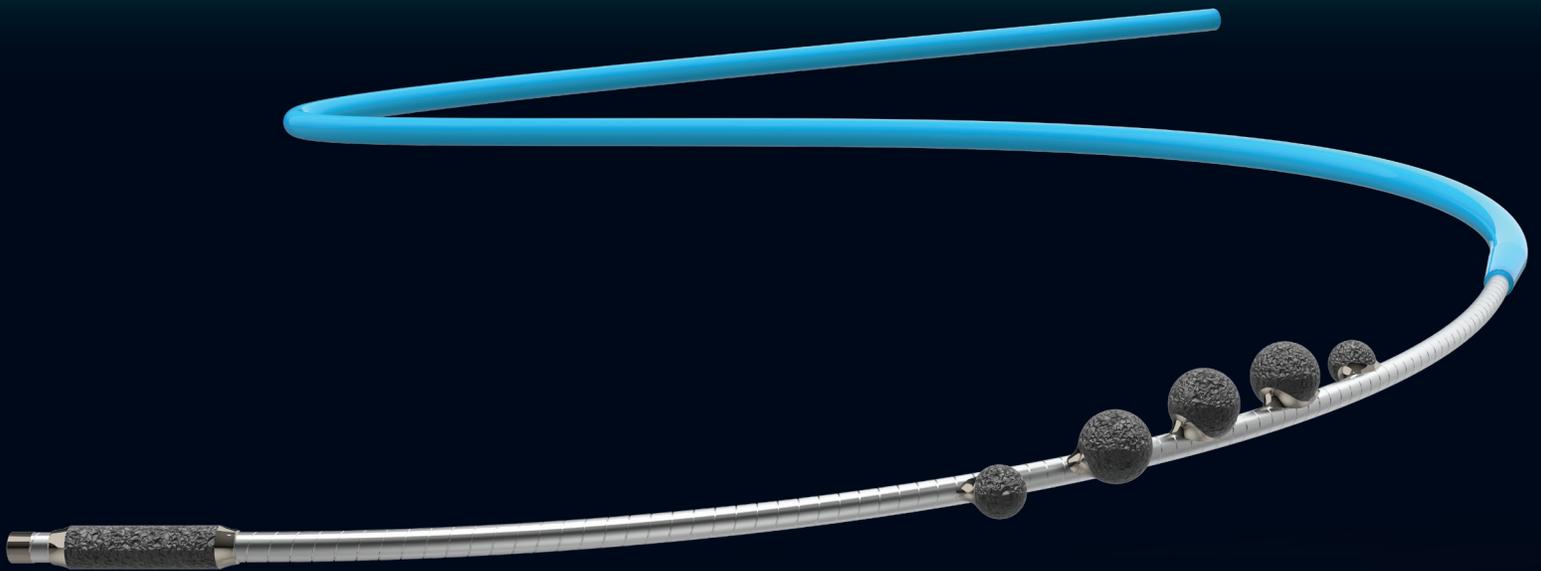


FreedomFlow[®]
by Cardiac Flow

Today's Platform for Complex PAD



MODERN ATHERECTOMY

FreedomFlow



A modern mechanism of action in a dynamic new PAD platform

Current atherectomy technologies are decades old and constrained by capital equipment and design limitations.

FreedomFlow provides physicians with the freedom from those constraints and enables them to treat complex PAD from hip to heel with a simple, effective, and versatile device that is easy to operate, optimizes work flow, and minimizes capital costs and inventory.

It's the ideal choice for today's hospitals, ambulatory surgery centers, and office-based labs.

FreedomFlow[®]
by Cardio Flow

MODERN ATHERECTOMY

Leveraging the Power of Angular Momentum

Helical pattern of diamond-coated spheres powers through complex lesions

FreedomFlow's unique spiral geometry leverages the power of angular momentum—a rotational vortex that puts five diamond-coated spheres in constant contact with the vessel wall, no matter if advancing or retracting.

Two rotational speeds (50K and 76K RPM) make it possible to treat complex lesions at lower speeds.

