



DIAMONDBACK 360[®] Peripheral Orbital Atherectomy System Exchangeable Series

Including the Orbital Atherectomy Device, Handle, Orbital Atherectomy Cartridge, Saline Pump, VIPERWIRE ADVANCE[®] Peripheral Atherectomy Guide Wire, and VIPERWIRE ADVANCE[®] with FLEXTIP Peripheral Atherectomy Guide Wire

Instructions for use

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

The following are trademarks of Cardiovascular Systems, Inc.:

CSI[®], Cardiovascular Systems[®], DIAMONDBACK 360[®], VIPERWIRE[®], VIPERWIRE ADVANCE[®], VIPERWIRE ADVANCE[®] with FLEXTIP, VIPERSLIDE[®], GlideAssist[™]

Explanation of Symbols on Package Labels

Refer to the package labels to see which symbols apply to specific products.



Lot number



Model number



Consult IFU www.csi360.com (USA) (Symbol appears in blue when placed on the device itself)



Caution: Consult IFU www.csi360.com (USA)



Do not reuse.



Do not re-sterilize



Sterilized with Ethylene Oxide



Manufacturer



Use by



Maximum guide wire tip diameter



Maximum guide wire shaft diameter



Guide wire length



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

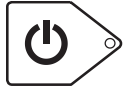


Contains phthalates

Explanation of Symbols on the Saline Pump



Low saline red LED indicator



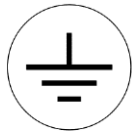
Start button and pump ON green LED indicator



Pump status yellow LED indicator



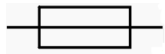
Prime button



Ground



Type CF Applied Part



Slow Blow Type T Fuse

Explanation of Symbols on the Handle



Prime button



Low speed button



Medium speed button



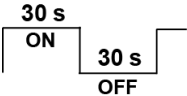
High speed button



Rotate Symbol



Eject Symbol



≤ 8 min

Non-continuous use; spin cycles of 30 seconds on, 30 seconds off with maximum spin time of ≤ 8 minutes per cartridge using no more than three cartridges per handle

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1. System description

The Cardiovascular Systems, Inc. (CSI) DIAMONDBACK 360 Peripheral Orbital Atherectomy System (OAS) Exchangeable Series is a minimally invasive, catheter-based OAS designed for improving luminal diameter in patients with peripheral arterial disease (PAD). PAD is caused by the accumulation of plaque in the arteries of the leg or foot and reduces blood flow that may lead to pain, tissue loss, and eventual foot amputation, leg amputation or death. This system treats a broad range of plaque types in the lower limbs and reduces or removes occlusive material by using a spinning, orbiting diamond-coated crown, within peripheral arteries, in order to restore lumen patency.

The OAS consists of a hand-held CSI DIAMONDBACK 360 Orbital Atherectomy Device (OAD), the CSI Saline Pump (OAS pump), the CSI VIPERWIRE ADVANCE Peripheral Atherectomy Guide Wire (guide wire) or CSI VIPERWIRE ADVANCE with FLEXTIP Peripheral Atherectomy Guide Wire (guide wire), and the CSI VIPERSLIDE Lubricant (lubricant).

The Exchangeable Series allows for multiple treatment options by offering a variety of cartridges, with different crown sizes, for use with a single handle. The following Exchangeable Series package options are available:

- OAD - handle, cartridge, and saline line
- Handle-only with a saline line
- Cartridge-only

2. System and component descriptions

2.1. Orbital Atherectomy Device (OAD) description

The OAD is a hand-held, over-the-wire device consisting of a handle, a cartridge, and a saline line (Figure 1). The cartridge includes a sheath-covered drive shaft and a diamond-coated crown. The diamond coating on the crown provides an abrasive surface with which to reduce or remove occlusive material within peripheral arteries. The handle includes control buttons for operating the OAD and contains the motor and electronics that power the rotation of the drive shaft. The GlideAssist feature facilitates advancing and retracting the OAD crown over the guide wire.

Warning: The device is designed to track and spin only over the CSI Peripheral VIPERWIRE ADVANCE Guide Wire or the VIPERWIRE ADVANCE with FLEXTIP Guide Wire. Do not use any other guide wire with this device.

Select a crown size according to the crown's ability to cross the lesion within the minimum proximal reference vessel diameter at the treatment site. See Table 1, Table 2, and Table 3 for available crown sizes. See Appendices C and D for orbit performance.

Table 1

Micro Crown

Model Number	Crown Size	Shaft Length	Nose Length*
DBP-125MICRO145 (OAD) DBCART-125MICRO145 (Cartridge)	1.25 mm	145 cm	7 mm
DBP-125MICRO75 (OAD) DBCART-125MICRO145 (Cartridge)	1.25 mm	75 cm	7 mm

*Nose length is the length of the drive shaft from the crown to the distal tip of the shaft.

Table 2

Solid Crown			
Model Number	Crown Size	Shaft Length	Nose Length*
DBP-125SOLID75 (OAD) DBCART-125MICRO145 (Cartridge)	1.25 mm	75 cm	7 mm
DBP-125SOLID145 (OAD) DBCART-125MICRO145 (Cartridge)	1.25 mm	145 cm	7 mm
DBP-150SOLID145 (OAD) DBCART-125MICRO145 (Cartridge)	1.50 mm	145 cm	10 mm
DBP-200SOLID145 (OAD) DBCART-125MICRO145 (Cartridge)	2.00 mm	145 cm	30 mm
DBP-125SOLID200** (OAD) DBCART-125MICRO145 (Cartridge)	1.25 mm	200 cm	10 mm
DBP-150SOLID200** (OAD) DBCART-125MICRO145 (Cartridge)	1.50 mm	200 cm	10 mm
DBP-175SOLID180** (OAD) DBCART-125MICRO145 (Cartridge)	1.75 mm	180 cm	30 mm

*Nose length is the length of the drive shaft from the crown to the distal tip of the shaft.

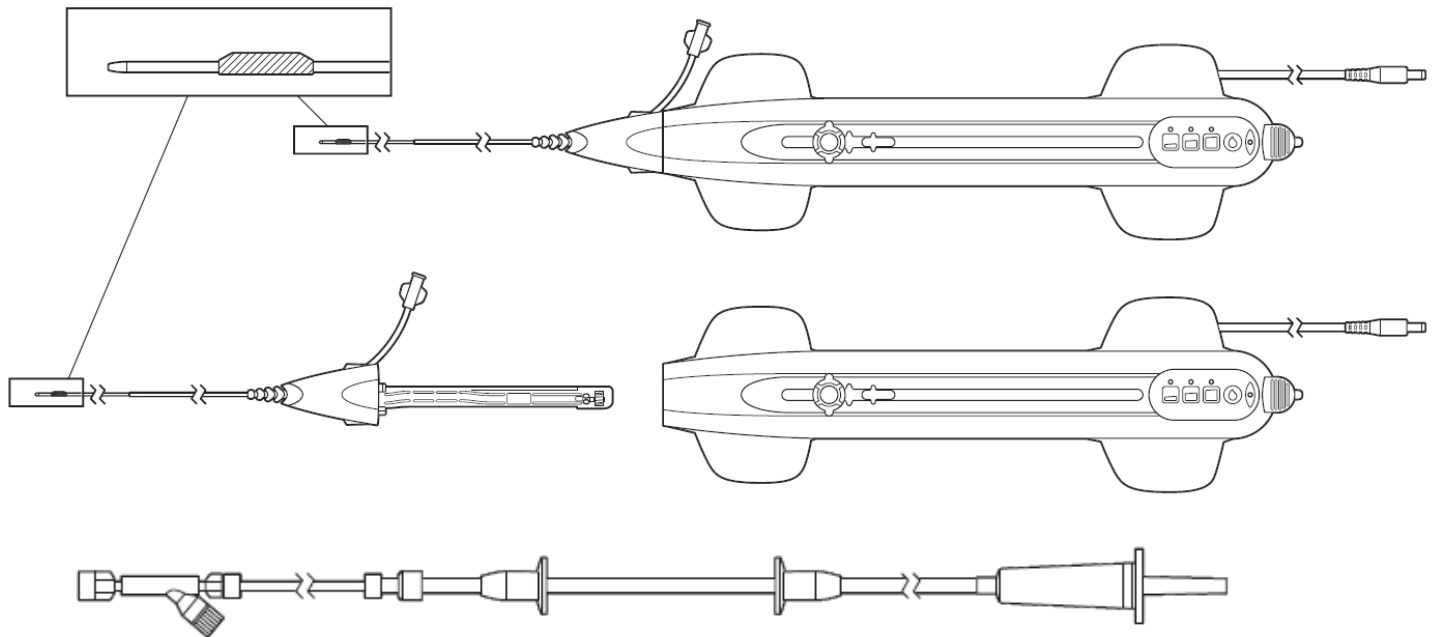
**180 cm and 200 cm length devices are intended to accommodate patient anatomy and physician preferred access methodology, for example radial access. See Section 10.3 Initiating the Atherectomy Procedure.

Table 3

Classic Crown			
Model Number	Crown Size	Shaft Length	Nose Length*
DBP-150CLASS145 (OAD) DBCART-125MICRO145 (Cartridge)	1.50 mm	145 cm	15 mm
DBP-200CLASS145 (OAD) DBCART-125MICRO145 (Cartridge)	2.00 mm	145 cm	20 mm

*Nose length is the length of the drive shaft from the crown to the distal tip of the shaft.

Figure 1. OAD - includes the handle, cartridge, and saline line



Cartridge

- A. Nose length
- B. Crown
- C. Saline line port connector
- D. Rotation grips
- E. Saline sheath
- F. Drive Shaft

Handle

- G. Crown advancer knob
- H. On/Off button
- I. Speed buttons and indicators
- J. Prime button
- K. Guide wire brake lever
- L. Electrical power cord
- M. Brake light indicator
- N. Cartridge eject button

Saline line

- O. Saline bag spike
 - P. Saline tubing positioners
 - Q. Saline tubing
 - R. Injection port
 - S. Saline line port connector
-

OAD Features:

- On/Off Button to control when the crown starts and stops
- 3 speed control buttons to select the crown rotation speed
- Saline prime button
- 15 cm crown advancement with travel measurement indicators
- Ability to lock crown advancer knob to maintain crown position relative to handle
- Manual guide wire brake to restrict both the rotational and axial movement of the guide wire
- Eccentrically-mounted, diamond-coated crown that provides an abrasive surface with which to reduce or remove occlusive tissue
- GlideAssist to facilitate advancing and retracting the OAD crown over the VIPERWIRE guide wire.
- Ability to separate the cartridge from the handle to allow the use of multiple cartridges in one case
- Crown advancement measurement indicators
- Able to load guidewire through proximal end of OAD

2.2. Package contents: OAD, handle, or cartridge

2.2.1. OAD

The OAD and accessories are supplied sterile and are for single-use only. Each package contains:

- OAD (fully assembled – one handle and one cartridge)
- Saline line (connects the OAD to the OAS pump)

2.2.2. Handle

The handle and accessories are supplied sterile and are for single-use only. Each package contains:

- One handle
- Saline line (connects the OAD to the OAS pump)

2.2.3. Cartridge

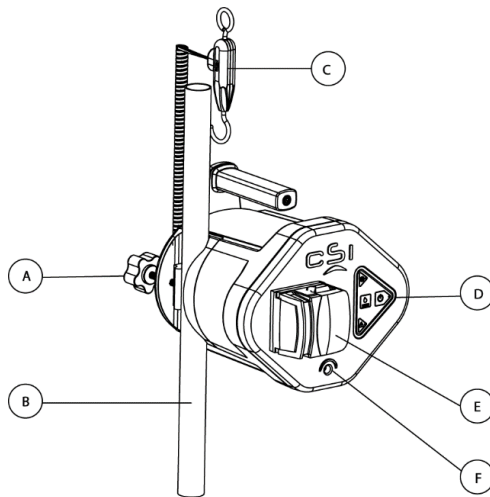
The cartridge is supplied sterile and is for single-use only. Each package contains:

- One cartridge

2.3. OAS pump description

The OAS pump provides the saline pumping mechanism and power to the device. The small, reusable, and portable OAS pump attaches to a standard five-wheel rolling intravenous (IV) pole (Figure 2) and plugs in to a wall power outlet. The OAS pump includes a built-in, audible 25 second spin time notification, system power and priming buttons, and status indicators.

