English

InQwire® AMPLATZ

Guide Wires

INSTRUCTIONS FOR USE

DESCRIPTION:
Merit Medical Amplatz guide wires are fabricated from high quality stainless steel with PTFE coating. Amplatz wires have increased stiffness which provides added strength and stability. Guide wires are packaged in a plastic hoop fitted with a luer hub. This packaging facilitates compliance with the manufacturer recommended guidelines that the guide wire be flushed with saline or heparinized saline prior to use. Guide wires are supplied sterile and non-pyrogenic.

INDICATIONS FOR USE:
Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

CONTRAINDICATIONS:
InQwire diagnostic guide wires are contraindicated for use in the coronary and cerebral vasculature.

POTENTIAL COMPLICATIONS:
Potential complications which may result from the use of the device include but are not limited to: Air Embolism/Thromboembolism, Allergic Reaction, Cardiac Arrhythmia, Amputation, Arteriovenous (AV) Fistula, Breathing Difficulty, Death, Embolism, Hematoma, Hemorrhage, Hemoglobinuria, Infection or Sepsis/Infection, Myocardial Ischemia and/or Infarction, Pseudoaneurysm, Stroke (CVA)/Transient Ischemic Attacks (TIA), Thrombus, Vessel Occlusion, Vessel Perforation, Vessel Dissection, Vessel Trauma or Damage, Vessel Spasm, Wire Entrapment/Entanglement, Foreign body/Wire Fracture. Some of the stated potential adverse events may require additional surgical intervention.

INSPECTION PRIOR TO USE:
Product is sterile if package is unopened and undamaged. Prior to use, carefully examine all guide wires to verify that the sterile package or product has not been damaged in shipment. Prior to use and when possible during the procedure, inspect the guidewire carefully for coil separation, bends or kinks which may have occurred. Do not use a wire which has a damaged tip.

PREPARATION FOR USE:
Caution: A guide wire is a delicate instrument. Any time that a guide wire is used there is a possibility of thrombus formation/ emboli, vessel wall damage, and plaque dislodgement, which could result in adverse procedural complications and /or adverse patient outcomes. The physician should be familiar with the use of angiography products and the literature concerning the complications of angiography. Angiography should be undertaken only by an experienced angiographer.
Note: Distal tip of wire may be positioned inside the flush hoop to protect the fragile tip.

Note: Confirm guide wire and needle compatibility prior to use.

Caution: To avoid damaging the guide wire tip during removal from the flush hoop, slide proximal portion of guide wire body forward in the flush hoop loop allowing the distal wire tip to exit the flush hoop. Gently grasp guide wire tip and J straightener together as a unit and gently pull forward to withdraw the distal wire portion from the flush hoop.

1. Attach flush filled syringe to flush hoop luer.
2. Inspect and prepare the catheter or device to be used according to the manufacturer's instructions. This includes flushing the catheter to be used with saline solution.
3. Inject saline into hoop to completely fill loop until dripping out opposite end.

   Note: In order to reduce the potential of clot formation, it is recommended that the guide wire be flushed with saline or heparinized saline prior to use.
4. Detach syringe from flush hoop luer.
5. Dispense guide wire into the port of the catheter.

Note: Employ an aseptic technique during removal from the package and during use.

Caution: Advancement with excessive force may cause coil penetration and vessel damage.

INSTRUCTIONS FOR USE:
Warning: Use extreme caution when withdrawing PTFE coated guide wires back through a metal needle. The sharp edge of the needle may scrape the coating. It is suggested that a catheter or PTFE vessel dilator replace the access needle as soon as the guide wire has reached the appropriate position.

1. Insert the guide wire J-straightener into the guide wire port of the intended catheter or device.
2. Carefully advance the distal guide wire tip through the J straightener and device lumen. Remove the J straightener by withdrawing it over the guidewire.

   Warning: Extreme care should be taken when manipulating a catheter and wire combination within the vessel to prevent possible intravascular tissue damage. If resistance is felt during advancement, manipulation or removal from the catheter, stop immediately and confirm the guide wire and catheter tip position under fluoroscopy. The guide wire and catheter should be removed as a unit when possible to prevent potential damage to the vessel wall.
3. Confirm guide wire tip placement under fluoroscopy to assure that the distal tip is intraluminal and in the intended vessel.
4. Hold the guide wire in position while manipulating the catheter over the guide wire to prevent unintended movement of the distal wire tip.

