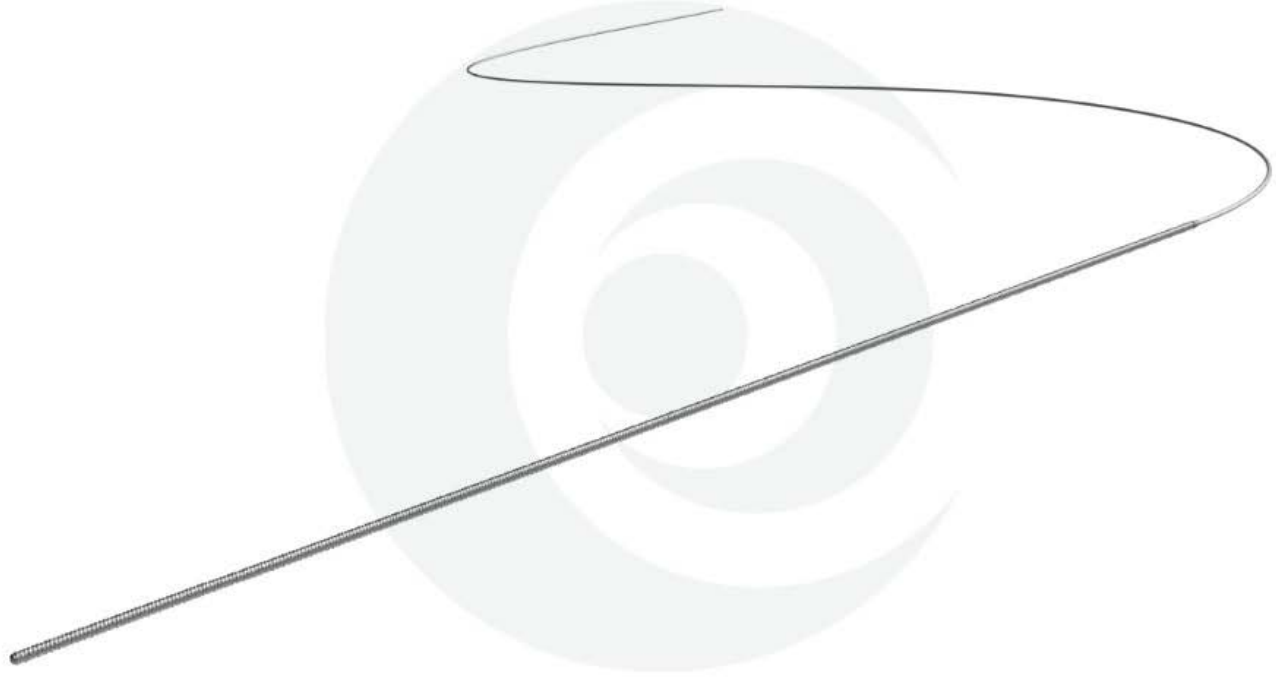
Cardio Flow

FreedomFlow® Peripheral Guidewire

Instructions for Use

Model: GW1001



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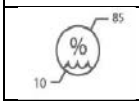
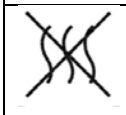
Symbols Glossary

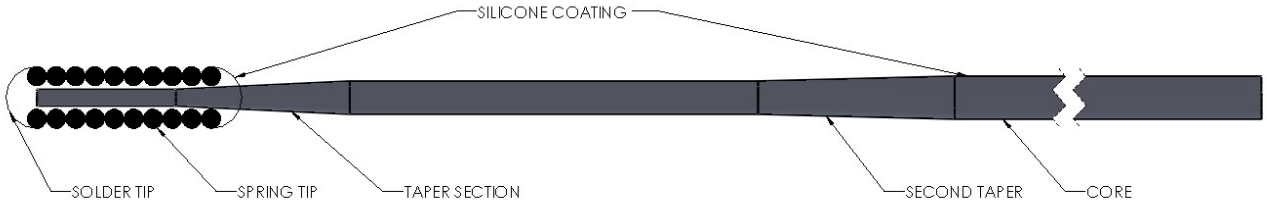
Symbol	Symbol Title - Reference Number	Standard	Meaning
	Catalogue Number - 5.1.6 (Model number)	ANSI AAMI ISO 15223-1:2016 Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 1: General requirements	Indicates the manufacturer's catalogue 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. 888 East Avenue, Mahtomedi, MN 55115
	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.

