

Dialysis Access value with **GORE® ACUSEAL Vascular Graft**

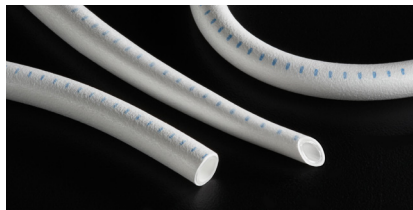


About W. L. Gore & Associates



- 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



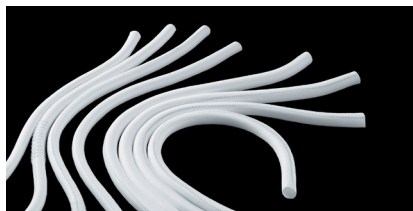
GORE® ACUSEAL Vascular Graft



GORE® PROPATEN® Vascular Graft



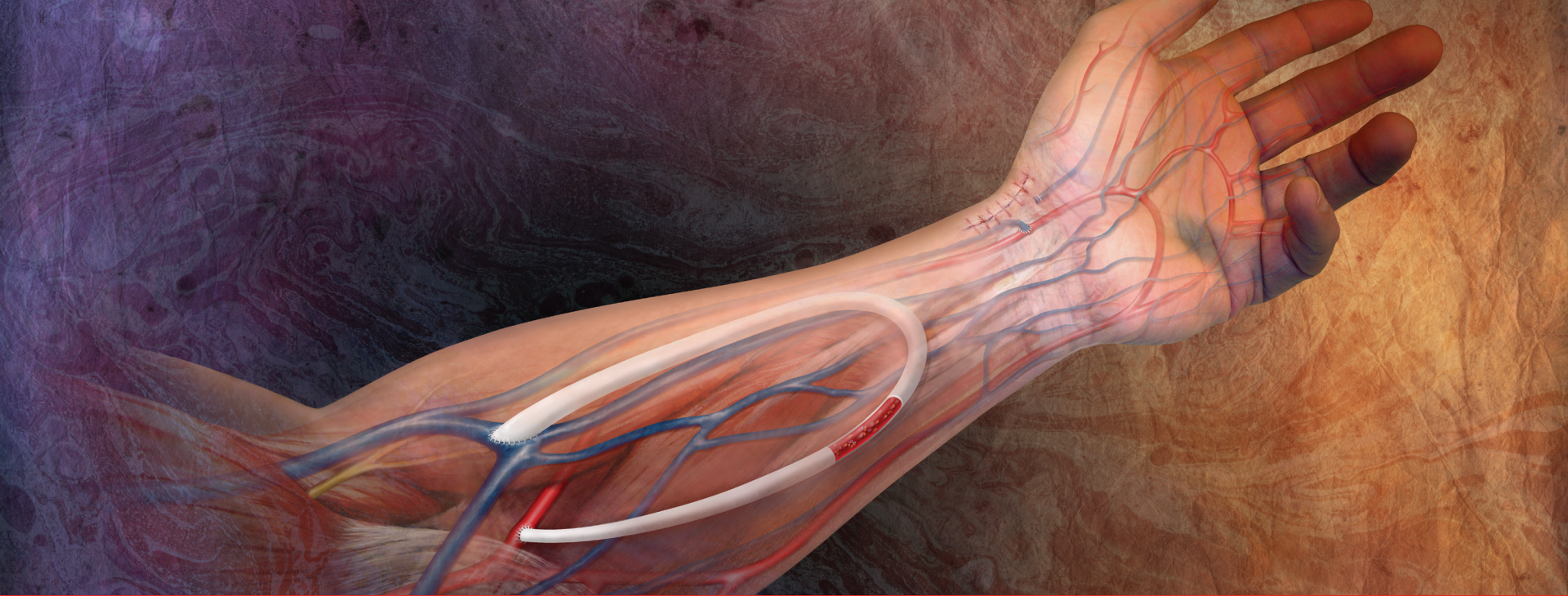
GORE-TEX® Vascular Graft



GORE-TEX® Stretch Vascular Graft



GORE® VIABAHN® Endoprosthesis



Dialysis Access

Prevalence and risks

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.

