Diamondback 360[™]

Coronary Orbital Atherectomy System

SEVERE CALCIUM. ONE SOLUTION.

DUAL-ACTION + VERSATILE + PROVEN







DIAMONDBACK 360™ CORONARY ORBITAL ATHERECTOMY SYSTEM (OAS)

Diamondback 360[™] is the only atherectomy system with a diamond-coated crown that orbits 360 degrees, specifically designed to target severe calcium for optimal stent delivery, expansion and apposition.^{1,2-4}

SINGLE 1.25 MM CROWN

eccentrically mounted diamond-coated crown with bi-directional capabilities that treats a range of vessels enabling single device treatment of multiple lesions and vessel sizes



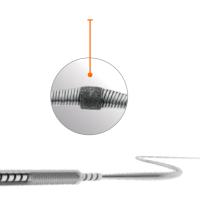
makes device power up effortless

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DIAMONDBACK360

GLIDEASSIST™

enables the crown to spin at a slower speed for easy tracking and device removal



VIPERWIRE ADVANCE™ NITINOL

coronary nitinol guide wire with flex tip

ELECTRIC-POWERED HANDLE WITH SMART SUITE SOFTWARE^{5,6}

allows two-minute set up and features software designed to maintain and monitor device function[†]

TWO CONVENIENT SPEED CONTROLS

allow for quick speed adjustments within the sterile field

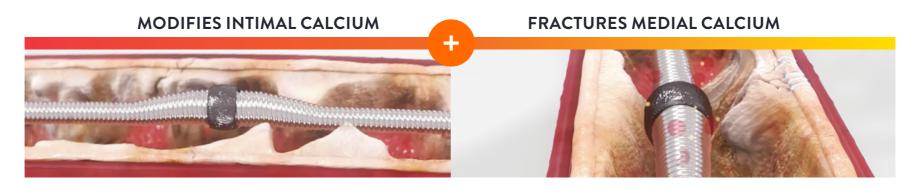
Data on file at Abbott, unless otherwise noted. See references on page 7. † Set up times may vary.

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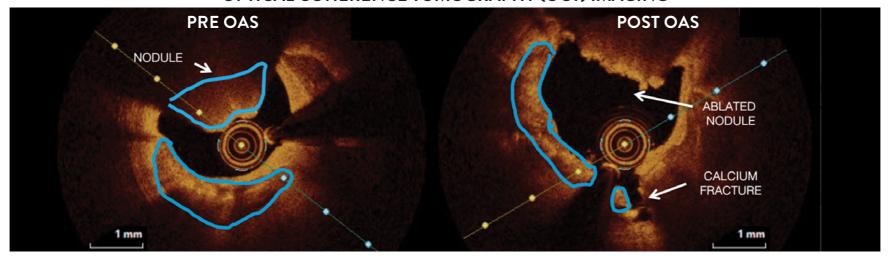


DUAL-ACTION

Uniquely designed for calcium: Differential sanding and pulsatile forces enable 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.^{1,2-4,7,8}



OPTICAL COHERENCE TOMOGRAPHY (OCT) IMAGING





VERSATILE

Patients with percutaneous coronary intervention procedures can be challenging. Diamondback 360™ OAS gives you the versatility to treat those challenging cases, including the most severely calcified lesions, with under 2-minute setup^{5,6} and predictable procedure times.²

Facilitates antegrade and retrograde treatment of:

LONG, DIFFUSE LESIONS
 Successfully treated lesions up to 60 mm in length in real-world study.⁹