Figure 2. OAS pump



- A. IV pole screw clamp
- B. IV pole (not included)
- C. Low saline level sensor and connector cord
- D. Control panel
- E. OAS Pump door
- F. OAD connection

2.4. OAS Pump package contents

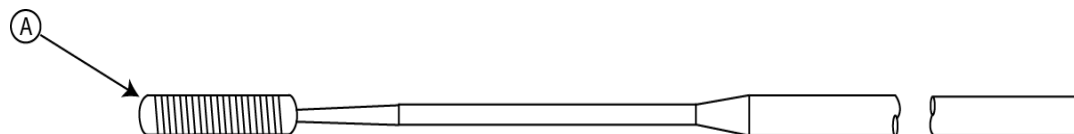
The OAS pump and accessories are supplied non-sterile. Each package contains:

- OAS Pump with attached IV pole screw clamp
- Power cord
- Low saline level sensor and connector cord

2.5. VIPERWIRE ADVANCE Peripheral Guide wire description

The guide wire is a smooth, stainless steel wire, with a silicone coating, and a radiopaque distal spring tip (Figure 3). The guide wire allows for proper positioning of the OAD crown within peripheral arteries and provides a center of rotation for the OAD drive shaft. The guide wire torquer is a small, plastic accessory, packaged with the guide wire, and provides a gripping surface for manipulating the guide wire, if desired. Guide wires are available in a variety of spring tip diameters (Tables 4 and 5).

Figure 3. Guide wire



A. Distal spring tip

Table 4 VIPERWIRE ADVANCE Peripheral 0.014” Guide Wires

OAD Device Shaft Length Compatibility	Model Number	Guide wire Spring Tip Diameter	Guide wire Length
75 and 145 cm	VPR-GW-14	0.014”	335 cm
75 and 145 cm	VPR-GW-17	0.017”	335 cm
180 and 200 cm	VPR-GW-EL14	0.014”	475 cm
180 and 200 cm	VPR-GW-EL18	0.018”	475 cm

Table 5 VIPERWIRE ADVANCE with FLEXTIP Peripheral 0.014”Guide Wire

OAD Device Shaft Length Compatibility	Model Number	Guide wire Spring Tip Diameter	Guide wire Length
75 and 145 cm	VPR-GW-FT14	0.014”	335 cm
75 and 145 cm	VPR-GW-FT18	0.018”	335 cm
75 and 145 cm	VPR-GW-FLEX14	0.014”	335 cm
75 and 145 cm	VPR-GW-FLEX18	0.018”	335 cm
180 and 200 cm	VPR-GW-ELFLEX14	0.014”	475 cm
180 and 200 cm	VPR-GW-ELFLEX18	0.018”	475 cm

2.6. VIPERWIRE ADVANCE Peripheral Guide Wire package contents

The guide wire and guide wire torquer are packaged separately from the OAD, are supplied sterile and are for single-use only. Each VIPERWIRE ADVANCE package contains:

- Five (5) guide wires
- Five (5) torquers

2.7. Lubricant description

VIPERSLIDE Lubricant reduces friction between the OAD drive shaft and the guide wire. It is packaged separately from the OAD.

Note: Please refer to the VIPERSLIDE Lubricant IFU prior to starting the atherectomy procedure.

3. Indications for use

The DIAMONDBACK 360 Peripheral Orbital Atherectomy System Exchangeable Series is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.

The OAS supports removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt). The system is a percutaneous orbital atherectomy system indicated as a therapy in patients with occluded hemodialysis grafts who are acceptable candidates for percutaneous transluminal angioplasty.

4. Contraindications

Use of the OAS is contraindicated in the following situations:

- The guide wire cannot be passed across the peripheral lesion.
- The system cannot be used in coronary arteries.
- The target lesion is within a bypass graft or stent.
- The patient has angiographic evidence of thrombus; thrombolytic therapy must be instituted prior to atherectomy.
- The patient has angiographic evidence of significant dissection at the treatment site. The patient may be treated conservatively to permit the dissection to heal before treating the lesion with the OAS.

5. Restrictions

The OAS should only be used by physicians who are experienced in peripheral angioplasty at their institutions and trained on the use of the OAS. Contact a CSI representative for information on training.

6. Warnings

- Do **not** use the OAD in a vessel that is too small for the crown. The reference vessel diameter at the treatment area must be at least 2.00 mm in diameter for the 1.25mm micro crown.
- If mechanical failure of the OAD occurs before or during the atherectomy procedure, discontinue use immediately. Do not attempt to use a damaged OAD or other system component. Use of damaged components may result in system malfunction or patient injury.
- Do **not** use the OAD during spasm of the vessel.
- Only use the approved CSI VIPERWIRE ADVANCE 0.014-inch (0.3556 mm) × 335-cm guide wires for 75cm and 145 cm length CSI crown and shaft configurations. Only use the approved CSI VIPERWIRE ADVANCE 0.014-inch (0.3556 mm) x 475 cm guide wires for 180 cm and 200 cm length CSI crown and shaft configurations. See Table 4 and Table 5 for the appropriate guide wire to use based on the OAD shaft configuration. Follow CSI's instructions related to guide wire use.
- Do **not** continue treatment if the guide wire or the OAD becomes sub-intimal.
- Immediately stop use if the OAD stalls. Review for complications and mechanical failure if a stall condition occurs. Do not change to a higher speed if the OAD stalls.
Note: If a stall occurs, the **On/Off** button is inactive for five seconds. If the On/Off button is pressed during this five second lockout period, the lockout period will begin again.
- Performing treatment in vessels or bifurcations that are excessively tortuous or angulated may result in vessel damage.

- Always use fluoroscopy when advancing the guide wire to avoid misplacement, dissection, or perforation. The OAD tracks over the guide wire, so it is imperative that the guide wire be initially placed through the stenotic lumen and not in a false channel.
- Do **not** inject contrast while OAD crown is spinning. OAD failure or patient harm may occur.
- Handle the OAD and guide wire carefully. A tight loop, kink, or bend in the guide wire may cause damage and system malfunction during use.
- Never operate the OAD without normal saline and lubricant solution. Flowing saline and lubricant solution is required for cooling and lubricating the OAD during use to avoid overheating and permanent damage to the OAD and possible patient injury.
- The crown at the distal tip of the OAD operates at very high speeds. Do not allow body parts or clothing to come into contact with the crown. Physical injury or entanglement may occur.
- Never advance the orbiting crown to the point of contact with the guide wire spring tip. Distal detachment and embolization of the tip may result.
- Always advance the orbiting, abrasive crown by using the crown advancer knob. Never advance the orbiting crown by advancing the shaft or handle. Guide wire buckling may occur, and perforation or vascular trauma may result.
- Always keep the crown advancing or retracting while it is at high rotational speeds. Do not allow the crown to remain in one location for more than 2–3 seconds. Maintaining the crown in one location while it is orbiting at high speeds may lead to excessive tissue removal.
- Do **not** start or stop orbiting of the crown when tight in a lesion.
- Never force the crown when rotational or translational resistance occurs; vessel perforation may occur. If resistance to motion is noted, retract the crown and stop treatment immediately. Use fluoroscopy to analyze the situation.
- When treating chronic total occlusion (CTO), create a channel at low or medium speed before traversing the lesion at high speed. Crossing the CTO on high speed may cause the shaft and/or guide wire to fracture as a result of excessive force.
- While advancing the crown through the introducer sheath/guide catheter, do not activate crown rotation. The crown must not spin while located within the introducer sheath/guide catheter.
- The maximum travel of the crown advancer knob—and therefore the shaft tip—is 15 cm. Moving the crown advancer knob forward moves the shaft tip an equal distance toward the guide wire spring tip. When moving the crown advancer knob, make sure there is sufficient distance between the guide wire spring tip and the distal end of the shaft (10 cm minimum). If the distance between the shaft tip and the guide wire spring tip is insufficient, the shaft tip may damage the guide wire spring tip and result in dislodgement of the guide wire spring tip. Use contrast injections and fluoroscopy to monitor movement of the shaft tip in relation to the guide wire spring tip.
- Do **not** prolapse or bend the guide wire core. If the spring tip becomes prolapsed, keep the bend/prolapse contained within the spring tip section only. A prolapsed or bent guide wire core can result in damage to the guide wire or OAD.
- The system should not be used on pregnant women or children.

- Do **not** re-use or re-sterilize the OAD. If the OAD is re-used, the OAD may not function as intended and serious infection, leading to potential harm and/or death, may occur.
- Do **not** spin the crown in GlideAssist, with the guide wire brake lever in the unlocked position, without first securing the guide wire by holding it with fingers or by using the guide wire torquer. If using the guide wire torquer, ensure that it is securely fastened to the guide wire before starting to spin the crown. Failure to secure the guide wire when the brake is unlocked could allow the guide wire to spin while in GlideAssist mode which may result in patient harm.

7. Precautions

- If the sterile packaging appears damaged or shelf life has expired, do **not** use the product.
- Do **not** flip contents of trays into the sterile field as damage may occur. Components within trays must be carefully removed and placed into sterile field to avoid damage.
- Follow standard hospital atherectomy policies and procedures, including those related to anticoagulation and vasodilator therapy.
- Radiographic equipment for fluoroscopy should be used to provide high-resolution images. Guide wires and catheters should only be manipulated under fluoroscopy.
- Because of the torque responsiveness of CSI-approved guide wires, they are more difficult to handle than other commercially available guide wires used in peripheral angioplasty. Exercise care when using these guide wires.
- Use only normal saline and lubricant solution as the infusate. (Drugs such as vasodilators are added to the infusate at the physician's discretion). The OAD may malfunction if contrast or other substances are injected into the OAD infusion port.
- Do **not** operate the OAD without recommended lubricants at the manufacturers' recommended concentration. Maximum speeds may not be achieved without lubricants.
- Ensure the OAD strain relief remains straight during atherectomy treatment.
- To relieve compression in the driveshaft, lock the crown advancer knob at 1cm from the full back position, advance device over the wire to a position proximal from the lesion, deploy the guide wire brake, then unlock the crown advancer knob and move it fully proximal. If the OAD is started with existing compression in the driveshaft, it may result in the crown springing forward.
- If 1:1 motion is not observed between the crown advancer knob and the crown, retract and re-advance the crown into the lesion. Repeat retracting and advancing the crown into the lesion until 1:1 movement is observed. If the knob and the crown are not moving together, the crown may be driven into the lesion with too much force and may result in the crown springing forward on exiting the lesion.
- When moving the eccentric diamond-coated crown back and forth across the lesion, employ a series of intermittent treatment intervals and rest periods.
- Rest periods are recommended after 30-second treatment intervals, with a maximum total treatment time of 8 minutes per cartridge.
- Monitor the saline fluid level during the procedure. Normal saline and lubricant solution infusion is critical to OAD performance.

- Do **not** kink or crush the saline tubing. Flow of saline will be reduced.
- Check the saline tubing and connections for leaks during the procedure.
- Do **not** allow fluid to leak onto electrical connections of the OAS pump.
- Do **not** detach the cartridge from the handle when the OAD is over the guide wire. Kinking of the guide wire and/or not being able to reconnect the cartridge and the handle may occur.
- Do **not** track only the cartridge into the patient and then attempt to connect the handle. Kinking of the guide wire and/or not being able to reconnect the cartridge and the handle may occur.
- Do **not** attempt to load a guide wire with a crossing profile >0.014 " through the proximal end OAD. Guide wire with a crossing profile >0.014 " will not fit through the internal components of the OAD.
- Do not attempt to remove the cartridge from the handle when spinning.

8. Storage and handling

8.1.1. Storage

Store all system components at room temperature and in a clean environment away from magnets and sources of electromagnetic interference (EMI).

Do not store ViperSlide Lubricant above 25°C (77°F). Do not freeze ViperSlide Lubricant. Refer to the ViperSlide Lubricant IFU prior to starting the atherectomy procedure.

8.1.2. Handling

- All system and Exchangeable Series components are intended to be used in typical operating room/catheterization laboratory environments.
- Additional components should be on hand in the event of damage to any of the components or to component packaging.
- Do not reuse or resterilize the OAD, handle, cartridge, guide wire, guide wire torquer, or lubricant as these components are designed for single-use only.
- Do not use the OAD, handle, cartridge, or the guide wire if their sterile package barriers are compromised or damaged.
- Do not resterilize any component after exposure of the component to body tissue or body fluids.
- Do not use the OAD, handle, cartridge, or OAS pump if any of them were dropped onto a hard surface, from a height at or greater than 12 in (30 cm), as these components may be damaged and may fail to operate properly.
- Do not use any system components after their use-by date.
- Do not use Viperslide Lubricant if it is exposed to temperatures outside the range indicated on the package labels.