Rotational Speeds



Offset diamond-coated spheres – efficient plaque modification

FreedomFlow features five diamond-coated spheres mounted eccentrically on the driveshaft which, when rotated, move outwards due to centrifugal force, providing constant and consistent contact with the vessel wall for efficient plaque modification.



Driveshaft – dynamic, predictable action

The spiral pattern created by the rotating spheres also maximizes the dynamic motion of the outward force.

This outward force is not only greater and more predictable, but allows physicians to achieve larger orbits at lower speeds.

Diamond-coated hypotube – eases through tight lesions

The FreedomFlow driveshaft also incorporates an innovative diamond-coated hypotube at the tip of the driveshaft, which helps ease the tip through tight blockages and improves access into areas even smaller than the sphere diameter.

Combined with a diamond-coated tip that eases the driveshaft through tight blockages, this new mechanism of action gives physicians a highly efficient, effective, and flexible way to treat complex PAD in vessels ranging from 2 mm to 8 mm in diameter.

Vessel Range

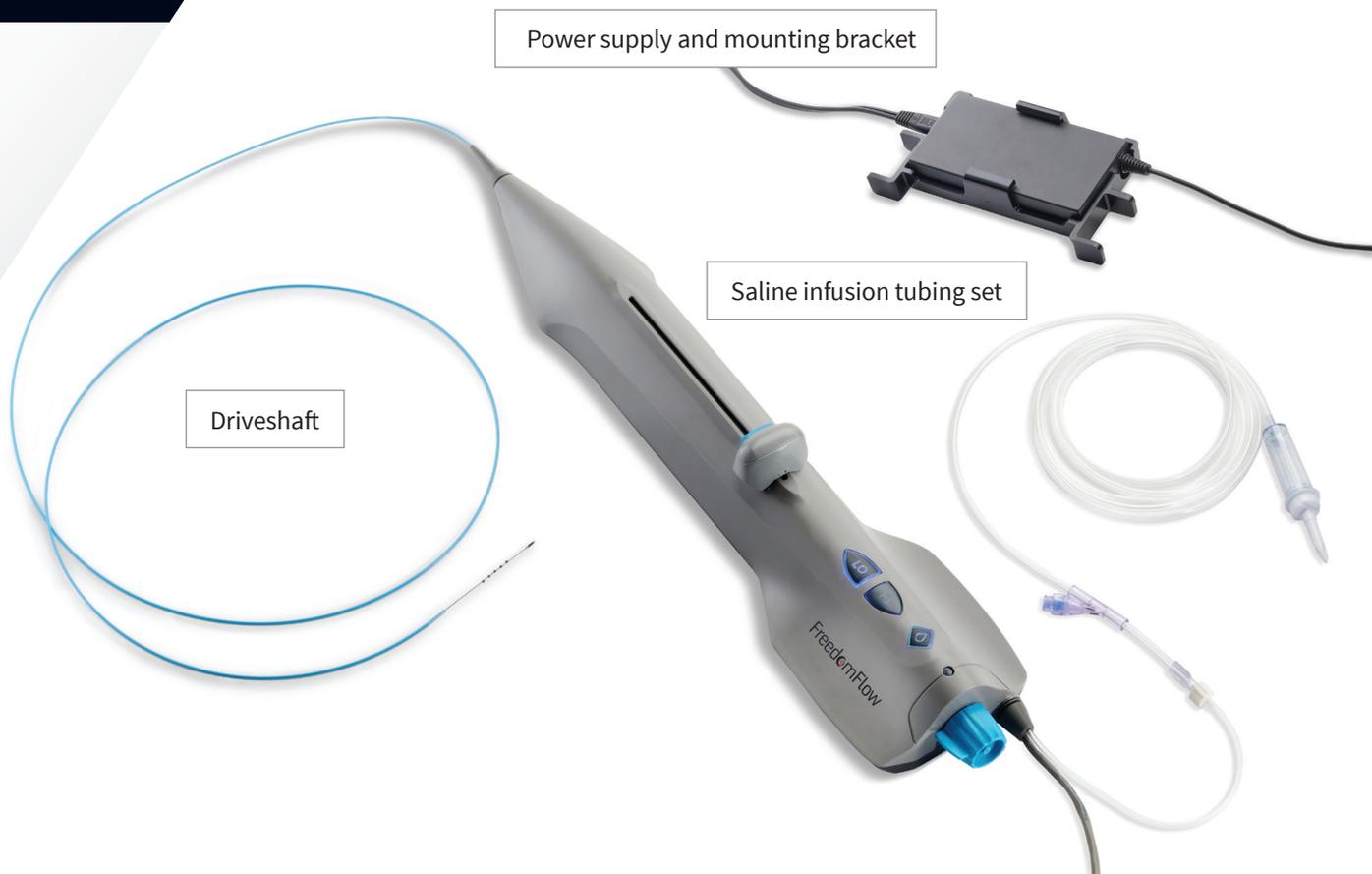
5 Fr

5 Fr catheter is approximately 1.5 mm (0.062") in diameter and treats vessels 2 mm – 4 mm

6 Fr

6 Fr catheter is approximately 2.0 mm (0.082") in diameter and treats vessels 4 mm – 8 mm





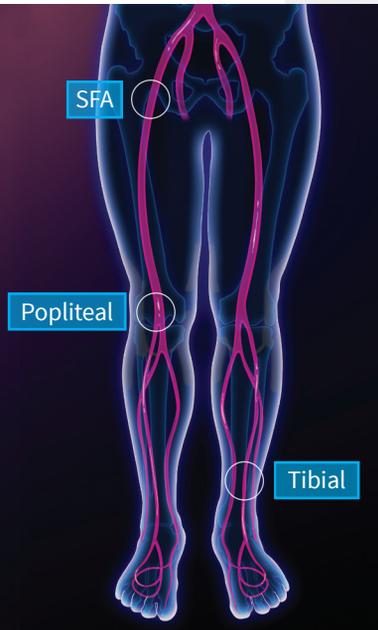
Selecting Catheter and Orbital Speed for Vessel Size

	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	
5 Fr	2.0 - 2.9	1.5, 5 Fr	LOW	Luminal gain 0.47 mm after <i>approximately 1 min</i>	2.2