Warning: When reintroducing a guide wire into a catheter or device within a vessel, confirm that the catheter tip is free within the lumen (i.e. not against the vessel wall).
Warning: Always advance or withdraw a wire slowly. Free movement of the guidewire within a catheter provides valuable tactile information. Never push, auger, or withdraw a guidewire which meets resistance as this could potentially affect other indwelling devices. Resistance may be felt tactilely or noted by tip buckling during fluoroscopy. Test all systems for resistance prior to use.

REUSE PRECAUTION STATEMENT:
For Single Patient Use Only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DISPOSAL: After use, dispose of product and packaging in accordance with hospital protocol.

In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go to the European database on medical devices (Eudamed), where it is linked to the basic UDI-DI. https://ec.europa.eu/tools/eudamed.

Basic UDI-DI: 088445048761E4

SYMBOL	DESIGNATION
	Single Use
	Caution
	Sterilized Using Ethylene Oxide
	Do Not Use If Package is Damaged or Opened and Consult Instruction for Use
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Non-Pyrogenic
MD	Medical Device
EC REP	Authorized Representative in European Community
	Manufacturer
REF	Catalog Number
	Date of Manufacture
LOT	Lot Number
	Single Sterile Barrier System
	Use-By Date
UDI	Unique Device Identifier

MERITMEDICAL®

www.merit.com

Manufacturer:
Merit Medical Systems, Inc. 1600 West Merit Parkway, South Jordan, Utah 84095
U.S.A. 1-801-253-1600 U.S.A Customer Service 1-800-356-3748

EC REP Authorized Representative:
Merit Medical Ireland Ltd, Parkmore Business Park West, Galway, Ireland
EC Customer Service +31 43 3588222

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Chinese

InQwire® AMPLATZ GUIDEWIRE 造影导丝

使用说明

产品描述：
Amplatz 造影导丝由带 PTFE 涂层的绕丝和芯丝组成，绕丝和芯丝为304V不锈钢。 导丝包装在配有鲁尔接口的塑料箍中。这种包装便于按照制造商推荐的方法进行操作，即在使用前将导丝用盐水或肝素化盐水冲洗。导丝以无菌且无热原的形式供应。

适用范围：
该产品用于外周血管系统在诊断及介入手术期间有助于装置的放置。

禁忌症：
禁止将 InQwire 诊断导丝用在冠状血管系统和脑血管系统中。

潜在并发症：
使用本器械可能导致的潜在并发症包括但不限于：空气栓塞/血栓栓塞、过敏反应、心律失常、截肢、动静脉 (AV) 瘘、呼吸困难、死亡、栓塞、血肿、出血、血红蛋白尿、感染或脓毒症/感染、心肌缺血和/或梗死、假性动脉瘤、卒中 (CVA)/短暂性脑缺血发作 (TIA)、血栓、血管闭塞、血管穿孔、血管夹层、血管创伤或损伤、血管痉挛、导丝卡压/缠绕、异物/导丝断裂。某些所述的潜在不良事件可能需要额外的手术干预。

使用前的检查：
如果包装未打开且未损坏，则产品为无菌的。在使用之前，仔细检查所有导丝，确认无菌包装或产品在装运过程中没有损坏。在使用之前以及可能的话在手术期间，仔细检查导丝是否有可能发生线圈分离、弯曲或扭结。请勿使用尖端损坏的导丝。

使用准备：
警示：导丝是一种精密仪器。任何时候使用导丝都有可能造成血栓形成/栓子、血管壁损伤和斑块脱落，这可导致不利的手术并发症和/或患者预后不良。医生应该熟悉血管造影术产品的使用和有关血管造影术并发症的文献。血管造影术应该由有经验的医生进行。

注意：导丝的远端可以置于冲洗套内部，以保护易碎的尖端。

注意：使用前，请确认导丝和穿刺针的兼容性。

警示：为避免在从冲洗箍中移除期间导丝尖端损坏，请将导丝主体的近侧部分在冲洗箍环中向前滑动，以使远侧导丝尖端退出冲洗箍。将导丝尖端和 J 矫直器作为一个整体一起轻轻地抓紧，并且轻轻地向前拉动以将远侧导丝部分从冲洗箍抽出。