9. Adverse events

Potential adverse events that may occur and/or require intervention include, but are not limited to:

- Allergic reaction to medication/media/OAD components
- Amputation
- Anemia

- Aneurysm
- Bleeding complications which may require transfusion
- Cerebrovascular accident (CVA)
- Death
- Distal embolization
- Entry site complications
- Hemolysis
- Hypotension/hypertension
- Infection
- Myocardial infarction
- Pain
- Pseudoaneurysm
- Restenosis of treated segment that may require revascularization
- Renal insufficiency/failure
- Slow flow or no reflow phenomenon
- Thrombus
- Vessel closure, abrupt
- Vessel injury, including dissection and perforation that may require surgical repair
- Vessel spasm
- Vessel occlusion

10. Clinical trials summary

See www.CSI360.com for clinical trial information

11. Equipment, setup, and test

11.1. Equipment

In addition to the OAS components, equip the operating room with the following:

- Introducer, guide sheath, or guide catheter - see Appendix B for sizing recommendations
- Standard IV pole with five wheels and a 20 inch diameter base
- 1000 mL bag of normal saline
- Fluoroscopic imaging equipment
- Standard hospital grade, electrical wall outlet
- Other equipment, as needed, for interventional procedures

11.2. OAS Pump set up

1. Use the IV pole screw clamp to attach the OAS pump to a standard IV pole making sure to attach the OAS pump to the IV pole at a distance not greater than 60 in (153 cm) from the floor to the top edge of the OAS pump.
2. Hang the low saline level sensor and cord, by the closed loop, from the horizontal arm of the standard IV pole.
3. Plug the low saline level sensor connector into the back of the OAS pump (Figure).

Figure 4. Plug in the low saline level sensor



4. Verify that the power cord is connected to the back of the OAS pump.
5. Insert the other end of the power cord into the electrical wall outlet.

Warning: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Warning: Ensure the power cord connection to the OAS pump and the on/off switch is accessible at all times.

Caution: Do **not** allow fluid to leak onto electrical connections of the OAS pump.

11.3. Initiating the atherectomy procedure

1. Gain vessel access using the physician's preferred methodology.
2. Access the treatment site with an appropriately sized introducer, guide sheath, or guide catheter.

Note: For radial access, use a preferred guide catheter or guide sheath of an appropriate length.

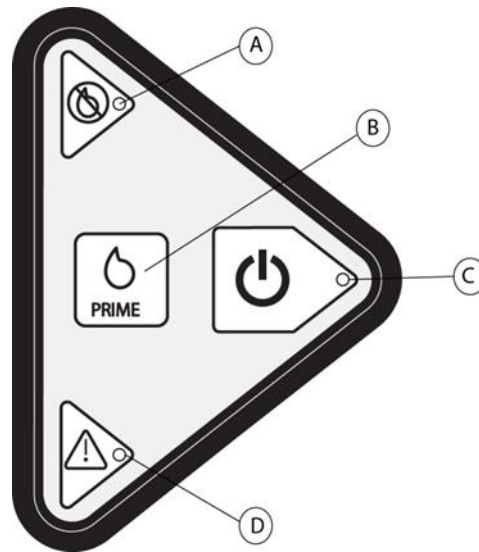
3. Use angiography to locate, visualize, and evaluate the lesion.
4. If desired, use the thumb and index finger to gently impart a slight curve or J-shape to the distal spring tip of the guide wire.
5. If use of the guide wire torquer is desired, attach the torquer to the guide wire by holding the distal end of the torquer and rotating the proximal end counterclockwise to tighten.

6. Approach and cross the lesion, with the guide wire, using the physician's preferred methodology.

11.4. Preparing the bag of saline and lubricant

1. Ensure that the OAS pump is powered off by pressing the **Master Power** switch on the back of the OAS pump to off and ensure that no LEDs are illuminated on the OAS pump control panel (Figure 5).

Figure 5. OAS Pump control panel



- A. Low saline red LED indicator
 - B. Prime button
 - C. Start button and green LED indicator
 - D. Status yellow LED indicator
-

2. Prepare a full 1000 mL bag of normal saline solution with lubricant. Refer to the VIPERSLIDE Lubricant Instructions for Use for lubricant preparation instructions.
3. Hang the prepared saline bag with lubricant from the low saline level sensor on the standard IV pole.

Caution: Do **not** use glass bottles for the saline solution with lubricant or hang multiple saline bags from the low saline level sensor as this will disable the Low Saline Information signal.

11.5. OAD set up

Carefully remove the OAD (or individual OAD handle and cartridge) from the tray(s) and set onto a stable surface.

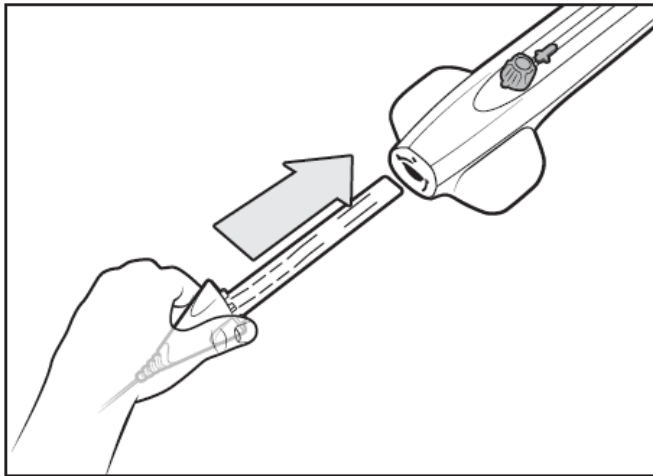
Note: Removal of the OAD from the packaging by tipping the tray and allowing the OAD to fall out can result in damage to the OAD or ancillary devices underneath the OAD.

11.5.1. Connect the cartridge to the handle

If the handle and cartridge are not pre-connected, perform the following:

1. Insert the cartridge into the handle, see Figure 6 Figure 6. Cartridge Insertion.

Figure 6. Cartridge Insertion



2. Rotate the cartridge to lock the cartridge in place. There will be two tactile **clicks**. If crown advancer cannot move, ensure cartridges is fully rotated, see Figure 7.

Figure 7. Cartridge Rotation.

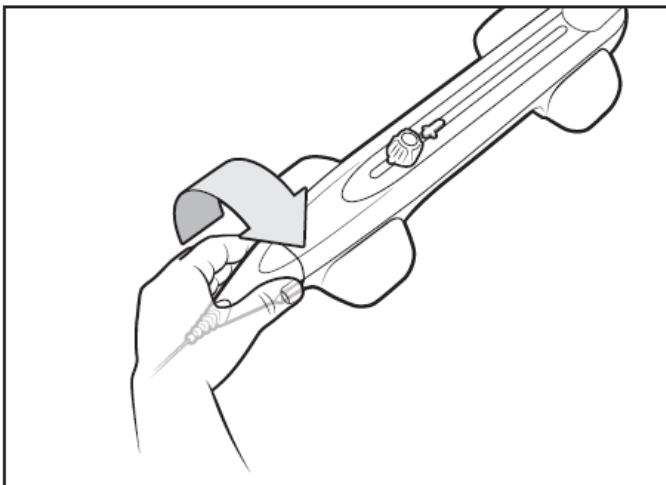
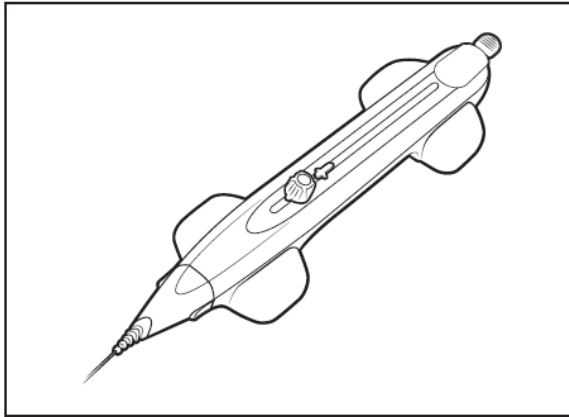


Figure 8. Assembled OAD.



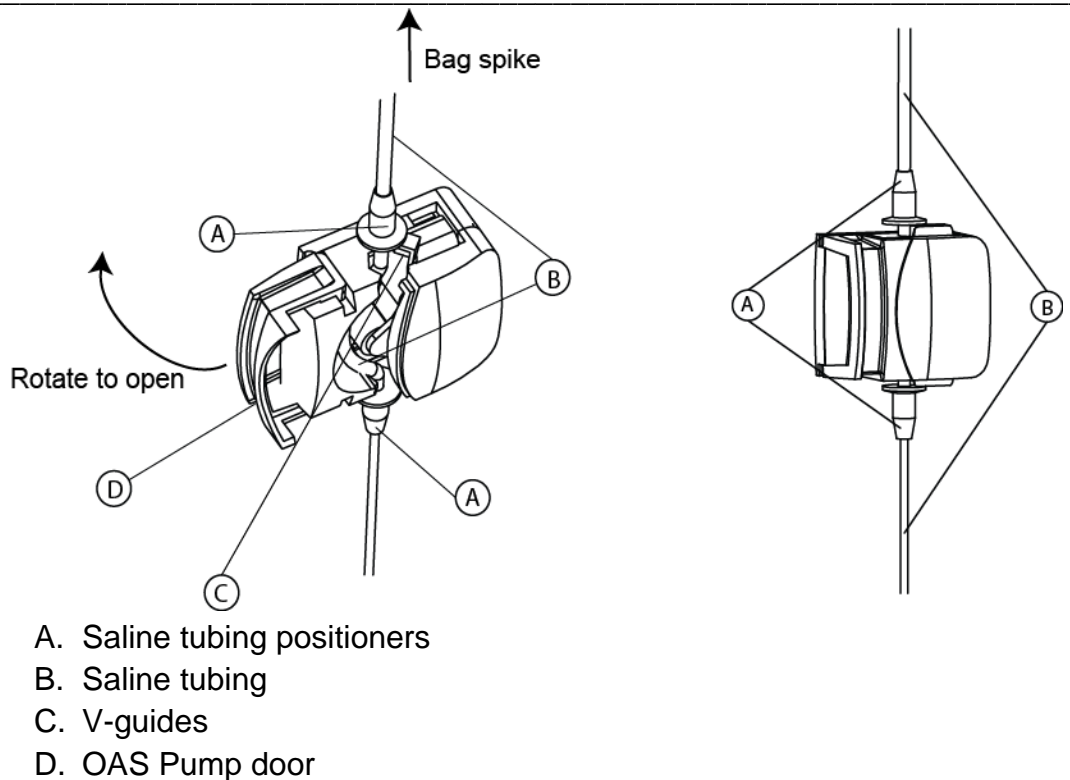
11.6. Connecting the OAD to the OAS Pump

Remove the sterile saline tubing from the OAD package and pass the saline bag spike end of the saline tubing out of the sterile field. Connect the other end of the saline tubing luer to the device luer. Additionally, pass the OAD power cord out of the sterile field.

Perform the following:

1. Connect the saline tubing to the saline bag with lubricant using standard institution procedures.
2. Open the door, located on the front of the OAS pump, by rotating the door in the direction of the arrow (Figure 9).
3. Place the saline tubing over the pump rollers so that the tubing positioners align with the top and bottom V-guides on the pump (Figure 9).

Figure 9. Placing the saline tubing within the OAS Pump



4. While closing the door, verify that there is no pinching of the saline tubing and ensure that there is slack in the saline tubing between the OAS pump and saline bag with lubricant.
5. Verify that the saline tubing is properly inserted into the saline tubing V-guides and that there are no kinks or damage to the saline tubing.
6. Press the **Master Power** switch, on the back of the OAS pump, and verify that the red or yellow LED is illuminated on the OAS pump control panel.
7. Connect the OAD power cord to the OAS pump (Figure 10).

Figure 10. Connect the OAD power cord to the OAS pump



8. Remove the driveshaft from the dispenser coil.

9. Purge air from the OAD and the saline tubing as follows:
 - a. Verify that the saline tubing is connected to the OAD.
 - b. Press the green **Start** button on the OAS pump control panel to start saline flowing through the saline tubing. Verify that the green LED illuminates.
 - c. Press and hold the **Prime** button on the OAS pump control panel to purge air from the saline tubing. Continually pressing the **Prime** button will pump saline through the tubing at an increasing flow rate. Releasing the **Prime** button will decrease the flow to the low flow rate after two seconds.
 - d. Verify that saline is exiting from the OAD sheath near the crown.
 - e. Continue priming to ensure there are no air bubbles within the saline tubing and use standard hospital procedures to aspirate or purge air from the lines.
 - f. After verifying there are no air bubbles within the saline tubing, discontinue priming.

11.7. Testing the OAD

11.7.1. Testing OAD crown advancement

Before inserting any portion of the OAD into the body, ensure that axial movement of the OAD crown advancer knob will produce smooth travel of the crown.

Caution: Do **not** spin the crown during this test.

