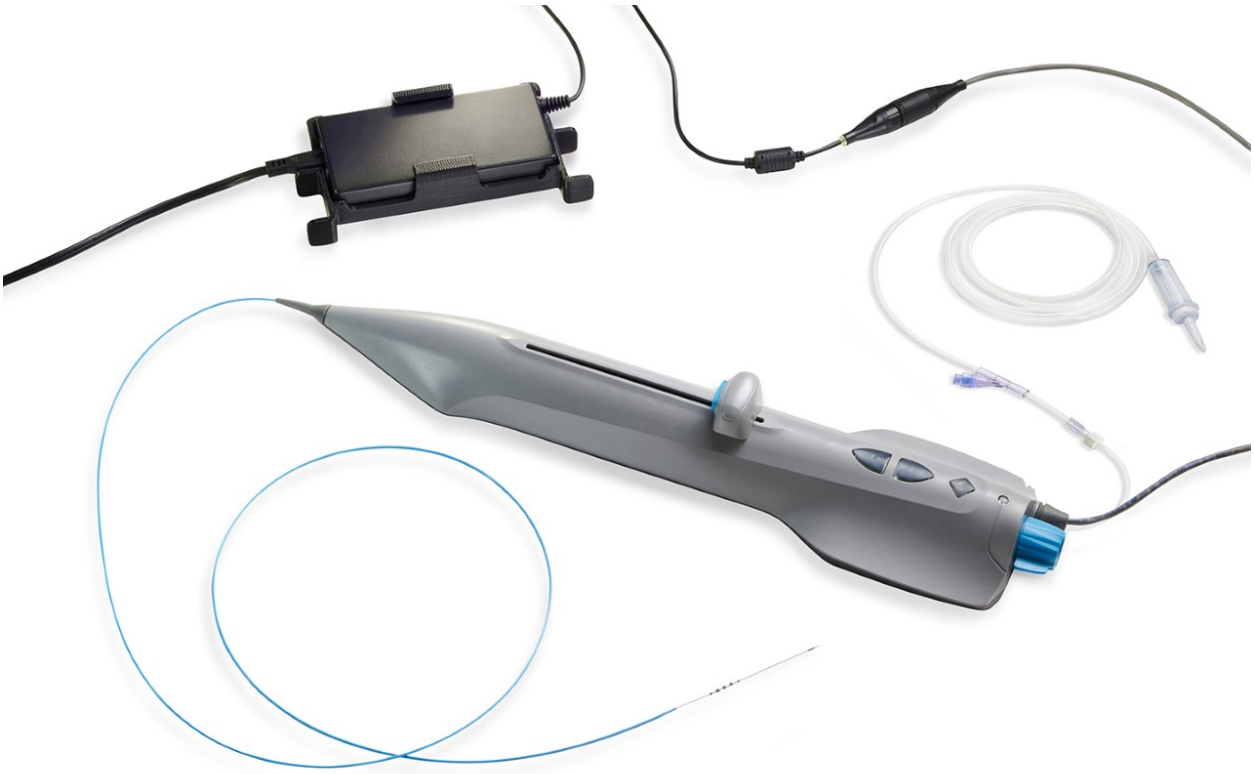
Cardio Flow

FreedomFlow™ H6001, H6002

Orbital Circumferential Atherectomy System - Electric

Instructions for Use



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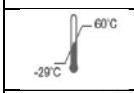
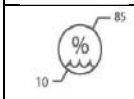
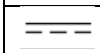
Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician

Symbols Glossary

Symbol	Symbol Title - Reference Number	Standard	Meaning
	Catalogue Number - 5.1.6 (Model number)	ANSI AAMI ISO 15223-1:2016 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Batch code - 5.1.5 (Lot number)		Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Manufacturer - 5.1.1		Indicates the medical device Manufacturer. Manufactured For: Cardio Flow, Inc.
	Date of manufacture - 5.1.3 (YYYY-MM-DD)		Indicates the date when the medical device was manufactured.
	Use-by date - 5.1.4 (YYYY-MM-DD)		Indicates the date after which the medical device is not to be used.
	Sterilized using ethylene oxide - 5.2.3		Indicates a medical device that has been sterilized using ethylene oxide.
	Do not re-use - 5.4.2		Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not Resterilize - 5.2.6		Indicates a medical device that is not to be resterilized.
	Do not use if package is damaged - 5.2.7		Indicates a medical device that should not be used if the package has been damaged or opened.
	Caution - 5.4.4		Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Consult instructions for use - 5.4.3		Indicates the need for the user to consult the instructions for use.
	Temperature Limit - 5.3.7		Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation - 5.3.8		Indicates the range of humidity to which the medical device can be safely exposed.
Rx Only	USA Prescription Only		Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician

