ORBITAL ATHERECTOMY BY THE NUMBERS

REAL-WORLD ANGIOGRAPHIC COMPLICATIONS AND 30-DAY MI:[8]
(Lee MS, et al. Study: real-world multi-center retrospective study.)

0.7% Slow flow/no reflow

0.7% Perforation

0.9% Dissection

1.1% MI

PROCEDURAL EFFICIENCY:[7]
(Chambers J, et al.: PMA pivotal trial that is core lab adjudicated with common protocol.)

18.2 min Average fluoroscopy time

52.5 min Average procedure time

STENT EXPANSION AND WALL APPOSITION:[9]
(Kini A, et al.: Study assessing the mechanistic effect of RA & OA using OCT.) n=20

4.4% Malapposed struts

91.6% Average stent expansion

DURABLE OUTCOMES:[10]
(Généreux P, et al. Am J Cardiol ORBIT II 1-year results.)

3.4% TLR-rate at 1 year in DES patients

DURABLE OUTCOMES:[11]
(Chambers J, et al.: PMA pivotal trial that is core lab adjudicated with common protocol.)

17% Lower procedural cost with fewer complications and decreased length of stay compared to Medicare data and HORIZONS-AMI/ACUITY trials

Note: These data points come 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 of the respective publications. Contact CSI Scientific Communications for more information at 651-202-4861.

DIAMONDBACK 360™ AT-A-GLANCE

1. **Diamondback 360 OAS Device / Handle**

2. **ViperWire Advance™ Coronary Guide Wire with Flex Tip:**
   Designed to be easy to use and to provide tactile feedback to increase physician's ability to navigate the wire throughout the vessel.

3. **ViperSlide™ Lubricant:**
   ViperSlide increases the lubricity, therefore reducing friction between the device and the *ViperWire Advance* Guide Wire.

4. **OAS Pump:**
   The OAS Pump keeps pace with the evolving Cath Lab environment, focusing on safety, simple set up and ease of use.

5. **1.25 mm Eccentrically Mounted Diamond-Coated Crown:**
   Orbiting diamond-coated crown combining bi-directional differential sanding and pulsatile force to safely, effectively and efficiently treat severely calcific lesions.

DIAMONDBACK 360™
CORONARY ORBITAL ATHERECTOMY SYSTEM

DIAMONDBACK 360™ ORBITAL ATHERECTOMY DEVICE

Model #	Crown Size	Shaft Length	Quantity
C-2DB-CL125-135	125 mm Classic	135 cm	1 each

VIPERWIRE ADVANCE™ CORONARY GUIDE WIRE

Model #	Size	Shaft Length	Quantity
NEW GWC 12325LG-FT	0.012"/0.014" Flex Tip	325 cm	5 per box

VIPERSLIDE™ LUBRICANT

Model #	Description	Quantity
VPR-SLD2	100 mL Package	10 bags per box

OAS PUMP

Model #	Description	Quantity
SIP-3000	OAS Pump	1 each

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, or has hypersensitivity to egg-, soya-, or peanut protein or to any of the active substances or excipients of the *ViperSlide™* lubricant 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; Patients with ejection fractions (EF) less than 30% may require additional precautions due to compromised heart function. 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.

1. Généreux P, et al. J Am Coll Cardiol. 2014;63:1845-54.
2. Bourantas CV, et al. Heart. 2014;100:1158-64.
3. Mintz GS. JACC Cardiovasc Imaging. 2015;8:461-71.
4. Shlofmitz E, et al. Expert Rev Med Devices. 2017:14(11):867-879.
5. Sotomi Y, et al. Interv Cardiol. 2016;11(1):33-38.
6. CSI data on file: based on cadaver atherosclerotic lesions, porcine coronary lesions and graphite block test models.
7. Chambers J, et al. JACC Cardiovasc Interv. 2014;7(5):510-518.
8. Lee MS, et al. J Interv Cardiol. 2016;29(4):357-362.
9. Kini A, et al. Catheter Cardiovasc Interv. 2015;86(6):1024-1032.
10. Généreux P, et al. Am J Cardiol 2015;115(12):1685-1690.
11. Chambers J, et al. Ther Adv Cardiovasc Dis. 2016;10(2):74-85.
12. Yamamoto M, et al. Catheter Cardiovasc Interv. 2019;93(7):1211-1218.
13. Shlofmitz E, et al. Interv Cardiol. 2019;14(3):169-173.