1. Ensure that the crown advancer knob is in the unlocked position as this will allow free axial travel of the crown advancer knob.
2. While visually monitoring the crown, slowly move the crown advancer knob in a back and forth motion. The maximum travel of the crown advancer knob, and the corresponding maximum travel of the shaft tip, is 5.9 inches (15 cm).

11.7.2. Optional: Testing OAD crown rotation

This test is optional, but is performed chronologically after testing crown advancement.

Note: Hold the guide wire firmly during the test. When the test is complete, the OAD is ready for use and the guide wire can be inserted through the introducer, guide sheath, or guide catheter.

1. Push the crown advancer knob fully proximal, away from the nose of the handle, and release the guide wire brake before threading the guide wire through the OAD drive shaft.
2. Grasp the proximal end of the guide wire and thread the guide wire through the opening in the OAD drive shaft distal tip.

Caution: Do **not** operate the OAD if there is a bend, kink, or tight loop in the guide wire. A bend, kink, or tight loop in the guide wire may cause damage to and malfunctioning of the OAD during use.

3. Continue feeding the guide wire into the OAD drive shaft until the guide wire appears at the rear of the OAD.
4. Lock the guide wire in place by pressing down on the guide wire brake lever as the crown will not spin if the guide wire brake is unlocked.
5. Verify that saline is still flowing freely out of the saline sheath tip. Verify that the saline tubing is properly connected to the saline bag, that the saline tubing routes correctly through the saline tubing guides, and that the saline tubing is properly connected to the OAD.
6. Hold the OAD sheath a few centimeters from the crown while making sure that the crown is not in contact with any objects. Verify there is no pinching of the OAD sheath at any time during OAD operation.
7. Press and release the **On/Off** button located on top of the crown advancer knob to activate crown rotation. The OAD is preset to low speed, and the illuminated LED on the OAD will indicate that the OAD is operating at low speed.
8. Check that the flow of saline is increasing and that the shaft and crown are beginning to spin.
9. Immediately press and release the **On/Off** button to stop the shaft and crown from spinning and to complete the test.

12. OAS Directions for Use

12.1. Performing the atherectomy procedure

1. Ensure that the OAD guide wire brake lever is open (in the up position).
2. Lock the crown advancer knob at 1 cm from the fully proximal position.
3. While keeping guide wire placement stationary, advance the OAD drive shaft over the guide wire and through the hemostasis valve.
4. Under direct visualization, gently advance the OAD crown over the guide wire to a position approximately 1 cm proximal to the lesion. Verify that the OAD distal tip is not within the lesion when the crown and drive shaft begin to spin.

(Optional) Use the GlideAssist feature to facilitate advancing the OAD crown over the VIPERWIRE guide wire.

Warning: Spinning the crown using GlideAssist can be done with the OAD guide wire brake lever in either the locked or unlocked position. If using GlideAssist with the guide wire brake in the unlocked position, the **guide wire must be held** using

either fingers or the guide wire torquer. If using the guide wire torquer, ensure that it is securely fastened to the guide wire before starting to spin using GlideAssist.

- a. Enable GlideAssist mode by pressing and holding the low speed button. Release the button once the low speed light begins to slowly blink. The slowly blinking light indicates GlideAssist mode is enabled.
- b. Ensure the **guide wire is secure** by locking the guide wire brake or by holding the guide wire with either fingers or the guide wire torquer.
- c. Press and release the On/Off button on top of the crown advancer knob to activate crown rotation. The low speed light will rapidly blink indicating the crown is spinning in GlideAssist mode.
- d. Stop the OAD crown rotation by pressing and releasing the On/Off button on top of the crown advancer knob. The low speed light will slowly blink indicating the OAD is no longer spinning but continues to be in GlideAssist mode.
- e. Disable GlideAssist mode by pressing and immediately releasing any speed button while the crown is not spinning. The low speed light will stop blinking, yet remains illuminated indicating the OAD is now in treatment mode.

Note: If the brake configuration is changed from either the locked or unlocked position while spinning in GlideAssist mode, the crown will automatically stop spinning yet the OAD will remain in GlideAssist mode.

5. Inject contrast medium through a port in the hemostasis valve to verify that the size of the crown is compatible with the treatment area diameter (see Appendix C).
6. Verify that the guide wire spring tip is distal to the lesion and is not in danger of coming in contact with the advancement of the spinning crown and drive shaft tip.
7. Push down on the guide wire brake lever to engage the guide wire brake. The crown will not spin if the guide wire brake is not locked.
8. Unlock and move the crown advancer knob to the fully proximal position to relieve any compression in the driveshaft.
9. Press and release the **On/Off** button on top of the crown advancer knob to activate crown rotation. The OAD is preset to low speed, and the illuminated LED on the OAD will indicate that the device is operating at low speed.
10. Audibly verify that the OAD drive shaft and crown are orbiting at a stable speed.
11. Slowly advance the crown advancer knob to begin atherectomy of the lesion at a travel rate between 1 mm per second and 10 mm per second. Using imaging, continually verify that the crown and the crown advancer knob are moving 1:1 with one another. Ensure that the OAD handle remains horizontal during the procedure to minimize saline leakage from the OAD.
12. Using a series of intermittent treatment intervals and rest periods, slide the crown advancer knob to move the crown back and forth across the lesion always returning to the proximal side of the lesion when the interval set is complete.

Warning: Once the OAD has reached full speed (as indicated by a stable pitch), do **not** allow the orbiting crown to remain in one location as it may lead to vessel

damage. Continue to maintain a travel rate between 1 mm per second and 10 mm per second.

A rest period of 30 seconds, is recommended for every 30 seconds of treatment, with a maximum treatment time of 8 minutes per cartridge. The OAS pump will emit a beep after every 25 second interval of treatment time. Use contrast injections through the introducer, guide sheath, or guide catheter only during rest periods to fluoroscopically evaluate results.

Warning: Maximum total treatment time should not exceed 8 minutes per cartridge. If maximum total treatment time is exceeded, the OAD shaft, crown, and VIPERWIRE guide wire may begin to exhibit signs of wear and result in a device malfunction and possible injury to the patient.

13. If reduction of the stenosis is not adequate, perform one of the following:
 - Continue to treat the lesion by moving the crown back and forth across the lesion per the instructions above.
 - Increase the rotational speed of the crown by using the crown rotation speed buttons on the handle of the device.
14. Evaluate the reduction of the stenosis
15. Perform a final angiogram.

12.1.1. Load a Guidewire through the Proximal End of the OAD

Guidewires with crossing profile <0.014 " can be loaded through the proximal end of the OAD.

1. Ensure the OAD brake is unlocked and the device is not spinning.
2. If the OAD is in the patient, keep the pump power on.
3. If there is a guidewire in the OAD, remove the guidewire from the proximal end of the OAD.
4. A dilator may be inserted into the green strain relief to aid insertion of the guidewire. Insert the new guidewire through the proximal strain relief.

Warning: The device is designed to track and spin only over the CSI Peripheral VIPERWIRE ADVANCE Guide Wire or the VIPERWIRE ADVANCE with FLEXTIP Guide Wire.

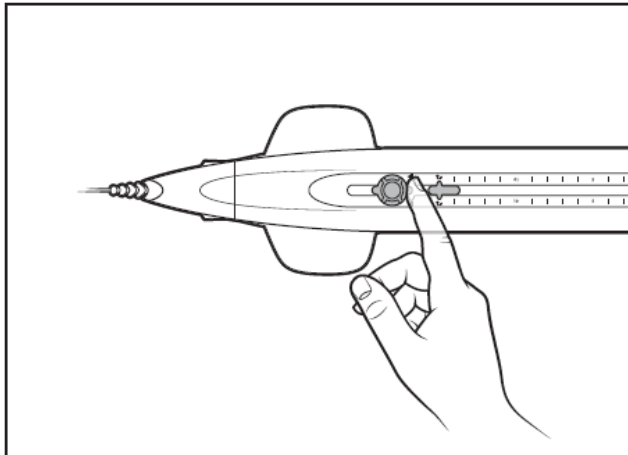
CAUTION: Do **not** attempt to load a guide wire with crossing profile >0.014 " through the proximal end OAD. Guide wire with crossing profile >0.014 " will not fit through the internal components of the OAD.

12.1.2. Exchanging the cartridge

Note: Each handle can only accept up to three different cartridges.

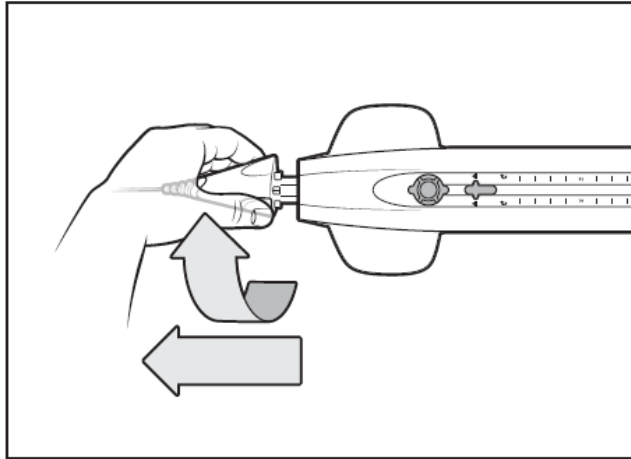
1. Stop the spinning crown and drive shaft by pressing and releasing the **On/Off** button on top of the crown advancer knob.
2. Leave the introducer, guide sheath, or guide catheter and the guide wire in place, release the guide wire brake on the OAD, and retract the OAD sheath and drive shaft, from the introducer, guide sheath, or guide catheter, while monitoring and maintaining guide wire position.
3. Once the OAD drive shaft and sheath are fully retracted, power off the OAS pump by pressing the green **Start** button on the OAS pump control panel to stop saline from flowing through the saline tubing and verify that the green LED, on the OAS pump control panel, is not illuminated.
4. Disconnect the saline tubing from the cartridge and set aside for use with the next cartridge.
5. Disconnect the cartridge from the handle:
 - a) Slide the crown advancer knob to the most distal position on the handle. The yellow button will align with the rotate symbol on the handle, see Figure 11.

Figure 11. Cartridge Exchange



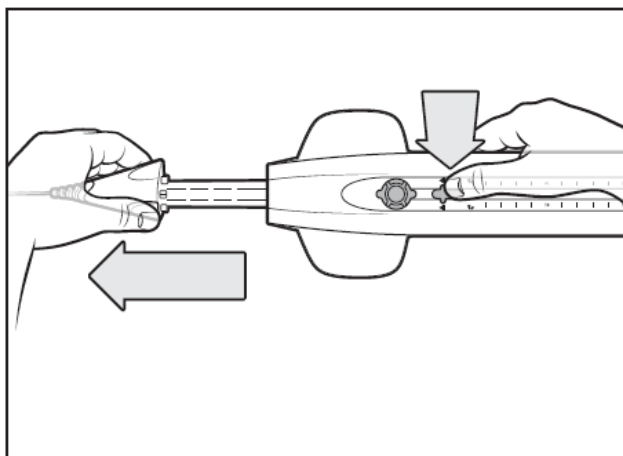
- b) Unlock the cartridge by grasping and rotating the cartridge. Next pull out the cartridge until it stops. The yellow button will now align with the eject symbol on the handle, see Figure 12.

Figure 12. Cartridge Rotation



- c) Press and hold the yellow button on the handle while pulling on the cartridge until it is fully removed from the handle, see Figure 13.

Figure 13. Cartridge Removal



6. Obtain a new cartridge and follow the steps described in 11.5 to connect the new cartridge to the handle.

Note: The cartridge is for single-use only and cannot be used with any other handles once it is used with the original handle.

7. Connect the saline line to the new cartridge
8. Press the green **Start** button on the OAS pump control panel to start the saline flowing through the saline tubing and verify that the green LED illuminates.
9. Purge the air from the new cartridge.
10. Test the OAD crown advancement per the instructions in Section 11.7.1.
11. Load the OAD drive shaft over the CSI guide wire.

12.1.3. Replacing the bag of saline and lubricant

The low saline level sensor triggers an audible information signal every 5 seconds, for a total of 30 seconds, if there is less than 200 mL (+/- 100 mL) remaining in the bag of saline and lubricant during a treatment period. If the low saline level sensor triggers during a rest period, only the red low saline LED is illuminated. Perform the following to replace the bag of saline and lubricant:

1. Ensure that the OAS pump is stopped by pressing the green **Start** button on the OAS pump control panel and verify that the green LED, on the OAS pump control panel, is not illuminated.
2. Prepare a new 1000 mL bag of normal saline solution with lubricant. Refer to the VIPERSLIDE Lubricant Instructions for Use for lubricant preparation instructions.
3. Remove the low bag of saline and lubricant from the low saline level sensor on the IV pole.
4. Hang the new bag of saline and lubricant from the low saline level sensor on the standard IV pole.