• HEAVILY STENOSED LESIONS

Crossed >99% of lesions with <2% pre-dilatation in the ORBIT II study.^{1,10}

NODULAR LESIONS

Effectively treats nodular calcification.^{7,8}

OSTIAL LESIONS

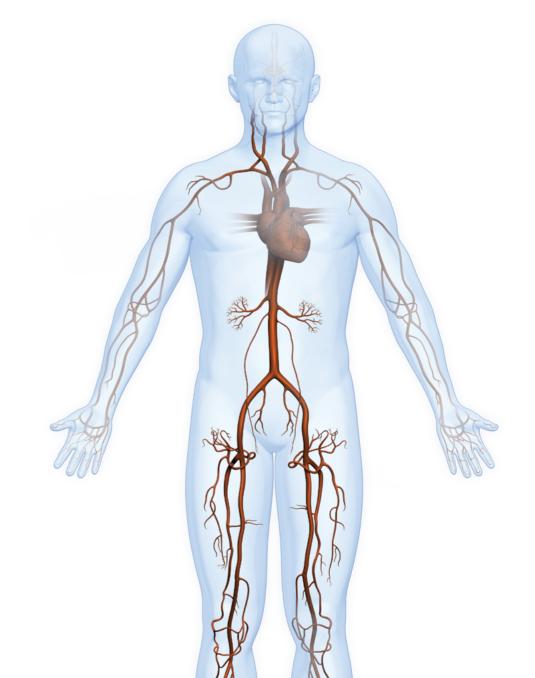
Safely treats ostial lesions.¹¹

Low Profile

6F compatible for femoral or radial access.

Multiple Vessel Sizes

Single device treatment of multiple lesions and vessel sizes.



See references on page



PROVEN

Extensively studied, and with over 100,000 patients treated, orbital atherectomy has been demonstrated to perform effectively and safely in the treatment of severely calcified lesions.

>2,200
Patients Across
11 Robust Studies^{7,9}

PROVEN SAFETY

<1%

Component Angiographic Complications in Two Real-world Studies^{9,12} **PROCEDURAL SUCCESS**

97.7%

Crossing and Stent Deployment in ORBIT II Study¹ **LOW Q-WAVE MI RATE**

0.9%

In the ORBIT II Study at 30 days¹

ORBIT II TARGET LESION REVASCULARIZATION (TLR)13

Sustained Clinical PerformanceData are for ORBIT II TLR in the OA+DES

3.4% AT1YEAR

5.1% AT 2 YEARS 6.6% AT 3 YEARS

The ORBIT II trial included patients with severely calcified lesions and demonstrated low rates of TLR at 1, 2, and 3 years.

patient cohort.



PRODUCT ORDERING INFORMATION

Diamondback 360™ Orbital Atherectomy Device

MODEL NUMBER	CROWN SIZE	LENGTH	QUANTITY
C-2DB-CL125-135	1.25 mm Classic	135 cm	1 each

ViperWire Advance™ Coronary Guide Wire with Flex Tip

MODEL NUMBER	DESCRIPTION	LENGTH	QUANTITY
GWC-12325LG-FT	.012" Shaft/.014" Flex Tip	325 cm	5 per box

ViperSlide™ Lubricant

MODEL NUMBER	DESCRIPTION	QUANTITY
VPR-SLD2	100 mL Bag	10 bags per box

OAS Pump

MODEL NUMBER	DESCRIPTION	QUANTITY
SIP-3000	Saline Pump	1 each



- 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. Lee, MS, et al., J Invasive Cardiol. 2016;28(4):147-150.
- Moses, J., Cardiac Interventions Today. 2015; May/June:75. Link accessed November 20, 2023. https://citoday.com/articles/2015-may-june/vessel-preparation-with-orbital-atherectomy-for-treating-severe-coronary-calcium-for-stent-delivery.
- 7. Shlofmitz, E., et al., *Interv Cardiol*. 2019;14(3):169-173.
- 8. Abellas-Sequeiros, M., et al., REC Interv Cardiol. 2022;4(2):163-164.
- 9. Beohar, N., Orbital Atherectomy for Treating De Novo Severely Calcified Coronary Lesions. A Tertiary Center Experience, Presented at TCT Connect 2020.
- 10. Data on file at Abbott (CLN-0001-R.D_ORBIT II Clinical Report). 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.
- 11. Lee, et al., J Interv Cardiol. 2018;31(1):15-20.
- 12. Lee, MS, et al., J Interv Cardiol. 2016;29(4):357-362.
- 13. Data on file at Abbott (CLN-0001-R.D supplement: Kaplan-Meier Tables 3-year data-stent type 05Feb16).

These instructions do not replace the Diamondback 360^{TM} Coronary OAS with GlideAssistTM Instructions for Use (IFU). Refer to the Diamondback 360^{TM} Coronary OAS with GlideAssistTM IFU for the use and operation of the Diamondback 360^{TM} Coronary OAS.

Diamondback 360^{TM} Coronary Orbital Atherectomy System is manufactured and distributed by Cardiovascular Systems, Inc. (CSI). CSI is a subsidiary of the Abbott Group of Companies.

CAUTION: These products are intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott, at medical.abbott/manuals or at csi360.com/product-solutions/instructions-for-use/ for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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