

DIAMONDBACK 360[®]
CORONARY ORBITAL ATHERECTOMY SYSTEM



THE SMART SOLUTION

FOR COMPLEX PCI PATIENTS

FLEXIBLE TO THE CORE:

The first nitinol coronary atherectomy guide wire delivering a winning combination with nitinol core and stainless steel shapeable tip.

NEW
NITINOL
CORONARY
GUIDE WIRE

INTRODUCING:

VIPERWIRE Advance[®]
CORONARY GUIDE WIRE WITH FLEX TIP



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

TRACKABILITY

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



SHAPEABLE
TIP

PERFORMANCE

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



REDUCED
WIRE BIAS

2 WIRE OPTIONS: VIPERWIRE ADVANCE WITH FLEX TIP AND VIPERWIRE ADVANCE

THE ORBITAL ADVANTAGE

Coronary calcium tends to be underestimated. Severe coronary calcium is present in 6 to 20% of patients undergoing PCI.^{1,2} Calcium considered mild or moderate by angiography may actually be severe in advanced imaging such as intravascular ultrasound (IVUS) or optical coherence tomography (OCT).³

DUAL
MECHANISM
OF ACTION

Diamondback 360[®] Coronary Orbital Atherectomy System (OAS) reduces severe calcium, enabling successful stent delivery to help optimize stent expansion and PCI outcomes.⁷

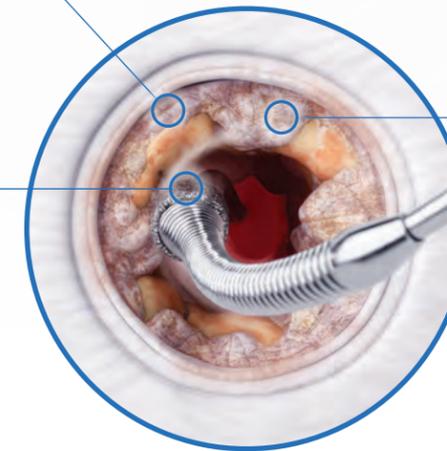
- Bi-directional differential sanding
- Pulsatile forces

DIFFERENTIAL SANDING⁴

The diamond-coated crown sands intimal calcium into particulate with an average size of approximately 2 μm —which is smaller than a capillary vessel.

PULSATILE FORCES⁴

The pulsatile impact of the crown against deep plaque may create microfractures that modify deep calcium.

