English

InQwire®

Diagnostic Guide Wires

INSTRUCTIONS FOR USE

DESCRIPTION
Merit Medical guide wires are fabricated from high quality stainless steel utilizing a sophisticated construction process and are available with or without a PTFE coating. Guide wires are supplied sterile, non-pyrogenic, and are intended for single use only.

Merit Medical guide wires are packaged in a plastic hoop, which is fitted with a luer hub. This packaging is provided to facilitate compliance with the manufacturer recommended guidelines that the wire be flushed with saline or heparinized saline prior to use (See directions for use - Note).

INDICATIONS
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.

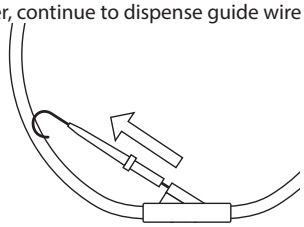
PRECAUTIONS
Angiography should be undertaken only by an experienced angiographer.

FOR ONE TIME USE ONLY
Guide wires will collect blood and other foreign material in their lumens; neither autoclaving nor ultrasonic cleaning will completely remove foreign material, therefore guide wires are recommended for one-time use.

Inspect all guide wires prior to use. Do not use any unit if the package is open or damaged.

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

All guide wires are secured in the hoop dispenser by the locking J-tip straightener. To avoid damaging the guide wire during removal from the flush hoop, grasp the J-tip straightener near the base and slide it forward approximately 5mm or until the J-tip straightener is no longer attached to the flush hoop adaptor. Holding both the guide wire and J-tip straightener, continue to dispense guide wire from the hoop.



Do not use excessive force to advance the moveable core while the guide wire is in a vessel. Advancement with excessive force may cause coil penetration and vessel damage. Never push, auger, or withdraw a guidewire which meets resistance as the could potentially affect other indwelling devices.
Avoid 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 needle as soon as the guide wire has reached the appropriate position.

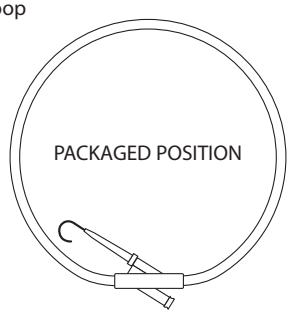
During advancement of the catheter and guide wire within the aorta, it is recommended that the guide wire be removed at the appropriate level of the aorta.

Care should be taken when manipulating a catheter during placement and withdrawal 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 tip position under fluoroscopy. Note proximity of other potential indwelling devices within the patient's anatomy. 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.

A guide wire is a delicate instrument and remains the most fallible instrument used in a percutaneous procedure. 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 myocardial infarction, cardiac arrhythmia, stroke or death. The physician should be familiar with the use of angiography products and the literature concerning the complications of angiography.

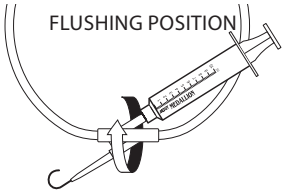
In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State.

FLUSH HOOP INSTRUCTION GUIDE
1. Attach flush filled syringe to flush port luer
2. Rotate syringe clockwise (as pictured)
3. Inject saline into hoop
4. Detach syringe from hoop



5. Dispense guide wire

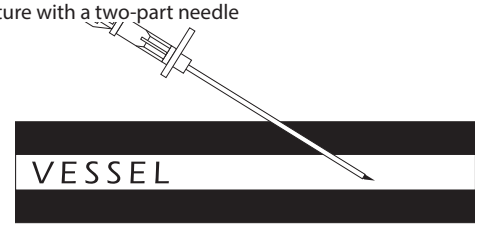
Note: In order to reduce the potential of clot formation, it is recommended that the guide wire be flushed with saline or heparinized saline prior to use. Attach a filled syringe to the luer hub located at the end of the plastic hoop, flush several times. After flushing, remove guide wire from hoop and use as described above.



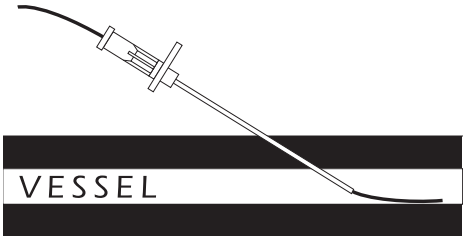
DIRECTIONS FOR USE
NOTE: Confirm guide wire and needle compatibility prior to use.