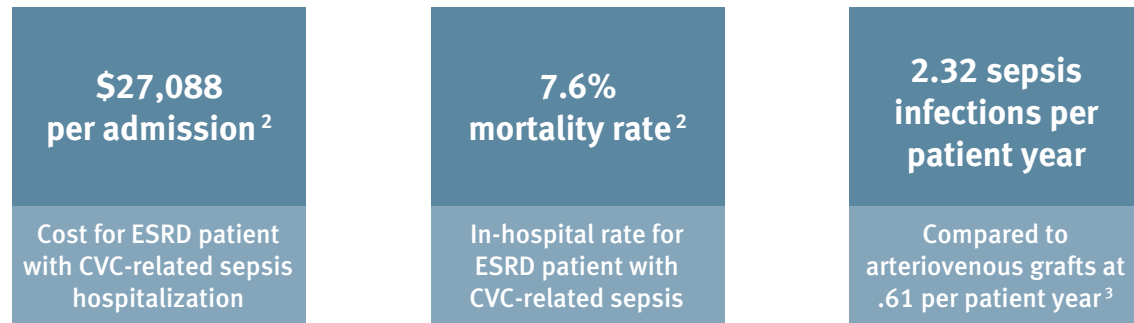
Dialysis catheters and patient risk

- 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

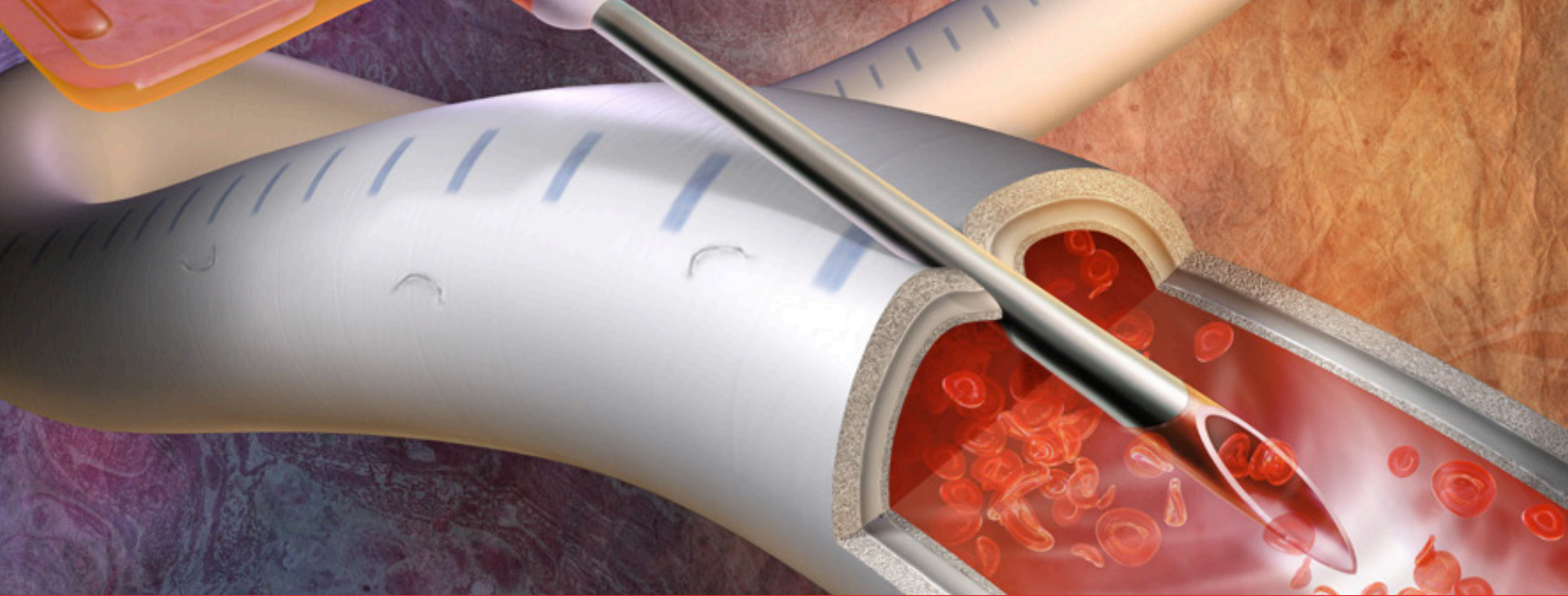


1. Torio CM, Andrews RM. Agency for Healthcare Research and Quality. Health Care Cost and Utilization Project H-CUP. National inpatient hospital costs: the most expensive conditions by payer, 2011. HCUP Statistical Brief #160. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb160.pdf>. Published August 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.