Caution: Do not use glass bottles for the saline solution with VIPERSLIDE Lubricant or hang multiple saline bags from the low saline level sensor as this will disable the Low Saline Level Sensor.

5. Remove the bag spike from the empty bag of saline and Lubricant and spike the new bag of saline and lubricant.
6. Power on the OAS pump by pressing the green **Start** button on the OAS pump control panel.
7. Ensure that no air is present in the saline tubing.

12.1.4. Replacing the OAD

Caution: Do not reuse cartridges from the existing handle to the new replacement handle. Replace the entire OAD with both a new handle and a new cartridge.

If the OAD (handle plus cartridge) needs replacing, perform the following:

1. Stop the spinning crown and drive shaft by pressing and releasing the **On/Off** button on top of the crown advancer knob.
2. Disconnect the OAD power cord from the OAS pump.
3. Leave the introducer, guide sheath, or guide catheter and the guide wire in place, release the guide wire brake on the OAD, and retract the OAD sheath and drive shaft, from the introducer, guide sheath, or guide catheter, while monitoring and maintaining guide wire position.
4. Power off the OAS pump by pressing the green **Start** button on the OAS pump control panel to stop saline from flowing through the saline tubing and verify that the green LED, on the OAS pump control panel, is not illuminated.
5. Disconnect the saline tubing from the OAD currently in use and set aside for use with the replacement OAD.
6. Obtain a new replacement OAD and carefully remove the new replacement OAD from the package.

Note: Removal of the OAD from the packaging by tipping the tray and allowing OAD to fall out can result in damage to the OAD or ancillary devices underneath the OAD.

7. First, connect the existing saline tubing to the new replacement OAD, then connect the new replacement OAD power cord to the OAS pump.
8. Press the green **Start** button on the OAS pump control panel to start the saline flowing through the saline tubing and verify that the green LED illuminates.
9. Purge the air from the OAD.
10. Load the new replacement OAD drive shaft over the existing guide wire.
11. Test the OAD crown advancement per the instructions in Section 11.7.1.

12.2. Completing the Atherectomy Procedure

To complete the atherectomy procedure, perform the following:

1. While the crown is spinning, retract the crown and drive shaft proximal to the lesion.
2. Stop the spinning crown and drive shaft by pressing and releasing the **On/Off** button on top of the crown advancer knob.

3. Carefully remove the OAD drive shaft and crown from the introducer, guide sheath, or guide catheter.

(Optional): Use the GlideAssist feature to facilitate retracting the OAD crown over the guide wire.

Caution: Do **not** spin while retracting the crown within a guide catheter or touhy. Damage to the guide catheter, touhy, and/or OAD may occur.

4. Press the green **Start** button on the OAS pump control panel to stop saline from flowing through the saline tubing and verify that the green LED is not illuminated. Turn off the OAS pump at the **Master Power** switch on the back of the OAS pump.
5. Disconnect the OAD power cord from the OAS pump.
6. Disconnect the saline tubing from the OAD and remove the saline tubing from the OAS pump.
7. Remove and dispose of the guide wire and introducer, guide sheath, or guide catheter according to standard hospital procedures.
8. Treat the puncture site according to standard interventional procedure protocol.

Note: The OAD, guide wire, and lubricant are designed for single-use only and should **not** be reused or re-sterilized.

12.3. Disposal of the OAD

The OAD is designed for single use and should **not** be reused or resterilized. Discard the OAD and saline tubing according to standard hospital protocol.

Certain states may have additional requirements for disposal of certain batteries. Please verify your state's requirements for disposal of CR lithium coin cells (CR2032 or equivalent) prior to disposal.

California, USA Only: Perchlorate Material – special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate

12.4. Maintaining the OAS pump

The OAS pump does not require routine maintenance, periodic maintenance, or calibration. The OAS pump has been designed to function for 875 hours minimum, with 350 hours of minimum OAD use, which equates to 5 years. Contact CSI Customer Service if there are questions about OAS pump function or performance.

12.4.1. Cleaning the OAS Pump

Clean the OAS pump immediately after each use by following the steps below:

Caution: Ensure that the OAS pump is powered off at the **Master Power** switch on the back of the pump and disconnect the OAS pump from wall power before cleaning the pump.

Caution: Do **not** immerse the OAS pump into fluids. Do **not** use solvents or abrasive cleaners to clean the OAS pump as these may damage the OAS pump and OAS pump components.

Caution: Completely dry the OAS pump before reconnecting the OAS pump to wall power and powering on the OAS pump.

1. Prepare an enzymatic detergent, such as Enzol[®], per manufacturer's directions.
2. Thoroughly wipe down the pump, using a clean soft cloth that has been dampened with the prepared detergent, until all visible soil is removed.
3. Thoroughly rinse the pump using a clean soft cloth that has been dampened with lukewarm tap water.
4. Dry the pump using a clean, soft cloth and, if available, filtered, pressurized air at ≤40 psi.

12.4.2. Disinfecting the OAS Pump

Disinfect the OAS pump after each use by following the steps below:

1. Verify no debris is present after pump has been cleaned and rinsed with enzymatic detergent. Repeat the above cleaning procedure if any debris continues to be visible.
2. Put on a pair of disposable protective gloves. Check the expiration date on container and remove a fresh moist Super Sani-Cloth®. Wring excess solution from the wipe, ensuring it is saturated, but not dripping. Discard wipes as they become dry.
3. Disinfect the front pump face, ensuring that all the indicated surfaces are completely covered with solution during the wiping process for a **total of 2 ½ minutes** to ensure an adequate “dwell” time. Dwell time means the number of minutes that a product must be in contact with the surface, **and remain wet**, in order to assure proper efficacy, or effectiveness to kill organisms. **Surfaces must not become dry at any point during disinfection.** Refer to the following steps for surfaces to be wiped:
 - a. Open the pump head cover (see Figure 14).
 - b. Thoroughly wipe the edge of the pump head cover all along the closure seam on both sides (see Figure 15 and Figure 16 below).

Figure 14. Open pump head cover

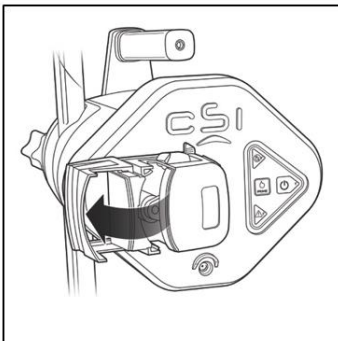


Figure 15. Wipe closure seam.

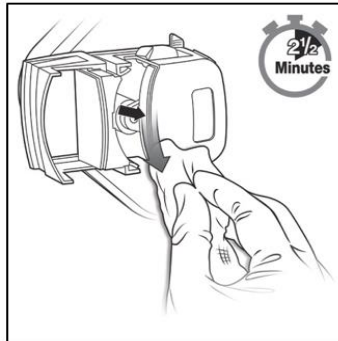


Figure 16. Wipe Closure Seam



4. Thoroughly wipe the seams and crevices of the pump head cover, around the edges of the lettering, around the button area, and around the power outlet (see Figure 17). Thoroughly wipe all surfaces of the front face of the pump (see Figure 18). Continue to keep all surfaces **wet** for a minimum of two and a half minutes. Discard the wipes.

Figure 17. Thoroughly wipe these areas

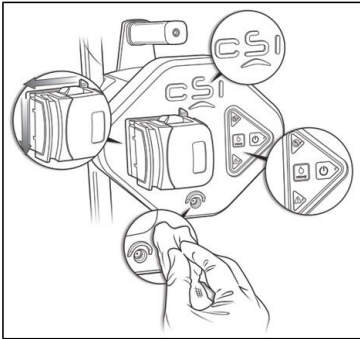
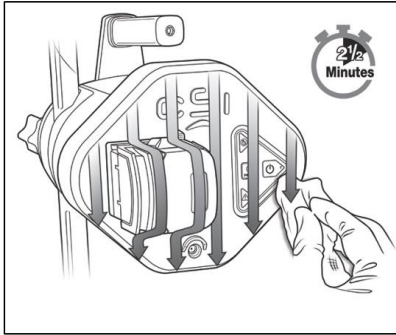


Figure 18. Wipe all surfaces of front face



12.5. Returning System Components

Contact CSI Customer Service if system components need to be returned. See the back of this Instruction for Use for CSI contact information.

13. Specifications

13.1. OAD (handle plus cartridge) Specifications

Parameter	Value
Electrical cable length: OAD to OAS pump	3.4 m (11 ft.)
Electrical connector type (OAD power)	Type CF applied Part –DC barrel (48 V DC)
Fluid connector type	Polycarbonate Luer fitting
Saline line tubing length (from pump to OAD port)	3.2 m (10.5 ft.) minimum
Visual alerts	Speed and brake indicators
Sterilization	Ethylene oxide (EtO) cycle
Storage conditions	Room temperature in a clean environment away from magnets and sources of electromagnetic interference (EMI).
Operating conditions	Typical operating room/catheterization laboratory environment
Operating life: Cartridge	8 minutes of total therapy time
Operating life: Handle	24 minutes of total therapy time
Water Ingress Protection	IPX1: Protection against water ingress
Approximate saline flow rate for 145 cm (4 Fr) OAD	7 mL/min to 16 mL/min
Approximate saline flow rate for 145 cm (5 and 6 Fr) OAD	10 mL/min to 30 mL/min
Approximate saline flow rate for 75 cm (4 Fr) OAD	10 mL/min to 23 mL/min
Approximate saline flow rate for 200 cm (5 Fr) OAD	10 mL/min to 34 mL/min
Approximate saline flow rate for 180 cm (5 Fr) OAD	16 mL/min to 35 mL/min

OAS pump specifications

Parameter	Value
Depth	<30.6 cm (12.0 in)

Parameter	Value
Height	20.3 cm (8.0 in)
Width	25.4 cm (10.0 in)
Weight	<5.0 kg (11 lbs)
Electrical cable length: OAS pump to electrical outlet	6.1 m (20 ft.)
Master Fuse	250 V 4A SLOW BLOW (Type T)
External housing	ABS Plastic
Electrical connector type (Main Power)	Mains Power Plug (100–240 V AC @ 50–60 Hz)
Audible information signals	Audible information signal for approximately every 25 sec of OAD spin time.* Audible information signal every 5 sec for a total of 30 sec when the saline level falls below 200 mL during a treatment period.
Visual alerts	<ul style="list-style-type: none"> • Start button • Low Saline Information Signal when ≤ 200 mL (± 100 mL) remaining out of a 1000-mL bag of saline • Yellow LED
Storage conditions	Room temperature in a clean environment away from magnets and sources of electromagnetic interference (EMI).
Operating conditions	Typical operating room/catheterization laboratory environment
Operating life	875 hours minimum, with 350 hours of therapy minimum or 5 years
Water Ingress Protection	IPX1: Protection against water ingress

* Timer resets when crown spinning stops.

13.2. VIPERWIRE ADVANCE Guide Wire Specifications

	VPR-GW 14	VPR-GW-17	VPR-GW-FT14 VPR-FLEX14	VPR-GW-FT18 VPR-FLEX18	VPR-GW-EL-14 VPR-ELFLEX14	VPR-GW-EL18 VPR-ELFLEX18
Guide Wire Length	335 cm	335 cm	335 cm	335 cm	475 cm	475 cm
Guide Wire Coating	Silicone	Silicone	Silicone	Silicone	Silicone	Silicone
Core wire diameter	.014"	.014"	.014"	.014"	.014"	.014"
Core wire material	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel	Stainless Steel
Spring Tip Length	3 cm	3 cm	3 cm	3 cm	3 cm	3 cm
Spring Tip Diameter	.014"	.017"	.014"	.018"	.014"	.018"
Spring Tip Material	Platinum/ Tungsten	Platinum/ Tungsten	Platinum/ Tungsten	Platinum/ Tungsten	Platinum/ Tungsten	Platinum/ Tungsten
Spring Tip Shape	Straight	Straight	Straight	Straight	Straight	Straight

14. OAS Pump Declaration of Conformity

CSI declares that the peripheral system is in conformity with the requirements of: IEC 60601-1. The OAS pump is compatible for use in a standard catheter laboratory environment.

15. EMC Declaration

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC). Install and use medical electrical equipment according to the EMC information below:

- Do not have portable and/or mobile radio-frequency (RF) communications equipment within close proximity of medical electrical equipment as portable and mobile RF communications equipment can affect medical electrical equipment.
- Ensure that power frequency magnetic fields are at levels characteristic of a typical commercial or hospital environment.
- Under an EMC phenomena the OAS may stop operation, and may require user intervention to recycle the power to resume operation.