	Refer to instruction manual/ booklet - Table D.2 - 1	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Refer to instruction manual/ booklet
	Alternating current - Table D.1 - 20		Alternating current
	Direct current - Table D.1 - 4		Direct current
	Type BF applied part - Table D.1 - 20		Type BF applied part
	Class II equipment - Table D.1 - 9 (no ground required)		Class II equipment
IPX1	Degrees of protection provided by enclosures - (IP Code)	IP degrees in accordance with IEC 60529:1999 - Degrees of Protection Provided by Enclosures (IP Code).	Protected against vertically falling water drops
	For indoor use only - 5957	IEC 60417:2002 - Graphical symbols for use on equipment	For indoor use only
	Symbol for the marking of EEE	Directive 2012/19/EU of the European Parliament and of the Council on Waste Electrical and Electronic Equipment (WEEE) 4 July 2012	Separate collection for EEE

1 Description

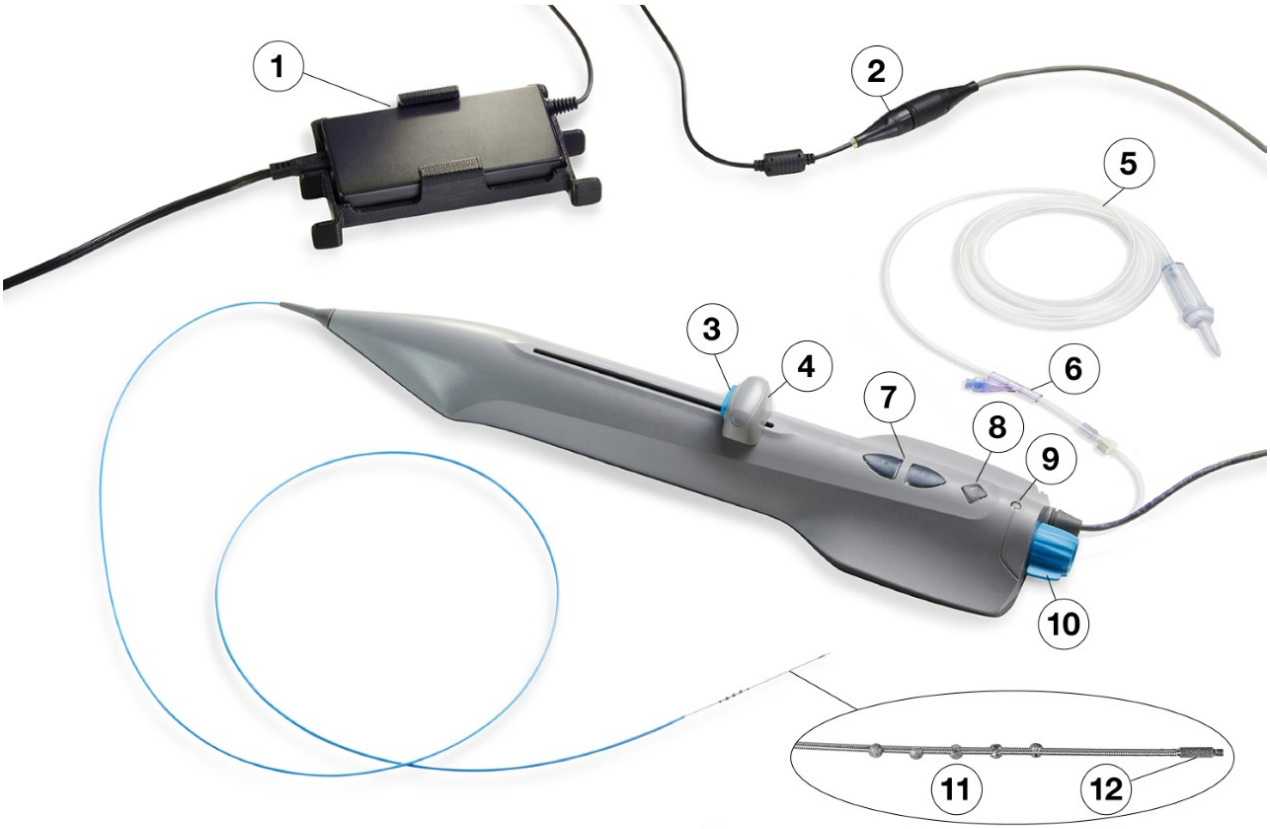
The FreedomFlow™ Orbital Circumferential Atherectomy System is a flexible over-the-wire rotational device used to ablate atherosclerotic plaque from arterial blood vessels within the body. The FreedomFlow™ Orbital Circumferential Atherectomy System is used together with a compatible introducer sheath and 0.014-inch diameter x 300 cm (minimum length) atherectomy guidewire. The driveshaft is introduced into the patient's vasculature by traditional minimally invasive techniques. The FreedomFlow™ User Handle is available in model numbers that are listed below with vessel size ranges. See Appendix A for additional information on selecting the appropriate size introducer sheath.

