



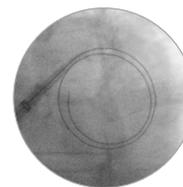
ProTrack™
Pigtail Wire



INSTANT ANCHOR. SECURE ACCESS.™

ProTrack™ Pigtail Wire

Efficiently achieve and maintain left atrial access with a flexible spiral tip. Support large sheath exchange and cushion against the left atrial wall.

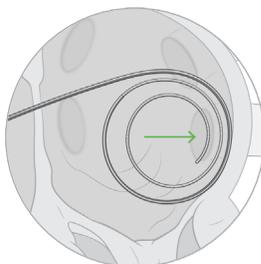


Radiopaque coil



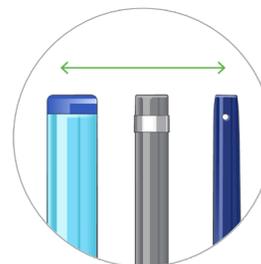
Save Time

Quicker introduction of devices into the LA.¹
Simply deploy the pigtail wire for instant, anchored access into the left atrium.



Flexible Cushion

Cushion gently against the left atrial wall with a flexible, atraumatic tip.



Exchange & Support

The stiff stainless steel body facilitates large sheath exchange and provides sheath stabilization.

SPECIFICATIONS

Feature	Specifications
Body outer diameter	0.025 in
Overall length	175 cm, 230 cm
Functional exchange length	152 cm, 207 cm
Spring coil length	13 cm
Spiral coil diameter	4.1 cm
Shaft material	Stainless steel
Coil material	Stainless steel

ORDERING INFORMATION

Overall Length	Product Code
175 cm	PTW-25-175
230 cm	PTW-25-230

ProTrack™ Pigtail Wire

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.

ADVERSE EVENTS: Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

EP-1515204-AA

¹Buchner S, et al. J Interv Cardiol. doi: 10.1111/joic.12224

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EP-1558005-AA