The Orbital Atherectomy System has been tested to IEC 60601-1-2:2014 levels and to IEC 60601-1-2:2007. The Orbital Atherectomy System has been tested to Immunity and Emission

Test Levels of a Professional Healthcare Facility Environment. The OAS is Group 1 (Therapy ME Equipment and Systems) and therefore must meet CISPR 11 Class A.

Note: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

16. FCC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Cardiovascular Systems, Inc. has not approved any changes or modifications to this device by the user. Any changes or modifications to the device could void the user's authority to operate the equipment.

17. Disclaimer of Warranty

Although Cardiovascular Systems, Inc. (CSI) uses reasonable care in the manufacture of its devices, they are used in difficult environment within the human body with many biological differences between individual patients. CSI has no control over the conditions under which this device is used, condition of the patient, methods of administration or handling after the device leaves CSI's possession. THEREFORE, CSI DISCLAIMS ALL WARRANTIES WHETHER EXPRESSED OR IMPLIED, WRITTEN OR ORAL, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE. CSI DOES NOT WARRANT EITHER FOR A GOOD EFFECT OR AGAINST ALL ILL EFFECT FOLLOWING ITS USE. CSI (INCLUDING ITS AFFILIATED ENTITIES, OWNERS, DIRECTORS, OFFICERS, EMPLOYEES, AGENTS AND VENDORS) SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE ARISING FROM OR RELATED TO THE USE OF THIS DEVICE.

No person has authority to bind CSI to any representation, warranty, or liability except as set forth in this Disclaimer of Warranty.

CSI may, at its sole discretion, replace any device that is determined to have been out of specification at the time of shipment.

The exclusions, disclaimers, and limitations set forth in this Disclaimer of Warranty are not intended to, and shall not be construed as to, contravene mandatory provisions of any applicable law or regulation. If any part of this Disclaimer of Warranty is held to be illegal or unenforceable by a court of competent jurisdiction, the part shall be modified so as to be

enforceable to the maximum extent possible. If the part cannot be modified, then that part may be severed and the other parts of this Disclaimer of Warranty shall remain in full force and effect.

Appendix A. System Troubleshooting

If issues with the OAD cannot be resolved in each of the situations below, replace the recommended part of the OAD and continue with the procedure. Contact CSI Customer Service for returning OAS components. See the back of these instructions for use for CSI contact information.

Issue number	Issue	Solution
1	The crown stops spinning during the procedure	<ol style="list-style-type: none"> 1. Immediately discontinue treatment. Stop the OAD from spinning, but leave the OAS pump running. 2. Verify that saline is flowing. 3. Check that the OAS pump green LED OAS pump on light is on and that the device green LED light is on. If the OAS pump green LED is flashing, press the pump start button twice. 4. Check to ensure that the OAS pump power cord is connected to the back of the OAS pump and that the OAD power cord is connected to the OAS pump. 5. Check that the OAD guide wire brake lever is in the down/locked position. 6. Retract the crown proximal to the lesion. Use fluoroscopy to analyze the situation prior to attempting a low speed orbit of the crown.
2	Blood is backing up into the OAD	<ol style="list-style-type: none"> 1. Immediately discontinue treatment. Stop the crown from spinning, but leave the OAS pump running. 2. Verify that the saline tubing is properly connected to the saline bag, that the saline tubing is routed correctly through the OAS pump saline tubing guides, and that the saline tubing is properly connected to the OAD. 3. If the saline tubing is properly connected and blood continues to back into the OAD sheath, replace the OAD.
3	Crown rotational speeds are	<ol style="list-style-type: none"> 1. Immediately discontinue treatment. Stop the crown from spinning, but leave the OAS pump running.

Issue number	Issue	Solution
	variable and will not stabilize	<ol style="list-style-type: none"> 2. Verify that saline is flowing. Verify VIPERSLIDE Lubricant is present in the saline bag. See the VIPERSLIDE Lubricant Instructions for Use for information. Verify that the saline tubing is properly connected to the saline bag, that the saline tubing is routed correctly through the OAS pump saline tubing guides, and that the saline tubing is properly connected to the OAD. 3. Verify that the crown advancer knob moves smoothly. 4. Retract the crown proximal to the lesion. Using a travel rate between 1 mm per second and 10 mm per second, continue treatment on low speed. 5. If rotational speeds will not stabilize, replace the OAD or guide wire.
4	The crown stops spinning and all speed indicator LEDs on the OAD handle are illuminated	Immediately discontinue treatment and replace the OAD.
5	The crown is not moving one-to-one with the crown advancer knob	<p>During start up in the vessel:</p> <ol style="list-style-type: none"> 1. Verify the Tuohy valve is not over-tightened. 2. Verify the crown advancer knob moves smoothly. 3. Retract the crown advancer knob until the crown moves with the knob. <p>While spinning:</p> <ol style="list-style-type: none"> 1. Immediately discontinue treatment. Stop the crown from spinning, but leave the OAS pump running. 2. Verify the Tuohy valve is not over-tightened. 3. Verify that the crown advancer knob moves smoothly. 4. Retract the crown advancer knob until the crown moves with the knob.

Issue number	Issue	Solution
		<ol style="list-style-type: none"> 5. Verify that contrast media injections are not above 400 psi and are not occurring during crown orbit. 6. Engage and disengage the lesion using a travel rate between 1 mm per second and 10 mm per second while maintaining one-to-one crown to advancer knob movement.
6	The OAD will not exit GlideAssist mode	<ol style="list-style-type: none"> 1. Press and immediately release any speed button. 2. Turn the pump power off and on.
7	The OAS pump will not power on and no LEDs are illuminated on the OAS pump control panel	<ol style="list-style-type: none"> 1. 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. 2. Ensure that the Master Power switch, on the back of the OAS pump, is in the on position. 3. Contact CSI Customer Service at the phone number on the back of this instructions for use to return to CSI for evaluation, including fuse inspection.
8	The OAS pump will not pump saline	<ol style="list-style-type: none"> 1. Ensure that the OAS pump is properly powered on – see Issue number 7. 2. Ensure that the saline bag and saline tubing (i.e. bag spike) are properly connected and a sufficient amount of saline is in the saline bag such that the low saline level sensor is not active and the red LED on the OAS pump control panel is not illuminated. 3. Ensure that the OAS pump head is properly aligned with the OAS pump base. 4. Ensure that the saline tubing is routed correctly through the OAS pump saline tubing guides and that the OAS pump saline tubing door is closed. 5. Ensure that the yellow LED is off and the green LED is illuminated. If the green LED is not illuminated, press the green Start button and verify that the yellow LED is off and that the green LED illuminates.

Issue number	Issue	Solution
		<p>6. Ensure that the yellow LED is off and the green LED is illuminated. If the green LED is flashing while the yellow LED is illuminated, press the green Start button twice and verify that the yellow LED is off and that the green LED illuminates.</p>
9	<p>The green (start) LED is illuminated, but the OAS pump does not pump and the yellow LED is illuminated as well</p>	<p>Ensure that the saline tubing is routed correctly through the OAS pump saline tubing guides and that the OAS pump saline tubing door is closed.</p> <p>Contact CSI Customer Service at the phone number on the back of this instructions for use.</p>
10	<p>The OAS pump was running, but has stopped pumping and the yellow LED is illuminated</p>	<p>Press the Master Power switch, on the back of the OAS pump, to power off the OAS pump. Wait five (5) seconds and press the Master Power switch to power on the pump.</p>
11	<p>The low saline level sensor (red LED) is illuminated</p>	<p>Note: The OAS pump will stop pumping saline and supplying power to the OAD 30 seconds after the low saline level sensor activates while the OAD is spinning, as indicated by an audible information signal every 5 seconds.</p> <ol style="list-style-type: none"> 1. If there is less than 200 mL of saline left in the bag of saline and lubricant, replace the bag with a new 1000 mL bag of normal saline and lubricant solution. 2. Ensure that the bag of saline and lubricant is hanging freely from the saline bag open hook and that the low saline level sensor cord is properly inserted into the connector on the sensor and the connector on the back of the OAS pump.

Issue number	Issue	Solution
		<ol style="list-style-type: none"> 3. Verify that the red low saline LED on the OAS pump control panel turns off and either the yellow LED or the green LED illuminates. If the yellow LED illuminates, press the Start button on the OAS pump and verify that the green LED illuminates.
12	The OAS pump will not power on	<p>Note: The OAS pump is designed to stop pumping saline and cut the supply of power to the OAD if the OAS pump encounters internal errors, such as: improper OAS pump pumping speed, problems with the power supply, inadvertent opening of the saline tubing door, etc.</p> <ol style="list-style-type: none"> 1. Ensure that the saline tubing door is closed. 2. Attempt to restart the OAS pump by pressing the green Start button (twice if the green LED is blinking) on the OAS pump control panel and verify that the green LED illuminates. 3. If the OAS pump does not restart after completing the above mentioned 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.
13	All OAD LEDs illuminate and stay on.	<ol style="list-style-type: none"> 1. Discontinue treatment. 2. Turn off the power module switch on the back of the OAS pump. After a few seconds, turn the power module switch to on and press the green Start button. 3. If the OAD LEDs continue to stay on, replace the OAD.
14	All OAD LEDs blink rapidly	<ol style="list-style-type: none"> 1. Discontinue treatment. 2. Reboot the OAD.

Issue number	Issue	Solution
		3. If rebooting does not correct the issue, replace the OAD.
15	OAD LED runaway pattern (Low, Medium, High)	<ol style="list-style-type: none"> 1. Discontinue treatment. 2. Replace the OAD.
16	The crown cannot spin.	<ol style="list-style-type: none"> 1. Discontinue treatment. 2. Check that the brake is locked. 3. Check the OAS pump and OAD indicator LEDs. 4. Check the power cords. 5. Verify that the OAS pump and OAD are receiving power.
17	There is no saline flow.	<ol style="list-style-type: none"> 1. Discontinue or do not initiate treatment. 2. Verify that the saline tubing is properly connected and saline is flowing. 3. Ensure that saline tubing is installed properly in the roller OAS pump. 4. Verify that the green LED on the front of the OAS pump is on after pressing the Power button. 5. If the OAD is properly connected and no flow is noted, replace the saline tubing, bag, and/or OAD. 6. Verify that the OAS pump door is closed. 7. Verify that there are no kinks in all saline tubing and the OAD saline sheath.
18	No LED's lit on front panel of the OAS pump.	<ol style="list-style-type: none"> 1. Ensure that the OAS pump is properly powered up (see above). 2. If none of the LEDs on the front cover light up after powering the OAS pump, contact CSI Customer Service.
19	The crown will not stop spinning	<ol style="list-style-type: none"> 1. Press the power button on the OAS pump. 2. Unplug the OAD from the OAS pump. 3. Unplug the OAS pump from the power source.
20	All three LEDs on the front panel of	<ol style="list-style-type: none"> 1. Press the Master Power switch, on the back of the OAS pump, to power off the

Issue number	Issue	Solution
	the OAS pump remain illuminated	<p>OAS pump. Wait a few seconds and press the Master Power switch to power on the pump.</p> <p>2. Contact CSI Customer Service at the phone number on the back of this instructions for use.</p>
21	After OAS pump power up, all three LEDs on the front panel of the OAS pump blink three times and there is an audible notification signal three times.	Contact CSI Customer Service at the phone number on the back of this instructions for use.

Appendix B. Introducer, Guide Sheath, or Guide Catheter Size

Table B1. Micro Crown

Crown Diameter mm	Model Number	Orbital Atherectomy Device Maximum Outer Diameter mm (inches)	Minimum Introducer or Guide Sheath Internal Diameter, French (inches)	Guide Catheter Sizing
1.25	DBP-125MICRO75	1.35 (0.053)	4 (0.053)*	See guide catheter manufacturer specifications for lumen diameter.
1.25	DBP-125MICRO145	1.32 (0.052)	4 (0.053)*	See guide catheter manufacturer specifications for lumen diameter.

* For manual contrast injection with DBP-125MICRO75 and DBP-125MICRO145 use introducer sheath > 4 Fr.