Model Number	Description	Introducer Sheath Size (Fr)	Vessel Size Range (mm)	Working Length (cm)
H6001	User Handle 5 Fr 5-Sphere 150 cm Length	5 French	2.0 – 4.0 mm	150 cm
H6002	User Handle 6 Fr 5-Sphere 135 cm Length	6 French	4.0 – 8.0 mm	135 cm

The FreedomFlow Orbital Circumferential Atherectomy System - Electric (FreedomFlow™) includes an integrated driveshaft with multiple abrasive spheres on a rotating driveshaft. The abrasive spheres are eccentrically mounted onto the driveshaft so that when the driveshaft is rotated, they move outward due to centrifugal force. These abrasive spheres are spaced along the driveshaft in a spiral configuration to optimize plaque modification within a vessel while still maintaining flexibility for treating tortuous arterial anatomy. The User Handle includes two rotational speeds: low speed at 50,000 revolutions per minute (RPM) and high speed at 76,000 RPM. The System is described further in Figure 1.

The FreedomFlow Orbital Circumferential Atherectomy System - Electric (FreedomFlow™) is powered by Cardio Flow Power Supply H7001, which is a hospital-grade portable, reusable component. H7001 provides DC power to rotate the FreedomFlow™ driveshaft. H7001 also provides DC power to a saline pump integrated into the FreedomFlow™ User Handle. During operation the saline pump delivers saline to the distal tip of the driveshaft.

Figure 1. FreedomFlow™ Orbital Circumferential Atherectomy System - Electric[1]



1. H7001 Power Supply and mounting bracket
2. Power connector
3. Blue activation button
4. Motor carriage to advance and retract driveshaft
5. Saline infusion tubing set
6. Saline tubing connector
7. LO/HI (low/ high) speed selection icon buttons
8. Saline pump icon button
9. Guidewire clamp lock indicator light
10. Guidewire clamp
11. Diamond-coated spheres on driveshaft
12. Diamond-coated distal tip of driveshaft

[1] User Handle and Saline Infusion Tubing Set are listed as Items 2-12. Item 1 is listed as the reusable Power Supply

1.1 Contents of package

The FreedomFlow™ orbital atherectomy User Handle is supplied single patient use, sterile. The package contents include the following items.

- FreedomFlow™ orbital atherectomy User Handle with integrated electric motor and saline pump
- Saline infusion tubing set

Note: The nonsterile reusable power supply (H7001), shown as Item 1 in Figure 1, is shipped separately. See Power supply (Section 10) for instructions and specifications. For ordering information contact a Cardio Flow, Inc. representative.

2 Indications for use

The FreedomFlow™ Orbital Circumferential Atherectomy System is indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries. The therapy is intended for patients who are acceptable candidates for percutaneous transluminal atherectomy.

3 Contraindications

The FreedomFlow™ System is contraindicated as follows:

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

4 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.
- The FreedomFlow™ System should only be used in facilities where sustainable line power is present or uninterruptable power supply.

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5 Warnings

- The FreedomFlow™ System should not be used on pregnant women or children.
- The FreedomFlow™ System should not be used in direct cardiac application.
- 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 for User Handle Model H6001 and 4 mm for User Handle Model H6002.
- 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.
- 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.
- Do not use device during spasm of the vessel.
- Performing treatment in vessels or bifurcations that are excessively tortuous or angulated may result in vessel damage. Rotating diamond-coated spheres through bends tighter than 3.5 cm radius may cause User Handle failure to occur.
- Use only 0.014-inch diameter x 300 cm (minimum length) compatible atherectomy guidewire. Follow manufacturer instructions related to guidewire use.
- Do not continue treatment if the guidewire or the device becomes sub-intimal.
- 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.
- Move the User Handle and guidewire carefully. A tight loop, kink, or bend in the guidewire may cause damage and system malfunction during use.
- 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.
- Immediately stop rotation of the User Handle if the driveshaft stalls during use. Review fluoroscopy and/or ultrasound for possible complications and review User Handle for mechanical failure if a stall condition occurs, then, if no issues are noted, resume procedure.
- 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 spheres during rotation by moving the User Handler motor 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, do not activate rotation.