The following schematic shows a typical procedure for percutaneous entry utilizing the Seldinger technique. Variations in individual patient anatomy may preclude the utilization of this technique.

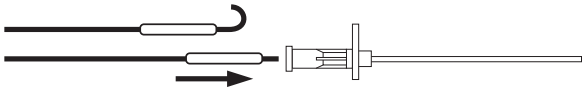
1. Vessel puncture with a two-part needle



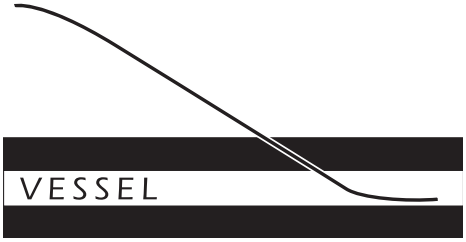
2. When using a two-part needle remove stylet leaving cannula in place, insert flexible (distal) end of guide wire through cannula and into vessel



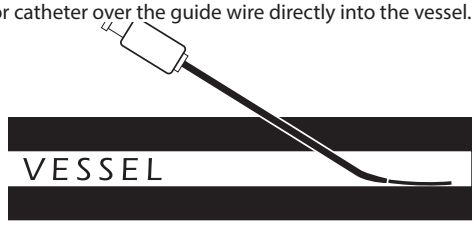
3. "J" guide wires are shipped with "J" straightener to aid in the insertion of the wire into the puncture needle. Advance the straightener until 2-3 mm of the tip extends from the tip. Insert wire into hub and through needle. Remove "J" straightener proximally and discard.



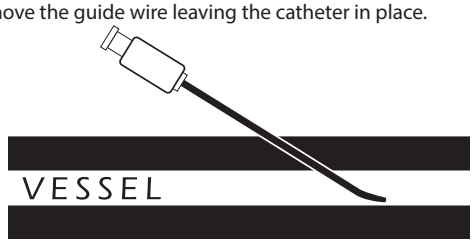
4. Remove needle cannula leaving the guide wire within the lumen of the vessel.



5. Pass dilator or catheter over the guide wire directly into the vessel.



6. Carefully remove the guide wire leaving the catheter in place.



NOTE: Device is sterilized as stated on the package label.

WARNING: After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.

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.

NOTE: Sterile if package is unopened and undamaged.

NOTE: Device is non-pyrogenic.

HOW SUPPLIED: Individually packaged 5-10 per box, refer to catalog for ordering information.

SYMBOL	DESIGNATION
	Single Use
	Do Not Re-sterilize
	Caution
STERILE EO	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
	Manufacturer
REF	Catalog Number
	Date of Manufacture
LOT	Lot Number
	Single Sterile Barrier System
	Use-By Date
UDI	Unique Device Identifier

MERIT MEDICAL®

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

InQwire®

Chinese

造影导丝

使用说明

产品描述
麦瑞通医用导丝是由不锈钢制造而成，带聚四氟乙烯涂层。所提供的造影导丝为无菌、无热原产品，并且仅作为一次性使用。

麦瑞通导丝包装在一个带有路厄端口的环型塑料套管中。采用此包装便于遵从生产商推荐的指南，即导丝在使用前用盐水或肝素化盐水冲洗（见使用说明 - 注意）。

适用范围
该产品用于方便在诊断与介入手术中放置器械。

禁忌症
InQwire诊断造影导丝禁用于冠状动脉和脑血管。

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。

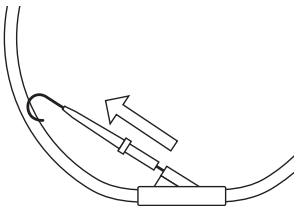
警告
血管造影术只能由有经验的血管造影操作者操作。

一次性使用
造影导丝的腔内会留有血液和其它异物；高压灭菌和超声波清洗都不能完全去除异物，因此建议造影导丝作为一次性使用。

使用前检查造影导丝。如果单个包装被打开或损坏则不要使用。

去除包装和使用时使用无菌技术。

所有造影导丝都用一个J型头调直器固定安置于环形塑料冲洗套管中。为避免造影导丝从冲洗套管中取出时损坏，抓住靠近末部的J型头调直器，向前滑动近5mm或者直到J型头调直器不再与冲洗套管的端口接触。握住造影导丝和J型头调直器，继续将洗造影导丝从套管中取出。