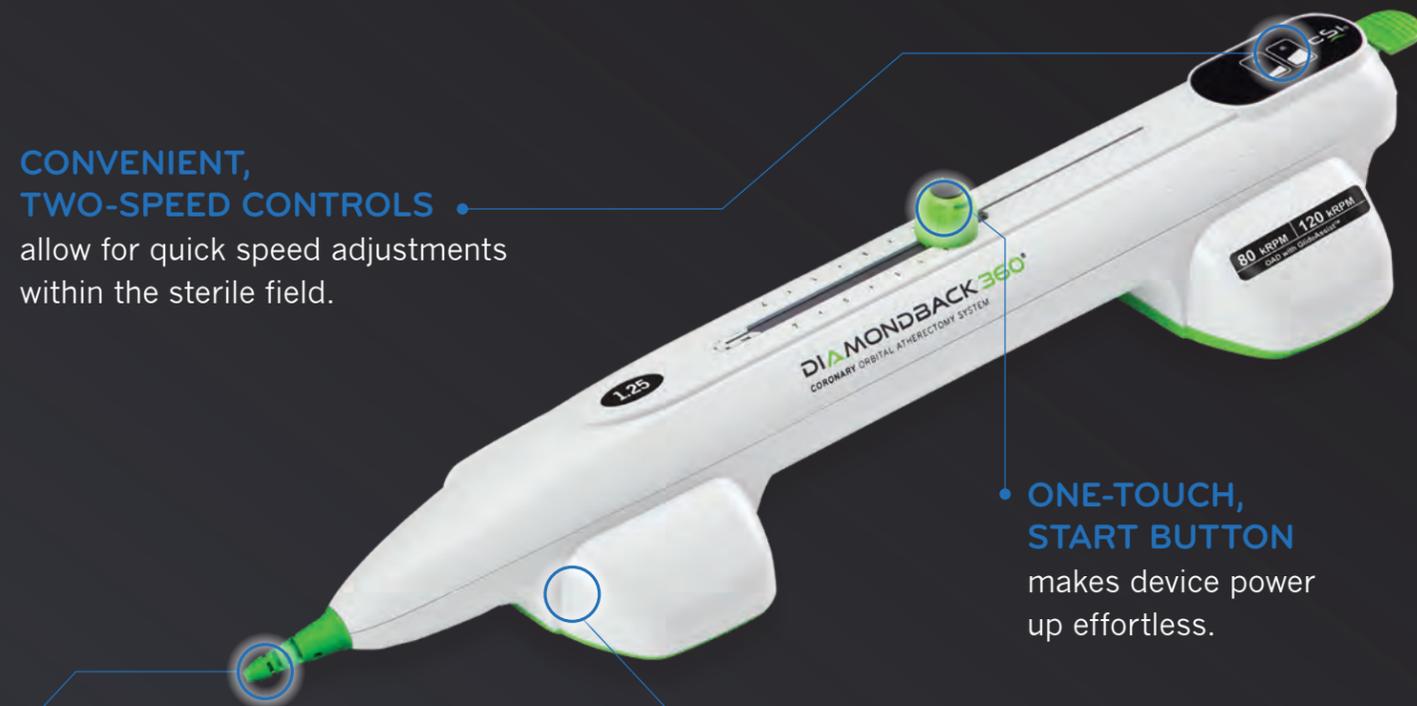


PROCEDURAL SAFETY⁵

With the Diamondback 360 OAS, healthy tissue safely flexes away from the crown during operation, reducing impact to the medial layer. The orbital movement of the crown allows blood and saline to flow continuously during procedures, minimizing risk of thermal injury and slow flow/no reflow events.

**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.*

*Set up times may vary

TREAT 2.5 TO 4.0MM * VESSELS with a single crown through a 6F guide enabling radial access.⁶

Orbiting diamond-coated crown combining bi-directional differential sanding and pulsatile force to safely, effectively and efficiently treat severely calcific lesions.^{4,5}

- A single 1.25mm crown treats vessels 2.5 to 4.0mm through a 6F access.⁶
- Reduce plaque while potentially minimizing damage to the medial layer of the vessel.⁴
- With average particulate size of about 2 µm—smaller than a capillary vessel—and continuous blood flow during orbit, Diamondback 360® may reduce risk of slow flow and no reflow.^{4,5}

INTRODUCING GLIDEASSIST®

OPTIMIZING PROCEDURAL WORKFLOW

This feature enables the crown to spin at slow speed (5 kRPM) for easier tracking and removal of the device over the guide wire.*

*CSI Data on file



EASIER TRACKING AND REMOVAL

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

ORBITAL ATHERECTOMY BY THE NUMBERS

Prepping vessels first 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.*

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 APPPOSITION:⁹

(Kini A, et al.: Study assessing the mechanistic effect of RA & OA using OCT.)

- 4.4%** Malapposed struts
- 91.6%** Average stent expansion

DURABLE OUTCOMES:¹⁰

(Genereux P, et al. Am J Cardiol ORBIT II 1-year results.)

- 3.4%** TLR-rate at 1 year in DES patients

REDUCED COST: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. Wire Options:

- a. ViperWire Advance[®] Coronary Guide Wire – Flex Tip Option Now Available
- b. ViperWire Advance Coronary Guide Wire was designed to be easy to use and to provide tactile feedback to increase physicians' 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. It mounts directly onto an I.V. pole and provides power and the pumping mechanism for the Diamondback 360 System.

5. 1.25mm 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® ORBITAL ATHERECTOMY DEVICE

Model Number	Crown Size	Shaft Length	Quantity
DBEC-125	125 mm Classic	135 cm	1 each

VIPERWIRE ADVANCE® CORONARY GUIDEWIRES

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

VIPERSLIDE® LUBRICANT

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

OAS PUMP

Model Number	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 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.

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

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

1225 Old Hwy 8 NW St. Paul, MN 55112

T: 651-259-1600 | 877-274 0901

F: 612-677-3355

W: csi360.com

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