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Technology

What is the GORE® Hybrid Vascular Graft?

The GORE® Hybrid Vascular Graft is an expanded polytetrafluoroethylene (ePTFE) vascular prosthesis that has a section reinforced with nitinol. The nitinol reinforced section is partially constrained to allow for easy insertion and deployment into a vessel. The GORE® Hybrid Device has a continuous lumen with immobilized heparin bonded to the luminal surface.

What are the features and benefits of the GORE® Hybrid Vascular Graft?

Features:
- Nitinol reinforced section allows for convenient vessel insertion
- CARMEDA® BioActive Surface (CBAS® Surface) consisting of stable end-point covalently bonded heparin
- Low permeability film
- Uninterrupted luminal surface
- Simple deployment system
- Unmatched graft handling characteristics

Benefits:
- Designed to reduce intimal hyperplasia
  - Improved outflow hemodynamics; laminar flow in line with the host vessel
  - Sutureless outflow anastomosis
- Proven thromboresistant surface
- Shields the vessel lumen most susceptible to failure
- Expands treatment options; challenging site locations and deep vessels
- Embedded low permeability film provides a barrier to ultrafiltration

See IFU for complete information

For what clinical applications can the GORE® Hybrid Vascular Graft be used?

GORE® Hybrid Vascular Grafts are intended for use as vascular prostheses for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, or for other vascular procedures.

What is unique about the design and construction of the GORE® Hybrid Vascular Graft?

The GORE® Hybrid Vascular Graft is the only vascular graft with the CBAS® Surface that creates an endoluminal anastomosis. The device incorporates several trusted Gore technologies including:
- Nitinol reinforced section
- Heparin Bonded CBAS® Surface
- Embedded low permeability film provides a barrier to ultrafiltration
- Unmatched graft handling characteristics

How can the GORE® Hybrid Vascular Graft potentially improve clinical outcomes?

The GORE® Hybrid Vascular Graft is designed to address the three major causes of graft failure:

Intimal Hyperplasia:
- The nitinol reinforced section creates an endoluminal anastomosis which provides a smoother hemodynamic transition as compared to a standard end-to-side anastomosis, as well as a reduction in variation of wall shear stress as compared to a conventional end-to-side anastomosis.

Thrombosis:
- The entire lumen of the GORE® Hybrid Device is coated with the CBAS® Surface consisting of a stable, end-point covalently bonded reduced molecular weight heparin of porcine origin.

Fluid Leakage and Seroma:
- A low permeability ePTFE film embedded in the wall of the GORE® Hybrid Device reduces fluid leakage and therefore provides a barrier to ultrafiltration as compared to standard ePTFE vascular grafts.
What wall shear stress values have been reported in the literature for platelet and leukocyte activation and the onset of intimal hyperplasia?

Wall shear stress is the force that acts on the vessel wall because of blood flow and has been shown to play an important role in platelet and leukocyte activation and the formation of intimal hyperplasia. The table below specifies critical vessel wall shear stress values from the literature.

<table>
<thead>
<tr>
<th>Wall Shear Stress (dynes/cm²)</th>
<th>Biological Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 100</td>
<td>Platelet Activation</td>
</tr>
<tr>
<td>&gt; 75</td>
<td>Leukocyte Activation</td>
</tr>
<tr>
<td>10 – 40</td>
<td>Physiological Range in Arteries</td>
</tr>
<tr>
<td>1 – 6</td>
<td>Physiological Range in Veins</td>
</tr>
<tr>
<td>&lt; 2</td>
<td>Intimal Hyperplasia Development</td>
</tr>
</tbody>
</table>

Table 1

How can the endoluminal anastomosis created by the Gore® Hybrid Vascular Graft improve hemodynamics?

Computational fluid dynamics studies have demonstrated the following improvements in flow hemodynamics at the endoluminal anastomosis of the Gore® Hybrid Vascular Graft as compared to the conventional end-to-side anastomosis:

- Reduction in Variation of Wall Shear Stress (WSS)
  - Favorable wall shear stress values below threshold values for platelet and leukocyte activation
  - Favorable wall shear stress values above threshold values for the development of intimal hyperplasia

Image 1

[Conventional End-to-Side Anastomosis]

[Endoluminal Anastomosis with the Gore® Hybrid Vascular Graft]
• Reduction in Oscillatory Shear Index (OSI):
  – High values of OSI have been shown to be a predictor of the development of intimal hyperplasia.

