

Orbital Atherectomy with ViperWire Advance® Coronary Guide Wire with Flex Tip Guidewire in a Heavily Calcified Ostial Left Anterior Descending Artery Lesion after Successful Intervention in a Circumflex Chronic Total Occlusion

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Diamondback 360® Coronary Orbital Atherectomy System (Cardiovascular Systems, Inc.) performs successfully in heavily stenosed anatomies, demonstrating a less than 1 percent no cross rate in severely calcified lesions.¹ Using the Diamondback system with the new nitinol coronary ViperWire Advance® with Flex Tip atherectomy guidewire (Cardiovascular Systems, Inc. Figure 1) we successfully treated a severely stenosed ostial lesion.

A 68-year-old woman with prior coronary bypass graft surgery presented with progressive exertional dyspnea. She had undergone percutaneous coronary intervention of a proximal circumflex 12 months prior, followed by occlusive in-stent restenosis. Five months prior she had undergone an unsuccessful percutaneous coronary intervention (PCI) attempt of the circumflex chronic total occlusion (CTO). Stress testing revealed anterior and lateral ischemia. Coronary angiography demonstrated occlusion of the ostial circumflex (arrowhead, Figure 1A) with a lesion in the left anterior descending artery (LAD, arrow, Figure 1A) ostium and diffuse disease in the mid LAD (asterisk, Figure 1A) proximal to the left internal mammary artery graft (LIMA) distal anastomosis (arrow, Figure 1B). A saphenous vein graft (SVG) to the obtuse marginal branch (Figure 1C) and a SVG to the right posterior descending artery (PDA) were both patent. The instantaneous wave-free ratio (iFR) in the large first diagonal branch was 0.78. A decision was made to intervene on both the ostial circumflex CTO and the ostial LAD lesion.

The circumflex CTO was crossed using an angulated catheter (Figure 1E) and a stiff polymer-jacketed guidewire (Figure 1F), and balloon angioplasty restored antegrade flow. Intravascular ultrasonography showed a severe lesion in the LAD ostium with heavy calcification and minimum



TRACKABILITY Shapeable floppy tip and flexible nitinol body for navigation in complex anatomy

Nitinol core 2.5 cm 1.0 g tip with stainless steel support coil (.014")



PERFORMANCE Flexible nitinol body providing reduced wire bias in complex anatomy, plus kink resistance

Solid nitinol core, 325 cm length (.012")



lumen area of 3.0 mm² (Figure 2B). A ViperWire Advance with Flex Tip (CSI) atherectomy guidewire was advanced into the diagonal branch. After removal of the other LAD and the circumflex guidewire, the Diamondback crown was slowly advanced across the lesion maintaining a 1mm per second speed, gentle forward and back motion and maintaining 1:1 motion between the crown and advancer. The duration of runs was kept <15 seconds to minimize the risk of distal embolization and >60 second pauses were held in-between runs to allow recovery of the microcirculation. Initially, there was a high pitch sound during atherectomy, which was no longer present at the end of atherectomy, suggesting effective plaque modification. The electrocardiogram and pressure tracing were carefully monitored during orbital atherectomy runs and did not show any change, hence coronary angiography was only performed after atherectomy was completed. Six runs of orbital atherectomy were performed at a speed of 80,000 rpm. Subsequent balloon inflation showed good balloon expansion (Figure 2E).

After implantation of a crossover stent from the left main into the LAD and POT (proximal optimization technique) with a 4.0x8 mm non-compliant balloon an excellent final result was achieved. The patient had an uneventful post-procedural course and her dyspnea resolved.

Severe calcification can hinder both wire and balloon crossing, as well as equipment delivery and stent expansion. In our case, the microcatheter provided strong guidewire support that enabled crossing of the circumflex CTO.² The ostial LAD lesion was causing significant ischemia, as confirmed by iFR measurement. Orbital atherectomy was able to cross and treat this heavily stenosed lesion. Instead of replacing the existing workhorse LAD guidewire for a ViperWire Advance over a microcatheter, the LAD was directly wired with the more flexible ViperWire Advance with Flex Tip which provides excellent trackability and performance.³ Excellent lesion and stent expansion were achieved with resolution of the patient's symptoms.