- Moving the User Handle motor carriage forward moves the driveshaft tip an equal distance. The maximum travel of the carriage is approximately 12 cm. When moving the carriage, make sure there is a minimum distance of 16 cm between the guidewire spring tip and the distal tip of the driveshaft. If the distance between the driveshaft 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 inject contrast while driveshaft is rotating. User Handle failure or patient harm may occur.
- Do not re-use or re-sterilize User Handle or Saline Infusion 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 connector of the User Handle.
- The FreedomFlow™ Orbital Circumferential Atherectomy System has not been tested for defibrillation-safe parts. If defibrillation of the patient is required with the FreedomFlow™ device inserted into the patient's peripheral arteries, avoid placing the defibrillation electrode on or over the shaft of the FreedomFlow™ to minimize the possibility of shunting defibrillation current through the shaft.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. i.e. diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, and metal detectors.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of FreedomFlow™ Orbital Circumferential Atherectomy System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

6 Precautions

- If the User Handle/Saline Infusion 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 devices should only be manipulated under fluoroscopy and/or ultrasound.
- Follow standard atherectomy policies and procedures as they relate to anticoagulation and vasodilator therapy. Drugs such as vasodilators are added to the saline infusate bag at the physician's discretion. The User Handle may malfunction if contrast or other substances are injected into the User Handle. Injection port on the saline infusion tubing set is to be utilized with low pressure injection only while the saline pump is on.
- 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 Saline Infusion Tubing Set. Flow of saline will be reduced. Check the saline infusion tubing and connections for leaks during the procedure.
- Do not allow fluid to leak onto electrical connections of the Power Supply.
- There are no known significant risks of interference posed by the presence of the User Handle. This system has been tested and found to comply with EN60601-1-2 Edition 4.0 and EN55011 Class A limits (electromagnetic compatibility information provided in Appendix B). 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 System and the other equipment.
    - Connect the other equipment into an outlet on a circuit different from the power supply connection.
    - Consult Cardio Flow Inc. for help.

7 Adverse events

Possible risks associated with the Cardio Flow FreedomFlow™ Orbital Circumferential 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

8 Instructions for use

8.1 Connecting the FreedomFlow™ Orbital Circumferential Atherectomy System

Use standard aseptic techniques when handling the sterile User Handle and sterile saline infusion tubing set. The power supply is non-sterile and must remain outside the sterile field.

Caution: Visually examine driveshaft and saline infusion tubing set for any abnormal signs of damage, such as kinks. Dispose of User Handle and infusion tubing set and continue with a new product if damage is observed. Return damaged product to Cardio Flow, Inc. for evaluation.

1. Sterile operator connects saline infusion tubing to User Handle
2. Transfer saline infusion tubing set to nonsterile operator for connection to saline supply
3. Transfer power connection on User Handle to a nonsterile operator for connection to reusable power supply

   Note: The saline pump will turn ON as soon as power is applied to the User Handle. The standard flow rate is set constant at 27 ml/min.

   Note: If there is a software error, speed and pump lights on the User Handle will blink indefinitely. Return damaged product to Cardio Flow, Inc. for evaluation.
4. Visually verify that saline is pumping through the tubing and is exiting at the distal tip of the catheter.

8.2 Performing the atherectomy procedure

Interventionalist will place commercially available 0.014-inch atherectomy guidewire through appropriate size introducer sheath based on FreedomFlow™ User Handle Model. See Appendix A.

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, ensure that the guidewire clamp at the back of the User Handle is rotated to the open position.
2. Insert distal tip of the driveshaft onto the proximal end of the placed guidewire.
3. Use imaging technology (fluoroscopy and/or ultrasound) to advance the driveshaft over the guidewire through the introducer sheath and into the patient's vasculature.
4. Continue advancement of the driveshaft and spheres until positioned proximal to the target lesion.

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

5. Once the driveshaft is in the desired location, rotate guidewire clamp clockwise until guidewire lock indicator light turns on.
6. Select the appropriate speed for the vessel size. Refer to Appendix A.

