Boston Scientific
Advancing science for life™

COMET™ II
Pressure Guidewire

For total confidence in your treatment decision.

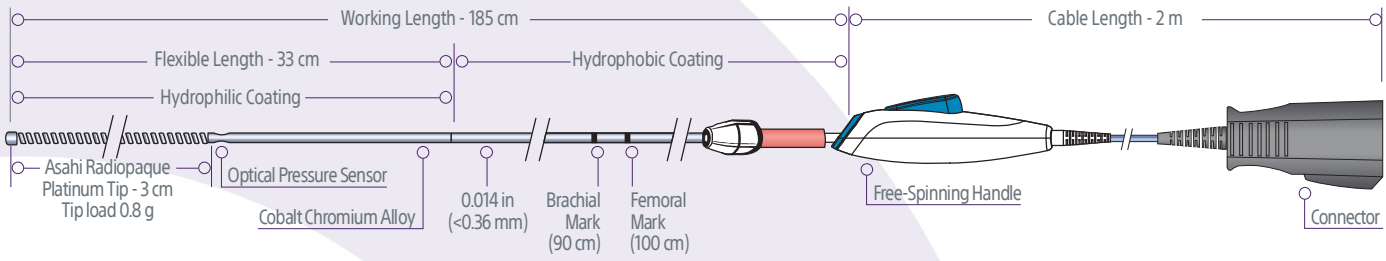
Deliverability
- Shapeable and atraumatic Asahi tip
- Precision cut body for 1:1 torque

Accuracy
- Optical technology for exceptional drift performance and reliable signal connection

Usability
- Optimized rail support for device delivery
- Free-spinning, quick-release handle
- One wire for the entire procedure

ASAHI TECHNOLOGY

COMET™ II
Pressure Guidewire



Ordering Information

Order Number (GTIN)	Ref/Catalog Number	Description
08714729960140	H749 **3935911** 0	COMET II Pressure Guidewire

The C-code used for the COMET II Pressure Guidewire is C1769. C-codes are used for hospital outpatient device reporting for Medicare and some private payers. Boston Scientific is not responsible for correct use of codes on submitted claims; this information does not constitute reimbursement or legal advice.

Integration Options

POLARIS Multi-Modality Guidance System	FFR Direct
• Single system to inform treatment decisions for coronary physiology and IVUS • Fully integrated and mobile options available to fit seamlessly in any facility • All physiological indices—FFR, DFR™, and Pd/Pa—available for use	A solution for customers with a physiology calculation module on the hemodynamic system • Integrates into existing hemodynamic system* • Minimal capital footprint • Physiology result transmits directly into patient record

*Hemodynamic systems which are compatible with ANSI/AAMI BP22 interface standards for blood pressure signaling.

Comet™ II Pressure Guidewire

INTENDED USE/INDICATIONS FOR USE: The Comet II Pressure Guidewire measures blood pressure gradient across coronary and peripheral lesions during endovascular procedures. FFR (Fractional Flow Reserve) pressure guidewire may also be used as a coronary or peripheral guidewire for interventional treatments. The Comet II Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels. **CONTRAINDICATIONS** The Comet II Pressure Guidewire is contraindicated for use in the cerebral vasculature. **WARNINGS** • Resulting pressure guidewire fractures/separations might require additional percutaneous intervention or surgery. • Use extreme caution and careful judgment in patients for whom anticoagulation is not indicated. • Severe reaction may occur in response to contrast agents that cannot be adequately premedicated. **PRECAUTIONS** Maintain diligent control of the distal tip at all times during an intervention to avoid vessel dissections and perforations. Wire damage may occur when the pressure guidewire is manipulated in a sharp bend, such as that caused by incomplete coaxial alignment of the delivery catheter and ostium, creating a sharp bend of the pressure guidewire between the delivery catheter and the vessel wall. Sharp bends are more likely to occur when using a less supportive delivery catheter, such as a diagnostic catheter. When crossing a stent, exercise care to avoid entanglement between the pressure guidewire and the stent. Avoid abrasion of the pressure guidewire coating. • To avoid damage to the hydrophilic coating, do not withdraw or manipulate the pressure guidewire in a metal cannula or sharp object. • Excessive tightening of the torque device onto the pressure guidewire may result in abrasion of the coating on the pressure guidewire. Use only the optical cable provided to connect the pressure guidewire to FFR Link. Use of a different optical cable will produce inaccurate pressure readings. The accuracy of the diagnostic information is affected by, but not limited to: • Failure to achieve maximum coronary and myocardial hyperemia if using FFR (Fractional Flow Reserve) modality.• Interventional devices, such as balloon catheters, which are positioned so as to affect the blood flow or guidewires that stretch the vessel. • Pressure wire positioning relative to the lesion. • Microvascular resistance. Carefully check and match therapeutic device compatibility to the pressure guidewire prior to use. Do not use the pressure guidewire in conjunction with atherectomy catheters. **ADVERSE EVENTS** Potential adverse events which may result from the use of the device include but are not limited to: • Abrupt closure • Allergic reaction • Embolism • Exposure to biohazardous material • Infection • Prolonged procedure • Restenosis (reocclusion) • Spasm • Stroke/cerebral vascular accident (CVA)/transient ischemic attack (TIA) • Vascular thrombus • Vessel trauma (dissection, perforation, rupture or injury) In addition, when used for interventional procedures: • Angina or unstable angina • Arrhythmias • Cardiac tamponade/pericardial effusion • Contrast induced renal insufficiency or renal failure • Death • Myocardial infarction or ischemia

Some of the above potential adverse events may require additional surgical intervention.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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