Figure 1. Coronary angiography demonstrating an ostial circumflex chronic total occlusion (arrowhead, panel A), with a severe ostial left anterior descending artery lesion (arrow, panel A) and diffuse disease in the mid LAD (asterisk, panel A). The LIMA to LAD (panel B), saphenous vein graft to the obtuse marginal branch (panel C) and saphenous vein graft to the right posterior descending artery (panel D) were patent. The circumflex chronic total occlusion was successfully crossed using a microcatheter (panel E) and a guidewire (panel F).

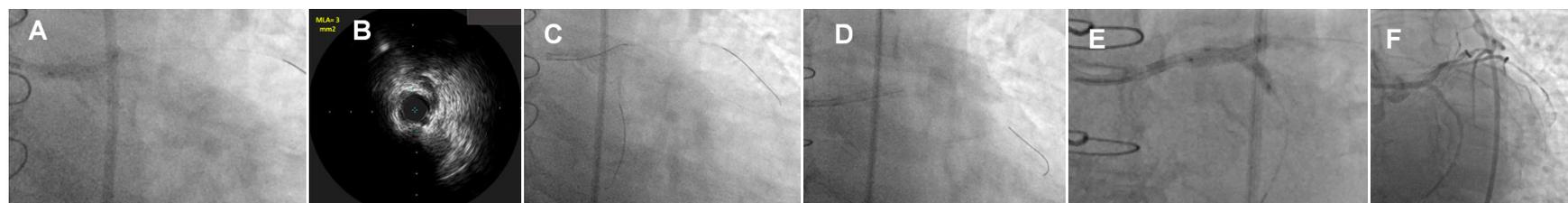
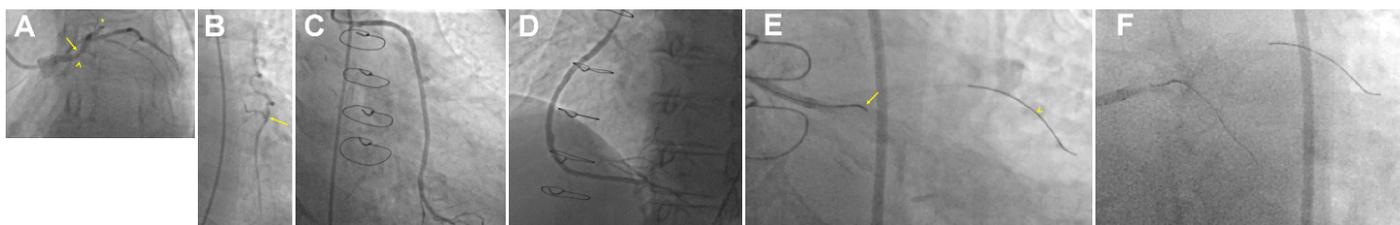


Figure 2. The proximal LAD lesion was undilatable despite multiple balloon inflations (panel A). Intravascular ultrasound revealed severe calcification (panel B). The LAD was wired using the ViperWire Flex Tip which has a reduced wire bias⁴ (panel C) and six orbital atherectomy runs were performed (panel D), leading to LAD lesion expansion (panel E) and an excellent final result after stenting (panel F).

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References

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- In comparison with ViperWire Advance® Coronary Guide Wire.

Indication: The Diamondback 360 Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to *de novo*, severely calcified coronary artery lesions. **Contraindications:** The OAS is contraindicated when the ViperWire Advance® Coronary Guide Wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children. **Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage. The OAS was only evaluated in severely calcified lesions. A temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated. See the instructions for use before performing Diamondback 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.