Table 2

<table>
<thead>
<tr>
<th>OSI (0 – 0.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conventional End-to-Side</td>
</tr>
<tr>
<td>GORE® Hybrid Vascular Graft</td>
</tr>
<tr>
<td>0.25</td>
</tr>
<tr>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

• Reduction in Helicity:
  – Helicity, or flow disturbance, within a vessel has been shown to correlate with smooth muscle cell migration and the development of intimal hyperplasia.

Table 3

<table>
<thead>
<tr>
<th>Helicity (m / s²)</th>
<th>Conventional End-to-Side Anastomosis</th>
<th>GORE® Hybrid Vascular Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vein Diameter (mm)</td>
<td>4.8</td>
<td>5.5</td>
</tr>
<tr>
<td>ΔH</td>
<td>690.16</td>
<td>504.96</td>
</tr>
</tbody>
</table>

What are the benefits of using the GORE® Hybrid Vascular Graft over a surgically created end-to-end anastomosis?

• Reduced suture line stenosis
  – Ballyk et al. have shown that the suture line of a conventionally sutured end-to-side anastomosis corresponds to high wall shear stress and to the development of intimal hyperplasia. The endoluminal anastomosis created by the GORE® Hybrid Vascular Graft reduces the endothelial damage caused by suturing and therefore has the potential to reduce suture line stenosis.
• Simplifies access to deeper and harder to reach vessels
• Potential to reduce surgery time
Does the vascular graft section of the GORE® Hybrid Vascular Graft utilize stretch technology?

Yes. The GORE® Hybrid Vascular Graft retains similar handling characteristics and extensibility as that of the GORE-TEX® Stretch Vascular Graft. The GORE® Hybrid Device should be tensioned like the GORE-TEX® Stretch Device using moderate tension. Reasonable assurance of moderate tension is provided when the blue orientation markers, illustrated in the following two images, change configuration from "relaxed" to "moderate tension."

![Image 2](image2.png)

Does the GORE® Hybrid Vascular Graft utilize the CBAS® Surface?

Yes. The entire lumen of GORE® Hybrid Vascular Graft is coated with the CBAS® Surface, consisting of a stable, covalently bonded reduced molecular weight heparin of porcine origin.

What is unique about the heparin technology on the GORE® Hybrid Vascular Graft?

The unique features of the CBAS® Surface of the GORE® Hybrid Vascular Graft include:

- A proven thromboresistant surface
- Proprietary end-point covalent bonding
- Sustained bioactivity

The heparin molecules are covalently bonded to the entire luminal surface of the GORE® Hybrid Vascular Graft through a proprietary end-point covalent bonding CBAS® Surface which serves to anchor heparin molecules to the luminal surface while still maintaining heparin’s intrinsic bioactive properties. The result is a proven thromboresistant surface with a long-term, safe, clinical history. There are two decades of clinical use across multiple applications and more than 400 scientific and clinical publications pertaining to the CBAS® Surface.

![Image 3](image3.png)

How long does the heparin bioactivity of the GORE® Hybrid Vascular Graft last?

Preclinical and Other Studies:

- GORE® PROPATEN® Vascular Graft explants (utilizing the same proprietary end-point covalent bonding as the GORE® Hybrid Vascular Graft) from an in vivo canine model demonstrated the continued presence of heparin on the graft surface and showed sustained heparin bioactivity for a period of 12 weeks. 8
- Reisenfeld has reported substantial bioactivity on Berlin Heart Ventricular Assist Device (same end-point CBAS® Surface bonding technology as the GORE® Hybrid Device) removed from a patient after 855 days.

Clinical:

- One human GORE® PROPATEN® Vascular Graft explant at approximately eight months and one at three years post implantation have demonstrated substantial heparin activity in the same range as that shown in the canine study.

Does heparin release from the luminal surface of the GORE® Hybrid Vascular Graft?