	3.0 - 3.9	1.5, 5 Fr	HIGH	Luminal gain 1.18 mm	2.7
6 Fr	4.0 - 5.9	2.0, 6 Fr	LOW	Luminal gain 1.38 mm	3.4
	6.0 - 8.0	2.0, 6 Fr	HIGH	Luminal gain 1.75 mm	3.8

5 Fr catheter is approximately 1.5 mm (0.062") in diameter and treats vessels 2 mm - 4 mm. A 5 Fr introducer and 0.014-inch diameter x 300 cm (minimum length) atherectomy guidewire are required. Follow manufacturer instructions related to guidewire use.

6 Fr catheter is approximately 2.0 mm (0.082") in diameter and treats vessels 4 mm - 8 mm. A 6 Fr introducer and 0.014-inch diameter x 300 cm (minimum length) atherectomy guidewire are required. Follow manufacturer instructions related to guidewire use.

The freedom to treat complex PAD hip to heel



Unprecedented flexibility in a single, streamlined device

FreedomFlow's unique mechanism of action, adjustable speed, and ease of use provides greater versatility and efficiency in treating multiple arteries, lesions, and vessel diameters—all with a single device.

With two catheter sizes and two rotational speeds, a flexible driveshaft, and diamond-coated tip, the FreedomFlow platform gives physicians the freedom to help patients in new ways—even treating multiple blockages in the same vessel with the same device, from the common femoral to the distal tibial arteries. The electric motor also provides smooth acceleration and enhances the physician's tactile feel for predictable plaque modification.

In short, FreedomFlow is a simple yet effective platform that provides physicians and their patients with better treatment options.

