Abbott

COROFLOW‡ CARDIOVASCULAR SYSTEM

Used with the wireless PressureWire™ X Guidewire, provides a comprehensive physiology solution that can assess for both epicardial disease and Coronary Microvascular Dysfunction (CMD)*[1]

* With Fractional Flow Reserve (FFR), Resting Full-Cycle Ratio (RFR), Index of Microcirculatory Resistance (IMR) and Coronary Flow Reserve (CFR).

1. PressureWire™ X Guidewire Instructions for Use (IFU). Refer to IFU for additional information. CoroFlow‡ Cardiovascular System IFU. Refer to IFU for additional information.

See Important Safety Information referenced within.

Information contained herein for DISTRIBUTION in the U.S. only.

PressureWire™ X Guidewire and the CoroFlow‡ Cardiovascular System, lead the way in physiology innovation by providing the only* comprehensive solution for patients suffering from epicardial disease and coronary microvascular dysfunction (CMD)[1,2]

PressureWire™ X Guidewire and the CoroFlow‡ Cardiovascular System can assess both the epicardial arteries and the microvasculature[1]

* With Fractional Flow Reserve (FFR), Resting Full-Cycle Ratio (RFR), Index of Microcirculatory Resistance (IMR) and Coronary Flow Reserve (CFR).

1. PressureWire™ X Guidewire Instructions for Use (IFU). Refer to IFU for additional information. CoroFlow‡ Cardiovascular System IFU. Refer to IFU for additional information.
2. Ford TJ, et al. 1-year outcomes of angina management guided by invasive coronary function testing (CorMicA). *JACC Intv.* 2020; 13:33-45.

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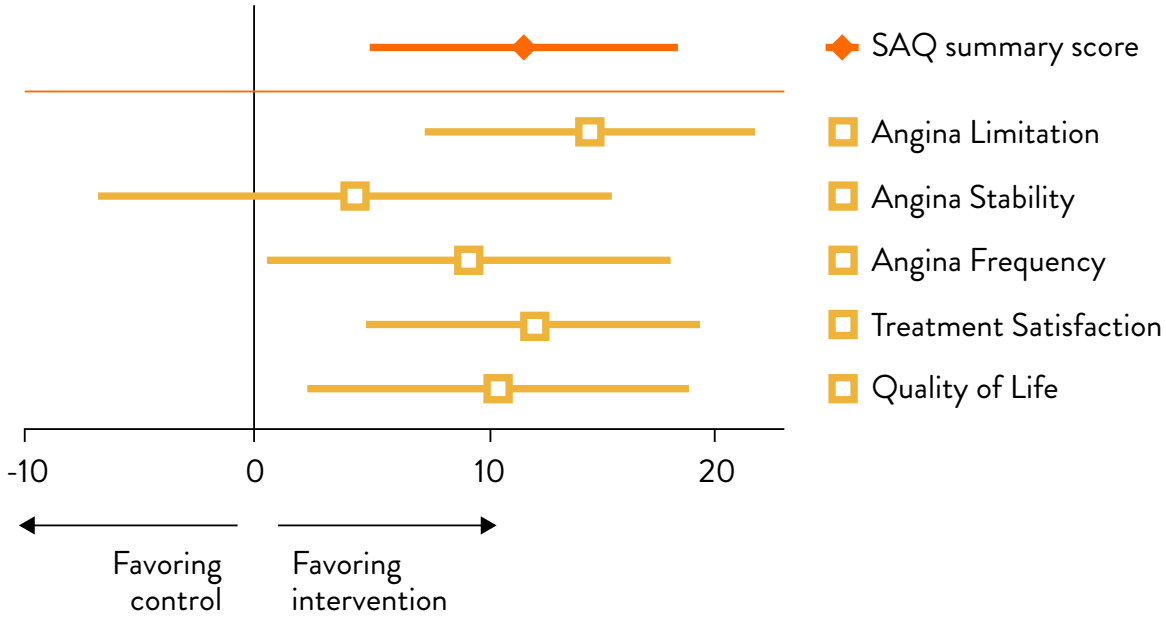
IMPROVING QUALITY OF LIFE FOR CMD PATIENTS[1]

In the CorMicA trial, diagnosing and treating CMD with stratified medical therapy led to sustained angina improvement and improved quality of life[1]



Full CMD assessment and intervention with medical therapy compared to angio-only assessment

Definition of the SAQ summary score:

Forest plot of mean treatment in angina summary score (95% CI) and breakdown of the Seattle Angina Questionnaire (SAQ) score domains. The angina summary score is the mean of 3 angina domains (limitation, frequency, and overall quality of life).

