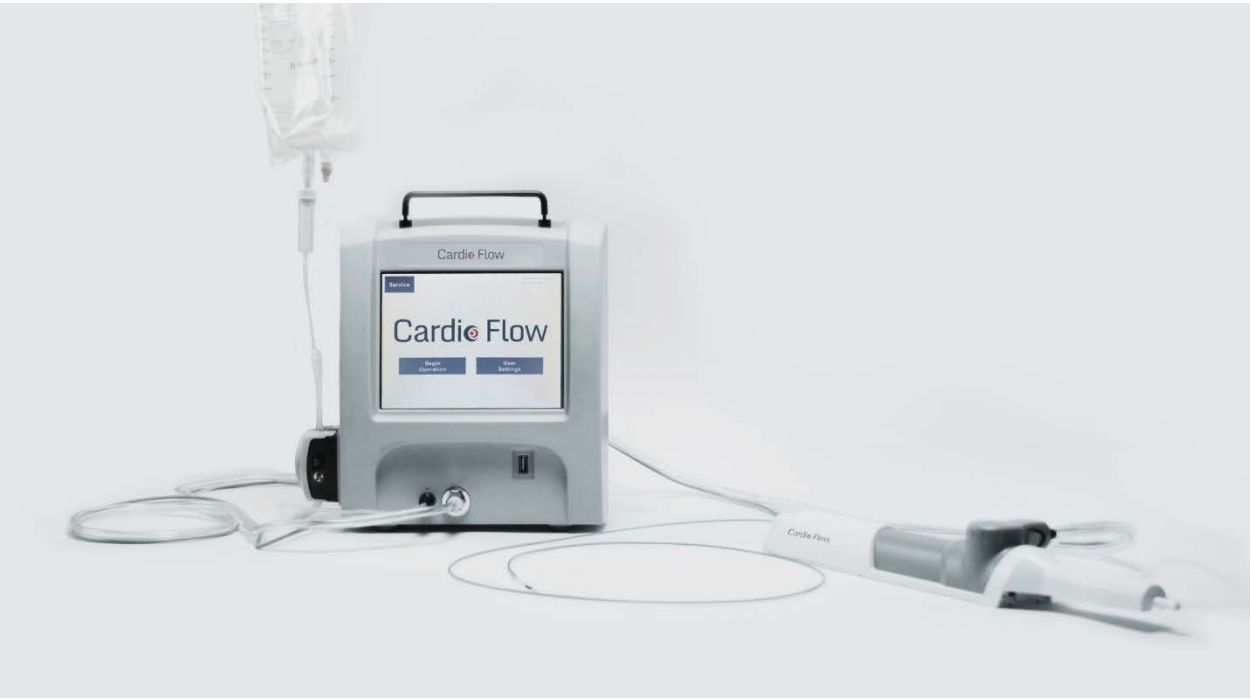
Cardio Flow

FreedomFlow™ Orbital Atherectomy System

Instructions for Use



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Caution: Investigational device. Limited by United States law to investigational use.

Manufactured for: Cardio Flow, Inc.

Cardio Flow

888 East Ave., Mahtomedi, MN 55115
800-294-5517
www.cardioflow.net

Explanation of Symbols on Control Module

	Model Number
	Serial Number
	Protection Against Ingress of Solids and Liquids
	Alternating Current
	Power On
	Power Off
	Type BF Applied Part
	Ground
	Passive Universal Serial Bus Drive Port
	**Attention:** Consult Accompanying Documentation
	**Caution:** Investigational device. Limited by United States law to investigational use.

Explanation of Symbols on Labels

	Manufactured For: Cardio Flow, Inc. 888 East Avenue, Mahtomedi, MN 55115
	Date of Manufacture (YYYY-MM-DD)
	Use By date (YYYY-MM-DD)
	Model Number
	Lot Number
	Type BF Applied Part
	Protection Against Ingress of Solids and Liquids
	Sterilized by Ethylene Oxide (EO)
	Do Not Reuse
	Do Not Resterilize
	Do Not Use if Package is Damaged
	**Caution:** Consult Instructions for Use
	**Caution:** Investigational device. Limited by United States law to investigational use.

Glossary of Icons on Control Module Touchscreen

	Return to Main Menu
	Speed display in thousands of revolutions per minute (kRPM).
	Speed selection
	Pressure display in pounds per square inch (PSI). Up/Down arrows at right of PSI display adjust pressure.
	Empty gray drop indicates peristaltic pump is OFF.
	Solid blue drop indicates peristaltic pump is ON.
	Saline flush icon should be continuously touched to speed priming of the User Handle prior to procedure.

Introduction

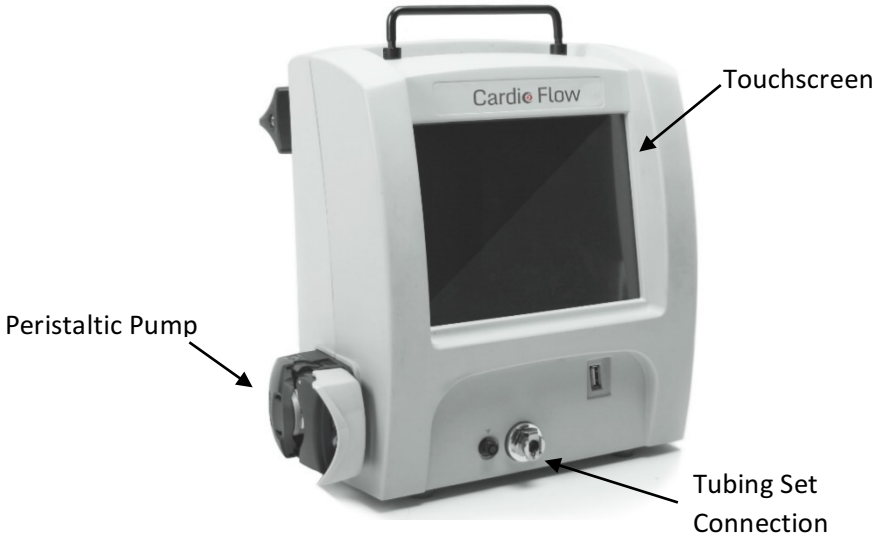
The FreedomFlow™ Orbital Atherectomy System is a device used to treat patients suffering from peripheral artery disease (PAD)—a condition caused by the accumulation of plaque in arteries of the legs and feet. The system is a minimally invasive, catheter-based endovascular device for removing atherosclerotic plaque from arterial blood vessels within the body. The system treats a wide range of vessels sizes above and below the knee and may provide more efficient removal of plaque with less run time than existing orbital atherectomy treatments.