Table B2. Solid Crown

Crown Diameter mm	Model Number	Orbital Atherectomy Device Maximum Outer Diameter mm (inches)	Minimum Introducer or Guide Sheath Internal Diameter, French (inches)	Guide Catheter Sizing
1.25	DBP-125SOLID75	1.35 (0.053)	4 (0.053)*	See guide catheter manufacturer specifications for lumen diameter.
1.25	DBP-125SOLID145	1.32 (0.052)	4 (0.053)*	See guide catheter manufacturer specifications for lumen diameter.
1.50	DBP-150SOLID145	1.60 (0.063)	5 (0.065)	See guide catheter manufacturer specifications for lumen diameter.
2.00	DBP-200SOLID145	2.00 (0.079)	6 (0.079)	See guide catheter manufacturer specifications for lumen diameter.
1.25	DBP-125SOLID200	1.60 (0.063)	5 (0.065)	See guide catheter manufacturer specifications for lumen diameter.
1.50	DBP-150SOLID200	1.60 (0.063)	5 (0.065)	See guide catheter manufacturer specifications for lumen diameter.

1.75	DBP-175SOLID180	1.75 (0.069)	5 (0.070)	See guide catheter manufacturer specifications for lumen diameter.
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* For manual contrast injection with DBP125SOLID75 and DBP-125SOLID145 use introducer sheath > 4 Fr.

Table B3. Classic Crown

Crown Diameter mm	Model Number	Orbital Atherectomy Device Maximum Outer Diameter mm (inches)	Minimum Introducer or Guide Sheath Internal Diameter, French (inches)	Guide Catheter Sizing
1.50	DBP-150CLASS145	1.60 (0.063)	5 (0.065)	See guide catheter manufacturer specifications for lumen diameter.
2.00	DBP-200CLASS145	2.00 (0.079)	6 (0.079)	See guide catheter manufacturer specifications for lumen diameter.

Appendix C. Maximum Orbit and Resulting Lumen Diameter

The following tables show the maximum orbit and resulting lumen diameter for all crown sizes, at incremental rotational speeds, for 20 passes (approximately 5 min of treatment time). Quantitative angiography is recommended to determine minimum vessel diameter.

Note: A **pass** is defined as once out and back across the lesion. Orbit data presented are based on a 6 cm pass distance at a travel rate of 10 mm per second.

Table C1. Micro Crown Size and Rotational Speed

Model Number	Crown Size (mm)	Rotational Speed (rpm)	Max. Lumen Diameter* (mm) Average +2 SD
DBP-125MICRO145 DBCART-125MICRO145	1.25	60,000	1.66
		90,000	1.73
		140,000	1.81
DBP-125MICRO75	1.25	60,000	
		90,000	
		140,000	

SD = standard deviation

* These lumens are based on *in vitro* test results at approximately 5 minutes of treatment time (20 passes) at a rate of approximately 10 mm per second of travel speed. Actual clinical results may vary.

Table C2. Solid Crown Size and Rotational Speed

Model Number	Crown Size (mm)	Rotational Speed (rpm)	Max. Lumen Diameter* (mm) Average +2 SD
DBP-125SOLID75	1.25	60,000	
		90,000	
		140,000	
DBP-125SOLID145	1.25	60,000	1.89
		90,000	2.37
		120,000	2.95
DBP-150SOLID145	1.50	60,000	2.05
		90,000	2.90
		120,000	3.91
DBP-200SOLID145	2.00	60,000	3.18
		90,000	4.36
		120,000	6.05
DBP-125SOLID200	1.25	60,000	1.97
		90,000	2.33
		120,000	2.86
DBP-150SOLID200	1.50	60,000	2.44
		90,000	2.98

		120,000	3.86
DBP-175SOLID180	1.75	60,000	2.73
		90,000	3.52
		120,000	4.62

SD = standard deviation

* These lumens are based on *in vitro* test results at approximately 5 minutes of treatment time (20 passes) at a rate of approximately 10 mm per second of travel speed. Actual clinical results may vary.

Table C3. Classic Crown Size and Rotational Speed

Model Number	Crown Size (mm)	Rotational Speed (rpm)	Max. Lumen Diameter* (mm) Average +2 SD
DBP-150CLASS145	1.50	60,000	1.82
		90,000	2.08
		140,000	2.34
DBP-200CLASS145	2.00	60,000	2.44
		90,000	2.63
		140,000	2.95

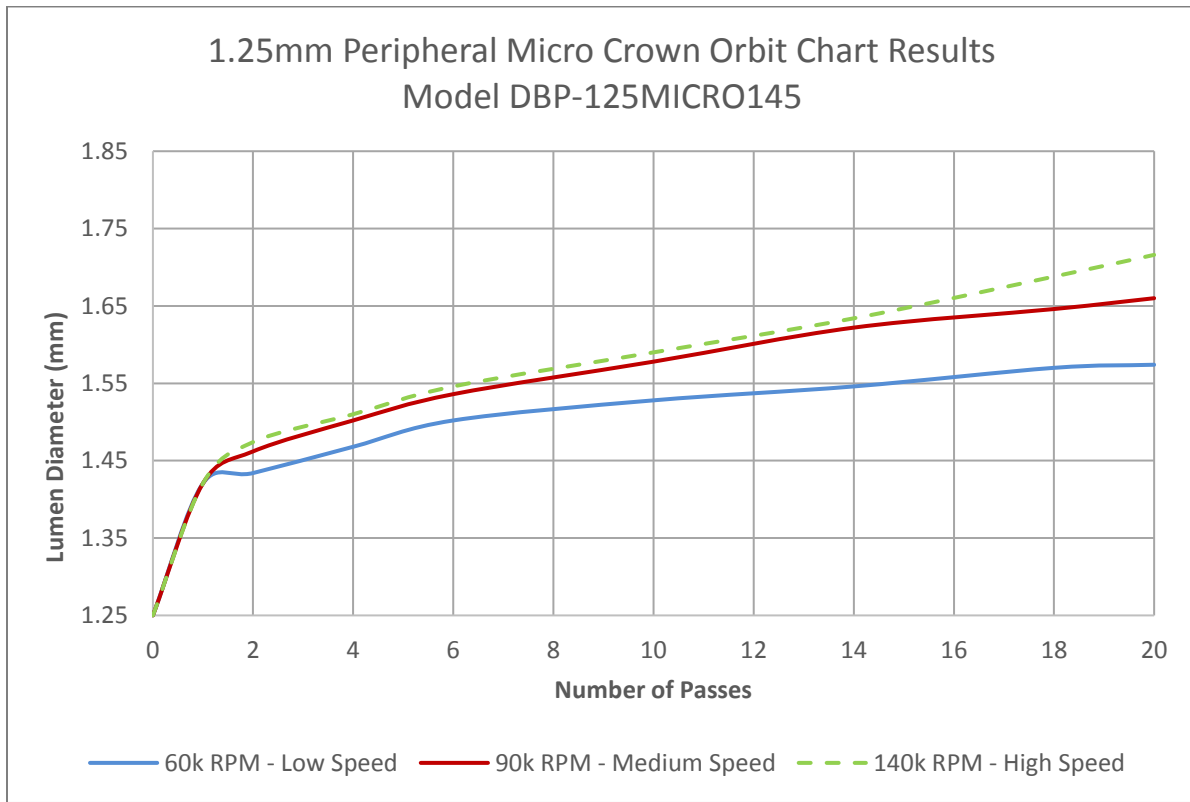
SD = standard deviation

* These lumens are based on *in vitro* test results at approximately 5 minutes of treatment time (20 passes) at a rate of approximately 10 mm per second of travel speed. Actual clinical results may vary.

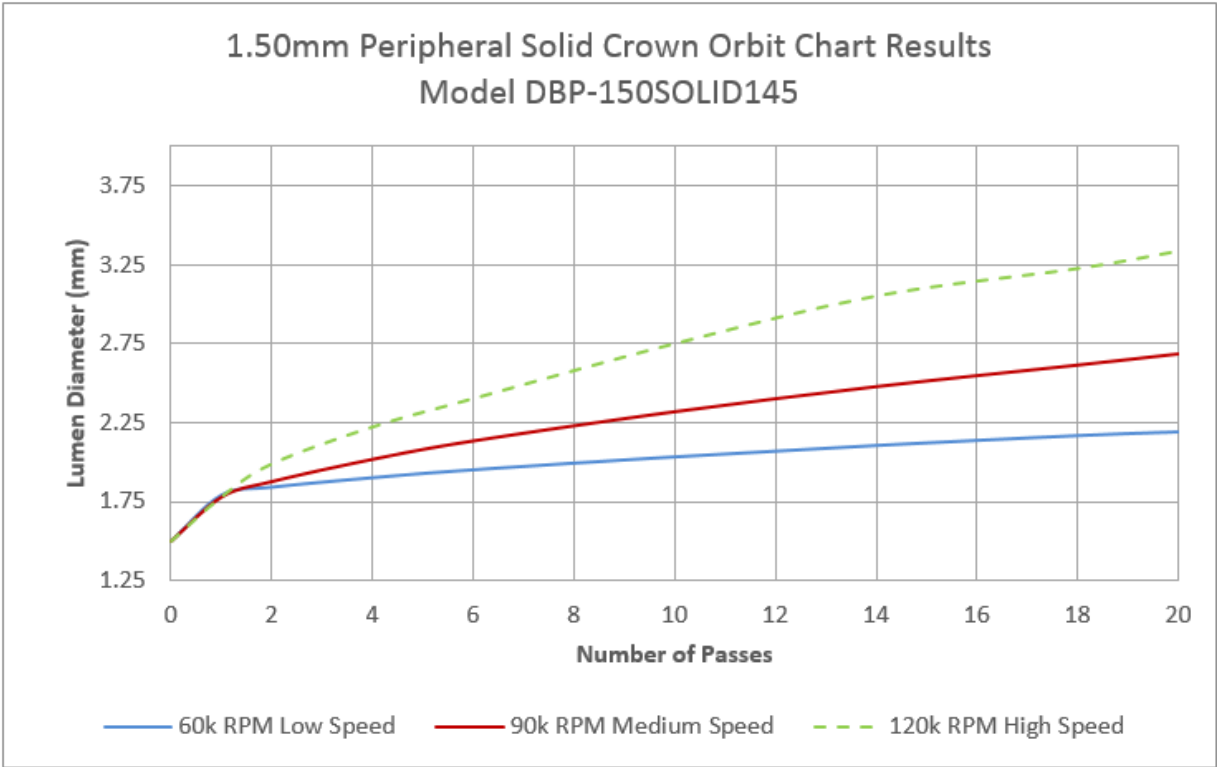
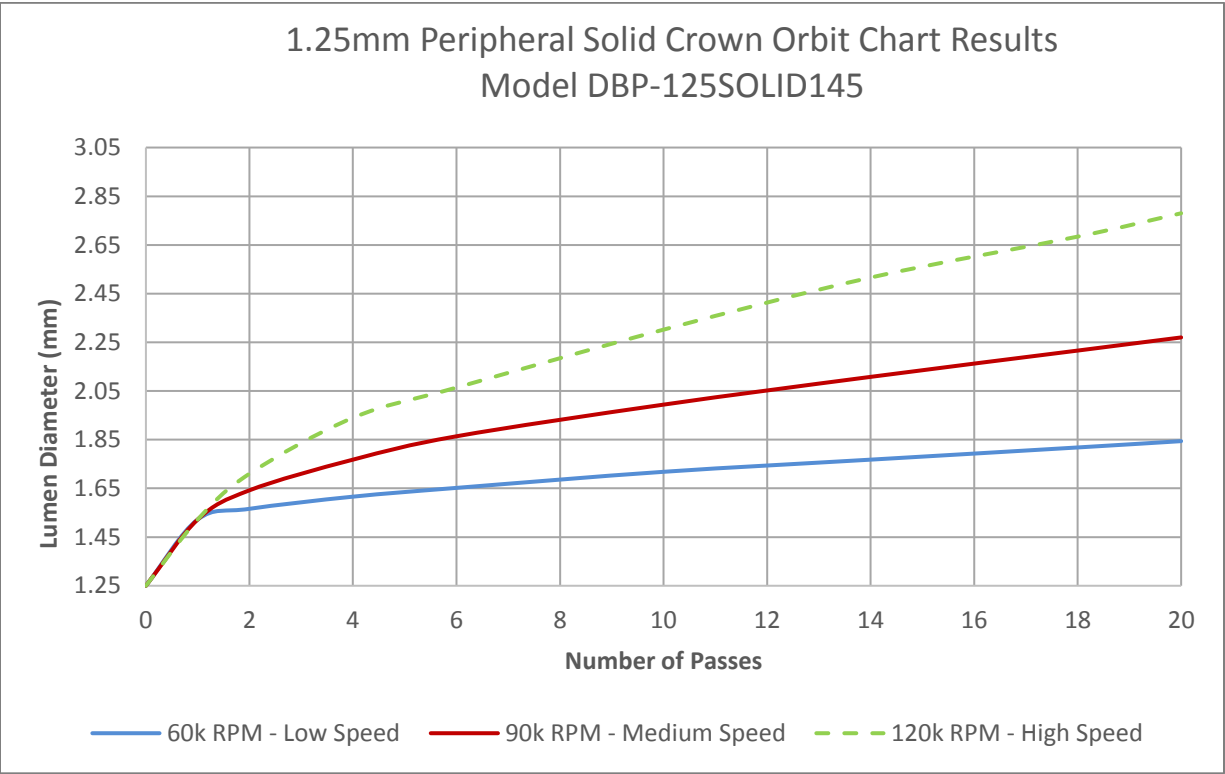
Appendix D. Orbit Performance

The following charts demonstrate typical orbit diameter vs. duration of operation (as measured in simulated calcified lesions.) These charts are for reference only. Actual orbit performance may vary.