1. Ford TJ, et al. CorMicA Trial. *JACC*. 2018; 23(72):2841-55.

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COROFLOW‡ CARDIOVASCULAR SYSTEM

DIAGNOSING CORONARY MICROVASCULAR DYSFUNCTION

The innovative PressureWire™ X Guidewire is the world's only[1,2] wireless physiology wire that is able to assess a broad range of hemodynamic indices[2]

Pressure and temperature sensors

- The temperature sensors on PressureWire™ X Guidewire enables Index of Microcirculatory Resistance (IMR) and Coronary Flow Reserve (CFR) measurements, which are physiological indices used to diagnose CMD[3]
- IMR indicates the level of microcirculatory resistance in the target artery territory[4]
- CFR indicates the maximum increase in coronary artery flow above the normal resting volume[5]
- IMR is more reproducible and specific for assessing the microvasculature than CFR and may be more predictive of outcomes[6]

* With Fractional Flow Reserve (FFR), Resting Full-Cycle Ratio (RFR), Index of Microcirculatory Resistance (IMR) and Coronary Flow Reserve (CFR).

1. Volcano Corp. Verrata‡ guidewire and PrimeWire Prestige‡ Plus guidewire IFUs, Opsens Inc. OptoWire‡ guidewire and OptoWire‡ II guidewire IFUS, ACIST Medical Systems. Navvus‡ Microcatheter IFU, Boston Scientific Corporation. Comet‡ guidewire IFU.
2. PressureWire™ X Guidewire Instructions for Use (IFU). Refer to IFU for additional information.
3. PressureWire™ X Guidewire Instructions for Use (IFU). Refer to IFU for additional information. CoroFlow‡ Cardiovascular System IFU. Refer to IFU for additional information.
4. Fearon et al. Novel Index for Invasively Assessing the Coronary Microcirculation. *Circulation* 2003;107:3129-3132.
5. Ford TJ, et al. CorMicA Trial. *JACC.* 2018; 23(72):2841-55.
6. Fearon WF, et al. Prognostic value of the Index of Microcirculatory Resistance measured after primary percutaneous coronary intervention. *Circulation.* 2013;127(24):2436-2441.

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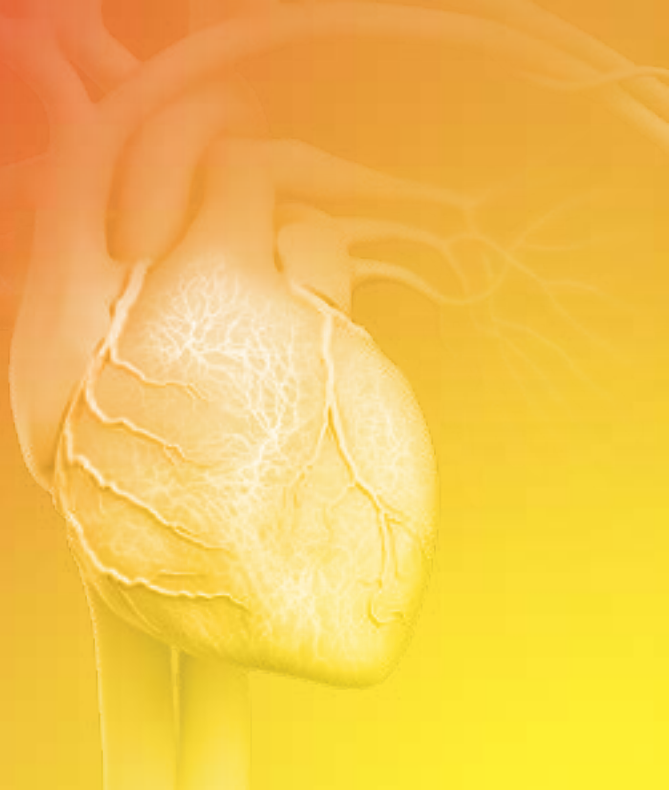
COROFLOW‡ CARDIOVASCULAR SYSTEM

PROVIDING HEMODYNAMIC DATA FOR THE ENTIRE CORONARY VASCULATURE



Features[1]

