English

True Form™

Reshapable Guide Wire

DESCRIPTION OF THE PRODUCT

The True Form Reshapable Guide wire is a hydrophilically coated and polymer jacketed stainless steel guide wire with a 2 cm shapeable distal tip. The True Form Reshapable Guide Wire may be packaged with the following components:

- 1 Torque device
- 1 Insertion tool/ guide wire shaper
- 1 Tip straightener

INDICATIONS FOR USE

The True Form Reshapable Guide Wire is intended to facilitate the placement of catheters within the peripheral and coronary vasculature for various diagnostic and interventional procedures.

The True Form Reshapable Guide Wire should not be used in the neurovasculature.

CONTRAINDICATIONS

There are no known contraindications with the use of this product.

PRECAUTIONS

- **℞ Only** Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician trained and/or experienced in the use of this device.
- Do not use in case of any surface irregularities, bends, or kinks. Any damage of the guide wire may change its characteristics likely to affect its performance.
- Use the device prior to the "Use Before" date noted on the package.
- 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.
- This device should be used only by physicians thoroughly trained in percutaneous intravascular techniques and procedures in relevant areas of the anatomy.
- Do not attempt to move the guide wire without observing the guide wire tip. Always maintain visualization of the guide wire under appropriate imaging.
- Do not push, pull, or rotate the wire against resistance. If resistance is met, discontinue movement of the guide wire, determine the reason for resistance and take appropriate action before continuing. Movement of the catheter or guide wire against resistance may result in separation of the catheter or guide wire tip, damage to the catheter, or vessel perforation.
- The hydrophilic coating has a lubricious surface only when properly hydrated.
- Do not wipe the guide wire with dry gauze as it may damage the hydrophilic coating.
- Do not move the torque device on the guide wire when the torque device is tightened as it may damage the guide wire.
- If using a Y-connector on the catheter, do not manipulate the guide wire with the Y-connector in the locked position as the guide wire may be damaged.
- Do not expose guide wires to extreme temperatures.
- Extreme care should be taken when shaping the guide wire distal tip. Over-manipulation of the guide wire distal tip may cause damage. Damaged guide wires should not be used.
- Do not withdraw through a metal entry needle or metal dilator, or use this wire with devices that contain metal parts such as artherectomy catheters or laser catheters.
- Use of alcohol, antiseptic solutions, or other solvents must be avoided.
- Consider the use of systemic anticoagulation to prevent or reduce clotting.

STORAGE

Store the True Form Reshapable Guide wire in a cool, dark, dry area.

Avoid hot or humid temperatures, direct sunlight, UV rays or anywhere where the product could become wet when storing.

ADVERSE REACTIONS

Procedures requiring percutaneous catheter introduction should not be attempted by physicians unfamiliar with the possible complications listed below. Possible complications may include, but are not limited to the following:

- Hemorrhage
- Systemic or Disseminated Infection
- Ischemia
- Thrombus formation
- Vessel spasm
- Vessel damage
- Inflammatory reaction – Systemic
- Vasoconstriction
- Vascular Perforation
- Vascular Dissection
- Death
- Foreign Body Reaction
- Embolism
- Pulmonary Embolism
- Thrombosis
- Cerebral Infarction
- Chemical Toxic Effects
- Myocardial Infarction

PREPARATION FOR USE

1. Utilizing sterile technique, carefully open the pouch and remove the hoop from the pouch.
2. Flush the hoop with heparinized saline prior to guide wire removal.
3. Gently remove the guide wire from the carrier hoop and inspect the wire prior to use to verify that it is undamaged.
4. If desired, the distal tip of the guide wire can be carefully shaped to the desired tip shape according to standard practices. **Warning**: If the guide wire is to remain unused at any time during the procedure, be sure to rehydrate with heparinized saline prior to reinsertion.

INSTRUCTIONS FOR USE

1. Carefully insert the guide wire, flexible end first, into the prepared catheter lumen using a guide wire insertion tool. Test the guide wire for free movement within the catheter. Exercise caution to make sure the tip of the guide wire is not damaged. Warning: If resistance is felt during advancement, stop movement to assess and define cause of resistance. Remove wire and inspect tip for damage prior to proceeding.
2. To aid in steering the guide wire, secure the supplied torque device by slipping the torque device over the proximal end of the guide wire. When the torque device is in the desired location on the guide wire, secure the torque device in place.
3. Use accepted angiographic techniques to steer and position the guide wire in the intended location(s) as needed. Warning: Always maintain visualization of the guide wire under fluoroscopy, ensuring that the tip is moving freely when torque is applied.
4. When the desired guide wire position is achieved, secure the guide wire in place while gently advancing the catheter over the wire and into the treatment location.
5. Once the catheter is in position, gently remove the guide wire prior to any intervention.
6. Gently wipe away blood on the surface of the product when removing the guide wire from the patient using gauze wet with heparinized saline.

℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	2	Single use
	Caution: Consult accompanying documents. Read instructions prior to use.	2 STERILIZE	Do not resterilize
STERILE EO	Sterilized using ethylene oxide		Do not use if package is damaged
	Non-pyrogenic		

MERIT MEDICAL®

CE 0086

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True Form™

Reshapable Guide Wire 微导丝

产品描述

可塑形的微导丝是一种具有亲水涂层和聚合物护套的不锈钢微导丝，带有一个 2 厘米可塑形的头端。可塑形的微导丝可与以下组件一起包装：

- 1 个扭控器
- 1 个插入工具
- 1 个头端矫直工具

适用范围

微导丝用于辅助将导管放置在外周血管系统中，以进行各种诊断和介入手术。

微导丝不应用于神经血管系统。

禁忌证

本产品目前没有已知的禁忌证。

注意事项

- Rx ONLY 警示：联邦（美国）法律规定此器械仅限于依据或遵循在此器械的使用方面经过培训和/或有相应经验的医生的指示下进行销售。
- 如果出现任何表面不规则、弯曲或扭结，请勿使用。微导丝的任何损坏都可能改变其特性，从而可能影响其性能。
- 在包装上标注的“使用截止日期”之前使用器械。
- 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器械的结构完整性，并且/或者导致器械故障，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器械污染的风险，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。
- 该器械应仅由经过经皮血管内技术和解剖学相关领域手术全面培训的医生使用。
- 在未观察微导丝头端的情况下，请勿尝试移动微导丝。始终在透视下观察微导丝。
- 请勿在遇到阻力时推动、拉动或旋转导线。如果遇到阻力，请勿移动微导丝，确定阻力原因并在继续之前采取适当措施。导管或微导丝为抵抗阻力而移动可导致导管或微导丝头端分离、导管损坏或血管穿孔。
- 亲水涂层仅在适当水合时才具有润滑表面。
- 请勿用干纱布擦拭微导管，因为可能会损坏亲水涂层。
- 拧紧扭控装置时，请勿在微导丝上移动扭控装置，否则可能会损坏微导丝。
- 如果在导管上使用 Y阀，则请勿在 Y阀处于锁定位置的情况下操纵微导丝，否则可能会损坏微导丝。
- 请勿将微导丝暴露在极端温度下。
- 在微导丝头端塑形时应特别小心。过度塑形微导丝头端可能导致损坏。不应使用已损坏的微导丝。
- 请勿通过金属穿刺针或金属扩张器撤回微导丝，或将此微导丝与含有金属部件的器械一起使用，例如斑块旋切导管或激光导管。
- 切勿与酒精、防腐剂溶液或其他溶剂共同使用。
- 考虑使用抗凝剂来预防或减少血栓。

储存

可塑形的微导丝 存放在阴凉、干燥的地方。

请勿将产品放置在高温或潮湿、阳光直射、紫外线照射或任何可能导致产品变湿的地方。

不良反应

不熟悉下列可能的并发症的医生不应进行经皮导管介入手术。并发症包括但不限于以下内容：

- 出血
- 全身性或播散性感染
- 局部缺血
- 血栓形成
- 血管痉挛
- 血管损伤
- 炎症反应 - 全身
- 血管收缩
- 血管穿孔
- 血管夹层
- 死亡
- 异物反应
- 栓塞
- 肺动脉栓塞
- 血栓形成
- 脑梗死
- 化学毒性效应
- 心肌梗死

使用准备

1. 无菌操作下，小心地打开袋子，取出环形套管。

2. 在微导丝移除之前用肝素化盐水冲洗环形套管。

3. 从环形套管上轻轻取下微导丝，并在使用前检查微导丝，确认微导丝是否损坏。

4. 如果需要，可以根据标准操作将微导丝的头端小心地塑造为所需的头型。警告：如果在手术过程中一直未使用微导丝，请务必在重新插入前用肝素化盐水充分水合。

使用说明

1. 使用导丝插入工具将微导丝（首先是柔性末端）插入准备好的导管内腔。测试微导丝是否可在导管内自由移动。请务必小心，确保微导丝的头端没有损坏。警告：如果在前进过程中感觉到阻力，则停止移动以评估和确定阻力原因。在继续操作之前，拆下微导丝并检查头端是否损坏。

2. 为了协助微导丝旋转，通过将扭控器滑过导丝的近端来固定所提供的扭控器。当扭控器处于微导丝上的预定位置时，将扭控器固定就位。

3. 使用公认的血管造影技术，根据需要将微导丝旋转并固定在预定位置。警告：始终在透视下观察微导丝，确保在扭转时头端可自由移动。

4. 当到达所需的位置时，将微导丝固定在适当位置，同时将导管轻轻推进微导丝并进入治疗位置。

5. 导管就位后，在进行任何干预之前轻轻取下微导丝。

6. 使用经肝素化盐水润湿的纱布从患者身上取下微导丝时，轻轻擦去产品表面的血液。

产品名称：微导丝

结构及组成：该产品由微导丝、扭控器、插入工具、头端矫直工具组成。产品经环氧乙烷灭菌，一次性使用，货架有效期3年。

型号、规格：TF14145S, TF14165S, TF14180S, TF14180A

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

注册人及生产企业联系方式：1-801-253-1600

生产地址：2265-3 Kamiyabe-cho, Totsuka-ku, Yokohama-shi, Kanagawa, 245-0053 Japan

受托企业联系方式：+81-45-548-9888

受托企业名称：PIOLAX MEDICAL DEVICES, INC.

受托企业住所：2265-3 Kamiyabe-cho, Totsuka-ku, Yokohama-shi, Kanagawa, 245-0053 Japan

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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

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有效期：3年

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生产日期和失效日期：见产品标签

Rx Only	警示：联邦（美国）法律将此器械限制为由医生销售或订购。		不得二次使用
	警告		不得二次灭菌
STERILE EO	经环氧乙烷灭菌		如包装破损切勿使用
	无热原		

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