The GORE® Hybrid Vascular Graft utilizes the same proprietary end-point covalent bonding CBAS® Surface as the GORE® PROPATEN® Vascular Graft. In vitro experiments with the GORE® PROPATEN® Vascular Graft have shown that less than 20 IU of heparin are released into solution during the first 24 hours after initiation of flow.
Can the CBAS® Surface on the GORE® Hybrid Vascular Graft cause or contribute to the condition of Heparin Induced Thrombocytopenia (HIT)?

- There have been no reported incidents of HIT in controlled, clinical studies of Gore Vascular Devices with an immobilized heparin surface.
- In a study by Heyligers, et al. 11, HIT inducing antibodies were not detected in any of the patients who received the GORE® PROPATEN® Vascular Graft even after six weeks of implantation.

Can a GORE® Hybrid Vascular Graft be implanted in patients with existing Heparin Induced Thrombocytopenia (HIT)?

All Gore Vascular Devices with CBAS® Surface, including the GORE® Hybrid Vascular Graft, are contraindicated for use in patients with known hypersensitivity to heparin, including those patients who have had a previous (or existing) incidence of HIT type II.

What treatment protocol should I follow if a GORE® Hybrid Vascular Graft patient develops Heparin Induced Thrombocytopenia (HIT)?

The incidence of HIT type II is extremely low in vascular bypass patients receiving heparin over a period of several days. If HIT type II is diagnosed, established procedures for the treatment of this condition, including immediate cessation of systemic heparin administration, should be followed 12. If symptoms persist, or the health of the patient appears compromised, alternative pharmaceutical or surgical procedures may be considered at the discretion of the attending physician.

How is the nitinol reinforced section of the GORE® Hybrid Vascular Graft constructed, and how does it deploy?

Construction:
- The GORE® Hybrid Vascular Graft features a flexible, self-expanding, nitinol reinforced section.

Deployment:
- Deployment of the nitinol reinforced section of the GORE® Hybrid Device occurs from the tip to the hub.

How does the GORE® Hybrid Vascular Graft resist ultrafiltration?

The low permeability ePTFE film embedded in the wall of the GORE® Hybrid Vascular Graft reduces fluid leakage and therefore provides a barrier to ultrafiltration as compared to standard ePTFE vascular grafts. Specifically, in vitro seroma models have demonstrated a significant reduction in fluid permeation through the wall of the GORE® Hybrid Device as compared to standard ePTFE vascular grafts at identical pressures.

Ultrafiltration Benchtop Comparison
The GORE® Hybrid Vascular Graft and two competitive vascular grafts were tested in a pressurized benchtop comparison using bovine serum.

A. GORE® Hybrid Vascular Graft: No weeping at 30 psi
B. Competitor Graft 1: Weeping recorded at 6 psi
C. Competitor Graft 2: Weeping recorded at 10 psi

Does the embedded low permeability film of the GORE® Hybrid Vascular Graft affect abluminal tissue in-growth?

The low permeability film is within the wall of the GORE® Hybrid Vascular Graft so tissue in-growth on the abluminal surface should not be affected. The luminal and abluminal microstructure of the GORE® Hybrid Device is similar to the GORE® PROPATEN® Vascular Graft.
Clinical Practice - Preoperative

How can an appropriately sized nitinol reinforced section of the GORE® Hybrid Vascular Graft be selected for a particular patient?

In selecting the appropriately sized nitinol reinforced section of the GORE® Hybrid Vascular Graft, a careful assessment of the vessel is necessary. In general, to assure adequate anchoring, the diameter of the nitinol reinforced section of the GORE® Hybrid Device should be approximately 5 – 20% larger than the vessel diameter.

<table>
<thead>
<tr>
<th>Nitinol Reinforced Section (mm)</th>
<th>Recommended Vessel Diameter Nitinol Reinforced Section (mm)</th>
<th>Recommended Balloon Diameter for Nitinol Reinforced Section Touch-up (mm)</th>
<th>Constrained Nitinol Reinforced Section Diameter (Fr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>4.8 – 5.5</td>
<td>6.0</td>
<td>11</td>
</tr>
<tr>
<td>7</td>
<td>5.6 – 6.5</td>
<td>7.0</td>
<td>12</td>
</tr>
<tr>
<td>8</td>
<td>6.6 – 7.5</td>
<td>8.0</td>
<td>14</td>
</tr>
<tr>
<td>9</td>
<td>7.6 – 8.5</td>
<td>9.0</td>
<td>14</td>
</tr>
</tbody>
</table>

What ensures that the nitinol reinforced section of the GORE® Hybrid Vascular Graft remains anchored in the vessel?