Epicardial Assessment

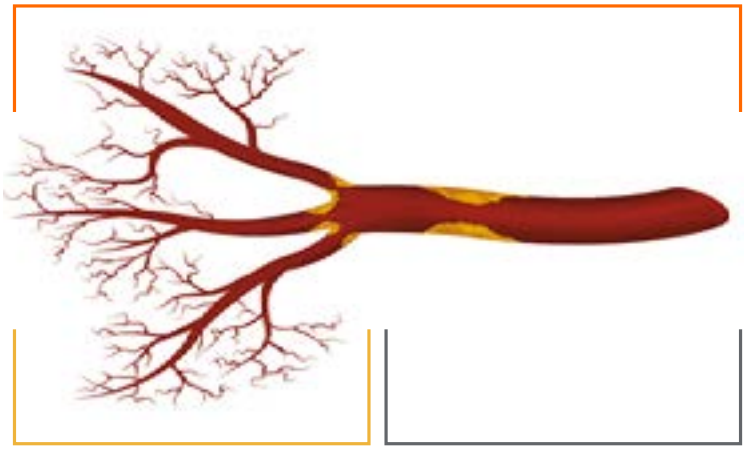
- FFR (Fractional Flow Reserve)
- RFR (Resting Full-Cycle Ratio)
- Pd/Pa
- Pullback measurements

Microvascular Assessment

- CFR (Coronary Flow Reserve)
- IMR (Index of Microcirculatory Resistance)

CFR

Flow assessment across both the microvasculature and epicardial arteries[2]



IMR

Assessment of the microvasculature

FFR, RFR, Pd/Pa

Assessment of the epicardial arteries

IMR is more accurate in assessing the microvasculature than CFR[3]

1. CoroFlow‡ Cardiovascular System Instructions for Use (IFU). Refer to IFU for additional information.
2. Fearon WF, et al. Novel Index for Invasively Assessing the Coronary Microcirculation. *Circulation* 2003;107:3129-3132.
3. Fearon WF, et al. Prognostic value of the Index of Microcirculatory Resistance measured after primary percutaneous coronary intervention. *Circulation*. 2013;127(24):2436-2441. doi:10.1161/CIRCULATIONAHA.112.000298.

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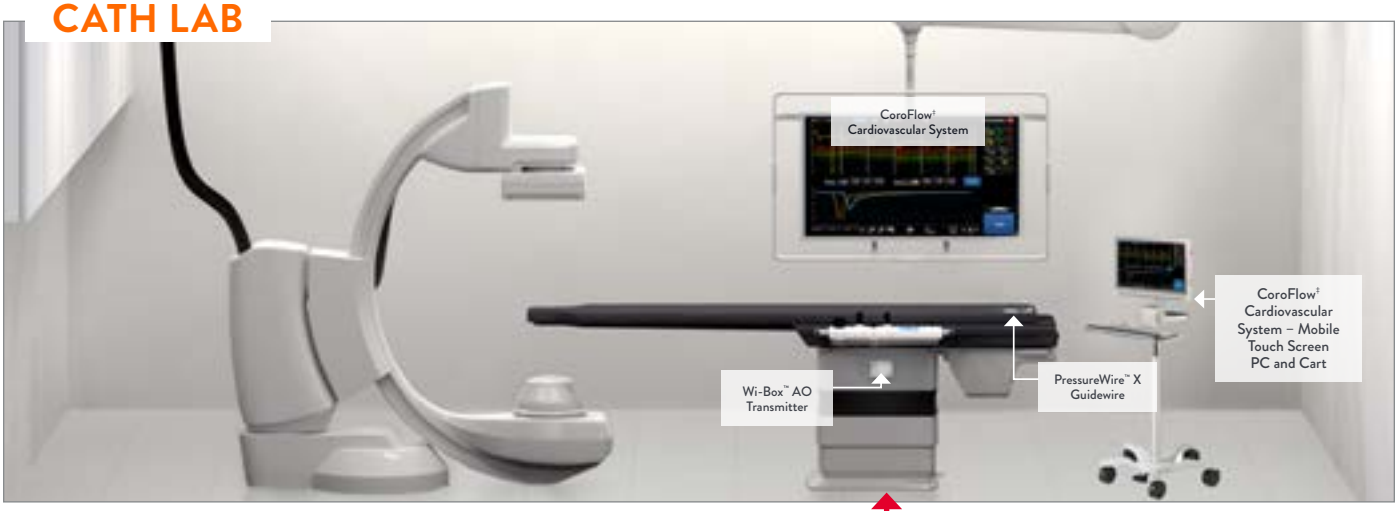
SEAMLESS INTEGRATION WITH INTUITIVE WORKFLOW[1]

