Because the unique dialysis fistula requirements can theoretically be accommodated by the biomechanic and blood interface properties of the native vasculature, the rationale for the use of a native vein segment as part of an arteriovenous fistula, it seems reasonable to assume that the ideal graft for fistula creation should be derived from a biological source. Attempts to develop bioprosthetic conduits have included utilization of the human saphenous and umbilical veins and xenogeneic carotid arteries. A modified carotid artery graft first introduced in the early 1970s is derived from bovine carotid artery digested to remove all components except collagen. In contrast to arteries, larger caliber veins have a high elastin to collagen ratio related to the requirement to propagate flow. The mesenteric vein in particular has a high ratio of extracellular proteins to cell mass, a complete internal elastic membrane and mural architecture consisting of an inner and outer media oriented approximately 90 degrees to each other providing for radial, circumferential and longitudinal compliance. The ProCol® bioprosthesis is based on the philosophy that the mesenteric vein should be preserved to maintain these desirable natural characteristics. A proprietary method of tissue preservation combines glutaraldehyde crosslinking with gamma irradiation resulting in function mimetic of native veins and also rendering the cellular and extracellular components immunologically silent. Elastin and elastin like polypeptides have been shown to provide a less thrombogenic blood interface surface and the internal elastic lamina which serves as the blood interface may be a contributor to the overall patency.

Clinical experience using ProCol® as a vascular access graft has established its versatility in providing a site for hemodialysis with particular success in patients representative of the vast majority of the hemodialysis population. **Redo Patients** - In a prospective, multicenter study of patients with at least one prior failed synthetic graft, results for 183 ProCol® grafts were compared to ePTFE grafts. The ProCol® graft provided the patient with superior secondary graft patency (60% at 24 months and 54% at 36 months) over both the same patient’s own prior synthetic graft (18% at 24 months and 10% at 36 months) and a ePTFE reference group (42% at 24 months). Patients receiving the ProCol® graft experienced significant reductions in incidences of thrombosis, infection and interventions and because the wall of this bioprosthesis is nonporous there were no occurrences of seroma. The ProCol® graft provided a means of extending vascular access to this challenging patient population. **Hypercoagulable Patient History** - ProCol® has performed well in patients with diagnosed hypercoagulopathies including lupus and multiple myelomas. Published results show that with postoperative low molecular weight heparin therapy these patients have maintained access via their ProCol® graft without recurrent thrombotic events or episodes of bleeding. **Patients at High Risk of Infection** - In a study of 23 ProCol® and 23 ePTFE patients serious infections occurred significantly more often in the ePTFE group. Of the 7 ePTFE graft infections 6 resulted in explantation with two patient deaths from sepsis. The two infections in the ProCol® group were successfully treated by antibiotic therapy and, in one case, incision and drainage. In a larger study involving 183 ProCol® grafts the risk of infection in the reference group of patients receiving ePTFE was 4.4 fold greater than in the ProCol® cohort. Anecdotal experience has similarly reported success using ProCol® to replace or repair previously infected hemoaccess conduits. **Size Mismatch** - Anastomotic challenges found in the very young, thin or elderly patients, particularly women, are not infrequent. In many instances the major vessel difficulty is the arterial inflow where most conduits present a significant mismatch in size and compliance. The ProCol® graft is well suited to deal with these issues as it can be tapered, crimped or easily banded at the time of implant. Adjustment to the setting can be managed on an intuitive basis due to the tissue characteristics, particularly the accommodating nature of the compliant graft wall. **Thigh Access Grafts** - The thigh is often the last resort after other sites have failed. When this position is not utilized, patients may be left with long term catheter dialysis as their only dialysis option. Secondary patency at 24 months was 71% in 50 patients receiving the ProCol® bioprostheses as an access graft in the thigh position.

The ProCol® graft demonstrates that with the proper choice of tissue source and processing designed to maintain the characteristics of the native tissue the objective of providing a conduit filling the requirements of an ideal access site can be achieved.