1. 将冲洗填充注射器附接到冲洗套鲁尔接口。
2. 根据制造商的说明检查并准备要使用的导管或装置。这包括使用生理盐水冲洗要使用的导管。
3. 将生理盐水注入套内，使其完全充满回路，直到从另一端滴出。
   注意：为了降低血凝块形成的可能性，建议在使用前用生理盐水或肝素化生理盐水冲洗导丝。
4. 将注射器与冲洗套鲁尔接口分离。
5. 将导丝分配到导管的端口中。

注意：从包装中取出和使用过程中采用无菌技术。
警示：过度用力推进可能会导致线圈刺穿和血管损伤。

产品名称：造影导丝
生产日期和失效日期：见产品标签
说明书编制或修订日期：2021年9月。
注册证编号/产品技术要求编号： 国械注进20203030048
有效期：3年
储存条件：干燥通风阴凉处储存
型号、规格：IQA509; IQA510; IQA511; IQA512; IQA513; IQA528; IQA518; IQA521;IQA522; IQA527; IQA524; IQA517; IQA519; IQA520; IQA523; IQA525;IQA526; IQA563; IQA564; IQA500; IQA501; IQA502; IQA503; IQA 504.
注册人及生产企业名称：美国麦瑞通医疗设备有限公司 Merit Medical Systems, Inc.
注册人及生产企业住所：1600 West Merit Parkway, South Jordan, Utah 84095 USA
生产地址：Parkmore Business Park West, Galway, Ireland
中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司
中国境内代理人及售后服务单位住所：北京市朝阳区东大桥路9号楼2单元801室内B01、B02及B03单元
中国境内代理人及售后服务单位电话：010 - 85610788
中国境内代理人及售后服务单位传真：010 - 85616981

结构及组成：该产品由带聚四氟乙烯（PTFE）涂层的绕丝和芯丝组成。芯丝和绕丝的材料为304V不锈钢。产品经环氧乙烷灭菌，一次性使用。货架有效期3年

注册人及生产企业联系方式：1 - 801 - 253 - 1600
说明书编制或者修订日期：2021年9月

使用说明：
警告：当通过金属针回撤PTFE涂层导丝时要极其小心。针的锋利边缘可能会刮掉涂层。建议在导丝到达适当位置后，立即将穿刺针更换为导管或PTFE血管扩张器。
1. 将导丝 J 型矫直器插入预期导管或装置的导丝端口。
2. 小心地推进远侧导丝尖端穿过 J 矫直器和装置内腔。沿导丝移除J矫直器。
警告：警告：在血管内操纵导管和导丝的组合时应极其小心，以防止可能的血管内组织损伤。如果在推进、操纵或从导管中移除期间中感觉到阻力，请立即停止并在透视下确认导丝和导管尖端的位置。应当尽可能将导丝和导管作为一个整体来移除，以防止对血管壁的潜在损伤。
3. 在透视下确认导丝尖端的放置，以确保远侧尖端在腔内和预期血管中。
4. 沿导丝操纵导管时要保持导丝的位置不动，以防止导丝远侧尖端的非预期运动。

警告：当将导丝重新引入血管内的导管或装置中时，确认导管尖端在腔内是自由的（即不抵靠血管壁）。
警告：始终缓慢推进或回撤导丝。导丝在导管内的自由运动提供有价值的触觉信息。切勿推动、钻动或回撤遇到阻力的导丝。阻力可能通过触觉被感知或通过在透视下看到尖端屈曲而被注意到。在使用前针对阻力测试所有系统。

防止重复使用声明：
本品仅限一位患者使用。请勿重复使用、重复处理或重复消毒。重复使用、重复处理或重复消毒可能会破坏该设备的结构完整性，并且/或者导致设备故障，进而可能导致患者受伤、患病甚至死亡。重复使用、重复处理或重复消毒还有可能带来设备污染的风险，并且/或者导致患者受到感染或交叉感染，包括但不限于传染病在患者之间传播。设备污染可能会导致患者受伤、患病甚至死亡。
处置：使用后，按照医院协议处置产品和包装。

符号	说明
	不得二次使用
	警告
	经环氧乙烷灭菌
	如包装破损切勿使用
	查阅使用说明 如需电子副本扫描二维码，或跳转至www.merit.com/ifu并输入IFU ID。如需打印副本，请致电U.S.A或EU客户服务部
	警告：联邦（美国）法律规定本产品仅限于由医生销售或购买。
	无热原
	医疗器械
	欧盟授权代表
	制造商
	产品编号
	生产日期
	批号
	单一无菌屏障系统
	失效日期
	医疗器械唯一标识