

SEVERE CALCIUM. ONE SOLUTION.



➤ **DUAL-ACTION** ➤ **VERSATILE** ➤ **PROVEN**

**ONLY ORBITAL ATHERECTOMY
BRINGS IT ALL TOGETHER**

The Diamondback 360[®] Orbital Atherectomy System is a single solution for severely calcified coronary artery disease, with proven success in challenging anatomies and lesions. Enabling treatment of both intimal and medial calcium with one device, Diamondback[®] sands surface lesions and facilitates fracture of medial calcium to optimize stent delivery, expansion and apposition.¹⁻⁵

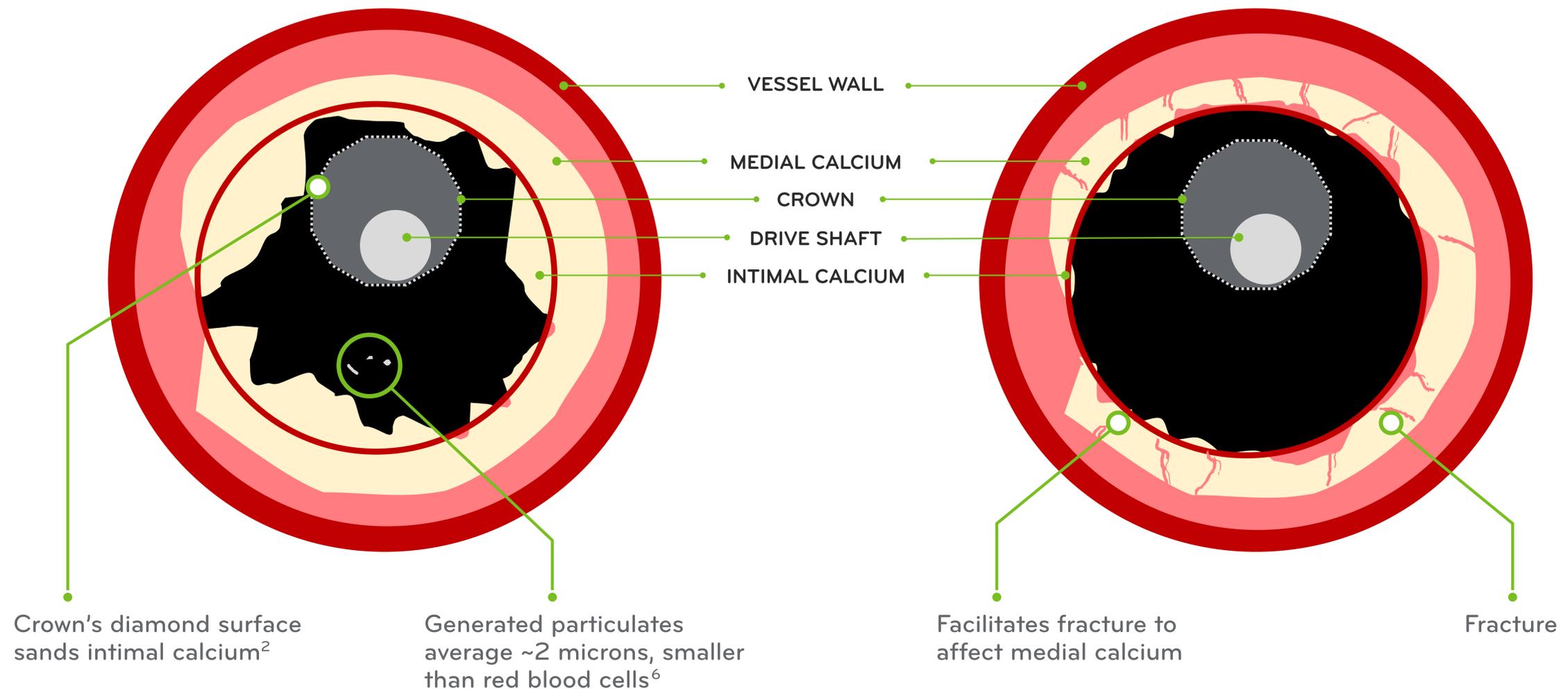
DUAL-ACTION

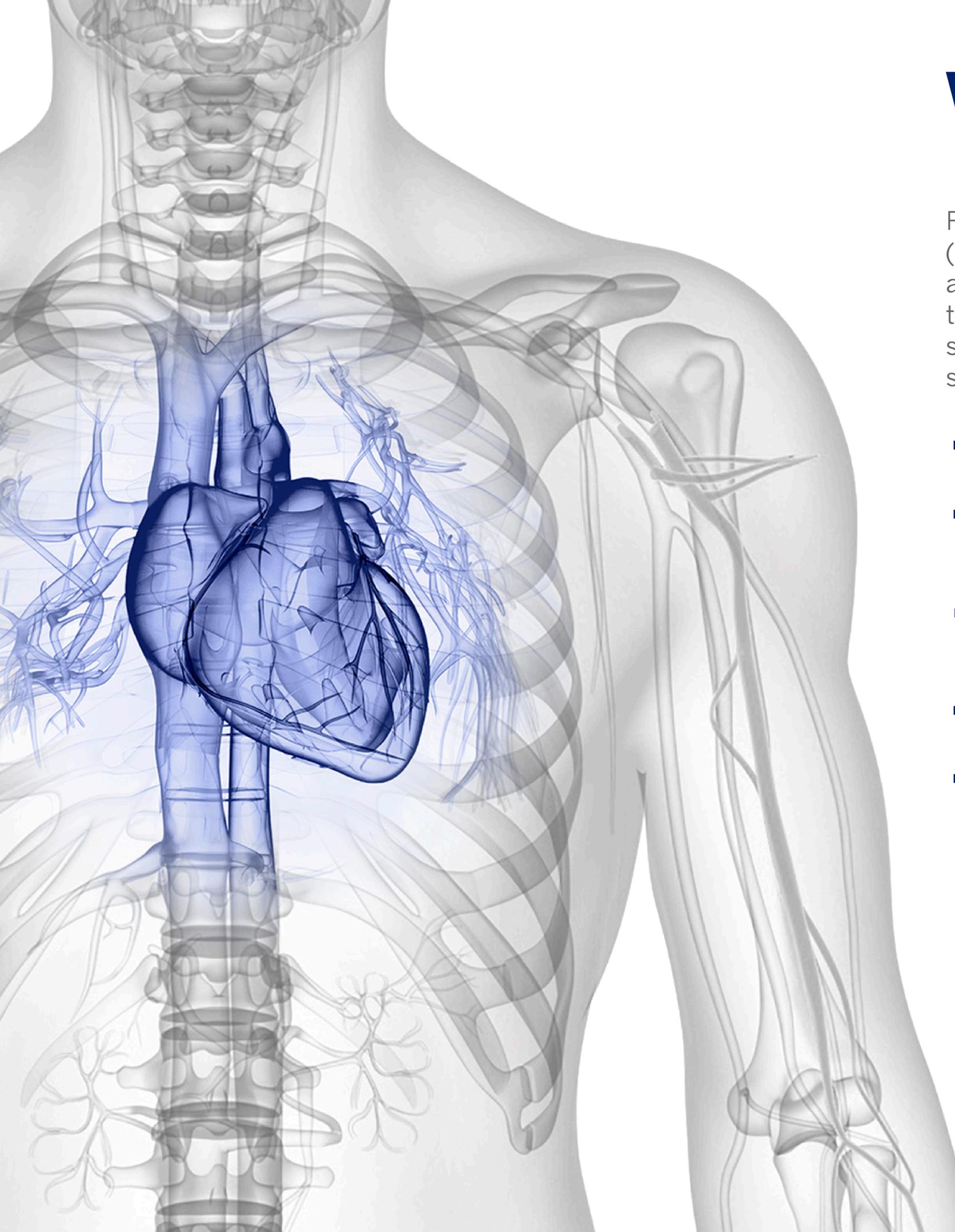
Uniquely designed for calcium: Enables simultaneous modification of both intimal and medial calcium for optimal stent delivery, expansion and apposition in severely calcified lesions. One device treats eccentric, concentric, and nodular calcium.¹⁻⁵

