REFERENCES

The overall weighted average* infection rate of 1.9% reported in GORE® PROPATEN® Vascular Graft literature is within or below the historical incidence rate for prosthetic grafts used in infrainguinal bypass. Inclusion criteria are clinical journal articles in English language, with non-overlapping patient populations, and 50 or more bypasses with GORE® PROPATEN® Vascular Graft.


GORE® PROPATEN® Vascular Graft infections not reported (N = 39 limbs)


GORE® PROPATEN® Vascular Graft infections not reported (N = 40 limbs)


0 graft infections (N = 99 limbs)


2 deep infections (N = 240 limbs)


0 graft infections (N = 41 limbs)


5 wound or graft infections (N = 139 limbs)


8 surgical site infections in groin (N = 68 limbs)


GORE® PROPATEN® Vascular Graft infections not reported (N = 272 limbs)


1 major graft infection; 4 minor wound or graft infections (N = 75 limbs)

(Continued on back)
HISTORICAL DATA
Infection incidence rates for prosthetic vascular grafts in infrainguinal bypass.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Infection Incidence (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pounds LL, et al. 2005</td>
<td>29.3</td>
</tr>
<tr>
<td>Brothers TE, et al. 2009</td>
<td>18</td>
</tr>
<tr>
<td>Ploeg A, et al. 2007</td>
<td>6.2</td>
</tr>
<tr>
<td>Back MR. 2010</td>
<td>0.9 – 4.6</td>
</tr>
<tr>
<td>Nguyen BN, et al. 2014</td>
<td>2.7</td>
</tr>
<tr>
<td>Moriera CC, et al. 2016</td>
<td>4.5</td>
</tr>
</tbody>
</table>

* Weighted average calculation includes only those literature articles reporting infections.