- The CoroFlow‡ Cardiovascular System is available in multiple configurations for flexibility, to ensure that we can meet whatever unique needs you have in your cath lab
- The workstation PC version allows for an integrated feel
- Alternatively, the mobile cart option has a sleek touchscreen and allows for flexible use between different rooms, with a long-lasting battery pack to reduce the clutter and obstacles that cables can cause

CATH LAB



CONTROL ROOM

CoroHub‡ Receiver

Workstation PC

Control Room Monitor

1. CoroFlow‡ Cardiovascular System Instructions for Use (IFU). Refer to IFU for additional information.

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GUIDELINES RECOMMEND GUIDEWIRE-BASED MEASUREMENTS

The ESC guidelines[1] 2019 were updated to include an increased focus on microvascular dysfunction.

RECOMMENDATIONS	CLASS[a]	LEVEL[b]
Guidewire-based CFR and/or microcirculatory resistance measurements should be considered in patients with persistent symptoms, but coronary arteries that are either angiographically normal or have moderate stenosis with preserved iwFR/FFR.	IIa	B

The AHA/ACC Clinical Practice Guideline[2] on Chest Pain includes Class IIa recommendation for guidewire-based assessment for INOCA patients.

RECOMMENDATIONS FOR PATIENTS WITH INOCA	CLASS[a]	LEVEL[b]
For patients with persistent stable chest pain and nonobstructive CAD and at least mild myocardial ischemia on imaging, it is reasonable to consider invasive coronary function testing to improve the diagnosis of coronary microvascular dysfunction and to enhance risk stratification.	IIa	B-NR

CFR = coronary flow reserve; FFR = fractional flow reserve; iwFR = instantaneous wave-free ratio; INOCA = ischemia and no obstructive coronary artery disease
a Class of recommendation b Level of evidence.

Level (Quality) of Evidence Level B-NR (non-randomized): moderate-quality evidence from 1 or more well designed, well executed nonrandomized studies, observational studies or registry studies. RCTs. Meta-analyses of such studies

PHYSIOLOGY INDICES GUIDE

	RFR Resting Full-cycle Ratio	FFR Fractional Flow Reserve	CFR Coronary Flow Reserve	IMR Index of Microcirculatory Resistance
Cut-off (defer)	>0.89[2]	>0.80[3]	≥2.0[1*]	<25[1*]

* For INOCA patients.

1. Knuuti J, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. *European Heart Journal* 2019.
2. Gulati M, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.
3. Kunadian V, et al. An EAPCI Expert Consensus Document on Ischaemic with Non-Obstructive Coronary Arteries in Collaboration with European Society of Cardiology Working Group on Coronary Pathophysiology & Microcirculation Endorsed by Coronary Vasomotor Disorders International Study Group. *European Heart Journal*. 2020; 0:1-21.

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FULLY INTEGRATED WITH VERSATILE FUNCTIONALITY

Wireless communication with the PressureWire™ X Guidewire and Wi-Box™ AO transmitter

Digital imaging and communications in medicine (DICOM) compatibility

Cloud-based data management allowing for secure remote data access and multicenter study projects

Automated study data management as well as encrypted data storage/user access with Windows‡ 10

Multiple export options of calculated measurement parameters and raw waveform data

PressureWire™ X Guidewire Instructions for Use (IFU). Refer to IFU for additional information. CoroFlow‡ Cardiovascular System IFU. Refer to IFU for additional information.

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OFFERING AUTOMATED AND INTUITIVE DATA MANAGEMENT

Data & baseline characteristics

Automated data indexing

Study level data filtering/ anonymization export to Excel‡/MATLAB‡

CoroFlow‡ Cardiovascular System Instructions for Use (IFU). Refer to IFU for additional information.