当导丝在血管中时不要用力推送可移动的内芯，过度推送导丝将导致弹簧线圈穿透和血管损伤。
避免通过穿刺针时回收带聚四氟乙烯涂层的造影导丝。穿刺针锋利的边缘可能会刮擦涂层。
建议当造影导丝接近适当位置时，即使用导管或四氟乙烯导管扩张器替代穿刺针。
导管向前推进并且导丝在主动脉中时，建议造影导丝被移动到主动脉合适的水平。
在替代和撤换时操作导管应该小心以防止血管内组织损伤。如果在推进、操作或从导管中移动造影导丝时感觉到阻力，应立即停止操作并在X线透视下确认导丝头端位置。注意与患者解剖结构内其他留置器械的接近程度。切勿推送、转动或撤回遇到阻力的导丝，因为这可能会影响其他留置器械。在X线透视期间可能会感觉到阻力或通过头端屈曲注意到阻力。导丝和导管应该作为一个整体移动以防止潜在的血管壁损伤。

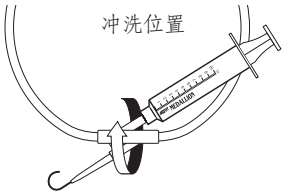
造影导丝是精细的产品并且是经皮手术中使用的最容易出现问题的器械，任何时候使用造影导丝都有可能出现血栓形成/栓子、血管壁损坏，斑块脱落以致于造成心肌梗塞、心律不齐、中风或死亡。外科医生应该熟悉造影产品的使用和有关造影术并发症的相关文献。

在欧盟，与该器械相关的任何严重事件均应报告给制造商和相关成员国主管机构。

冲洗套说明指南
1. 将注满的冲洗注射器与冲洗端路厄接口连接
2. 顺时针旋转注射器（如图所示）
3. 向冲洗套管中注射盐水
4. 从冲洗环上取下注射器

5. 让盐水覆盖造影导丝

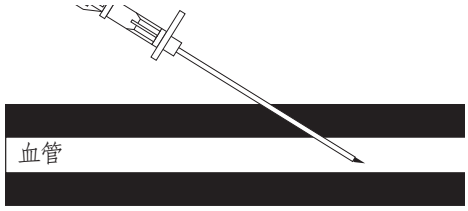
注意：为了减少潜在的凝血出现，建议使用前用盐水或肝素化盐水冲洗导丝。将注满的注射器与塑料套管末端的路厄接口连接，冲洗数次。冲洗后，按以上所述将造影导丝从环形套管中取出使用。



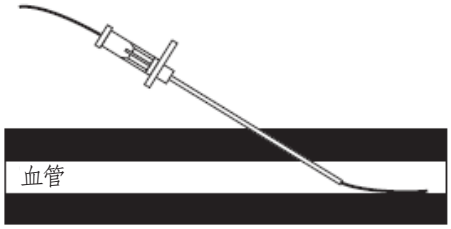
使用说明
注意：使用前确认导丝与穿刺针的兼容性。

以下为使用经股动脉穿刺术进行经皮穿刺的一般过程。病人个体的解剖差异可能会排斥这种技术的使用。

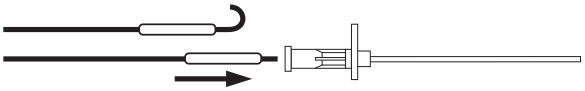
1. 使用组合针进行血管穿刺。



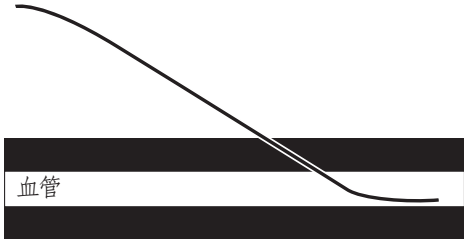
2. 去掉针芯，只留套管，插入造影导丝灵活的尾部（末端）并穿过套管进入血管。



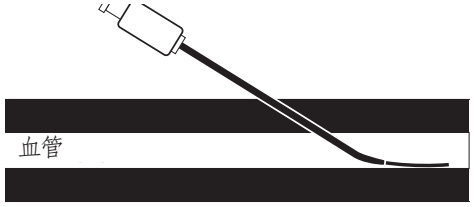
3. J型头造影导丝带有J型头调直器有助于将造影导丝插入经皮穿刺针。将调直器向前滑动至距尖端2-3mm长度的位置。将导丝插入Hub端口并穿过针。取下J型头调直器并扔掉。