Document Scope

This document describes operation of the FreedomFlow™ system and its three primary components: Control Module, Tubing Set, and User Handle. Read this document thoroughly before using the FreedomFlow™ system.

Control Module

The Control Module, Model CM1001, is a portable, reusable component of the system that integrates delivery of saline and pneumatic power to the User Handle. The Control Module touchscreen is the primary interface for operating the peristaltic pump and regulating orbital speed of the User Handle. The pre-programmed Control Module includes a pneumatic pressure hose and hospital-grade electrical plug. The Control Module can be placed on a table or mounted to a standard 5-wheel IV pole.
NOTE: Detailed information on selecting appropriate orbital speed for vessel size is included in Appendix B.

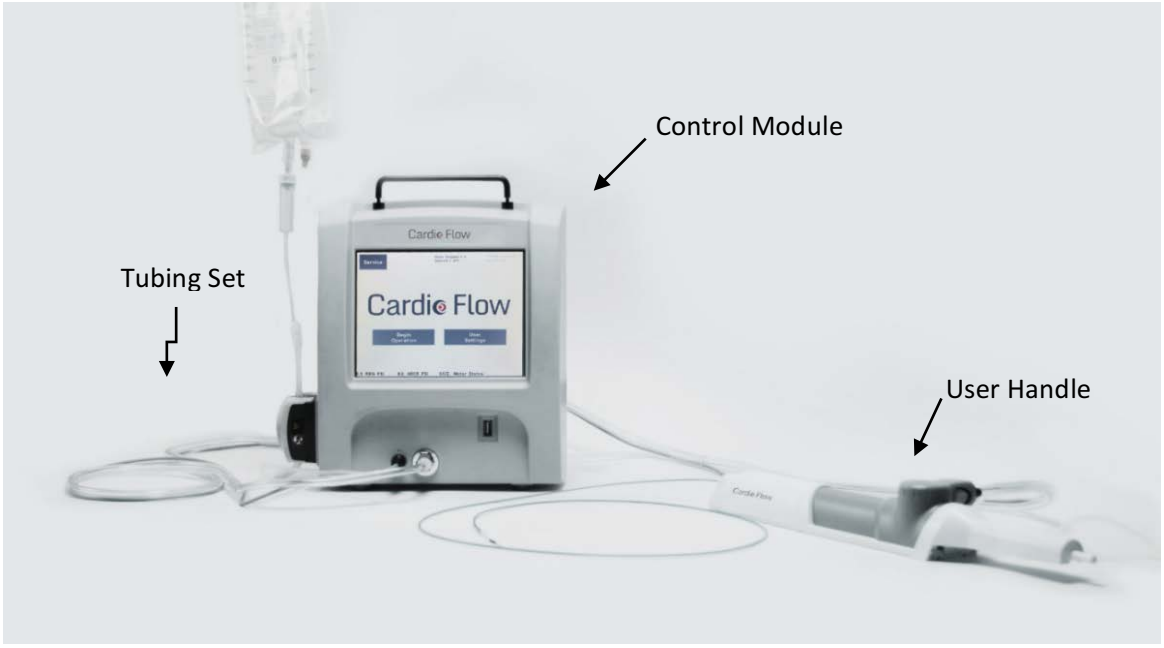


Indications for Use

The FreedomFlow™ system is applied as therapy to remove atherosclerotic plaque within peripheral arterial vessels. The therapy is intended for patients who are acceptable candidates for percutaneous transluminal atherectomy.

The Cardio Flow FreedomFlow™ Orbital Atherectomy System

The FreedomFlow™ Orbital Atherectomy System consists of a Control Module, Tubing Set, and User Handle. It is designed to remove atherosclerotic plaque from peripheral arteries by rotation of diamond-coated spheres mounted eccentrically on a coiled driveshaft. The Control Module is reusable capital equipment. The Tubing Set and User Handle are single-use sterile devices. The User Handle is used to activate rotation and advance the driveshaft on a 0.014-inch bare-metal atherectomy guidewire. The guidewire and introducer sheath are not included with the system. The Tubing Set and User Handle are the only applied part of the system to the patient.