SFA Angiography



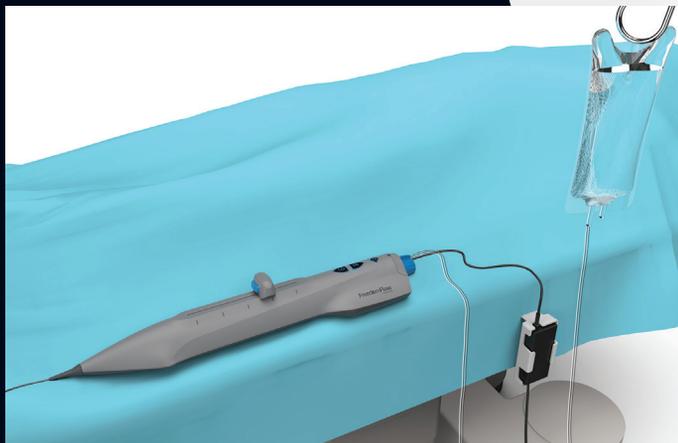
Baseline



Final

Freedom and flow for physicians and clinics

Time savings and cost efficiencies in a simple yet effective platform



FreedomFlow's modern, streamlined platform offers time savings and cost efficiencies—with no capital equipment, no lubricant, and reduced inventory needs. It also provides faster procedural run times, consistent treatment outcomes, and a nearly flat learning curve for physicians.

With two basic catheter SKUs and a simple set-up with saline—together with the flexibility to treat a range of vessel sizes—FreedomFlow offers compelling productivity, consistent and predictable plaque modification, and enhanced patient safety for today's hospitals, ambulatory surgery centers, and office-based labs.

Single-use disposable

No capital equipment

No lubricant

Reduced inventory

FreedomFlow® Orbital Atherectomy Platform

Catheter

The single-use catheter with integrated electric motor and saline pump provides control over the rotational and translational movement of the integrated driveshaft. Two catheters are available to treat a wide range of vessel sizes—from 2 mm to 8 mm:



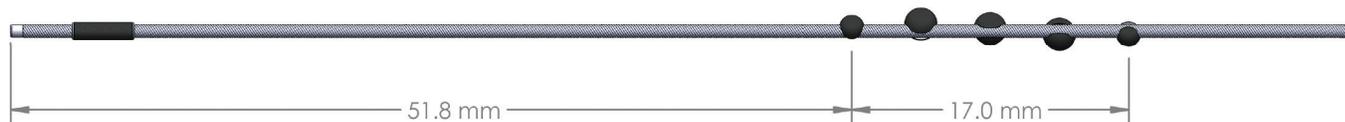
5 French 5-Sphere Driveshaft



5 Fr

Catheter H6001 (5 Fr introducer) is approx. 1.5 mm (0.062") in diameter and treats vessels 2 mm – 4 mm in diameter with a 150 cm working length

6 French 5-Sphere Driveshaft



6 Fr

Catheter H6002 (6 Fr introducer) is approx. 2.0 mm (0.082") in diameter and treats vessels 4 mm – 8 mm in diameter with a 135 cm working length



The tubing set delivers standard saline to the saline pump and is integrated into the catheter.

Electric Power Supply

The power supply is a reusable, non-sterile AC-to-DC Medical Grade Class II power converter with bracket. **Model H7001.**



FreedomFlow® Peripheral Guidewire

Cardio Flow's FreedomFlow stainless-steel guidewire features a fixed distal silicone-coated spring coil that eases the crossing of difficult lesions, while the medium-stiff coil facilitates superior torque transmission and control. **Model GW1001.**



Item Number	Description	UOM
H6001	Electric Catheter, 5 Fr 150 cm 5-Sphere	1/Bx
H6002	Electric Catheter, 6 Fr 135 cm 5-Sphere	1/Bx
H7001	Electric Power Supply	1/Bx
GW1001	Guidewire, 325 cm	5/Bx

How to Order

Please contact Cardio Flow at 800-294-5517 to order FreedomFlow® components.



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

INDICATIONS FOR USE: The Cardio Flow FreedomFlow® Orbital Atherectomy Peripheral Platform 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.