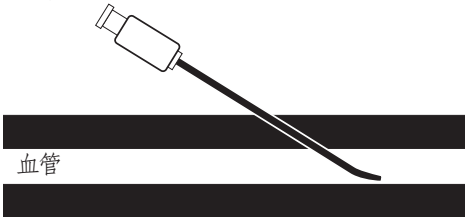
4. 取下针管，将导丝在留在血管腔中。



5. 将扩张器或导管通过导丝直接进入血管 。



6. 小心将造影导丝取出，将导管留在合适的位置。



注意：如外包装所示，产品为无菌产品。

警告：使用后，按照符合生物危害废物处置标准方案的方式处置器械。

重复使用注意事项声明：仅供单名患者使用。请勿重复使用、再加工或重复灭菌。重复使用、再加工或重复灭菌可能破坏器械的结构完整性和/或导致器械失效，进而可能导致患者受伤、患病或死亡。重复使用、再加工或重复灭菌也可能造成器械污染风险和/或导致患者感染或交叉感染，包括但不限于感染性疾病从一名患者传播到另一名患者。器械污染可能导致患者受伤、患病或死亡。

注意：如果包装未打开且未损坏，则为无菌。

注意：器械无热原。

供应方式：独立包装，每盒5-10个，订购信息参见产品目录。

符号	说明
	不得二次使用
	不得二次灭菌
	警告
STERILE EO	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
℞ ONLY	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
MD	医疗器械
	制造商
REF	产品编号
	生产日期
LOT	批号
	单一无菌屏障
	失效日期
UDI	医疗器械唯一标识

有效期: 3 年

储存条件：室温，通风，干燥，避光

运输条件：运输过程中，避免接触高温潮湿

产品名称：造影导丝

结构及组成：该产品采用 304 不锈钢材料制成，表面带聚四氟乙烯涂层。 一次性使用，环氧乙烷灭菌。货架有效期三年。
注册证编号：国械注进20193031842
产品技术要求编号：国械注进 20193031842
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
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, UT 84095
生产地址：1600 West Merit Parkway, South Jordan, Utah 84095, USA; Parkmore Business Park West Galway, Ireland.
注册人及生产企业联系方式：1-801-253-1600
说明书编制或修订日期：2021 年 9 月
生产日期和失效日期：见产品标签

型号、规格：

编号	型号规格	编号	型号规格
1	IQ35F150S	31	IQ38F260J3
2	IQ35F260S	32	IQR35F150J3
3	IQ38F150S	33	IQR35F260J3
4	IQ38F260S	34	IQR38F150J3
5	IQR35F150S	35	IQ38F50J3
6	IQR35F260S	36	IQ35F150J3F
7	IQ35F150NLT	37	IQ38F180J3F
8	IQ35F150NLLT	38	IQ38F150J3F
9	IQ35F150NLLLT	39	IQR35F150J3F
10	IQ35F150B	40	IQR38F150J3F
11	IQ35F180B	41	IQR35F180J3F
12	IQ35F260B	42	IQ35F180J3F
13	IQ38F150B	43	IQ38F150J6
14	IQ35F80B	44	IQR35F150J6
15	IQR35F150B	45	IQ35F150J6
16	IQR35F150BST	46	IQR35F150J15
17	IQ35F150BST	47	IQ35F150J15
18	IQ35F180BST	48	IQ38F150J15
19	IQ38F150BST	49	IQ35F180J15
20	IQ35F180BC	50	IQ35F150J105RS
21	IQ38F150BC	51	IQ35F180J105RS
22	IQ35F150BC	52	IQ38F150J105RS
23	IQ35F80BC	53	IQ35F80J105RS
24	IQ35F150J105	54	IQ35F150J105S
25	IQR35F150J105	55	IQ35F150J3S
26	IQ35F80J3	56	IQ38F150J3S
27	IQ35F150J3	57	IQ35F180J3S
28	IQ35F180J3	58	IQR35F150J3S
29	IQ35F260J3	59	IQ35F150J3SHD
30	IQ38F150J3		

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Merit Medical Systems, Inc.
1600 West Merit Parkway, South Jordan, Utah 84095 U.S.A.