Hypercoagulability is a major factor in ePTFE AV access graft thrombosis often found in patients with multiple graft thromboses and in patients with nonanatomic causes for thrombosis. One study reported 42% of their patients with repeated thrombosis had hypercoagulability as the only determinable cause of thrombosis. An increased prevalence of the hypercoagulable factors lupus anticoagulant and anticardiolipin antibody are associated with systemic lupus erythematosus and it has been reported that lupus patients on hemodialysis have a 3.1 times greater risk of developing vascular access thrombosis compared to non-lupus patients.

ProCol® is manufactured from bovine mesenteric vein processed to preserve the native components and maintain its natural compliance. Elastin polypeptides have been shown to be a non-thrombogenic coating in vascular applications and the intact elastin lamina which serves as the blood interface surface may contribute to ProCol®'s dramatically lower rate of recurrent thrombotic events and improved outcomes in hypercoagulable patients including patients with lupus compared to ePTFE grafts.

Antithrombotic therapies in graft patients with a diagnosed hypercoagulable state were studied in dialysis patients with a history of recurrent AV graft thrombosis. Of 14 ProCol® grafts 71% were patent with no incidence of thrombosis compared to 50% of ePTFE grafts after an average 8.2 months follow-up. Patency results with Warfarin and low molecular weight heparin (30 or 40 mg of enoxaparin subcutaneous once daily) were both superior to unfractionated heparin in the ProCol® group however Warfarin was associated with a higher incidence of bleeding complications.

In another study identically processed bovine mesenteric vein was utilized as a systemic-to-pulmonary shunt in 13 infants with 3 or more identifiable thrombophilic risk factors with no postoperative anticoagulants administered. Technique related issues required intervention in three instances however there were no complications attributable to the graft material leading to the conclusion ProCol® "could be the choice of graft for use without the administration of antiagregant and anticoagulants in patients with thrombophilic risk factors."

INDICATIONS FOR USE The ProCol® Vascular Bioprosthesis is intended for the creation of a bridge graft for vascular access subsequent to at least one previously failed prosthetic access graft. CONTRAINDICATIONS None known. WARNINGS The device should not be used when host vessels are of insufficient quality to avoid anastomotic aneurysms. PRECAUTIONS The device should not be used when host vessels are of insufficient quality to avoid anastomotic aneurysms. The device should not be used when host vessels are of insufficient quality to avoid anastomotic aneurysms. The device should not be used when host vessels are of insufficient quality to avoid anastomotic aneurysms. The device should not be used when host vessels are of insufficient quality to avoid anastomotic aneurysms. The device should not be used when host vessels are of insufficient quality to avoid anastomotic aneurysms. 

"ProCol® should be the graft of choice in this complex group of patients." The rate of thrombosis in the ProCol® group was significantly less than in the ePTFE control group while still offering superior functional patency (59% ProCol® vs. 15% ePTFE) at 24 months.