The following factors potentially aid in the secure placement of the nitinol reinforced section of the GORE® Hybrid Vascular Graft:

- Depth of insertion (≥ 2.5 cm)
- Oversizing by 5 – 20%
- Two longitudinal stay sutures
- Size of venotomy / arteriotomy
- Tissue in-growth post implantation

Should stay sutures be placed through the nitinol reinforced section of the GORE® Hybrid Vascular Graft? Where and how should the sutures be positioned?

Yes. Two longitudinal stay sutures should be placed through the vessel wall and the nitinol reinforced section of the GORE® Hybrid Vascular Graft, spaced approximately 180° apart, in order to provide additional anchoring to the vessel wall.

Should the nitinol reinforced section of the GORE® Hybrid Vascular Graft be oversized compared to the vessel?

Yes. In general, to assure adequate anchoring, the diameter of the nitinol reinforced section of the GORE® Hybrid Vascular Graft should be approximately 5 – 20% larger than the vessel diameter.

Should the nitinol reinforced section of the GORE® Hybrid Vascular Graft be placed in the outflow or inflow vessel?

The nitinol reinforced section of the GORE® Hybrid Vascular Graft is intended to be placed in the outflow vessel.

Is predilatation of the vessel required before introducing the nitinol reinforced section of the GORE® Hybrid Vascular Graft into the vessel?

Predilatation may not be required for a non-diseased vein or artery. However, if the recipient vessel is diseased, predilatation may be required.

What kind of suture should be used with the GORE® Hybrid Vascular Graft?

GORE-TEX® Suture CV-5 and CV-6 are recommended for the GORE® Hybrid Vascular Graft.
Clinical Practice – Intraoperative

What are the different implantation techniques of the GORE® Hybrid Vascular Graft?

- Standard Implantation Technique
- Over the Wire Implantation Technique

What are the steps for the standard implantation technique?

The order of implantation steps for the standard implantation technique of the GORE® Hybrid Vascular Graft is at the discretion of the physician. However, the following steps are recommended:

1. Tunnel the vascular graft first and then deploy the nitinol reinforced section of the GORE® Hybrid Device, OR deploy the nitinol reinforced section of the GORE® Hybrid Device and then tunnel the vascular graft section. If deploying the nitinol reinforced section first, it is important to ensure that the nitinol reinforced section does not pull out of the vessel while tunneling the vascular graft section.
2. Place two stay sutures through the nitinol reinforced section of the GORE® Hybrid Device and the vessel.
3. Perform the sutured anastomosis.

What are the steps for the over the wire implantation technique?

The order of implantation steps for the over the wire implantation technique of the GORE® Hybrid Vascular Graft is at the discretion of the physician. However, the following steps are recommended:

1. Deploy the nitinol reinforced section of the GORE® Hybrid Device first and then tunnel the vascular graft section, OR tunnel the vascular graft section first and then deploy the nitinol reinforced section. If deploying the nitinol reinforced section first, it is important to ensure that the nitinol reinforced section does not pull out of the vessel while tunneling the vascular graft section.
2. Place two stay sutures through the nitinol reinforced section of the GORE® Hybrid Device and the vessel.
3. Perform the sutured anastomosis.

What are the potential benefits of the over the wire implantation technique?

The over the wire implantation technique of the GORE® Hybrid Vascular Graft lends itself to a number of benefits including:

- Reduction in vessel dissection and manipulation
- Expands treatment options; challenging site locations and deep vessels
- Elimination of the need for vessel clamps or loops
- Potential reduction in wound complications
- Potential improvement in hemostasis

Is a peel/tear-away sheath required when implanting the GORE® Hybrid Vascular Graft using the over the wire implantation technique?

Yes. When using an over the wire technique, a 0.035” guidewire and a peel/tear-away sheath of the appropriate size should be used (Table 5 below). The guidewire and peel/tear-away sheath manufacturers’ instructions should be observed. The guidewire access to the vessel is gained using the Seldinger technique. A peel/tear-away sheath is then introduced into the vessel over the guidewire. The dilator is removed, and the nitinol reinforced section of the GORE® Hybrid Vascular Graft is threaded over the guidewire into the peel/tear-away sheath. The peel/tear-away sheath is then carefully peeled away while simultaneously advancing the nitinol reinforced section into the vessel.