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

7. Fully depress the blue activation button to initiate rotation and maintain selected speed

8. Once rotation is started, slowly advance the motor carriage forward and backward through the target lesion.

Caution: The saline pump must **not** be turned OFF at this point in the procedure. Turning the pump off or disconnecting the saline line will halt the operation. Turn saline pump on and reset desired speed to continue procedure.

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.

9. Release blue activation button to stop driveshaft rotation.

Caution: If driveshaft fails to stop upon release of activation button, any of the following actions will stop the rotation:

- Turn off saline pump by tapping pump icon button on User Handle
- Disconnect power to User Handle
- Unplug power supply
- Unlock guidewire clamp counterclockwise

10. To move the driveshaft to a different target lesion, rotate the guidewire clamp counterclockwise to allow the driveshaft to move independently of guidewire.
11. Rotate guidewire clamp clockwise until guidewire lock indicator light turns on.

8.3 Removal of the driveshaft

1. Release blue activation button to stop rotation and retract driveshaft proximal to the lesion using the motor carriage.
2. Rotate guidewire clamp counterclockwise so that the User Handle and driveshaft can move independently of guidewire.
3. Carefully remove the driveshaft from the guidewire through introducer sheath.
4. Turn off saline pump by tapping the pump icon button on the User Handle
5. Dispose of User Handle and saline infusion tubing set according to standard hospital practice

8.4 Changing a saline infusion bag

To change a saline infusion bag during a procedure, the operation must be paused. If the saline pump is turned off during a procedure, the driveshaft will cease rotation immediately.

1. Remove the driveshaft from patient
2. Turn off saline pump by tapping the pump icon button on the User Handle
3. Disconnect current saline infusion bag from IV spike 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
5. Turn on saline pump by tapping the pump icon button on the User Handle
6. Visually verify that saline is pumping through the tubing and is exiting at the distal tip of the driveshaft

9 Specifications

Driveshaft outer diameter	H6001 - 5Fr 0.062 inch (1.5 mm) H6002 - 6Fr 0.079 inch (2.0 mm)
Recommended introducer sheath	H6001 - 5Fr 0.062 inch (1.5 mm) H6002 - 6Fr 0.079 inch (2.0 mm)
Recommended guidewire	Atherectomy Wire, 0.014-inch diameter x 300 cm (minimum length)
Driveshaft effective length	H6001 – 150 cm H6002 – 135 cm
Low speed target	50k revolutions per minute (RPM)
High speed target	76k revolutions per minute (RPM)
Time to reach speed (ramp)	Within 2 seconds
Environmental parameters	
Transport conditions	Temperature range: -29°C to 60°C Humidity (non-condensing): 10% to 85%
Storage and operating conditions	Temperature range: 15-35ºC Humidity (non-condensing): 30% to 50% Standard atmospheric pressure: 50-106 kPa.
Ingress Protection	IPX1 protected from dripping liquid
Applied Part	Type BF

10 Power supply

10.1 Description

H7001 Power Supply is reusable, non-sterile, and provides 24V DC power to the FreedomFlow™ Orbital Circumferential Atherectomy System - Electric.

10.2 Contents of package

- Electrical cord
- 90W AC to DC Medical Grade Class II power converter
- Bracket for attaching power supply to standard hospital bed

10.3 Warnings and precautions

Cleaning - To avoid injury or damage to the power supply, follow these recommendations:

- The power supply must be powered off and unplugged from the wall power outlet prior to cleaning. Ensure that the power supply is completely dry before reconnecting to wall power outlet.

- The power supply should be cleaned between procedures with a hospital-grade disinfectant solution. The power supply should not be immersed in cleaning solutions, and solvents and abrasive chemicals should not be used.

Maintenance - To ensure proper function of power supply, follow these recommendations:

- The power supply shall be maintained, serviced, and repaired only by Cardio Flow, Inc. personnel. Contact a Cardio Flow, Inc. representative for further instructions.
- The power supply has a minimum anticipated life of 2 years of use. Additional equipment life can be determined through Cardio Flow, Inc. maintenance and evaluation.

10.4 Instructions for use

Please refer to FreedomFlow™ instructions for use (Section 8). If the power supply does not function as anticipated, stop the procedure and contact Cardio Flow, Inc. Disconnect the power cord at any connector to remove power.

10.5 Specifications

Power rating	90W, 100-240 VAC, 50-60 Hz
Cord length	Two cord length options are provided: 2 meter and 4 meter length (6.5 feet and 13.1 feet)
Classification	Medical Grade Class II
Environmental parameters	
Transport conditions	Temperature range: -29°C to 60°C Humidity (non-condensing): 10% to 85%
Storage and operating conditions	Temperature range: 15-35oC Humidity (non-condensing): 30% to 50% Standard atmospheric pressure: 50-106 kPa.