Combines differential sanding and pulsatile forces to safely, effectively and efficiently treat severely calcified lesions.^{1,2,6}

MODIFIES INTIMAL CALCIUM⁵

FACILITATES FRACTURE OF MEDIAL CALCIUM⁵





VERSATILE

Patients with percutaneous coronary intervention (PCI) procedures can be challenging. Orbital atherectomy gives you the versatility to treat those challenging cases, including the most severely calcified lesions, with under 2-minute setup and predictable procedure times.⁶

- **OSTIAL LESIONS**

Safely treats ostial lesions.⁷

- **HEAVILY STENOSED LESIONS**

Crossed **>99%** of lesions with **<2%** pre-dilatation in the ORBIT II study.^{1,8}

- **LONG, DIFFUSE LESIONS**

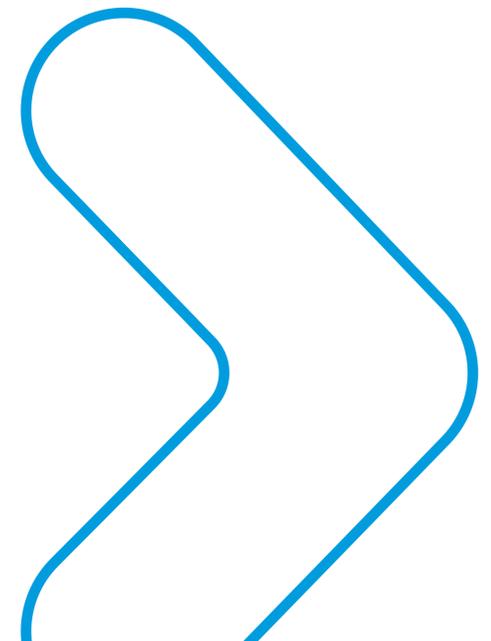
Successfully treated lesions up to **60 mm** in length in real-world study.⁹

- **LOW PROFILE**

6 Fr compatible.

- **MULTIPLE VESSEL SIZES**

Treats a range of vessels enabling **single device treatment** of multiple lesions and vessel sizes.