<table>
<thead>
<tr>
<th>Nitinol Reinforced Section Diameter (mm)</th>
<th>Size of Peel / Tear-away Sheath (Ft)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>8</td>
<td>14</td>
</tr>
<tr>
<td>9</td>
<td>14</td>
</tr>
</tbody>
</table>

Table 5
Should the nitinol reinforced section of the GORE® Hybrid Vascular Graft be deployed under fluoroscopy?

When implanting the GORE® Hybrid Vascular Graft using the over the wire implantation technique, it is recommended to deploy the nitinol reinforced section under fluoroscopy in order to correctly position the nitinol reinforced section of the GORE® Hybrid Device.

Should the entire nitinol reinforced section of the GORE® Hybrid Vascular Graft be introduced into the vessel?

No. The nitinol reinforced section of the GORE® Hybrid Vascular Graft should be introduced into the vessel by at least approximately 2.5 cm with some portion of the nitinol reinforced section transitioning out of the vessel.

How should the nitinol reinforced section of the GORE® Hybrid Vascular Graft be securely deployed within the vessel lumen?

While stabilizing the nitinol reinforced section of the GORE® Hybrid Vascular Graft as depicted in the image below, slowly pull the deployment line keeping it as parallel to the vascular prosthesis as possible. The deployment will occur from the tip of the delivery constraint towards the vascular graft section. Once deployment has started, repositioning of the nitinol reinforced section should not be attempted.

How should the vascular graft section just beyond the nitinol reinforced section of the GORE® Hybrid Vascular Graft be positioned?

Ensure that approximately three centimeters of the graft adjacent to the nitinol reinforced section of the GORE® Hybrid Vascular Graft is implanted in a straight orientation.

Should post-deployment balloon dilatation of the nitinol reinforced section of the GORE® Hybrid Vascular Graft be performed?

After deployment, it is recommended that the nitinol reinforced section of the GORE® Hybrid Vascular Graft be smoothed and seated against the vessel wall by inflating an angioplasty balloon. The following techniques should be considered:

- The balloon should be inflated to the desired diameter along the entire length of the nitinol reinforced section of the GORE® Hybrid Device.
- The balloon procedure should be done under fluoroscopy to ensure that the balloon dilatation does not extend beyond the ends of the device and into the healthy vessel as this may induce restenosis and subsequent graft failure.
- If residual folds or invaginations are visualized in the nitinol reinforced section of the GORE® Hybrid Device using a fluoroscope, further balloon inflations may be necessary.

Post-deployment balloon angioplasty may be required for a diseased recipient vessel, a non-diseased recipient artery, or when using the over the wire implantation technique.

For the vessel receiving the nitinol reinforced section of the GORE® Hybrid Vascular Graft, what is the recommended length and direction of the venotomy or arteriotomy?

The length and direction of the venotomy or arteriotomy is at the discretion of the physician. Some physicians have recommended that a venotomy or arteriotomy be made such that the size of the incision is just large enough to introduce the constrained nitinol reinforced section of the GORE® Hybrid Vascular Graft into the vessel.
Can the GORE® Hybrid Vascular Graft be revised?

All standard revision procedures may be performed on the GORE® Hybrid Vascular Graft including lytic therapy and balloon thrombectomy. If performing a thrombectomy in an early graft failure when tissue in-growth may be limited, it is recommended to use fluoroscopy and deflate the thrombectomy balloon at the nitinol reinforced section-vessel interface to prevent displacement of the nitinol reinforced section.

When can the GORE® Hybrid Vascular Graft be cannulated?

After implantation of the GORE® Hybrid Vascular Graft, the physician should wait several weeks before allowing cannulation similar to the GORE-TEX® Stretch Vascular Graft and the GORE® PROPATEN® Vascular Graft. The Kidney Disease Outcomes Quality Initiative (KDOQI) recommends that vascular grafts should not be cannulated for at least two weeks after placement.

Can the nitinol reinforced section of the GORE® Hybrid Vascular Graft be cannulated?