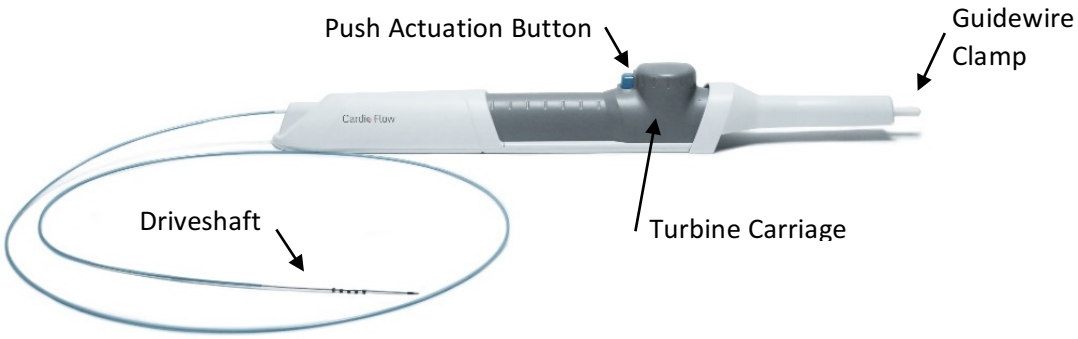


Tubing Set

The Tubing Set is a single-use component that is packaged with the User Handle. The Tubing Set is supplied sterile (via Ethylene Oxide gas). The set delivers saline and pressurized gas from the Control Module to the User Handle. A cable and sensor relay orbital speed back to the Control Module.

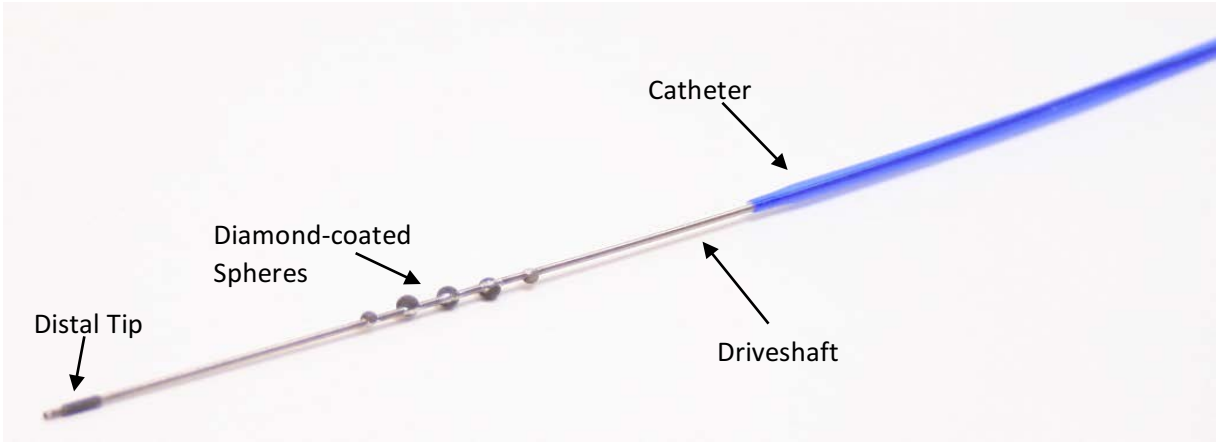
User Handle

The User Handle is a single-use component that provides control over rotation and transluminal movement of the integrated driveshaft. The User Handle is supplied sterile (via Ethylene Oxide gas). A spring-loaded button on the User Handle is depressed to activate the pneumatic driveshaft and released to stop rotation. The turbine carriage of the User Handle has approximately 7 cm of travel and is used to advance and retract the driveshaft's diamond-coated distal tip and eccentrically mounted diamond-coated spheres independently of the catheter tubing. The User Handle guidewire clamp prevents guidewire movement during use.



Driveshaft Details

The driveshaft is a hollow multi-strand cable that drives the spinning of the diamond-coated spheres. The off-axis eccentric attachment of the spheres onto the driveshaft force the spheres in an outward centrifugal direction during rotation. The diamond-coated distal tip is designed to add stability and may ease transition into a tight stenotic lesion.



Contraindications, Restrictions, Warnings, Precautions, and Adverse Events

The following contraindications, restrictions, warnings, precautions and adverse events should be reviewed prior to the use of this device.

Contraindications

- The atherectomy guidewire cannot be passed across the peripheral lesion.
- The system cannot be used in coronary or carotid arteries.
- The target lesion is within a bypass graft or stent.
- If 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.

Restrictions

- The FreedomFlow™ system should only be used by physicians who are experienced in peripheral interventions and are trained on the use of the system.

Caution: Investigational device. Limited by United States law to investigational use.

Warnings

- To avoid the risk of electrical shock, the control module must only be connected to a supply mains with protective earth.
- Do not use this device in a vessel that is too small for the device. The vessel diameter at the treatment area must be at least 2 mm in diameter.
- If mechanical failure of the system occurs before or during the atherectomy procedure, discontinue use immediately. Do not attempt to use a damaged User Handle or other system component. Use of damaged components may result in system malfunction or patient injury.
- Do not use device during spasm of the vessel.
- Use only 0.014-inch diameter x 300 cm (minimum length) bare-metal atherectomy guidewire. Follow manufacturer instructions related to guidewire use.
- Do not continue treatment if the guidewire or the device becomes sub-intimal.
- Immediately stop use of the User Handle if the driveshaft stalls. Review for complications and mechanical failure if a stall condition occurs.
- Performing treatment in vessels or bifurcations that are excessively tortuous or angulated may result in vessel damage.
- Always use fluoroscopy and/or ultrasound when advancing the guidewire to avoid misplacement, dissection, or perforation. The User Handle driveshaft tracks over the guidewire, so it is imperative that the guidewire be initially placed through the stenotic lumen and not in a false channel.

