

TriActiv FX™ System

a report by

Kensey Nash Corporation

Cardiovascular surgeons performing coronary artery bypass grafting (CABG) procedures for coronary artery disease (CAD) frequently utilise the saphenous vein as the bypass graft. However, these vein grafts typically become diseased with increasing frequency, from three years after implantation, and have an average lifespan of between five and 10 years. Approximately 75% will develop significant narrowing and almost half will have occluded within 10 years of surgery.¹ Saphenous vein graft (SVG) disease is an expedited form of atherosclerotic disease common to native arteries. These lesions are thrombotic, friable and often diffuse and are therefore predisposed to embolisation during intervention, with resulting complications ranging from transient ischaemia, slow or no-reflow to myocardial infarction (MI) and death.²⁻⁴

The clinical frequency of spontaneous or provoked microvascular obstruction occurs in a far greater number of patients than ever envisioned. Many studies now show a clear relationship between microvascular obstruction and deleterious long-term clinical outcome and survival,³ with associated increase in mortality.⁵

The revolutionary TriActiv FX™ system has been developed to protect the microvasculature from the unpredictable event of distal embolisation and the resulting sequelae that may occur during SVG intervention.

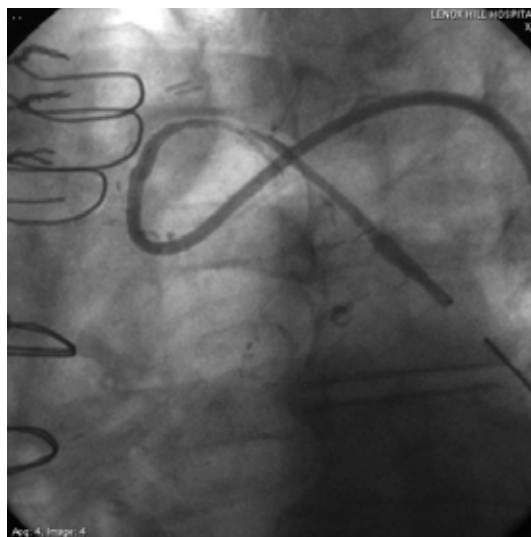
The TriActiv FX system includes active protection of the target vein graft with a protection balloon, followed by active flush and extraction of debris from the treated vessel, thus preventing embolisation to the distal vascular bed.

Active Protection

Atherothrombotic debris liberated in the target vessel during percutaneous coronary intervention (PCI) is trapped by temporarily occluding the vessel distal to the target lesion via a compliant CO₂-filled balloon integrated with a 0.014" guidewire (ShieldWire™ balloon guidewire).

The protection balloon is inflated with a pre-filled CO₂ inflator (ShieldWire Inflator) during contrast injection prior to treatment, trapping contrast in the vessel and creating a 'protected space' whereby debris cannot migrate distally to the microvasculature. Superior visibility of the vessel is possible due to the standing column of contrast contained by the balloon.

Figure 1



1. Goldmann S, Zadina K, Moritz T et al., "Long-Term Patency of Saphenous Vein and Left Internal Mammary Artery Grafts After Coronary Artery Bypass Surgery", *JACC* (2004);44: pp. 2,149-2,156.
2. Watson P S et al., "Angiographic and Clinical Outcomes Following Acute Infarct Angioplasty on Saphenous Vein Grafts", *Am. J. Cardiol.* (1999);83: pp. 1,018-1,021.
3. Topol E J, Yadav J S, "Recognition of the Importance of Embolization in Atherosclerotic Vascular Disease", *Circulation* (2000);101: p. 570.
4. Skyschally A et al., "Coronary Microembolization", *Circ. J.* (2003);67: pp. 279-286.
5. Hong M K et al., "Creatine Kinase-MB Enzyme Elevation Following Successful Saphenous Vein Graft Intervention Is Associated With Late Mortality", *Circulation* (1999);100: pp. 2,400-2,405.

Figure 2: TriActiv FX™ Mechanisms of Action – Protect, Flush and Extract

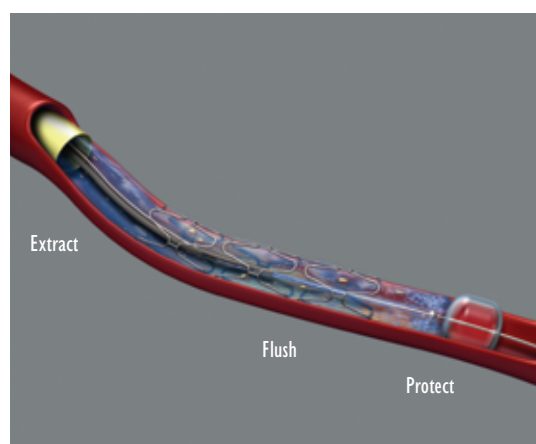


Figure 3: TriActiv FX™ System



Active Flush and Extraction

Once the interventional procedure has been performed, a monorail flush catheter (FX™ catheter) is advanced over the integrated balloon guidewire. The FX catheter is primed with normal saline, loaded onto the ShieldWire balloon guidewire and advanced to the tip stop located proximal to the balloon on the guidewire.

The AutoStream™ flow control is switched on and extraction utilising a piston pump and diaphragm pump extraction system is commenced via the guide catheter (connected via a two-armed TriActiv Tuohy to the flow control), thereby removing debris from the vessel. Active flushing dislodges debris from the balloon surface, vessel wall and stent struts.

The FX catheter is withdrawn back into the guide catheter and TriActiv Tuohy and turning off the AutoStream flow control ceases flush and extraction. The ShieldWire balloon is deflated and blood flow is restored to the target vessel. The TriActiv FX System is the only distal embolic protection system to actively and uniformly flush and extract debris from the target vessel.

The TriActiv FX system is indicated for protection of saphenous vein grafts during PCI with subsequent product extensions to include protection of native coronary arteries and carotid arteries during intervention. Future applications may include the peripheral vasculature.

The advantages of the TriActiv FX system include:

- ease of use, including no wire preparation time;
- low balloon crossing profile (and less requirement for pre-dilation of the lesion to allow the wire to cross the lesion);
- rapid inflation and deflation of the balloon with CO₂ allowing visibility of the vessel with a standing column of contrast (rapid balloon inflation with CO₂ allows more complete contrast capture);
- complete vessel wall apposition;
- entrapment of debris and humoral vaso-active factors;
- no extruded debris that may occur upon retrieval of filter baskets;
- no limit on the amount of retrieved material;
- control over vessel occlusion;
- shorter 'landing zone' requirements distal to the target lesion;
- automated active flushing and extraction, flushing of the balloon surface, vessel wall and stent struts for adherent debris;
- multiple catheter exchanges over the sealed ShieldWire balloon guidewire; and
- guidewire sealing until balloon deflation is required.

The TriActiv FX system was developed by the Kensey Nash Corporation. ■