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PRODUCT SPECIFICATIONS[1]

Available Parameters Description

RFR	Resting Full-Cycle Ratio
FFR	Fractional Flow Reserve
CFR	Coronary Flow Reserve
CFR_Norm	Normalized CFR: CFR/FFR
PB-CFR	Pressure bounded CFR: CFR estimated from resting & hyperemic pressure gradients
IMR	Index of Microcirculatory Resistance
IMR Corr	IMR Corrected with wedge pressure or Yong approximation
BRI	Baseline Resistance Index
RRR	Resistance Reserve Ratio
Q	Absolute Flow (L/min) through continuous thermo-dilution
Q_Norm	Normalized Q: Q/FFR
R	Absolute Resistance (mmHg/L/min)
dP/dt	First derivate of distal pressure
Tau	Diastolic relaxation constant

CoroHub‡ Radio Receiver

Frequency range
2.4000-2.4835 GHz (ISM-band)

Type
Frequency Hopping Spread Spectrum

Range 0-10 m

NOTE: Radio range is reduced by objects and walls. Keep transmitter and CoroHub‡ Receiver in line of sight wherever possible

CoroFlow‡ Cardiovascular System Data Storage

Sampling rate 100 Hz

Pressure resolution 0.1 mmHg

Temperature resolution 0.01° C

REORDER NUMBER	DESCRIPTION
C12059	PressureWire™ X Wireless FFR Guidewire, 175 cm
C12783	Wi-Box™ AO transmitter
12000	CoroFlow‡ Cardiovascular System
12011	Coro PC Workstation
12012	Coro All-in-One Touch Screen / Mobile PC
12012-01	Coro Mobile Cart

1. PressureWire™ X Guidewire Instructions for Use (IFU). Refer to IFU for additional information. CoroFlow‡ Cardiovascular System IFU. Refer to IFU for additional information.

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IMPORTANT SAFETY INFORMATION

℞ ONLY COROVENTIS‡ COROFLOW‡ CARDIOVASCULAR SYSTEM

INDICATIONS

CoroFlow‡ is indicated to provide hemodynamic information for use in the diagnosis of patients with cardiovascular diseases.

CoroFlow‡ is intended for use in catheterization and related cardiovascular specialty laboratories to compute and display various physiological parameters based on the output from one or more measuring devices.

CONTRAINDICATIONS

The system has no patient alarm functions. Do not use for cardiac/vital signs monitoring.

WARNINGS

- If CoroFlow‡ is used together with 3rd party infusion catheters for assessment of Absolute Flow and Resistance, ensure that the maximum infusion rate per manufacturers instruction is not exceeded or vessel injury may occur.
- Do not use the CoroFlow‡ measurement system if there is reason to believe the system's security has been compromised or if the system was unaccounted for a period of time (i.e. misappropriated, modified or tampered with).
- Do not leave the CoroFlow‡ measurement system unattended when logged in as a PC Administrator.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access-controlled environment.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), the PC on to which CoroFlow‡ is installed must be configured according to the Installation Instructions in this manual. Failure to configure the PC correctly may result in increased risk for unauthorized release of protected health information. Windows settings include:
  - Activation and configuration of restricted user Access
  - Activation of Windows Firewall and blocking of network connections
  - Activation of Windows Bitlocker drive encryption
  - Activation of Windows Secure Boot
  - Activation of Windows Anti-Virus scanning
  - Activation of Windows update
- 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.
- Use of accessories, transducers and cables other than those specified or provided by Coroventis‡ 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 CoroFlow‡, including cables specified by Coroventis‡. Otherwise, degradation of the performance of this equipment could result.

PRECAUTIONS

- The PC and CoroHub‡ shall not be placed within the patient environment (1.5 m from patient).
- For operation of other devices used in conjunction with CoroFlow‡ consult the IFU for each of these devices for details on indication, handling and safety information.
- It is recommended to ensure local routines for data backup of stored recordings. CoroFlow‡ does not create backup of stored data.
- Always check minimum performance requirement on PC to ensure compatibility with CoroFlow‡.
- It is recommended to install CoroFlow‡ on a PC with backup battery to avoid interruption in case of power failure.
- Always manually review and confirm valid cursor positions and detected heart beats.
- Ensure that Pa and Pd pressure waveforms are aligned in phase and offset after equalization, or indices can be mis-calculated.
- Confirm that the correct Wi-Box is selected by manually matching the Wi-Box ID number with the Wi-Box in the lab.
- Changing parameter settings outside of default values may affect measurement performance, only for research purposes.
- Only to be used by healthcare professionals
- Using a network location to store data may cause previously unidentified risks if the network malfunctions
- The assembly of medical electrical systems and modifications during the actual service life require evaluation to the requirements according to IEC 60601-1 standard series.
- CoroHub‡ does not have any serviceable parts and require no field maintenance. No modification or tampering with CoroHub‡ is permitted.
- CoroHub‡ shall not be immersed in liquid.
- CoroHub‡ shall not be used if it has been subject to damage.
- Direct connection to a non-secure network, like the internet, may interfere with correct operation and/or result in inappropriate access to patient information. Furthermore, it should be noted that reconfiguring a used network may lead to inability to import patient as well as export examination data, ultimately leading to a risk of loss of patient and examination data. To avoid this problem Coroventis‡ recommends verifying network settings in the system setup after each change.