- Do not inject contrast while driveshaft is spinning. User Handle failure or patient harm may occur.
- Move the User Handle and guidewire carefully. A tight loop, kink, or bend in the guidewire may cause damage and system malfunction during use.
- Spinning diamond-coated spheres through bends tighter than 3.5cm radius may cause User Handle failure to occur.
- Never operate the User Handle without standard USP 0.9% sterile saline solution. Flowing saline prevents blood backup into the catheter and is required for cooling and lubricating the User Handle, driveshaft, and guidewire during use to avoid overheating and permanent damage to the User Handle and possible patient injury.
- The diamond coated distal tip and diamond coated spheres of the User Handle driveshaft operate at very high speeds. Do not allow body parts or clothing to contact the driveshaft. Physical injury or entanglement may occur.
- Always advance the orbiting, spheres by moving the User Handler turbine carriage. Never advance the orbiting spheres by moving the driveshaft or User Handle. Guidewire buckling may occur, and perforation or vascular trauma may result.
- Always keep the spheres advancing or retracting while driveshaft is rotating. To avoid excess tissue removal, do not allow the spheres to remain in one location for more than 5 seconds during rotation.
- Never force the spheres when rotational or translational resistance occurs; vessel perforation may occur. If resistance to motion is noted, retract the spheres and stop treatment immediately. Use fluoroscopy and/or ultrasound to analyze the situation.
- While advancing the spheres through the introducer sheath/guide catheter, do not activate rotation. The spheres must not spin while located within the introducer sheath/guide catheter.
- The travel of the turbine carriage—and therefore the driveshaft tip—is approximately 7 cm. Moving the User Handle turbine carriage forward moves the driveshaft tip an equal distance. When moving the turbine carriage, make sure there is sufficient distance between the guidewire spring tip and the distal tip of the driveshaft (16 cm minimum). If the distance between the distal tip and the guidewire spring tip is insufficient, the distal tip may damage or dislodge the guidewire spring tip. Use ultrasound and/or contrast injections and fluoroscopy to monitor movement of the driveshaft tip in relation to the guidewire spring tip.
- Do not prolapse or bend the guidewire core. If the spring tip becomes prolapsed, keep the prolapse/bend contained within spring tip section only. A prolapsed or bent guidewire core can result in damage to the guidewire or User Handle.
- The FreedomFlow™ system should not be used on pregnant women or children.
- Do not re-use or re-sterilize User Handle or Tubing Set as the device may not function as intended and serious infection leading to potential harm and/or death may occur.
- Do not block access to the power entry unit of the control module. The unit must be installed to allow access to disconnect power at the back of the control module.

Precautions

- If the User Handle/Tubing Set sterile package appears damaged or shelf life has expired, do not use.
- Follow standard hospital atherectomy policies and procedures, including those related to anticoagulation and vasodilator therapy.
- Ultrasound and/or radiographic equipment for fluoroscopy should be used to provide high-resolution images. Atherectomy guidewires and catheters should only be manipulated under fluoroscopy and/or ultrasound.
- Use only sterile normal saline as the infusate. (Drugs such as vasodilators are added to the infusate at the physician's discretion). The User Handle may malfunction if contrast or other substances are injected into the User Handle.
- Ensure entire driveshaft and catheter tubing remain kink-free during atherectomy treatment.
- Frequent rest periods to evaluate treatment under fluoroscopy and/or ultrasound are recommended, with a maximum total treatment time of 3 minutes.
- Monitor the saline fluid level during the procedure. Normal saline infusion is critical to the User Handle performance. Do not kink or crush the Tubing Set. 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 Control Module.
- There are no known significant risks of interference posed by the presence of the control module. Therefore, the Control Module is not likely to cause, or be influenced by, any interference in nearby electronic equipment.
- This equipment has been tested and found to comply with EN60601-1-2 Edition 4.0 and EN55011 Class A limits. These limits are designed to provide reasonable protection against harmful interference. This equipment, if not installed and used in accordance with the instructions, may cause harmful interference to other equipment. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
    - Reorient or relocate the other equipment.
    - Increase the separation between the Control Module and the other equipment.
    - Connect the other equipment into an outlet on a circuit different from the Control Module's connection.
    - Consult Cardio Flow Inc. for help.

Adverse Events

Possible risks associated with the Cardio Flow FreedomFlow™ Orbital Atherectomy System that may occur and/or require intervention include, but are not limited to:

- Allergic reaction to medication/media/device components
- Amputation

- Anemia
- Aneurysm
- Bleeding complications which may require transfusion
- Cerebrovascular accident (CVA)
- Death
- Distal embolization
- Device embolization
- Entry site complications including hematoma
- 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
- Dissection
- Perforation
- Thrombus
- Vessel closure, abrupt
- Vessel injury, including dissection and perforation that may require surgical repair
- Vessel spasm
- Vessel occlusion

Transport, Storage, and Operating Conditions

The Cardio Flow Control Module is shipped nonsterile and is not intended to be sterilized. The Cardio Flow User Handle and Tubing Set are shipped sterile for single-use.

- The System shall be transported within the following conditions:
  - Temperature range: -29°C to 60°C
  - Humidity (non-condensing): 10% to 85%
- The System shall be stored and operated within the following conditions:
  - Temperature range: 15-35°C
  - Humidity (non-condensing): 30% to 50%
  - Standard atmospheric pressure: 50-106 kPa.

Control Module Maintenance

The Cardio Flow Control Module is shipped nonsterile and is not intended to be sterilized.

- The Control Module should be cleaned between procedures with a hospital-grade disinfectant solution (ie. Sani-Wipes). The Control Module should not be immersed in cleaning solutions, and solvents and abrasive chemicals should not be used.

Caution: The Control Module must be powered off and unplugged from the wall power outlet prior to cleaning. Ensure that the Control Module is completely dry before reconnecting to wall power outlet.