Appendix A: Selecting User Handle Model and orbital speed for vessel size

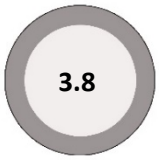
Model H6001 is approximately 1.5mm in diameter (0.062”) and treats vessels 2mm-4mm.

- 5 Fr introducer and 0.014-inch diameter x 300 cm (minimum length) 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 with a 1.5 mm pilot lumen
2.0 – 2.9	**1.5 mm, 5 Fr**	**LOW**	Luminal gain 0.69 mm End Lumen Diameter 2.2 mm Material removed 34% 
3.0 – 4.0	**1.5 mm, 5 Fr**	**HIGH**	Luminal gain 1.18 mm End Lumen Diameter 2.7 mm Material removed 29% 

Model H6002 is approximately 2.0mm in diameter (0.082”) and treats vessels 4mm-8mm.

- 6 Fr introducer and 0.014-inch diameter x 300 cm (minimum length) 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 with a 2.0 mm pilot lumen
4.0 – 5.9	**2.0 mm, 6 Fr**	**LOW**	Luminal gain 1.38 mm End Lumen Diameter 3.4 mm Material removed 34% 
6.0 – 8.0	**2.0 mm, 6 Fr**	**HIGH**	Luminal gain 1.75 mm End Lumen Diameter 3.8 mm Material removed 22% 

Appendix B: Electromagnetic Emissions and Immunity

Guidance and manufacturer's declaration – electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or end user of the equipment should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions EN 55011 CISPR 11 2010	Group 1	RF emissions from the equipment are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011 CISPR 11 2010	Class A	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.

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/-8 kV contact +/-2, 4, 8, 15 kV air	+/- 8 kV contact +/- 2, 4, 8, 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst (EFT/B) IEC 61000-4-4	+/-2 kV for power supply lines	+/-2 kV for power supply lines	Mains power quality should be that of a typical clinical or hospital environment.
Surge IEC 61000-4-5	+/-1 kV Line 1 to Neutral	+/-1 kV differential mode	Mains power quality should be that of a typical clinical or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% Reduction for 0.5 cycles 100% reduction for 1 cycle 30% reduction for 25 cycles 100% reduction for 300 cycles	100% Reduction for 0.5 cycles 100% reduction for 1 cycle 30% reduction for 25 cycles 100% reduction for 300 cycles	Mains power quality should be that of a typical clinical or hospital environment. The device should be used in facilities where sustainable line power is present, or if the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Power frequency magnetic field IEC 61000-4-8	60 Hz at 30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical clinical or hospital environment.
Conducted Immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz ISM and Amateur Band frequencies at 6 Vrms	3 Vrms 6 Vrms	Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	RF wireless frequencies listed in IEC 60601-1-2:2014, test levels between 9 and 28V/m.	9-28 V/m	

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix C: Troubleshooting Guide

The following list is meant to serve as a most-common troubleshooting guide. Discontinue use and Contact Cardio Flow personnel for any issue not described or easily resolved.

Potential Issue	Device Response	Trouble Shooting Recommended Action(s)
User Handle does not power-up upon connection to power supply	No automated-power up sequence occurs; which includes activation of LED low-speed button and pump-on default with LED.	Check power supply connections to user handle and MAINs for complete connection. Disconnect and reconnect all connections.
User Handle driveshaft rotation unanticipated stops during therapy delivery	Device will stop rotation to protect the patient if it sees an unexpected event condition.	Ensure three active LED light indicators are ON prior to rotation attempt. Release enable button and reengage if all LEDs are properly lit. If not resolved, discontinue use and return device to Cardio Flow for evaluation.
All LEDs on User Handle flash on and off in a cycle pattern	A non-recoverable error condition has occurred within the User Handle.	Discontinue use and return device to Cardio Flow for evaluation.
All LEDs on User Handle are lit-up at the same time	A switch button on User Handle was detected as stuck during power up.	Press User Handle buttons to attempt to unstick a button. If not resolved, discontinue use and return device to Cardio Flow for evaluation.
User Handle does not have saline flowing from catheter after flush-sequence and throughout procedure	No flowing fluid is visible from tubing set or catheter after flush sequence.	Evaluate saline bag and tubing to ensure no kinks or restrictions are evident. Disconnect luer connection to verify fluid is flowing from saline bag. Ensure saline LED button is activated. User should be able to hear pump motor function. If not resolved, discontinue use and return device to Cardio Flow for evaluation.
An LED or button switch does not function as intended	One speed button (Low or High) is required to be active prior to use. The pump LED and function should be able to be turned on and off. The guidewire clamp LED indicator should correlate to “tab up” physical lock placement to engage guidewire clamp.	Discontinue use and return device to Cardio Flow for evaluation.
Device does not rotate when enable push button is pressed	User Handle requires one speed button selected (Low or High), the pump ON, and the guidewire clamp locked in order to enable rotation of drive motor.	Ensure three active LED light indicators are ON prior to rotation attempt. If all three LED light indicators are ON, and system will not rotate, evaluate the following: • A guidewire kink within device could cause device to reach overcurrent limit condition • Retract driveshaft proximal to any tight lesion and re-evaluate. An extremely tight lesion could cause device to reach overcurrent limit condition If not resolved, discontinue use and return device to Cardio Flow for evaluation.