℞ ONLY PressureWire™ X Guidewire

INDICATIONS

The PressureWire™ X Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels. Physiological parameters include blood pressure. The PressureWire™ X Guidewire can also measure blood temperature.

CONTRAINDICATIONS

This guidewire is contraindicated for use in the cerebral vasculature.

WARNINGS

- No modification of this device is allowed.
- The PressureWire™ X Guidewire is supplied sterile. Discard the guidewire if the pouch is opened or damaged, compromising the sterile barrier. The guidewire is designed for single use only and shall not be reused or resterilized. Adverse effects of using a non-sterile or resterilized guidewire may include, but are not limited to:
  - Local and/or systemic infection
  - Mechanical damage
  - Inaccurate readings
- Observe all guidewire movements. Whenever the guidewire is moved or torqued, the tip movement should be examined under fluoroscopy. Never push, withdraw, or torque the guidewire if it meets resistance or without observing corresponding movement of the tip, otherwise vessel/ventricle trauma may occur.
- Torquing or excessive manipulation of the guidewire in a sharp bend, against resistance, or repeated attempts to cross a total vessel occlusion may:
  - Cause dissection or perforation of blood vessels
  - Cause vessel spasm
  - Damage and/or fracture the guidewire
- When introducing the guidewire, flush the catheter and administer anticoagulation as for a standard catheterization procedure or clotting may occur.
- Do not use the guidewire in the ventricles if the patient has a prosthetic mechanical or biological valve. It may result in damage to both the prosthesis and the guidewire, which may cause injury or death.
- Use of the PressureWire™ X Guidewire in conjunction with interventional devices with a short rapid exchange may result in a folded or fractured guidewire.
- High frequency surgical devices must not be used on a patient at the same time as the guidewire.

PRECAUTIONS

- The PressureWire™ X Guidewire is a delicate instrument and should be handled carefully.
- Make sure that the transmitter is kept dry to ensure accurate pressure and/or temperature readings. Inaccurate readings may necessitate device replacement.
- Do not use the guidewire in conjunction with atherectomy catheters. It may damage the guidewire.
- Do not withdraw or manipulate the guidewire in a sharp-edged object. It may result in abrasion of the guidewire coating.
- Factors that may affect the accuracy of the diagnostic information include, but are not limited to:
  - Improper placement of the aortic pressure sensor.
  - Failure to achieve maximum coronary and myocardial hyperemia in FFR procedures
  - Blood flow affected by the position of interventional devices, such as balloon catheters.
- Guidewire readings may be affected by defibrillation. Rezero the guidewire after defibrillation use.

IMPORTANT SAFETY INFORMATION CONT.

- Do not measure pressure when the guidewire sensor element is in a sharp bend or in contact with atrial or ventricular walls. It might result in pressure artifacts.
- Do not use the PressureWire™ X Guidewire together with another guidewire, for so called jailed wire technique, due to difficulty in guidewire withdrawal and possible guidewire entrapment.
- Store at room temperature in a dry and dark place.

POTENTIAL ADVERSE EVENTS

Potential complications which may be encountered during all catheterization procedures include, but are not limited to: vessel dissection or occlusion, perforation, embolus, spasm, local and/or systemic infection, pneumothorax, congestive heart failure, myocardial infarction, hypotension, chest pain, renal insufficiency, serious arrhythmias, or death.

In addition, this device has a coating containing Polyethylene Glycol (PEG); potential allergic reactions (anaphylaxis) may occur during the interventional procedure if the patient is allergic to PEG.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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