- Prior to powering off the Control Module, it is recommended that users return to the main menu screen to ensure a proper power down cycle.
- The Control Module shall be maintained, serviced, and repaired only by Cardio Flow, Inc. personnel. Contact a Cardio Flow representative for further instructions.
- The Control Module shall have a minimum anticipated life of 2 years of use. Additional equipment life can be determined through Cardio Flow maintenance and evaluation.
- Store the Control Module at room temperature, in a dry condition away from magnets or possible electromagnetic interference.

The Control Module may not function as anticipated. Please refer to Appendix A for Control Module troubleshooting information. If this does not quickly resolve the issue, stop the procedure and contact Cardio Flow, Inc. for further instruction. Removal of the power cord connection via the power switch at the back of the control module isolates the internal circuits from the supply mains.

Using the FreedomFlow™ Orbital Atherectomy System

Required Supplies and Equipment

Carefully read this section to ensure all supplies and equipment are available prior to performing the atherectomy procedure.

FreedomFlow™ system

- The Cardio Flow Control Module
- User Handle and Tubing Set.

Atherectomy Guidewire and Introducer Sheath

- The FreedomFlow™ system **must** be used with commercially available 0.014-inch diameter x 300 cm (minimum length) bare-metal atherectomy guidewire. Following this guideline is critical to the function of the system and the safety of the patient.
- The Cardio Flow User Handle must enter a patient's anatomy through a commercially available 5 Fr introducer sheath.

Saline Solution and IV Pole

- A standard sterile USP 0.9% saline solution infusion bag in 1,000-ml volume size is required. Glass bottles **cannot** be used as the Tubing Set does not support a vented spike.

- A standard 5-wheel IV pole should be used for hanging the saline infusion bag and mounting the Control Module.

Power and Gas Supply

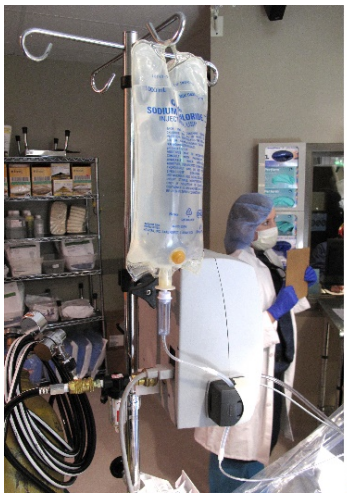
- A standard US 120 V / 60 Hz or OUS 240 V / 50 Hz electrical wall outlet is required to power the module.
- Cardio Flow supplied electrical cord is required for use. Contact Cardio Flow for a new electrical cord if another one is required.
- The system is powered by compressed gas connected to the control module. The gas supply, which can be provided via tanks or a compressor, must meet these requirements:
  - Gas must be air or nitrogen.
  - Gas must be clean, dry, oil free, or supplied through an appropriate filter.
  - Gas pressure must be maintained between 85–116 psi (586.0-799.8 kPa) at the Control Module inlet.
  - Supply must be capable of delivering gas at a minimum rate of 4 standard cubic feet per minute (SCFM).

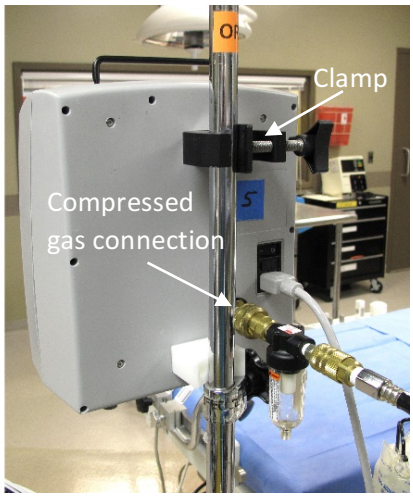
Other Interventional Supplies

- Other supplies necessary for using the system are based on standard interventional procedures. This includes fluoroscopic and/or ultrasound imaging equipment per the physician's lab practice.

Control Module Setup

1. The Control Module power rating is 100VA, 120-240 VAC, 50-60 Hz.
2. The Control Module is to be transported by hand utilizing the handle at the top of the unit. Do not transport the Control Module mounted onto an IV pole.
3. When ready to utilize the system, mount the Control Module to the 5-wheel IV pole utilizing the clamp on the back of the Control Module. Keep the Control Module on the IV pole high enough to easily view yet low enough to allow the saline infusion bag to hang above the Control Module. Adjust the IV pole to obtain desired position.



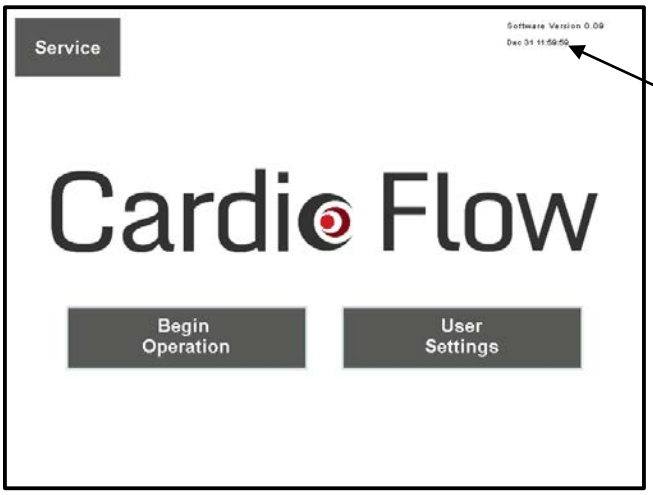


4. Connect the compressed gas supply hose to the ¼-inch NPT male fitting on the back of the control module. If an adapter fitting is required, attach adapter prior to supply hose tubing.
5. Plug the power cord into the Control Module and into the wall power outlet.
6. Turn Control Module on with switch on back of module.