Appendix D: Clinical Trial Summary

FAST II Trial was a prospective, non-randomized, multicenter single-arm clinical study to evaluate the safety and effectiveness of the FreedomFlow™ Orbital Circumferential Atherectomy System when used in patients with symptomatic lower extremity peripheral arterial disease. **F**reedomFlow™ Orbital Circumferential **A**therectomy **S**ystem to **T**reat Peripheral Artery Disease (FAST II Trial) was conducted in the United States (NCT03635190) and included 112 subjects.

FAST II Summary of Safety and Effectiveness (n=112 patients)	
Parameter	**Result**
Demographics & Medical History information:	
Age, mean	70.1 ± 9.8 yr.
% male	67/112 (59.8%)
Current Tobacco use	36/112 (32.1%)
Hypertension	107/112 (95.5%)
History, Coronary Artery Disease (CAD)	67/112 (59.8%)
History, Myocardial Infarction	30/112 (26.8%)
Hyperlipidemia	90/112 (80.4%)
Diabetes Mellitus	62/112 (55.4%)
History of Amputation	6/112 (5.4%)
Rutherford Class 2-3	64/112 (57.1%)
Rutherford Class 4-5	48/112 (42.9%)
ABI, mean	0.69 ± 0.22
Safety Endpoint:	
Primary safety endpoint: Number (%) of patients without at least one major serious adverse event complication within 30 days. **Freedom From Serious Major Adverse Event:**	108/112 (96.4%)
Cardiovascular Related Death	0/112 (0%)
Myocardial Infarction	0/112 (0%)
Clinically Driven TLR	0/112 (0%)
Clinically Significant Target Vessel Dissection	1/112 (0.9%)
Clinically Significant Target Vessel Perforation	0/112 (0%)
Unplanned Major Target Limb Amputation	0/112 (0%)
Clinically Relevant Distal Embolization *Serious Distal Embolization*	8/112 (7.1%) *4/112 (3.6%)*
Pseudoaneurysm	0/112 (0%)
Baseline Lesion Characteristics:	
Per Lesion Analysis	**Core Laboratory:**
Number of Lesions	147
Reference vessel diameter	4.5 ± 1.20 mm
Baseline % DS	74.4 ± 17.7%
Target Lesion Length	90.5 ± 7.10 mm
Chronic Total Occlusion	26.9%
Severely Calcified Lesions	82.1%

FAST II Summary of Safety and Effectiveness (n=112 patients)	
Parameter	**Result**
Treatment information:	
Quantitative speed applied, Revolutions per minute (RPM):	Low Speed (50k), High Speed (76k)
% of cases where High speed was utilized	67/96 (69.8%)
Per Lesion Analysis	**Core Laboratory:**
Primary effectiveness endpoint: Technical Success; <50% residual stenosis post atherectomy alone:	67.4%
Post-Atherectomy % DS	47.0 ± 21.2%
Mean Reduction %DS	26.6 ± 20.2%
Post Adjunctive Therapy [Final] %DS	24.2 ± 12.9%
Additional Secondary Endpoints:	
Procedure success: <50% residual stenosis post adjunctive therapy [Final] without MAE or device malfunction causing the procedure to be aborted	93/104 (89.4%)
Clinical success: <50% residual stenosis post adjunctive therapy [Final]	143/144 (99.3%)
Clinical success: <30% residual stenosis post adjunctive therapy [Final] using visual angiography (post-hoc analysis)	153/154 (99.4%)
Mean ABI at 6 months	0.85 ± 0.29
Freedom from Clinically Driven TVR at 6-months	103/109 (94.5%)
Freedom from Clinically Driven TLR at 6 months	103/109 (94.5%)
Rutherford Class Improvement (> 1 class) at 6-months	92/103 (89.3%)
VascuQoL Score improvement at 6-months	75/103 (72.8%)
ABI = ankle brachial index; DS = diameter stenosis; TVR = target vessel revascularization; TLR = target lesion revascularization	