	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
	Keep dry - 5.3.4	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 a medical device that needs to be protected from moisture
	Keep away from sunlight - 5.3.2		Indicates a medical device that needs protection from light sources. For indoor use only
	For indoor use only - 5957	IEC 60417:2002 - Graphical symbols for use on equipment	For indoor use only
Rx Only	Prescription Only	21 CFR 801.109	Federal (USA) Law restricts this device to sale by or on the order of a physician
	Non-pyrogenic - 5.6.3	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	Indicates a medical device that is non-pyrogenic

1 Description

The Cardio Flow FreedomFlow™ Peripheral Guidewire facilitates insertion, navigation and placement of therapeutic devices. The Cardio Flow Peripheral Guidewire is designed as a 304V stainless steel mandrel guidewire with a fixed distal spring coil. The coil is radiopaque to facilitate visualization and selection of the blood vessel and confirmation of the position of the guidewire's distal end by fluoroscopy. The coil is medium-stiffness in load-force and the distal end is coated in silicone to facilitate crossing difficult peripheral lesions. The guidewire has a nominal length of 325 cm (GW1001) and a maximum outer diameter of 0.36 mm (0.014-inch).

Figure 1. Cardio Flow Peripheral Guidewire Construct



1.1 Contents of package

The Cardio Flow Peripheral Guidewire is supplied as a sterile, non-pyrogenic, single patient use device. The package contents include five (5) guidewires, each in an individual sterile pouch configuration.

2 Indications for use

The Cardio Flow peripheral guidewire is intended for temporary placement in peripheral vasculature to facilitate the placement and exchange of diagnostic and therapeutic devices during percutaneous intravascular procedures. This guidewire device is intended for peripheral vascular use only.

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

3 Contraindications

The Guidewire is contraindicated as follows:

- The guidewire cannot be used in coronary, carotid, or neurovascular arteries.

4 Restrictions

- The guidewire should only be used by physicians who are experienced in peripheral interventions.

5 Warnings

- The Guidewire should not be used on pregnant women or children.
- The Guidewire should not be used in direct cardiac, carotid, or neurovascular applications.
- 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.
- Always use fluoroscopy and/or ultrasound when advancing the guidewire to avoid misplacement, dissection, or perforation.
- Move the guidewire carefully. A tight loop, kink, or bend in the guidewire may cause vessel damage.
- The coil section of the guidewire is fragile, use care when bending or forming to prevent guidewire damage.
- Do not use a damaged guide wire.
- Never use metallic cannula or metallic sheaths for insertion and withdrawal of the guide wire.
- Always advance and withdraw the guide wire slowly.
- 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 vessel.
- Do not re-use or re-sterilize guidewire as the device may not function as intended and serious infection leading to potential harm and/or death may occur.
- The Guidewire has not been tested for defibrillation-safe parts. If defibrillation of the patient is required with the device inserted into the patient's peripheral arteries, avoid placing the defibrillation electrode on or over the guidewire to minimize the possibility of shunting defibrillation current through the wire.
- Never push, auger, withdraw, or torque the guidewire if it meets resistance. If any resistance is felt due to vessel spasm or the guidewire appears bent or trapped while operating the guidewire in the blood vessel or removing it, do not move or torque the guidewire. Stop the procedure. Determine the cause of resistance under fluoroscopy and take appropriate action to resolve.
- When torqueing this guidewire inside the blood vessel, do not torque continuously in the same direction, rotate it clockwise and counterclockwise alternately. Do not exceed two rotations (720°) in the same direction.

6 Precautions

- If the sterile package appears damaged or shelf life has expired, do not use.
- Follow standard hospital 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. Guidewires and devices should only be manipulated under fluoroscopy and/or ultrasound.
- Ensure Guidewire remains kink-free during use.
- Inspect the guide wire carefully for damage such as bends, kinks, or other damage prior to use and whenever possible during the procedure. Do not use guidewire if damaged.
- When shaping the distal end, use the minimum force needed to not damage the coil.

  Do not modify this guidewire.