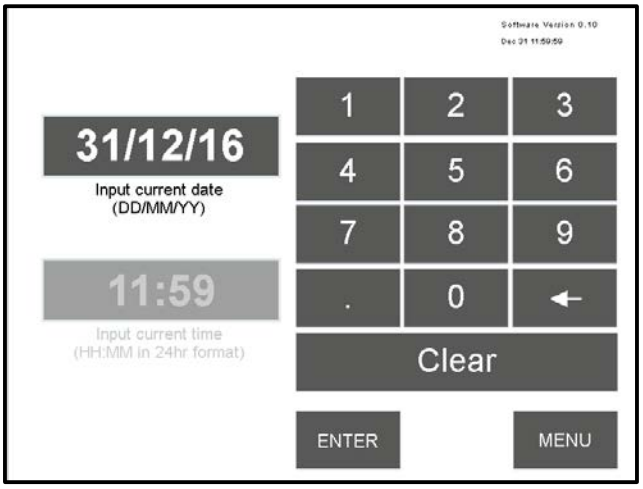
7. Wait for Control Module to boot and ensure main menu appears on touch screen.
8. Verify that date and time in upper right corner of the screen are correct prior to use.
9. On new control modules, date and time must be set prior to use.

Setting date and time:

10. Select User Settings from main menu touch screen.

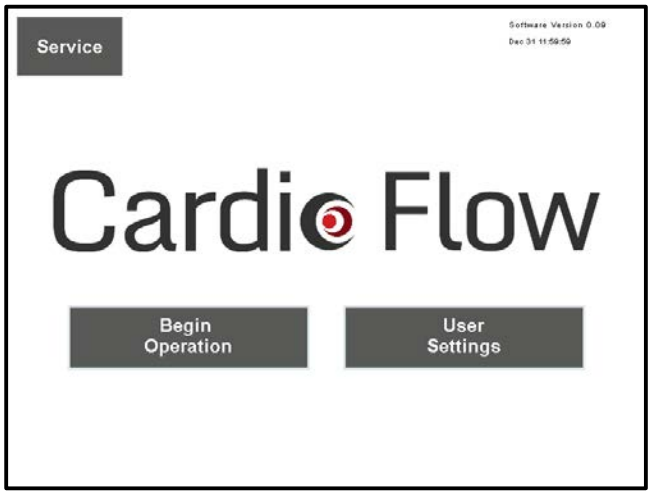


11. Input date and select ENTER. Input time and select ENTER. Select MENU to return to the main menu.

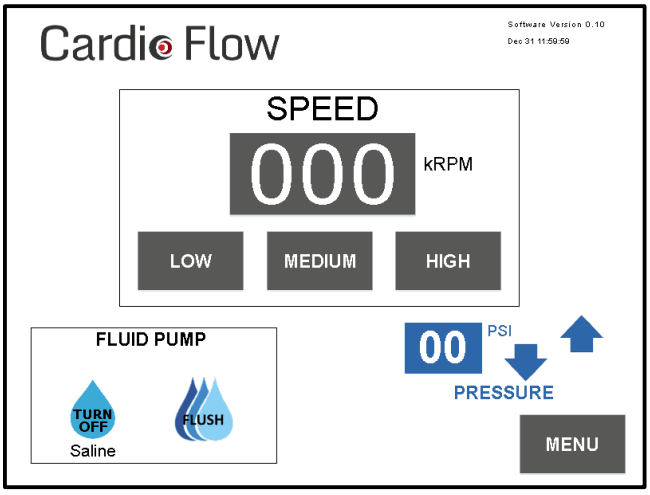


Begin Operations Screen:

1. Select Begin Operation from main menu touch screen.



2. The Begin Operation screen allows the user to set up and perform the atherectomy procedure. See Appendix B for details on selecting the appropriate speed for vessel size.



Service Screen:

The Service icon on the upper-left hand of the main menu allows Cardio Flow, Inc. personnel to access the Control Module settings. Only Cardio Flow, Inc. personnel have access to this password-protected screen. The Service screen also allows Cardio Flow, Inc. personnel to access and download case data for engineering analysis through the USB port on the front face of the control module. This USB port is to be utilized by Cardio Flow, Inc. technical personnel only and will not function without access to the service screen. This USB port located on the front of the control module is intended only for passive devices, such as flash storage devices.

Preparing the FreedomFlow™ Orbital Atherectomy System

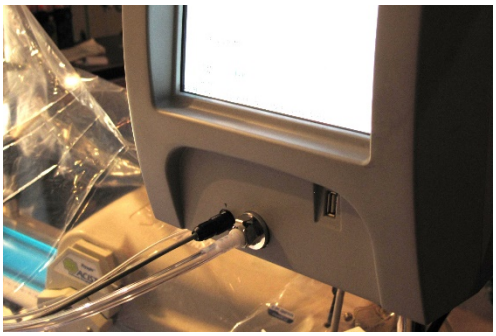
The Control Module is nonsterile and must remain outside the sterile field. To be utilized directly by the physician, the Control Module can be bagged with a commercially available sterile drape to be positioned in the sterile field. The User Handle and Tubing Set are provided sterile.

Connecting the User Handle:

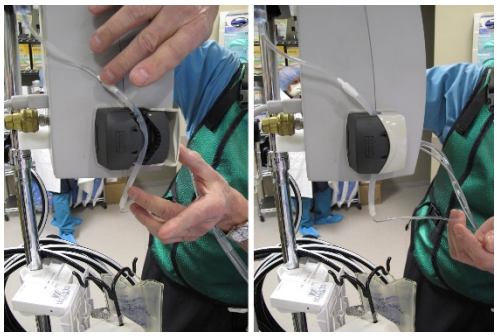
1. Transfer the User Handle and Tubing Set through two-person hand off into sterile field from packaging tray.
2. Transfer User Handle Tubing Set onto sterile patient table.