PROVEN

Extensively studied, and with over 85,000 patients treated, orbital atherectomy has been demonstrated to perform effectively and safely in the treatment of severely calcified lesions.

EXTENSIVELY STUDIED
>2,200
PATIENTS ACROSS
11 ROBUST STUDIES^{5,9}

PROVEN SAFETY
<1%
COMPONENT ANGIOGRAPHIC
COMPLICATIONS IN
2 REAL-WORLD STUDIES^{9,10}

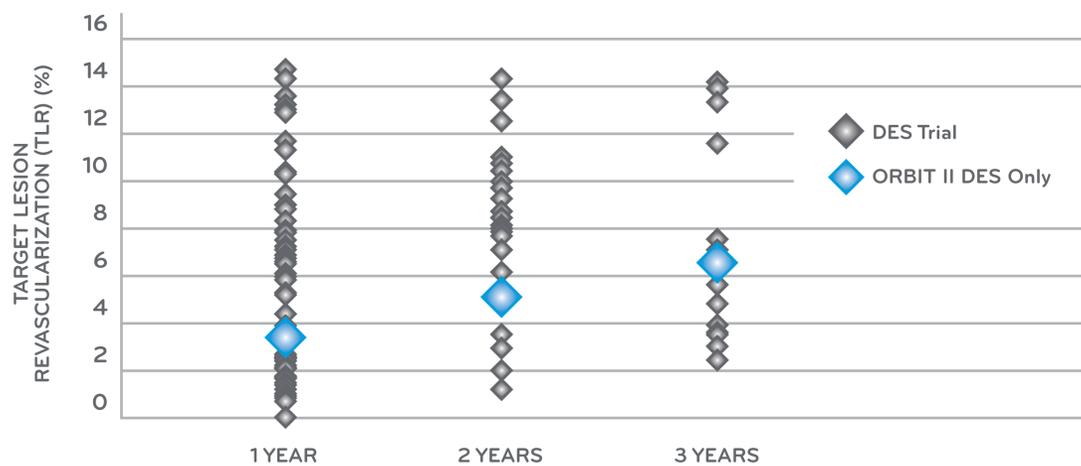
PROCEDURAL SUCCESS
100%
CROSSING AND STENT
DEPLOYMENT IN
REAL-WORLD STUDY⁹

LOW Q-WAVE MI RATE
0.9%
IN THE ORBIT II STUDY
AT 30 DAYS¹

SUSTAINED CLINICAL PERFORMANCE

3.4% TLR AT 1 YEAR AND 6.6% AT 3 YEARS WITH DES

ORBIT II Target Lesion Revascularization¹²



The ORBIT II trial included patients with severely calcified lesions and demonstrated low rates of TLR at 1 and 3 years. Drug Eluting Stent (DES) trials shown here did not all include severe calcium and long term results vary.



DIAMONDBACK 360[®]

CORONARY ORBITAL ATHERECTOMY SYSTEM

Prepping vessels with the Diamondback 360[®] Coronary OAS can provide a wide variety of benefits ranging from streamlined procedures and optimal stent placement to durable patient outcomes and reduced costs.

Easy setup and prep <2 minutes⁶
Single 1.25 mm crown

DIAMONDBACK 360[®]
CORONARY ORBITAL ATHERECTOMY SYSTEM



For more information, please contact your local CSI representative or call **1-877-274-0901**.

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.

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1. Chambers J, et al. JACC Cardiovasc Interv. 2014;7(5):510-518.
2. Shlofmitz E, et al. Expert Rev Med Devices. 2017;14(11):867-879.
3. Yamamoto M, et al. Catheter Cardiovasc Interv. 2019;93(7):1211-1218.
4. Kini A, et al. Catheter Cardiovasc Interv. 2015;86(6):1024-1032.
5. Shlofmitz E, et al. Interv Cardiol. 2019;14(3):169-173.
6. CSI Data on File.
7. Lee, et al. J Interven Cardiol. 2018;31:15-20.
8. CSI Data on file. In the ORBIT II study, the OAS was inserted and activated in 434 subjects, but in 2 cases, the OAS was unable to cross the lesion.
9. Vinardell, TCT2020, No. 165.
10. Lee M, et al. Cardiovasc Revasc Med. 2017 Jun;18(4):261-264.
11. Genereux P, et al. Am J Cardiol 2015;115(12):1685-1690.
12. Lee MS, et al. Coronary Orbital Atherectomy. 2018. P. Lanzer (ed.), Textbook of Catheter-Based Cardiovascular Interventions, https://doi.org/10.1007/978-3-319-55994-0_42. Note: These data are from different studies that differ in terms of treatment protocols, inclusion/exclusion criteria, patient populations, among other things. Physicians should draw their own conclusions based on the findings in the respective publications.



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