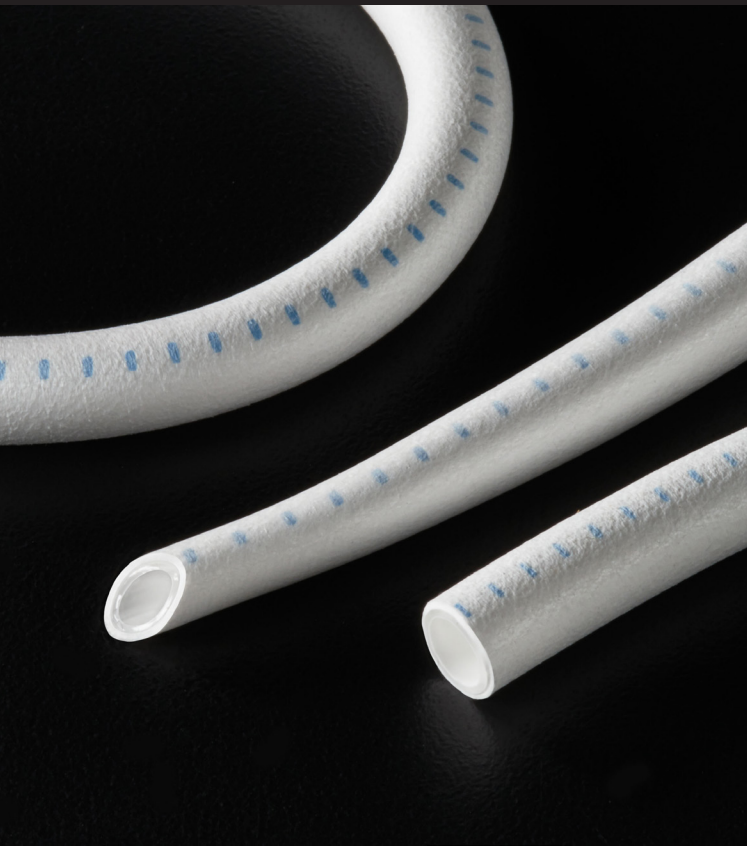


GORE® ACUSEAL Vascular Graft

Value summary



GORE® ACUSEAL Vascular Graft



- FDA clearance – April 2013
- Early cannulation capable within 24 hours
- 78% cumulative patency at 12 months¹
- *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 Study¹

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 outcomes¹

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 study¹
- Clinical literature for the non-ecAVG^{2, 3}
- Publicly available cost sources²⁻⁴

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

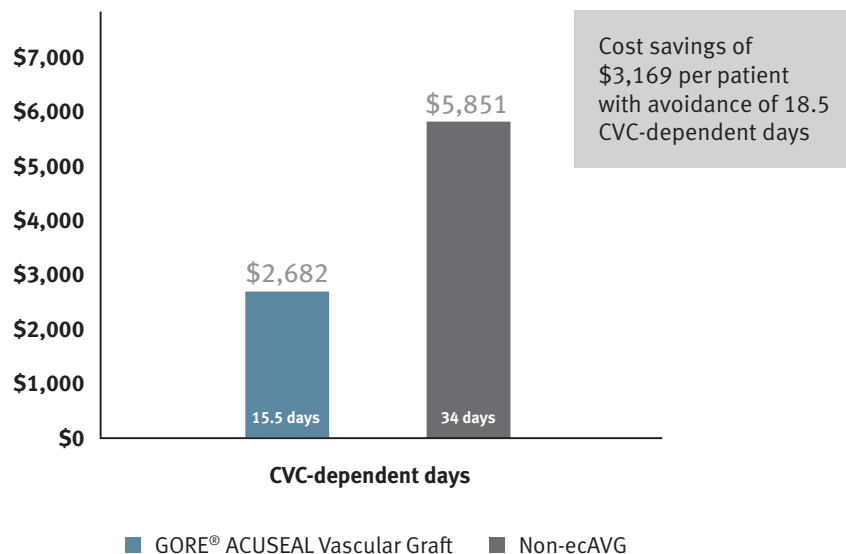
Cost savings¹

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

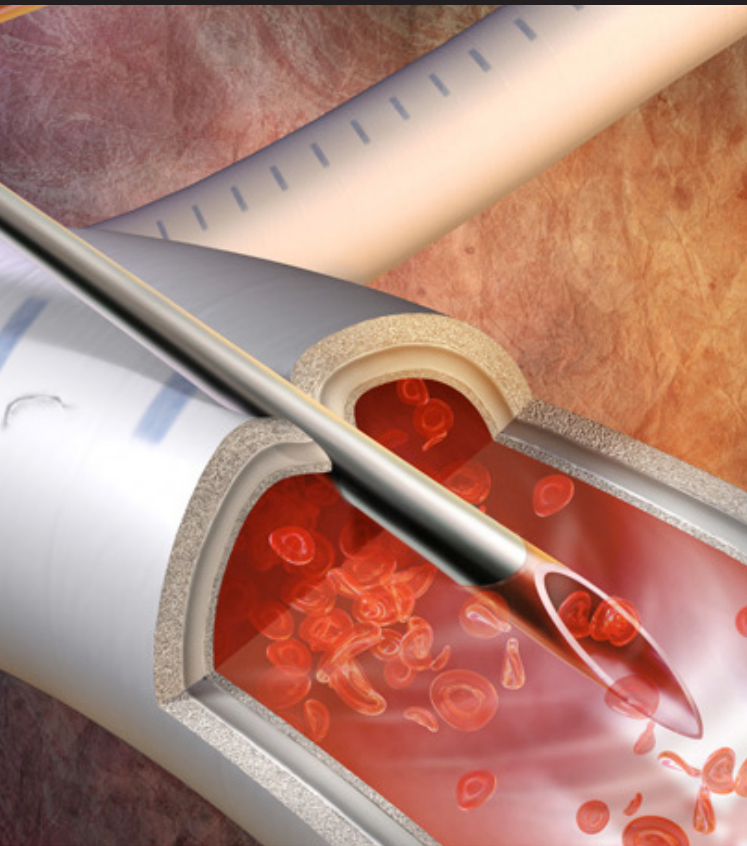
Average sepsis costs per patient¹



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

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