

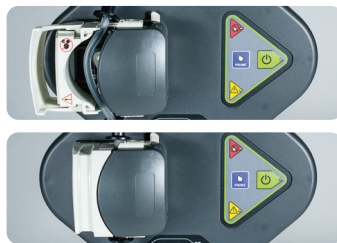
SET-UP GUIDE

DIAMONDBACK 360
CORONARY ORBITAL ATHERECTOMY SYSTEM

- 1** Place prepped 1000 mL volume bag of normal saline and 20 mL of *ViperSlide* Lubricant on low saline level sensor.



- 2** Open pump door. Insert tubing into the grooved guides of the roller pump (centered between two “black hats”). Close pump door.



- 3** Slide green control knob fully proximal, away from the nose of the handle, and release the brake.



- 4** Connect saline line to handle.



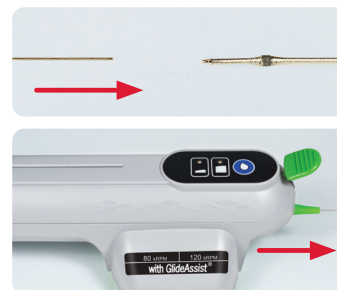
- 5** Turn on the Master Power switch on the back of the OAS pump to activate. Connect power cable from orbital atherectomy system to pump.



- 6** Press green button on pump control to power pump. The green light on the device handle will be illuminated.



- 7** Verify saline is coming out of the saline sheath, load the *ViperWire Advance* Coronary Guide Wire through the device tip, continue loading until wire is pushed through the back end of device handle.



- 8** Press down on the brake to lock the *ViperWire Advance* Coronary Guide Wire in place. Unlock the crown advancer knob and move it fully proximal.



TOTAL SET-UP TIME ≤ 2 MINUTES

This system set-up guide does not replace the *Diamondback 360* Coronary Orbital Atherectomy System Instructions For Use (IFU). Refer to the *Diamondback 360* Coronary Orbital Atherectomy System IFU for use and operation of the *Diamondback 360* Coronary OAS included in the packaging.

TROUBLESHOOTING

DIAMONDBACK 360
CORONARY ORBITAL ATHERECTOMY SYSTEM

ISSUE

SOLUTION

The OAS pump will not power on and no LEDs are illuminated on the OAS pump control panel.

Ensure that the power cord is properly inserted into the power module on the back of the OAS pump and that the power cord is connected to a functioning wall power outlet.



Ensure that the Master Power switch, on the back of the OAS pump, is in the on position.



The OAS pump will not power on.

Ensure that the saline tubing door is closed.



Attempt to restart the OAS pump by pressing the green Start button on the OAS pump control panel and verify that the green LED illuminates.



If the OAS pump does not restart after completing the aforementioned steps, press the Master Power switch to power off the OAS pump. Wait a few seconds and press the Master Power switch to power on the OAS pump. Verify that the OAS pump powers on.



This system set-up guide does not replace the *Diamondback 360* Coronary OAS Instructions For Use (IFU). Refer to the *Diamondback 360* Coronary Orbital Atherectomy System IFU for use and operation of the *Diamondback 360* Coronary OAS as well as the OAS pump. <http://www.csi360.com/products.html>

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.

MANUFACTURED BY:

