

# ORBITAL ATHERECTOMY IS SAFE AND EFFECTIVE

## REAL-WORLD ANGIOGRAPHIC COMPLICATIONS AND 30-DAY MI:<sup>8</sup>

(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:<sup>7</sup>

(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

## DURABLE OUTCOMES:<sup>10</sup>

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

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

## DURABLE OUTCOMES:<sup>11</sup>

(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**
  - 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.
- 5. 1.25 mm Eccentrically Mounted Diamond-Coated Crown:**

Orbiting crown enables simultaneous modification of both intimal and medial calcium for optimal stent delivery, expansion and apposition in severely calcified lesions.<sup>4,7,9,12,13</sup>

# DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM

DIAMONDBACK 360 ORBITAL ATHERECTOMY DEVICE			
Model #	Crown Size	Shaft Length	Quantity
DBEC-125	125 mm Classic	135 cm	1 each
VIPERWIRE ADVANCE CORONARY GUIDE WIRE			
Model #	Size	Shaft Length	Quantity
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	

**Indications:** 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.

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. Généreux P, et al. Am J Cardiol 2015;115(12):1685-1690.  
10. Chambers J, et al. Ther Adv Cardiovasc Dis. 2016;10(2):74-85.  
11. Yamamoto M, et al. Catheter Cardiovasc Interv. 2019;93(7):1211-1218.  
12. Shlofmitz E, et al. Interv Cardiol. 2019;14(3):169-173.

## MANUFACTURED BY:



CARDIOVASCULAR SYSTEMS, INC.

1225 Old Hwy 8 NW St. Paul, MN 55112  
T: 651-259-1600 | 877-274 0901  
F: 612-677-3355  
W: [csi360.com](http://csi360.com)

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# DIAMONDBACK 360 CORONARY ORBITAL ATHERECTOMY SYSTEM



# THE SMART SOLUTION FOR COMPLEX PCI PATIENTS

## MANUFACTURED BY:



CARDIOVASCULAR SYSTEMS, INC.

# FLEXIBLE TO THE CORE

INTRODUCING:  
**VIPERWIRE Advance**  
CORONARY GUIDE WIRE WITH **FLEX TIP**



NEW  
NITINOL  
CORONARY  
GUIDE WIRE

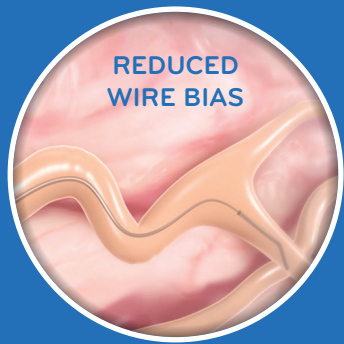
.014" TIP DIAMETER  
.012" CORE DIAMETER  
16.5 CM GRIND LENGTH



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

# 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.<sup>4,7,9,12-13</sup>

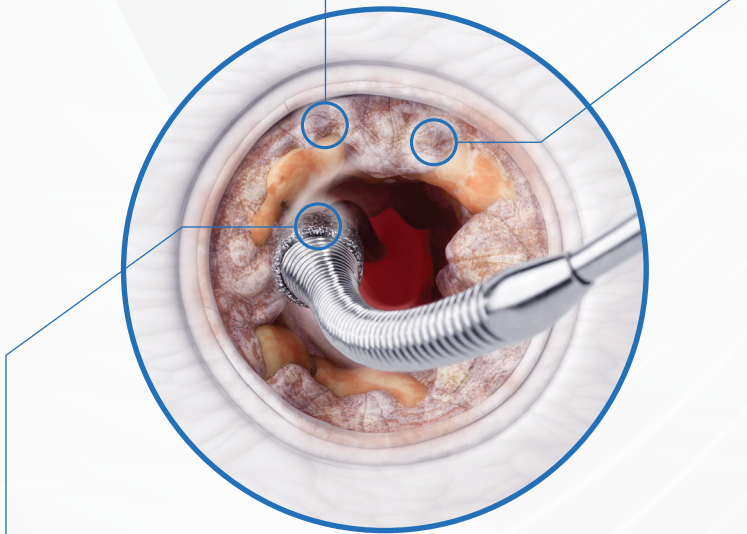


DUAL-ACTION

Combines differential sanding and pulsatile forces to safely, effectively and efficiently treat severely calcified lesions.<sup>4,6,7</sup>

MODIFIES  
INTIMAL  
CALCIUM<sup>4</sup>

FRACTURES  
MEDIAL CALCIUM<sup>4</sup>



## PROCEDURAL SAFETY<sup>5</sup>

- 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.

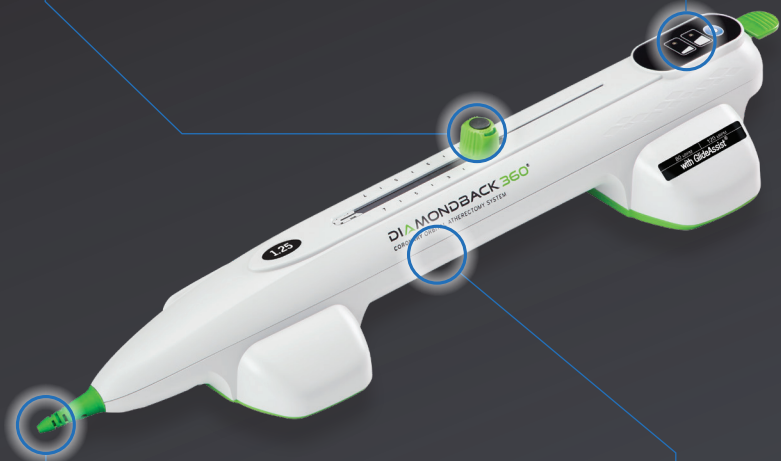
# DIAMONDBACK 360<sup>®</sup>

CORONARY ORBITAL ATHERECTOMY SYSTEM

## CONVENIENT, TWO-SPEED CONTROLS

allow for quick speed adjustments within the sterile field.

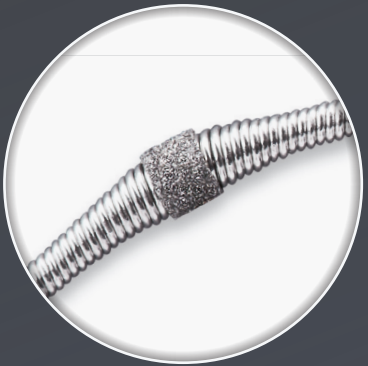
- **ONE-TOUCH, START BUTTON** makes device power up effortless.



- **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<sup>6</sup>
- 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