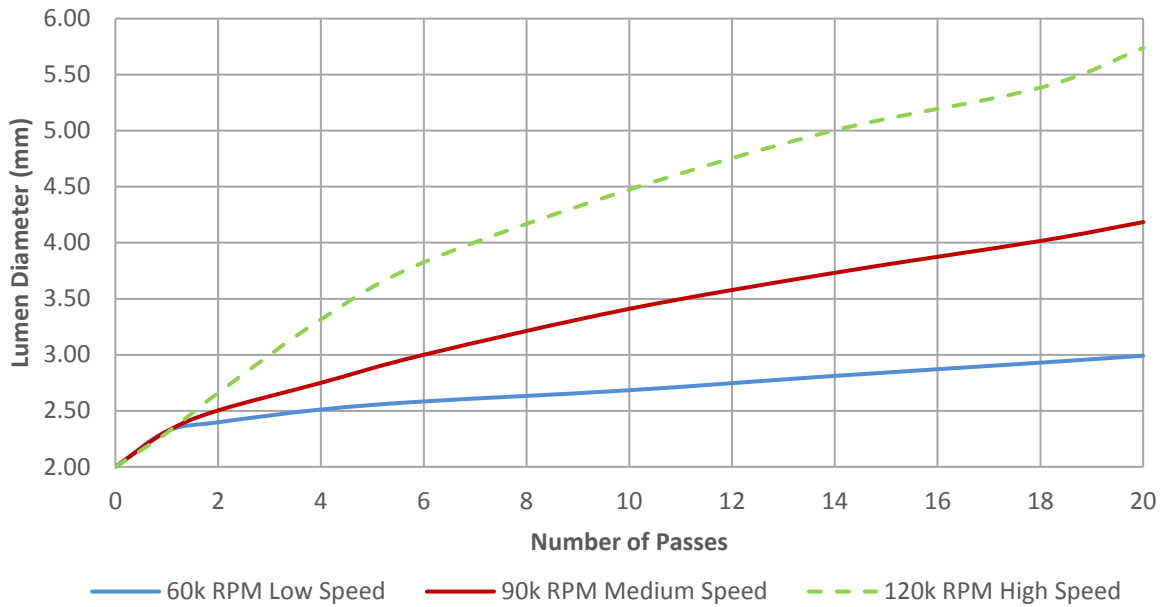
Need 1.25 75 cm micro



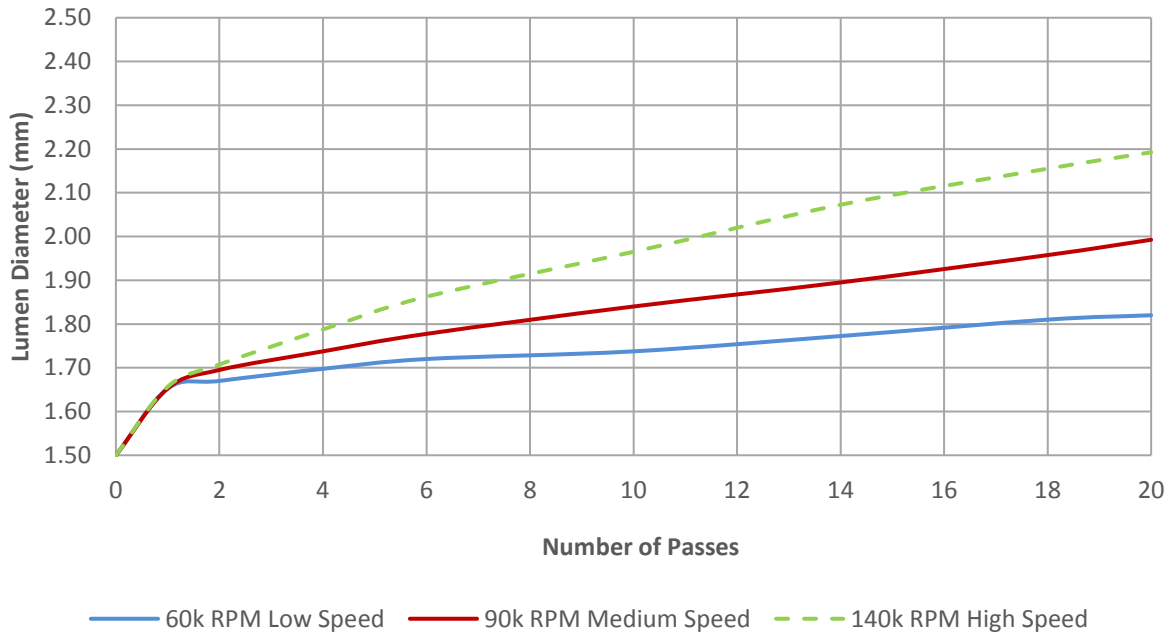
Need 1.25 solid 75 cm



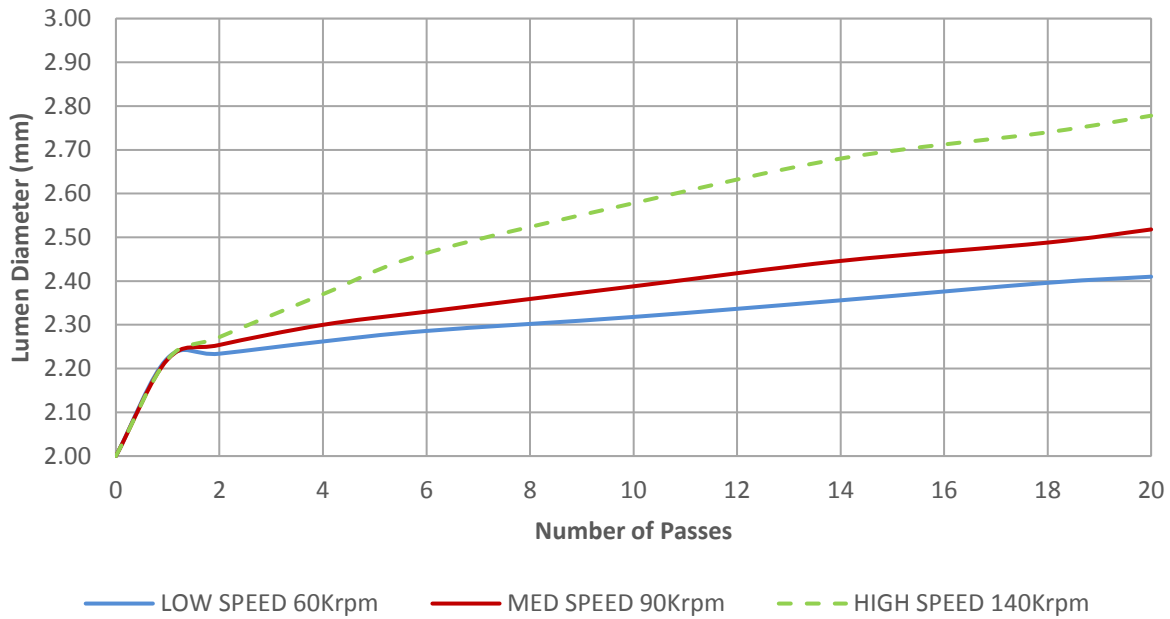
2.00mm Peripheral Solid Crown Orbit Chart Results
Model DBP-200SOLID145



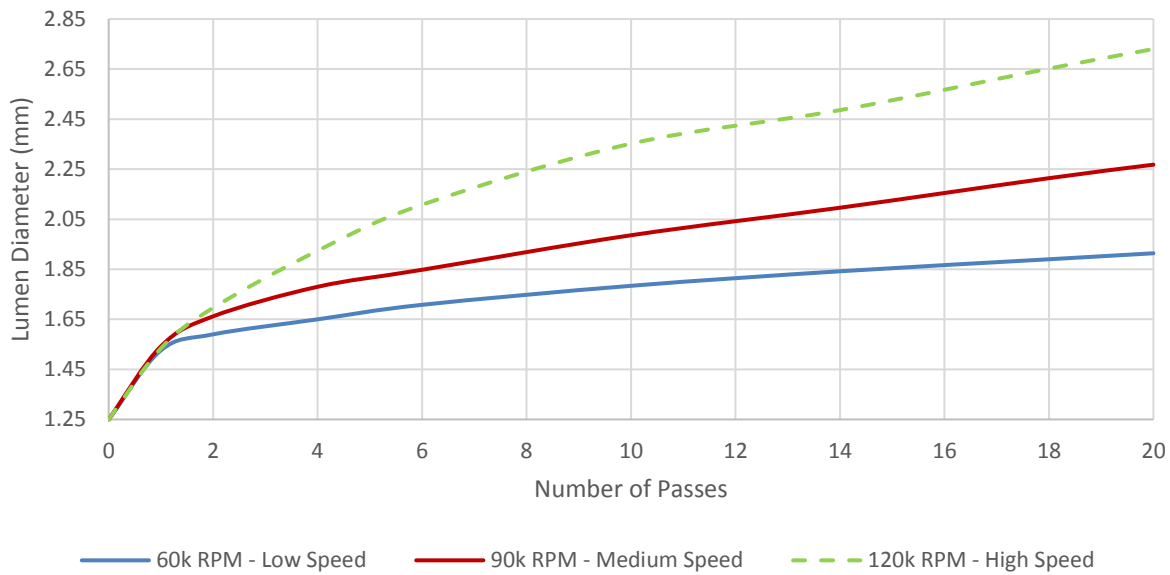
1.50mm Peripheral Classic Crown Orbit Chart Results
Model DBP-150CLASS145



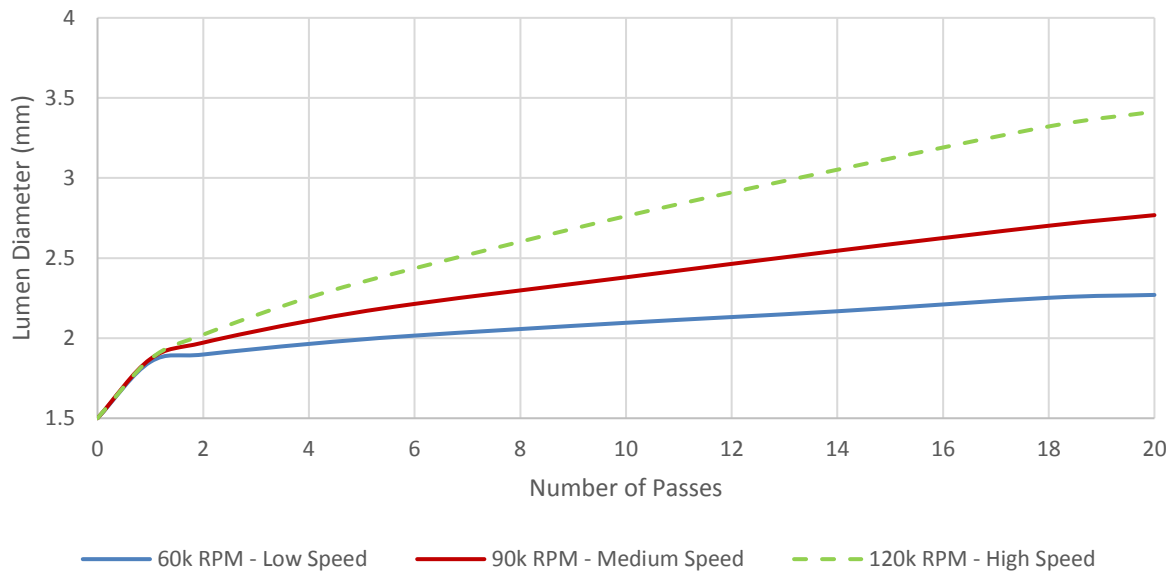
2.00mm Peripheral Classic Crown Orbit Chart Results Model DBP-200CLASS145



1.25mm Extended Length Diamondback Peripheral Orbit Chart Results Model DBP-125SOLID200



1.50mm Extended Length Diamondback Peripheral Orbit Chart
Results
Model DBP-150SOLID200





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