The primary safety endpoint was met, with a rate of freedom from major adverse events of 92.9% (104/112) and a lower 95% confidence interval of 86.4%, meeting the performance goal of 85%. However, the primary effectiveness endpoint was not met, with a core lab adjudicated technical success rate of 67.4% (89/132) and a lower 95% confidence interval of 58.7%, missing the performance goal of 86%.

Therefore, an additional effectiveness comparison to Real World Data (RWD) using the Vascular Quality Initiative (VQI) Peripheral Vascular Intervention (PVI) registry was conducted as a blinded and randomized study with independent core lab adjudication. Utilizing the PVI registry, a candidate group of comparable peripheral cases was sent along with FAST II data for a blinded and randomized core laboratory assessment. After core lab adjudication, a well-balanced set of baseline covariates were assessed using Inverse Probability Treatment Weighting of the Average Treatment Effect of the Treated (IPTW-ATT) propensity scoring to obtain a final cohort for debulking effectiveness comparison.

The mITT population consisted of core laboratory adjudication from 110 FAST II subjects with 149 lesions to compare to 173 PVI subjects with 195 lesions. The primary effectiveness endpoint was evaluated on a per lesion basis as mean post-atherectomy stenosis with success in demonstrating non-inferiority assessment to that of the marketed orbital and rotational atherectomy devices in the PVI registry. A summary of the IPTW-ATT FAST II to PVI registry effectiveness data is provided below.

IPTW-ATT Weighted Effectiveness Comparison between FAST II and PVI Registry (per lesion analysis)				
Characteristic	**FAST II**		**PVI Registry**	
Number of Subjects	110		173	
Age (year, mean ± sd)	70.9 ± 9.7		70.4 ± 8.5	
Sex (male %)	60.4%		56.9%	
Rutherford Category %				
2 or 3	55.7%		59.0%	
4 or 5	44.3%		41.0%	
Number of Lesions*	149		195	
Artery Category				
Below the Knee	29 (19.5%)		22 (11.3%)	
SFA-Popliteal	114 (76.5%)		166 (85.1%)	
Common Femoral	6 (4.0%)		7 (3.6%)	
Lesion Length (mm, mean ± sd)*	63.5 ± 53.6		65.0 ± 40.8	
RVD (mm, mean ± sd)*	3.8 ± 1.2		3.8 ± 1.1	
Calcium Grading % (PARC)*				
None, Focal, Mild	90 (60.4%)		81 (41.5%)	
Moderate, Severe	59 (39.6%)		114 (58.5%)	
Diameter Stenosis (%)*	Mean ± SD	95% Confidence Intervals	Mean ± SD	95% Confidence Intervals
Baseline Diameter Stenosis (%)*	62.1 ± 23.0	58.4 – 65.8	62.4 ± 18.6	59.3 – 65.5
Post-Atherectomy Diameter Stenosis (%)*	41.1 ± 19.2	38.0 – 44.2	46.2 ± 17.1	43.3 – 49.0
Stenosis Reduction (%)*‡	21.0 ± 23.6	17.2 – 24.9	16.2 ± 16.6	13.5 – 19.0
Final Diameter Stenosis (%)*	21.9 ± 10.9	20.2 – 23.7	23.2 ± 12.6	21.0 – 25.3

* Values utilized from independent Core Laboratory

‡ Stenosis Reduction is defined as the difference between baseline and post atherectomy stenosis (without adjunctive therapy)

The primary endpoint of this study was post atherectomy stenosis. This endpoint was evaluated for non-inferiority utilizing an alpha of 0.025 and a 7.0% non-inferiority margin (NIM). The upper bound of the difference, Freedom Flow FAST II – PVI registry was calculated to be 0.363%, which is less than the -7.0% NIM. Therefore, the null hypothesis is rejected and non-inferiority is demonstrated (p = 0.0000029). Therefore, the FreedomFlow Atherectomy device can be considered equivalent in performance as compared to similar, commercially-available products.

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