7 Adverse events

Possible risks associated with the Cardio Flow Peripheral Guidewires that may occur and/or require intervention include, but are not limited to:

- Allergic reaction to medication/media/device components
- Aneurysm
- Bleeding complications which may require transfusion
- Bradycardia or palpitations
- Device embolization, separation or breakage of the device
- Dissection
- Distal embolization
- Entry site complications including hematoma
- Fistula of artery or vein
- Hypotension, or Hypertension
- Infection
- Pain
- Perforation
- Pseudoaneurysm
- Thrombus
- Trauma
- Vessel closure, abrupt
- Vessel injury, including dissection and perforation that may require surgical repair
- Vessel occlusion
- Vessel spasm

8 Instructions for use

8.1 Inspection and Preparation

Use standard aseptic techniques when handling the sterile Peripheral Guidewire. Before use, inspect the packaging and guidewire to confirm there is no damage.

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

1. Transfer guidewire and holder hoop tubing to sterile field from guidewire pouch using standard aseptic technique.
2. Confirm guidewire is compatible with the interventional devices to be used.
3. Before pulling the guide wire out of the holder hoop tubing, flush it with heparinized saline from the holder tube end. If it is difficult to pull the guide wire out of the holder hoop tube, repeat flush.
4. Release the proximal end of the guidewire from the tail clip and slowly push it through the holder hoop.
5. When the distal end of the guidewire is extended beyond the holder hoop, shape the tip according to standard interventional practice.

Caution: The distal spring tip of the guidewire spring coil is very fragile. Pay careful attention not to damage the spring coil when shaping the distal end. Inspect the coil and guidewire for damage prior to further use.

6. Slowly remove the entire guidewire from the holder hoop from the proximal end.
7. After pulling the guide wire out of the holder hoop, inspect it to make sure that it is not damaged.

8.2 Guidewire Procedure

Interventionalist will place the guidewire through appropriate size introducer sheath. See specifications for maximum outer diameter.

1. Insert distal tip of the guidewire into the lumen of the introducer sheath and/or dilator.
2. Advance the guidewire through the introducer.
3. Use imaging technology (fluoroscopy and/or ultrasound) to advance the guidewire through patient's vasculature. Once in desired position past vascular lesion, remove the dilator (or guidewire introducer) at the introducer sheath over the guidewire core, if utilized.
4. Attach a standard torque device to the guidewire, if necessary.
5. Insert proximal end of guidewire into the lumen of the interventional device.
6. Use imaging technology (fluoroscopy and/or ultrasound) to advance the device over the guidewire while preventing the guidewire from movement through the introducer sheath and into the patient's vasculature.
7. Advance the interventional device carefully using imaging technology to visualize the device and guidewire spring tip.

Caution: Visualize guidewire movement in the vessels utilizing imaging technology. Do not torque or move a guidewire without visualizing corresponding movement of the guidewire spring tip.

Caution: Do not utilize guidewire in any vessels were visibility using imaging technology is reduced or absent.

8. Remove the guidewire torquer device, if utilized.

8.2 Removing the Guidewire

Interventionalist will remove the guidewire through appropriate size introducer sheath.

1. To move the guidewire to a different target lesion, rotate the guidewire and retract or advance utilizing imaging technology.
2. To remove the guidewire, slowly retract while monitoring the movement utilizing imaging technology.
3. After pulling the guide wire out of the body, keep it wet with heparinized saline.

Caution: If the guidewire is to be reinserted after removal, visualize guidewire and spring tip for possible damage prior to insertion. If damage is visible, do not reuse.

4. Dispose of guidewire according to standard hospital practice.

9 Specifications

Nominal Core Outer Diameter	0.013 inch (0.33 mm)
Maximum Core Outer Diameter	0.014 inch (0.36 mm)
Maximum Spring Tip Outer Diameter	0.0144 inch (0.366 mm)
Recommended introducer sheath	0.014 inch minimum (0.36 mm) lumen compatibility
Length	GW1001 – 325 cm
Tip Load Force	13 gf (Reference)

Environmental parameters

Transport conditions	Temperature range: -29ºC to 60ºC 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. This guide wire must be kept out of water. Store in a cool, dark and dry place.

Manufactured for: Cardio Flow, Inc.
888 East Ave., Mahtomedi, MN 55115
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