.5 days to potential CVC removal | 100 CVC patients receive implant<br>2.32 CVC sepsis infection rate per patient year<br>34 days to potential CVC removal |
| *= 9.9 potential CVC sepsis infections*<br>× $27,088 / CVC sepsis infection | *= 21.6 potential CVC sepsis infections*<br>× $27,088 / CVC sepsis infection |
| = $268,171 total CVC sepsis costs<br>and $2,682 CVC sepsis costs per patient | = $585,101 total CVC sepsis costs<br>and $5,851 CVC sepsis costs per patient |

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 [1]

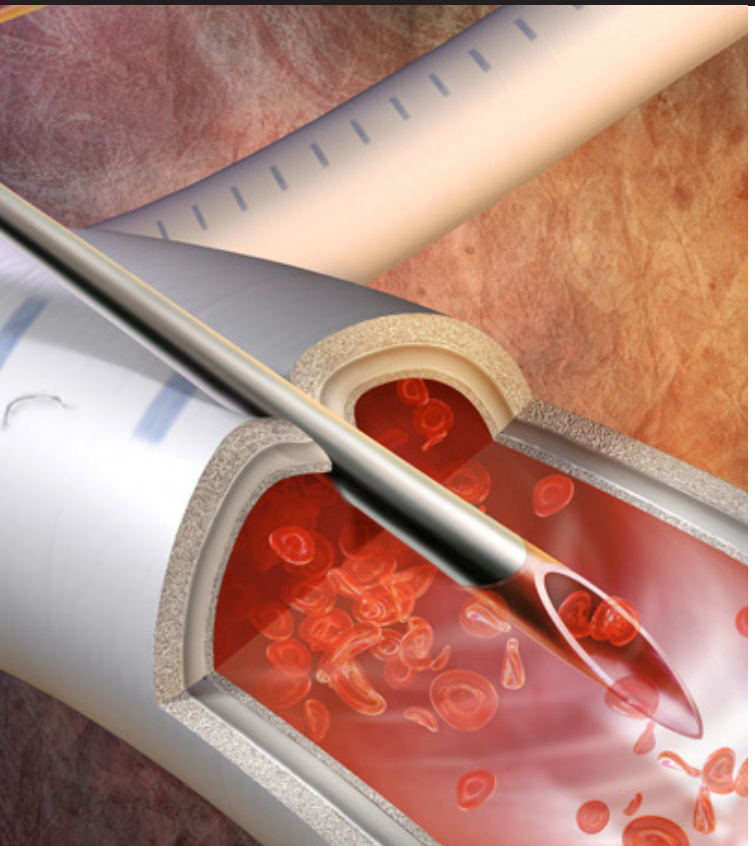



Cost savings of $3,169 per patient with avoidance of 18.5 CVC-dependent days

Note: Poster does not include product costs for either arm of the analysis.

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)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

**goremedical.com**

Consult Instructions for Use

Products listed may not be available in all markets.



GORE
Creative Technologies Worldwide