> **Caution:** Visually review User Handle and Tubing Set for any abnormal signs of damage, such as catheter kinks. Dispose of User Handle and Tubing Set and continue with a new product if damage is observed. Return damaged product to Cardio Flow, Inc. for evaluation.

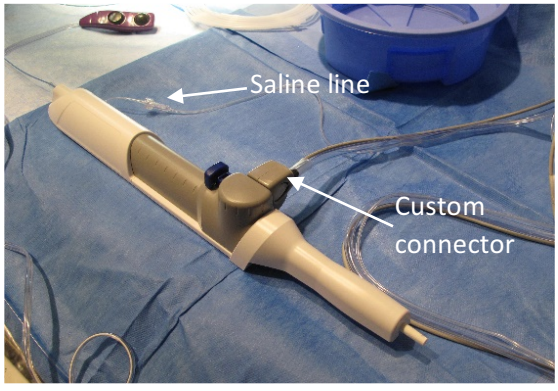
3. Transfer Control Module connections of Tubing Set to a non-sterile operator for connection to Control Module. Non-sterile operator connects Tubing Set to Control Module via fittings on front of module.



4. Non-sterile operator connects IV spike on Tubing Set to saline infusion bag. The peristaltic pump tubing is then routed through the pump and the pump door is closed.



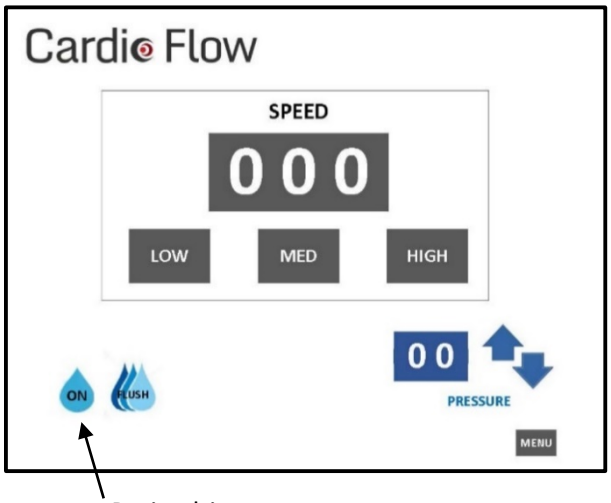
5. Sterile operator connects Tubing Set to User Handle. A custom connector integrates pneumatic power and speed sensing. The saline line is connected separately with standard luers.



Flushing the User Handle and driveshaft:

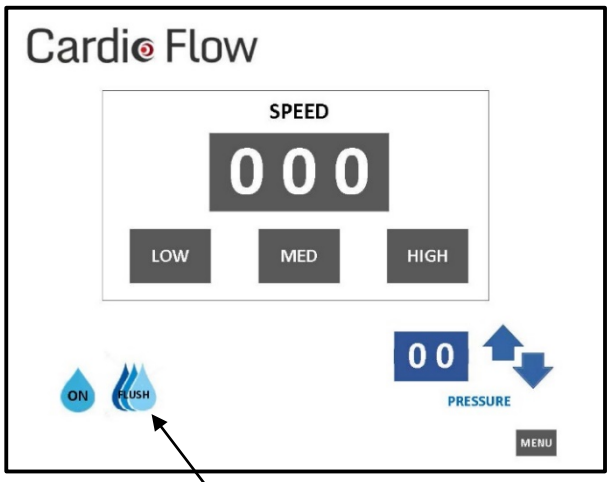
The User Handle and driveshaft need to be flushed with sterile saline fluid to remove air from the system prior to use.

1. Navigate to the Begin Operations screen and turn the peristaltic pump ON. The standard flow rate is set constant at 18 ml/min. Visually verify that fluid is pumping through the Tubing Set and is exiting at the distal end of the catheter.



Peristaltic
Pump is ON

2. The peristaltic pump FLUSH icon can be manually held by a non-sterile operator on the control module to increase the flow of saline to 75 ml/min and speed the flushing process.



Peristaltic
Pump FLUSH

Caution: The saline pump must **not** be turned OFF at this point in the procedure. Turning the pump off or opening the pump door will halt the operation and notify the user on the control module. If this occurs repeat steps to flush the User Handle and driveshaft.

Performing the Atherectomy Procedure

Interventionalist will place commercially available 0.014-inch bare-metal atherectomy guidewire through 5 Fr introducer sheath.

Caution: If the physician suspects the guidewire is placed sub-intimally, the atherectomy procedure must be aborted and alternative care performed.

1. Once the system is prepped with sterile saline, the distal tip of the User Handle driveshaft can be inserted onto the proximal end of the placed guidewire. Ensure that the guidewire clamp at the back of the User Handle is rotated to the open position to allow the guidewire to exit the User Handle.
2. While utilizing imaging technology (fluoroscopy and/or ultrasound), the physician advances the User Handle driveshaft over the guidewire through the introducer sheath and into the patient's vasculature. Continue advancement of the driveshaft and spheres until positioned proximal to the target lesion.

Caution: Verify that the guidewire distal tip is advanced as far distally in patient vasculature as feasible to ensure User Handle driveshaft does not contact the distal tip of the guidewire.