DIAMONDBACK 360™
CORONARY ORBITAL ATHERECTOMY SYSTEM

THE SMART SOLUTION

FOR COMPLEX PCI PATIENTS

FLEXIBLE TO THE CORE

INTRODUCING:

VIPERWIRE Advance™
CORONARY GUIDE WIRE WITH FLEX TIP

NEW NITINOL CORONARY GUIDE WIRE

.014" TIP DIAMETER
.012" CORE DIAMETER
16.5 CM GRIND LENGTH

SHAPEABLE TIP

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

REDUCED WIRE BIAS

PERFORMANCE
Flexible *nitinol* body providing reduced wire bias in complex anatomy and improved kink resistance to allow for advanced vessel prep in severe calcium

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THE ORBITAL ADVANTAGE

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.[4,7,9,12-13]
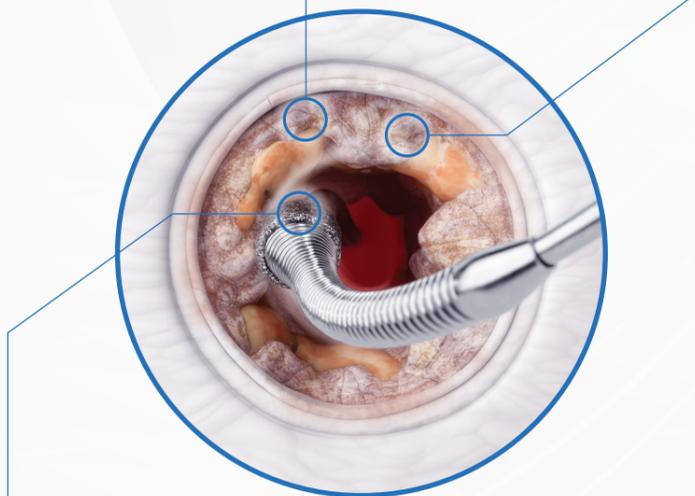
DUAL ACTION

Combines differential sanding and pulsatile forces to safely, effectively and efficiently treat severely calcified lesions.[4,6,7]

MODIFIES INTIMAL CALCIUM[4]

FACILITATES FRACTURE OF MEDIAL CALCIUM[4]

PROCEDURAL SAFETY[5]

• Healthy tissue safely flexes away from the crown reducing impact to the medial layer.

• Continuous blood and saline flow during orbit minimizes risk of thermal injury and slow flow/no reflow events.

DIAMONDBACK 360™
CORONARY ORBITAL ATHERECTOMY SYSTEM

CONVENIENT, TWO-SPEED CONTROLS
allow for quick speed adjustments within the sterile field.

• **ONE-TOUCH, START BUTTON** makes device power up effortless.

ELECTRIC-POWERED HANDLE
allows two-minute set up and provides efficient torque transfer to the shaft and crown.*

• **ORBITAL DIAMOND COATED CROWN**

• A single 6 Fr, 1.25 mm crown treats vessels 2.5 to 4.0 mm[6]

• 2.5 mm vessel access enables radial approach

*Set up times may vary

INTRODUCING *GLIDEASSIST*™

GLIDEASSIST FEATURE
GlideAssist is the innovative solution that allows for easier tracking and removal and smoother repositioning of the device — especially in challenging anatomies.*

DESIGNED TO REDUCE PROCEDURAL TIME WITH 5 EASY STEPS:

1. Enable *GlideAssist* Mode

2. Secure Guide Wire

3. Spin in *GlideAssist* Mode

4. Stop Spinning in *GlideAssist* Mode

5. Disable *GlideAssist* Mode

*CSI data on file