No. Do not cannulate or puncture the nitinol reinforced section of the GORE® Hybrid Vascular Graft. Cannulation of the nitinol reinforced section may cause damage to the external nitinol support, resulting in compromised performance or failure of the graft.

Would vein dilatation after creation of an arteriovenous conduit with the GORE® Hybrid Vascular Graft impede the secure placement of the nitinol reinforced section of the device?

Pre-clinical canine studies and post-market clinical studies have demonstrated that arterialization occurs beyond the nitinol reinforced section of the GORE® Hybrid Vascular Graft. Therefore, the vein dilatation should not affect the security of the nitinol reinforced section of the GORE® Hybrid Device.

Should an antiplatelet and/or anticoagulation regime be used after implantation of the GORE® Hybrid Vascular Graft?

Intraoperative and postoperative anticoagulation and antiplatelet therapy should be determined by the physician and be based on the pharmacological requirements and medical history of the patient. A prospective, randomized study has shown that clopidogrel plus acetylsalicylic acid confers benefit in patients receiving prosthetic grafts for below-knee bypassing without significantly increasing major bleeding risks. Anticoagulation and antiplatelet regimens have the potential to cause bleeding associated with cannulation of patients on hemodialysis.

Can a patient with an implanted GORE® Hybrid Vascular Graft have Magnetic Resonance Imaging (MRI)?

The GORE® Hybrid Vascular Graft is magnetic resonance conditional. No adverse events related to heating effects of the nitinol reinforced section of the GORE® Hybrid Device in the MRI environment are known.
Data – Preclinical and Clinical

Have preclinical studies been performed with the GORE® Hybrid Vascular Graft?

Yes. An in vivo 90-day canine study has been performed in which an endoluminal anastomosis in the femoral vein was created with the GORE® Hybrid Vascular Graft. The vascular graft portion of the GORE® Hybrid Device was sutured to the femoral artery. The data shown in the table below suggests that the endoluminal anastomosis created with the GORE® Hybrid Device may reduce stenosis near the venous outflow as compared to a conventional end-to-side anastomosis created by a standard ePTFE vascular graft.

<table>
<thead>
<tr>
<th></th>
<th>Conventional End-to-Side Anastomosis (Historical Data)</th>
<th>GORE® Hybrid Vascular Graft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suture Line</td>
<td>79% ± 19</td>
<td>11% ± 14</td>
</tr>
<tr>
<td>Nitinol Reinforced Section Tip</td>
<td></td>
<td>15% ± 19</td>
</tr>
<tr>
<td>Vein Downstream from Nitinol Reinforced Section</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent Stenosis</td>
<td>79% ± 19</td>
<td>11% ± 14</td>
</tr>
<tr>
<td>n</td>
<td>13</td>
<td>6</td>
</tr>
</tbody>
</table>

Have clinical evaluations been performed with the GORE® Hybrid Vascular Graft?

- More than 130 clinical implants of the GORE® Hybrid Vascular Graft were performed across the United States during a six-month limited clinical evaluation phase which concluded in March 2011.
- De Novo dialysis access procedures at three-month follow-up trends toward a reduction in percutaneous transluminal angioplasty procedures, thrombosis events and seroma as compared to historical data.¹

<table>
<thead>
<tr>
<th></th>
<th>Dialysis Access</th>
<th>Arterial Bypass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Number</td>
<td>125</td>
<td>9</td>
</tr>
<tr>
<td>Implantation Technique</td>
<td>78% (97/125) Over the Wire</td>
<td>100% (9/9) Over the Wire</td>
</tr>
<tr>
<td></td>
<td>22% (28/125) Open Surgical</td>
<td></td>
</tr>
<tr>
<td>Procedure Type</td>
<td>79% (99/125) De Novo</td>
<td>100% (9/9) AK Femoral Popliteal Bypass</td>
</tr>
<tr>
<td></td>
<td>21% (26/125) Revision</td>
<td></td>
</tr>
</tbody>
</table>

For what clinical applications has the GORE® Hybrid Vascular Graft been used?

The GORE® Hybrid Vascular Graft has been successfully used for a wide variety of indications including arteriovenous access creation, AV access revision, and arterial bypass procedures (above-knee femoral popliteal bypass).


* Sustained CBAS® Surface heparin bioactivity has been measured in a controlled three-month animal study.