3. Once the driveshaft is in the desired location, rotate guidewire clamp clockwise and verify that the guidewire can no longer freely move. Verify that no saline solution is leaking from the guidewire clamp.
4. Select the appropriate speed for the vessel size on the touch screen. Refer to Appendix B.

Caution: A tight lesion stenosis may require a lower speed, prior to sequential higher speed treatments. Start rotation proximal to a tight lesion stenosis.

5. Fully depress the blue activation button to initiate rotation and maintain selected speed.
6. Once rotation is started, slowly advance the turbine carriage forward and backward through the target lesion.

Caution: Do not leave the spheres of the driveshaft in one location for more than 5 seconds during rotation. Smooth, slow, continuous motion of the driveshaft forward and backward is recommended.

Caution: Frequent imaging evaluation, such as contrast fluoroscopy and/or ultrasound, should be utilized throughout treatment to evaluate lesion removal progress.

7. To stop driveshaft rotation, release blue activation button.

Caution: If rotation does not cease with release of blue activation button, disconnect the Tubing Set from the User Handle. See Appendix A for further details.

8. To move the driveshaft to a different target lesion, rotate the guidewire clamp counterclockwise to allow the driveshaft to move independently of guidewire.
9. Rotate guidewire clamp clockwise to lock guidewire before activating the driveshaft again.

Removal of the User Handle and Driveshaft

1. Release blue activation button to stop rotation and retract driveshaft proximal to the lesion using the turbine carriage.
2. Rotate guidewire clamp counterclockwise so that User Handle and driveshaft can move independently of guidewire.
3. Carefully remove the driveshaft from the guidewire through introducer sheath.
4. Turn off peristaltic pump by tapping the OFF icon on the Control Module touch screen.
5. Dispose of User Handle and Tubing Set according to standard hospital practice.

Changing a Saline Infusion Bag

To change a saline infusion bag during a procedure, the operation must be paused. If the peristaltic pump door is opened during a procedure, pneumatic power to the User Handle will cease immediately.

1. Remove the User Handle and driveshaft from patient (see instructions above).
2. Turn off peristaltic pump by tapping the OFF icon on the Control Module touch screen.
3. Disconnect current saline infusion bag from IV spike on the Tubing Set and hold the spike upward to prevent the introduction of air.
4. Without touching the sterile IV spike tip, insert a new saline infusion bag onto the IV spike and rehang on the IV pole.
5. Repeat a complete flush cycle of the User Handle and driveshaft (see page 17)

Appendix A: FreedomFlow™ Orbital Atherectomy System Troubleshooting

Description	**Actions to be taken**	
User Handle driveshaft fails to stop upon release of User Handle activation button.	Any of the following actions will stop the User Handle driveshaft: ▪ Disconnect Tubing Set at User Handle or Control Module ▪ Open peristaltic pump door ▪ Switch off power to Control Module ▪ Disconnect compressed gas line from back of Control Module ▪ Unplug power cord from back of Control Module.	
User Notification	**Description**	**Actions to be taken**
The Pump Door was Opened while the Pump was Running. The Case will now end.	If the peristaltic pump door is opened at any time while the pump is running, this notification will occur. Gas pressure to the tubing set is immediately shut off when this notification occurs.	Ensure no air has entered Tubing Set, reclose the saline pump door onto tubing, return to operation screen, turn saline pump back on, and reset desired speed to continue procedure.
Fluid Pump must be ON while air pressure is active. Press 'OK' to return.	If the peristaltic pump is turned OFF at the touch screen while Gas pressure is active (device operational), this notification will occur. Gas pressure to the Tubing Set is immediately shut off when this notification occurs.	Turn saline pump back on and reset desired speed to continue procedure.
Check all cable connections. Press 'OK' to return.	If the speed sensor cable is not connected to the control module, this notification will occur.	Ensure Tubing Set (speed sensor cable and pneumatic tubing) are securely connected to both the Control Module and the User Handle during entire procedure.
	If the pneumatic tubing is not connected to the Control Module or the User Handle, gas pressure can escape from the tubing set and gas pressure will be different than anticipated, and this notification will occur.	
	If pneumatic gas pressure supplied to the Control Module is not sufficient to provide gas pressure that is anticipated, this notification will occur.	Check input gas pressure settings on compressed gas source to ensure pressures in the range of 85–116 psi (586.0-799.8 kPa).
Logging Functionality Disabled. Device will continue to operate normally. Contact Cardio Flow, Inc. for Service.	The internal log of case data has been corrupted and logging is no longer possible. The device will still operate and function normally; however, no case technical data can be recovered.	Finalize procedure and contact Cardio Flow, Inc. for technical assistance.

The stored settings have been lost. Restoring default settings.	If the stored parameters in internal flash are corrupted, this notification will occur.	Discontinue procedure and contact Cardio Flow, Inc. for technical assistance.

Appendix B: Selecting Appropriate Orbital Speed for Vessel Size

User Handle driveshaft is approximately 1.5mm in diameter (0.059") and treats vessels 2mm-5mm.

- 5 Fr introducer and 0.014-inch diameter x 300 cm (minimum length) bare-metal atherectomy guidewire are required. Follow manufacturer instructions related to guidewire use.

Vessel diameter range (mm)	Device size (mm, French)	Speed	Largest lumen (mm) achieved during 3-minute run time *Results based on device operation in a graphite block
2.0 – 2.9	**1.5, 5 Fr**	**LOW**	Luminal gain 0.79 mm *after approximately 1 min* Material removed 40% 
3.0 – 3.9	**1.5, 5 Fr**	**MED**	Luminal gain 0.92 mm Material removed 31% 
4.0 – 4.9	**1.5, 5 Fr**	**HIGH**	Luminal gain 0.92 mm Material removed 23%